THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. _____

MICHAEL RYAN,
SHARON MOLINA,
and EARBY MOXON,
on behalf of themselves,
and all others similarly situated,

Plaintiffs,

v.

SUSAN E. BIRCH, in her official capacity only as
Executive Director of the COLORADO
STATE DEPARTMENT OF HEALTH
CARE POLICY& FINANCING,

Defendant.

CLASS ACTION COMPLAINT

For their Class Action Complaint against Defendant, Plaintiffs allege as follows on behalf of themselves and a class of similarly situated people they seek to represent.

I. INTRODUCTION

1. This is a case about the unlawful denial by the State of Colorado of treatment coverage to Medicaid eligible individuals who are infected by the insidious and life threatening Hepatitis C Virus ("HCV"). Plaintiffs are Medicaid enrollees who suffer from this communicable disease that afflicts millions of Americans. According to the Centers for Disease Control, HCV is the most deadly infectious disease in the United States, killing more Americans than the next 60 infectious diseases combined. Left untreated, the Hepatitis C Viral disease is a chronic, systemic inflammatory illness that can cause health problems both within and outside of

the liver at all stages of its progression. Manifestations of the disease outside of the liver, known as "extrahepatic" effects, include kidney disease, hypertension, lymphoma, intractable fatigue, joint pain, arthritis, vasculitis, thyroid disease, depression, memory loss, sore muscles, mental changes, heart attacks, diabetes, nerve damage, jaundice, and various cancers. HCV can also progressively destroy the liver by scarring its tissue and impairing function. When allowed to proceed unabated, HCV can thus lead to fibrosis, cirrhosis, and cancer of the liver, as well as the need for a liver transplant, and, in some instances, even death.

2. Fortunately for the thousands of Coloradoans who are living with HCV, the U.S. Food and Drug Administration began approving in 2011 a series of pharmaceutical treatments belonging to a drug class called "Direct Acting Antivirals" ("DAAs") that constitute a *de facto* cure for HCV. Over the course of the next several years, the FDA labeled these drugs as "breakthrough therapy," and approved a succession of treatments within the DAA class.

3. DAA treatment is now the standard of care for the treatment of Hepatitis C at all stages of disease progression. DAA treatment is strongly urged by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. The importance of covering DAA treatment is expressly urged by the federal agency responsible for administering Medicaid. DAA treatment is covered without regard to disease severity by Medicare, the Veteran's Administration and the overwhelming majority of commercial health insurers. DAA treatment is the consensus medical standard of care in Colorado and across the United States, for the simple reason that it is the only feasible solution to the disease.

4. The promise of DAA treatment has proven illusory, however, for thousands of Coloradoans because the Defendant has imposed an illegal access criterion that withholds

Medicaid coverage until the disease has caused significant liver damage, as measured by tests for fibrosis, which is scarring of the liver tissue. This case is the story of how the State of Colorado brought about this discordant and disconsonant result. And this case is about overturning it.

II. JURISDICTION AND VENUE

5. Jurisdiction is proper under 28 U.S.C. § 1331, because this action arises under the laws of the United States. Specifically, Plaintiffs' causes of action arise under 42 U.S.C. § 1983 to redress deprivations of rights guaranteed him by 42 U.S.C. §§1396a(a)(10)(A), 1396a(a)(10)(B)(i) & (ii), and 1396a(a)(8).

6. Venue is proper under 28 U.S.C. § 1391(b)(1) and (2), because all of the actions, events or omissions giving rise to Plaintiffs' claims occurred in the District of Colorado and the defendant resides here.

III. PARTIES

7. **Defendant Susan E. Birch** is the Executive Director of the Colorado State Department of Health Care Policy & Financing ("HCPF"). HCPF is a Department of the State of Colorado and is the sole state agency responsible for administering the Colorado Medicaid Program. It is HCPF that has established and is implementing the restriction on access to DAAs challenged here. At all times relevant to this Complaint, the actions and inactions of Ms. Birch were and are being carried out under color of state law. Ms. Birch is sued in her official capacity, for prospective relief only.

7. **Plaintiff Michael Ryan** is a 59-year-old carpenter who lives in northern Colorado and is infected with chronic HCV. He is enrolled in Colorado Medicaid.

8. **Plaintiff Sharon Molina** is a 48-year-old resident of Colorado who is infected with chronic HCV. She is enrolled in Colorado Medicaid.

9. **Plaintiff Earby Moxon** is a resident of Colorado and is infected with chronic HCV. He is enrolled in Colorado Medicaid.

10. Each of the plaintiffs challenges a policy of the Defendant that denies treatment coverage for chronic Hepatitis C to patients on the ground that their disease has not yet progressed to the point of demonstrating a specified level of damage to the liver, as measured by tests for liver fibrosis.

IV. THE ESSENTIAL STORY

The Disease

20. Chronic HCV is one of the viruses that can cause Hepatitis. It is a systemic, life-threatening, communicable, blood-borne viral disease which, when left untreated, can cause chronic inflammation throughout the body, liver damage, liver failure, liver cancer, and death. There is no vaccine for it.

21. Hepatitis can be self-limiting or can progress to fibrosis (scarring), cirrhosis (liver impairment due to scarring) or liver cancer. Chronic Hepatitis viruses are the most common cause of Hepatitis in the world, but other infections, toxic substances, and autoimmune diseases can also cause Hepatitis.

22. HCV is mostly transmitted through exposure to infected blood. This may happen through transfusions of HCV-contaminated blood and blood products, transplants of infected organs and tissues, contaminated injections during medical procedures, and through injection drug use. Sexual transmission is also possible, but is much less common, because the disease

must be passed by blood. However, there are patients who get HCV without any known exposure to blood or to drug use.

23. Those individuals most at risk for HCV infection are people who had blood transfusions, blood products, or organ transplants before June 1992, when sensitive tests for HCV were introduced for blood screening. Also at risk are health care workers from needle-sticks involving HCV-positive blood, and infants born to HCV-positive mothers.

24. Infection with HCV is a systemic, inflammatory disease in and of itself, regardless of liver involvement.

25. Actual damage to the liver is an acute and severe result of infection with HCV. The severity of liver damage due to HCV is measured by a scoring system. Liver disease is graded according to the level of liver scarring and assigned a Metavir Fibrosis Score ("MFS"). An MFS of F0 or F1 indicates no or minimal liver scarring; F2 is an intermediate stage of fibrosis or liver scarring; a score of F3 indicates severe fibrosis; F4 indicates cirrhosis.

26. HCV is a chronic inflammatory condition. Lack of liver damage does not suggest that the individual does not have the disease (which can be confirmed by blood tests) or that the individual is not suffering other, extrahepatic symptoms of the disease. All the F score measures is liver damage, which is only one of multiple effects of the disease. *See generally*, Gill, Ghazinian, Manch, Gish, *Hepatitis C Virus as a Systemic Disease: Reaching Beyond the Liver*, Hepatology International, Vol. 9, No. 4 (2015).

27. The Centers for Disease Control and Prevention ("CDC") estimates that nearly 20,000 deaths were associated with HCV in 2014, making it the most deadly infectious disease in the United States.

28. Approximately 70,000 Coloradoans suffer HCV infections. *See* David Olinger, *Ninety Percent of Colorado Residents with Hepatitis C Going Untreated*, DENVER POST (May 18, 2016 8:22 AM).[1]

29. It is estimated that approximately five million individuals in the United States are infected with HCV, accounting for over 1% of the population.

30. HCPF recently reported that 14,400 Colorado Medicaid beneficiaries are infected with the virus. It also recently boasted to the Colorado Legislature that it had saved $49,814,827 through denying requests for authorization for treatment with DAAs by HCV-infected individuals. DEPARTMENT OF HEALTH CARE POLICY AND FINANCING'S LEGISLATIVE REPORT ON THE PHARMACY UTILIZATION PLAN TO THE HOUSE HEALTH, INSURANCE, AND ENVIRONMENT COMMITTEE, December 1, 2015.[2]

31. Even in the initial stages of the disease, individuals infected with HCV can experience serious symptoms, including kidney disease, hypertension, lymphoma, intractable fatigue, joint pain, arthritis, vasculitis, thyroid disease, depression, memory loss, sore muscles, mental changes, heart attacks, diabetes, nerve damage, jaundice, and various cancers.

32. William J. Burman, M.D., the interim CEO of Denver Health and Hospital Authority, recently advised Director Birch that:

> HCV causes a chronic infection in 70–80% of infected persons, leading to severe, irreversible liver damage (advanced fibrosis and cirrhosis) in 20–30% of individuals with persistent infection. Furthermore, HCV infection at all stages of liver fibrosis is associated with adverse health effects. The burden of HCV-related disease is alarming; CDC estimates that HCV kills more people than the 60 other reportable infections combined.

[1] Available at http://www.denverpost.com/2016/05/18/ninety-percent-of-colorado-residents-with-hepatitis-c-going-untreated/

[2] Available at http://www2.cde.state.co.us/artemis/hcpserials/hcp118internet/hcp118201516internet.pdf.

WILLIAM J. BURMAN LETTER TO SUE BIRCH, JUNE 29, 2016. *See* **Exhibit A**. This statement is supported by statistics from the CDC, which indicate that an estimated 2.7–3.9 million people in the United States have chronic Hepatitis C. HEPATITIS C FAQS FOR HEALTH PROFESSIONALS.[3] The CDC further estimates that HCV infection becomes chronic in approximately 75%–85% of cases; that 60%–70% will develop chronic liver disease; that 5%–20% will develop cirrhosis over a period of 20–30 years; and that up to 5% will die as a result of the disease from liver cancer or cirrhosis. *Id.* Not surprisingly, HCV is the leading indicator for liver transplants in the United States. *Id.*

33. Delaying treatment by observation has a variety of adverse effects including increasing the risk of death, causing irreversible liver damage, heightening the risk of cancer and other adverse health outcomes, and needlessly prolonging suffering associated with the disease. It also significantly increases the chance that the individual will require a liver transplant. Conversely, the benefit of treatment at low fibrosis stages is well documented in the medical literature.

The Cure

34. Prior to the introduction of DAA treatment, the standard therapy for HCV consisted of a three-drug treatment regimen consisting of boceprevir, interferon, and ribavirin. At best, this course of treatment cured HCV in only 70% of patients, and it was often accompanied by significant adverse side effects such as bone pain, muscle pain, joint pain, anemia, insomnia, memory loss, anxiety, depression, nausea, liver failure, and death. In addition, this treatment regimen was lengthy, often requiring almost one year to complete.

[3] Available at http://www.cdc.gov/Hepatitis/hcv/hcvfaq.htm.

35. Starting in 2011, FDA has approved a series of DAAs for the treatment of HCV, which, unlike the earlier HCV drugs, are capable of curing the disease within a relatively short course of once-daily pills over the course of 8–12 weeks, with minimal side effects. They include Viekira Pak (ombitasvir, paritaprevlr, ritonavir, dasabuvir); Daklinza (daclatisvlr); Epclusa (sorosbuvir/velpatasivir); Harvoni (sofosbuvir/ledipasvir); Olysio (simeprevir); Solvadi (sofosbuvir); Technivie (ombitasvir, paritaprevir, ritonavir); Zepatier (elbasvir/grazoprevir). These medications have been shown to result in a *de facto* cure for more than 90% of patients, when treated according to the recommended protocol. For example, Harvoni, approved by the FDA on October 10, 2014, has a success rate approaching 100%, and is accompanied by few, if any, side effects. All of these drugs were designated as "breakthrough therapies" by the FDA, an official classification that is reserved for drugs that have proven to provide substantial improvement over available therapies for patients with serious or life-threatening diseases.

36. There are no disease severity limits in the FDA approved label on whom should be treated with DAAs. The FDA has thusly approved their use on HCV infected patients regardless of fibrosis score.

37. The efficacy, safety and FDA approval of DAAs are supported by multiple, well-designed controlled studies or well-designed experimental studies.

38. There is no alternative treatment, or sequence of treatments, for HCV that are at least as likely to produce equivalent therapeutic results.

39. According to evidence-based, expert-developed guidelines published by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America ("AASLD/IDSA Guidelines"), DAAs are "recommended for *all* patients with chronic

HCV infection," with the narrow exception of patients "with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy." AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES & INFECTIOUS DISEASES SOCIETY OF AMERICA, HCV GUIDANCE: RECOMMENDATIONS FOR TESTING, MANAGING, AND TREATING HEPATITIS C.[4] (emphasis added).

40. DAAs are the only medication or medical intervention for HCV that produce a Sustained Virological Response ("SVR") in more than 90% of patients. SVR status means that the virus is virtually undetectable in a patient, and is considered to be a *de facto* cure of the infection. The prior treatment with boceprevir, interferon, and ribavirin produced SVR in only approximately 70% of patients, and resulted in a host of adverse side effects.

41. The AASLD/IDSA GUIDELINES specifically urge early treatment of HCV (as in patients with fibrosis scores of F0 and F1), explicitly repudiating the idea that DAA drugs should be prescribed only for patients with significant liver damage, and instead urging that virtually all individuals infected by HCV receive DAA treatments regardless of their fibrosis score.

