

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

Case No.: _____

M.D., C.F., and E.M., individually
and on behalf of a class
of similarly situated persons,

Plaintiffs,

CLASS REPRESENTATION

v.

CENTENE CORPORATION, INC. and
CENTENE MANAGEMENT
COMPANY, LLC.,

Defendants.

_____ /

CLASS ACTION COMPLAINT

Plaintiffs M.D., C.F., and E.M., individually and on behalf of a class of similarly situated persons (the “Class” or “Class Members”), file this Class Action Complaint against Defendants Centene Corporation, Inc. (“Centene”) and Centene Management Company, LLC (“CMC”).¹

NATURE OF THE ACTION

Plaintiffs and Class Members have hepatitis C, a potentially fatal and seriously debilitating disease, which scars the liver, making it increasingly fibrotic, then cirrhotic, until it no longer functions, resulting in liver failure and death. Since October 2014, drug treatments that cure hepatitis C have been available. Plaintiffs have asked their health

¹ Due to the sensitive nature of their health condition, Plaintiffs identify themselves by their initials so that they may keep their identities private. Plaintiffs will file a separate motion seeking this relief.

insurer, Celtic Insurance Company (“Celtic”), to pay for the cure because the health insurance policy that Celtic sold them promised to cover any treatments that are medically necessary. Celtic has refused, relying on pretextual “guidelines” developed and enforced by Centene and CMC.

Celtic is a subsidiary of Centene, which, through a web of subsidiaries, is the largest health insurer in the multistate marketplace for individual health insurance policies that was created by the Patient Protection and Affordable Care Act (“ACA”), 42 U.S.C. § 300gg1-19. Centene sells these policies through state ACA exchanges and refers to this marketplace as the “Health Insurance Marketplace” or “HIM.”² In furtherance of a scheme to avoid paying for hepatitis C drugs, Centene, in coordination with its subsidiary, CMC, has instructed Celtic and all other Centene subsidiaries to refuse to cover and pay for the breakthrough treatments that cure hepatitis C *unless an insured already has suffered severe, irreparable* liver damage.

Centene and CMC are employing and enforcing this unlawful cost-avoidance scheme across the entire line of individual health insurance policies, including all health insurance policies that were sold to Plaintiffs and Class Members. This conduct constitutes tortious interference with the uniform contractual promise in those health insurance policies to provide coverage, and pay for, medically necessary treatment.

² See <https://www.centene.com/who-we-help/health-insurance-marketplace.html>, last accessed on June 12, 2018. Centene and its affiliates target remote, rural and low-income areas that other insurers have exited, frequently making their policies the only game in town for middle class and working poor citizens who don’t have access to employer-sponsored health insurance. See <https://www.bloomberg.com/news/features/2017-11-16/how-to-make-a-fortune-on-obamacare>, last accessed on June 12, 2018.

Accordingly, Plaintiffs and the Class Members bring this action to end these unlawful practices, so Plaintiffs and thousands of Class Members finally will get the cure that at last is available for hepatitis C, a heretofore incurable, potentially fatal disease with which many of them have suffered for decades.

INTRODUCTION

1. Plaintiffs and the Class Members bought, and paid premiums for, health insurance policies that promised to cover and pay for treatment that is “medically necessary.” Plaintiffs and Class Members bought these health insurance policies from various subsidiaries of Centene. As stated above, Centene is a nationwide, multi-line health insurance enterprise with more than 40 subsidiaries that offer numerous lines of health insurance, including individual policies sold on state ACA exchanges, which Centene calls the “Health Insurance Marketplace,” or “HIM.” In the market for individual health insurance, Centene sells a “health insurance product” it calls “Ambetter.”

2. Plaintiffs and the Class Members have been diagnosed with hepatitis C—a potentially fatal disease that kills more people annually than any other infectious disease.³ It is a contagious blood-borne virus that kills by attacking the liver. Until October 2014, there was no cure for hepatitis C, and those afflicted with it were required to undergo extensive, expensive treatment regimens lasting twenty-four to forty-eight weeks and consisting of daily pills and weekly injections of Interferon. Those outdated treatments

³ About 400,000 people die each year from hepatitis C, mostly from cirrhosis or liver cancer. <http://www.who.int/mediacentre/factsheets/fs164/en/>, last accessed June 12, 2018.

caused debilitating side effects (the worst of which can be chemotherapy-like) and had an abysmal cure rate (less than 16%).

3. Since October 2014, pharmaceutical companies began marketing what the U.S. Food & Drug Association (the “FDA”) hailed as “breakthrough” treatments using direct-acting antiviral (“DAA”) drugs. These “breakthrough” treatments do not require use of Interferon and work by directly attacking the hepatitis C virus and eradicating it from the body. These drugs have an astounding cure rate of 94% to 100%, with little to no side effects. A patient need take only one pill daily for eight to twelve weeks (depending on the viral load in the body), to eliminate the virus from the body—forever. In October 2014, the FDA approved the first of these drugs, Harvoni, which was soon followed by others, including Viekira Pak, Epclusa, Zepatier, and Mavyret (collectively, the “Cure”).

4. When Harvoni, the first of these DAAs, came to market in October 2014, it was pricey, although substantially less expensive than a liver transplant or even Interferon treatment.⁴ In response, certain health insurers immediately deployed schemes to avoid paying for Harvoni treatment. Those schemes were designed to save money and force insureds to wait until the disease had caused them to suffer irreparable liver damage or switch policies (if they could find one providing coverage). Those schemes were

⁴ A liver transplant in 2014 cost more than \$500,000. The retail cost of Harvoni treatment was less than \$100,000, which doesn’t take account of substantial discounts obtained by major health insurers. Today, the price of DAAs has dropped significantly and insurers have obtained significant discounts from the drug manufacturers.

similar to the one defendants still employ, which denies the Cure to approximately 80% of hepatitis C sufferers until they develop severe and irreparable liver fibrosis or cirrhosis (the “fibrosis restrictions”).⁵

5. When insurers began limiting access to the Cure to those who already had suffered severe liver scarring (demonstrated by F3 or F4 METAVIR score after a painful and dangerous liver biopsy), this gambit was immediately condemned by leading medical societies. They stated that all insureds suffering from hepatitis C should have access to the Cure. Some analogized the practice as the equivalent to refusing to cover blood pressure medicine until an insured has suffered a heart attack. Indeed, requiring an insured to demonstrate F3/F4 levels of fibrosis or cirrhosis is reckless and dangerous, because in most cases severe scarring of the liver is irreversible and further increases the risk of developing liver cancer, which has one of the highest mortality rates of all cancers.

6. The standard of care for treatment of hepatitis C is published by the American Association for the Study of Liver Diseases (the “AASLD”), in conjunction with the Infectious Diseases Society of America (the “IDSA”). The AASLD publicly condemned fibrosis-based coverage restrictions, “adamantly disagreed” with “treat[ing]

⁵ Defendants’ fibrosis restrictions deem the Cure not medically necessary until an insured develops advanced liver scarring, which is classified based on a patient’s METAVIR fibrosis score (“METAVIR score”). Measured on a scale of F0 to F4, a METAVIR score between F0 and F2 represents no, or light, liver scarring (or fibrosis), while an F3 METAVIR score represents severe fibrosis, and F4 represents cirrhosis.

the sickest first,”⁶ and reiterated that it would be cost-effective to provide Harvoni treatment to everyone suffering from hepatitis C, regardless of their degree of liver fibrosis.⁷ The AASLD has repeatedly “recommend[ed] treatment for *all patients* with [hepatitis C], except those with short life expectancies that cannot be remediated by treating [it]” See <http://www.hcvguidelines.org/fullreport> at 30, last accessed on June 12, 2018. The AASLD also recognized that “strong and accumulating evidence argue against deferral” of treatment, and that “[d]eferral practices based on fibrosis stage alone are inadequate and shortsighted.” *Id.*

7. Other leading medical societies and experts in the field agree. For example, the co-chair of the panel that issued the AASLD report, Dr. David Thomas, called the “guidelines” at issue here “astonishing,” because DAAs can “cure most patients with as few as 84 pills” and “[i]t’s cheaper to treat patients than to wait for them to develop cirrhosis and complications and then get a liver transplant.”⁸ He also said that DAAs “are cost-effective It is cheaper to treat patients than to wait for them to develop cirrhosis and complications and then get a liver transplant.” Another public

⁶ See *AASLD Position on Treating Patients with Chronic Hepatitis C Virus*, <http://www.aasld.org/aasld-position-treating-patients-chronic-hcv#sthash.7KlZ3Xqy.dpuf> (emphasis added), last accessed June 12, 2018.

⁷ See *When and in Whom to Initiate HCV Therapy*, <https://www.hcvguidelines.org/evaluate/when-whom>, last accessed on June 12, 2018.

⁸ http://www.nytimes.com/2015/08/26/us/wider-reach-is-sought-for-new-hepatitis-c-treatments.html?_r=2, last accessed June 12, 2018 (also noting that “[i]f there were a cure for Alzheimer’s or breast cancer that cost \$40,000 or \$50,000, we would not be having this conversation”).

health law expert, a professor at Harvard Law School, was quoted as saying that “[t]hese criteria defy clinical guidelines and best practices.” *Id.*

8. It is thus no surprise that virtually all health insurers that used fibrosis restrictions to deny coverage for the Cure faced extreme backlash. For example, Florida Blue, United Healthcare, Anthem, and others, all were sued in class action lawsuits, and settled those lawsuits by abandoning the fibrosis restrictions. *E.g.*, *Oakes v. Blue Cross & Blue Shield of Fla., Inc.*, Case No. 16-cv-80028 (RLR) (S.D. Fla. 2016) (approving class action settlement providing approximately \$126 million worth of coverage to over 2,000 insureds suffering from hepatitis C); *Jones v. United Healthcare, Inc.*, Case No. 15-cv-61144 (RLR) (S.D. Fla. 2015) (approving class action settlement providing approximately \$300 million worth of coverage to over 4,000 insureds suffering from hepatitis C); *Sheynberg v. Anthem Blue Cross Life and Health Ins. Co.*, Case No. 3:15-cv-03417 (N.D. Cal. 2015) (settling case after removing fibrosis restrictions); *Shank v. Health Care Service Corp., et al.*, Case No. 1:16-cv-03993 (N.D. Ill. 2016) (same).

9. In addition to those lawsuits, the New York State Attorney General called the use of the fibrosis restrictions “misleading” and “deceptive,” and demanded that insurers stop using them. A copy of the complaint can be found here:

<https://ag.ny.gov/pdfs/FiledComplaint.pdf>. The New York State Attorney General later settled with seven health insurance companies, which agreed as part of the settlement to remove the fibrosis restrictions. *See* <https://ag.ny.gov/press-release/ag-schneiderman-announces-major-agreement-seven-insurers-expand-coverage-chronic>.

10. Prisoners also sued prisons and healthcare corporations that managed their prison system's healthcare, claiming that use of the fibrosis restrictions violated the Eighth Amendment as "cruel and unusual punishment" of inmates in the prison system. Numerous courts have sustained those complaints. *E.g.*, *Allah v. Thomas*, 2017 WL 568313 (3rd Cir. 2017) (reversing dismissal of state inmate's Eighth Amendment claim for refusal to provide Harvoni treatment); *Postawko v. Missouri Department of Corrections*, Case No. 2:16-4219-NKL, 2017 WL 1968317 (W.D. Mo. May 11, 2017) (denying defendants' motion to dismiss state inmate's Eighth Amendment claim for denial of DAA drugs (like Harvoni) for chronic Hepatitis C); *Bernier v. Trump*, 2017 WL 1048053 (D.D.C. Mar. 17, 2017) (same); *Henderson v. Tanner*, 2017 WL 1015321 (M.D. La. Mar. 15, 2017), *adopting Report and Recommendation* 2017 WL 1017927 (Feb. 16, 2017) (same); *Abu-Jamal v. Wetzel*, 2017 WL 34700 (M.D. Pa. Jan. 3, 2017) (granting preliminary injunctive relief to state prisoner); *Chimenti v. Pennsylvania Dep't of Corr.*, 2017 WL 3394605, at *7 (E.D. Aug. 8, 2017) (same).

11. State Medicaid agencies also were sued and forced to abandon the fibrosis restrictions in response to lawsuits because, as one court put it, "there is a consensus among medical experts and providers that the life-saving DAAs are 'medically necessary' for all HCV-infected persons, regardless of Fibrosis score." *B.E. v. Teeter*, 2016 WL 3033500, at *4 (W.D. Wash. May 27, 2016); *accord Ryan v. Birch*, 2017 WL 3896440, at *3 (D. Colo. Sept. 5, 2017) (sustaining complaint against Colorado Medicaid agency). In fact, in June 2016, the Agency for Healthcare Administration, which is responsible for the administration of Florida's Medicaid program, removed all

all fibrosis restrictions and required all insurance providers that administer Florida's Medicaid managed care program to similarly remove any such restrictions.

12. Incredibly, against this backdrop, and more than three years after the FDA approved the first of the breakthrough treatments, Centene, through its subsidiary CMC, has created, and is still requiring its subsidiaries to enforce, the same roundly-condemned fibrosis restrictions to deny coverage for the Cure, on the pretextual basis that the Cure is not medically necessary until and unless an insured has suffered and demonstrated severe and irreparable liver fibrosis or cirrhosis.

13. Centene and CMC are enforcing these restrictions across the nation, causing Plaintiffs' and the Class Members' insurers, including Celtic, to breach their promise to pay for medically necessary treatment. These fibrosis restrictions deviate from the standard of care in the medical community, and are being used to materially and directly breach the uniform, contractual promise of Plaintiffs' and Class Members' insurers to provide medically necessary treatment. Accordingly, Plaintiffs and the Class Members bring this class action against Centene and CMC to force them to discontinue use of the fibrosis restrictions, so that thousands of insureds across the nation can get cured.

THE PARTIES

14. Plaintiff M.D. is and was, at all relevant times, a citizen of Florida, residing in Miami-Dade County, Florida.

15. Plaintiff C.F. is and was, at all relevant times, a citizen of Florida, residing in Palm Beach County, Florida.

16. Plaintiff E.M. is and was, at all relevant times, a citizen of Florida, residing in Palm Beach County, Florida.

17. Defendant Centene is a Delaware corporation with its principal place of business in St. Louis, Missouri. Centene separately incorporates subsidiaries in each state in which it offers insurance. Through its affiliate CMC, Centene creates nationwide policies, procedures, and guidelines, that Centene and CMC use to control the coverage decisions of the insurer subsidiaries regarding hepatitis C, as further set forth below.

18. Defendant CMC is a member-managed Wisconsin limited liability company with its principal place of business in St. Louis, Missouri. The sole member of CMC is Centene. CMC is licensed to do business in Florida. CMC, at the direction of Centene, creates nationwide policies, procedures, and guidelines that are used to control coverage decisions of insurer subsidiaries regarding hepatitis C, and access to the Cure.

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction over all claims under the Class Action Fairness Act of 2005 (“CAFA”), Pub. L. No. 109-2, 119 Stat 4 (codified in various sections of 28 U.S.C. § 1332 (d)(2)), because this lawsuit has been brought as a class action on behalf of a proposed class in excess of 100 members, the aggregate of claims of the Class exceed \$5 million exclusive of interest and costs, and one or more of the members of the Class is a citizen of a different state than Centene and CMC.

20. This Court has personal jurisdiction over Centene and CMC under Florida’s long-arm statute, § 48.193(2), Fla. Stat., because Centene and CMC are engaged in substantial and not isolated activity within Florida.

21. This Court also has personal jurisdiction over Centene and CMC under Florida's long-arm statute, § 48.193(1)(a)(1), Fla. Stat., because Centene and CMC are operating, conducting, engaging in, or carrying on a business or business venture in Florida, and this action arises from that conduct.

22. This Court also has personal jurisdiction over Centene and CMC under Florida's long-arm statute, § 48.193(1)(a)(2), Fla. Stat., because Centene and CMC committed a tortious act in Florida.

23. Venue is proper in this forum because at all times material to this action, Plaintiff, M.D., resides in Miami-Dade County, Florida, a substantial portion of the acts complained of occurred in Miami-Dade County, Florida, and Defendants have received substantial compensation as a result of doing business in Miami-Dade County, Florida. Moreover, at all times material to this complaint, Defendants personally or through their agents:

- (a) operated, conducted, engaged in, and carried on a business or business venture in Miami-Dade County, Florida or had an office or agency in Miami-Dade County, Florida; and
- (b) engaged in substantial activity within this state and Circuit.

24. All conditions precedent to this action have occurred, been performed, waived or excused.

FACTUAL ALLEGATIONS

A. Hepatitis C

25. Hepatitis C is a deadly disease that attacks the liver and causes liver deterioration. It is the number one cause of liver cancer in the United States, as well as the number one reason for liver transplants. The disease's typical progression begins with inflammation of the liver and proceeds to cause irreparable scarring (fibrosis) of the liver and ultimately cirrhosis of the liver.

26. Cirrhosis is a late stage of hepatic fibrosis that prevents the liver from functioning properly. It can lead to liver failure, liver cancer, or death. A patient's degree of liver damage is measured by METAVIR scores, which range from F0 to F4. A normal liver is designated as stage F0 or F1. A patient in stage F2 suffers from significant fibrosis. A patient in F3 suffers from severe fibrosis, and a patient in F4 suffers from cirrhosis. Cirrhosis generally can only be treated through a liver transplant. Approximately 20% of hepatitis C sufferers develop cirrhosis, and of those with cirrhosis, up to 20% develop liver cancer.

27. When hepatitis C was discovered in the 1980s, Interferon was the primary treatment option. Interferon is a naturally occurring protein that cells secrete when they are attacked by a virus. Treatment with Interferon has many drawbacks. It requires injections and causes side effects, including flu-like symptoms such as fever, fatigue, muscle aches, and myalgia. Many patients report suffering flu-like symptoms during the entire course of Interferon treatment, which can last up to a year. The cure rate for

Interferon was low—6% and 16% for twenty-four and forty-eight-week regimens, respectively.

28. In 1998, the FDA approved the use of Ribavirin, an anti-viral drug, for use in combination with Interferon to treat hepatitis C. The Interferon and Ribavirin combination marginally improved the cure rate for patients to 34% for twenty-four weeks and 42% for forty-eight-week regimens.

29. Despite approval of Ribavirin, the low cure rate left doctors still searching for what they referred to as the “holy grail” of hepatitis C treatment—a once-daily pill that was a direct-acting antiviral or DAA, which would directly attack the virus and did not require Interferon.⁹ A pharmaceutical company named Gilead, Inc., developed the first such Cure and called it Harvoni. It was the first DAA and had a cure rate higher than 90%, with little to no side effects. The FDA granted Harvoni “breakthrough therapy” designation and approved it for sale in October 2014. Following Harvoni’s approval, other DAAs were approved with a similar cure rate.

B. Treatment for All Is the Standard of Care for Hepatitis C

30. As set forth above, the AASLD is the leading medical society that sets the standard of care for the treatment of liver diseases, including hepatitis C. The AASLD periodically issues guidelines that provide its recommendations for treating hepatitis C. Since January 2014, the AALSD and the IDSA have recommended early treatment of

⁹ See Douglas Dieterich, M.D., *The End of the Beginning for Hepatitis C Treatment*, 55 HEPATOLOGY 664 (2012) (discussing clinical trials in 2012 of new drugs that signaled “a giant step toward the ‘Holy Grail’ of HCV therapy: once-daily, oral IFN-free treatment”).

hepatitis C as the standard of care—meaning treatment should begin as soon as the patient is diagnosed with hepatitis C.

31. In response to insurers’ use of fibrosis restrictions to limit Harvoni coverage, the AASLD condemned that approach:

Unfortunately payers across America are denying treatment when a doctor has prescribed it for their patient. *We adamantly disagree with this decision.* Our Guidance is not intended to be used by payers to deny access to treatment. In no way does this position contradict the evidence evaluated to produce the Guidance and the recommendation made in the Guidance to treat the sickest first, but *recognizes need to treat all.*

See AASLD Position on Treating Patients with Chronic Hepatitis C Virus,

<http://www.aasld.org/aasld-position-treating-patients-chronic-hcv#sthash.7KlZ3Xqy.dpuf>

(emphasis added), last accessed on June 12, 2018.

32. In its most up-to-date version, the AASLD concluded that treating all hepatitis C patients would be cost-effective and that “strong and accumulating evidence argue against deferral” of treatment. *See When and Whom to Initiate HCV Therapy,*

<https://www.hcvguidelines.org/evaluate/when-whom>, last accessed on June 12, 2018.

“Deferral practices based on fibrosis stage alone are inadequate and shortsighted.” *Id.*

Numerous courts have recognized that “there is a consensus among medical experts and providers that the life-saving DAAs are ‘medically necessary’ for all [hepatitis c]-infected persons, regardless of Fibrosis score.” *E.g., Teeter*, 2016 WL 3033500, at *4.

C. The Cure Satisfies the Definition of Medical Necessity in the Contract

33. The Policies at issue are materially identical for Plaintiffs and the Class Members. The Policies promise to cover treatment that satisfies the objective definition

of medical necessity in the contract. That definition of medical necessity is materially identical throughout the Plaintiffs' and Class Members' contracts.

34. A representative policy (that of Plaintiff C.F.) is attached as **Exhibit A**. It defines medical necessity as “any medical service, supply, or treatment authorized by a *physician* to diagnose and treat a *member's illness or injury* which”:

1. Is consistent with the symptoms or diagnosis;
2. Is provided according to generally accepted medical practice standards;
3. Is not *custodial care*;
4. Demonstrates that the member is significantly improving in his/her functional ability;
5. Is not solely for the convenience of the *physician* or the *member*;
6. Is not *experimental or investigational*;
7. Is provided in the most cost effective care facility or setting;
8. Does not exceed the scope, duration, or intensity of that level of care that is needed to provide safe, adequate and appropriate diagnosis or treatment; and
9. When specifically applied to a *hospital* confinement, it means that the diagnosis and treatment of *your* medical symptoms or conditions cannot be safely provided as an outpatient or in a lower level or alternative setting of care.

See Ex. A at 22 (emphasis in original).

35. The Policies define “generally accepted standards of medical practice” to mean “standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying primarily on controlled clinical trials.” *See* Ex. A at 18.

36. The Cure is a covered service under the Policies because it satisfies the objective definition of medical necessity. Moreover, the Cure does not fall within any of

the Policies' exclusions, because it is neither "experimental" nor "investigational." Further, treating the Plaintiffs' and Class Members' hepatitis C with DAAs also comports with "generally accepted medical practice standards." In fact, there is *no* evidence supporting prioritizing or restricting DAA treatment to only those with severe liver fibrosis or cirrhosis. Instead, all of the peer-reviewed medical literature and leading medical societies expressly recommend DAA treatment for all who suffer from hepatitis C as early as possible.

37. Nothing in the Policies or in standard medical practice requires the condition of insureds who suffer from hepatitis C to worsen and deteriorate to the point of severe fibrosis or cirrhosis before the Cure may be considered medically necessary. Moreover, there is no standard of acceptable medical practice in the United States, and no contractual provision in the Policies, which would allow for pretextual restrictions on coverage for the Cure that would require Plaintiffs' and Class Members' health to deteriorate to an irreversible and irreparable level before receiving the Cure.

D. Centene and CMC Developed and Enforce the Fibrosis Restrictions so that Centene's Subsidiaries Will Deny Coverage for Medically Necessary Treatment

38. As set forth above, Centene is an enterprise with a web of subsidiaries that sell individual health insurance policies on numerous state exchanges. Plaintiffs and Class Members entered into contracts that are underwritten and sold by those subsidiaries, including Celtic, based on the uniform contractual promise that the insurer will provide coverage for medically necessary treatment. In order to harmonize the subsidiaries' application of the contractual definition of medical necessity, Centene,

through CMC, creates guidelines or instruction manuals that specify how the subsidiaries should apply the contractual definition of medical necessity to particular drugs, treatments or medical services prescribed by the insureds' doctors.

39. These guidelines or instruction manuals typically are provided to claims reviewers, who review requests for authorization submitted by doctors for coverage of a drug, treatment or medical service. They are designed to provide a broad-based application and interpretation of the contractual definition of medical necessity, including the most important part—whether a treatment, procedure, or drug accords with “generally accepted standards of medical practice.”

40. CMC, at Centene's behest, issues these guidelines and instruction manuals on a quarterly basis through what it calls a “Pharmacy and Therapeutics” committee. CMC, at Centene's behest, requires claims reviewers to apply these guidelines and instruction manuals to all requests for coverage of a drug, treatment or procedure. Accordingly, whenever insureds, including Plaintiffs and Class Members, submit a request for Celtic or any other subsidiary to cover the Cure, the claims reviewers apply CMC's fibrosis restrictions and deny the request unless the insured has suffered and demonstrated the irreparable bodily harm of severe liver fibrosis or cirrhosis.

E. Centene's Fibrosis Restrictions Cause Celtic to Breach Its Promise to Provide Medically Necessary Treatment

41. Plaintiff M.D. has hepatitis C. M.D.'s doctor recommended that M.D. receive the Cure known as Epclusa. On March 21, 2018, M.D.'s doctor submitted a prior authorization request for coverage of Epclusa treatment. Two days later, on March 23, 2018, that request was denied for the stated reason that the Cure was not medically

necessary because it did not satisfy the plan guideline known as “HIM.PA.SP1,” which is the fibrosis restriction that defendants created and are enforcing to restrict coverage for Epclusa treatment. This guideline bears the letterhead “Centene Corporation,” and at the bottom “reserves all rights” on behalf of Centene Corporation. The guideline has an “effective date” of August 2016 and “last review date” of August 2017. The guideline states that the line of business it applies to is the “Health Insurance Marketplace.”

42. Plaintiff C.F. has hepatitis C. C.F.’s doctor recommended that C.F. receive the Cure known as Epclusa. On December 4, 2017, C.F.’s doctor submitted a prior authorization request for coverage of Epclusa treatment. Two days later, on December 6, 2017, that request was denied for the stated reason that the Cure was not medically necessary because it did not satisfy the plan guideline known as “HIM.PA.SP1,” which is the fibrosis restriction that Defendants created and are enforcing to restrict coverage for Epclusa treatment. This guideline bears the letterhead “Centene Corporation,” and at the bottom “reserves all rights” on behalf of Centene Corporation. The guideline has an “effective date” of August 2016 and “last review date” of August 2017. The guideline states that the line of business it applies to is the “Health Insurance Marketplace.”

43. Defendants’ HIM.PA.SP1 guideline falsely represents that it is “based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.” The guideline also falsely

represents that it “is consistent with standards of medical practice current at the time that this clinical policy was approved.” A copy of the HIM.PA.SP1 guideline is attached as

Exhibit B.

44. Plaintiff E.M. has hepatitis C. E.M.’s doctor recommended that E.M. receive the Cure known as Harvoni. On November 27, 2017, her doctor submitted a prior authorization request for coverage of Harvoni treatment. Two days later, on November 29, 2017, this request was denied for the stated reason that the cure was not medically necessary because it did not satisfy plan guideline “HIM.PA.SP3,” which is the fibrosis restriction that Defendants created and are enforcing to restrict coverage of Harvoni treatment. This guideline bears the letterhead “Centene Corporation,” and at the bottom “reserves all rights” on behalf of Centene Corporation. The guideline has an “effective date” of August 2016 and “last review date” of August 2017. This guideline also states that the line of business it applies to is the “Health Insurance Marketplace.”

45. Defendants’ HIM.PA.SP3 guideline also falsely represents that it is “based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.” This guideline also falsely represents that it “is consistent with standards of medical practice current at the time that

this clinical policy was approved.” A copy of the HIM.PA.SP3 guideline is attached as **Exhibit C.**¹⁰

46. These guidelines all contain the fibrosis restrictions and are representative of all other guidelines that Defendants have created and enforced to deny the Cure to Plaintiffs and the Class Members.

F. Centene’s Interference with the Contractual Promises Made by Its Subsidiary Insurers is Wrongful, Pretextual, Fraudulent, and Deceptive

47. Through the use of the fibrosis restriction “guidelines,” defendants are both interfering with contractual promises made by Plaintiffs’ and Class Members’ health insurers to provide coverage for medically necessary treatment, and engaging in a wrongful, pretextual, fraudulent, and deceptive practice.

48. In 2016, when Centene and CMC created the fibrosis restrictions that required Plaintiffs’ and Class Members’ health insurers to deny coverage of the Cure, Centene and CMC knew or had reason to know that the standard of care for treatment of hepatitis C was to treat the illness with a Cure as soon as the patient was diagnosed with the disease. Indeed, Defendants’ fibrosis restrictions expressly state that they are “based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional

¹⁰ Plaintiffs and Class Members were not required to exhaust any appeals process before filing suit, but even if they were, they exhausted all applicable appeals. To the extent defendants might argue that any further appeal was required, such would have been futile because if an insured does not satisfy the guidelines, the appeal is denied.

organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.”

49. These fibrosis restrictions, which were used to deny coverage of the Cure to Plaintiffs and Class Members, are false, misleading, and deceptive because the undisputed standard of care for hepatitis C is immediate DAA treatment upon diagnosis, regardless of a patient’s fibrosis level. Moreover, the fibrosis restrictions are pretextual because the real reason defendants are instructing Plaintiffs’ and Class Members’ insurers to breach their uniform contractual promise to provide coverage for medically necessary treatment, is so that defendants can avoid the cost of treating Plaintiffs and the Class Members with a Cure. Because Centene and CMC may not lawfully instruct Plaintiffs’ and the Class Members’ insurers to breach their contracts based solely on the cost of an otherwise medically necessary treatment, defendants have disguised and covered up their cost-avoidance scheme by dressing it up in language that sounds authoritative in falsely representing that the Cure is not medically necessary.

50. Defendants’ false representations and misconduct constitute a fraudulent, false pretense, false promise, misrepresentation, misleading statement or deceptive trade practice made with the unlawful intent to induce Plaintiffs and Class Members to rely on them to their detriment and keep paying premiums.

CLASS ALLEGATIONS

A. Class Definition

51. Plaintiffs bring this action against defendants under Rule 23 of the Federal Rules of Civil Procedure on behalf of themselves and all other similarly situated persons, and seek to represent the following Class:

All persons who are, or were, insured by Centene's subsidiaries under a "Health Insurance Marketplace" plan, other individual or commercial plan, and (1) have hepatitis C and stage F0, F1, or F2 fibrosis, (2) have received a prescription from their treating physician for a Cure, and (3) have been denied coverage for such treatment by Centene's subsidiaries, based on Defendants' fibrosis restrictions. Excluded from the Class are Defendants' employees and any persons who have insurance through Medicare or Medicaid plans offered by any of Centene's subsidiaries.

52. Plaintiffs reserve the right to modify or amend the proposed Class definition before the Court determines whether class certification is appropriate.

B. Rule 23(a)(1) – Numerosity

53. The individual Class Members are so numerous that their individual joinder is impracticable. Centene's subsidiaries sell thousands of health insurance policies in the state of Florida and throughout the country and, as a general business practice, have failed to comply with applicable law at defendants' behest and instruction. Moreover, the Class Members easily can be identified from defendants' business records, because defendants know (a) who the insureds are, (b) under which plans they are insured, (c) what types of claims they have filed, and (d) how those claims were adjudicated.

54. On information and belief, the number of Class Members is in the thousands. Their precise number will be determined through discovery, but they are too

numerous to be individually joined as plaintiffs in one complaint, and it is impractical for each to bring an individual action.

