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.

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[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 livery 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

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[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 Bach 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 Ribavarin, an anti-viral drug, for use in combination with Interferon to treat hepatitis C. The Interferon and Ribavarin 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 Ribavarin, 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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