42. The AASLD/IDSA GUIDELINES represent the professionally-accepted clinical standard of care for treatment of HCV in the United States and in Colorado.

43. In addition to the benefits of SVR to the patient herself, individuals who achieve SVR are no longer able to transmit the virus to others, thereby compounding the benefits of treatment across the population.

44. Treatment of HCV with DAAs is cost-effective. Although "expensive," DAAs cost the same or less as the combination treatment for HCV given prior to the advent of the

[4] Available at http://www.hcvguidelines.org/

DAAs, and are cost-effective to the health care system in the long term, when the costs of treating advanced liver disease, cancer and associated manifestations of HCV are accounted for. The treatment is specifically cost-effective when provided to patients with lower fibrosis scores, because it provides a cure before the virus causes more serious adverse health outcomes.

45. As a result of the consensus over treatment of HCV infected individuals with DAAs, the Centers for Medicare and Medicaid Services ("CMS") (the federal agency responsible for administering Medicaid) issued Guidance on November 5, 2015, advising state Medicaid agencies that the new DAAs should be included in coverage of outpatient prescription drugs. CENTERS FOR MEDICARE AND MEDICAID SERVICES, ASSURING MEDICAID BENEFICIARIES ACCESS TO HEPATITIS C (HCV) DRUGS (Release No. 172), Nov. 5, 2015. *See* **Exhibit B.**

46. In issuing this Guidance, CMS was clear that its animating purpose was its concern "that some states are restricting access to DAA HCV drugs contrary to the statutory requirements in section 1927 of the Act by imposing conditions for coverage that may unreasonably restrict access to these drugs." *Id*.

47. Further, CMS warned the States that any restrictions on access to DAAs "should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments using DAA drugs for beneficiaries with chronic HCV infections." *Id*.

48. More than ten months after receiving this Notice from CMS, Colorado Medicaid continued to ignore CMS's guidance, as alleged below. It continued to ignore CMS's guidance even when it changed its policy on September 1, 2016, and rather than eliminate an MFS criteria completely, took the quarter step of only reducing the fibrosis score minimum for coverage from

F3 to F2 and eliminating fibrosis score as a criterion for women planning to become pregnant in the following year.

49. Without treatment coverage, Medicaid enrollees infected with chronic HCV will never rid themselves of the inflammatory disease, placing these Medicaid enrollees at significantly higher risk for symptoms not involving the liver. This is because, while the DAAs rid the body of HCV, they do not always reverse the effects of the virus that have already been caused, in the liver or elsewhere. Thus, delay in the provision of DAAs to infected persons until their liver deteriorates can cause irreversible non-hepatic damage and damage to their livers that may likely prove irreversible even with the delayed administration of a DAA. Moreover, the disease does not progress linearly, and someone could move from F0 to F3 in a short period of time and long before they are tested again.

50. Thus, it is simply not true that delays in treatment coverage for patients with low fibrosis score is a harmless policy decision. In addition to losing the connection to care during treatment for some patients, there is also the possibility that some patients who are turned away for treatment coverage may miss their opportunity to treat the disease altogether. For example, in an opinion finding that Washington's nearly identical Medicaid policy was illegal, the United States District Court for the Western District of Washington found as follows:

> An experience endured by a Medicaid enrollee provides a clear example of the substantial risk of deteriorating health and death presented by the Policy. L.B., a Washington Medicaid enrollee, was prescribed Solvaldi, a DAA, in July 2014. His request was denied. The [Agency]'s letter on August 21, 2014 states that because L.B. did not have a fibrosis score of "F3 or greater," the treatment was not 'medically necessary.' Soon after, in October 2014, Harvoni was approved by the FDA and L.B.'s provider submitted his prescription to WHCA. His provider noted that his 'cirrhosis and renal function [were] worsening. [He n]eeds HCV treatment ASAP' and that '[w]ithout it, [he will] likely die.' (*Id.*) Again, his request was denied. While he awaited a hearing on his Medicaid administrative appeal, 'his kidneys deteriorated so significantly that his

> provider could no longer recommend Harvoni.' **In other words, the window of L.B.'s ability to seek a cure for his HCV has likely closed**. This is not speculative harm. It is concrete evidence that under the Policy, an enrollee suffered such severe liver damage that DAA treatment may no longer be an available option.

B.E. v. Teeter, No. C16-227-JCC, 2016 WL 3033500, at *5 (W.D. Wash. May 27, 2016) (citations omitted) (emphasis added). The Court's example underscores the fact that HCV has systemic effects that should be treated at the earliest possible opportunity – in L.B.'s case, a worsening kidney condition ultimately doomed his candidacy for DAA treatment that would have been appropriate earlier.

51. Moreover, researchers have determined that common methods of determining fibrosis score do not always produce accurate results, leading to delays in treatment even among individuals with already significantly damaged livers.

52. Not surprisingly, the huge populations of patients covered by the Veteran's Administration, Medicare, and many commercial insurers are universally approved for HCV treatment with the new treatment regimens. Medicaid enrollees in Colorado are therefore being unduly subjected to a second-class standard of health insurance coverage for the sole reason that they are poor.

The Obligation to Cover the Cure

53. Medicaid is a financial, needs-based medical assistance program cooperatively funded by the federal and state governments, and administered by the states. The Medicaid Program was established under Title XIX of the Social Security Act of 1965 (42 U.S.C. Ch. 7, Subch. XIX) for the express purpose of enabling each State to furnish medical assistance to people "whose income and resources are insufficient to meet the costs of **necessary medical services**." 42 U.S.C. § 1396-1 (emphasis added). *See also*, 42 C.F.R. § 430.0; Colo. Rev. Stat.

Ann. § 25.5-4-104 ("The state department, by rules, shall establish a program of medical assistance **to provide necessary medical care** for the categorically needy.")

54. On the federal level, the Medicaid program is administered by CMS. On the state level, Medicaid in Colorado is administered by HCPF.

55. Although state participation is voluntary, once a state opts into the Medicaid program, it must administer the program in accordance with Federal law. All states have opted in, including Colorado. Colorado has also opted into the expansion of Medicaid under the Affordable Care Act, which is embodied in the PATIENT PROTECTION AND AFFORDABLE CARE ACT, Pub. L. No. 111-148, 124 Stat. 119 (2010) and the HEALTH CARE AND EDUCATION RECONCILIATION ACT OF 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

56. In order to participate in Medicaid, a state must submit a plan to the Federal government for approval. Colorado participates in Medicaid and has an approved state plan. The State Plan for Colorado is publicly available at https://www.colorado.gov/pacific/hcpf/colorado-medicaid-state-plan. ("COLORADO STATE PLAN").

57. A state Medicaid plan must provide coverage for treatment that is deemed "medically necessary" in order to comport with the objectives of the Social Security Act. *Beal v. Doe*, 432 U.S. 438, 444–45 (1977); *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989). Thus, under federal law, participating states such as Colorado have a general obligation to fund covered services and treatments that are medically necessary. *B.E. v. Teeter*, No. C16-227-JCC, 2016 WL 3033500, at *2 (W.D. Wash. May 27, 2016) ("Under § 1396a(a)(10)(A), the Medicaid Act 'prohibits states from denying coverage of 'medically necessary' services that fall under a category covered in their Medicaid plans.'") (indirectly quoting *Beal*, 432 U.S. at 444). *See also*

42 C.F.R. § 440.230(b) ("Each [Medicaid] service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.")

58. A state plan must provide "for making medical assistance available" to a wide variety of people know as "Categorically Needy" under 42 U.S.C. §1396d. 42 U.S.C.A. § 1396a(a)(10).

59. "Medical Assistance" means "payment of part or all of the cost of" identified goods and services to various defined groups of people "whose income and resources are insufficient to meet all of such cost." 42 U.S.C. 1396d(a). Those services include prescription drugs if the state has opted to provide them. 42 U.S.C. 1396d(a)(12).

60. Colorado has opted to provide prescriptions drugs. Colo. Rev. Stat. § 25.5-5-202(1)(a); C.R.S § 25.5-5-500, *et seq.*; COLORADO DEPARTMENT OF HEALTH CARE POLICY AND FINANCING, PREFERRED DRUG LIST ("Preferred Drug List").[5] It is thus required to make them available in accordance with federal law to eligible individuals.

61. State Medicaid plans that opt into the prescription drug benefit, including Colorado's, are generally required to provide coverage for any outpatient drug for its indicated use once the drug manufacturer enters into a rebate agreement and the medicine is approved by the FDA and prescribed by a provider. 42 U.S.C. §§ (a)(1), 1396r-8(d)(B), 1396r-8(k)(2)(A), 1396r-8 (k)(6); *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003). Covered prescription drugs, including DAAs, must be provided when medically necessary to treat an extant illness or condition. 42 U.S.C. §§ 1396a(a)(10)(A); 1396d(a)(12); 1396r-8; 42 C.F.R. 440.230(b); *Teeter*, 2016 WL 3033500, at *2. *See also* Colo. Rev. Stat. §§ 25.5-4-102

[5] Available at https://www.colorado.gov/pacific/sites/default/files/PDL%20effective%20January%201%202015.pdf

(legislative declaration); 25.5-5-202(1)(a) (prescription drugs); 25.5-5-202(3) (amount, duration and scope); 10 Colo. Code Regs. § 2505-10:8.800.

62. Colorado regulations define the term "medical necessity" as encompassing a program, good or service that "will, or is reasonably expected to prevent, diagnose, cure, correct, reduce, or ameliorate the pain and suffering, or the physical, mental, cognitive, or developmental effects of an illness, injury, or disability," or is included in "a course of treatment that includes mere observation or no treatment at all." 10 COLO. CODE REGS. § 2505-10:8.076(8). *Cf.* 10 COLO. CODE REGS. §§ 2505-10:8.280; 2505-10:8.590. The definition goes on to describe "medical necessity" further to mean:

> (a) Prescribed by a doctor of medicine;
>
> (b) Provided in accordance with generally accepted standards of medical practice in the United States;
>
> (c) Clinically appropriate in terms of type, frequency, extent, site, and duration;
>
> (d) Not primarily for the economic benefit of the provider or for the convenience of the client, caretaker, or provider; and
>
> (e) Administered in a cost effective and most appropriate setting required by the client's condition.

10 COLO. CODE REGS. § 2505-10:8.076(8). *See also, T.L. v. Colorado Dep't of Health Care Policy & Fin.*, 42 P.3d 63, 65 (Colo. App. 2001). For all of the reasons set forth in this Complaint, DAA treatment coverage for Plaintiffs and the class is "medically necessary."

63. Further, under Colorado's Medicaid program, if the treatment is covered and medically necessary, coverage must be provided with "reasonable promptness." 42 U.S.C. § 1396a(a)(8).

64. In addition, medically necessary prescription drug coverage, including access to DAAs, cannot be made available in a "lesser amount, duration or scope" than the coverage made available to any other individuals eligible under the State Medicaid Plan. 42 U.S.C. § 1396a(a)(10)(B); 42 C.F.R. § 440.240. This is known as Medicaid's "comparability" requirement.

65. HCPF's coverage criteria for HCV treatment must comply with all three of these requirements. It complies with none.

The Wrongful Denial of the Cure

66. Starting on June 1, 2014, HCPF adopted and implemented a policy of categorically denying coverage to individuals diagnosed as infected by HCV unless they had an MFS of F3 or F4, or fell into an extraordinarily narrow set of exceptions. This policy was illegal when first enacted, and throughout its implementation.

67. HCPF implemented the policy adopted on June 1, 2014 continuously until September 1, 2016. Its application was illegal throughout this entire time period, because it denied infected individuals coverage of medically necessary treatment with no medical justification.

68. On September 1, 2016, HCPF amended its Preferred Drug List to be effective October 1, 2016, which included modifications to the Prior Authorization Criteria used to determine eligibility for DAA treatment coverage ("Prior Authorization Criteria" or "the Policy"). *See* **Exhibit C** at 22. The Policy lowered the minimum MFS needed to obtain treatment coverage to F2, and eliminated it altogether for women who intend to get pregnant in the next 12

months. This half-measure is a step in the right direction, but is still illegal for the same reasons that the former policy was illegal.

69. There is an extraordinarily limited set of exceptions to these categorical coverage restrictions described above, related to "serious extrahepatic manifestations." "Extrahepatic" refers to effects of the disease beyond the liver, and the exceptions contain a short list of such conditions. *See id*. In practice, these exceptions are rarely utilized.

70. Contrary to the AASLD/IDSA GUIDELINES and the CMS Notice, HCPF's restriction of DAAs, first to those infected individuals with MFSs of F3 or F4, and now to those with MFSs of F2, F3, or F4, illegally restricts the coverage of medically necessary treatment. This restriction forces (and has in the past forced) stricken individuals to wait for treatment coverage until they have suffered measurable, and potentially irreparable and irreversible liver damage; flatly contradicts the AASLD/IDSA Guidelines, which advise that virtually all chronic HCV patients, regardless of their fibrosis score, receive DAA treatment upon diagnosis; violates the standard of medical care universally accepted throughout the United States and Colorado; and flaunts the clear instructions and warnings of CMS. Aside from the Kafkaesque effect of requiring eligible beneficiaries, who could be treated immediately, to wait until they get sicker for treatment coverage, the policy puts the healthy population at risk from the communicability of the disease.