C. Rule 23(a)(2) – Commonality

55. There are questions of law and fact that are common to Plaintiffs’ and Class Members’ claims.

56. Common questions of law and fact include, but are not limited to, the following:

- (a) Whether defendants are acting and/or refusing to act on grounds generally applicable to Plaintiffs and the Class Members;
- (b) Whether defendants’ use of the fibrosis restrictions to deny coverage for the Cures constitutes tortious interference with Plaintiffs’ and Class Members’ insurance contracts;
- (c) Whether defendants’ requirement that its subsidiaries use the fibrosis restrictions to deny their contractual promise to provide medically necessary treatment is a breach of contract;
- (d) Whether DAA treatment is medically necessary under the Policies;
- (e) Whether DAA treatment is the standard of care for treating hepatitis C;
- (f) Whether defendants were unjustly enriched; and
- (g) Whether the fibrosis restrictions are pretextual, fraudulent, deceptive, and misleading.

57. The foregoing common questions predominate over questions, if any, that might affect only individual Class Members.

58. Defendants have subjected Plaintiffs and Class Members to the same harm and did so in the same manner. The above-described conduct constitutes defendants' standard business practice.

D. Rule 23(a)(3) – Typicality

59. Records in the possession, custody, and control of defendants will demonstrate that Plaintiffs are Class Members. Plaintiffs' claims are typical of the Class Members' claims because they are based on the same legal theories, arise from the similarity, uniformity, and common purpose of defendants' unlawful conduct, and are not subject to any unique defenses. Members of the Class have sustained, and will continue to sustain, damages in the same manner as Plaintiffs because of defendants' wrongful conduct.

60. Moreover, defendants are enforcing identical fibrosis restrictions to deny coverage for the Cures to all Class Members. Thus, the promises and decisions that defendants made—and the practices they engaged in—with respect to Plaintiffs' treatment requests are materially the same with regard to the Class Members' treatment requests.

E. Rule 23(a)(4) – Adequacy of Representation

61. Plaintiffs are adequate representatives of the Class and will fairly and adequately protect the interests of the Class Members. Plaintiffs are committed to the vigorous prosecution of this action and have retained competent counsel who are experienced in litigation of this nature to represent them. There is no conflict or antagonism between the interests of Plaintiffs and the unnamed Class Members.

62. To prosecute this case, Plaintiffs have chosen the law firm of Rivero Mestre LLP, and are obligated to pay a fee for that representation. This firm is experienced in class action litigation and possesses the financial and legal resources to deal with the costs and legal issues inherent in this action.

F. Requirements of Fed. R. Civ. P. 23(b)(3)

63. Questions of law or fact common to the Plaintiffs' and the Class Members' claims predominate over any questions of law or fact affecting only individual Class Members. All claims by Plaintiffs and Class Members arise from defendants' common course of unlawful conduct that caused Plaintiffs' and Class Members' damages. The predominating questions of law and fact include those set forth above in Paragraph 56.

64. Common issues predominate where, as here, liability can be determined on a class-wide basis, even if there might be some need for some individualized damages determinations. As a result, in determining whether common questions predominate, courts focus on the liability issue, and if the liability issue is common to the class, as it is in this case, common questions will be held to predominate over individual questions.

G. Superiority

65. This class action is superior to individual actions, in part because of the following, non-exhaustive list of factors:

- (a) Individual joinder of all Class Members would impose extreme hardship and inconvenience on them, because they reside across the nation;

- (b) Individual claims by Class Members are impractical because the cost of pursuing an individual claim could exceed its value. As a result, individual Class Members have no interest in prosecuting and controlling separate actions;
- (c) There are no known Class Members who are interested in individually controlling the prosecution of separate actions;
- (d) The interests of justice will be served by resolving the common disputes of all Class Members in one forum;
- (e) Judicial and party resources will be conserved by resolving the common disputes of all Class Members in one forum;
- (f) Individual claims would not be cost effective or economically feasible to pursue through individual actions; and
- (g) The action is manageable as a class action.

H. Requirements of Fed. R. Civ. P. 23(b)(1)(a) & 23(b)(2)

66. The prosecution of separate actions by (or against) individual Class Members would create a risk of inconsistent or varying adjudications with respect to individual Class Members that would establish incompatible standards of conduct for defendants and any other party opposing the Class.

67. Defendants have acted or failed to act in a manner generally applicable to the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to all Class Members.

COUNT I
Tortious Interference

68. Plaintiffs and Class Members re-allege paragraphs 1 through 67 as if fully set forth here.

69. Through the Policies, Plaintiffs and Class Members have a contractual relationship with Celtic whereby Celtic promised to provide coverage for medically necessary treatment.

70. The Cure satisfies the definition of medical necessity under Plaintiffs' and Class Members' Policies, and otherwise satisfies all requirements of the Policies, such that Celtic had (and has) a contractual obligation to cover and pay for the Cure for Plaintiffs and Class Members.

71. Centene and CMC knew that the Cure satisfied the Policies' contractual definition of medical necessity and that the Policies obligate(d) Celtic to cover and pay for the Cure.

72. With knowledge of Celtic's contractual obligation to cover and pay for the cures, Centene and CMC have intentionally and tortiously interfered with that contractual obligation and unlawfully induced Celtic to breach the Policies, with knowledge that their conduct would harm Plaintiffs and the Class Members.

73. Centene and CMC have intentionally interfered with, and induced Celtic to breach the Policies through willful, oppressive, and malicious means, including inducing Celtic's breach through fraud and deception by misrepresenting that the Cure did not satisfy the Policies' definition of medical necessity.

74. As a result of Centene's and CMC's conduct, Plaintiffs and Class Members have suffered damages.

COUNT II
Unjust Enrichment

75. Plaintiffs and the Members re-allege paragraphs 1 through 67 as if fully set forth here.

76. As a result of defendants' deceptive, fraudulent, and misleading conduct, Plaintiffs and Class Members conferred a benefit on defendants, by which they were unjustly enriched, through the payment of insurance premiums to purchase and maintain the Policies, which promise to provide coverage for medically necessary treatment.

77. In these circumstances, it would offend fundamental principles of equity and good conscience to permit defendants to retain the ill-gotten benefits they received from Plaintiffs and Class Members, because the Policies did not provide their promised coverage for medically necessary treatment. It would be unjust or inequitable for defendants to retain these benefits, which equity requires them to disgorge and make restitution to Plaintiffs and Class Members, together with such other appropriate equitable and/or injunctive remedies as are appropriate.

COUNT III
Declaratory Relief

78. Under 28 U.S.C. § 2201, this case involves an actual controversy within the jurisdiction of this Court, and Plaintiffs and Class Members hereby ask the Court to declare rights of Plaintiffs and Class Members.

79. Plaintiffs and the Class Members purchased Policies that promise(d) to provide coverage for medically necessary treatment. Plaintiffs' and Class Members' doctors recommended that they receive treatment for, and be cured of hepatitis C, by receiving the Cure. Plaintiffs and Class Members allege that a Cure for hepatitis C satisfies the Policies' definition of medical necessity.

80. Despite the Cure's satisfaction of the Policies' definition of medical necessity, defendants have created and enforced guidelines that attempt to rewrite the Policies' definition so that a Cure is not deemed medically necessary until Plaintiffs and Class Members have suffered irreparable harm. Plaintiffs and Class Members allege that defendants are creating and enforcing these guidelines solely to save money and, in doing so, are blatantly ignoring the Policies' definition of medical necessity.

81. Accordingly, Plaintiffs and Class Members are in doubt about their rights, and a bona fide, present controversy exists between Plaintiffs and Class Members on the one hand, and defendants on the other, concerning the question whether a Cure satisfies the Policies' definition of medical necessity.

82. Accordingly, under 22 U.S.C. § 2201, Plaintiffs and Class Members seek obtain a declaration of rights, status, or other equitable or legal relations thereunder.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs on their own behalf and on behalf of all similarly situated persons (as defined above), demands judgment against defendants as follows:

- (1) Declaring (1) that this action is a proper class action maintainable under Rule 23(a), and one or more of Rules 23(b)(1)(a), 23(b)(2),

and 23(b)(3) of the Federal Rules of Civil Procedure, (2) that Plaintiffs shall serve as class representatives, and (3) that Rivero Mestre LLP shall serve as Class counsel;

- (2) Declaring that defendants' cost-avoidance scheme and fraudulent coverage guidelines are pretextual, fraudulent, and misleading;
- (3) Ordering Defendants to recalculate and issue unpaid benefits to Plaintiffs and Class Members, whose claims were denied as a result of Defendants' unlawful conduct;
- (4) Ordering such equitable, injunctive, and declaratory relief as may be appropriate, including restitution and/or requiring defendants to provide coverage to Plaintiffs and Class Members for the Cure medically necessary treatment, including the Cure;
- (5) Awarding Plaintiffs and Class Members their costs and disbursements, and reasonable allowances for expert fees and reimbursement of expenses, including reasonable attorney's fees, in amounts to be determined by the Court; and
- (6) Awarding such other and further relief as the interests of justice require.

DEMAND FOR JURY TRIAL

Plaintiffs and the Class request a trial by jury of any and all Counts for which a jury trial is permitted by law.

Respectfully submitted on June 13, 2018

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VICKI TUCCI KRUSEL

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EXHIBIT A



2018 Evidence of Coverage



Ambetter.SunshineHealth.com

**Celtic Insurance Company
Ambetter from Sunshine Health**

Home Office: 77 West Wacker Drive, Suite 1200, Chicago, IL 60601

Individual Member Contract

In this *contract*, the terms "*you*," "*your*" or "*yours*" will refer to the *member* or any dependents named on the *Schedule of Benefits*. The terms "*we*," "*our*," or "*us*" will refer to Celtic Insurance Company or Ambetter from Sunshine Health.

AGREEMENT AND CONSIDERATION

In consideration of the application and the timely payment of premiums, *we* will provide benefits to *you*, the *member*, for covered *services* as outlined in this *contract*. Benefits are subject to *contract* definitions, provisions, limitations and exclusions.

GUARANTEED RENEWABLE

Guaranteed renewable means that this *contract* will renew each year on the anniversary date unless terminated earlier in accordance with *contract* terms. *You* may keep this *contract* in force by timely payment of the required premiums. *We* may decide not to renew as of the renewal date if: (1) *we* decide not to renew all *contracts* issued on this form, with the same type and level of benefits, to residents of the state where *you* then live; or (2) there is fraud or an intentional material misrepresentation made by or with the knowledge of a *member* in filing a claim for *contract* benefits.

Rate changes are effective on a *member's* annual renewal date and will be based on each *member's* attained age, family structure, geographic region, tobacco usage and benefit plan at the time of renewal. *We* have the right to change premiums. *We* will notify the *member* in writing at least 45 days prior to the renewal date of any change in premium rates. If *we* discontinue offering and decide not to renew all policies issued on this form, with the same type and level of benefits, for all residents of the state where *you* reside, *we* will provide a written notice to you at least 90 days prior to the date that *we* discontinue coverage.

At least 45 days advanced written notice of any plan to take an action or make a change permitted by this clause will be delivered to *you* at *your* last address as shown in *our* records. *We* will make no change in *your* premium solely because of claims made under this *contract* or a change in a *member's* health. While this *contract* is in force, *we* will not restrict coverage already in force.


TEN DAY RIGHT TO RETURN CONTRACT

Please read *your contract* carefully. If *you* are not satisfied, return this *contract* to *us* or to *our* agent within 10 days after *you* receive it. All premiums paid will be refunded, less any benefits paid, and the *contract* will be considered null and void from the effective date.

This contract contains a deductible provision

This *contract* contains *prior authorization* requirements. *You* may be required to obtain a referral from a primary care physician in order to receive care from a specialist provider. Benefits may be reduced or not covered if the requirements are not met. Please refer to the *Schedule of Benefits* and the Prior Authorization Section.

Celtic Insurance Company

A handwritten signature in black ink, consisting of several overlapping loops and a long horizontal stroke at the bottom.

Anand Shukla, Senior Vice President

Individual Health

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INTRODUCTION

Welcome to Ambetter from Sunshine Health! This *contract* has been prepared by *us* to help explain *your* coverage. Please refer to this *contract* whenever *you* require medical services. It describes:

- How to access medical care.
- What health services *we* cover.
- What portion of the health care costs *you* will be required to pay.

This *contract*, the *Schedule of Benefits*, the application as submitted to the Health Insurance Marketplace and any amendments or riders attached shall constitute the entire contract under which *covered services* and supplies are provided or paid for by *us*.

This *contract* should be read in its entirety. Since many of the provisions are interrelated, *you* should read the entire *contract* to get a full understanding of *your* coverage. Many words used in the *contract* have special meanings: these words are *italicized* and are defined for you in the Definitions section. This *contract* also contains exclusions, so please be sure to read this *contract* carefully.

Throughout this *contract* *you* will see references to Celtic Insurance Company and Ambetter from Sunshine Health. Ambetter from Sunshine Health operates under its legal entity, Celtic Insurance Company, and both may be referred to as the “plan.”

How to Contact Us

Ambetter from Sunshine Health
1301 International Parkway, Suite 400
Sunrise, FL 33323

Normal Business Hours of Operation 8:00 a.m. to 5:00 p.m. EST

Member Services 1-877-687-1169
Relay FL 1-800-955-8770
Fax 1-866-796-0523
Emergency **911**

24/7 Nurse Advice Line 1-877-687-1169

Interpreter Services

Ambetter from Sunshine Health has a free service to help *our members* who speak languages other than English. This service allows *you* and your *physician* must be able to talk about *your* medical or behavioral health concerns in a way *you* both can understand. *Our* interpreter services are provided at no cost to *you*. We have representatives that speak Spanish and medical interpreters to assist with other languages. *Members* who are blind or visually impaired and need help with interpretation can call Member Services for an oral interpretation.

To arrange for interpretation services, call Member Services at 1-877-687-1169 (Relay FL 1-800-955-8770).

MEMBER RIGHTS AND RESPONSIBILITIES

We are committed to:

1. Recognizing and respecting *you* as a *member*.
2. Encouraging open discussions between *you*, *your physician* and *medical practitioners*.
3. Providing information to help *you* become an informed health care consumer.
4. Providing access to *covered services* and *our network providers*.
5. Sharing *our* expectations of *you* as a *member*.
6. Providing coverage regardless of age, ethnicity or race, religion, gender, sexual orientation, national origin, physical or mental disability, or expected health or genetic status.

You have the right to:

1. Participate with *your physician* and *medical practitioners* in making decisions about *your* health care. This includes working on any treatment plans and making care decisions. *You* should know any possible risks, problems related to recovery, and the likelihood of success. *You* shall not have any treatment without consent freely given by *you* or your legally authorized surrogate decision-maker. *You* will be informed of *your* care options.
2. Know who is approving and who is performing the procedures or treatment. All likely treatment and the nature of the problem should be explained clearly.
3. Receive the benefits for which *you* have coverage.
4. Be treated with respect and dignity.
5. Privacy of *your* personal health information, consistent with state and federal laws, and *our* policies.
6. Receive information or make recommendations, including changes, about *our* organization and services, *our* network of *physicians* and *medical practitioners*, and *your* rights and responsibilities.
7. Candidly discuss with *your physician* and *medical practitioners* appropriate and *medically necessary* care for *your* condition, including new uses of technology, regardless of cost or benefit coverage. This includes information from your *primary care physician* about what might be wrong (to the level known), treatment and any known likely results. Your *primary care physician* can tell you about treatments that may or may not be covered by the plan, regardless of the cost. *You* have a right to know about any costs *you* will need to pay. This should be told to *you* in words *you* can understand. When it is not appropriate to give *you* information for medical reasons, the information can be given to a legally authorized person. *Your physician* will ask for your approval for treatment unless there is an *emergency* and your life and health are in serious danger.
8. Make recommendations regarding member's rights, responsibilities and policies.
9. Voice complaints or *grievances* about: *our* organization, any benefit or coverage decisions *we* (or *our* designated administrators) make, *your* coverage, or care provided.
10. Refuse treatment for any condition, *illness* or disease without jeopardizing future treatment, and be informed by *your physician(s)* of the medical consequences.
11. See *your* medical records.
12. Be kept informed of *covered* and non-covered *services*, program changes, how to access services, *primary care physician* assignment, providers, advance directive information, referrals and *authorizations*, benefit denials, member rights and responsibilities, and *our* other rules and

guidelines. *We* will notify *you* at least 60 days before the *effective date* of the modifications. Such notices shall include:

- a. Any changes in clinical review criteria; or
 - b. A statement of the effect of such changes on the personal liability of the *member* for the cost of any such changes.
13. A current list of *network providers*. Select a health plan or switch health plans, within the guidelines, without any threats or harassment.
 14. Adequate access to qualified *medical practitioners* and treatment or services regardless of age, race, creed, sex, sexual preference, national origin or religion.
 15. Access *medically necessary* urgent and *emergency* services 24 hours a day, seven days a week.
 16. Receive information in a different format in compliance with the Americans with Disabilities Act, if *you* have a disability.
 17. Refuse treatment to the extent the law allows. *You* are responsible for *your* actions if treatment is refused or if the *primary care physician's* instructions are not followed. *You* should discuss all concerns about treatment with your *primary care physician*. *Your primary care physician* can discuss different treatment plans with *you*, if there is more than one plan that may help *you*. *You* will make the final decision.
 18. Select *your primary care physician* within the *network*. *You* also have the right to change your *primary care physician* or request information on *network providers* close to your home or work.
 19. Know the name and job title of people giving *you* care. *You* also have the right to know which *physician* is *your primary care physician*.
 20. An interpreter when *you* do not speak or understand the language of the area.
 21. A second opinion by a *network provider*, at no cost to *you*, if *you* believe your *network provider* is not authorizing the requested care, or if *you* want more information about *your* treatment.
 22. Make advance directives for healthcare decisions. This includes planning treatment before *you* need it.
 23. Advance directives are forms *you* can complete to protect *your* rights for medical care. It can help your *primary care physician* and other providers understand *your* wishes about your health. Advance directives will not take away *your* right to make *your* own decisions and will work only when *you* are unable to speak for yourself. Examples of advance directives include:
 - a. Living Will;
 - b. Health Care Power of Attorney; and
 - c. "Do Not Resuscitate" Orders. *Members* also have the right to refuse to make advance directives. *You* should not be discriminated against for not having an advance directive.

You have the responsibility to:

1. Read this *contract* in its entirety.
2. Treat all health care professionals and staff with courtesy and respect.
3. Give accurate and complete information about present conditions, past illnesses, hospitalizations, medications, and other matters about *your* health. *You* should make it known whether *you* clearly understand *your* care and what is expected of *you*. *You* need to ask questions of your *physician* until *you* understand the care *you* are receiving.
4. Review and understand the information *you* receive about *us*. *You* need to know the proper use of *covered services*.

5. Show *your* Member ID card and keep scheduled appointments with *your physician*, and call the *physician's* office during office hours whenever possible if *you* have a delay or cancellation.
6. Know the name of *your* assigned *primary care physician*. *You* should establish a relationship with *your physician*. *You* may change *your primary care physician* verbally or in writing by contacting *our* Member Services Department.
7. Read and understand to the best of *your* ability all materials concerning *your* health benefits or ask for help if *you* need it.
8. Understand *your* health problems and participate, along with *your* health care professionals and *physicians* in developing mutually agreed upon treatment goals to the degree possible.
9. Supply, to the extent possible, information that *we* or *your* health care professionals and *physicians* need in order to provide care.
10. Follow the treatment plans and instructions for care that *you* have agreed on with *your* health care professionals and *physician*.
11. Tell *your* health care professional and *physician* if *you* do not understand *your* treatment plan or what is expected of *you*. *You* should work with your *primary care physician* to develop treatment goals. If *you* do not follow the treatment plan, *you* have the right to be advised of the likely results of *your* decision.
12. Follow all health benefit plan guidelines, provisions, policies and procedures.
13. Use any emergency room only when *you* think you have a medical *emergency*. For all other care, *you* should call *your primary care physician*.
14. When *you* enroll in this coverage, give all information about any other medical coverage *you* have. If, at any time, *you* get other medical coverage besides this coverage, *you* must tell *us*.
15. Pay *your* monthly premiums on time and pay all *deductible amounts, copayment amounts, or cost-sharing percentages* at the time of service.
16. Inform the entity in which *you* enrolled for this *contract* if *you* have any changes in *your* name, address, or family members covered under this *contract* within 60 days from the date of the event.

Your Provider Directory

A listing of *network providers* is available online at Ambetter.SunshineHealth.com. *We* have plan *physicians, hospitals, and other medical practitioners* who have agreed to provide *you* with *your* healthcare services. *You* may find any of our *network providers* by completing the "Find a Doctor" function on *our* website and selecting Ambetter from Sunshine Health. There *you* will have the ability to narrow *your* search by provider specialty, zip code, gender, whether or not they are currently accepting new patients, and languages spoken. *Your* search will produce a list of providers based on *your* search criteria and will give *you* other information such as address, phone number, office hours, and qualifications.

At any time, *you* can request a copy of the provider directory at no charge by calling Member Services at 1-877-687-1169 (Relay FL 1-800-955-8770). In order to obtain benefits, *you* may be required to designate a *network primary care physician* for each *member*. *We* can also help *you* choose a *primary care physician*. *We* can make *your* choice of *primary care physician* effective on the next business day.

Call the *primary care physician's* office if you want to make an appointment. If *you* need help, call Member Services at 1-877-687-1169 (Relay FL 1-800-955-8770). *We* will help *you* make the appointment.

Your Member ID Card

When *you* enroll, we will mail *you* a Member ID card after *our* receipt of *your* completed enrollment materials which includes receipt of your initial binder payment. This card is proof that *you* are enrolled in the Ambetter plan. . *You* need to keep this card with *you* at all times. Please show this card every time *you* go for any service under the *contract*. The Member ID card will show *your* name, *member* ID# and *copayment amounts* required at the time of service. If *you* do not get your Member ID card within a few weeks after *you* enroll, please call Member Services at 1-877-687-1169 (Relay FL 1-800-955-8770). We will send *you* another card.

Our Website

Our website helps *you* get answers to many of *your* frequently asked questions and has resources and features that make it easy to get quality care. *Our* website can be accessed at Ambetter.SunshineHealth.com. It also gives *you* information on *your* benefits and services such as:

1. Finding a *network provider*.
2. *Our* programs and services, including programs to help *you* get and stay healthy.
3. A secure portal for *you* to check the status of *your* claims, make payments and obtain a copy of *your* Member ID card.
4. Member Rights and Responsibilities.
5. Notice of Privacy.
6. Current events and news.
7. *Our* Formulary or Preferred Drug List
8. *Deductible* and *copayment* accumulators.
9. Selecting a *Primary Care Provider*.
10. Health Risk Assessment form, "Welcome Survey."

If *you* have material modifications (examples include a change in life event such as marriage, death or other change in family status), or questions related to *your* health insurance coverage, contact the Health Insurance Marketplace (Exchange) at www.healthcare.gov or 1-800-318-2596.

Quality Improvement

We are committed to providing quality healthcare for *you* and *your* family. *Our* primary goal is to improve *your* health and help *you* with any illness or disability. *Our* program is consistent with National Committee on Quality Assurance (NCQA) standards and Institute of Medicine (IOM) priorities. To help promote safe, reliable, and quality healthcare, *our* programs include:

1. Conducting a thorough check on *physicians* when they become part of the *provider network*.
2. Monitoring *member* access to all types of healthcare services.
3. Providing programs and educational items about general healthcare and specific diseases.
4. Sending reminders to *members* to get annual tests such as a physical exam, cervical cancer screening, breast cancer screening, and immunizations.
5. Monitoring the quality of care and developing action plans to improve the healthcare *you* are receiving.
6. A Quality Improvement Committee which includes *network providers* to help us develop and monitor our program activities.

7. Investigating any *member* concerns regarding care received.

For example, if *you* have a concern about the care *you* received from your *network physician* or service provided by *us*, please contact our Member Services Department.

We believe that getting *member* input can help make the content and quality of *our* programs better. *We* conduct a *member* survey each year that asks questions about *your* experience with the healthcare and services *you* are receiving.

DEFINITIONS

In this *contract*, italicized words are defined. Words not italicized will be given their ordinary meaning. Wherever used in this *contract*:

Acute rehabilitation means two or more different types of therapy provided by one or more *rehabilitation licensed practitioners* and performed for three or more hours per day, five to seven days per week, while the *covered person* is confined as an *inpatient* in a *hospital*, rehabilitation facility, or *extended care facility*.

Advanced premium tax credit means the tax credit provided by the Affordable Care Act to help *you* afford health coverage purchased through the Health Insurance Marketplace. Advanced premium tax credits can be used right away to lower *your* monthly premium costs. If *you* qualify, *you* may choose how much advanced premium tax credit to apply to *your* premiums each month, up to a maximum amount. If the amount of advanced premium tax credits *you* receive for the year is less than the total premium tax credit *you're* due, *you'll* get the difference as a refundable credit when *you* file *your* federal income tax return. If the amount of advanced premium tax credits *you* receive for the year is more than the total tax credit that *you're* due, *you* must repay the excess advanced premium tax credit with *your* tax return.

Adverse Benefit Determination means a decision by *us* which results in:

- a. A denial of a request for service.
- b. A denial, reduction or failure to provide or make payment in whole or in part for a covered benefit.
- c. A determination that an admission, continued stay, or other health care service does not meet *our* requirements for *medical necessity*, appropriateness, health care setting, or level of care or effectiveness.
- d. A determination that a service is *experimental*, *investigational*, *cosmetic treatment*, not *medically necessary* or inappropriate.
- e. *Our* decision to deny coverage based upon an eligibility determination.
- f. A *rescission* of coverage determination as described in the General Provisions section of this *contract*.
- g. A prospective review or retrospective review determination that denies, reduces or fails to provide or make payment, in whole or in part, for a covered benefit.

Refer to the Internal Grievance, Internal Appeals and External Appeals Procedures section of this *contract* for information on *your* right to appeal an *adverse benefit determination*.

Allogeneic bone marrow transplant or ***BMT*** means a procedure in which bone marrow from a related or non-related donor is infused into the transplant recipient and includes peripheral blood stem cell transplants.

Applied behavior analysis means the design, implementation and evaluation of environmental modifications using behavioral stimuli and consequences to produce socially significant improvement in human behavior, including the use of direct observation, measurement, and functional analysis of the relationship between environment and behavior.

Autism spectrum disorder means autism spectrum disorder as defined by the most current version of the International Statistical Classification of Diseases (ICD),

Attending Physician means the physician responsible for the care of a patient or the physician supervising the care of patients by residents, or medical students.

Autologous bone marrow transplant or **ABMT** means a procedure in which the bone marrow infused is derived from the same person who is the transplant recipient and includes peripheral blood stem cell transplants.

Authorization or **Authorized** (also "Prior Authorization" or "Approval") means a decision to approve specialty or other *medically necessary* care for a *member* by the *member's primary care physician* or provider group.

Balance Billing means a *non-network provider* billing *you* for the difference between the provider's charge for a service and the *eligible service expense*. *Network providers* may not balance bill *you* for *covered service expenses*.

Bereavement counseling means counseling of members of a deceased person's *immediate family* that is designed to aid them in adjusting to the person's death.

Case Management is a program in which a registered nurse, known as a case manager, assists a *member* through a collaborative process that assesses, plans, implements, coordinates, monitors and evaluates options and health care benefits available to a *member*. Case management is instituted at the sole option of *us* when mutually agreed to by the *member* and the *member's physician*.

Center of Excellence means a *hospital* that:

1. Specializes in a specific type or types of *listed transplants* or other services such as cancer, bariatric or infertility; and
2. Has agreed with *us* or an entity designated by *us* to meet quality of care criteria on a cost efficient basis. The fact that a *hospital* is a *network provider* does not mean it is a *Center of Excellence*.

Child Health Supervision Services means physician-delivered or physician-supervised services that include the services described in the Major Medical Expense section of this *contract*. These services do not include hospital charges.

Chiropractic Care involves neuromuscular treatment in the form of manipulation and adjustment of the tissues of the body, particularly of the spinal column and may include physical medicine modalities or use of *durable medical equipment*.

Coinsurance means the percentage of *covered service expenses* that *you* are required to pay when *you* receive a service. *Coinsurance* amounts are listed in the *Schedule of Benefits*. Not all *covered services* have *coinsurance*.

Complaint means any expression of dissatisfaction expressed to the insurer by the claimant, or a claimant's authorized representative, about an insurer or its providers with whom the insurer has a direct or indirect contract.

Complications of pregnancy means:

1. Conditions whose diagnoses are distinct from pregnancy, but are adversely affected by pregnancy or are caused by pregnancy and not, from a medical viewpoint, associated with a normal pregnancy. This includes: ectopic pregnancy, spontaneous abortion, eclampsia, missed abortion,

and similar medical and surgical conditions of comparable severity; but it does not include: false labor, preeclampsia, edema, prolonged labor, *physician* prescribed rest during the period of pregnancy, morning sickness, and conditions of comparable severity associated with management of a difficult pregnancy, and not constituting a medically classifiable distinct complication of pregnancy.

2. An *emergency caesarean section* or a *non-elective caesarean section*.

Continuous loss means that *covered service expenses* are continuously and routinely being incurred for the active treatment of an *illness* or *injury*. The first *covered service expense* for the *illness* or *injury* must have been incurred before coverage of the *member* ceased under this *contract*. Whether or not *covered service expenses* are being incurred for the active treatment of the covered *illness* or *injury* will be determined by us based on generally accepted current medical practice.

Contract when *italicized*, means this *contract* issued and delivered to *you*. It includes the attached pages, including the Plan Information Page, *Schedule of Benefits* and any amendments.

Copayment, Copay or Copayment amount means the specific dollar amount that *you* must pay when *you* receive *covered services*. *Copayment amounts* are shown in the *Schedule of Benefits*. Not all *covered services* have a *copayment amount*.

Cosmetic treatment means treatments, procedures, or services that change or improve appearance without significantly improving physiological function and without regard to any asserted improvement to the psychological consequences or socially avoidant behavior resulting from an *injury*, *illness*, or congenital anomaly.

Cost sharing means the *deductible amount*, *copayment amount* and *coinsurance* that *you* pay for *covered services*. The *cost sharing* amount that *you* are required to pay for each type of *covered service* is listed in the *Schedule of Benefits*.

Cost sharing percentage means the percentage of *covered services* that is payable by *us*.

Cost-sharing reductions means reductions in cost sharing for an eligible individual enrolled in a silver level plan in the Health Insurance Marketplace or for an individual who is an American Indian and/or Alaskan Native enrolled in a *QHP* in the Health Insurance Marketplace.

Covered service or **covered service expenses** means services, supplies or treatment as described in this *contract* which are performed, prescribed, directed or authorized by a *physician*. To be a *covered service* the service, supply or treatment must be:

1. Provided or incurred while the *member's* coverage is in force under this *contract*;
2. Covered by a specific benefit provision of this *contract*; and
3. Not excluded anywhere in this *contract*.

Custodial care is treatment designed to assist a *member* with activities of daily living and which can be provided by a layperson and not necessarily aimed at curing or assisting in recovery from a sickness or bodily injury.

Custodial care includes (but is not limited to) the following:

1. Personal care such as assistance in walking, getting in and out of bed, dressing, bathing, feeding and use of toilet;
2. Preparation and administration of special diets;

3. Supervision of the administration of medication by a caregiver;
4. Supervision of self-administration of medication; or
5. Programs and therapies involving or described as, but not limited to, convalescent care, rest care, sanatoria care, educational care or recreational care.

Deductible amount or deductible means the amount that *you* must pay in a calendar year for *covered expenses* before we will pay benefits. For family coverage, there is a family *deductible amount* which is two times the individual *deductible amount*. Both the individual and the family *deductible amounts* are shown in the *Schedule of Benefits*.

If *you* are a covered *member* in a family of two or more *members*, *you* will satisfy *your deductible amount* when:

1. *You* satisfy *your individual deductible amount*; or
2. *Your* family satisfies the family *deductible amount* for the calendar year.

If *you* satisfy *your individual deductible amount*, each of the other *members* of *your* family are still responsible for the deductible until the family *deductible amount* is satisfied for the calendar year.

Dental services means *surgery* or services provided to diagnose, prevent, or correct any ailments or defects of the teeth and supporting tissue and any related supplies or oral appliances. Expenses for such treatment are considered *dental services* regardless of the reason for the services.

Dependent member means *your lawful spouse* or an *eligible child*.

Durable medical equipment means items that are used to serve a specific diagnostic or therapeutic purpose in the treatment of an *illness* or *injury*, can withstand repeated use, are generally not useful to a person in the absence of *illness* or *injury*, and are appropriate for use in the patient's home.

Effective date means the date a *member* becomes covered under this *contract* for *covered services*. The applicable *effective date* is shown:

1. On the *Schedule of Benefits* for this *contract* for initial *members*; and
2. On the date we approve the addition of any new *member*.

Eligible child means the child of a *covered person*, if that child is less than 26 years of age. As used in this definition, "child" means:

1. A natural child;
2. A legally adopted child;
3. A child placed with *you* for adoption;
4. A child for whom legal guardianship has been awarded to *you* or *your spouse*. It is *your* responsibility to notify the Health Insurance Marketplace if *your* child ceases to be an *eligible child*. *You* must reimburse *us* for any benefits that *we* provide or pay for a child at a time when the child did not qualify as an *eligible child*;
5. A child from the first of the month following the month in which the child turns age twenty-six (26) until the end of the calendar year in which the child turns thirty (30) years of age; and who is a resident of Florida or a full-time or part-time student; and is not provided coverage as a named member under any other group or individual health benefit plan; or is not entitled to benefits under Title XVIII of the Social Security Act.

If a dependent child is provided coverage under the *contract* after the child reaches age twenty-six (26) and the coverage for the child is subsequently terminated prior to the end of the Calendar Year in which

the child turns age thirty (30), the child is ineligible to be covered again under the *contract* unless the child was continuously covered by other creditable coverage without a coverage gap of more than sixty-three (63) days.

Eligible service expense means a *covered service* expense as determined below.

1. For *network providers*: When a *covered service* is received from a *network provider*, the *eligible service expense* is the contracted fee with that provider. The contracted fee will be paid directly to the *network provider*.
2. For *non-network providers*: When a *covered service* is received from a non-network provider, the *eligible service expense* is the minimum amount required by applicable federal or state law to be paid to the non-network provider for the service. If and only if there is no minimum amount required by applicable federal or state law, then the *eligible service expense* for a non-network provider shall be as determined below.
 - a. When a *covered service* is received from a *non-network provider* as a result of an *emergency* and there is not a *network provider* reasonably accessible to render the *covered service*, the *eligible service expense* is the lesser of (1) the negotiated fee, if any, that has been mutually agreed upon by *us* and the provider as payment in full (*you* will not be billed for the difference between the negotiated fee and the provider's charge), or (2) the amount accepted by the provider (not to exceed the provider's charge).
 - b. When a *covered service* is received from a *non-network provider* as a result of an *emergency* and there is a *network provider* reasonably accessible to render the *covered service*, the *eligible service expense* is the least of (1) the negotiated fee, if any, that has been mutually agreed upon by *us* and the provider as payment in full, (2) the amount accepted by the provider (not to exceed the provider's charge), or (3) the usual and customary charge for similar services in the community where the *covered services* were provided. *You* will not be billed for the difference between the amount paid and the provider's charge.
 - c. When a *covered service* is received from a *non-network provider* as approved or authorized by *us* that is not the result of an *emergency*, the *eligible service expense* is the negotiated fee, if any, that has been mutually agreed upon by *us* and the provider as payment in full (*you* will not be billed for the difference between the negotiated fee and the provider's charge). If there is no negotiated fee agreed to by the provider with *us*, the *eligible service expense* is the greater of (1) the amount that would be paid by Medicare, or (2) the contracted amount paid to *network providers* for the *covered service*. If there is more than one contracted amount with *network providers* for the *covered service*, the amount is the median of these amounts. *You* may be billed for the difference between the amount paid and the provider's charge.
 - d. When a *covered service* that is not the result of an *emergency* is received from a *non-network provider* at a facility that is a *network provider* and *you* do not have the ability and opportunity to choose an available *network provider* at such facility, the *eligible service expense* is the least of (1) the negotiated fee, if any, that has been mutually agreed upon by *us* and the provider as payment in full, (2) the amount accepted by the provider (not to exceed the provider's charge), or (3) the usual and customary charge for similar services in the community where the *covered services* were provided. *You* will not be billed for the difference between the amount paid and the provider's charge.
 - e. When a *covered service* is received from a *non-network provider* that is not the result of an *emergency* and is not approved or authorized by *us*, and is not within the scope of services provided by any *network provider*, the *eligible service expense* is the negotiated fee, if any, that has been mutually agreed upon by *us* and the provider as payment

in full (*you* will not be billed for the difference between the negotiated fee and the provider's charge). If there is no negotiated fee agreed to by the provider with *us*, the *eligible service expense* will be an amount that is no less than ten percentage points lower than the usual and customary percentage rate paid to *network providers*. *You* may be billed for the difference between the amount paid and the provider's charge.

Emergency means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) which requires immediate (no later than 24 hours after onset) medical or surgical care and such that an average person who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in:

1. Placing the health of the *member* (or, with respect to a pregnancy, the health of the *member* or the unborn child) in serious jeopardy;
2. Serious impairment to bodily functions; or
3. Serious dysfunction of any bodily organ or part.

With Respect to a pregnancy:

1. that there is inadequate time to effect a safe transfer to another hospital prior to delivery;
2. that the transfer may pose a threat to the health and safety of the patient or fetus; or
3. that there is evidence of the onset and persistence of uterine contractions or rupture of the membranes.

Emergency services and care shall mean medical screening, examination, and evaluation by a *physician*, or, to the extent permitted by applicable law, by other appropriate personnel under the supervision of a *physician*, to determine if any *emergency* medical condition exists and, if it does, the care, treatment, or surgery for a covered service by a *physician* necessary to relieve or eliminate the *emergency* medical condition, within the service capability of a *hospital*.

Follow-up care is not considered *emergency Care*. Benefits are provided for treatment of *emergency* medical conditions and *emergency* screening and stabilization services without *prior authorization*. Benefits for *emergency care* include facility costs and *physician* services, and supplies and prescription drugs charged by that facility. *You* must notify *us* or verify that *your physician* has notified *us* of *your* admission to a *hospital* within 48 hours or as soon as possible within a reasonable period of time. When *we* are contacted, *you* will be notified whether the *inpatient* setting is appropriate, and if appropriate, the number of days considered *medically necessary*. By contacting *us*, *you* may avoid financial responsibility for any *inpatient* care that is determined to be not *medically necessary* under *your* plan. If *your* provider does not contract with *us* *you* will be financially responsible for any care *we* determine is not *medically necessary*. Care and treatment provided once *you* are medically stabilized is no longer considered *emergency care*. Continuation of care from a non-participating provider beyond that needed to evaluate or stabilize *your* condition in an *emergency* will be covered as a non-network service unless *we* authorize the continuation of care and it is *medically necessary*.

Essential health benefits are defined by federal and state law and refer to benefits in at least the following categories: ambulatory patient services, emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, including behavioral health treatment, prescription drugs, rehabilitative and habilitative services and devices, laboratory services, preventive and wellness services and chronic disease management and pediatric services, including oral and vision care. Essential health benefits provided within this *contract* are not subject to lifetime or annual dollar maximums. Certain non-essential health benefits, however, are subject to either a lifetime or annual dollar maximum.

Expedited grievance means a *grievance* where any of the following applies:

1. The duration of the standard resolution process will result in serious jeopardy to the life or health of the claimant or the ability of the claimant to regain maximum function.
2. In the opinion of a *physician* with knowledge of the claimant's medical condition, the claimant is subject to severe pain that cannot be adequately managed without the care or treatment that is the subject of the *grievance*.
3. A *physician* with knowledge of the claimant's medical condition determines that the *grievance* shall be treated as an *expedited grievance*.

Experimental or investigational treatment means medical, surgical, diagnostic, or other health care services, treatments, procedures, technologies, supplies, devices, drug therapies, or medications that, after consultation with a medical professional, we determine to be:

1. Under study in an ongoing phase I or II clinical trial as set forth in the United States Food and Drug Administration ("*FDA*") regulation, regardless of whether the trial is subject to *FDA* oversight.
2. An *unproven service*.
3. Subject to *FDA* approval, and:
 - a. It does not have *FDA* approval;
 - b. It has *FDA* approval only under its Treatment Investigational New Drug regulation or a similar regulation; or
 - c. It has *FDA* approval, but is being used for an indication or at a dosage that is not an accepted off-label use. An accepted off-label use of a *FDA*-approved drug is a use that is determined by us to be:
 - i. Included in authoritative compendia as identified from time to time by the Secretary of Health and Human Services;
 - ii. Safe and effective for the proposed use based on supportive clinical evidence in peer-reviewed medical publications; or
 - iii. Not an *unproven service*.
 - d. It has *FDA* approval, but is being used for a use, or to treat a condition, that is not listed on the Premarket Approval issued by the *FDA* or has not been determined through peer reviewed medical literature to treat the medical condition of the *member*.
4. Experimental or investigational according to the provider's research protocols.

Items (3) and (4) above do not apply to phase I, II, III or IV *FDA* clinical trials.

Extended care facility means an institution, or a distinct part of an institution, that:

1. Is licensed as a *hospital*, *extended care facility*, *skilled nursing facility* or *rehabilitation facility* by the state in which it operates;
2. Is regularly engaged in providing 24-hour skilled nursing care under the regular supervision of a *physician* and the direct supervision of a registered nurse;
3. Maintains a daily record on each patient;
4. Has an effective utilization review plan;
5. Provides each patient with a planned program of observation prescribed by a *physician*; and
6. Provides each patient with active treatment of an *illness* or *injury*, in accordance with existing generally accepted standards of medical practice for that condition.

Extended care facility does not include a facility primarily for rest, the aged, treatment of *substance abuse*, *custodial care*, nursing care, or for care of *mental disorders* or the mentally incompetent.

Generally accepted standards of medical practice are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying primarily on controlled clinical trials.

If no credible scientific evidence is available, then standards based on physician specialty society recommendations or professional standards of care may be considered. *We* reserve the right to consult medical professionals in determining whether a health care service, supply, or drug is *medically necessary* and is a *covered service* under the *contract*. The decision to apply physician specialty society recommendations, the choice of medical professional, and the determination of when to use any such opinion, will be determined by *us*.

Grievance means any dissatisfaction with an insurer offering a health benefit plan or administration of a health benefit plan by the insurer that is expressed in writing in any form to the insurer by, or on behalf of, a claimant including any of the following:

1. Provision of services;
2. Determination to rescind a policy;
3. Determination of a diagnosis or level of service required for evidence-based treatment of autism spectrum disorders; and
4. Claims practices.

Habilitation or habilitation services means health care services that help *you* keep, learn, or improve skills and functioning for daily living. These services may include physical and occupational therapy, speech-language pathology, and other services for people with disabilities in a variety of *inpatient* or outpatient settings.

Home health aide services means those services provided by a home health aide employed by a *home health care agency* and supervised by a registered nurse, which are directed toward the personal care of a *member*.

Home health care means care or treatment of an *illness* or *injury* at the *member's* home that is:

1. Provided by a *home health care agency*; and
2. Prescribed and supervised by a *physician*.

Home health care agency means a public or private agency, or one of its subdivisions, that:

1. Operates pursuant to law as a *home health care agency*;
2. Is regularly engaged in providing *home health care* under the regular supervision of a registered nurse;
3. Maintains a daily medical record on each patient; and
4. Provides each patient with a planned program of observation and treatment by a *physician*, in accordance with existing generally accepted standards of medical practice for the *injury* or *illness* requiring the *home health care*.

An agency that is approved to provide *home health care* to those receiving Medicare benefits will be deemed to be a *home health care agency*.

Hospice means an institution that:

1. Provides a *hospice care program*;
2. Is separated from or operated as a separate unit of a *hospital*, *hospital-related* institution, *home health care agency*, mental health facility, *extended care facility*, or any other licensed health care institution;

3. Provides care for the *terminally ill*; and
4. Is licensed by the state in which it operates.

Hospice care program means a coordinated, interdisciplinary program prescribed and supervised by a *physician* to meet the special physical, psychological, and social needs of a *terminally ill member* and those of his or her *immediate family*.

Hospital means an institution that:

1. Operates as a *hospital* pursuant to law;
2. Operates primarily for the reception, care, and treatment of sick or injured persons as *inpatients*;
3. Provides 24-hour nursing service by registered nurses on duty or call;
4. Has staff of one or more *physicians* available at all times;
5. Provides organized facilities and equipment for diagnosis and treatment of acute medical, surgical, or mental conditions either on its premises or in facilities available to it on a prearranged basis; and
6. Is not primarily a long-term care facility; an *extended care facility*, nursing, rest, *custodial care*, or convalescent home; a halfway house, transitional facility, or *residential treatment facility*; a place for the aged, drug addicts, alcoholics, or runaways; a facility for wilderness or outdoor programs; or a similar establishment.

While confined in a separate identifiable *hospital* unit, section, or ward used primarily as a nursing, rest, *custodial care* or convalescent home, *rehabilitation facility*, *extended care facility*, or *residential treatment facility*, halfway house, or transitional facility, a *member* will be deemed not to be confined in a *hospital* for purposes of this *contract*.

This includes services of an osteopathic hospital when services are available in the service area.

Illness means a sickness, disease, or disorder of a *member*. *Illness* does not include learning disabilities, attitudinal disorders, or disciplinary problems. All *illnesses* that exist at the same time and that are due to the same or related causes are deemed to be one *illness*. Further, if an *illness* is due to causes that are the same as, or related to, the causes of a prior *illness*, the *illness* will be deemed a continuation or recurrence of the prior *illness* and not a separate *illness*.

Immediate family means the parents, *spouse*, children, or siblings of any *member*, or any person residing with a *member*.

Injury means accidental bodily damage sustained by a *member* and inflicted on the body by an external force. All *injuries* due to the same accident are deemed to be one *injury*.

Inpatient means that services, supplies, or treatment for medical, behavioral health or substance abuse are received by a person who is an overnight resident patient of a *hospital* or other facility, using and being charged for room and board.

Intensive care unit means a Cardiac Care Unit, or other unit or area of a *hospital* that meets the required standards of the Joint Commission on Accreditation of Hospitals for Special Care Units.

Intensive day rehabilitation means two or more different types of therapy provided by one or more *rehabilitation licensed practitioners* and performed for three or more hours per day, five to seven days per week.

Listed transplant means one of the following procedures and no others:

1. Heart transplants.
2. Lung transplants.
3. Heart/lung transplants.
4. Kidney transplants.
5. Liver transplants.
6. Bone marrow transplants for the following conditions:
 - a. *BMT* or *ABMT* for Non-Hodgkin's Lymphoma.
 - b. *BMT* or *ABMT* for Hodgkin's Lymphoma.
 - c. *BMT* for Severe Aplastic Anemia.
 - d. *BMT* or *ABMT* for Acute Lymphocytic and Nonlymphocytic Leukemia.
 - e. *BMT* for Chronic Myelogenous Leukemia.
 - f. *ABMT* for Testicular Cancer.
 - g. *BMT* for Severe Combined Immunodeficiency.
 - h. *BMT* or *ABMT* for Stage III or IV Neuroblastoma.
 - i. *BMT* for Myelodysplastic Syndrome.
 - j. *BMT* for Wiskott-Aldrich Syndrome.
 - k. *BMT* for Thalassemia Major.
 - l. *BMT* or *ABMT* for Multiple Myeloma.
 - m. *ABMT* for pediatric Ewing's sarcoma and related primitive neuroectodermal tumors, Wilm's tumor, rhabdomyosarcoma, medulloblastoma, astrocytoma and glioma.
 - n. *BMT* for Fanconi's anemia.
 - o. *BMT* for malignant histiocytic disorders.
 - p. *BMT* for juvenile.

Bone marrow transplants when the particular use of the bone marrow transplant procedure is determined to be accepted within the appropriate oncological specialty and not Experimental in accordance with applicable Florida law. As used in this *contract*, the term "bone marrow transplant" means human blood precursor cells administered to a patient to restore normal hematological and immunological functions following ablative or nonablative therapy with curative or life-prolonging intent. Human blood precursor cells may be obtained from the patient in an autologous transplant or from a medically acceptable related or unrelated donor, and may be derived from bone marrow, circulating blood, or a combination of bone marrow and circulating blood. If chemotherapy is an integral part of the treatment involving bone marrow transplantation, the term "bone marrow transplant" includes both the transplantation and the chemotherapy.

Loss means an event for which benefits are payable under this *contract*. A *loss* must occur while the *member* is covered under this *contract*.

Loss of minimum essential coverage means in the case of an employee or dependent who has coverage that is not COBRA continuation coverage, the conditions are satisfied at the time the coverage is terminated as a result of loss of eligibility (regardless of whether the individual is eligible for or elects COBRA continuation coverage). Loss of eligibility does not include a loss due to the failure of the employee or dependent to pay premiums on a timely basis or termination of coverage for cause (such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan). Loss of eligibility for coverage includes, but is not limited to:

1. Loss of eligibility for coverage as a result of legal separation, divorce, cessation of dependent status (such as attaining the maximum age to be eligible as a dependent child under the plan), death of an employee, termination of employment, reduction in the number of hours of employment, and any loss of eligibility for coverage after a period that is measured by reference to any of the foregoing;

2. In the case of coverage offered through an HMO, or other arrangement, in the individual market that does not provide benefits to individuals who no longer reside, live, or work in a service area, loss of coverage because an individual no longer resides, lives, or works in the service area (whether or not within the choice of the individual);
3. In the case of coverage offered through an HMO, or other arrangement, in the group market that does not provide benefits to individuals who no longer reside, live, or work in a service area, loss of coverage because an individual no longer resides, lives, or works in the service area (whether or not within the choice of the individual), and no other benefit package is available to the individual;
4. A situation in which an individual incurs a claim that would meet or exceed a lifetime limit on all benefits;
5. A situation in which a plan no longer offers any benefits to the class of similarly situated individuals (as described in § 54.9802-1(d)) that includes the individual;
6. In the case of an employee or dependent who has coverage that is not COBRA continuation coverage, the conditions are satisfied at the time employer contributions towards the employee's or dependent's coverage terminate. Employer contributions include contributions by any current or former employer that was contributing to coverage for the employee or dependent; and
7. In the case of an employee or dependent who has coverage that is COBRA continuation coverage, the conditions are satisfied at the time the COBRA continuation coverage is exhausted. An individual who satisfies the conditions for special enrollment, does not enroll, and instead elects and exhausts COBRA continuation coverage satisfies the conditions.

Managed drug limitations means limits in coverage based upon time period, amount or dose of a drug, quantity limits, age or gender limitations, requirements for previously tried and failed drugs or other specified predetermined criteria.

Maximum out-of-pocket amount is the sum of the deductible amount, *prescription drug deductible amount* (if applicable), *copayment amount* and *coinsurance percentage of covered expenses*, as shown in the *Schedule of Benefits*. After the *maximum out-of-pocket amount* is met for an individual, Celtic pays 100% of *eligible service expenses* for that individual. The family *maximum out-of-pocket amount* is two times the individual maximum out-of-pocket amount. Both the individual and the family *maximum out-of-pocket amounts* are shown in the *Schedule of Benefits*.

For family coverage, the family *maximum out-of-pocket* amount can be met with the combination of any *covered persons' eligible service expense*. A *covered person's maximum out-of-pocket* will not exceed the individual *maximum out-of-pocket amount*.

If you are a covered member in a family of two or more members, you will satisfy your *maximum out-of-pocket* when:

1. You satisfy your individual *maximum out-of-pocket*; or
2. Your family satisfies the family *maximum out-of-pocket* amount for the calendar year.

If you satisfy your individual *maximum out-of-pocket*, you will not pay any more *cost-sharing* for the remainder of the calendar year, but any other eligible members in your family must continue to pay *cost sharing* until the family *maximum out-of-pocket* is met for the calendar year.

The Dental out-of-pocket maximum limits do not apply to the satisfaction of the *maximum out-of-pocket* per calendar year as shown in the *Schedule of Benefits*.

Maximum therapeutic benefit means the point in the course of treatment where no further improvement in a *covered person's* medical condition can be expected, even though there may be fluctuations in levels of pain and function.

Medical practitioner includes but is not limited to the physicians, physician's assistants, nurses, nurse clinicians, nurse practitioners, pharmacists, marriage and family therapists, clinical social workers, mental health counselors, speech-language pathologists, audiologists, occupational therapists, respiratory therapists, physical therapists, ambulance services, hospitals, skilled nursing facilities, or other health care providers properly licensed in the State of Florida.

Medically necessary means any medical service, supply or treatment authorized by a *physician* to diagnose and treat a *member's illness or injury* which:

1. Is consistent with the symptoms or diagnosis;
2. Is provided according to generally accepted medical practice standards;
3. Is not *custodial care*;
4. Demonstrates that the member is significantly improving in his/her functional ability;
5. Is not solely for the convenience of the *physician* or the *member*;
6. Is not *experimental or investigational*;
7. Is provided in the most cost effective care facility or setting;
8. Does not exceed the scope, duration, or intensity of that level of care that is needed to provide safe, adequate and appropriate diagnosis or treatment; and
9. When specifically applied to a *hospital* confinement, it means that the diagnosis and treatment of *your* medical symptoms or conditions cannot be safely provided as an outpatient or in a lower level or alternative setting of care.

Charges incurred for treatment not *medically necessary* are not *eligible service expenses*.

Medically stabilized means that the person is no longer experiencing further deterioration as a result of a prior *injury* or *illness* and there are no acute changes in physical findings, laboratory results, or radiologic results that necessitate acute medical care. Acute medical care does not include *acute rehabilitation*.

Medicare opt-out practitioner means a *medical practitioner* who:

1. Has filed an affidavit with the Department of Health and Human Services stating that he or she will not submit any claims to Medicare during a two-year period;
2. Has been designated by the Secretary of that Department as a *Medicare opt-out practitioner*.

Medicare participating practitioner means a *medical practitioner* who is eligible to receive reimbursement from Medicare for treating Medicare-eligible individuals.

Member or **Covered Person** means an individual covered by the health plan including an enrollee, subscriber or *contract holder*.

Mental disorder means a behavioral, emotional, or cognitive pattern of functioning that is listed in the most recent editions of the Diagnostic and Statistical Manual of Mental Disorders (DSM) and the International Classification of Diseases (ICD),

Necessary medical supplies means medical supplies that are:

1. Necessary to the care or treatment of an *injury* or *illness*;
2. Not reusable or *durable medical equipment*; and
3. Not able to be used by others.

Necessary medical supplies do not include first aid supplies, cotton balls, rubbing alcohol, or like items routinely found in the home.

Network means a group of *physicians* and providers who have contracts that include an agreed upon price for health care services or expenses.

Network eligible service expense means the *eligible service expense* for services or supplies that are provided by a *network provider*. For facility services, this is the *eligible service expense* that is provided at and billed by a *network* facility for the services of either a *network* or non-*network provider*. *Network eligible service expense* includes benefits for *emergency* health services even if provided by a non-*network provider*.

Network provider means a *physician* or provider who is identified in the most current list for the *network* shown on *your* identification card.

Non-network provider means a *physician* or provider who is NOT identified in the most current list for the *network* shown on *your* identification card. Services received from a *non-network provider* are not covered, except as specifically stated in this *contract*.

Other plan means any plan or policy that provides insurance, reimbursement, or service benefits for *hospital*, surgical, or medical expenses. This includes payment under group or individual insurance policies, automobile no-fault or medical pay, workers compensation policy, homeowner insurance medical pay, premises medical pay, nonprofit health service plans, health maintenance organization subscriber contracts, self-insured group plans, prepayment plans, and Medicare when the *member* is enrolled in Medicare. *Other plan* will not include Medicaid.

Outpatient services include both facility, ancillary, facility use, and professional charges when given as an outpatient at a *hospital*, alternative care facility, retail health clinic, or other provider as determined by the plan. These facilities may include a non-*hospital* site providing diagnostic and therapy services, surgery, or rehabilitation, or other provider facility as determined by us. Professional charges only include services billed by a *physician* or other professional.

Outpatient surgical facility means any facility with a medical staff of *physicians* that operates pursuant to law for the purpose of performing *surgical procedures*, and that does not provide accommodations for patients to stay overnight. This does not include facilities such as: acute-care clinics, *urgent care centers*, ambulatory-care clinics, free-standing emergency facilities, and *physician* offices.

Period of extended loss means a period of consecutive days:

1. Beginning with the first day on which a *member* is a *hospital inpatient*; and
2. Ending with the 30th consecutive day for which he or she is not a *hospital inpatient*.

Pain management program means a program using interdisciplinary teams providing coordinated, goal-oriented services to a *member* who has chronic pain that significantly interferes with physical, psychosocial, and vocational functioning, for the purpose of reducing pain, improving function, and decreasing dependence on the health care system. A *pain management program* must be individualized and provide physical *rehabilitation*, education on pain, relaxation training, and medical evaluation.

Physician means a licensed *medical practitioner* who is practicing within the scope of his or her licensed authority in treating a bodily *injury* or sickness and is required to be covered by state law which includes

chiropractors, podiatrists, and osteopaths. A *physician* does **NOT** include someone who is related to a *covered person* by blood, marriage or adoption or who is normally a member of the *covered person's* household.

Post-service claim means any claim for benefits for medical care or treatment that is not a *pre-service claim*.

Pre-service claim means any claim for benefits for medical care or treatment that requires the approval of the plan in advance of the claimant obtaining the medical care.

Pregnancy means the physical condition of being pregnant, but does not include *complications of pregnancy*.

Prescription drug means any medicinal substance whose label is required to bear the legend "RX only."

Prescription drug deductible amount means the amount of *covered expenses*, shown in the *Schedule of Benefits*, if applicable, that must actually be paid during any calendar year before any *prescription drug* benefits are payable. The family *prescription drug deductible amount* is two times the individual *prescription drug deductible amount*. For family coverage, once a *covered person* has met the individual *prescription drug deductible amount*, any remaining family *prescription drug deductible amount* can be met with the combination of any one or more *covered persons' eligible service expenses*.

Primary care physician means a *physician* who is a family practitioner, general practitioner, pediatrician, internist, obstetrician or gynecologist.

Prior Authorization means a decision to approve specialty or other *medically necessary* care for a *member* by the *member's primary care physician* or provider group prior to rendering services.

Proof of loss means information required by *us* to decide if a claim is payable and the amount that is payable. It may include, but is not limited to, claim forms, medical bills or records, other plan information, payment of claim and *network* re-pricing information. *Proof of loss* must include a copy of all Explanation of Benefit forms from any other carrier, including Medicare.

Qualified health plan or QHP means a health plan that has in effect a certification that it meets the standards described in subpart C of part 156 issued or recognized by each Health Insurance Marketplace through which such plan is offered in accordance with the process described in subpart K of part 155.

Qualified individual means, with respect to a Health Insurance Marketplace, an individual who has been determined eligible to enroll through the Health Insurance Marketplace in a *qualified health plan* in the individual market.

Reconstructive surgery means *surgery* performed on an abnormal body structure caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease in order to improve function or to improve the patient's appearance, to the extent possible.

Rehabilitation means care for restoration (including by education or training) of one's prior ability to function at a level of *maximum therapeutic benefit*. This includes *acute rehabilitation*, *sub-acute rehabilitation*, or *intensive day rehabilitation*, and it includes *rehabilitation therapy* and *pain management programs*. An *inpatient* hospitalization will be deemed to be for *rehabilitation* at the time the patient has

been *medically stabilized* and begins to receive *rehabilitation therapy* or treatment under a *pain management program*.

Rehabilitation facility means an institution or a separate identifiable *hospital* unit, section, or ward that:

1. Is licensed by the state as a *rehabilitation facility*; and
2. Operates primarily to provide 24-hour primary care or *rehabilitation* of sick or injured persons as *inpatients*.

Rehabilitation facility does not include a facility primarily for rest, the aged, long term care, assisted living, *custodial care*, nursing care, or for care of the mentally incompetent.

Rehabilitation licensed practitioner means, but is not limited to, a *physician*, physical therapist, speech therapist, occupational therapist, or respiratory therapist. A *rehabilitation licensed practitioner* must be licensed or certified by the state in which care is rendered and performing services within the scope of that license or certification.

Rehabilitation therapy means physical therapy, occupational therapy, speech therapy, or respiratory therapy.

Rescission of a policy means a determination by an insurer to withdraw the coverage back to the initial date of coverage.

Residence means the physical location where *you* live. If *you* live in more than one location, and *you* file a United States income tax return, the physical address (not a P.O. Box) shown on *your* United States income tax return as *your* residence will be deemed to be *your* place of residence. If *you* do not file a United States income tax return, the *residence* where *you* spend the greatest amount of time will be deemed to be *your* place of *residence*.

Residential treatment facility means a facility that provides (with or without charge) sleeping accommodations, and:

1. Is not a *hospital*, *extended care facility*, or *rehabilitation facility*; or
2. Is a unit whose beds are not licensed at a level equal to or more acute than skilled nursing.

Respite care means *home health care* services provided temporarily to a *member* in order to provide relief to the *member's immediate family* or other caregiver.

Schedule of Benefits means a summary of the *deductible*, *copayment*, *coinsurance*, *maximum out-of-pocket* and other limits that apply when *you* receive *covered services and supplies*.

Skilled Nursing Facility means services that include *physician* services, room and board limited to semi-private rooms, unless a private room is *medically necessary* or a semi-private room is not available, and patient meals, general nursing care, rehabilitative services, drugs (drugs and biologicals), medical supplies and the use of appliances and equipment furnished by skilled nursing facility. Limitations apply, see *your Schedule of Benefits*.

Specialist physician means a *physician* who is not a *primary care physician*.

Spouse means *your* lawful wife or husband.

Sub-acute rehabilitation means one or more different types of therapy provided by one or more *rehabilitation licensed practitioners* and performed for one-half hour to two hours per day, five to seven days per week, while the covered person is confined as an *inpatient* in a *hospital, rehabilitation facility, or extended care facility*.

Substance abuse or substance abuse disorder means alcohol, drug or chemical abuse, overuse, or dependency. Covered *substance abuse disorders* are those listed in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders and the International Classification of Diseases, Tenth Revision (ICD-10).

Surgery or **surgical procedure** means:

1. An invasive diagnostic procedure; or
2. The treatment of a *member's illness* or *injury* by manual or instrumental operations, performed by a *physician* while the *member* is under general or local anesthesia.