71. Similar restrictions have been successfully challenged in the State of Washington, where a federal district court last year issued a preliminary injunction enjoining the state Medicaid agency from enforcing its policy of denying treatment coverage based on MFS scores, the very type of categorical denial Colorado Medicaid currently enforces, and ordered that DAA coverage be provided to beneficiaries without regard to those scores. *B.E. v. Teeter*, 2016 WL

3033500, at *1 (D.C. Wash. May 27, 2016). Similar litigation is pending in Indiana and Missouri. Medicaid agencies in a number of additional states, including Delaware, Florida, Pennsylvania, Massachusetts, and New York, have recently responded to legal and policy advocacy by rescinding such restrictions. This Court must order Colorado to do the same.

V. WRONGS TO INDIVIDUAL PLAINTIFFS

72. At all pertinent times, Plaintiffs were enrolled in Colorado's Medicaid Program, which is administered by HCPF.

73. Plaintiffs are "qualified individual[s]" as defined in 42 U.S.C. § 1396a(a)(10)(A).

74. Plaintiffs are currently diagnosed with chronic HCV, and have been prescribed treatment with DAAs by their treating medical providers, who are specialists in HCV and liver diseases.

75. Plaintiffs each have an MFS score of below F2, which disqualifies them for DAA treatment coverage under the Policy. Plaintiffs do not qualify for any of the extremely-limited exceptions to HCPF's fibrosis-score-based restriction.

76. Plaintiffs' treating physicians applied for treatment coverage for Plaintiffs with DAAs.

77. These applications were denied because Plaintiffs' MFS score was below F2.

78. Treatment coverage for DAAs is "medically necessary" for Plaintiffs. Those DAAs are likely to cure each Plaintiff completely; there is no equally effective, less costly alternative prescription drug or medical intervention available to them; and HCPF has offered none.

79. Plaintiffs remain ineligible for treatment coverage with DAAs under HCPF's current policy.

Michael Ryan

80. Michael Ryan does not meet the eligibility requirements of the Policy due to his fibrosis score.

81. Mr. Ryan is a patient of Dr. Daniel Freese, a gastroenterologist at UC Health. Dr. Freese determined DAA treatment to be medically necessary to treat chronic HCV and wrote a prescription, in accordance with the standard of care. In order to seek Medicaid coverage for this treatment, Dr. Freese submitted a prior approval request to Medicaid.

82. On December 8, 2016, the Defendant issued a denial for Mr. Ryan's treatment coverage. *See* **Exhibit D.**

83. Dr. Freese sought a formal appeal of this denial by resubmitting the request. On January 24, 2017, this second request was denied with a note stating:

> EPCLUSA PAR FOR MEMBER Y406764 DENIAL UPHELD. NO NEW INFORMATION PRESENTED TO OVERTURN DENIAL. NO EVIDENCE OF MINIMUM METAVIR F2. YOU MAY ASSIST MEMBER WITH FORMAL APPEAL PER INSTRUCTIONS IN DENIAL LETTER. M SUTTON 012417 1742.
> See **Exhibit E.**

84. Mr. Ryan is a member of the putative class who is ineligible for coverage of DAA treatment under the Prior Authorization Criteria and hereby seeks to strike down HCPF's policy and practice with respect to its utilization of fibrosis score to determine Medicaid coverage of DAA treatment.

Sharon Molina

85. Sharon Molina does not meet the eligibility requirements of the Policy due to her fibrosis score.

86. Ms. Molina's physician determined DAA treatment to be medically necessary to treat chronic HCV and wrote a prescription, in accordance with the standard of care.

87. Ms. Molina and her physician applied for coverage of DAA treatment in February 2017, after HCPF amended its Prior Authorization Criteria. On February 13, 2017, HCPF denied Ms. Molina's application on the basis of her fibrosis score. *See* **Exhibit F**.

88. Ms. Molina is a member of the putative class who is ineligible for coverage of DAA treatment under the Prior Authorization Criteria and hereby seeks to strike down HCPF's policy and practice with respect to its utilization of fibrosis score to determine Medicaid coverage of DAA treatment.

Earby Moxon

89. Earby Moxon does not meet the eligibility requirements of the Policy due to his fibrosis score.

90. Mr. Moxon's physician determined DAA treatment to be medically necessary to treat chronic HCV and wrote a prescription, in accordance with the standard of care.

91. Mr. Moxon applied for treatment coverage with DAAs under HCPF's previous Prior Authorization Criteria and was denied on June 11, 2016 because his fibrosis score did not evidence sufficient liver damage under HCPF's fibrosis score restrictions.

92. Mr. Moxon and his physician re-applied for coverage of DAA treatment in October 2016, after HCPF amended its Prior Authorization Criteria. On October 11, 2016, HCPF

again denied Mr. Moxon's application because of an insufficient fibrosis score. *See* **Exhibits G & H**. Mr. Moxon's request for Medicaid coverage of DAA treatment was specifically denied on the basis of his fibrosis score.

93. Mr. Moxon is a member of the putative class who is ineligible for coverage of DAA treatment under the Prior Authorization Criteria and hereby seeks to strike down HCPF's policy and practice with respect to its utilization of fibrosis score to determine Medicaid coverage of DAA treatment.

VI. CLASS ALLEGATIONS

94. **Class Definition**. The class for which Plaintiffs seek certification consists of all individuals:

> (i) who are or will in the future be enrolled in the Colorado Medicaid Program; and
>
> (ii) who have been or will be diagnosed as having a chronic infection of the Hepatitis C Virus; and
>
> (iii) who have been prescribed treatment by an infectious disease specialist, gastroenterologist, or hepatologist or by a primary care provider in consultation with an infectious disease specialist, gastroenterologist, or hepatologist; and
>
> (iv) who would be eligible for coverage of Direct Acting Antiviral medication but for the Policy's fibrosis score threshold.

All class members will benefit by the relief Plaintiffs seek -- elimination of the fibrosis score restriction in the Policy entirely.

95. Plaintiffs seek certification of a class under F.R.C.P. 23(b)(2). The requirements for class certification under Rule 23(b)(2) are the following:

(a) **Numerosity**. The class is so numerous that joinder of all members is impracticable;

(b) **Commonality**. There are questions of law or fact common to the class;

(c) **Typicality**. The claims or defenses of the representative parties are typical of the claims or defenses of the class;

(d) **Adequacy of Representation**. The representative parties will fairly and adequately protect the interests of the class; and

(e) **Action Common to Class**. The party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.

All of these requirements are satisfied here.

96. **Typicality**. Plaintiffs allege that: (i) they are Medicaid eligible under 42 U.S.C. §1396d; (ii) they have been diagnosed as infected with HCV; (iii) their doctors have recommended treatment with DAAs; and (iv) they are, have been, and will in the future be illegally precluded from receiving Medicaid coverage for these drugs by HCPF's requirement of a Metavir Fibrosis Score of at least F2. These are precisely the claims they wish to litigate on behalf of the class.

97. **Commonality**. All legal and factual questions inherent in the ultimate question of whether the restrictions on coverage of DAAs based on MFSs are illegal under the Medicaid Act are common to all or members of the class.

98. **Numerosity**. It has been estimated that approximately 70,000 Coloradoans suffer HCV infections. HCPF itself recently reported that 14,400 Colorado Medicaid beneficiaries are infected with the virus. Normal distribution ranges thus suggest that the class consists of thousands of people, joinder of which is not only impracticable but impossible.

99. **Adequacy of Representation**. Plaintiffs will fairly and adequately protect the interests of the class. Plaintiffs have no interest that is now or may be potentially antagonistic to the interests of the class. They are committed to and passionate about the case, and fully

understand responsibilities as class representatives. Plaintiffs are represented by highly competent attorneys with extensive experience in litigating class action cases in federal court.

100. **Action Common to the Class**: The Policy challenged by Plaintiffs applies class-wide and categorically to each member of the class by restricting access to coverage for DAA treatment as alleged above; and therefore, Defendant has acted or refused to act on grounds that apply generally to the class, such that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.

FIRST CLAIM FOR RELIEF.

(42 U.S.C. § 1983; 42 U.S.C. §1396a(a)(10)(A))
(EXCLUSION OF QUALIFIED INDIVIDUALS FROM COVERED AND NECESSARY MEDICAL ASSISTANCE UNDER THE MEDICAID ACT, IN VIOLATION OF 42 U.S.C. §1396a(a)(10)(A))

101. Plaintiffs incorporate all of the preceding paragraphs herein.

102. HCPF systematically denies coverage of all FDA approved and AASLD/IDSA recommended DAAs to qualified Medicaid beneficiaries infected with HCV by refusing, with *de minimis* exceptions, to approve prescription requests for prior authorization of treatment coverage with DAAs unless the applicant had an MFS score at or above a specified level, and by publishing and implementing a proscription of coverage of such drugs in the Preferred Drug List.

103. The Policy directly and categorically contradicts the prevailing clinical standard of care, and therefore denies Plaintiffs and those like them medically necessary care, as defined under federal and state law.

104. Pursuant to 42 U.S.C. § 1983 and 28 U.S.C. § 2201, Plaintiffs and the class are entitled to a judgment declaring that HCPF has violated Title XIX of the Social Security Act by denying treatment coverage for DAAs to qualified Medicaid beneficiaries chronically infected

with the Hepatitis C Virus based solely on their having a Metavir Score of less than a specified minimum, in violation 42 U.S.C. §1396a(a)(10)(A).

105. Based on the law governing the issuance of injunctions, and also upon 28 U.S.C. § 2202, Plaintiffs and the class are also entitled to a permanent injunction enjoining HCPF from denying treatment coverage for DAAs to qualified Medicaid beneficiaries chronically infected with the Hepatitis C Virus based solely on their having a Metavir Score of less than a specified minimum.

SECOND CLAIM FOR RELIEF

(42 U.S.C. § 1983; 42 U.S.C. § 1396a(a)(10)(B)(i) AND (ii))
(DENIAL OF COMPARABLE TREATMENT ACCESS IN VIOLATION OF 42 U.S.C. §1396a(a)(10)(B)(i) AND (ii) AND 42 C.F.R. § 440.240.)

106. Plaintiffs incorporate all of the preceding paragraphs herein.

107. While denying coverage of DAAs to Medicaid eligible individuals infected with chronic HCV, as alleged above, HCPF has at the same time provided coverage to similarly situated Medicaid enrollees, with no medically justifiable basis for such differential treatment.

108. Pursuant to 42 U.S.C. § 1983 and 28 U.S.C. § 2201, Plaintiffs and the class are entitled to a judgment declaring that HCPF has violated Title XIX of the Social Security Act by discriminating amongst similarly situated Medicaid individuals infected with the Hepatitis C Virus by denying treatment coverage for DAAs to those with Metavir Scores of less than a specified minimum, in violation of the Medicaid Act comparability requirements under 42 U.S.C. §1396a(a)(10)(B)(i) and (ii) and 42 C.F.R. § 440.240.

109. Based on the law governing the issuance of injunctions, and upon 28 U.S.C. § 2202, Plaintiffs and the class are also entitled to a permanent injunction enjoining HCPF from discriminating amongst similarly situated Medicaid individuals infected with the Hepatitis C

Virus by denying treatment coverage for DAAs to those with Metavir Scores of less than a specified minimum, in violation of the Medicaid Act comparability requirements under 42 U.S.C. §1396a(a)(10)(B)(i) and (ii) and 42 C.F.R. § 440.240.

THIRD CLAIM FOR RELIEF

(42 U.S.C. 1983; 42U.S.C. §1396a(a)(8))
(FAILURE TO PROVIDE NECESSARY MEDICAL ASSISTANCE WITH REASONABLE PROMPTNESS IN VIOLATION OF 42U.S.C. §1396a(a)(8))

110. Plaintiffs incorporate all of the preceding paragraphs herein.

111. By denying coverage of DAAs to Medicaid eligible individuals diagnosed as chronically infected with HCV, as alleged above, HCPF delays the coverage of demonstrably sick individuals until their disease has progressed to the point of causing measurable and potentially irreparable and irreversible liver damage.

112. Pursuant to 42 U.S.C. § 1983 and 28 U.S.C. § 2201, Plaintiffs and the class are entitled to a judgment declaring that HCPF has violated the "reasonable promptness" requirement of Title XIX of the Social Security Act by implementing a policy that delays the coverage of qualified Medicaid beneficiaries chronically infected with the Hepatitis C Virus, based solely on their having a Metavir Score of less than a specified minimum, in violation of 42 U.S.C. §1396a(a)(10)(A), and thus delaying coverage to demonstrably sick individuals until their disease has progressed to the point of causing measurable and potentially irreparable and irreversible liver damage.