Surveillance tests for ovarian cancer means annual screening using:

1. CA-125 serum tumor marker testing;
2. Transvaginal ultrasound; or
3. Pelvic examination.

Terminal illness counseling means counseling of the *immediate family* of a *terminally ill* person for the purpose of teaching the *immediate family* to care for and adjust to the *illness* and impending death of the *terminally ill* person.

Terminally ill means a *physician* has given a prognosis that a *member* has six months or less to live.

Third party means a person or other entity that is or may be obligated or liable to the *member* for payment of any of the *member's* expenses for *illness* or *injury*. The term "*third party*" includes, but is not limited to, an individual person; a for-profit or non-profit business entity or organization; a government agency or program; and an insurance company. However, the term "*third party*" will not include any insurance company with a policy under which the *member* is entitled to benefits as a named insured person or an insured *dependent member* of a named insured person except in those jurisdictions where statutes or common law does not specifically prohibit *our* right to recover from these sources.

Tobacco use or **use of tobacco** means use of tobacco by individuals who may legally use tobacco under federal and state law on average four or more times per week and within no longer than the six months immediately preceding the date application for this *contract* was completed by the *member*, including all tobacco products but excluding religious and ceremonial uses of tobacco.

Unproven service(s) means services, including medications, which are determined not to be effective for treatment of the medical condition, or not to have a beneficial effect on health outcomes, due to insufficient and inadequate clinical evidence from *well-conducted randomized controlled trials* or *well-conducted cohort studies* in the prevailing published peer-reviewed medical literature.

1. "*Well-conducted randomized controlled trials*" means that two or more treatments are compared to each other, and the patient is not allowed to choose which treatment is received.
2. "*Well-conducted cohort studies*" means patients who receive study treatment are compared to a group of patients who receive standard therapy. The comparison group must be nearly identical to the study treatment group.

Urgent care center means a facility, not including a *hospital emergency room* or a *physician's office*, that provides treatment or services that are required:

1. To prevent serious deterioration of a *member's* health;
2. As a result of an unforeseen *illness, injury*, or the onset of acute or severe symptoms.

Utilization review means a process used to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings. Areas of review may include ambulatory review, prospective review, second opinion, certification, concurrent review, *case management*, discharge planning, or retrospective review.

DEPENDENT MEMBER COVERAGE

Dependent Member Eligibility

Your *dependent members* become eligible for coverage under this *contract* on the latter of:

1. The date *you* became covered under this *contract*; or
2. The date of marriage to add a spouse; or
3. The date of a newborn's birth; or
4. The date that an adopted child is placed with you or your spouse for the purposes of adoption or you or your spouse assumes total or partial financial support of the child.

Effective Date for Initial Dependent Members

The *effective date* for your initial *dependent members*, if any, is shown on the *Schedule of Benefits*. Only *dependents* included in the application for this *contract* will be covered on your *effective date*.

Coverage for a Newborn Child

An eligible child born to you or your covered family member(s) will be covered from the time of birth if the newborn is enrolled timely as specified in the Special Enrollment provision.

The coverage, benefits or services for newborns shall consist of coverage for injury or sickness, including the necessary care or treatment of medically diagnosed congenital defects, birth abnormalities or pre-maturity and up to \$1,000 transportation costs of the newborn to and from the nearest appropriate facility staffed and equipped to treat the newborn's condition when such transportation is certified by the treating provider as necessary to protect the health and safety of the newborn child.

Additional premium will be required to continue coverage beyond the 31st day after the date of birth. The required premium will be calculated from the child's date of birth. If notice of the newborn is given to *us* by the Health Insurance Marketplace within the 31 days from birth, an additional premium for coverage of the newborn child will be charged for not less than 31 days after the birth of the child. If notice is not given within the 31 days from birth, *we* will charge an additional premium from the date of birth. If notice is given by the Health Insurance Marketplace within 60 days of the birth of the child, the *contract* may not deny coverage of the child due to failure to notify *us* of the birth of the child or to pre-enroll the child.

Coverage for an Adopted Child

Coverage for children under this *contract* will be provided for the adopted child of a *member* who has family coverage in force. Coverage is provided from the moment of placement to a child the *member* proposes to adopt who is placed in the *member's* residence in compliance with Chapter 63, Florida Statutes. A newborn infant who is adopted by the *member* is covered from the moment of birth if a written agreement to adopt such child has been entered into prior to the birth of the child, whether or not such agreement is enforceable. However, coverage will not be provided in the event the child is not ultimately placed in the *member's* residence in compliance with chapter 63, Florida Statutes.

The *member's* adopted child is covered from the moment of placement in the residence, or if a newborn, from the moment of birth, if the child is enrolled timely as specified in the Special and Limited Enrollment Period provision.

Additional premium will be required to continue coverage beyond the 31st day following *placement* of the child and *we* have received notification from the Marketplace. The required premium will be calculated from the date of *placement* for adoption. Coverage of the child will terminate on the 31st day following *placement*, unless *we* have received both: (A) Notification of the addition of the child from the Marketplace

within 60 days of the birth or placement and (B) any additional premium required for the addition of the child within 90 days of the date of *placement*

As used in this provision, "*placement*" means the earlier of:

1. The date that *you* or *your spouse* assume physical custody of the child for the purpose of adoption;
or
2. The date of entry of an order granting *you* or *your spouse* custody of the child for the purpose of adoption.

Adding Other Dependent Members

If *you* are enrolled in an off-exchange policy and apply in writing to add a *dependent member* and *you* pay the required premiums, *we* will send *you* written confirmation of the added *dependent member's effective date* of coverage and ID Cards for the added *dependent member*.

ONGOING ELIGIBILITY

For All Members

A *member's* eligibility for coverage under this *contract* will cease on the earlier of:

1. The date that a *member* has failed to pay premiums or contributions in accordance with the terms of this *contract* or the date that we have not received timely premium payments in accordance with the terms of this *contract*; or
2. The date the member has performed an act or practice that constitutes fraud or made an intentional misrepresentation of a material fact (e.g., the date that a member accepts any direct or indirect contributions or reimbursement by or on behalf of an employer, for any portion of the premium for coverage under this *contract*); or
3. The date a *member's* employer and a *member* treat this *contract* as part of an employer-provided health plan for any purpose, including tax purposes; or
4. The date *we* receive a request from *you* to terminate this *contract*, or any later date stated in *your* request, or if *you* are enrolled through the Marketplace, the date of termination that the Marketplace provides us upon your request of cancellation to the Marketplace; or
5. The date *we* decline to renew this *contract*, as stated in the Discontinuance provision; or
6. The date of a *member's* death; or
7. The date a *member's* eligibility for coverage under this *contract* ceases due to losing network access as the result of a permanent move.

For Dependent Members

A *dependent member* will cease to be a *member* at the end of the premium period in which he or she ceases to be *your dependent member* due to divorce or if a child ceases to be an *eligible child*. For eligible children, coverage will terminate the thirty-first of December the year that the dependent turns 30 years of age.

All enrolled *dependent members* will continue to be covered until the age limit listed in the definition of *eligible child* above.

We must receive notification within 90 days of the date a *dependent member* ceases to be an eligible *dependent member*. If notice is received by *us* more than 90 days from this date, any unearned premium will be credited only from the first day of the *contract*/calendar month in which *we* receive the notice.

A *member* will not cease to be a *dependent eligible child* solely because of age if the *eligible child* is:

1. Not capable of self-sustaining employment due to mental handicap or physical handicap that began before the age limit was reached; and
2. Mainly dependent on *you* for support.

If health benefits are denied for the stated reason that the child has reached the limiting age for dependent coverage specified in this *contract*, the *member* has the burden of establishing that the child continues to meet the criteria specified above. Failure to provide the required proof may result in the dependent's termination of coverage.

The coverage of the handicapped child may be continued, but not beyond the termination date of such incapacity or such dependence. This provision shall in no event limit the application of any other *contract* provisions terminating such child's coverage for any other reason than the attainment of the limiting age.

Out of Service Area Dependent Member Coverage

A *dependent member's* coverage will not cease should the *dependent member* live outside the service area if a court order requires the *member* to cover such *dependent member*.

Open Enrollment

There will be an open enrollment period for coverage on the Health Insurance Marketplace. The open enrollment period begins November 1, 2017 and extends through December 15, 2017. *Qualified individuals* who enroll on or before December 15, 2017 will have an *effective date* of coverage on January 1, 2018.

The Health Insurance Marketplace may provide a coverage *effective date* for a *qualified individual* earlier than specified in the paragraphs above, provided that either:

1. The *qualified individual* has not been determined eligible for *advance premium tax credits* or *cost-sharing reductions*; or
2. The *qualified individual* pays the entire premium for the first partial month of coverage as well as all cost sharing, thereby waiving the benefit of *advanced premium tax credit* and *cost-sharing reduction* payments until the first of the next month. We will send written annual open enrollment notification to each *member* no earlier than the first of September, and no later than the thirtieth of September.

Special and Limited Enrollment

A *qualified individual* has 60 days to report a qualifying event to the Health Insurance Marketplace and could be granted a 60 day Special Enrollment Period as a result of one of the following events:

1. A *qualified individual* or *dependent* loses *minimum essential coverage*; or
2. A *qualified individual* gains a *dependent* or becomes a *dependent* through marriage, birth, adoption or placement for adoption of a member or their spouse; or
3. An individual, who was not previously a citizen, national, or lawfully present individual gains such status; or
4. A *qualified individual's* enrollment or non-enrollment in a *qualified health plan* is unintentional, inadvertent, or erroneous and is the result of the error, misrepresentation, or inaction of an officer, employee, or agent of the Health Insurance Marketplace or HHS, or its instrumentalities as evaluated and determined by the Health Insurance Marketplace. In such cases, the Health Insurance Marketplace may take such action as may be necessary to correct or eliminate the effects of such error, misrepresentation, or inaction; or
5. An enrollee adequately demonstrates to the Health Insurance Marketplace that the *qualified health plan* in which he or she is enrolled substantially violated a material provision of its contract in relation to the enrollee; or
6. An individual is determined newly eligible or newly ineligible for *advance payments of the premium tax credit* or has a change in eligibility for *cost-sharing reductions*, regardless of whether such individual is already enrolled in a *qualified health plan*; or
7. A *qualified individual* or enrollee gains access to new *qualified health plans* as a result of a permanent move; or
8. Qualifying events as defined under section 603 of the Employee Retirement Income Security Act of 1974, as amended; or
9. An Indian, as defined by section 4 of the Indian Health Care Improvement Act, may enroll in a *qualified health plan* or change from one *qualified health plan* to another one time per month; or
10. A *qualified individual* or enrollee demonstrates to the Health Insurance Marketplace, in accordance with guidelines issued by HHS, that the individual meets other exceptional circumstances as the Health Insurance Marketplace may provide.

The Health Insurance Marketplace may provide a coverage *effective date* for a *qualified individual* earlier than specified in the paragraphs above, provided that either:

1. The *qualified individual* has not been determined eligible for *advanced payments of the premium tax credit* or *cost-sharing reductions*; or
2. The *qualified individual* pays the entire premium for the first partial month of coverage as well as all *cost sharing*, thereby waiving the benefit of *advanced payments of the premium tax credit* and *cost-sharing reduction* payments until the first of the next month.

PREMIUMS

Premium Payment

Each premium is to be paid on or before its due date. The initial premium must be paid prior to the coverage *effective date*, although an extension may be provided during the annual Open Enrollment period.

Grace Period

When a member is receiving a premium subsidy:

After the first premium is paid, a grace period of three (3) months from the premium due date is given for the payment of premium. Coverage will remain in force during the grace period. If full payment of premium is not received within the grace period, coverage will be terminated as of the last day of the first month during the grace period, if advance premium tax credits are received.

We will continue to pay all appropriate claims for *covered services* rendered to the *member* during the first month of the grace period, and may pend claims for *covered services* rendered to the *member* in the second and third month of the grace period. *We* will notify HHS of the non-payment of premiums, the *member*, as well as providers of the possibility of denied claims when the *member* is in the second and third month of the grace period. *We* will continue to collect advance premium tax credits on behalf of the *member* from the Department of the Treasury, and will return the advance premium tax credits on behalf of the *member* for the second and third month of the grace period if the *member* exhausts their grace period as described above. A member is not eligible to re-enroll once terminated, unless a member has a special enrollment circumstance, such as a marriage or birth in the family or during annual open enrollment periods.

When a member is not receiving a premium subsidy:

Premium payments are due in advance, on a calendar month basis. Monthly payments are due on or before the first day of each month for coverage effective during such month. There is a one (1) month grace period. This provision means that if any required premium is not paid on or before the date it is due, it may be paid during the grace period. During the grace period, the *Contract* will stay in force. *We* will notify HHS, as necessary, of the non-payment of premiums, the *member*, as well as providers of the possibility of denied claims when the *member* is in the grace period.

Third Party Premiums

Ambetter requires each policy holder to pay his or her premiums and this is communicated on *your* monthly billing statements. Ambetter payment policies were developed based on guidance from the Centers for Medicare and Medicaid Services (CMS) recommendations against accepting third party premiums. Consistent with CMS guidance, the following are the **ONLY** acceptable third parties who may pay Ambetter premiums on *your* behalf:

1. Ryan White HIV/AIDS Program under title XXVI of the Public Health Service Act;
2. Indian tribes, tribal organizations or urban Indian organizations;
3. State and Federal Government programs; or
4. Family members.

Upon discovery that premiums were paid by a person or entity other than those listed above, we will reject the payment and inform the member that the payment was not accepted and that the subscription charges remain due.

Misstatement of Age

If a *member's* age has been misstated, the benefits may be adjusted based on the relationship of the premium paid to the premium that should have been paid, based on the correct age.

Change or Misstatement of Residence

If you change *your residence*, you must notify the Health Insurance Marketplace of *your new residence* within 60 days of the change. As a result your premium may change and you may be eligible for a Special Enrollment Period. See the section on Special Enrollment Periods for more information.

Misstatement of Tobacco Use

The answer to the tobacco question on the application is material to *our* correct underwriting. If a *member's use of tobacco* has been misstated on the *member's* application for coverage under this *contract*, we have the right to rerate the *contract* back to the original *effective date*.

Billing/Administrative Fees

Upon prior written notice, we may impose an administrative fee for credit card payments. This does not obligate us to accept credit card payments. We will charge a \$20 fee for any check or automatic payment deduction that is returned unpaid.

COST SHARING FEATURES

Cost Sharing Features

We will pay benefits for *covered services* as described in the *Schedule of Benefits* and the Major Medical Expense Benefits section of this *contract*. Benefits we pay will be subject to all conditions, limitations, and *cost sharing* features of this *contract*. *Cost sharing* means that *you* participate or share in the cost of *your* healthcare services by paying *deductible amounts*, *copayments* and *coinsurance* for some *covered services*. For example, *you* may need to pay a *copayment* or *coinsurance* amount when *you* visit *your* physician or are admitted into the *hospital*. The *copayment* or *coinsurance* required for each type of service as well as *your deductible* is listed in *your Schedule of Benefits*.

Copayments

Members may be required to pay *copayments* at the time of services as shown in the *Schedule of Benefits*. Payment of a *copayment* does not exclude the possibility of an additional billing if the service is determined to be a *non-covered service*. *Copayments* do not apply toward the *deductible amount*, but do apply toward meeting the *maximum out-of-pocket amount*.

Coinsurance Percentage

Members may be required to pay a *coinsurance* percentage in excess of any applicable *deductible amount(s)* for a *covered service* or supply. *Coinsurance* amounts do not apply toward the *deductible* but do apply toward meeting the *maximum out-of-pocket amount*. When the annual *maximum out-of-pocket* has been met, additional *covered service expenses* will be 100%.

Deductible

The *deductible amount* means the amount of *covered service expenses* that must be paid by each/all *members* before any benefits are provided or payable. The *deductible amount* does not include any *copayment amount* or *coinsurance* amount. Not all *covered service expenses* are subject to the *deductible amount*. See your *Schedule of Benefits* for more details. *Deductible amounts* are applied for a calendar year and do not roll over to the next calendar year.

Refer to your *Schedule of Benefits* for Coinsurance Percentage and other limitations.

The amount provided or payable will be subject to:

1. Any specific benefit limits stated in the *contract*; and
2. A determination of *eligible service expenses*.

The applicable *deductible amount(s)*, *cost sharing percentage*, and *copayment amounts* are shown on the *Schedule of Benefits*.

Note: The bill *you* receive for services or supplies from a *non-network provider* may be significantly higher than the *eligible service expenses* for those services or supplies. In addition to the *deductible amount*, *copayment amount*, and *cost sharing percentage*, *you* are responsible for the difference between the *eligible service expense* and the amount the *non-network provider* bills *you* for the services or supplies. Any amount *you* are obligated to pay to the *non-network provider* in excess of the *eligible service expense* will not apply to *your deductible amount* or *maximum out-of-pocket*.

ACCESS TO CARE

Primary Care Physician

In order to obtain benefits, *you* must designate a *network primary care physician* for each *member*. *You* may select any *network primary care physician* who is accepting new patients. However, *you* may not change *your* selection more frequently than once each month. If *you* do not select a *network primary care physician* for each *member*, one will be assigned. *You* may obtain a list of *network primary care physicians* at our website or by contacting our Member Services department.

Your network primary care physician will be responsible for coordinating all covered health services and making referrals for services from other *network providers*. *You* do not need a referral from *your network primary care physician* for obstetrical or gynecological treatment and may seek care directly from a *network* obstetrician or gynecologist.

You may change *your network primary care physician* by submitting a written request, online at our website, or by contacting our office at the number shown on *your* identification card. The change to *your network primary care physician* of record will be effective no later than 30 days from the date we receive *your* request.

Referral Required For Maximum Benefits

You do not need a referral from *your network primary care physician* for obstetrical or gynecological treatment from a *network* obstetrician or gynecologist. For all other *network specialist physicians*, *you* may be required to obtain a referral from *your network primary care physician* for benefits to be payable under *your contract* or benefits payable under this *contract* may be reduced. Please refer to the *Schedule of Benefits*.

Network Availability

Your network is subject to change upon advance written notice. A *network service area* may not be available in all areas. If *you* move to an area where we are not offering access to a *network*, the *network* provisions of the *contract* will no longer apply. In that event, benefits will be calculated based on the *eligible service expense*, subject to the *deductible amount* for *network providers*. *You* will be notified of any increase in premium.

Coverage Under Other Policy Provisions

Charges for services and supplies that qualify as *covered service expenses* under one benefit provision will not qualify as *covered service expenses* under any other benefit provision of this *contract*.

MAJOR MEDICAL EXPENSE BENEFITS

Ambulance Service Benefits

Covered service expenses will include ambulance services for local transportation:

1. To the nearest *hospital* that can provide services appropriate to the *member's illness* or *injury* in cases of *emergency*.
2. To the nearest neonatal special care unit for newborn infants for treatment of *illnesses, injuries, congenital birth defects, or complications of premature birth* that require that level of care.
3. Transportation between *hospitals* or between a *hospital* and skilled nursing or rehabilitation facility when *authorized* by Ambetter from Sunshine Health.

Benefits for air ambulance services are limited to:

1. Services requested by police or medical authorities at the site of an *emergency*.
2. Those situations in which the *member* is in a location that cannot be reached by ground ambulance.

Exclusions:

No benefits will be paid for:

1. Expenses incurred for ambulance services covered by a local governmental or municipal body, unless otherwise required by law.
2. Non-*emergency* air ambulance.
3. Non-*emergency* transportation excluding ambulances (for example transport van, taxi).
4. Air ambulance:
 - a. Outside of the 50 United States and the District of Columbia;
 - b. From a country or territory outside of the United States to a location within the 50 United States or the District of Columbia; or
 - c. From a location within the 50 United States or the District of Columbia to a country or territory outside of the United States.
5. Ambulance services provided for a *member's* comfort or convenience.

Mental Health and Substance Use Disorder Benefits

Our behavioral health and substance use vendor oversees the delivery and oversight of covered behavioral health and substance use disorder services for Ambetter from Sunshine Health. If *you* need mental health or substance use disorder treatment, *you* may choose any provider participating in our behavioral health and substance use vendor's provider *network* and do not need a referral from *your primary care physician* in order to initiate treatment. *Deductible amounts, copayment or coinsurance amounts* and treatment limits for covered mental health and substance use disorder benefits will be applied in the same manner as physical health service benefits.

Covered services for mental health and substance use disorder are included on a non-discriminatory basis for all *members* for the diagnosis and *medically necessary* and active treatment of mental, emotional, or substance use disorders as defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association.

When making coverage determinations, our behavioral health and substance use vendor utilizes established level of care guidelines and medical necessity criteria that are based on currently accepted standards of practice and take into account legal and regulatory requirements: "Interqual" criteria for mental health determinations and "American Society of Addiction Medicine" criteria for substance abuse determinations. Services should always be provided in the least restrictive clinically appropriate setting.

Any determination that requested services are not medically necessary will be made by a qualified licensed mental health professional.

Covered *inpatient* and outpatient mental health or substance use disorder services are as follows:

Inpatient

1. *Inpatient* treatment;
2. *Inpatient* detoxification treatment;
3. Observation;
4. Crisis Stabilization;
5. Rehabilitation;
6. *Residential Treatment facility* for mental health and substance abuse;
7. *Inpatient* Psychiatric Hospitalization; and
8. Electroconvulsive Therapy (ECT).

Outpatient

1. Individual and group mental health evaluation and treatment;
2. Outpatient services for the purpose of monitoring drug therapy;
3. Medication management services;
4. Biofeedback;
5. Outpatient detoxification programs;
6. Psychological testing and assessment;
7. Outpatient rehabilitation treatment;
8. Applied Behavioral Analysis;
9. Telemedicine;
10. Partial Hospitalization Program (PHP);
11. Intensive Psychiatric Treatment Programs;
12. Intensive Outpatient Program (IOP);
13. Psychiatric observation for an acute psychiatric crisis;
14. Mental Health day treatment to support the recovery process with emphasis on developing healthy coping skills; and
15. Electroconvulsive Therapy (ECT).

Expenses for these services are covered if *medically necessary* and may be subject to prior authorization. Please see the *Schedule of Benefits* for more information regarding services that require prior authorization and specific benefit, day or visit limits, if any.

Autism Spectrum Disorder Benefits

Generally recognized services prescribed in relation to *autism spectrum disorder* by a *physician* or behavioral health practitioner in a treatment plan recommended by that *physician* or behavioral health practitioner.

For purposes of this section, generally recognized services may include services such as:

- evaluation and assessment services;
- *applied behavior analysis*;
- behavior training and behavior management;
- speech therapy;
- occupational therapy;
- physical therapy;

- habilitation services, limited to children ages 0 to 21 with a diagnosis of *autism spectrum disorder*; or
- medications or nutritional supplements used to address symptoms of *autism spectrum disorder*.

Habilitation, Rehabilitation and Extended Care Facility Expense Benefits

Covered service expenses include services provided or expenses incurred for *habilitation* or *rehabilitation* services or confinement in an *extended care facility*, subject to the following limitations:

1. *Covered service expenses* available to a *member* while confined primarily to receive *habilitation* or *rehabilitation* are limited to those specified in this provision.
2. *Rehabilitation* services or confinement in a *rehabilitation facility* or *extended care facility* must be for treatment of, or *rehabilitation* related to, the same *illness* or *injury* that resulted in the *hospital* stay.
3. *Covered service expenses* for *provider facility* services are limited to charges made by a *hospital*, *rehabilitation facility*, or *extended care facility* for:
 - a. Daily room and board and nursing services.
 - b. Diagnostic testing.
 - c. Drugs and medicines prescribed by a *physician*, filled by a licensed pharmacist and approved by the U.S. Food and Drug Administration.
4. *Covered service expenses* for non-*provider facility* services are limited to charges incurred for the professional services of *rehabilitation licensed practitioners*.
5. Outpatient physical therapy, occupational therapy and speech therapy.

See the *Schedule of Benefits* for benefit levels or additional limits.

Care ceases to be *rehabilitation* upon *our* determination of any of the following:

1. The *member* has reached *maximum therapeutic benefit*.
2. Further treatment cannot restore bodily function beyond the level the *member* already possesses.
3. There is no measurable progress toward documented goals.
4. Care is primarily *custodial care*.

Home Health Care Service Expense Benefits

Covered service expenses for *home health care* are limited to the following charges:

1. *Home health aide services* only if provided in conjunction with skilled nurse or licensed practical nursing services.
2. Services of a private duty registered nurse rendered on an outpatient basis.
3. Professional fees of a licensed respiratory, physical, occupational, or speech therapist required for *home health care*. Please refer to *your Schedule of Benefits* for any limits associated with this benefit.
4. I.V. medication and pain medication.
5. Hemodialysis, and for the processing and administration of blood or blood components.
6. *Necessary medical supplies*.
7. Rental of *medically necessary durable medical equipment*.
8. Sleep Studies.

I.V. medication and pain medication are *covered service expenses* to the extent they would have been *covered service expenses* during an *inpatient hospital* stay.

At *our* option, *we* may authorize the purchase of the equipment in lieu of its rental if the rental price is projected to exceed the equipment purchase price, but only from a provider that *we* authorize before the purchase.

Limitations:

See the *Schedule of Benefits* for benefit levels or additional limits for expenses related to home health aide services.

Exclusion:

No benefits will be payable for charges related to *respite care*, *custodial care*, or educational care under the Home Health Care Service Expense Benefit.

Hospice Care Service Expense Benefits

Hospice care benefits are allowable for a *terminally ill member* receiving *medically necessary* care under a *hospice care program*. *Covered services* include:

1. Room and board in a *hospice* while the *member* is an *inpatient*.
2. Occupational therapy.
3. Speech-language therapy.
4. The rental of medical equipment while the *terminally ill* covered person is in a *hospice care program* to the extent that these items would have been covered under the *contract* if the *member* had been confined in a *hospital*.
5. Medical, palliative, and supportive care, and the procedures necessary for pain control and acute and chronic symptom management.
6. Counseling the *member* regarding his or her *terminal illness*.
7. *Terminal illness counseling* of the *member's immediate family*.
8. *Bereavement counseling*.

Benefits for *hospice inpatient*, home and outpatient care are available for one continuous period up to one hundred eighty (180) days in a *covered person's* lifetime.

Exclusions and Limitations:

Any exclusion or limitation contained in the *contract* regarding:

1. An *injury* or *illness* arising out of, or in the course of, employment for wage or profit;
2. Medical necessity of services or supplies, to the extent such services or supplies are provided as part of a *hospice care program*; or
3. Expenses for other persons, to the extent those expenses are described above, will not be applied to this provision.

Respite Care Expense Benefits

Respite care is covered on an *inpatient* or outpatient basis to allow temporary relief to family members from the duties of caring for a covered person under Hospice Care. Respite days that are applied toward the *deductible amount* are considered benefits provided and shall apply against any maximum benefit limit for these services.

Medical Foods

We cover medical foods and formulas for outpatient total parenteral therapy; outpatient enteral therapy, outpatient elemental formulas for malabsorption and dietary formula when *medically necessary* for the treatment of Phenylketonuria (PKU) and inborn errors of metabolism.

Excluded are any other dietary formulas, oral nutritional supplements, special diets, prepared foods or meals, baby formula or food and formula for access problems.

Second Medical Opinion

Members are entitled to a second medical opinion under the following conditions:

1. Whenever a minor surgical procedure is recommended to confirm the need for the procedure;
2. Whenever a serious *injury* or *illness* exists; or
3. Whenever *you* feel that *you* are not responding to the current treatment plan in a satisfactory manner.

If requested, the second opinion consultation is to be provided by a *physician* of the *member's* choice. The *member* may select a *network provider* listed in the Ambetter from Sunshine Health Provider Directory. If a *member* chooses a *network provider*, he or she will only be responsible for the applicable *co-payment* for the consultation. Any lab tests or diagnostic and therapeutic services are subject to the additional *co-payment*.

Hospital Benefits

Covered service expenses are limited to charges made by a *hospital* for:

- a. Daily room and board and nursing services, not to exceed the *hospital's* most common semi-private room rate.
- b. Daily room and board and nursing services while confined in an *intensive care unit*.
- c. *Inpatient* use of an operating, treatment, or recovery room.
- d. Outpatient use of an operating, treatment, or recovery room for *surgery*.
- e. Services and supplies, including drugs and medicines, which are routinely provided by the *hospital* for use only while *you* are *inpatient*.
- f. *Emergency* treatment of an *injury* or *illness*, even if confinement is not required. See *your Schedule of Benefits* for limitations.

Medical and Surgical Expense Benefits

Covered service expenses are limited to charges:

1. For *surgery* in a *physician's* office or at an *outpatient surgical facility*, including services and supplies.
2. Made by a *physician* for professional services, including *surgery*.
3. Made by an assistant surgeon.
4. For the professional services of a *medical practitioner*.
5. For dressings, crutches, orthopedic splints, braces, casts, or other *necessary medical supplies*.
6. For diagnostic testing using radiologic, ultrasonographic, or laboratory services (psychometric, behavioral and educational testing are not included).
7. For chemotherapy and radiation therapy or treatment.
8. For hemodialysis, and the charges by a *hospital* or dialysis center for processing and administration of blood or blood components.
9. For the cost and administration of an anesthetic.
10. For dental treatment in a hospital or ambulatory surgical center. Benefits are available for general anesthesia and hospitalization services in connection with necessary dental treatment or surgery, subject to *prior authorization* by us.
 1. A *member* under age eight (8) whose treating health care professional, in consultation with the dentist, determines the child has a significantly complex dental condition or a developmental disability in which patient management in the dental office has proved to be ineffective; or

2. A *member* who has one (1) or more medical conditions that would create significant or undue medical risk for the individual in the course of delivery of any dental treatment or surgery if not rendered in a *hospital* or ambulatory surgical center.

Necessary dental treatment is that which, if left untreated, is likely to result in a medical condition. Use of general anesthesia in a *hospital* or ambulatory surgical center is subject to *prior authorization* by us. Please call Member Services to confirm *your* benefits for the use of general anesthesia in a *hospital* or ambulatory surgical center.

11. For oxygen and its administration.
12. For dental service expenses when a member suffers an injury, after the member's effective date of coverage, that results in:
 - a. Damage to his or her sound natural teeth; and
 - b. Expenses are incurred within six months of the accident or as part of a treatment plan that was prescribed by a *physician* and began within six months of the accident. *Injury* to the sound natural teeth will not include any injury as a result of chewing.
13. For *surgery*, excluding tooth extraction, to treat craniomandibular disorders, malocclusions, or disorders of the temporomandibular joint. See the *Schedule of Benefits* for benefit levels or additional limits.
14. For reconstructive breast surgery charges as a result of a partial or total mastectomy. Coverage includes surgery and reconstruction of the diseased and non-diseased breast and prosthetic devices necessary to restore a symmetrical appearance and treatment in connection with other physical complications resulting from the mastectomy including lymphedemas. Coverage for outpatient post-surgical care is provided in the most medically appropriate setting which may include a *hospital*, treating *physician's* office, outpatient center or the *member's* home. *Inpatient hospital* treatment for mastectomy will not be limited to any period that is less than that recommended by the attending *physician*.
15. For *medically necessary chiropractic care* treatment on an outpatient basis only. See the *Schedule of Benefits* for benefit levels or additional limits. *Covered service expenses* are subject to all other terms and conditions of the *contract*, including *deductible amount* and *cost sharing percentage* provisions.
16. *Covered service expenses* are permitted when a *member* receives services from a *network provider* specializing in obstetrics and gynecology for obstetrical or gynecological care or if medically necessary follow-up care is detected at the visit without a referral from the *member's primary care physician*.
17. For the following types of tissue transplants:
 - a. Cornea transplants;
 - b. Artery or vein grafts;
 - c. Heart valve grafts;
 - d. Prosthetic tissue replacement, including joint replacements; and
 - e. Implantable prosthetic lenses, in connection with cataracts.
18. Family Planning for certain professional provider contraceptive services and supplies, including but not limited to sterilization and vasectomies, tubal ligation and insertion or extraction of FDA-approved contraceptive devices.
19. Cochlear implants and related services. Excludes hearing aids.
20. *Covered services* for *medically necessary* diagnosis and treatment of osteoporosis for high-risk *member*, including, but not limited to, estrogen-deficient *members* who are at clinical risk for osteoporosis, *members* who have vertebral abnormalities, individuals who are receiving long-term hyperparathyroidism and *members* who have a family history of osteoporosis.
21. Cleft lip and cleft palate for an *eligible child* under the age of 18. *Covered services* includes medical, dental, speech therapy, audiology, and nutrition services only if such services are prescribed by the treating *physician* or surgeon and such *physician* or surgeon certifies that such services are *medically necessary* and consequent to treatment of the cleft lip or cleft palate.