113. Based on the law governing the issuance of injunctions, and upon 28 U.S.C. § 2202, Plaintiffs and the class are also entitled to a permanent injunction enjoining HCPF from denying treatment coverage for DAAs to qualified Medicaid beneficiaries chronically infected

with the Hepatitis C Virus based solely on their having a Metavir Score of less than a specified minimum.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that the following judgments and orders be entered against Defendant:

A. Certification of this case as a class action consisting of a class defined as all individuals:

(i) who are or will in the future be enrolled in the Colorado Medicaid Program; and

(ii) who have been or will be diagnosed as having a chronic infection of the Hepatitis C Virus; and

(iii) who have been prescribed treatment by an infectious disease specialist, gastroenterologist, or hepatologist or by a primary care provider in consultation with an infectious disease specialist, gastroenterologist, or hepatologist; and

(iv) who would be eligible for coverage of Direct Acting Antiviral medication but for the Policy's fibrosis score threshold.

B. An order designating Sharon Molina, Earby Moxon, and Michael Ryan as class representatives;

C. An Order appointing Mark Silverstein, Sara R. Neel, Paul Karlsgodt, and Kevin Costello as class counsel;

D. A Judgment declaring that the Policy's use of the Metavir Fibrosis Score as a criterion for DAA coverage violates Title XIX of the Social Security Act (also known as the Medicaid Act): (i) by excluding qualified Medicaid recipients from medically necessary treatment coverage as required by 42 U.S.C. §1396a(a)(10)(A); (ii) by discriminating among similarly situated Medicaid recipients on the basis of categorical restrictions that are not based upon prevailing clinical standards, as forbidden by 42 U.S.C. §1396a(a)(10)(B)(i); and (ii) by

denying qualified Medicaid recipients the provision of necessary coverage with "reasonable promptness," as required by 42 U.S.C. § 1396a(a)(8) and 42 C.F.R. § 440.240;

E. A permanent injunction enjoining HCPF from promulgating, instituting, or implementing any policy or protocol that denies coverage of Direct Acting Antiviral medication now or hereafter approved by the U.S. Food and Drug Administration for treatment of the Hepatitis C Virus, recommended for such use by the treatment Guidelines of AASLD/IDSA, and prescribed by an infectious disease specialist, gastroenterologist, or hepatologist (or by a primary care provider in consultation with an infectious disease specialist, gastroenterologist, or hepatologis) to any qualified Medicaid beneficiary diagnosed as chronically infected by the Hepatitis C Virus, because of a Metavir Fibrosis Score of any level;

F. An Order requiring HCPF to provide notice of the Court's judgment to known class members, in a form and by means to be determined by the Court;

H. An Order awarding Plaintiffs a service award for their service as class representatives in an amount to be determined by the Court;

I. An Order awarding Plaintiffs and the class their attorney fees and costs pursuant to 42 U.S.C. § 1988; and

J. Such other relief as the Court may deem appropriate.

Dated: April 13, 2017

/s/ Paul G. Karlsgodt
Paul G. Karlsgodt, #29004

BAKER & HOSTETLER LLP (CO)
1801 California Street, Suite 4400
Denver, CO 80202
Phone: 303.861.0600
Email: pkarlsgodt@bakerlaw.com
dmcmillan@bakerlaw.com
stillotson@bakerlaw.com

In cooperation with the ACLU Foundation of Colorado

/s/ Mark Silverstein
Mark Silverstein, #26979
Sara R. Neel, #36904

ACLU FOUNDATION OF COLORADO
303 E. Seventeenth Ave., Suite 350
Denver, CO 80203
Phone: 720.402.3107
Fax: 303.777.1773
Email: msilverstein@aclu-co.org
sneel@aclu-co.org

Kevin Costello

HARVARD LAW SCHOOL
CENTER FOR HEALTH LAW & POLICY INNOVATION
122 Boylston Street
Jamaica Plain, MA 02130
Phone: 617.390.2578
Email: kcostello@law.harvard.edu

ATTORNEYS FOR PLAINTIFFS

Plaintiffs' Address:

Michael Ryan, Earby Moxon, Sharon Molina
c/o ACLU Foundation of Colorado
303 E. Seventeenth Ave. Suite 350
Denver, CO 80203

DENVER HEALTH
Level One Care for ALL

June 29, 2016

Sue Birch
Executive Director, Colorado Department of Healthcare Policy and Finance
1570 Grant St.
Denver, Colorado 80203

Dear Director ~~Birch~~ Sue:

As the largest provider of health care for low-income individuals in Denver, we are concerned that the current Medicaid restrictions on treatment for Hepatitis C (HCV) infection are leading to worsening morbidity, mortality, and health disparities. We strongly encourage HCPF to make curative therapy more broadly available, in accordance with guidance from the Centers for Medicare and Medicaid Services.

Background

HCV causes a chronic infection in 70-80% of infected persons, leading to severe, irreversible liver damage (advanced fibrosis and cirrhosis) in 20-30% of individuals with persistent infection. Furthermore, HCV infection at all stages of liver fibrosis is associated with adverse health effects. The burden of HCV-related disease is alarming; CDC estimates that **HCV kills more people than the 60 other reportable infections combined**. Fortunately, new medications are now available that reliably cure HCV and are very well-tolerated. Furthermore, treatment can prevent transmission to others. Treatment as prevention is working for HIV disease: widespread use of antiretroviral therapy has decreased the rate of new HIV infections in Denver by more than 60% over the past decade. Despite these benefits to the individual and the community, a recent analysis from the state's all-payer claims database estimated that only 10% of individuals living with chronic HCV in Colorado have been treated.

Current restrictions

Current Colorado Medicaid guidelines require evidence of stage 3 or 4 liver fibrosis. This restriction is problematic for several reasons. First, staging is imprecise. What is assigned F2 on a biopsy may actually be F3 or F4 but the pathology report may inaccurate due to sampling error. Second, the rate of progression to cirrhosis is not always linear. Once a person has F2 fibrosis, progression to cirrhosis may occur quickly. Thus, a person denied treatment for an F2 score one year may present for follow-up a year later and be diagnosed with cirrhosis, which is irreversible and associated with an increased risk of cancer and death, even after HCV infection is cured. Third, access to the accepted staging methods is limited. Liver biopsy is associated with a low but significant risk of serious complications including hemorrhage and therefore no longer the preferred staging modality. Fourth, HCV infection is more difficult to cure when individuals develop cirrhosis. Finally, individuals with all levels of fibrosis have been shown to have significant rates of extrahepatic disease (kidney

Chief Executive Officer
777 Bannock Street Mail Code 0278 Denver, Colorado 80204-4507 Phone 303-602-4918

EXHIBIT A

disease, hypertension, lymphoma, diabetes, intractable fatigue, arthritis, vasculitis, thyroid disease, depression, memory loss).

The second major area of concern regarding current Colorado Medicaid HCV treatment restrictions is the requirement that individuals be free of illicit substances, alcohol and marijuana for six months prior to approval of treatment. This restriction is not evidence-based and restricts access to treatment for many individuals with advanced HCV liver disease. Several studies have demonstrated successful treatment of HCV among drug users. Most of the drugs prohibited by the restrictions (including marijuana) have no effect on liver health. Furthermore, we are not aware of other diseases for which treatment is restricted for Medicaid recipients based on lifestyle choices.

Access to specialty care is often very limited for patients with Medicaid in Colorado. Reports from around the country demonstrate high levels of success with primary care-based treatment of HCV. Thus, eliminating the specialty provider restriction could have tremendous benefit to Colorado Medicaid recipients.

Disparities

HCV disproportionately affects lower income populations. Current Colorado Medicaid treatment restrictions may worsen socio-economic health disparities. **Our experience providing HCV treatment at Denver Health reveals an alarming disparity in access to care**. Patients covered by Medicare and commercial insurance are universally approved for HCV treatment with new treatment regimens. However, the vast majority of our patients enrolled in Colorado Medicaid have been denied access to treatment for the reasons listed above. Even individuals with advanced disease (compensated cirrhosis) who are at the highest risk of severe complications of HCV infection are denied treatment by Medicaid if substance use disorders exist. Finally, limiting approved HCV treatment prescribers to specialists creates unnecessary barriers for Medicaid patients. **For these reasons, morbidity and mortality from HCV-related illness will continue to increase among our state's lowest income residents.**

Real World Experience

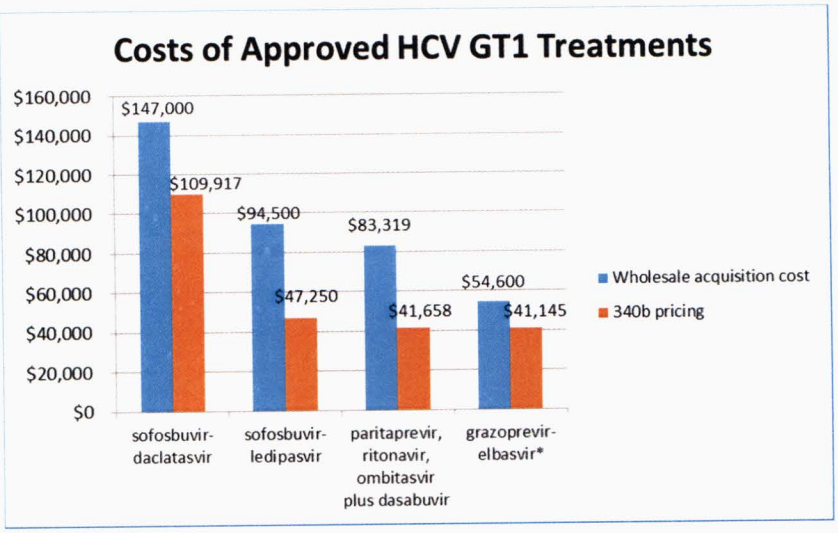
Current HCV treatment regimens are very safe and highly-effective. More than 6,000 patients have participated in phase 3 clinical trials of the recommended regimens. From hcvguidelines.org: "The safety profiles of all the recommended regimens above are excellent. Across numerous phase III programs, less than 1% of patients without cirrhosis discontinued treatment early and adverse events were mild. Discontinuation rates were higher for patients with cirrhosis (approximately 2% for some trials) but still very low."

DENVER HEALTH
Level One Care for ALL

The experience of treating HCV-HIV co-infected patients in the Denver Health Infectious Diseases Clinic and University of Colorado Infectious Diseases Group Practice Clinic illustrates the real-world efficacy of therapy in a high-risk group. In 2015, our clinics treated a total of 93 co-infected patients. **The cure rate for individuals who completed treatment and were assessed for sustained virologic response was 96%.** Only two patients were lost to follow-up while on treatment, one patient's treatment was stopped for an unrelated medical event, and three patients with severe liver disease (two were on the liver transplant list) failed treatment. No patient stopped treatment for a medication-related side effect or adverse event. Twenty patients had evidence of active substance abuse and nearly all were successfully treated through the AIDS Drug Assistance Program (which does not restrict treatment of individuals with addictions or substance use disorders).

Costs

While treatment is relatively expensive, prices are decreasing as new medications are approved (see Figure). Meanwhile, the costs of withholding HCV treatment are growing. In the past decade, hepatocellular carcinoma cases have doubled in Denver and hospitalizations for HCV-related conditions are steadily increasing. Multiple studies have shown that treatment with these new regimens cuts hospitalizations in half and leads to significantly lower follow-up healthcare costs compared to untreated individuals. A study reported this month's issue of Value in Health concluded that "Current Medicaid policies restricting hepatitis C treatment to patients with advanced disease are more costly and less effective than unrestricted, full-access strategies."



Importantly, **the evidence from other states demonstrates that expanding access will not result in dramatically increased treatment costs**. Only a minority of HCV-infected persons will seek care in a given year and they must complete the stages of diagnosis, linkage to care, and initial medical evaluation prior to initiating treatment. MassHealth, Massachusetts' Medicaid program, reported that in the first 18 months after treatment restrictions were eliminated, only 14% of HCV-infected individuals in their administrative database were treated. Similar findings were noted in New York.

Chief Executive Officer
777 Bannock Street Mail Code 0278 Denver, Colorado 80204-4507 Phone 303-602-4918

DENVER HEALTH
Level One Care for ALL

A phased approach to expanding access to treatment can allow broader access to treatment while controlling treatment costs. In California, the Medicaid program has eliminated urine drug and alcohol screens and extended treatment access to individuals with F2 or greater fibrosis, leading to better health care access for California residents, while still maintaining a prioritization process that cushions the Medicaid program from the full impact of HCV costs for the next couple of year as medication prices decrease.

Without a change, HCV treatment policies for Colorado Medicaid may be made in a courtroom, rather than in the exam room. Medicaid treatment restrictions in Washington state resulted in a federal court ruling that all restrictions be eliminated, a more costly outcome than the three changes to treatment restrictions that we recommend above. Similar lawsuits are underway regarding the Indiana Medicaid program and two state prison systems. Colorado should follow the lead of Medicaid programs in Florida, Connecticut, New York and Pennsylvania in increasing access to treatment rather than engage in expensive legal battles.

Proposed Changes

While we believe that all individuals living with chronic HCV need treatment, three revisions to the current CO Medicaid treatment criteria would substantially improve access, while controlling the costs of treatment. **First, we recommend removing drug and alcohol restrictions from the prior approval process so that all individuals with evidence of advanced disease can be treated. Second, we recommend extending treatment access to individuals with any evidence of F2 fibrosis. Third, we recommend that primary care providers be able to prescribe HCV treatment.**

Sincerely,

Bill

William J. Burman, M.D.
Interim CEO, Denver Health and Hospital Authority

Chief Executive Officer
777 Bannock Street Mail Code 0278 Denver, Colorado 80204-4507 Phone 303-602-4918

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and CHIP Services

NOVEMBER 5, 2015

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 172**

For State Technical Contacts

ASSURING MEDICAID BENEFICIARIES ACCESS TO HEPATITIS C (HCV) DRUGS

The Centers for Medicare & Medicaid Services (CMS) remains committed to Medicaid beneficiaries continuing to have access to needed prescribed medications, a commitment we know that states share. The purpose of this letter is to advise states on the coverage of drugs for Medicaid beneficiaries living with hepatitis C virus (HCV) infections. Specifically, this letter addresses utilization of the direct-acting antiviral (DAA) drugs approved by the Food and Drug Administration (FDA) for the treatment of chronic HCV infected patients.

Rules Regarding Medicaid Drug Coverage

Coverage of prescription drugs is an optional benefit in state Medicaid programs, though all fifty (50) states and the District of Columbia currently provide this benefit. States that provide assistance for covered outpatient drugs of manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Social Security Act (the Act) under their Medicaid fee-for-service (FFS) programs or Medicaid managed care plans are required to comply with the requirements of section 1927(d)(1) and (2) of the Act.

Section 1927(d)(1) of the Act provides that a state may subject a covered outpatient drug to prior authorization, or exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication as defined by section 1927(k)(6) of the Act, or the drug is included in the list of drugs or drug classes (or their medical uses), that may be excluded or otherwise restricted under section 1927(d)(2) of the Act.

Section 1927(k)(6) of the Act defines the term “medically accepted indication” as any use of a covered outpatient drug which is approved under the Food Drug And Cosmetic Act (FFDCA), or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i).

EXHIBIT B

When establishing formularies, states must ensure compliance with the requirements in section 1927(d)(4), including the requirements of section 1927(d)(4)(C) of the Act. Under this provision, a covered outpatient drug may only be excluded with respect to the treatment of a specific disease or condition for an identified population if, based on the drug's labeling, or in the case of a drug the prescribed use of which is not approved under the FFDCA, but is a medically accepted indication based on information from the appropriate compendia described in section 1927(k)(6), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

Accordingly, to the extent that states provide coverage of prescription drugs, they are required to provide coverage for those covered outpatient drugs of manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Act, when such drugs are prescribed for medically accepted indications, including the new DAA HCV drugs.

CMS is aware that, given the costs of these new DAA HCV drugs, states have raised concerns about the budgetary impact to their Medicaid programs and beneficiary access to needed care. The agency shares these concerns. However, the recent launch of multiple DAA HCV drugs in the marketplace is creating competition in this class that may result in downward pressure on the prices of these drugs. This competition may enhance the ability of states to negotiate supplemental rebates or other pricing arrangements with manufacturers to obtain more competitive prices for both their FFS and managed care programs, thereby reducing costs. CMS encourages states to take advantage of such opportunities.

To that end, manufacturers have a role to play in ensuring access and affordability to these medications. CMS has sent a letter to the manufacturers of these DAA HCV drugs, asking them to provide information regarding any value-based purchasing arrangements they offer for these drugs so that states might be able to participate in such arrangements.

Permissible Limitations to Medicaid Drug Coverage

CMS is concerned that some states are restricting access to DAA HCV drugs contrary to the statutory requirements in section 1927 of the Act by imposing conditions for coverage that may unreasonably restrict access to these drugs. For example, several state Medicaid programs are limiting treatment to those beneficiaries whose extent of liver damage has progressed to metavir fibrosis score F3, while a number of states are requiring metavir fibrosis scores of F4[1].

[1] The metavir scoring system is used to assess inflammation and fibrosis by histopathological evaluation of a liver biopsy of patients with hepatitis C. The stages, indicated by F0 through F4, represent the amount of fibrosis or scarring of the liver. F0 indicates no fibrosis while F4 represents cirrhosis; a chronic degenerative liver disease state in which normal liver cells are damaged and are then replaced by scar tissue. For more information about liver fibrosis please read Ramon Batallar and David A. Brenner, Liver fibrosis Journal of Clinical Investigation. 2005 Feb 1; 115(2): 209–218 by visiting http://www.ncbi.nlm.nih.gov/pmc/articles/PMC546435/

Certain states are also requiring a period of abstinence from drug and alcohol abuse as a condition for payment for DAA HCV drugs. In addition, several states are requiring that prescriptions for DAA HCV drugs must be prescribed by, or in consultation with specific provider types, like gastroenterologists, hepatologists, liver transplant specialists, or infectious disease specialists in order for payments to be provided for the drug.

While states have the discretion to establish certain limitations on the coverage of these drugs, such as preferred drug lists and use of prior authorization processes,[2] such practices must be consistent with requirements of section 1927(d) of the Act to ensure appropriate utilization.

As such, the effect of such limitations should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments using DAA drugs for beneficiaries with chronic HCV infections. States should, therefore, examine their drug benefits to ensure that limitations do not unreasonably restrict coverage of effective treatment using the new DAA HCV drugs.

CMS encourages states to exercise sound clinical judgment and utilize available resources to determine their coverage policies. These resources include pharmacy and therapeutics (P&T) committees, drug utilization review (DUR) boards, and comparative analysis of the costs to treat HCV patients in light of the efficacy of these newer regimens in terms of cure rates, when compared to those of preexistent therapies. Additionally, CMS notes the availability of guidelines for states to refer to regarding testing, managing, and treating HCV put forth by the American Association for the Study of Liver Diseases (AASLD), the Infectious Diseases Society of America (IDSA), and the International Antiviral Society-USA (IAS-USA), which can be found at http://www.hcvguidelines.org/full-report-view. CMS also suggests that states consider implementing programs that provide patients on HCV treatment with supportive care that will enhance their adherence to regimens, thereby increasing the success rates.

Coverage under Medicaid Managed Care Plans

CMS is also concerned that in many states, Medicaid managed care organizations (MCOs) or other managed care arrangements' conditions for payment for DAA HCV drugs appear to be more restrictive than coverage under the states' fee-for-service (FFS) programs. Furthermore, in states with multiple MCOs or arrangements, the conditions for payment for DAA HCV drugs often differ between various plans.

CMS reminds states that the drugs under the approved state plan must be available to individuals enrolled in Medicaid managed care arrangements. As with their FFS program, states are urged to carefully monitor the DAA HCV drug coverage policies of their MCOs to ensure enrollees have appropriate access. States have the option to include these drugs in the managed care contracts and capitation rates or to "carve out" the drugs used in the treatment of chronic HCV

[2] In accordance with section 1927(d)(5) of the Act, a state plan may establish a prior authorization program as a condition of coverage or payment for a covered outpatient drug; however, the program must provide responses by telephone or other telecommunication device within 24 hours of a request for prior authorization, and, except for those drugs restricted or excluded from coverage pursuant to section 1927(d)(2) of the Act, provide for the dispensing of at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation.

infections from managed care contracts and capitation rates and instead provide access to these drugs through FFS or other arrangements.

Consistent with the regulation at 42 CFR §438.210, services covered under Medicaid managed care contracts (with MCOs, prepaid inpatient health plans, and prepaid ambulatory health plans) must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services for beneficiaries under FFS Medicaid. While managed care plans may place appropriate limits on DAA HCV drugs using criteria applied under the state plan, such as medical necessity, the managed care plan may not use a standard for determining medical necessity that is more restrictive than is used in the state plan.

CMS notes that managed care plans are permitted to use other utilization controls provided that the services, as controlled under the health plan's policies, can be reasonably expected to achieve their purpose. However, states should carefully monitor utilization controls and the HCV coverage policies of their managed care plans to ensure that the organizations are providing appropriate access to covered services and benefits consistent with 42 CFR §438.210.

CMS recognizes the challenges of defining policies in the face of new and innovative drug treatments. It will monitor the policies and conditions states impose for the coverage of DAA HCV drugs to ensure compliance with the requirements of the Act and access to effective, clinically appropriate, and medically necessary treatments for beneficiaries. CMS will monitor state compliance with their approved state plans, the statue, and regulations to assure that access to these medications is maintained.

CMS shares with states the common goal of ensuring access to quality care for Medicaid beneficiaries. Given the complexities that have arisen with the introduction of the DAA HCV drugs, CMS will continue to work with State Medicaid agencies to continue providing and improving care to persons infected with chronic HCV infections. If you have any questions, please contact John M. Coster, Ph.D., R.Ph., Director of the Division of Pharmacy, at John.Coster@cms.hhs.gov.

/s/

Alissa Mooney DeBoy
Acting Director
Disabled and Elderly Health Programs Group

COLORADO
Department of Health Care Policy & Financing

Colorado Department of Health Care Policy and Financing
Preferred Drug List (PDL)
Effective October 1, 2016

PA Forms: Available online at https://www.colorado.gov/hcpf/provider-forms

PA Requests: Please note the below changes **effective 10/31/16**: Colorado Pharmacy Call Center Phone Number: 1-800-424-5725
Colorado Pharmacy Call Center Fax Number: 1-800-424-5881

The PDL applies to Medicaid fee-for-service members. It does not apply to members enrolled in Rocky Mountain Health HMO or Denver Health Medicaid Choice.

Brand Name Required = BNR, Prior Authorization = PA

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred products will be approved for one year unless otherwise stated.)
ALZHEIMER'S AGENTS *Effective 4/1/2016*	**No PA Required (*Must meet eligibility criteria)** Donepezil tab Donepezil ODT Galantamine Galantamine ER Memantine	**PA Required** ARICEPT (donepezil) ARICEPT 23mg (donepezil) ARICEPT ODT (donepezil) EXELON (rivastigmine) (cap, soln. and patch) MESTINON (pyridostigmine) (tab, syrup) NAMENDA IR (memantine) NAMENDA XR (memantine) NAMZARIC (memantine/donepezil)	***Eligibility criteria for Preferred Agents –** All preferred products will be approved without PA if the member has a diagnosis of dementia which can be verified by SMART PA. Non-preferred products will be approved if the member has failed treatment with one of the preferred products in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) Members currently stabilized on a non-preferred product can receive approval to continue on that agent for one year if medically necessary and if there is a diagnosis of dementia.

EXHIBIT C

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
		RAZADYNE (galantamine) (tab, oral soln) RAZADYNE ER (galantamine)	
ANTICOAGULANTS- ORAL *Effective 10/1/2016*	**No PA Required (*Must meet eligibility criteria)** Warfarin *XARELTO (rivaroxaban) (2nd line) *PRADAXA (dabigatran) (2nd line)	**PA Required** COUMADIN (warfarin) ELIQUIS (apixaban) SAVAYSA (edoxaban)	**ELIQUIS®** will be approved if: • The member has a diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE) **OR** • The member is need of prophylaxis for DVT following knee or hip replacement surgery **OR** • The member has a diagnosis of non-valvular atrial fibrillation **AND** • The member does not have a mechanical prosthetic heart valve **AND** • The member has failed warfarin or is not a candidate for warfarin as defined as meeting one of the following criteria: o The member has a labile INR for reasons other than noncompliance (e.g, member has an INR outside of 2-3 > 60% of the time for a period of two months) **OR** o The member has significant difficulty with complying with monitoring **OR** o The member is on dialysis (For members on dialysis, treatment failure with Xarelto and Pradaxa NOT required) o The member has an allergy or intolerance to warfarin **AND** • The member has failed a one month trial of Xarelto® OR Pradaxa. (Failure is defined as : lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) ***PRADAXA®** will be approved if: • The member is not on dialysis **AND** • The member has a diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE) **OR** • The member is in need of a prophylaxis of deep vein thrombosis (DVT) and pulmonary embolism (PE) following hip replacement surgery • The member has a diagnosis of non-valvular atrial fibrillation **AND** • The member does not have a mechanical prosthetic heart valve **AND**

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)

			• The member has failed warfarin or is not a candidate for warfarin as defined as meeting one of the following criteria:
			  ○ The member has a labile INR for reasons other than noncompliance (e.g, member has an INR outside of 2-3 > 60% of the time for a period of two months) **OR**
			  ○ The member has significant difficulty with complying with monitoring **OR**
			  ○ The member has an allergy or intolerance to warfarin
			