22. For Dermatology services which are limited to the following: *Medically necessary* minor surgery, tests, and office visits provided by a dermatologist who is a *network provider*.
23. Mammograms as follows: (a) A baseline mammogram for any *covered person* who is 35 to 40 years of age; (b) A mammogram every 2 years for any *covered person* who is 40 to 50 years of age or older, or more frequently based on the patient's *physician's* recommendations; (c) A mammogram every year for any *covered person* who is 50 years of age or older; (d) One or more mammograms a year, based upon a physician's recommendation for any *covered person* who is at risk for breast cancer because of a personal or family history of breast cancer, because of having a history of biopsy-proven benign breast disease, because of having a mother, sister, or daughter who has had breast cancer, or because a *covered person* has not given birth before the age of 30. This benefit is not subject to *deductibles* or *copayments*.
24. For *medically necessary* genetic blood tests.
25. For *medically necessary* immunizations to prevent respiratory syncytial virus (RSV).
26. For *medically necessary* biofeedback services.
27. For *medically necessary* allergy treatment including allergy injection.

Diabetic Care

For *medically necessary* services and supplies used in the treatment of diabetes. *Covered service expenses* include, but are not limited to, exams including podiatric exams; routine foot care such as trimming of nails and corns; laboratory and radiological diagnostic testing; self-management equipment, and supplies such as urine or ketone strips, blood glucose monitor supplies (glucose strips) for the device, and syringes or needles; orthotics and diabetic shoes; urinary protein/microalbumin and lipid profiles; educational health and nutritional counseling for self-management, eye examinations, and prescription medication.

Outpatient Medical Supplies Expense Benefits

Covered expenses for miscellaneous outpatient medical supplies are limited to charges:

1. For artificial eyes or larynx, breast prosthesis, or basic artificial limbs (but not the replacement thereof, unless required by a physical change in the *covered person* and the item cannot be modified). If more than one prosthetic device can meet a *covered person's* functional needs, only the charge for the most cost effective prosthetic device will be considered a *covered expense*.
2. For one pair of foot orthotics per year per *covered person*.
3. For two mastectomy bras per year if the *covered person* has undergone a covered mastectomy.
4. For rental of *medically necessary* durable medical equipment.
5. For the purchase or rental of one Continuous Passive Motion (CPM) machine per *covered person* following a covered joint surgery.
6. For the cost of one wig per *covered person* necessitated by hair loss due to cancer treatments or traumatic burns.
7. For one pair of eyeglasses or contact lenses per *covered person* following a covered cataract surgery. See the *Schedule of Benefits* for benefit levels or additional limits.

Durable Medical Equipment, Prosthetics, and Orthotic Devices

The supplies, equipment and appliances described below are *covered services* under this benefit. If the supplies, equipment and appliances include comfort, luxury, or convenience items or features which exceed what is *medically necessary* in *your* situation or needed to treat *your* condition, reimbursement will be based on the maximum allowable amount for a standard item that is a covered service, serves the same purpose, and is *medically necessary*. Any expense that exceeds the maximum allowable amount for the standard item which is a covered service is *your* responsibility. For example, the reimbursement for a motorized wheelchair will be limited to the reimbursement for a standard wheelchair, when a standard wheelchair adequately accommodates your condition. Repair, adjustment and replacement of purchased

equipment, supplies or appliances as set forth below may be covered, as approved by *us*. The repair, adjustment or replacement of the purchased equipment, supply or appliance is covered if:

- The equipment, supply or appliance is a covered service;
- The continued use of the item is *medically necessary*; and
- There is reasonable justification for the repair, adjustment, or replacement (warranty expiration is not reasonable justification).

In addition, replacement of purchased equipment, supplies or appliance may be covered if:

1. The equipment, supply or appliance is worn out or no longer functions.
2. Repair is not possible or would equal or exceed the cost of replacement. An assessment by a habilitation equipment specialist or vendor should be done to estimate the cost of repair.
3. Individual's needs have changed and the current equipment is no longer usable due to weight gain, rapid growth, or deterioration of function, etc.
4. The equipment, supply or appliance is damaged and cannot be repaired.

Benefits for repairs and replacement do not include the following:

- Repair and replacement due to misuse, malicious breakage or gross neglect.
- Replacement of lost or stolen items.

We may establish reasonable quantity limits for certain supplies, equipment or appliance described below.

Durable medical equipment

The rental (or, at our option, the purchase) of durable medical equipment prescribed by a *physician* or other provider. Durable medical equipment is equipment which can withstand repeated use; i.e., could normally be rented, and used by successive patients; is primarily and customarily used to serve a medical purpose; is not useful to a person in the absence of illness or injury; and is appropriate for use in a patient's home. Examples include but are not limited to wheelchairs, crutches, *hospital* beds, and oxygen equipment. Rental costs must not be more than the purchase price. The plan will not pay for rental for a longer period of time than it would cost to purchase equipment. The cost for delivering and installing the equipment are *covered services*. Payment for related supplies is a covered service only when the equipment is a rental, and medically fitting supplies are included in the rental; or the equipment is owned by the member; medically fitting supplies may be paid separately. Equipment should be purchased when it costs more to rent it than to buy it. Repair of medical equipment is covered.

Covered Services may include, but are not limited to:

1. Hemodialysis equipment.
2. Crutches and replacement of pads and tips.
3. Pressure machines.
4. Infusion pump for IV fluids and medicine.
5. Glucometer.
6. Tracheotomy tube.
7. Cardiac, neonatal and sleep apnea monitors.
8. Augmentive communication devices are covered when *we* approve based on the *member's* condition.

Exclusions:

Non-covered items may include but are not limited to:

1. Air conditioners.
2. Ice bags/coldpack pump.
3. Raised toilet seats.

4. Rental of equipment if the member is in a Facility that is expected to provide such equipment.
5. Translift chairs.
6. Treadmill exerciser.
7. Tub chair used in shower.

Medical and surgical supplies

Coverage for non-durable medical supplies and equipment for management of disease and treatment of medical and surgical conditions.

Covered Services may include, but are not limited to:

1. Allergy serum extracts.
2. Chem strips, Glucometer, Lancets.
3. Clinitest.
4. Needles/syringes.
5. Ostomy bags and supplies except charges such as those made by a pharmacy for purposes of a fitting are not *covered services*.

Exclusions:

Non *Covered Services* include but are not limited to:

1. Adhesive tape, band aids, cotton tipped applicators.
2. Arch supports.
3. Doughnut cushions.
4. Hot packs, ice bags.
5. Vitamins (except as provided for under Preventive benefits).
6. Medijectors.
7. Items usually stocked in the home for general use like Band-Aids, thermometers, and petroleum jelly.

Prosthetics

Artificial substitutes for body parts and tissues and materials inserted into tissue for functional or therapeutic purposes. *Covered services* include purchase, fitting, needed adjustment, repairs, and replacements of prosthetic devices and supplies that:

1. Replace all or part of a missing body part and its adjoining tissues; or
2. Replace all or part of the function of a permanently useless or malfunctioning body part.

Prosthetic devices should be purchased not rented, and must be *medically necessary*. Applicable taxes, shipping and handling are also covered.

Covered Services may include, but are not limited to:

1. Aids and supports for defective parts of the body including but not limited to internal heart valves, mitral valve, internal pacemaker, pacemaker power sources, synthetic or homograft vascular replacements, fracture fixation devices internal to the body surface, replacements for injured or diseased bone and joint substances, mandibular reconstruction appliances, bone screws, plates, and vitallium heads for joint reconstruction.
2. Left Ventricular Artificial Devices (LVAD) (only when used as a bridge to a heart transplant).
3. Breast prosthesis whether internal or external, following a mastectomy, and four surgical bras per benefit period, as required by the Women's Health and Cancer Rights Act. Maximums for Prosthetic devices, if any, do not apply.
4. Replacements for all or part of absent parts of the body or extremities, such as artificial limbs, artificial eyes, etc.

5. Intraocular lens implantation for the treatment of cataract or aphakia. Contact lenses or glasses are often prescribed following lens implantation and are *covered services*. (If cataract extraction is performed, intraocular lenses are usually inserted during the same operative session). Eyeglasses (for example bifocals) including frames or contact lenses are covered when they replace the function of the human lens for conditions caused by cataract surgery or injury; the first pair of contact lenses or eyeglasses are covered. The donor lens inserted at the time of surgery are not considered contact lenses, and are not considered the first lens following surgery. If the injury is to one eye or if cataracts are removed from only one eye and the *member* selects eyeglasses and frames, then reimbursement for both lenses and frames will be covered.
6. Cochlear implant.
7. Colostomy and other ostomy (surgical construction of an artificial opening) supplies directly related to ostomy care.
8. Restoration prosthesis (composite facial prosthesis).
9. Wigs (the first one following cancer treatment, not to exceed one per benefit period).

Exclusions:

Non-covered Prosthetic appliances include but are not limited to:

1. Dentures, replacing teeth or structures directly supporting teeth.
2. Dental appliances.
3. Such non-rigid appliances as elastic stockings, garter belts, arch supports and corsets.
4. Artificial heart implants.
5. Wigs (except as described above following cancer treatment).
6. Penile prosthesis in member's suffering impotency resulting from disease or injury.

Orthotic devices

Covered Services are the initial purchase, fitting, and repair of a custom made rigid or semi-rigid supportive device used to support, align, prevent, or correct deformities or to improve the function of movable parts of the body, or which limits or stops motion of a weak or diseased body part. The cost of casting, molding, fittings, and adjustments are included. Applicable tax, shipping, postage and handling charges are also covered. The casting is covered when an orthotic appliance is billed with it, but not if billed separately.

Covered orthotic devices may include, but are not limited to, the following:

1. Cervical collars.
2. Ankle foot orthosis.
3. Corsets (back and special surgical).
4. Splints (extremity).
5. Trusses and supports.
6. Slings.
7. Wristlets.
8. Built-up shoe.
9. Custom made shoe inserts.

Orthotic appliances may be replaced once per year per member when *medically necessary* in the *member's* situation. However, additional replacements will be allowed for *members* under age 18 due to rapid growth, or for any *member* when an appliance is damaged and cannot be repaired.

Exclusions:

Non-covered services include but are not limited to:

1. Orthopedic shoes (except therapeutic shoes for diabetics).

2. Foot support devices, such as arch supports and corrective shoes, unless they are an integral part of a leg brace.
3. Standard elastic stockings, garter belts, and other supplies not specially made and fitted (except as specified under medical supplies).
4. Garter belts or similar devices.

Prescription Drug Expense Benefits

Covered service expenses in this benefit subsection are limited to charges from a licensed *pharmacy* for:

1. A *prescription drug*.
2. Any drug that, under the applicable state law, may be dispensed only upon the written prescription by a *physician*.

See the Formulary and *Schedule of Benefits* for additional information on drug coverage, benefit levels or additional limits.

The appropriate drug choice for a *member* is a determination that is best made by the *member* and his or her *physician*.

Non-Formulary Prescription Drugs:

Under Affordable Care Act, *you* have the right to request coverage of prescription drugs that are not listed on the plan formulary (otherwise known as “non-formulary drugs”). To exercise this right, please get in touch with *your medical practitioner*. *Your medical practitioner* can utilize the usual *prior authorization* request process. See “Prior Authorization” below for additional details.

Prescription Drug Exception Process

1. Standard exception request

A *member*, a *member’s* designee or a *member’s* prescribing *physician* may request a standard review of a decision that a drug is not covered by the plan. The request can be made in writing or via telephone. Within 72 hours of the request being received, *we* will provide the *member*, the *member’s* designee or the *member’s* prescribing physician with *our* coverage determination. Should the standard exception request be granted, *we* will provide coverage of the non-formulary drug for the duration of the prescription, including refills.

2. Expedited exception request

A *member*, a *member’s* designee or a *member’s* prescribing *physician* may request an expedited review based on exigent circumstances. Exigent circumstances exist when a *member* is suffering from a health condition that may seriously jeopardize the *member’s* life, health, or ability to regain maximum function or when a *member* is undergoing a current course of treatment using a non-formulary drug. Within 24 hours of the request being received, *we* will provide the *member*, the *member’s* designee or the *member’s* prescribing physician with *our* coverage determination. Should the expedited exception request be granted, *we* will provide coverage of the non-formulary drug for the duration of the exigency.

3. External exception request review

If *we* deny a request for a standard exception or for an expedited exception, the *member*, the *member’s* designee or the *member’s* prescribing *physician* may request that the original exception request and subsequent denial of such request be reviewed by an independent review organization. *We* will make *our* determination on the external exception request and notify the *member*, the *member’s* designee or the *member’s* prescribing *physician* of *our* coverage determination no later than 72 hours following receipt of the request, if the original request was a standard exception, and no later than 24 hours following its receipt of the request, if the original request was an expedited exception.

If we grant an external exception review of a standard exception request, we will provide coverage of the non-formulary drug for the duration of the prescription. If we grant an external exception review of an expedited exception request, we will provide coverage of the non-formulary drug for the duration of the exigency.

Notice and Proof of Loss:

In order to obtain payment for *covered service expenses* incurred at a *pharmacy for prescription orders*, a notice of claim and *proof of loss* must be submitted directly to us.

Non-Covered Services and Exclusions:

No benefits will be paid under this benefit subsection for services provided or expenses incurred:

1. For *prescription drugs* for the treatment of erectile dysfunction or any enhancement of sexual performance unless listed on the formulary.
2. For immunization agents, blood, or blood plasma, except when used for preventative care and listed on the formulary.
3. For medication that is to be taken by the *member*, in whole or in part, at the place where it is dispensed.
4. For medication received while the *member* is a patient at an institution that has a facility for dispensing pharmaceuticals.
5. For a refill dispensed more than 12 months from the date of a *physician's* order.
6. Due to a *member's* addiction to, or dependency on foods, unless such medications are listed on the formulary.
7. For more than the predetermined *managed drug limitations* assigned to certain drugs or classification of drugs.
8. For a *prescription order* that is available in over-the-counter form, or comprised of components that are available in over-the-counter form, and is therapeutically equivalent, except for over-the-counter products that are covered on the formulary or when the over-the-counter drug is used for preventative care.
9. For drugs labeled "Caution - limited by federal law to investigational use" or for investigational or experimental drugs.
10. For more than a 31-day supply when dispensed in any one prescription or refill or for maintenance drugs up to a 90-day supply when dispensed by mail order or a pharmacy that participates in extended day supply network.
11. For *prescription drugs* for any *member* who enrolls in Medicare Part D as of the date of his or her enrollment in Medicare Part D. *Prescription drug* coverage may not be reinstated at a later date.
12. For any drug that we identify as therapeutic duplication through the Drug Utilization Review program.
13. Drugs or dosage amounts determined by Ambetter to be ineffective, unproven or unsafe for the indication for which they have been prescribed, regardless of whether the drugs or dosage amounts have been approved by any governmental regulatory body for that use.
14. Foreign Prescription Medications, except those associated with an Emergency Medical Condition while you are traveling outside the United States, or those you purchase while residing outside the United States. These exceptions apply only to medications with an equivalent FDA-approved Prescription Medication that would be covered under this section if obtained in the United States.
15. For any controlled substance that exceeds state established maximum morphine equivalents in a particular time period, as established by state laws and regulations.

Pediatric Vision Expense Benefits

Covered service expenses in this benefit subsection include the following for an *eligible child* under the age of 19 who is a *member*:

1. Routine vision screening, including dilation and with refraction every calendar year;
2. One pair of prescription lenses (single vision, lined bifocal, lined trifocal or lenticular) in glass or plastic, or initial supply of standard contacts every calendar year,
 - a. Other lens options included are: Fashion and Gradient Tinting, Ultraviolet Protective Coating, Oversized and Glass-Grey #3 Prescription Sunglass lenses, Polycarbonate lenses, Blended Segment lenses, Intermediate Vision lenses, Standard Progressives, Premium Progressives (Varilux®, etc.), Photochromic Glass Lenses, Plastic Photosensitive Lenses (Transitions®), Polarized Lenses, Standard Anti-Reflective (AR) Coating, Premium AR Coating, Ultra AR Coating, and Hi-Index Lenses.
3. One pair of frames every calendar year; and
4. Low vision optical devices including low vision services, and an aid allowance with follow-up care when *prior-authorized*.

Covered service expenses do not include:

1. Visual therapy;
2. Two pair of glasses as a substitute for bifocals;
3. Replacement of lost or stolen eyewear;
4. Any vision services, treatment or material not specifically listed as a *covered service*; or
5. Out of network care except when *prior-authorized*.

Medically Necessary Vision Services

Eye exams for the treatment of medical conditions of the eye are covered when the service is performed by a participating *network* provider (optometrist or ophthalmologist). *Covered services* include office visits, testing, and treatment of eye conditions producing symptoms that if left untreated may result in the loss of vision.

Excluded services for routine and non-routine vision include:

- Visual Therapy;
- Any vision services, treatment or material not specifically listed as a covered service;
- Low vision services and hardware for adults; and
- Out of *network* care, except when *prior-authorized*.

Preventive Care Expense Benefits

Covered service expenses are expanded to include the charges incurred by a *member* for the following preventive health services if appropriate for that *member* in accordance with the following recommendations and guidelines:

1. Evidence based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force.
2. Immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to an individual which includes pediatric and adult immunizations.
3. Evidence-informed preventive care and screenings for infants, children, and adolescents, in accordance with comprehensive guidelines supported by the Health Resources and Services Administration which includes well-child care from birth.
4. Additional preventive care and screenings not included in (1) above, in accordance with comprehensive guidelines supported by the Health Resources and Services Administration.
5. Covers without cost sharing:

- a. Screening for *tobacco use*; and
- b. For those who *use tobacco* products, at least two (2) cessation attempts per year. For this purpose, covering a cessation attempt includes coverage for:
 - i. Four (4) tobacco cessation counseling sessions of at least ten (10) minutes each (including telephone counseling, group counseling and individual counseling) without *prior authorization*; and
 - ii. All Food and Drug Administration (FDA) approved tobacco cessation medications (including both prescription and over-the-counter medications) for a 90-day treatment regimen when prescribed by a health care provider without *prior authorization*.

Benefits for preventive health services listed in this provision, except under the administration of reasonable medical management techniques discussed in the next paragraph, are exempt from any *deductible amounts, cost sharing percentage* provisions, and *copayment amounts* under the *contract* when the services are provided by a *network provider*. If a service is considered diagnostic or non-preventive care, your “plan” *copayment, coinsurance* and *deductible* will apply. It’s important to know what type of service you’re getting. If a diagnostic or non-preventive service is performed during the same healthcare visit as a preventive service, *you* may have *copayment* and *coinsurance* charges.

Benefits for *covered expenses* for preventive care expense and chronic disease management benefits may include the use of reasonable medical management techniques authorized by federal law to promote the use of preventive services from *network providers*. Reasonable medical management techniques may result in the application of *deductibles, coinsurance* provisions, or *copayment amounts* to services when a *covered person* chooses not to use a high value service that is otherwise exempt from *deductibles, coinsurance* provisions, and *copayment amounts*, when received from a *network provider*.

As new recommendations and guidelines are issued, those services will be considered *covered service expenses* when required by the United States Secretary of Health and Human Services, but not earlier than one year after the recommendation or guideline is issued.

Child Health Supervision Services

The following *covered service* is provided for an *eligible child* in accordance with the Florida Child Health Assurance Act which includes *covered services* from the moment of birth to age 16 years. A waiver of the *deductible amount* applies to all *eligible service expenses* for Child Health Supervision Services.

Child Health Supervision Services means *physician-delivered* or *physician-supervised* services that include the services described in the *Schedule of Benefits*. These services do not include *hospital* charges.

Child Health Supervision Services include periodic visits, which shall include:

- History
- Physical Examination
- Developmental Assessment
- Anticipatory Guidance
- Appropriate Immunizations
- Laboratory Testing

These services and periodic visits will be provided in accordance with prevailing medical standards consistent with the Recommendations for Preventive Pediatric Health Care of the American Academy of Pediatrics.

Eligible service expenses for child health supervision services are limited to one visit payable to one provider for all the services provided at each visit.

Newborns' and Mothers' Health Protection Act Statement of Rights

If services provided or expenses incurred for *hospital* confinement in connection with childbirth are otherwise included as *covered Service expenses*, we will not limit the number of days for these expenses to less than that stated in the Maternity Care provision.

Maternity care

Coverage for outpatient and *inpatient* pre- and post-partum care including exams, prenatal diagnosis of genetic disorder, laboratory and radiology diagnostic testing, health education, nutritional counseling, risk assessment, childbirth classes, services of nurse-midwives and midwives licensed according to Florida law, and the services of birth centers licensed according to Florida law, if such services are available within the *service area*, and *hospital* stays for delivery or other *medically necessary* reasons (less any applicable *copayments, deductible amounts, or cost sharing percentage*). Other maternity benefits include *complications of pregnancy*, parent education, assistance, and training in breast or bottle feeding and the performance of any necessary and appropriate clinical tests. Coverage will only be provided for maternity services or care of the newborn child when such services have been *authorized* by *your* participating health care provider.

Under federal law, health insurance issuers generally may not restrict benefits otherwise provided for any *hospital* length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a vaginal delivery or less than 96 hours following a delivery by cesarean section. However, *we* may provide benefits for *covered service expenses* incurred for a shorter stay if the attending provider (e.g., *your* physician, nurse midwife or physician assistant), after consultation with the mother, discharges the mother or newborn earlier.

The level of benefits and out-of-pocket costs for any later part of the 48-hour (or 96-hour) stay will not be less favorable to the mother or newborn than any earlier part of the stay. *We* do not require that a *physician* or other health care provider obtain *authorization* for prescribing a length of stay of up to 48 hours (or 96 hours).

Note: This provision does not amend the *contract* to restrict any terms, limits, or conditions that may otherwise apply to *covered service expenses* for childbirth.

Clinical Trial Coverage

Clinical Trial Coverage includes routine patient care costs incurred as the result of an approved phase I, II, III or phase IV clinical trial and the clinical trial is undertaken for the purposes of prevention, early detection, or treatment of cancer or other life-threatening disease or condition . Coverage will include routine patient care costs incurred for (1) drugs and devices that have been approved for sale by the Food and Drug Administration (FDA), regardless of whether approved by the FDA for use in treating the patient's particular condition, (2) reasonable and *medically necessary* services needed to administer the drug or use the device under evaluation in the clinical trial and (3) all items and services that are otherwise generally available to a qualified individual that are provided in the clinical trial except:

- The investigational item or service itself;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; and
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Phase I and II clinical trials must meet the following requirements:

- Phase I and II of a clinical trial is sanctioned by the National Institutes of Health (NIH) or National Cancer Institute (NCI) and conducted at academic or National Cancer Institute Center; and
- The insured is enrolled in the clinical trial. This section shall not apply to insureds who are only following the protocol of phase I or II of a clinical trial, but not actually enrolled.

Phase III and IV clinical trials must be approved or funded by one of the following entities:

- One of the National Institutes of Health (NIH);
- The Centers for Disease Control and Prevention;
- The Agency for Health Care Research and Quality;
- The Centers for Medicare & Medicaid Services;
- An NIH Cooperative Group or Center;
- The FDA in the form of an investigational new drug application;
- The federal Departments of Veterans' Affairs, Defense, or Energy;
- An institutional review board in this state that has an appropriate assurance approved by the Department of Health and Human Services assuring compliance with and implementation of regulations for the protection of human subjects; or
- A qualified non-governmental research entity that meets the criteria for NIH Center support grant eligibility.

In a clinical trial, the treating facility and personnel must have the expertise and training to provide the treatment and treat a sufficient volume of patients. There must be equal to or superior, noninvestigational treatment alternatives and the available clinical or preclinical data must provide a reasonable expectation that the treatment will be superior to the noninvestigational alternatives.

Providers participating in clinical trials shall obtain a patient's informed consent for participation in the clinical trial in a manner that is consistent with current legal and ethical standards.

Transplant Expense Benefits

Covered Services For Transplant Service Expenses:

If we determine that a *member* is an appropriate candidate for a *listed transplant*, medical service expense benefits will be provided for:

1. Pre-transplant evaluation;
2. Pre-transplant harvesting;
3. Pre-transplant stabilization, meaning an *inpatient* stay to medically stabilize a *member* to prepare for a later transplant, whether or not the transplant occurs;
4. High dose chemotherapy;
5. Peripheral stem cell collection;
6. The transplant itself, not including the acquisition cost for the organ or bone marrow (except at a *Center of Excellence*); and
7. Post-transplant follow-up.

Transplant Donor Expenses:

We will cover the medical expenses incurred by a live donor as if they were medical expenses of the *member* if:

1. They would otherwise be considered *covered service expenses* under the *contract*;
2. The *member* received an organ or bone marrow of the live donor; and
3. The transplant was a *listed transplant*.

Ancillary "Center Of Excellence" Service Benefits:

A *member* may obtain services in connection with a *listed transplant* from any *physician*. However, if a *listed transplant* is performed in a *Center of Excellence*:

1. *Covered service expenses* for the *listed transplant* will include the acquisition cost of the organ or bone marrow.
2. We will pay a maximum amount shown in the *Schedule of Benefits* for the following services:
 - a. Transportation for the *member*, any live donor, and the *immediate family* to accompany the *member* to and from the *Center of Excellence*.
 - b. Lodging at or near the *Center of Excellence* for any live donor and the *immediate family* accompanying the *member* while the *member* is confined in the *Center of Excellence*. We will pay the costs directly for transportation and lodging, however, *you* must make the arrangements.

Non-Covered Services and Exclusions:

No benefits will be provided or paid under these Transplant Expense Benefits:

1. For search and testing in order to locate a suitable donor.
2. For a prophylactic bone marrow harvest or peripheral blood stem cell collection when no *listed transplant* occurs.
3. For animal to human transplants.
4. For artificial or mechanical devices designed to replace a human organ temporarily or permanently.
5. For procurement or transportation of the organ or tissue, unless expressly provided for in this provision.
6. To keep a donor alive for the transplant operation.
7. For a live donor where the live donor is receiving a transplanted organ to replace the donated organ.
8. Related to transplants not included under this provision as a *listed transplant*.
9. For a *listed transplant* under study in an ongoing phase I or II clinical trial as set forth in the United States Food and Drug Administration ("*FDA*") regulation, regardless of whether the trial is subject to *FDA* oversight. Note: This exclusion does not apply to bone marrow transplants.

Limitations on Transplant Service Expense Benefits:

In addition to the exclusions and limitations specified elsewhere in this section:

1. *Covered service expenses* for *listed transplants* will be limited to two transplants during any 10- year period for each *member* with the exception of *Bone Marrow Transplants* which will be covered when *medically necessary*.
2. Bone marrow transplant coverage for the reasonable costs of searching for a donor will be limited to a search among family members and donors identified through the National Bone Marrow Donor Program.
3. If a designated *Center of Excellence* is not used, *covered service expenses* for a *listed transplant* will be limited to a maximum for all expenses associated with the transplant. See the *Schedule of Benefits* for benefit levels or additional limits.
4. If a designated *Center of Excellence* is not used, the acquisition cost for the organ or bone marrow is not covered.

Wellness and Other Program Benefits

Benefits may be available from time to time to *members* for participating in certain programs that *we* may make available in connection with this *contract*. Such programs may include wellness programs, disease or case management programs, and other programs. The benefits available to *members* for participating in such programs are described on the Schedule of Benefits. You may obtain information regarding the particular programs

available at any given time by visiting *our* website at Ambetter.SunshineHealth.com or by contacting Member Services by telephone at 1-877-687-1169. The programs and benefits available at any given time are made part of this *contract* by this reference and are subject to change from time to time by *us* through an update to program information available on *our* website or by contacting *us*.

PRIOR AUTHORIZATION

Prior Authorization Required

Some *covered service expenses* require *prior authorization*. *Network providers* must obtain *authorization* from *us* prior to providing a service or supply to a *member*. However, there are some *network eligible service expenses* for which *you* must obtain the prior authorization.

For services or supplies that require *prior authorization*, as shown on the *Schedule of Benefits*, *you* must obtain authorization from *us* before *you* or *your dependent member*:

1. Receives a service or supply from a *non-network provider*;
2. Are admitted into a *network facility* by a *non-network provider*; or
3. Receive a service or supply from a *network provider* to which *you* or *your dependent member* were referred by a *non-network provider*.

Prior Authorization requests must be received by phone, efax, or Provider portal as follows:

1. At least 5 days prior to an elective admission as an *inpatient* in a *hospital, extended care or rehabilitation facility, or hospice facility*.
2. At least 30 days prior to the initial evaluation for organ transplant services.
3. At least 30 days prior to receiving clinical trial services.
4. At least 5 days prior to a scheduled *inpatient* behavioral health or substance abuse treatment admission.
5. At least 5 days prior to the start of *home health care*.

After *prior authorization* has been requested and all required or applicable documentation has been submitted, *we* will notify *you* and *your provider* if the request has been approved as follows:

1. For immediate request situations, within 1 business day, when the lack of treatment may result in an emergency room visit or *emergency* admission.
2. For urgent concurrent review within 24 hours of receipt of the request.
3. For urgent pre-service, within 72 hours from date of receipt of request.
4. For non-urgent pre-service requests within 5 days but no longer than 15 days of receipt of the request.
5. For post-service requests, with in 30 calendar days of receipt of the request.

How to Obtain Prior Authorization

To obtain prior authorization or to confirm that a *network provider* has obtained *prior authorization*, contact *us* by telephone at the telephone number listed on *your* health insurance identification card before the service or supply is provided to the *member*.

Failure to Obtain Prior Authorization

Failure to comply with the *prior authorization* requirements will result in benefits being reduced.

Network providers cannot bill *you* for services for which they fail to obtain *prior authorization* as required.

Benefits will not be reduced for failure to comply with *prior authorization* requirements prior to an *emergency*. However, *you* must contact *us* as soon as reasonably possible after the *emergency* occurs.

Prior Authorization Does Not Guarantee Benefits

Our authorization does not guarantee either payment of benefits or the amount of benefits. Eligibility for, and payment of, benefits are subject to all terms and conditions of the contract.