			SAVAYSA® will be approved if all the following criteria have been met:
			• Member is not on dialysis **AND**
			• Member does not have CrCl > 95 mL/min **AND**
			• The member has a diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE) **OR**
			• The member has a diagnosis of non-valvular atrial fibrillation **AND**
			• The member does not have a mechanical prosthetic heart valve **AND**
			• The member has failed warfarin or is not a candidate for warfarin as defined as meeting one of the following criteria:
			  ○ The member has a labile INR for reasons other than noncompliance (e.g, member has an INR outside of 2-3 > 60% of the time for a period of two months) **OR**
			  ○ The member has significant difficulty with complying with monitoring **OR**
			  ○ The member has an allergy or intolerance to warfarin
			AND
			• The member has failed a one month trial of Xarelto® OR Pradaxa. (Failure is defined as : lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)
			
			***XARELTO®** will be approved if all the following criteria have been met:
			• The member is not on dialysis **AND**
			• The member has a diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE) **OR**
			• The member is in need of a prophylaxis of DVT following knee or hip replacement surgery **OR**

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
			• The member has a diagnosis of non-valvular atrial fibrillation **AND** • The member does not have a mechanical prosthetic heart valve **AND** • The member does not have an active pathological bleed **AND** • The member has failed warfarin or is not a candidate for warfarin as defined as meeting one of the following criteria: o Labile INR for reasons other than noncompliance (e.g, member has an INR outside of 2-3 > 60% of the time for a period of two months) **OR** o The member has significant difficulty with complying with monitoring **OR** o The member has an allergy or intolerance to warfarin **Grandfathering:** Members currently stabilized on a non-preferred agent can receive approval to continue on that agent for one year if medically necessary
ANTI-EMETICS *Effective 1/1/2016*	**No PA Required** Ondansetron tablets Ondansetron ODT tab Ondansetron oral solution (members under 5 years only) DICLEGIS (doxylamine/pyridoxine)	**PA Required** AKYNZEO (netupitant/palensetron) ANZEMET (dolasetron) EMEND (apepritant) KYTRIL (granisetron) SANCUSO (granisetron) VARUBI (rolapitant) ZOFRAN (ondansetron) tabs ZOFRAN (ondansetron) suspension ZOFRAN ODT (ondansetron) ZUPLENZ (ondansetron)	Non-preferred products will be approved for members who have failed treatment with brand or generic ondansetron within the last year. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.) **Ondansetron suspension** will be approved for members < 5 years and those members ≥ 5 years of age with a feeding tube. **Diclegis** will be approved if the member has nausea and vomiting associated with **pregnancy.** **Emend** will be approved upon verification that the member is undergoing moderately emetogenic or highly emetogenic chemotherapy as part of a regimen with a corticosteroid and a 5HT3 antagonist. **Verification may be provided from the prescriber or the pharmacy.** **Emend** will be approved for prophylaxis of postoperative nausea and vomiting (one 40mg capsule will be approved). **Verification may be provided from the prescriber or the pharmacy.**

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
ANTI-DEPRESSANTS **Newer Generation Antidepressants** *Effective 1/1/2016*	**No PA Required** Bupropion IR, SR, XL Citalopram Escitalopram Fluoxetine Mirtazapine Paroxetine Sertraline Venlafaxine IR tabs Venlafaxine XR capsules	**PA Required** APLENZIN ER (bupropion ER) CYMBALTA (duloxetine) CELEXA (citalopram) Desvenlafaxine ER Desvenlafaxine fumarate ER Duloxetine EFFEXOR IR EFFEXOR XR FETZIMA (levomilnacipran) Fluvoxamine (generic Luvox) IRENKA (duloxetine) KHEDEZLA (desvenlafaxine base) LEXAPRO (escitalopram) LUVOX CR (fluvoxamine CR) Nefazodone (generic Serzone)PRISTIQ (desvenlafaxine succinate) PEXEVA (paroxetine) Paroxetine CR	Non-preferred products will be approved for members who have failed treatment with three Preferred Products with exceptions for Cymbalta (see below). (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **Grandfathering:** Members currently stabilized on a Non-preferred newer generation antidepressant can receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.** Cymbalta or duloxetine: Members will NOT need to fail on two preferred products if the diagnosis is Diabetic Peripheral Neuropathic Pain. Cymbalta will also be approved for patients with chronic musculoskeletal pain (e.g. osteoarthritis or chronic lower back pain) who have demonstrated failure on a one month consecutive trial of two analgesic agents (e.g. acetaminophen, NSAID) at maximally tolerated doses.

<table>
<tr><th>Therapeutic Drug Class</th><th>Preferred Agents</th><th>Non-preferred Agents</th><th>Prior Authorization Criteria
(All Non-preferred Products will be approved for one year unless otherwise stated.)</th></tr>
<tr><td></td><td></td><td>PAXIL CR (paroxetine controlled release)

PROZAC Weekly (fluoxetine)

SARAFEM (fluoxetine)

TRINTELLIX (vortioxetine)

VIIBRYD (vilazodone)

WELLBUTRIN IR, SR, XL (bupropion)</td><td></td></tr>
<tr><td>ANTI-HERPETIC AGENTS

Effective 1/1/2016</td><td>No PA Required

Acyclovir tablet, capsule, suspension (generic)</td><td>PA Required

FAMVIR (famciclovir)

Famcyclovir

SITAVIG (acyclovir)

VALTREX (valacyclovir)

Valacyclovir

VALCYTE (valgancyclovir)

Valgancyclovir (oral solution)

ZOVIRAX (acyclovir)</td><td>Non-preferred products will be approved for members who have failed an adequate trial with acyclovir (dose and duration) as deemed by approved compendium (see below) (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)

<table>
<tr><th>Indication</th><th>Adult</th><th>Pediatric</th></tr>
<tr><td>Genital herpes simplex: initial</td><td>400 mg orally 3 times daily for 7 to 10 days or 200 mg orally 5 times daily (guideline dosing) for 10 days.</td><td>12 years or older, 1000 to 1200 mg/day orally in 3 to 5 divided doses for 7 to 10 days.</td></tr>
<tr><td>Genital herpes simplex: episodic</td><td>400 mg orally 3 times daily for 5 days or 800 mg orally twice daily for 5 days or 800 mg orally 3 times daily for 2 days (guideline dosing); or 200 mg orally every 4 hours, 5 times daily for 5 days; initiate at earliest sign or symptom of recurrence.</td><td>12 years or older, 1000 to 1200 mg/day orally in 3 divided doses for 3 to 5 days</td></tr>
<tr><td>Genital herpes simplex: Suppressive</td><td>400 mg orally twice daily for up to 12 months; alternative</td><td>12 years or older, 800 to 1200 mg/day orally in 2 divided doses for up to 12 months</td></tr>
</table></td></tr>
</table>

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)		
			An adequate trial of acyclovir for Genital Herpes Simplex (Suppressive) will be one month.	dosing, 200 mg orally 3 to 5 times daily.	
			Genital Herpes Simplex with HIV infection: Initial or Recurrent	400 mg ORALLY 3 times daily for 5 to 14 days	< 45 kg: 20 mg/kg (MAX, 800 mg) ORALLY 4 times daily for 7 to 10 days or until no new lesions appear for 48 hours. Adolescents: 400 mg ORALLY twice daily for 5 to 14 days.
			Genital Herpes Simplex with HIV infection: Chronic suppression	400 mg orally twice daily	
			Herpes labialis	400 mg orally 3 times daily for 5 to 10 days	
			Herpes zoster, Shingles	800 mg orally every 4 hours 5 times a day for 7 to 10 days	
			Herpes Zoster, Shingles with HIV infection	800 mg orally 5 times daily for 7 to 10 days	
			Varicella	800 mg orally 4 times a day for 5 days	2 years or older: 20 mg/kg ORALLY 4 times a day for 5 days; over 40 kg, 800 mg ORALLY 4 times a day for 5 days
			Varicella with HIV infection	20 mg/kg (MAX, 800 mg) ORALLY 5 times daily for 5 to 7 days	20 mg/kg (MAX, 800 mg) ORALLY 4 times daily for 7 to 10 days or until no new lesions appear for 48 hours.

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
ANTI-HISTAMINES **Newer Generation Antihistamines** *Effective 7/1/2016*	**No PA Required** Cetirizine (generic OTC Zyrtec) 5mg and 10mg tab, chew tab, syrup Loratadine (generic OTC Claritin) 10mg tab and syrup	**PA Required** ALAVERT (loratadine) ALLEGRA (fexofenadine) CLARINEX (desloratadine) CLARITIN (loratadine) Desloratadine Fexofenadine Levocetirizine Loratadine ODT XYZAL (levocetirizine) ZYRTEC (cetirizine)	Non-preferred antihistamines and antihistamine/decongestant combinations will be approved for members who have failed treatment with two preferred products in the last 6 months. For members with respiratory allergies, an additional trial of an intranasal corticosteroid will be required in the last 6 months. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.
Antihistamine/Decongestant Combinations *Effective 7/1/2016*	**No PA Required**	**PA Required** ALLEGRA-D (fexofenadine/PSE) Cetirizine-D CLARINEX-D (desloratadineD) CLARITIN-D (loratadine-D) Loratadine-D SEMPREX-D (acrivastine-D) ZYRTEC-D (cetirizine-D)	
ANTI-HYPERTENSIVES	**No PA Required** BENICAR	**PA Required** ATACAND (candesartan)	Non-preferred ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products will be approved for members who have failed treatment with three preferred products in the last 12 months

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
Angiotensin Receptor Blockers (ARBs) *Effective 7/1/2016*	(olmesartan) Valsartan Irbesartan Losartan	AVAPRO (irbesartan) Candesartan COZAAR (losartan) DIOVAN (valsartan) EDARBI (azilsartan) Eprosartan MICARDIS (telmisartan) Telmisartan TEVETEN (eprosartan)	(Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction). Renin inhibitors and combinations will not approved in patients with diabetes. Renin inhibitors are contraindicated when used in combination with an ACE-inhibitor, ACE-inhibitor combination, ARB, or ARB-combination.
ARB Combinations *Effective 7/1/2016*	**No PA Required** BENICAR HCT *BNR* (olmesartan/HCTZ) DIOVAN HCT *BNR* (valsartan/HCTZ) Losartan/HCTZ	**PA Required** Amlodipine/valsartan Amlodipine/valsartan/hctz ATACAND HCT (candesartan/HCTZ) Candesartan/HCTZ AVALIDE (irbesartan/HCTZ) AZOR (amlodipine/olmesartan) EDARBYCLOR (azilsartan/chlorthalidone) Eprosartan/HCTZ	

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
		EXFORGE (amlodipine/valsartan) EXFORGE HCT (amlodipine/valsartan/hctz) HYZAAR HCT (losartan/hctz) Irbesartan/HCTZ MICARDIS-HCT (telmisartan/HCTZ) Telmisartan/HCTZ Telmisartan/amlodipine TEVETEN HCT (eprosartan/HCTZ) TRIBENZOR (olmesartan/amlodipine/hctz) TWYNSTA (telmisartan/amlodipine) Valsartan/HCTZ	
Renin Inhibitors & Renin Inhibitor Combinations *Effective 7/1/2016*	**No PA Required**	**PA Required** TEKTURNA (aliskiren) TEKTURNA HCT (aliskiren/HCTZ)	
ANTI-PLATELETS *Effective 1/1/2016*	**No PA Required** AGGRENOX (ASA/dipyridamole) ASA/dipyridamole Clopidogrel	**PA Required** EFFIENT (prasugrel) PLAVIX (clopidogrel) TICLID (ticlopidine)	**EFFIENT®** will be approved for patients that have a contraindication or intolerable side effects to Brilinta. • EFFIENT should only be considered for patients < 75 years of age and patients weighing ≥ 60 kg without a known diagnosis of TIA or ischemic stroke. • **Grandfathering**: Members currently stable on Effient will be granted prior authorization approval.