Requests for Predeterminations

You may request a predetermination of coverage. We will provide one if circumstances allow us to do so. However, we are not required to make a predetermination of either coverage or benefits for any particular treatment or medical expense. Any predetermination we may make will be reviewed after the medical expense is incurred and a claim is filed. A review that shows one or more of the following may cause us to reverse the predetermination:

1. *The predetermination was based on incomplete or inaccurate information initially received by us.*
2. *Another party has already paid or is responsible for payment of the medical expense.*

We will make all benefit determinations after a loss in good faith. All benefit determinations are subject to our receipt of proper proof of loss.

Services from Non- Network Providers

Except for emergency medical services and nonparticipating facility-based physician and provider, unless covered services are not available from network providers within a reasonable proximity such services will not be covered. If required medically necessary services are not available from network providers you or the network provider must request prior authorization from us before you may receive services from non-network providers. Otherwise you will be responsible for all charges incurred.

Florida law requires that we provide you with the following disclosure about your health benefit plan coverage. ""WARNING: LIMITED BENEFITS WILL BE PAID WHEN NONPARTICIPATING PROVIDERS ARE USED. You should be aware that when you elect to utilize the services of a nonparticipating provider for a covered nonemergency service, benefit payments to the provider are not based upon the amount the provider charges. The basis of the payment will be determined according to your policy's out-of-network reimbursement benefit. Nonparticipating providers may bill insureds for any difference in the amount. YOU MAY BE REQUIRED TO PAY MORE THAN THE COINSURANCE OR COPAYMENT AMOUNT. Participating providers have agreed to accept discounted payments for services with no additional billing to you other than coinsurance, copayment, and deductible amounts. You may obtain further information about the providers who have contracted with your insurance plan by consulting your insurer's website or contacting your insurer or agent directly."

Hospital Based Providers

When receiving care at an Ambetter participating hospital it is possible that some hospital-based providers (for example, anesthesiologists, radiologists, pathologists) may not be under contract with Ambetter as participating providers. These providers may not bill you for the difference between Ambetter's allowed amount and the providers billed charge – this is known as "balance billing". However, we encourage you to inquire about the providers who will be treating you before you begin your treatment, so you can understand their participation status with Ambetter.

GENERAL NON-COVERED SERVICES AND EXCLUSIONS

No benefits will be provided or paid for:

1. Any service or supply that would be provided without cost to the *member* in the absence of insurance covering the charge.
2. Expenses, fees, taxes or surcharges imposed on the *member* by a provider (including a *hospital*) but that are actually the responsibility of the provider to pay.
3. Any services performed for a *member* by a *member's immediate family*.
4. Any services not identified and included as *covered service expenses* under the *contract*. You will be fully responsible for payment for any services that are not *covered service expenses*.
5. Court ordered care- unless *medically necessary* and a *covered service expense*.

Even if not specifically excluded by this *contract*, no benefit will be paid for a service or supply unless it is:

1. Administered or ordered by a *physician*; and
2. *Medically necessary* to the diagnosis or treatment of an *injury* or *illness*, or covered under the Preventive Care Expense Benefits provision.

Covered service expenses will not include, and no benefits will be provided or paid for any charges that are incurred:

1. For services or supplies that are provided prior to the *effective date* or after the termination date of this *contract*, except as expressly provided for under the Benefits after Coverage Terminates clause in this *contract's* Termination section.
2. For any portion of the charges that are in excess of the *eligible service expense*.
3. For weight modification, or for surgical treatment of obesity, including wiring of the teeth and all forms of intestinal bypass *surgery*.
4. For breast reduction or augmentation except post-mastectomy for breast cancer.
5. For reversal of sterilization and reversal of vasectomies.
6. For abortion (unless the life of the mother would be endangered if the fetus were carried to term).
7. For expenses for television, telephone, or expenses for other persons.
8. For marriage, family, or child counseling for the treatment of premarital, marriage, family, or child relationship dysfunctions.
9. For telephone consultations or for failure to keep a scheduled appointment.
10. For stand-by availability of a *medical practitioner* when no treatment is rendered.
11. For *dental service expenses*, including braces for any medical or dental condition, *surgery* and treatment for oral *surgery*, except as expressly provided for under the Medical and Surgical Expense Benefits provisions.
12. For *cosmetic treatment*, except for *reconstructive surgery* that is incidental to or follows *surgery* or an *injury* that was covered under the *contract* or is performed to correct a functional defect or birth defect in a child who has been a *member* from its birth until the date *surgery* is performed.
13. For diagnosis or treatment of learning disabilities.
14. For charges related to, or in preparation for, tissue or organ transplants, except as expressly provided for under the Transplant Service Expense Benefits.
15. For high dose chemotherapy prior to, in conjunction with, or supported by *ABMT/BMT*, except as specifically provided under the Transplant Service Expense Benefits.
16. For eye refractive *surgery*, when the primary purpose is to correct nearsightedness, farsightedness, or astigmatism.
17. While confined primarily to receive *rehabilitation, custodial care*, educational care, or nursing services (unless expressly provided for in this *contract*).
18. For vocational or recreational therapy, vocational *rehabilitation*, outpatient speech therapy, or occupational therapy, except as expressly provided for in this *contract*.

19. For alternative or complementary medicine using non-orthodox therapeutic practices that do not follow conventional medicine.
20. For eyeglasses, contact lenses, hearing aids, eye refraction, visual therapy, or for any examination or fitting related to these devices, except as expressly provided in this *contract*.
21. For *experimental or investigational treatment(s) or unproven services*. The fact that an *experimental or investigational treatment or unproven service* is the only available treatment for a particular condition will not result in benefits if the procedure is considered to be an *experimental or investigational treatment or unproven service* for the treatment of that particular condition.
22. For treatment received outside the United States, except for a medical *emergency* while traveling for up to a maximum of 90 consecutive days. If travel extends beyond 90 consecutive days, no coverage is provided for medical *emergencies* for the entire period of travel including the first 90 days.
23. As a result of an *injury or illness* arising out of, or in the course of, employment for wage or profit, if the *member* is insured, or is required to be insured, by workers' compensation insurance pursuant to applicable state or federal law. If *you* enter into a settlement that waives a *member's* right to recover future medical benefits under a workers' compensation law or insurance plan, this exclusion will still apply. In the event that the workers' compensation insurance carrier denies coverage for a *member's* workers' compensation claim, this exclusion will still apply unless that denial is appealed to the proper governmental agency and the denial is upheld by that agency.
24. As a result of:
 - a. Intentionally self-inflicted bodily harm.
 - b. The *member* taking part in a riot.
 - c. The *member's* commission of, or participation in, a felony, whether or not charged.
25. For any *illness or injury* incurred as a result of the *member* being intoxicated, as defined by applicable state law in the state in which the *loss* occurred, or under the influence of illegal narcotics or controlled substance unless administered or prescribed by a *physician*, except as expressly provided for under the Mental Health and Substance Use Disorder Benefits provision.
26. For or related to surrogate parenting.
27. For or related to treatment of hyperhidrosis (excessive sweating).
28. For fetal reduction surgery.
29. Except as specifically identified as a *covered service expense* under the *contract*, services or expenses for alternative treatments, including acupressure, acupuncture, aroma therapy, hypnotism, massage therapy, rolfing, and other forms of alternative treatment as defined by the Office of Alternative Medicine of the National Institutes of Health.
30. As a result of any *injury* sustained during or due to participating, instructing, demonstrating, guiding, or accompanying others in any of the following: professional or Semi-professional sports; intercollegiate sports (not including intramural sports); racing or speed testing any motorized vehicle or conveyance; racing or speed testing any Non-motorized vehicle or conveyance (if the *member* is paid to participate or to instruct); rodeo sports; horseback riding (if the *member* is paid to participate or to instruct); rock or mountain climbing (if the *member* is paid to participate or to instruct); or skiing (if the *member* is paid to participate or to instruct).
31. As a result of any *injury* sustained while operating, riding in, or descending from any type of aircraft if the *member* is a pilot, officer, or member of the crew of such aircraft or is giving or receiving any kind of training or instructions or otherwise has any duties that require him or her to be aboard the aircraft.
32. For *prescription drugs* for any *member* who enrolls in Medicare Part D as of the date of his or her enrollment in Medicare Part D. Prescription drug coverage may not be reinstated at a later date.
33. For the following miscellaneous items: Infertility treatment including but not limited to; Artificial Insemination, Vitro, Intra-Cytoplasmic Sperm Injection(ICSI), Gamete Intrafallopian Transfer(GIFT), Zygote Intrafallopian Transfer(ZIFT) (except where required by federal or state

law); biofeedback; blood and blood products; care or complications resulting from non-covered services; chelating agents; domiciliary care; food and food supplements, except for what is indicated in the Medical Foods section; routine foot care, foot orthotics or corrective shoes; health club memberships, unless otherwise covered; home test kits; care or services provided to a non-member biological parent; nutrition or dietary supplements; pre-marital lab work; processing fees; private duty nursing; rehabilitation services for the enhancement of job, athletic or recreational performance; routine or elective care outside the service area; sclerotherapy for varicose veins ; treatment of spider veins; transportation expenses, unless specifically described in this contract; incontinence supplies; expenses related to home or vehicle modification; or convenience items.

34. For illness or injury caused by the acts or omissions of a *third party*, we will not cover a loss to the extent that it is paid as part of a settlement or judgment by any *third party*.
35. For diagnostic testing, laboratory procedures, screenings or examinations performed for the purpose of obtaining, maintaining or monitoring employment.

Limitations on Benefits for Services Provided By Medicare Opt-Out Practitioners

Benefits for *covered service expenses* incurred by a Medicare-eligible individual for services and supplies provided by a *Medicare opt-out practitioner* will be determined as if the services and supplies had been provided by a *Medicare participating practitioner*. (Benefits will be determined as if Medicare had, in fact, paid the benefits it would have paid if the services and supplies had been provided by a *Medicare participating practitioner*.)

PLAN ADMINISTRATION

In consideration of the payment of premiums, *we* will provide coverage for the *member* and any *eligible dependents*. In doing so, *we* may enter into agreements with providers of health care and such other individuals and entities as may be necessary to enable *us* to fulfill *our* obligations under this *contract*.

We agree to provide coverage without discrimination because of race, color, national origin, disability, sex, gender identity, sexual orientation, religion, or any other basis prohibited by law.

Commencement of Coverage

Commencing on the *contract effective date* *we* agree to provide the coverage stipulated in this *contract* to the *member* and his/her *dependents*, if any. Such coverage begins on the *member's* effective date, which will be the first of the month after the receipt and approval of the application by *us*, unless this *contract* specifies a date other than the first of the month. *We* accept no liability for benefits related to expenses incurred prior to *your* effective date or after *your* termination date, which will be on the last day of the coverage month, except or as specified in the Terms of Renewal provision.

Plan Renewal

This *contract* is guaranteed renewable. Guaranteed renewable means that this *contract* will renew each year on the anniversary date unless terminated earlier in accordance with *contract* terms. *You* may keep this *contract* in force by timely payment of the required premiums. *We* may decide not to renew as of the renewal date if: (1) *we* decide not to renew all *contracts* issued on this form, with the same type and level of benefits, to residents of the state where *you* then live; or (2) there is fraud or an intentional material misrepresentation made by or with the knowledge of a *member* in filing a claim for *contract* benefits. Rate changes are effective on a *member's* annual renewal date and will be based on each *member's* attained age, family structure, geographic region, tobacco usage and benefit plan at the time of renewal. *We* will notify the *member* in writing at least thirty (30) days prior to the renewal date of any change in premium rates.

For *members* who have elected the electronic funds transfer option of payment, should premiums change at renewal, *we* will continue to draft the new monthly premium.

Term of Renewal

We guarantee the *member* the right to renew the *contract* each year, at the *member's* option. However, *we* may refuse to renew this *contract*, and all coverage provided under this *contract*, if one of the following circumstances has occurred:

1. Failure to timely pay premium in accordance with the terms of the contract;
2. *We* cease offering this contract to all *members*;
3. The *member* has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of this contract;
4. The *member* no longer lives in *our* geographic service area;
5. *We* elect to discontinue all individual health coverage in the State of Florida; and
6. *We* elect to discontinue offering individual health coverage through the Health Insurance Marketplace.

With the exception of non-payment of premium or loss of eligibility, if *we* decides to terminate or non-renew this contract for any of the reasons set forth in this *contract*, *we* will give the *member* at least forty-five (45) days advance written notice prior to renewal. If *we* discontinue offering all individual coverage in Florida, *we* will give all *members* and the Office of Insurance Regulation 180 day's written notice prior to the *contract* non-renewal date.

Termination of This Contract by the Member

The *member* may terminate this *contract* at any time with appropriate notice of at least fourteen (14) days to either *us* or the Health Insurance Marketplace. Coverage will terminate on the date specified by the *member*, or fourteen (14) days after termination is requested, whichever is later. If the *member* requests termination in fewer than fourteen (14) days, and *we* can effectuate this request in a shorter period of time, then coverage will terminate on the date determined by *us*. No benefits will be provided as of the effective date of termination of this *contract* for whatever reason.

Should the *member* or any covered dependents terminate coverage because of eligibility for Medicaid, Children's Health Insurance Program (CHIP) or a Basic Health Plan or termination is due to the *member* moving from one *qualified health plan* to another during an Annual or Special Enrollment Period, the termination effective date will be the day before the effective date of the new coverage.

Discontinuance of a Benefit Plan

We may discontinue offering a particular benefit plan to all *members* if:

1. *We* provide at least ninety (90) day notice to each *member* prior to the contract renewal date;
2. *We* offer each *member* the option to purchase any other coverage offered in the individual Health Maintenance Organization (HMO) market; and
3. *We* act uniformly without regard to any health status-related factor of each *member*.

Discontinuance of All Coverage in the Individual Market

We may discontinue offering all coverage in Florida if:

1. *We* provide notice to the Office of Insurance Regulation and each *member* and enrollee 180 days prior to renewal; and
2. All health coverage issued or delivered for issuance in Florida is discontinued and coverage under such health coverage is not renewed.

Termination of this Plan by Us

Except for nonpayment of premium or termination of eligibility, *we* may not cancel or terminate or non-renew this *contract* without giving the *member* at least forty-five (45) days written notice. The written notice will state the reason or reasons for the cancellation, termination or non-renewal.

We may terminate this *contract* as of any premium due date if the *member* has not paid the required premium by the end of the Grace Period, as defined in the Grace Period provision. The *member* is liable to *us* for any unpaid premium for the time the Plan was in force.

Upon termination of coverage, *we* will have no further liability for the payment of any covered services provided after the date of the *member's* termination.

Plan Termination Due to Non-Payment of Premium

If the *member* is receiving premium subsidies, the following provision applies:

- If the required monthly premium is not received by the end of the ninety (90) day Grace Period, *we* will terminate coverage effective at midnight on the last day of the first month of the three (3) month grace period.

If the *member* is not receiving premium subsidies, the following provision applies:

- If the required monthly premium is not received by the end of the thirty (30) day grace period, *we* will terminate this *contract*, without prior notification, retroactive to the last date for which premium was received, subject to the Grace Period provision. Termination will be effective as of midnight of the date that the premium was due provided *we* mail written notice of termination to the *member* prior to forty-five (45) days after the date the premium was due.

Termination of Coverage by the Health Insurance Marketplace or Us

The Health Insurance Marketplace may terminate coverage in a qualified health plan and will also permit *us* to terminate coverage for any of the following reasons.

1. Loss of eligibility to purchase a qualified health plan through the Health Insurance Marketplace.
2. Nonpayment of premiums provided that the grace period has elapsed.
3. Coverage is rescinded.
4. *We* terminate or are decertified by the Health Insurance Marketplace.
5. An enrollee switches to another qualified health plan during an Annual Open Enrollment Period or a Special Enrollment Period.

Terms of Renewal

We guarantee the *member* the right to renew the *contract* each year, at the *member's* option. However, *we* may refuse to renew this *contract*, and all coverage provided under this contract, if one of the following circumstances has occurred:

1. The *member* fails to timely pay premium in accordance with the terms of the contract;
2. *We* cease offering this contract to all *members*;
3. The *member* has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of this *contract*;
4. The *member* no longer lives or works in our geographic *service area*; and
5. *We* elect to discontinue all individual health coverage in the State of Florida.

With the exception of non-payment of premium or loss of eligibility, if *we* decide to terminate or non-renew this *contract* for any of the reasons set forth in this *contract*, *we* will give the *member* at least forty-five (45) days advance written notice.

Discontinuance

90-Day Notice: If *we* discontinue offering and refuse to renew all contracts issued on this form, with the same type and level of benefits, for all residents of the state where *you* reside, *we* will provide a written notice to *you* and all enrollees at least 90 days prior to the date that *we* discontinue coverage. *You* will be offered an option to purchase any other coverage in the individual market *we* offer in *your* state at the time of discontinuance of this *contract*. This option to purchase other coverage will be on a guaranteed issue basis without regard to health status.

180-Day Notice: If *we* discontinue offering and refuse to renew all individual contracts in the individual market in the state where *you* reside, *we* will provide a written notice to *you*, all enrollees, and the Commissioner of Insurance at least 180 days prior to the date that *we* stop offering and terminate all existing individual contracts in the individual market in the state where *you* reside.

Notification Requirements

It is the responsibility of *you* or *your* former *dependent member* to notify *us* within 31 days of *your* legal divorce or *your dependent member's* marriage.

Benefits After Coverage Terminates

If a *network provider* terminates his or her contract with Ambetter from Sunshine Health or is terminated by us for any reason other than for cause, a *member* receiving active treatment may continue coverage and care with that *network provider* when *medically necessary* and through completion of treatment of a condition for which the *member* was receiving care at the time of the termination until:

1. The *member* selects another treating provider or during the next open enrollment period, whichever is longer, but not longer than ninety (90) days (or additional if approved by Ambetter from Sunshine Health) after termination of the provider's contracts;
2. The *member* who is pregnant and who has initiated a course of prenatal care regardless of the trimester in which care was initiated, completes postpartum care.

A *network provider* may refuse to continue to provide care to a *member* who is abusive, non-compliant, or in arrears in payment for services provided.

Benefits for *covered service expenses* incurred after a *member* ceases to be covered are provided for certain *illnesses* and *injuries*. However, no benefits are provided if this *contract* is terminated because of:

1. A request by *you*;
2. Fraud or material misrepresentation on *your* part; or
3. *Your* failure to pay premiums.

The *illness* or *injury* must cause a *period of extended loss*, as defined below. The *period of extended loss* must begin before coverage of the *member* ceases under this *contract*. No benefits are provided for *covered service expenses* incurred after the *period of extended loss* ends.

In addition to the above, if this *contract* is terminated because we refuse to renew all contracts issued on this form, with the same type and level of benefits, to residents of the state where *you* live, termination of this *contract* will not prejudice a claim for a *continuous loss* that begins before coverage of the *member* ceases under this *contract*. In this event, benefits will be extended for that *illness* or *injury* causing the *continuous loss*, but not beyond the earlier of:

1. The date the *continuous loss* ends; or
2. 12 months after the date renewal is declined.

SUBROGATION AND RIGHT OF REIMBURSEMENT

As used herein, the term “*third party*” means any party that is, or may be, or is claimed to be responsible for *injuries* or *illness* to a *member*. Such *injuries* or *illness* are referred to as “*third party injuries*.” “Responsible party” includes any parties actually, possibly or potentially responsible for payment of expenses associated with the care or treatment of *third party injuries*.

Celtic retains the right to repayment of the full cost of all benefits provided by this plan on behalf of the *member* that are associated with the *third party injuries*. Celtic’s rights of recovery apply to any recoveries made by or on behalf of the *member* from any sources, including but not limited to:

- Payments made by a *third party* or any insurance company on behalf of the *third party*;
- Any payments or awards under an uninsured or underinsured motorist coverage policy;
- Any Workers’ Compensation or disability award or settlement;
- Medical payments coverage under any automobile policy, premises or homeowners medical payments coverage or premises or homeowners insurance coverage; and
- Any other payments from a source intended to compensate a *member* for *third party injuries*.

By accepting benefits under this plan, the *member* specifically acknowledges Celtic’s right of subrogation. When this plan provides health care benefits for expenses incurred due to *third party injuries*, Celtic shall be subrogated to the *member’s* rights of recovery against any party to the extent of the full cost of all benefits provided by this plan. Celtic may proceed against any party with or without the *member’s* consent.

By accepting benefits under this plan, the *member* also specifically acknowledges Celtic’s right of reimbursement. This right of reimbursement attaches when this plan has provided health care benefits for expenses incurred due to *third party injuries* and the member or the *member’s* representative has recovered any amounts from any source. Celtic’s right of reimbursement is cumulative with and not exclusive of Celtic’s subrogation right and Celtic may choose to exercise either or both rights of recovery.

As a condition for *our* payment, the *member* or anyone acting on his or her behalf (including, but not limited to, the guardian, legal representatives, estate, or heirs) agrees:

1. To fully cooperate with *us* in order to obtain information about the *loss* and its cause;
2. To immediately inform *us* in writing of any claim made or lawsuit filed on behalf of a *member* in connection with the *loss*;
3. To include the amount of benefits paid by *us* on behalf of a *member* in any claim made against any *third party*;
4. To give Celtic a first-priority lien on any recovery, settlement or judgment or other sources of compensation which may be had from any party to the extent of the full cost of all benefits associated with *third party injuries* provided by this plan (regardless of whether specifically set forth in the recovery, settlement, judgment or compensation agreement);
5. To pay, as the first priority, from any recovery, settlement, judgment, or other source of compensation, any and all amounts due Celtic as reimbursement for the full cost of all benefits associated with *third party injuries* provided by this plan (regardless of whether specifically set forth in the recovery, settlement, judgment, or compensation agreement, and regardless of whether such payment will result in a recovery to the *member* which is insufficient to make the *member* whole or to compensate the member in part or in whole for the damages sustained);
6. That *we*:
 - a. Will have a lien on all money received by a *member* in connection with the *loss* equal to the benefit amount *we* have provided or paid;
 - b. May give notice of that lien to any *third party* or *third party’s* agent or representative.
 - c. Will have the right to intervene in any suit or legal action to protect *our* rights;
 - d. Are subrogated to all of the rights of the *member* against any *third party* to the extent of the benefits paid on the *member’s* behalf; and
 - e. May assert that subrogation right independently of the *member*.

7. To take no action that prejudices *our* reimbursement and subrogation rights. This includes, but is not limited to, refraining from making any settlement or recovery which specifically attempts to reduce or exclude the full cost of all benefits provided by this plan;
8. To sign, date, and deliver to *us* any documents *we* request that protect *our* reimbursement and subrogation rights;
9. To not settle any claim or lawsuit against a *third party* without providing *us* with written notice of the intent to do so;
10. To reimburse *us* from any money received from any *third party*, to the extent of benefits *we* paid for the *illness or injury*, whether obtained by settlement, judgment, or otherwise, and whether or not the *third party's* payment is expressly designated as a payment for medical expenses;
11. That *we* may reduce other benefits under the *contract* by the amounts a *member* has agreed to reimburse *us*.

We have a right to be reimbursed in full regardless of whether or not the *member* is fully compensated by any recovery received from any *third party* by settlement, judgment, or otherwise.

We will not pay attorney fees or costs associated with the *member's* claim or lawsuit. In the event *you* or *your* representative fail to cooperate with Celtic, *you* shall be responsible for all benefits paid by this plan in addition to costs and attorney's fees incurred by Celtic in obtaining repayment.

If a dispute arises as to the amount a *member* must reimburse *us*, the *member* (or the guardian, legal representatives, estate, or heirs of the *member*) agrees to place sufficient funds in an escrow or trust account to satisfy the maximum lien amount asserted by *us* until the dispute is resolved.

COORDINATION OF BENEFITS

Ambetter from Sunshine Health coordinates benefits with other payers when a *member* is covered by two or more group health benefit plans. Coordination of Benefits (COB) is the industry standard practice used to share the cost of care between two or more carriers when a *member* is covered by more than one health benefit plan.

It is a contractual provision of a majority of health benefit contracts. Ambetter from Sunshine Health complies with Federal and state regulations for COB and follows COB guidelines published by National Association of Insurance Commissioners (NAIC).

Under COB, the benefits of one plan are determined to be primary and are first applied to the cost of care. After considering what has been covered by the primary plan, the secondary plan may cover the cost of care up to the fully allowed expense according to the plan's payment guidelines. Ambetter from Sunshine Health Claims COB and Recovery Unit procedures are designed to avoid payment in excess of allowable expense while also making sure claims are processed both accurately and timely.

"Allowable expense" is the necessary, reasonable, and customary item of expense for health care, when the item is covered at least in part under any of the plans involved, except where a statute requires a different definition. When a Plan provides benefits in the form of services, the reasonable cash value of each service will be considered as both an allowable expense and a benefit paid.

"Plan" is a form of coverage written on an expense-incurred basis with which coordination is allowed.

The term "Plan" includes:

1. Group health insurance benefits and group blanket or group remittance health benefits coverage, whether uninsured arrangements of group coverage, insured, self-insured, or self-funded. This includes group HMO insurance and other prepayment, group practice and individual practice plans, and blanket contracts, except as excluded below.
2. Plan includes medical benefits coverage, in group and individual automobile "no-fault" and traditional liability "fault" type contracts.
3. Plan includes hospital, medical, and surgical benefits coverage of Medicare or a governmental plan offered, required, or provided by law, except Medicaid.
4. Plan does not include blanket school accident coverage or coverages issued to a substantially similar group (e.g., Girl Scouts, Boy Scouts) where the school or organization pays the premiums.
5. Plan does not include Individual or Family:
Insurance contracts, direct payment subscriber contracts, coverage through health maintenance organizations (HMO's) or coverage under other prepayment, group practice and individual practice plans.
6. Plan whose benefits are by law excess to any private benefits coverage.

"Primary plan" is one whose benefits must be determined without taking the existence of any other plan into consideration. A plan is primary if either:

- (1) The Plan has no order of benefits rules or its rules differ from those required by regulation; or (2) all plans which cover the person use the order of benefits rules required by regulation and under those rules the plan determines its benefits first. More than one plan may be a primary plan (for example, two plans which have no order of benefit determination rules).

“Secondary plan” is one which is not a primary plan. If a person is covered by more than one secondary plan, the order of benefit determination rules decide the order in which their benefits are determined in relation to each other.

Order of Benefit Determination Rules

The first of the rules listed below in paragraphs 1-6 that applies will determine which plan will be primary:

1. The primary plan pays or provides its benefits as if the Secondary plan or plans did not exist. A Plan may consider benefits paid or provided by another Plan in determining its benefits only when it is secondary to that other Plan.
2. If the other plan does not contain a coordination of benefits provision that is consistent with this provision is always primary. There are two exceptions:
 - a. Coverage that is obtained by virtue of membership in a group that is designed to supplement a part of a basic package of benefits may provide that the supplementary coverage shall be excess to any other parts of the Plan provided by the contract holder; and
 - b. Any noncontributory group or blanket insurance coverage which is in force on January 1, 1987 which provides excess major medical benefits intended to supplement any basic benefits on a covered person may continue to be excess to such basic benefits.

The first of the following rules that describes which Plan pays its benefits before another Plan is the rule to use.

3. If the person receiving benefits is the *member* and is only covered as an *eligible dependent* under the other plan, this *contract* will be primary.
4. Subject to State Statues: Social Security Act of 1965, as amended makes Medicare secondary to the plan covering the person as a dependent of an active employee, the order of benefit determination is:
 - a. If a child is covered under the plans of both parents and the parents are not separated or divorced, the plan of the parent whose birthday falls earlier in the year (excluding year of birth) shall be primary.
 - b. If both parents have the same birthday, the plan which covered the parent longer will be primary. To determine whose birthday falls earlier in the year, only the month and day are considered. However, if the other plan does not have this birthday rule, but instead has a rule based on the sex of the parent and as a result the plans do not agree on which is primary, then the rule in the other plan will determine which plan is primary.
5. If a child is covered by both parents’ plans, the parents are separated or divorced, and there is no court decree between the parents that establishes financial responsibility for the child’s health care expenses:
 - a. The plan of the parent who has custody will be primary.
 - b. If the parent with custody has remarried, and the child is also covered as a child under the step-parent’s plan, the plan of the parent with custody will pay first, the step-parent’s plan will pay second, and the plan of the parent without custody will pay third.
 - c. If a court decree between the parents says which parent is responsible for the child’s health care expenses, then that parent’s plan will be primary if that plan has actual knowledge of the decree.
6. If the person receiving services is covered under one plan as an active employee or member (i.e., not laid-off or retired), or as the spouse or child of such an active employee, and is also covered under another plan as a laid-off or retired employee or as the spouse or child of such a laid-off or retired employee, the plan that covers such person as an active employee or spouse or child of an active employee will be primary. If the other plan does not have this rule, and as a result the plans do not agree on which will be primary, this rule will be ignored.
7. If none of the above rules determine which plan is primary, the plan that covered the person receiving services longer will be primary.

Effects of Coordination

When this plan is secondary, its benefits will be reduced so that the total benefits paid by the primary plan and this plan during a claim determination period will not exceed Ambetter's maximum available benefit for each Covered Service. Also, the amount Ambetter pays will not be more than the amount Ambetter would pay if Ambetter were primary. As each claim is submitted, Ambetter will determine its obligation to pay for allowable expenses based upon all claims that have been submitted up to that point in time during the claim determination period.

Right to Receive and Release Needed Information

Certain fact about heath care coverage and services are needed to apply these COB rules and to determine benefits payable under this Plan and other plans. We may get the facts we need from, or give them to, other organizations or persons for the purpose of applying these rules and determining benefits payable under this Plan and other plans covering the person claiming benefits. *We* need not tell or get the consent of, any person to do this.

CLAIMS

Notice of Claim

When a *non-participating provider* renders services, notice of a claim for benefits must be given to *us*. The notice must be in writing, should include the name of the insured and *member* identification number, and any claim will be based on that written notice. The notice must be received by *us* within 20 days after the date of the injury or the first treatment date for the sickness on which the claim is based and may be given to *us* or *your* agent. If this required notice is not given in time, the claim may be reduced or invalidated. If it can be shown that it was not reasonably possible to submit the notice within the 20 day period and that notice was given as soon as possible, the claim will not be reduced or invalidated.

Proof of Loss

We must receive written *proof of loss* within 90 days of the *loss* or as soon as is reasonably possible. *Proof of loss* furnished more than one year late will not be accepted, unless *you* had no legal capacity to submit such proof during that year.

Cooperation Provision

Each *member*, or other person acting on his or her behalf, must cooperate fully to assist *us* in determining *our* rights and obligations under the *contract* and, as often as may be reasonably necessary:

1. Sign, date and deliver to *us* authorizations to obtain any medical or other information, records or documents *we* deem relevant from any person or entity.
2. Obtain and furnish to *us*, or *our* representatives, any medical or other information, records or documents *we* deem relevant.
3. Answer, under oath or otherwise, any questions *we* deem relevant, which *we* or *our* representatives may ask.
4. Furnish any other information, aid or assistance that *we* may require, including without limitation, assistance in communicating with any person or entity (including requesting any person or entity to promptly provide to *us*, or *our* representative, any information, records or documents requested by *us*).

If any *member*, or other person acting on his or her behalf, fails to provide any of the items or information requested or to take any action requested, the claim(s) will be closed and no further action will be taken by *us* unless and until the item or information requested is received or the requested action is taken, subject to the terms and conditions of the *contract*.

In addition, failure on the part of any *member*, or other person acting on his or her behalf, to provide any of the items or information requested or to take any action requested may result in the denial of the claim at issue to the covered person.

Time for Payment of Claims

Benefits will be paid as soon as *we* receive proper *proof of loss*. *We* will reimburse all claims or any portion of any claim within 45 days after receipt of the claim. If a claim or a portion of a claim is contested, *you* or *your* assignees shall be notified, in writing, that the claim is contested or denied, within 45 days after *we* receive the claim from *you*. The notice that a claim is contested shall identify the contested portion of the claim and the reasons for contesting the claim. Upon receipt of the additional information requested *you* or *your* assignees, *we* shall pay or deny the contested claim or portion of the contested claim, within 60 days.

"Clean claims" means a claim submitted by you or a provider that has no defect, impropriety, or particular circumstance requiring special treatment preventing payment. If we have not received the information we need to process a claim, we will ask for the additional information necessary to complete the claim. You will receive a copy of that request for additional information. In those cases, we cannot complete the processing of the claim until the additional information requested has been received. We will make our request for additional information within 30 days of our initial receipt of the claim and will complete our processing of the claim within 15 days after our receipt of all requested information.

We shall pay or deny any claim no later than 120 days after receiving the claim. Payment shall be treated as being made on the date a draft or other valid instrument which is equivalent to payment was placed in the United States mail in a properly addressed, postpaid envelope or, if not so posted, on the date of delivery. All overdue payments shall bear simple interest at the rate of 10 percent per year.

Upon *your* written notification, we will investigate any claim of improper billing by a *physician, hospital, or other health care provider*. We will determine if *you* were properly billed for only those procedures and services that the *covered person* actually received. If we determine that *you* have been improperly billed, we shall notify *you* and the provider of our findings and shall reduce the amount of payment to the provider by the amount determined to be improperly billed. If a reduction is made due to such notification by us, we shall pay to *you* 20 percent of the amount of the reduction up to \$500.

Payment of Claims

We may elect to pay, in our discretion, all or any part of the benefits provided by this contract for hospital, surgical, nursing, or medical services, directly to the hospital or other party providing such services to you. By reserving the right to pay, in our discretion, all or any part of the benefits provided for in this contract directly to a hospital or other person providing surgical, nursing, or medical services to you, we are not granting any hospital or other person rendering surgical, nursing or medical services any right to demand direct payment or any right to enforce any provision of this contract; nor are we waiving the Non-Assignment provision of this contract set forth below.

Foreign Claims Incurred for Emergency Care

Claims incurred outside of the United States for *emergency* care and treatment of a *member* must be submitted in English or with an English translation. Foreign claims must also include the applicable medical records in English to show proper *proof of loss* and evidence of payment to the provider.

Non-Assignment

The coverage, rights, privileges and benefits provided for under this contract are not assignable by you or anyone acting on your behalf. Any assignment or purported assignment of coverage, rights, privileges and benefits provided for under this contract that you may provide or execute in favor of any hospital, physician, or any other person or entity shall be null and void and shall not impose any obligation on us.

Notwithstanding the foregoing, you may specifically authorize, in writing, the payment of benefits that we have determined to be due and payable directly to any hospital, physician, or other person who provided you with any covered service and we will honor this specific direction and make such payment directly to the designated provider of the covered service.

No Third Party Beneficiaries

This contract is not intended to, nor does it, create or grant any rights in favor of any third party, including but not limited to any hospital, physician or medical practitioner providing services to you, and this contract shall not be construed to create any third party beneficiary rights.

Medicaid Reimbursement

The amount provided or payable under this *contract* will not be changed or limited for reason of a *member* being eligible for coverage under the Medicaid program of the state in which he or she lives.

We will pay the benefits of this *contract* to the State if:

1. A *member* has coverage under his or her state's Medicaid program; and
2. We receive proper *proof of loss* and notice that payment has been made for *covered service expenses* under that program.

Our payment to the State will be limited to the amount payable under this *contract* for the *covered service expenses* for which reimbursement is due. Payment under this provision will be made in good faith. It will satisfy *our* responsibility to the extent of that payment.

Custodial Parent

This provision applies if the parents of a covered *eligible child* are divorced or legally separated and both the custodial parent and the non-custodial parent are subject to the same court or administrative order establishing custody. The custodial parent, who is not a *member*, will have the rights stated below if we receive a copy of the order establishing custody.

Upon request by the custodial parent, we will:

1. Provide the custodial parent with information regarding the terms, conditions, benefits, exclusions and limitations of the *contract*;
2. Accept claim forms and requests for claim payment from the custodial parent; and
3. Make claim payments directly to the custodial parent for claims submitted by the custodial parent. Payment of claims to the custodial parent, which are made under this provision, will fully discharge *our* obligations.

A custodial parent may, with *our* approval, assign claim payments to the *hospital* or *medical practitioner* providing treatment to an *eligible child*.

Physical Examination

We shall have the right and opportunity to examine a *member* while a claim is pending or while a dispute over the claim is pending. These examinations are made at *our* expense and as often as we may reasonably require.

Legal Actions

No suit may be brought by *you* on a claim sooner than 60 days after the required *proof of loss* is given. No suit may be brought more than five years after the date *proof of loss* is required.

Prior to initiating any action at law, *you* are encouraged to first complete all the steps in the complaint/*grievance* procedures made available to resolve disputes in Florida under the *contract*. After completing that complaint/*grievance* procedures process, if *you* want to bring legal action against *us* on that dispute, *you* must do so within five years of the date we notified *you* of the final decision on *your* complaint/*grievance*.

GRIEVANCE AND COMPLAINT PROCEDURES

Applicability/Eligibility

The internal *grievance* procedures apply to any hospital or medical policy or certificate, but not to accident only or disability only insurance.

We hope you will always be happy with us and our providers. If you are not happy, please let us know. Ambetter from Sunshine Health has steps for handling problems you may have. Ambetter from Sunshine Health offers all of our members the following ways to get member satisfaction:

- Complaint
- Internal Grievance process
- Internal Appeal process
- External Appeal process

Complaint

A complaint is the lowest form of problem. It gives Ambetter from Sunshine Health the opportunity to resolve *your* problem without it becoming a formal grievance. Complaints are generally resolved within 3 business days following receipt of the issue. If *you* are not satisfied with the status of the complaint, *you* can request that *your* complaint be moved to the formal grievance system.

Grievance

A grievance is an expression of dissatisfaction about any matter other than an “action”. Filing a grievance will not affect *your* healthcare services. *We* will not treat *you* differently. *We* want to know *your* concerns so *we* can improve *our* services.

Appeal

An appeal is a request to review a Notice of Adverse Benefit Determination or a claim that has been denied in whole or part.

Internal Complaint Process

To file a complaint with Ambetter from Sunshine Health, please contact *our* Member Services Department at 877-687-1169 or TDD/TTY: 800-955-8770.

We will need the following information:

- *Your* first and last name;
- *Your* Ambetter from Sunshine Health ID number;
- *Your* address and telephone number;
- What *you* are unhappy with;
- What *you* would like to have happen.

Complaints

Basic elements of a *complaint* include:

1. The complainant is the claimant or an authorized representative of the claimant;
2. The submission may or may not be in writing;
3. The issue may refer to any dissatisfaction about:
 - a. *Us* (as the insurer); e.g., member service *complaints* - “the person to whom I spoke on the phone was rude to me”.
 - b. Providers with whom *we* have a direct or indirect contract.

- i. Lack of availability or accessibility of *network* providers not tied to an unresolved benefit denial.
Note: When the dissatisfaction is related to services from or access to a *network* provider, notify the Network Administration Department.
 - ii. Quality of care/quality of service issues;
4. Written expressions of dissatisfaction regarding quality of care/quality of service are processed as *grievances*;
5. Oral expressions of dissatisfaction regarding quality of care/quality of service are processed as *complaints* as indicated in standard oral *complaint* instructions; and
6. Any of the issues listed as part of the definition of *grievance* received from the *claimant* or the claimant's authorized representative where the caller has not submitted a written request but calls us to escalate their dissatisfaction and request a verbal/oral review.

Complaints received from the Florida Office of Insurance Regulation

The Commissioner may require *us* to treat and process any *complaint* received by the Florida Office of Insurance Regulation by, or on behalf of, a claimant as a *grievance* as appropriate. *We* will process the Florida Office of Insurance Regulation *complaint* as a *grievance* when the Commissioner provides *us* with a written description of the *complaint*.

Internal Grievance Process

A grievance may be filed orally or in writing at any time. *We* can be reached Monday through Friday, 8:00 am to 8:00 pm by calling Member Services at 877-687-1169 or TDD/TTY: 800-955-8770. If *you* file a grievance verbally, *you* will need to send *your* written consent within 10 days of calling in *your* grievance.

We will need the following information:

- *Your* first and last name;
- *Your* Ambetter from Sunshine Health ID number;
- *Your* address and telephone number;
- What *you* are unhappy with;
- What *you* would like to have happen.

If *you* file a grievance, the Grievance & Appeal Coordinator will send *you* a letter within 5 business of receipt letting *you* know that *we* have received *your* grievance. If *you* have any more information to help with *your* grievance, *you* may send it to us. *We* will add it to *your* case. *You* may send *us* the information at:

Ambetter from Sunshine Health
Grievance and Appeal Coordinator
1301 International Parkway, Suite 400
Sunrise, FL 33323
Phone: 877-687-1169 or TDD/TTY: 800-955-8770
Fax: 866-534-5972
Email: Sunshine.Appeals@centene.com

In some cases, obtaining information to help *us* review *your* grievance may take extra time. The time for deciding *your* grievance can be extended for 14 days if *you* think extra time to get information will benefit *you*. If Ambetter from Sunshine Health requests more time to gather the information, *we* will send *you* a letter to tell *you* why. *We* will only do this if the information *we* are waiting for could help with *your* grievance.

You may ask for copies of any information that Ambetter from Sunshine Health used to make the decision about *your* care.

You can expect a resolution and written answer from Ambetter from Sunshine Health within 30 days of receiving *your* grievance.

Internal Appeal Process

An appeal is a request to review a Notice of Action. *You* can request this review by phone or in writing. *You* must follow a request by phone in writing unless it is an expedited appeal.

An adverse decision can be when Ambetter from Sunshine Health:

- Denies the care requested;
- Decreases the amount of care;
- Ends care that has previously been approved;
- Denies payment for care and *you* may have to pay for it.

You will know that Ambetter from Sunshine Health is taking action because *we* will send *you* a letter. The letter is called a **Notice of Action**. If *you* do not agree with the action, *you* may request an **Appeal**.

Expedited Appeals

You or *your* doctor may want *us* to make a fast decision. *You* can ask for an expedited review if *you* or *your* doctor feel that *your* health is at risk. *Your* doctor must send information in writing telling *us* why *you* need a faster review. Expedited appeal reviews are available for *members* in situations deemed urgent. If Ambetter from Sunshine Health agrees that the request is urgent, *your* appeal will be resolved within 72 hours.

Who May File an Appeal?

- *You*, the *member* (or the guardian of a minor *member*).
- A person *you* have authorized to act for *you*.

You must give written permission if someone else files an appeal for *you*. Ambetter from Sunshine Health will include a form with the Notice of Action. Contact Member Services at 1-877-687-1169 if *you* need help. *We* can assist *you* with filing an appeal.

When does an Appeal Have to be Filed?

The Notice of Action will tell *you* about this process. ***You may file an appeal within 180 days from the date of the Notice of Action.*** If *you* make your request by phone, *you* must also send Ambetter from Sunshine Health a letter confirming *your* request within 10 days of making the request by phone. Ambetter from Sunshine Health will give *you* a written decision within **30 days (if the service has not been provided) or 60 days (if the service has already been provided)** of the date *we* receive *your* written request.

You, or someone authorized to do so, can act for *you* or help *you* with the appeal. *You* can tell *us* the name of the person authorized to help *you* by completing a Request for an Appeal or Grievance Form. *We* can help *you* fill out this form. Call *us* at 877-687-1169 or TTY/TDD at 800-955-8770 to ask for help, including if *you* need an interpreter.

You may send *us* health information about why *we* should pay for the service. This information can be sent with the Request for an Appeal or Grievance Form or in a separate letter. *You* can call *your* doctor if *you* need more medical information for *your* appeal. In some cases, getting the health information may take extra time. The time for deciding *your* appeal can be extended for 14 days if *you* or *your* doctor thinks the

extra time to get the health information will benefit *you*. If Ambetter from Sunshine Health requests more time to gather the health information, *we* will send *you* a letter to tell *you* why. This extension will be for 14 days. *We* will only do this if the health information *we* are waiting for could help with *your* plan appeal.

You may send the Request for an Appeal or Grievance Form, or *your* written request for a plan appeal and any health information to *us* by sending a letter to:

Ambetter from Sunshine Health
Grievance and Appeal Coordinator
1301 International Parkway, Suite 400
Sunrise, FL 33323
Fax: 866-534-5972

If the Notice of Action that *you* were sent said that *we* were terminating, suspending, or reducing a service that *you* were getting as an Ambetter from Sunshine Health *member*, *you* have the right to keep getting the service. If *you* let *us* know that *you* want to continue the service within ten (10) days of the Notice of Action letter, *we* will approve *you* to continue this service until the plan appeal decision is made. To do this, Ambetter from Sunshine Health must have been approving *you* to get the service before, the services were ordered by an authorized provider, and the time of the approval for that service has not ended. If after the review of *your* plan appeal Ambetter from Sunshine Health decides that the decision to terminate, suspend, or reduce the service was right and *you* kept getting the service, *you* may have to pay for the service.

You may request these documents by contacting:

Ambetter from Sunshine Health
Grievance and Appeal Coordinator
1301 International Parkway, Suite 400
Sunrise, FL 33323
Phone: 877-689-1169
Fax: 866-534-5972
TTY/TDD: 800-955-8770
Sunshine.Appeals@centene.com

If *you* have questions, call *us* at 877-687-1169 or TDD/TTY at 800-955-8770.

External Review

If you are dissatisfied with the Ambetter from Sunshine Health appeal decision, you have the right to have an independent review of certain final decisions made by Ambetter from Sunshine Health. Ambetter from Sunshine Health *members* are offered two levels of appeal for *adverse benefit determinations* related to a service that requires medical review. An external review decision is binding on *us*. An external review decision is binding on the claimant except to the extent the claimant has other remedies available under applicable federal or state law. *We* will pay for the costs of the external review performed by the independent reviewer.

You can make a request for external review in writing to **Ambetter from Sunshine Health Plan** at:

Ambetter from Sunshine Health
Appeals Department
1301 International Parkway
Sunrise, FL 33323

If assistance is needed with completing the written request, *you* may contact Ambetter from Sunshine Health at:

Phone 877-687-1169
TTY/TDD 800-955-8770
Fax 1-866-534-5972

Applicability/Eligibility

The external review procedures apply to any hospital or medical policy or certificate; excluding accident only or disability income only insurance.

External review is available for *grievances* that involve:

1. Medical judgment, including but not limited to those based upon requirements for *medical necessity*, appropriateness, health care setting, level of care or effectiveness of a covered benefit; or the determination that a treatment is *experimental* or *investigational*, as determined by an external reviewer.
2. *Rescissions* of coverage.

After exhausting the internal review process, the claimant can make a written request to the Appeals & Grievance Department for external review after the date of receipt of *our* internal response. *We* will send *your* request to the IRO. *You* must contact the IRO or *us* within 120 calendar days (4 months) of the date of your appeal resolution letter. If *you* do not file *your* appeal for an external independent review within 120 days, it cannot be reviewed. If *you* are not sure whether *your* appeal is eligible, or if *you* want more information, please contact Ambetter from Sunshine Health.

1. The internal appeal process must be exhausted before the claimant may request an external review unless the claimant files a request for an expedited external review at the same time as an internal *expedited grievance* or *we* either provide a waiver of this requirement or fail to follow the appeal process.
2. A health plan must allow a claimant to make a request for an expedited external review with the plan at the time the claimant receives:
 - a. An *adverse benefit determination* if the determination involves a medical condition of the claimant for which the timeframe for completion of an internal *expedited grievance* would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an internal *expedited grievance*.
 - b. A final internal *adverse benefit determination*, if the claimant has a medical condition where the timeframe for completion of a standard external review would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal *adverse benefit determination* concerns an admission, availability of care, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from a facility.
3. Claimants may request an expedited external review at the same time the internal *expedited grievance* is requested and an Independent Review Organization (IRO) will determine if the internal *expedited grievance* needs to be completed before proceeding with the expedited external review.

External Review Process

1. *We* have five (5) business days (immediately for expedited) following receipt of the request to conduct a preliminary review of the request to determine whether:

- a. The individual was a *covered person* at the time the item or service was requested;
 - b. The service is a *covered service* under the claimant's health plan but for the plan's *adverse benefit determination* with regard to *medical necessity experimental or investigational, medical judgment, or rescission*;
 - c. The claimant has exhausted the internal process; and
 - d. The claimant has provided all of the information required to process an external review.
2. Within one (1) business day (immediately for expedited) after completion of the preliminary review, *we* will notify the claimant in writing as to whether the request is complete but not eligible for external review and the reasons for its ineligibility or, if the request is not complete, the additional information needed to make the request complete. *We* will include notification of the *member's* right to submit written testimony to be included in the materials sent to the IRO.
 3. *We* must allow a claimant to perfect the request for external review within the four-month filing period or within the 48-hour period following the receipt of notification.
 4. *We* will assign an IRO on a rotating basis from *our* list of contracted IROs.
 5. Within five business days after the date of assignment of the IRO, *we* must provide the documents and any information considered in making the *adverse benefit determination* to the IRO.
Note: For expedited, after assignment of the IRO, *we* must provide the documents and any information considered in making the *adverse benefit determination* to the IRO electronically or by telephone or facsimile or any other available expeditious method.
 6. If *we* fail to timely provide the documents and information, the IRO may terminate the external review and make a decision to reverse the *adverse benefit determination*.
 7. Within 10 business days, the assigned IRO will timely notify the claimant in writing of the request's eligibility and acceptance for external review. The notice will include a statement that the claimant may submit in writing additional information to the IRO to consider.
 8. Upon receipt of any information submitted by the claimant, the IRO must forward the information to *us* within one business day.
 9. Upon receipt of the information, *we* may reconsider *our* determination. If *we* reverse our *adverse benefit determination*, *we* must provide written notice of the decision to the claimant and the IRO within one business day after making such decision. The external review would be considered terminated.
 10. Within 45 days (72 hours for expedited) after the date of receipt of the request for an external review by the health plan, the IRO will review all of the information and provide written notice of its decision to uphold or reverse the *adverse benefit determination* to the claimant and to *us*. If the notice for an expedited review is not in writing, the IRO must provide written confirmation within 48 hours after the date of providing the notice.
 11. Upon receipt of a notice of a decision by the IRO reversing the *adverse benefit determination*, *we* will approve the covered benefit that was the subject of the *adverse benefit determination*.

After *you* receive a decision from Ambetter by Sunshine Health concerning *your* benefits and feel further action is needed, *you* have the right to file a complaint with the Department of Financial Services, Division of Consumer Services.

You may request assistance of the Department of Financial Services, Division of Consumer Services by telephone at 1-877-MY-FL-CFO (1-877-693-5236), or if calling from outside of Florida (1-850-413-3089), by email at ConsumerServices@myfloridacfo.com, or online at: <http://www.myfloridacfo.com/Division/Consumers/>

You, or someone *you* authorized to do so, shall be provided, upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to the claimant's claim for benefits. All comments, documents, records and other information submitted by the claimant relating to

the claim for benefits, regardless of whether such information was submitted or considered in the initial *adverse benefit determination*, will be considered in the internal appeal.

Grievance Panel

The internal process requires that *your* appeal is handled by a grievance panel that does not include the person who made the initial determination or a subordinate of the original reviewer. During the grievance process, the initial decision maker may be consulted. The majority of the panel will consist of providers with the appropriate expertise. The panel must be requested within 30 days after Ambetter from Sunshine Health's transmission of an adverse determination. The panel will also provide a notice to the *member* and to the provider, if any, who filed on behalf of the *member*. In any case where the review process does not resolve a difference of opinion between the Ambetter from Sunshine Health and the *member*, the member (or provider) may submit a written grievance through an external review process. *Members* may voluntarily pursue binding arbitration (which *you* may incur some costs for this arbitration) after completing Ambetter from Sunshine Health's grievance procedure and as an alternative to the external review process (refer to the External Review section for more information). Arbitration shall not preclude review pursuant to Rule 690-191.081 and shall be conducted pursuant to Ch. 682, F.S.

When the *adverse benefit determination* is based in whole or in part on a medical judgment, the *grievance* panel will consult with a licensed health care provider with expertise in the field relating to the *grievance* and who was not consulted in connection with the original *adverse benefit determination*.

Expedited Appeal

An *expedited appeal* may be submitted orally or in writing. All necessary information, including *our* determination on review, will be transmitted between the claimant and *us* by telephone, facsimile, or other available similarly expeditious method.

For an appeal to be processed as expedited at least one of the following must apply:

1. The duration of the standard resolution process will result in serious jeopardy to the life or health of the *claimant* or the ability of the claimant to regain maximum function.
2. In the opinion of a *physician* with knowledge of the claimant's medical condition, the claimant is subject to severe pain that cannot be adequately managed without the care or treatment that is the subject of the *grievance*.
3. A *physician* with knowledge of the claimant's medical condition determines that the *grievance* shall be treated as an *expedited grievance*.

An *expedited appeal* provides for evaluation by appropriate clinical peers or peer (who were not involved in the initial adverse determination) within 24 hours. An *expedited appeal* shall be resolved as expeditiously as the *claimant's* health condition requires but not more than 72 hours after receipt of the *appeal*. Written notification of the decision must be provided no later than 2 business days or three calendar days if the initial notification was not in writing.

A *member* has the right to request both an internal and external level expedited appeal, related to the denial of a service requiring medical review, simultaneously. If the expedited appeal is unresolved, the *member* may appeal through the external review process (refer to the External Review section for more information).

Upon written request, *we* will mail or electronically mail a copy of the claimant's complete contract to the claimant or the claimant's authorized representative as expeditiously as the *appeal* is handled.

Written Grievance/Appeal Response

Grievance and *appeal* response letters shall describe, in detail, the *grievance and appeal* procedure and the notification shall include the specific reason for the denial, determination or initiation of disenrollment.

The panel's written decision must include:

1. The disposition of and the specific reason or reasons for the decision;
2. Any corrective action taken on the *grievance or appeal*;
3. The signature of one voting *member* of the panel;
4. A written description of position titles of panel *members* involved in making the decision;
5. If upheld or partially upheld, it is also necessary to include:
 - a. A clear explanation of the decision;
 - b. Reference to the specific plan provision on which the determination is based;
 - c. A statement that the claimant is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to the claimant's claim for benefits;
 - d. If an internal rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination, either the specific rule, guideline, protocol, or other similar criterion; or a statement that such rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of the rule, guideline, protocol, or other similar criterion will be provided free of charge to the claimant upon request;
 - e. If the *adverse benefit determination* is based on a *medical necessity* or *experimental treatment* or similar exclusion or limit, either an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request;
 - f. Identification of medical experts whose advice was obtained on behalf of the health plan, without regard to whether the advice was relied upon in making the *adverse benefit determination*;
 - g. The date of service;
 - h. The health care provider's name;
 - i. The claim amount;
 - j. The diagnosis and procedure codes with their corresponding meanings, or an explanation that the diagnosis or procedure codes are available upon request;
 - k. The health plan's denial code with corresponding meaning;
 - l. A description of any standard used, if any, in denying the claim;
 - m. A description of the external review procedures, if applicable;
 - n. The right to bring a civil action under state or federal law;
 - o. A copy of the form that authorizes the health plan to disclose protected health information, if applicable;
 - p. That assistance is available by contacting the specific state's consumer assistance department, if applicable; and
 - q. A culturally linguistic statement based upon the claimant's county or state of *residence* that provides for oral translation of the *adverse benefit determination*, if applicable.

GENERAL PROVISIONS

Entire Contract

This contract, with the application and any rider-amendments is the entire contract between you and us. No party or agent of a party may:

1. Change or alter the terms of this contract;
2. Waive any provision of this contract;
3. Extend the time for payment of premiums;
4. Waive any of our rights or requirements under the contract; or
5. Waive any of your obligations under the contract.

Non-Waiver

If we fail to enforce or to insist on strict compliance with any of the terms, conditions, limitations or exclusions of the *contract* that will not be considered a waiver of any rights under the *contract*. A past failure to strictly enforce the *contract* will not be a waiver of any rights in the future, even in the same situation or set of facts.

Rescissions

No misrepresentation of fact made regarding a *member* during the application process that relates to insurability will be used to void/rescind the coverage or deny a claim unless:

1. The misrepresented fact is contained in a written application, including amendments, signed by a *member*;
2. A copy of the application, and any amendments, has been furnished to the *member(s)*, or to their beneficiary; and
3. The misrepresentation of fact was intentionally made and material to *our* determination to issue coverage to any *member*. A *member's* coverage will be voided/rescinded and claims denied if that person performs an act or practice that constitutes fraud. "Rescind" has a retroactive effect and means the coverage was never in effect.

We will provide the *member* forty-five (45) days advance written notice before coverage is rescinded.

Time Limit on Certain Defenses

Relative to a misstatement in the application, after 2 years from the issue date, only fraudulent misstatements in the application may be used to void the contract or deny any claim for loss incurred or disability starting after the 2-year period.

Repayment for Fraud, Misrepresentation or False Information

During the first two years a *member* is covered under the *contract*, if a *member* commits fraud, misrepresentation or knowingly provides false information relating to the eligibility of any *member* under this *contract* or in filing a claim for *contract* benefits, we have the right to demand that *member* pay back to us all benefits that we provided or paid during the time the *member* was covered under the *contract*. We will return any premium paid during the time period for which the member returned benefit payments.

Conformity with State Laws

Any part of this *contract* in conflict with the laws of Florida on this *contract's effective date* or on any premium due date is changed to conform to the minimum requirements of Florida state laws.

Construction

We have the full power, authority, and discretion to construe and interpret any and all provisions of this contract to the greatest extent allowed by applicable law.

Performance Outcomes and Financial Data

You may obtain information regarding performance outcomes and financial data for Celtic Insurance Company published by the State of Florida Agency for Health Care Administration by accessing Ambetter from Sunshine Health's website: Ambetter.SunshineHealth.com. This website includes the link to FloridaHealthStat where this information is published, or *you* can go directly to www.floridahealthstat.com.

Statement of Non-Discrimination

Ambetter from Sunshine Health complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Ambetter from Sunshine Health does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

Ambetter from Sunshine Health:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Qualified sign language interpreters
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages

If you need these services, contact Ambetter from Sunshine Health at 1-877-687-1169 (Relay FL 1-800-955-8770).

If you believe that Ambetter from Sunshine Health has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: Grievance/Appeals Unit Sunshine Health, 1301 International Parkway, Suite 400, Sunrise, Florida 33323, 1-877-687-1169 (Relay Florida 1-800-955-8770), Fax, 1-866-534-5972. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, Ambetter from Sunshine Health is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD).

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.



Spanish:	Si usted, o alguien a quien está ayudando, tiene preguntas acerca de Ambetter de Sunshine Health, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 1-877-687-1169 (Relay Florida 1-800-955-8770).
French Creole:	Si oumenm, oubyen yon moun w ap ede, gen kesyon nou ta renmen poze sou Ambetter from Sunshine Health, ou gen tout dwa pou w jwenn èd ak enfòmasyon nan lang manman w san sa pa koute w anyen. Pou w pale avèk yon entèprèt, sonnen nimewo 1-877-687-1169 (Relay Florida 1-800-955-8770).
Vietnamese:	Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Ambetter from Sunshine Health, quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 1-877-687-1169 (Relay Florida 1-800-955-8770).
Portuguese:	Se você, ou alguém a quem você está ajudando, tem perguntas sobre o Ambetter from Sunshine Health, você tem o direito de obter ajuda e informação em seu idioma e sem custos. Para falar com um intérprete, ligue para 1-877-687-1169 (Relay Florida 1-800-955-8770).
Chinese:	如果您，或是您正在協助的對象，有關於 Ambetter from Sunshine Health 方面的問題，您有權利免費以您的母語得到幫助和訊息。如果要與一位翻譯員講話，請撥電話 1-877-687-1169 (Relay Florida 1-800-955-8770)。
French:	Si vous-même ou une personne que vous aidez avez des questions à propos d'Ambetter from Sunshine Health, vous avez le droit de bénéficier gratuitement d'aide et d'informations dans votre langue. Pour parler à un interprète, appelez le 1-877-687-1169 (Relay Florida 1-800-955-8770).
Tagalog:	Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Ambetter from Sunshine Health, may karapatan ka na makakuha nang tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 1-877-687-1169 (Relay Florida 1-800-955-8770).
Russian:	В случае возникновения у вас или у лица, которому вы помогаете, каких-либо вопросов о программе страхования Ambetter from Sunshine Health вы имеете право получить бесплатную помощь и информацию на своем родном языке. Чтобы поговорить с переводчиком, позвоните по телефону 1-877-687-1169 (Relay Florida 1-800-955-8770).
Arabic:	إذا كان لديك أو لدى شخص تساعد أسئلة حول Ambetter from Sunshine Health ، لديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مترجم اتصل بـ 1-877-687-1169 (Relay Florida 1-800-955-8770).
Italian:	Se lei, o una persona che lei sta aiutando, avesse domande su Ambetter from Sunshine Health, ha diritto a usufruire gratuitamente di assistenza e informazioni nella sua lingua. Per parlare con un interprete, chiami il 1-877-687-1169 (Relay Florida 1-800-955-8770).
German:	Falls Sie oder jemand, dem Sie helfen, Fragen zu Ambetter from Sunshine Health hat, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 1-877-687-1169 (Relay Florida 1-800-955-8770) an.
Korean:	만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Ambetter from Sunshine Health 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 1-877-687-1169 (Relay Florida 1-800-955-8770) 로 전화하십시오.
Polish:	Jeżeli ty lub osoba, której pomagasz, macie pytania na temat planów za pośrednictwem Ambetter from Sunshine Health, macie prawo poprosić o bezpłatną pomoc i informacje w języku ojczystym. Aby skorzystać z pomocy tłumacza, zadzwoń pod numer 1-877-687-1169 (Relay Florida 1-800-955-8770).
Gujarati:	જો તમને અથવા તમે જમની મદદ કરી રહ્યા હોય તેમને, Ambetter from Sunshine Health વિશે કોઈ પૂછ હોય તો તમને, કોઈ ખર્ચ વિના તમારી ભાષામાં મદદ અને માહિતી પ્રાપ્ત કરવાનો અધિકાર છે. દુભાષિયા સાથે વાત કરવા માટે 1-877-687-1169 (Relay Florida 1-800-955-8770) ઉપર કોલ કરો.
Thai:	หากท่านหรือผู้ที่ท่านให้ความช่วยเหลืออยู่ในขณะนี้ ต้องการเกี่ยวกับ Ambetter from Sunshine Health ท่านมีสิทธิที่จะได้รับความช่วยเหลือและข้อมูลในภาษาของท่าน โดยไม่เสียค่าใช้จ่ายใด ๆ ทั้งสิ้น หากต้องการใช้บริการถาม กรุณาโทรศัพทติดต่อที่หมายเลข 1-877-687-1169 (Relay Florida 1-800-955-8770)

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EXHIBIT B

Clinical Policy: Sofosbuvir/Velpatasvir (Epclusa)

Reference Number: HIM.PA.SP1

Effective Date: 08/16

Last Review Date: 08/17

Line of Business: Health Insurance Marketplace

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Sofosbuvir; velpatasvir (Epclusa[®]) is a combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor.

FDA approved indication

Epclusa is indicated:

- For the treatment of adult patients with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
- For the treatment of adult patients with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection with decompensated cirrhosis for use in combination with ribavirin

Policy/Criteria

Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Chronic Hepatitis C Infection (must meet all):

1. Diagnosis of chronic hepatitis C infection as evidenced by detectable HCV ribonucleic acid (RNA) levels over a six-month period;
2. Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist;
3. Confirmed HCV genotype is 1, 2, 3, 4, 5 or 6;
4. Life expectancy \geq 12 months with HCV treatment;
5. Documented sobriety from alcohol and illicit IV drugs for \geq 6 months prior to starting therapy, if applicable;
6. Advanced liver disease defined as one of the following (a or b):
 - a. Advanced fibrosis indicated by i or ii:
 - i. Liver biopsy showing a METAVIR score of F3 or equivalent (Knodell, Scheuer, Batts-Ludwig – F3; Ishak – F4/5);
 - ii. One serologic test and one radiologic test showing an equivalent score to METAVIR F3 per Appendix B;
 - b. Cirrhosis indicated by i, ii or iii:
 - i. Hepatocellular carcinoma (HCC) - and the HCC is amenable to resection, ablation or transplant;
 - ii. Liver biopsy showing a METAVIR score of F4 or equivalent (Knodell, Scheuer, Batts-Ludwig – F4; Ishak - F5/6);
 - iii. Both of the following (a and b):

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- a) One serologic test showing an equivalent score to METAVIR F4 per Appendix B;
- b) One radiologic test showing an equivalent score to METAVIR F4 per Appendix B or other radiologic test showing evidence of cirrhosis (e.g., portal hypertension);
7. Prescribed regimen is consistent with an FDA or AASLD-IDS A regimen in Appendix D or E (*if regimens are applicable to post-liver transplantation they are specifically designated*);
8. For genotype 1, 4, 5, 6 member has contraindications or clinically significant adverse effects to Harvoni, unless indicated treatment regimen with Harvoni is > 12 weeks;
9. Member agrees to participate in a medication adherence program meeting both of the following components (a and b):
 - a. Medication adherence monitored by pharmacy claims data or member report;
 - b. Member's risk for non-adherence identified by adherence program or member/prescribing physician follow-up at least every 4 weeks;
10. Dose does not exceed 400/100 mg/day (1 tablet/day).

Approval duration: 8 weeks

B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Chronic Hepatitis C Infection (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. Pharmacy claims support adherence to therapy;
4. If request is for a dose increase, new dose does not 400/100 mg/day (1 tablet/day).

Approval duration: up to a total of 24 weeks*

(*Approved duration should be consistent with a regimen in Appendix D)

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 for specialty months (whichever is less); or

2. Refer to HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents

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Appendix A: Abbreviation/Acronym Key

APRI: AST to platelet ratio
 AASLD: American Association for the Study of Liver Diseases
 CTP: Child Turcotte Pugh
 CrCl: creatinine clearance
 DAA: direct-acting antiviral
 FDA: Food and Drug Administration
 FIB-4: Fibrosis-4 index
 HCC: hepatocellular carcinoma
 HCV: hepatitis C virus
 IDSA: Infectious Diseases Society of America
 IV: intravenous
 MRE: magnetic resonance elastography
 NS3/4A, NS5A/B: nonstructural protein
 Peg-IFN: pegylated interferon
 PI: protease inhibitor
 RBV: ribavirin
 RNA: ribonucleic acid

Appendix B: Approximate Scoring Equivalencies using METAVIR F3/F4 as Reference

Fibrosis/ Cirrhosis	Serologic Tests*				Radiologic Tests†		Liver Biopsy‡	
	Fibro Test	FIBRO Spect II	APRI	FIB-4	FibroScan (kPa)	MRE (kPa)	METAVIR	Ishak
Advanced fibrosis	≥0.59	≥42	>1.5	>3.25	≥9.5	≥4.11	F3	F4-5
Cirrhosis	≥0.75	≥42	>1.5	>3.25	≥12.0	≥4.71	F4	F5-6

*Serologic tests:

FibroTest (available through Quest as FibroTest or LabCorp as FibroSure)

FIBROSpect II (available through Prometheus Laboratory)

APRI (AST to platelet ratio index)

FIB-4 (Fibrosis-4 index: includes age, AST level, platelet count)

†Radiologic tests:

FibroScan (ultrasound-based elastography)

MRE (magnetic resonance elastography)

‡Liver biopsy (histologic scoring systems):

METAVIR F3/F4 is equivalent to Knodell, Scheuer, and Batts-Ludwig F3/F4 and Ishak F4-5/F5-6

METAVIR fibrosis stages: F0 = no fibrosis; F1 = portal fibrosis without septa; F2 = few septa; F3 = numerous septa without cirrhosis; F4 = cirrhosis

Appendix C: Direct-Acting Antivirals (DAAs) for Treatment of HCV Infection

Brand Name	Drug Class				
	NS5A Inhibitor	Nucleotide Analog NS5B Polymerase Inhibitor	Non-Nucleoside NS5B Palm Polymerase Inhibitor	NS3/4A Protease Inhibitor (PI)**	CYP3A Inhibitor
Daklinza	Daclatasvir				
Epclusa*	Velpatasvir	Sofosbuvir			

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Brand Name	Drug Class				
	NS5A Inhibitor	Nucleotide Analog NS5B Polymerase Inhibitor	Non-Nucleoside NS5B Palm Polymerase Inhibitor	NS3/4A Protease Inhibitor (PI)**	CYP3A Inhibitor
Harvoni*	Ledipasvir	Sofosbuvir			
Olysio				Simeprevir	
Sovaldi		Sofosbuvir			
Technivie*	Ombitasvir			Paritaprevir	Ritonavir
Viekira XR/PAK*	Ombitasvir		Dasabuvir	Paritaprevir	Ritonavir
Zepatier*	Elbasvir			Grazoprevir	

*Combination drugs

**Additional PIs no longer recommended: Victrelis (boceprevir), Incivek (telaprevir)

Appendix D: FDA-Approved Regimens and Treatment Durations

Treatment Naive/Experienced	Genotype	Failed Treatment Regimen	Recommended Regimen <i>See footnotes for duration</i>
No Cirrhosis or Compensated Cirrhosis (CTP/Child-Pugh Class A)			
Treatment naive	1a, 1b, 2, 3, 4	None	Epclusa§
	5, 6	None	Epclusa§
Treatment experienced	1*	NS3 PI/Peg-IFN/RBV**	Epclusa§
	1a, 1b, 2, 4	Peg-IFN/RBV	Epclusa§
		Sovaldi/RBV	Epclusa + RBV§
	3	Peg-IFN/RBV	Epclusa§
		Sovaldi/RBV	Epclusa + RBV§
5, 6	Peg-IFN/RBV	Epclusa§	
Decompensated Cirrhosis (CTP/Child-Pugh Class B or C)			
Treatment experienced	1*, 4	Sovaldi/NS5A-based regimen	Epclusa + RBV†
Not specified	1*, 2, 3, 4, 5, 6	Not specified	Epclusa + RBV§
	1*, 4	Not specified	Epclusa† <i>If RBV ineligible.</i>

*Subtype a or b, or unknown subtype

**NS3 includes Victrelis (boceprevir), Incivek (telaprevir) or Olysio (simeprevir)

§Treatment duration - 12 weeks

†Treatment duration - 24 weeks

Appendix E: AASLD-IDSAS Recommended Regimens and Treatment Durations

Treatment Naive/Experienced	Genotype	Failed Treatment Regimen	Recommended Regimen <i>See footnotes for duration</i>
No Cirrhosis or Compensated Cirrhosis (CTP/Child-Pugh Class A)			
Treatment naive	1a, 1b, 2, 3, 4	None	Epclusa§
	5, 6	None	Epclusa§
Treatment experienced	1*	NS3 PI/Peg-IFN/RBV**	Epclusa§
	1a, 1b, 2, 4	Peg-IFN/RBV	Epclusa§
		Sovaldi/RBV	Epclusa + RBV§
	3	Peg-IFN/RBV	Epclusa§
		Sovaldi/RBV	Epclusa + RBV§

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Treatment Naive/Experienced	Genotype	Failed Treatment Regimen	Recommended Regimen <i>See footnotes for duration</i>
	5, 6	Peg-IFN/RBV	Epclusa§
<i>Decompensated Cirrhosis (CTP/Child-Pugh Class B or C)</i>			
Treatment experienced	1*, 4	Sovaldi/NS5A-based regimen	Epclusa + RBV†
Not specified	1*, 2, 3, 4	Not specified	Epclusa + RBV§
	1*, 4	Not specified	Epclusa† <i>If RBV ineligible.</i>

*Subtype a or b, or unknown subtype

**NS3 includes Victrelis (boceprevir), Incivek (telaprevir) or Olysio (simeprevir)

§Treatment duration - 12 weeks

†Treatment duration - 24 weeks

V. References

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	08/16	
Removed age, as age is not an absolute contraindication.	04/17	08/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.



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This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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EXHIBIT C

Clinical Policy: Ledipasvir/Sofosbuvir (Harvoni)

Reference Number: HIM.PA.SP3

Effective Date: 08/16

Last Review Date: 08/17

Line of Business: Health Insurance Marketplace

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Ledipasvir/sofosbuvir (Harvoni[®]) is a combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor.

FDA approved indication

Harvoni is indicated:

- For the treatment of HCV in adults with genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
- For the treatment of HCV in adults with genotype 1 infection with decompensated cirrhosis, in combination with ribavirin
- For the treatment of HCV in adults with genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin
- For the treatment of pediatric patients 12 years of age and older or weighing at least 35 kg with genotype 1, 4, 5, or 6 without cirrhosis or with compensated cirrhosis

Policy/Criteria

Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Chronic Hepatitis C Infection (must meet all):

1. Diagnosis of chronic hepatitis C infection as evidenced by detectable HCV ribonucleic acid (RNA) levels over a six-month period;
2. Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist;
3. Age \geq 12 years or body weight \geq 35kg;
4. Confirmed HCV genotype is 1, 4, 5 or 6;
5. Life expectancy \geq 12 months with HCV treatment;
6. Documented sobriety from alcohol and illicit IV drugs for \geq 6 months prior to starting therapy, if applicable;
7. Advanced liver disease defined as one of the following (a or b):
 - a. Advanced fibrosis indicated by i or ii:
 - i. Liver biopsy showing a METAVIR score of F3 or equivalent (Knodell, Scheuer, Batts-Ludwig – F3; Ishak – F4/5);
 - ii. One serologic test and one radiologic test showing an equivalent score to METAVIR F3 per Appendix B;
 - b. Cirrhosis indicated by i, ii or iii:

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- i. Hepatocellular carcinoma (HCC) - and the HCC is amenable to resection, ablation or transplant;
- ii. Liver biopsy showing a METAVIR score of F4 or equivalent (Knodell, Scheuer, Batts-Ludwig – F4; Ishak - F5/6);
- iii. Both of the following (a and b):
 - a) One serologic test showing an equivalent score to METAVIR F4 per Appendix B;
 - b) One radiologic test showing an equivalent score to METAVIR F4 per Appendix B or other radiologic test showing evidence of cirrhosis (e.g., portal hypertension);
8. Prescribed regimen is consistent with an FDA or AASLD-IDSA recommended regimen (*see Appendix D and E for reference*);
9. If member is > 18 years of age and prescribed treatment duration is >12 weeks, member has contraindication or clinically significant adverse effects to Epclusa;
10. Member agrees to participate in a medication adherence program meeting both of the following components (a and b):
 - a. Medication adherence monitored by pharmacy claims data or member report;
 - b. Member's risk for non-adherence identified by adherence program or member/prescribing physician follow-up at least every 4 weeks;
11. If prescribed with ribavirin, at time of request, member has none of the following contraindications:
 - a. Pregnancy or possibility of pregnancy - member or partner;
 - b. Coadministration with didanosine;
 - c. Significant/unstable cardiac disease;
 - d. Hemoglobinopathy (e.g., thalassemia major, sickle cell anemia);
 - e. Hemoglobin < 8.5 g/dL;
 - f. Creatinine clearance < 50 ml/min;
12. Dose does not exceed 90/400 mg/day (1 tablet/day).

Approval duration: Up to a total of 24 weeks*

(*Approved duration should be consistent with a regimen in Appendix D or E)

B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Chronic Hepatitis C Infection (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. Pharmacy claims support adherence to therapy;
4. If request is for a dose increase, new dose does not exceed 90/400 mg/day (1 tablet/day).

Approval duration: Up to a total of 24 weeks*

(*Approved duration should be consistent with a regimen in Appendix D or E)

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A. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 for specialty months (whichever is less); or

2. Refer to HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents

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Appendix A: Abbreviation/Acronym Key

APRI: AST to platelet ratio

AASLD: American Association for the Study of Liver Diseases

CTP: Child Turcotte Pugh

FDA: Food and Drug Administration

FIB-4: Fibrosis-4 index

HCC: hepatocellular carcinoma

HCV: hepatitis C virus

IDSA: Infectious Diseases Society of America

IV: intravenous

MRE: magnetic resonance elastography

NS3/4A, NS5A/B: nonstructural protein

Peg-IFN: pegylated interferon

PI: protease inhibitor

RBV: ribavirin

RNA: ribonucleic acid

Appendix B: Approximate Scoring Equivalencies using METAVIR F3/F4 as Reference

Fibrosis/ Cirrhosis	Serologic Tests*				Radiologic Tests†		Liver Biopsy‡	
	Fibro Test	FIBRO Spect II	APRI	FIB-4	FibroScan (kPa)	MRE (kPa)	METAVIR	Ishak
Advanced fibrosis	≥0.59	≥42	>1.5	>3.25	≥9.5	≥4.11	F3	F4-5
Cirrhosis	≥0.75	≥42	>1.5	>3.25	≥12.0	≥4.71	F4	F5-6

*Serologic tests:

FibroTest (available through Quest as FibroTest or LabCorp as FibroSure)

FIBROSpect II (available through Prometheus Laboratory)

APRI (AST to platelet ratio index)

FIB-4 (Fibrosis-4 index: includes age, AST level, platelet count)

†Radiologic tests:

FibroScan (ultrasound-based elastography)

MRE (magnetic resonance elastography)

‡Liver biopsy (histologic scoring systems):

METAVIR F3/F4 is equivalent to Knodell, Scheuer, and Batts-Ludwig F3/F4 and Ishak F4-5/F5-6

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METAVIR fibrosis stages: F0 = no fibrosis; F1 = portal fibrosis without septa; F2 = few septa; F3 = numerous septa without cirrhosis; F4 = cirrhosis

Appendix C: Direct-Acting Antivirals for Treatment of HCV Infection

Brand Name	Drug Class				
	NS5A Inhibitor	Nucleotide Analog NS5B Polymerase Inhibitor	Non-Nucleoside NS5B Palm Polymerase Inhibitor	NS3/4A Protease Inhibitor (PI)**	CYP3A Inhibitor
Daklinza	Daclatasvir				
Epclusa*	Velpatasvir	Sofosbuvir			
Harvoni*	Ledipasvir	Sofosbuvir			
Olysio				Simeprevir	
Sovaldi		Sofosbuvir			
Technivie*	Ombitasvir			Paritaprevir	Ritonavir
Viekira XR/PAK*	Ombitasvir		Dasabuvir	Paritaprevir	Ritonavir
Zepatier*	Elbasvir			Grazoprevir	

*Combination drugs

**Additional PIs no longer recommended: Victrelis (boceprevir), Incivek (telaprevir)

Appendix D: FDA-Approved Regimens and Treatment Durations Adult Patients

Treatment Naive/Experienced	Genotype	Failed Treatment Regimen	Recommended Regimen <i>See footnotes for duration</i>
No Cirrhosis			
Treatment naive	1*	None	Harvoni [^] <i>If pretreatment HCV RNA < 6 million IU/mL.</i>
	1*, 4	None	Harvoni + RBV [§] <i>If post-liver transplantation.</i>
	1*, 4, 5, 6	None	Harvoni [§]
Treatment experienced	1*, 4	NS3 PI/Peg-IFN/RBV**	Harvoni + RBV [§] <i>If post-liver transplantation.</i>
	1*, 4, 5, 6	NS3 PI/Peg-IFN/RBV**	Harvoni [§]
Compensated Cirrhosis (CTP/Child-Pugh Class A)			
Treatment naive	1*, 4	None	Harvoni + RBV [§] <i>If post-liver transplantation.</i>
	1*, 4, 5, 6	None	Harvoni [§]
Treatment experienced	1*	NS3 PI/Peg-IFN/RBV**	Harvoni + RBV [§] Harvoni [†] <i>If RBV ineligible.</i>
	1*, 4	NS3 PI/Peg-IFN/RBV**	Harvoni + RBV [§] <i>If post-liver transplantation.</i>
	4, 5, 6	NS3 PI/Peg-IFN/RBV**	Harvoni [§]
Decompensated Cirrhosis (CTP/Child-Pugh Class B or C)			
Treatment naive	1*, 4	None	Harvoni + RBV [§]
Treatment experienced	1*, 4	NS3 PI/Peg-IFN/RBV**	Harvoni + RBV [§]

*Subtype a or b, or unknown subtype

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**NS3 includes Victrelis (boceprevir), Incivek (telaprevir) or Olysio (simeprevir)

^Treatment duration - 8 weeks

§Treatment duration - 12 weeks

†Treatment duration - 24 weeks

Pediatric Patients (≥ 12 years or ≥ 35 kg)

Treatment Naive/Experienced	Genotype	Failed Treatment Regimen	Recommended Regimen <i>See footnotes for duration</i>
No Cirrhosis			
Treatment naive	1*, 4, 5, 6	None	Harvoni§
Treatment experienced	1*, 4, 5, 6	Peg-IFN/RBV	Harvoni§
Compensated Cirrhosis (CTP/Child-Pugh Class A)			
Treatment naive	1*, 4, 5, 6	None	Harvoni§
Treatment experienced	1*	Peg-IFN/RBV	Harvoni†
	4, 5, 6	Peg-IFN/RBV	Harvoni §

*Subtype a or b, or unknown subtype

§Treatment duration - 12 weeks

†Treatment duration - 24 weeks

Appendix E: AASLD-IDSAS Recommended Regimens and Treatment Durations

Treatment Naive/Experienced	Genotype	Failed Treatment Regimen	Recommended Regimen <i>See footnotes for duration</i>
No cirrhosis			
Treatment naive	1*, 4	None	Harvoni + RBV§ <i>If liver transplant recipient.</i>
	1a, 1b, 4, 5, 6	None	Harvoni§
Treatment experienced	1*	Sovaldi/Peg-IFN/RBV	Harvoni + RBV§
		NS3 PI/Peg-IFN/RBV**	Harvoni§
	1*, 4	Not specified	Harvoni + RBV§ <i>If post-liver transplantation.</i>
	1a, 1b, 4, 5, 6	Peg-IFN/RBV	Harvoni§
Compensated cirrhosis (CTP/Child-Pugh Class A)			
Treatment naive	1*, 4	None	Harvoni + RBV§ <i>If post-liver transplantation.</i>
			Harvoni† <i>If post-liver transplantation and if RBV ineligible.</i>
	1a, 1b, 4, 5, 6	None	Harvoni§
Treatment experienced	1*	Sovaldi/Peg-IFN/RBV	Harvoni + RBV†
		NS3 PI/Peg-IFN/RBV**	Harvoni + RBV§
			Harvoni† <i>If RBV ineligible.</i>
	1*, 4	Not specified	Harvoni + RBV§ <i>If post-liver transplantation.</i>
	1a, 1b, 4	Peg-IFN/RBV	Harvoni + RBV§
		Peg-IFN/RBV	Harvoni†

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Treatment Naive/Experienced	Genotype	Failed Treatment Regimen	Recommended Regimen <i>See footnotes for duration</i>
	5, 6	Peg-IFN/RBV	Harvoni§
Decompensated cirrhosis (CTP/Child-Pugh Class B or C)			
Treatment naive	1*, 4	Not specified	Harvoni + RBV§ <i>If post-liver transplantation.</i>
Treatment experienced	1*, 4	Sovaldi-based regimen	Harvoni + RBV†
		Not specified	Harvoni + RBV§ <i>If post-liver transplantation.</i>
Not specified	1*, 4	Not specified	Harvoni + RBV§
			Harvoni† <i>If RBV ineligible.</i>

*Any or unknown subtype

**NS3 includes Victrelis (boceprevir), Incivek (telaprevir) or Olysio (simeprevir)

§Treatment duration - 12 weeks

†Treatment duration - 24 weeks

V. References

1. Harvoni Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; April 2017. Available at http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf. Accessed April 2017
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Reviews, Revisions, and Approvals	Date	P&T Approval Date
<p>New policy created.</p> <p>In relation to the current CP.PHAR.17 Hepatitis C Therapies policy, please note the following modifications or additions:</p> <ul style="list-style-type: none"> • HCV RNA levels over six-month period added to confirm infection is chronic per AASLD guidelines. • Life expectancy “greater than or equal to 12 months if HCC and awaiting transplant” is modified to indicate “greater than or equal to 12 months with HCV therapy” per AASLD guidelines. • Testing criteria reorganized by “no cirrhosis”/“cirrhosis” consistent with the regimen tables; HCC population is included under “cirrhosis” and broadened to incorporate HCC amenable to curative measures (resection, ablation, transplant) per the AASLD HCC guidelines (guidelines are added to the reference section). In the regimen tables, HCC can fall under compensated or decompensated cirrhosis but not under “no cirrhosis” per section I criteria. • Methods to diagnose fibrosis/cirrhosis are modified to require presence of HCC, liver biopsy or a combination of one serologic and one radiologic test per AASLD guidelines. Serologic and radiologic tests are updated and correlated with METAVIR per Appendix B. Note that Hepascore has been discontinued and that both LabCorp and Quest offer FibroTest. FibroSpect II has been recently updated to correlate with METAVIR F3/F4 and is offered now by Prometheus rather than Quest. APRI and FIB-4 are calculations based on AST and platelets. • Removed creatinine clearance restriction – not a contraindication. • Criteria added excluding post-liver transplantation unless regimens specifically designate. • Dosing regimens are presented in Appendix D and E per AASLD guidelines and FDA-approved indications. • The initial approval period is shortened to 8 weeks to accommodate verification of HCV RNA status within that time - AASLD guidelines recommended testing at 4 and 6 weeks. 	08/16	
<p>Added pediatric (≥ 12 years or ≥ 35 kg) indication expansion for genotype 1,4,5,6. Updated contraindications.</p> <p>Allowed full therapy regimen at initial approval duration.</p>	04/17	08/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted

CLINICAL POLICY

Ledipasvir/Sofosbuvir

standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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CIVIL COVER SHEET

JS 44 (Rev. 06/17) FLSD Revised 06/01/2017

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.) **NOTICE: Attorneys MUST Indicate All Re-filed Cases Below.**

I. (a) PLAINTIFFS M.D., C.F., E.M.

DEFENDANTS Centene Corporation, Inc., and Centene Management Company, LLC

(b) County of Residence of First Listed Plaintiff Miami-Dade, Florida
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant St. Louis, Missouri
(IN U.S. PLAINTIFF CASES ONLY)

(c) Attorneys (Firm Name, Address, and Telephone Number)
Rivero Mestre LLP, 2525 Ponce de Leon Blvd., 305-445-2500

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.
Attorneys (If Known)

(d) Check County Where Action Arose: MIAMI-DADE MONROE BROWARD PALM BEACH MARTIN ST. LUCIE INDIAN RIVER OKEECHOBEE HIGHLANDS

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff
- 2 U.S. Government Defendant
- 3 Federal Question (U.S. Government Not a Party)
- 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | | | | | |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| | PTF | DEF | | PTF | DEF |
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input checked="" type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

- | | | | | |
|---|---|--|--|---|
| CONTRACT | TORTS | FORFEITURE/PENALTY | BANKRUPTCY | OTHER STATUTES |
| <input type="checkbox"/> 110 Insurance | PERSONAL INJURY | <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 | <input type="checkbox"/> 422 Appeal 28 USC 158 | <input type="checkbox"/> 375 False Claims Act |
| <input type="checkbox"/> 120 Marine | <input type="checkbox"/> 310 Airplane | <input type="checkbox"/> 690 Other | <input type="checkbox"/> 423 Withdrawal 28 USC 157 | <input type="checkbox"/> 376 Qui Tam (31 USC 3729 (a)) |
| <input type="checkbox"/> 130 Miller Act | <input type="checkbox"/> 315 Airplane Product Liability | | | <input type="checkbox"/> 400 State Reapportionment |
| <input type="checkbox"/> 140 Negotiable Instrument | <input type="checkbox"/> 320 Assault, Libel & Slander | | | <input type="checkbox"/> 410 Antitrust |
| <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment | <input type="checkbox"/> 330 Federal Employers' Liability | | | <input type="checkbox"/> 430 Banks and Banking |
| <input type="checkbox"/> 151 Medicare Act | <input type="checkbox"/> 340 Marine | | | <input type="checkbox"/> 450 Commerce |
| <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) | <input type="checkbox"/> 345 Marine Product Liability | | | <input type="checkbox"/> 460 Deportation |
| <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits | <input type="checkbox"/> 350 Motor Vehicle | LABOR | PROPERTY RIGHTS | <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations |
| <input type="checkbox"/> 160 Stockholders' Suits | <input type="checkbox"/> 355 Motor Vehicle Product Liability | <input type="checkbox"/> 710 Fair Labor Standards Act | <input type="checkbox"/> 820 Copyrights | <input type="checkbox"/> 480 Consumer Credit |
| <input checked="" type="checkbox"/> 190 Other Contract | <input type="checkbox"/> 360 Other Personal Injury | <input type="checkbox"/> 720 Labor/Mgmt. Relations | <input type="checkbox"/> 830 Patent | <input type="checkbox"/> 490 Cable/Sat TV |
| <input type="checkbox"/> 195 Contract Product Liability | <input type="checkbox"/> 362 Personal Injury - Med. Malpractice | <input type="checkbox"/> 740 Railway Labor Act | <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application | <input type="checkbox"/> 490 Securities/Commodities/Exchange |
| <input type="checkbox"/> 196 Franchise | | <input type="checkbox"/> 751 Family and Medical Leave Act | <input type="checkbox"/> 840 Trademark | <input type="checkbox"/> 890 Other Statutory Actions |
| | CIVIL RIGHTS | <input type="checkbox"/> 790 Other Labor Litigation | SOCIAL SECURITY | <input type="checkbox"/> 891 Agricultural Acts |
| REAL PROPERTY | <input type="checkbox"/> 440 Other Civil Rights | <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act | <input type="checkbox"/> 861 HIA (1395ff) | <input type="checkbox"/> 893 Environmental Matters |
| <input type="checkbox"/> 210 Land Condemnation | <input type="checkbox"/> 441 Voting | | <input type="checkbox"/> 862 Black Lung (923) | <input type="checkbox"/> 895 Freedom of Information Act |
| <input type="checkbox"/> 220 Foreclosure | <input type="checkbox"/> 442 Employment | PRISONER PETITIONS | <input type="checkbox"/> 863 DIWC/DIWW (405(g)) | <input type="checkbox"/> 896 Arbitration |
| <input type="checkbox"/> 230 Rent Lease & Ejectment | <input type="checkbox"/> 443 Housing/Accommodations | Habeas Corpus: | <input type="checkbox"/> 864 SSID Title XVI | <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision |
| <input type="checkbox"/> 240 Torts to Land | <input type="checkbox"/> 445 Amer. w/Disabilities - Employment | <input type="checkbox"/> 463 Alien Detainee | <input type="checkbox"/> 865 RSI (405(g)) | <input type="checkbox"/> 950 Constitutionality of State Statutes |
| <input type="checkbox"/> 245 Tort Product Liability | <input type="checkbox"/> 446 Amer. w/Disabilities - Other | <input type="checkbox"/> 510 Motions to Vacate Sentence | | |
| <input type="checkbox"/> 290 All Other Real Property | <input type="checkbox"/> 448 Education | Other: | FEDERAL TAX SUITS | |
| | | <input type="checkbox"/> 530 General | <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) | |
| | | <input type="checkbox"/> 535 Death Penalty | <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609 | |
| | | <input type="checkbox"/> 540 Mandamus & Other | | |
| | | <input type="checkbox"/> 550 Civil Rights | | |
| | | <input type="checkbox"/> 555 Prison Condition | | |
| | | <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement | | |
| | | <input type="checkbox"/> 462 Naturalization Application | | |
| | | <input type="checkbox"/> 465 Other Immigration Actions | | |

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding
- 2 Removed from State Court
- 3 Re-filed (See VI below)
- 4 Reinstated or Reopened
- 5 Transferred from another district (specify)
- 6 Multidistrict Litigation Transfer
- 7 Appeal to District Judge from Magistrate Judgment
- 8 Multidistrict Litigation - Direct File
- 9 Remanded from Appellate Court

VI. RELATED/RE-FILED CASE(S) (See instructions): a) Re-filed Case YES NO b) Related Cases YES NO
JUDGE: _____ **DOCKET NUMBER:** _____

VII. CAUSE OF ACTION
 Cite the U.S. Civil Statute under which you are filing and Write a Brief Statement of Cause (Do not cite jurisdictional statutes unless diversity):
 LENGTH OF TRIAL via _____ days estimated (for both sides to try entire case)

VIII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND \$50,000,001.00 CHECK YES only if demanded in complaint
JURY DEMAND: Yes No

ABOVE INFORMATION IS TRUE & CORRECT TO THE BEST OF MY KNOWLEDGE
 DATE: June 13, 2018 SIGNATURE OF ATTORNEY OF RECORD: _____

FOR OFFICE USE ONLY
 RECEIPT # _____ AMOUNT _____ IFP _____ JUDGE _____ MAG JUDGE _____

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Southern District of Florida

M.D., C.F., E.M.

Plaintiff(s)

v.

Centene Corporation, Inc., and Centene Management Company, LLC

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) Centene Management Company, LLC
C T CORPORATION SYSTEM
1200 SOUTH PINE ISLAND ROAD
PLANTATION, FL 33324

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Andres Rivero, Rivero Mestre LLP, 2525 Ponce de Leon Blvd., Coral Gables, Florida 33146

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: 06/13/2018

Signature of Clerk or Deputy Clerk

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

I returned the summons unexecuted because _____ ; or

Other *(specify)*:

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

Print

Save As...

Reset

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Southern District of Florida

M.D., C.F., E.M.

Plaintiff(s)

v.

Centene Corporation, Inc., and Centene Management Company, LLC

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) Centene Corporation, Inc. Centene Plaza 7700 Forsyth Blvd. St. Louis, MO 63105

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Andres Rivero Rivero Mestre LLP 2525 Ponce de Leon Blvd. Coral Gables, Florida 33146

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: 06/13/2018

Signature of Clerk or Deputy Clerk

Civil Action No. _____

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was received by me on *(date)* _____ .

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

I returned the summons unexecuted because _____ ; or

Other *(specify)*:

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

Print

Save As...

Reset

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: [Class Action: Centene Corp. Subsidiary Only Covers Hep C Cure In Cases of 'Severe, Irreparable' Liver Damage](#)