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
	BRILINTA (tigacrelor)	Ticlopidine ZONTIVITY (vorapaxar)	Patients taking BRILINTA must also be taking a maintenance dose of aspirin not exceeding 100 mg/day. Ticlopidine should only be considered for patients who can be monitored for neutropenia and thrombocytopenia during the first four months of therapy. ZONTIVITY will be approved for patients with a diagnosis of myocardial infarction or peripheral artery disease without a history of stroke, transient ischemic attack, intracranial bleeding, or active pathological bleeding. Patients must also be taking aspirin and/or clopidogrel concomitantly.
ATYPICAL ANTI-PSYCHOTICS (oral) *Effective 4/1/2016*	**No PA Required**** ABILIFY *BNR* (aripiprazole) tab Aripiprazole oral solution ABILIFY ODT *BNR* (aripiprazole) Clozapine CLOZARIL (clozapine) GEODON (ziprasidone) LATUDA (lurasidone) Olanzapine Quetiapine* Risperidone Risperidone ODT	**PA Required** Aripiprazole FANAPT (iloperidone) FAZACLO (clozapine ODT) INVEGA (paliperidone) Olanzapine ODT NUPLAZID (pimavanserin) REXULTI (brexpiprazole) RISPERDAL oral soln (risperidone) SAPHRIS (asenapine) SEROQUEL XR (quetiapine) SYMBYAX (olanzapine/fluoxetine) VERSACLOZ susp (clozapine) VRAYLAR (cariprazine)	**IR quetiapine when given at sub therapeutic doses may be restricted for therapy. Low-dose quetiapine (<150mg/day) is only FDA approved as part of a drug titration schedule to aid patients in getting to the target quetiapine dose. PA will be required for quetiapine < 150mg per day except for utilization (when appropriate) in members 65 years or older.* Non-preferred products will only be approved for their FDA approved indications and age limits and only if the member has failed on three preferred products in the last 5 years. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions). See Table 1. **Age Limits: All products including preferred products will require a PA for members younger than the FDA approved age for the agent. Members younger than the FDA approved age for the agent who are currently stabilized on an atypical antipsychotic will be eligible for grandfathering. See Table 3. **New Atypical Antipsychotic prescriptions for members under 5 years of age will be reviewed on an individual basis by a clinical health care professional at the Department. PA approval will be based upon medical necessity, evidence to support therapy, proposed monitoring and additional risk/benefit information supplied by the prescriber. Members under 5 years will be reviewed annually for appropriateness of therapy and proper monitoring.**

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
	RISPERDAL (risperidone) RISPERDAL M-tab (risperidone ODT) SEROQUEL IR* (quetiapine) Ziprasidone ZYPREXA (olanzapine)	ZYPREXA ZYDIS (olanzapine ODT) *** for injectable Atypical Antipsychotics please see Appendix P for criteria**	**Grandfathering**: Members currently stabilized on a non-preferred atypical antipsychotic can receive approval to continue on that agent for two years even if the member does not meet the age, dosing or FDA approved indication requirements. **Verification may be provided from the prescriber or the pharmacy.** Quantity Limits: All products including preferred products will have quantity limits. In order to receive approval for off-label dosing, the member must have an FDA approved indication and must have tried and failed on the FDA approved dosing regimen. See Table 2. Fazaclo will be approved for the treatment of schizophrenia if the member is 18 years of age or older and has tried and failed treatment with three preferred products (one of which must be generic clozapine) in the last 5 years. Invega will be approved for the treatment of schizophrenia or schizoaffective disorder if the member is 18 years of age or older (12 years or older for schizophrenia) and has tried and failed treatment with / has had adherence issues with three preferred products in the last 5 years. A maximum of one tablet per day will be approved. Seroquel XR will be approved if the member is 18 years of age or older, has tried and failed treatment with three preferred products in the last five years and is being treated for one of the FDA approved indications. See Table 1. If a member has been stabilized on quetiapine for at least 30 days with a positive response but is unable to tolerate the side effects, Seroquel XR may be approved without failure of two additional agents. Zyprexa Zydis will be approved for the treatment of schizophrenia or bipolar 1 disorder if the member is 13 years of age or older and has tried and failed treatment with three preferred products (one of which must be an olanzapine tablet) in the last 5 years.

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)

For members that are stabilized on Zyprexa tablets with a documented need for occasional supplementation to treat acute symptoms, up to 5 tablets per month will be allowed without three product failures.

Table 1: Approved Indications

Drug	Indication
Fanapt®	• Acute treatment of schizophrenia in adults
Fazaclo®	• Treatment-resistant schizophrenia • Reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder
Invega®	• Schizophrenia • Schizoaffective disorder
Saphris®	• Acute and maintenance of schizophrenia • Bipolar mania, monotherapy • Maintenance treatment of bipolar I disorder as an adjunct to lithium or divalproex
Seroquel XR®	• Treatment of schizophrenia • Acute treatment of manic or mixed episodes associated with bipolar I disorder, as monotherapy or as an adjunct to lithium or divalproex • Maintenance treatment of bipolar I disorder as an adjunct to lithium or divalproex • Adjunctive treatment of major depressive disorder (MDD)
Vraylar	• Schizophrenia • Bipolar (acute treatment)

Table 2: Quantity Limits

Brand Name	Generic Name	Quantity Limits
Abilify	Aripiprazole	Maximum one tablet per day
	Clozapine	Maximum dosage of 900mg per day
Fazaclo	Clozapine	Maximum dosage of 900mg per day
Fanapt	Iloperidone	Maximum two tablets per day
Invega	Paliperidone	Maximum one tablet per day

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)

Latuda	Lurasidone	Maximum one tablet per day
	Olanzapine	Maximum one tablet per day (see Zyprexa Zydis criteria for Zydis information)
	Quetiapine	Maximum three tablets per day
	Risperidone	Maximum two tablets per day except 4mg tablets will be approved for up to 4 tablets per day
Saphris	Asenapine	Maximum two tablets per day
Seroquel XR	Quetiapine XR	Maximum one tablet per day (for 300mg & 400mg tablets max 2 tablets per day)
	Ziprasidone	Maximum two tablets per day
Vraylar	Cariprazine	Maximum one tablet per day

Table 3: FDA Approved Dosing by Age

Drug	FDA Approved Indication	FDA Approved Age	Max FDA App'd Dose
Asenapine (Saphris®)	APPROVED FOR ADULTS ONLY		
Aripiprazole (Abilify®)	Autism/Psychomotor Agitation Bipolar Disorder/Mixed Mania Schizophrenia Gilles de la Tourette's syndrome	6-17 years 10-17 years 13-17 years 6-17 years	15mg/day 30mgday 30mg/day 20mg/day
Clozapine (Fazaclo®, Clozaril®)	APPROVED FOR ADULTS ONLY		
Iloperidone (Fanapt®)			
Lurasidone (Latuda®)			
Olanzapine (Zyprexa®)	Schizophrenia	13-17 years 13-17 years	10mg/day 10mg/day

<table>
<tr><th>Therapeutic Drug Class</th><th>Preferred Agents</th><th>Non-preferred Agents</th><th>Prior Authorization Criteria
(All Non-preferred Products will be approved for one year unless otherwise stated.)</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Olanzapine (Zyprexa Zydis®)</td><td>Bipolar Disorder/Mixed Mania</td><td></td><td></td></tr>
<tr><td>Paliperidone (Invega ER®)</td><td>Schizophrenia</td><td>12-17 years</td><td>12mg/day</td></tr>
<tr><td>Risperidone (Risperdal®)</td><td>Autism/Psychomotor Agitation
Bipolar Disorder/Mixed Mania
Schizophrenia</td><td>5-16 years
10-17 years
13-17 years</td><td>3mg/day
6mg/day
6mg/day</td></tr>
<tr><td>Quetiapine Fumarate (Seroquel®)</td><td>Schizophrenia
Bipolar Disorder/Mixed Mania</td><td>13-17 years
10-17 years</td><td>800 mg/day
800 mg/day</td></tr>
<tr><td>Quetiapine Fumarate (Seroquel XR®)</td><td colspan="3">APPROVED FOR ADULTS ONLY</td></tr>
<tr><td>Ziprasidone (Geodon®)</td><td colspan="3">APPROVED FOR ADULTS ONLY</td></tr>
</table>
</td></tr>
<tr><td>BISPHOSPHONATES (oral)
Effective 10/1/2016</td><td>No PA Required

Alendronate (generic)
5mg,
10mg,
35mg,
70mg tablets</td><td>PA Required

ACTONEL (risedronate)

ACTONEL w/Calcium (risedronate w/calcium)

ATELVIA (risedronate)

BINOSTO (alendronate)

BONIVA (ibandronate)

DIDRONEL (etidronate)

FOSAMAX (alendronate)

alendronate oral solution</td><td>Non-preferred products will be approved for members who have failed treatment with at least one strength of alendronate. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)

PA will be approved for etidronate in members with heterotopic ossification without treatment failure.

For members who have a low risk of fracture, prior authorization will be required for members exceeding 5 years of either a preferred or non-preferred bisphosphonate. Low risk will be defined as having an osteopenic bone mineral density (most recent T-score between -1 and -2.5) AND no history of vertebral fracture.</td></tr>
</table>

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
		FOSAMAX plus D (alendronate w/D) Etidronate	
DIABETES MANAGEMENT CLASSES **Amylin** *Effective 10/1/2016*	**No PA Required (*Must meet eligibility criteria)**	**PA Required** SYMLIN (pramlintide)	Symlin® will only be approved after a member has failed a three month trial of metformin and a DPP4-inhibitor or a GLP-1 analogue. Failure is defined as: lack of efficacy (e.g., hemoglobin A1C $\geq$ 7%) OR the member cannot tolerate metformin, DPP4-inhibitor and GLP-1 analogue due to allergy, intolerable side effects, or a significant drug-drug interaction. **For all products**, dosing will be limited to FDA approved dosing. PA will be required for doses in excess of FDA approved dosing. PA will be approved for Symlin products for members with Diabetes Mellitus Type 1 without failed treatment
Biguanides *Effective 10/1/2016*	**No PA Required** Metformin 500mg, 850mg, 1000mg tablets Metformin ER 500mg tablets (generic Glucophage XR)	**PA Required** FORTAMET (metformin) GLUCOPHAGE (brand) (metformin) GLUCOPHAGE XR (brand) (metformin XR) GLUMETZA ER (metformin) Metformin ER 750mg Metformin ER 500 and 1000mg (generic Fortamet, generic Glumetza) RIOMET 500mg/5ml (metformin)	Non-preferred products will be approved for members who have failed treatment with two Preferred Products. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.) Liquid metformin will be approved for members who meet one of the following: • under the age of 12 • with a feeding tube who have difficulty swallowing
DPP-4 Inhibitors *Effective 10/1/2016*	**No PA Required (*Must meet eligibility criteria)**	**PA Required** Alogliptin JANUVIA (sitagliptin)	*Approval for preferred products require a three month trial of (or documented contraindication to) metformin therapy prior to initiation of therapy.

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
	*TRADJENTA (linagliptin)	NESINA (alogliptin) ONGLYZA (saxagliptin)	**For all products**, dosing will be limited to FDA approved dosing. PA will be required for doses in excess of FDA approved dosing. Non preferred DPP-4 inhibitors will be approved after a member has failed a three month trial of metformin and Tradjenta®. Failure is defined as lack of efficacy (e.g., hemoglobin A1C ≥ 7%), OR the member cannot tolerate Tradjenta and metformin due to allergy, intolerable side effects, or a significant drug-drug interaction.
GLP-1 Analogues *Effective 10/1/2016*	**No PA Required (*Must meet eligibility criteria)** *BYETTA (exenatide) *VICTOZA (liraglutide) (second line)	**PA Required** BYDUREON (exenatide) TANZEUM (albiglutide) TRULICITY (dalaglutide)	*Approval for preferred products require a three month trial of (or documented contraindication to) metformin therapy prior to initiation of therapy. **For all products**, dosing will be limited to FDA approved dosing. PA will be required for doses in excess of FDA approved dosing. Non preferred GLP-1 agonists will be approved after a member has failed a three month trial of metformin and Byetta® and Victoza®. Failure is defined as lack of efficacy (e.g., hemoglobin A1C ≥ 7%) OR the member cannot tolerate Byetta® or Victoza® and metformin due to allergy, intolerable side effects, or a significant drug-drug interaction.
Hypoglycemic Combinations *Effective 10/1/2016*	**No PA Required**	**PA Required** Alogliptin/metformin Alogliptin/pioglitazone ACTOPLUS MET (pioglitazone/metformin) ACTOPLUS MET XR (pioglitazone/metformin) Pioglitazone/metformin AVANDAMET (rosiglitazone/metformin)	Non-preferred products will be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
		AVANDARYL (rosiglitazone/glimepiride) DUETACT (pioglitazone/glimepiride) Pioglitazone/glimepiride Glipizide/metformin GLUCOVANCE (glyburide/metformin) Glyburide/metformin GLYXAMBI (empagliflozin/linagliptin) INVOKAMET (canagliflozin/metformin) JANUMET (sitagliptin/metformin) JANUMET XR (sitagliptin/metformin) JENTADUETO (linagliptin/metformin) JENTADUETO XR (linagliptin/metformin) KAZANO (alogliptin/metformin) KOMBIGLYZE (saxaglipin/metformin) METAGLIP (glipizide/metformin) OSENI (alogliptin/pioglitazone)	

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
		PRANDIMET (repaglinide/metformin) Repaglinide/metformin SYNJARDY (empagliflozin/metformin) XIGDUO XR (dapagliflozen/metformin)	
Meglitinides *Effective 10/1/2016*	**No PA Required**	**PA Required** Nateglinide PRANDIN (repaglinide) Repaglinide STARLIX (nateglinide)	Non-preferred products will be approved for members who have failed treatment with one Sulfonylurea (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)
SGLT-2 Inhibitors *Effective 10/1/2016*	**No PA Required** INVOKANA (canaglifozin)	**PA Required** FARXIGA (dapagliflozin) JARDIANCE (empagliflozin)	Non-preferred SGLT-2 inhibitors will only be approved after a member has had a three month trial of metformin and failed a three month trial of Invokana®. Failure is defined as: lack of efficacy (e.g., hemoglobin A1C $\geq$ 7%) OR the member cannot tolerate metformin and Invokana due to allergy, intolerable side effects, or a significant drug-drug interaction. **For all products**, dosing will be limited to FDA approved dosing. PA will be required for doses in excess of FDA approved dosing.
Thiazolidinediones *Effective 10/1/2016*	**No PA Required** Pioglitazone	**PA Required** ACTOS (pioglitazone) AVANDIA (rosiglitazone)	Non preferred DPP-4 inhibitors will be approved after a member has failed a three month trial of metformin and failed a three month trial of pioglitazone. Failure is defined as lack of efficacy (e.g., hemoglobin A1C $\geq$ 7%), OR the member cannot tolerate pioglitazone and metformin due to allergy, intolerable side effects, or a significant drug-drug interaction.
ERYTHROPOIESIS STIMULATING AGENTS *Effective 10/1/2016*	***Must meet eligibility criteria**	**PA Required**	***Eligibility Criteria for all agents in the class** Members must meet all criteria in one of the following four areas:

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
	EPOGEN (epoetin alfa)*	ARANESP (darbepoetin alfa) MIRCERA (methoxy peg-epoetin beta) PROCRIT (epoetin alfa)	• A diagnosis of cancer, currently receiving chemotherapy, with chemotherapy-induced anemia, and hemoglobin of 10g/dL or lower. • A diagnosis of chronic renal failure, and hemoglobin below 10g/dL • A diagnosis of hepatitis C, currently taking Ribavirin and failed response to a reduction of Ribavirin dose, and hemoglobin less than 10g/dL (or less than 11g/dL if symptomatic). • A diagnosis of HIV, currently taking Zidovudine, hemoglobin less than 10g/dL, and serum erythropoietin level of 500mUnits/mL or less. Hemoglobin results must be from the last 30 days. Medication must be administered in the member's home or long-term care facility. **Non-preferred products:** • Same as above; **and** • Failed treatment with Epogen. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.) **Note: The FDA has announced a risk evaluation mitigation strategy for the use of Erythropoeisis Stimulating Agents (ESAs) in patients with cancer, who are currently receiving chemotherapy, and who are experiencing chemotherapy induced anemia. Patients must receive a medication guide outlining the risks and benefits of treatment, and patient consent must be obtained before therapy. Prescribers are required to enroll and register in the ESA APPRISE Oncology program and complete training prior to prescribing ESAs to patients with cancer. For non-cancer indications, the distribution of a medication guide to the patient is the only requirement currently.**
FIBROMYALGIA AGENTS *Effective 7/1/2016*	**No PA Required** LYRICA (pregabalin) Duloxetine	**PA Required** CYMBALTA (duloxetine) SAVELLA (milnacipran)	Non-preferred agents will be approved for fibromyalgia if member has failed an adequate trial (8 weeks) of both Lyrica and duloxetine OR the member has contraindication to Lyrica and duloxetine For members with no epilepsy diagnosis in the last two years (as confirmed by SMART PA), PA will be required for LYRICA

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
			prescriptions requiring more than 3 capsules per day or for prescriptions requiring doses greater than 600mg per day. Generic DULOXETINE will be approved if the member has diagnosis of fibromyalgia.
FLUOROQUINOLONE (oral) *Effective 1/1/2016*	**No PA Required** Ciprofloxacin tablet CIPRO oral suspension (<5 years old) Levofloxacin tablet	**PA Required** AVELOX (moxifloxacin) CIPRO TABLET (ciprofloxacin) FACTIVE (gemifloxacin) LEVAQUIN TABLET (levofloxacin) LEVAQUIN oral solution Levofloxacin oral solution NOROXIN (norfloxacin) Ofloxacin	Non-preferred products will be approved for members who have failed an adequate trial (7 days) with at least one preferred product. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.) CIPRO suspension approved for members < 5 years of age without PA For members ≥ 5 years of age, CIPRO suspension will only be approved for those members who cannot swallow a whole or crushed tablet Levofloxacin solution will be approved for members who require administration via feeding tube OR who have failed an adequate trial (7 days) of ciprofloxacin suspension. (Failure is defined as: lack of efficacy, presence of feeding tube, allergy, intolerable side effects, or significant drug-drug interaction.)
GROWTH HORMONES *Effective 4/1/2016*	**No PA Required** GENOTROPIN NORDITROPIN	**PA Required** HUMATROPE NUTROPIN OMNITROPE SAIZEN SEROSTIM ZOMACTON ZORBTIVE	Non-preferred Growth Hormones will be approved if **both** of the following criteria are met: • Member failed treatment with Genotropin OR Norditropin within the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) • Member has a qualifying diagnosis: o Prader-Willi o Chronic renal insufficiency/failure o Turner's Syndrome o Hypopituitarism: as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma o Wasting associated with AIDS or cachexia o Noonan Syndrome Grandfathering: If the member has a diagnosis for short bowel syndrome OR cachexia associated with AIDS, member will be

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
			grandfathered and receive approval for a non-preferred agent due to medical necessity based on FDA approved indications.
HEPATITIS C VIRUS TREATMENTS *Effective 10/1/2016*	**Must meet eligibility criteria*** **Genotype 1:** VIEKIRA PAK, XR (ombitasvir/paritaprevir/ritonavir/dasabuvir) **Genotype 2 and 3:** EPCLUSA (sofosbuvir/velpatasvir) **Genotype 4:** TECHNIVIE (ombitasvir/paritaprevir/ritonavir)	**PA Required** DAKLINZA (daclatasvir) HARVONI (sofosbuvir/ledipasvir) OLYSIO (simeprevir) SOVALDI (sofosbuvir) ZEPATIER (elbasvir/grazoprevir)	All preferred agents will be granted prior authorization if the following criteria are met: 1. Physician attests to the member's readiness for adherence **AND** 2. Physician attests to provide SVR12 and SVR24 **AND** 3. **AND** 4. Must have received or in process of receiving full courses of both Hepatitis A and Hepatitis B vaccinations, or have immunity **AND** 5. Member is 18 years of age and older **AND** 6. Member is not a pregnant female or a male with a pregnant female partner (ribavirin contraindication). Initial pregnancy test must be performed not more than 30 days prior to beginning therapy **AND** 7. Women of childbearing potential and their male partners must use two forms of effective (non-hormonal) contraception during treatment (for ribavirin containing regimens only) **AND** 8. Prescribed an infectious disease specialist, gastroenterologist, or hepatologist **OR** prescribed by any primary care provider in consultation with an infectious disease specialist, gastroenterologist or hepatologist **AND** 9. Meets one of the following categories: • Members with serious extra-hepatic manifestations of HCV such as leukocytoclastic vasculitis, hepatocellular carcinoma meeting Milan criteria, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia despite mild liver disease; • Members with fibrosing cholestatic HCV; • Member has cirrhosis (F4) based on: o Biopsy within 5 years; OR o FibroScan; OR o Imaging indicating definitive evidence of cirrhosis, portal hypertension, splenomegaly or history of varices or ascites; OR o Fibrometer not more than 6 months old; OR o FibroTest not more than 6 months old; OR o Shear Wave Elastography indicating cirrhosis; **OR**

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)

			• Member has a fibrosis score equivalent to METAVIR F2 or F3 based on:
			  ○ Biopsy within 5 years; OR
			  ○ Fibroscan; OR
			  ○ Imaging indicating definitive fibrosis stage 2 or 3; OR
			  ○ Concordance among either FibroTest (within 6 months) or FibroMeter (within 6 months) PLUS either APRI or FIB4; OR
			  ○ Shear Wave Elastography indicating fibrosis stage 2 or 3; **OR**
			• Member is a woman who is planning on becoming pregnant in the next year; **OR**
			• Member is post liver transplant **AND**
			10. Members must have genotyping results within one (1) year of anticipated therapy start date **AND**
			11. If member is abusing/misusing alcohol or controlled substances, they must be receiving or be enrolled in counseling or substance use treatment program for at least one month prior to starting treatment **AND**
			12. All approvals will initially be for an 8 week time period, with further approvals dependent on the submission of the HCV RNA level at week 4, week 12, and week 24 to justify continuing drug therapy **AND**
			13. If the week 4 HCV RNA is detectable (>25 copies) while on therapy, HCV RNA will be reassessed in 2 weeks. If the repeated HCV RNA level has not decreased (i.e., >1 log10 IU/ml from nadir) all treatment will be discontinued unless documentation is provided which supports continuation of therapy **AND**
			14. Preferred products must be prescribed in accordance with approved regimens and duration (see tables below) **OR**
			15. For non-preferred products or treatment regimens, documentation must be provided indicating rationale for not prescribing a preferred treatment regimen. (Rationale may include, for example, patient specific medical contraindications to a preferred treatment)

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
			Ribavirin ineligibility criteria: • Pregnant women and men whose female partners are pregnant • Known hypersensitivity to ribavirin • Autoimmune hepatitis • Hemoglobinopathies • Creatinine Clearance < 50mL/min • Coadministered with didanosine **Note:** The Department will only cover a once per lifetime treatment with any DAA. **Refills:** Should be reauthorized in order to continue the appropriate treatment plan. The member MUST receive refills within one week of completing the previous fill. Please allow ample time for reauthorization after HCV RNA levels are submitted. **Treatment Readiness**: Prescribers should utilize assessment tools to evaluate readiness of the patient for treatment, some examples are available at: http://www.integration.samhsa.gov/clinical-practice/screening-tools#drugs or Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C) is available at: https://prepc.org/

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)

Viekira Table:

Patient Population	Treatment	Duration
Members with genotype 1a, without cirrhosis	Viekira + ribavirin	12 weeks
Members with genotype 1a, treatment naive, with compensated cirrhosis	Viekira + ribavirin	12 weeks
Members with genotype 1a, treatment experienced, with compensated cirrhosis	Viekira + ribavirin	24 weeks
Members with genotype 1b, with or without cirrhosis	Viekira	12 weeks
Post-transplant members	Viekira + ribavirin	24 weeks

Members must be adherent to treatment regimen, and the proCeed Nurse Connector program should be used for patients taking **Viekira** or **Technivie** (To enroll by Phone: 1-855-984-3547 or Fax: 1-866-299-1687 or online at: https://www.viekira.com/proceed-program) to re-enforce adherence. This is a free benefit for the patient and provider.

Technivie Table:

Patient Population	Treatment	Duration
Members with genotype 4 who are treatment naïve, with or without cirrhosis	Technivie + ribavirin	12 weeks

Epclusa Table:

Patient Population	Treatment	Duration
Members without cirrhosis and members with compensated cirrhosis	Epclusa	12 weeks
Members with decompensated cirrhosis	Epclusa + ribavirin	12 weeks

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
INSULIN *Effective 4/1/2016* **Rapid Acting**	**No PA Required** NOVOLOG vial/ pen	**PA Required** AFREZZA APIDRA all forms HUMALOG vial/ pen/ kwikpen	Non-preferred products will be approved if the member has failed treatment with one of the preferred products in the last month (Failure is defined as: allergy or intolerable side effects) AFREZZA (human insulin) will be approved for members with the following criteria: • Member is 18 years or older AND • Member has intolerable side effects or severe allergic reactions to Novolog AND • Member must not have chronic lung disease such as asthma and COPD AND • If member is a type 1 diabetic, must use in conjunction with long-acting insulin AND • Member must not be a smoker
Short Acting	HUMULIN R vial	NOVOLIN R all forms HUMULIN R kwikpen	Non-preferred products will be approved if the member has failed treatment with one of the preferred products in the last month (Failure is defined as: allergy or intolerable side effects)
Intermediate Acting	HUMULIN N vial/ pen/ kwikpen	NOVOLIN N all forms	Non-preferred products will be approved if the member has failed treatment with one of the preferred products in the last month (Failure is defined as: allergy or intolerable side effects)
Long Acting	LEVEMIR vial/ pen *LANTUS (2nd line)	BASAGLAR (glargine) all forms TOUJEO all forms TRESIBA (degludec) all forms	Non-preferred products will be approved if the member has failed treatment with Levemir and Lantus (Failure is defined as: allergy or intolerable side effects) Lantus will be approved if the member has failed treatment with Levemir in the last month (Failure is defined as: allergy or intolerable side effects)
Mixtures	HUMULIN 70/30 vial/ pen/ kwikpen HUMALOG MIX 50/50 vial/ pen HUMALOG MIX 75/25 vial/ pen NOVOLOG MIX 70/30 vial/ pen	NOVOLIN 70/30 vial	Non-preferred products will be approved if the member has failed treatment with one of the preferred products in the last month (Failure is defined as: allergy or intolerable side effects)

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
INTRANASAL CORTICOSTEROIDS *Effective 4/1/2016*	**No PA Required** Fluticasone (generic FLONASE) NASONEX (mometasone)	**PA Required** BECONASE AQ (beclomethasone diproprionate) Budesonide CHILD NASACORT (triamcinolone) DYMISTA (azelastine/ fluticasone propionate) FLONASE (fluticasone) Flunisolide NASAREL (flunisolide) NASACORT AQ (triamcinolone) OMNARIS (ciclesonide) QNASL (beclomethasone diproprionate) RHINOCORT AQ (budesonide) Triamcinolone acetonide VERAMYST (fluticasone furoate) ZETONNA (ciclesonide)	Non-preferred Intranasal Corticosteroids will be approved if the member has failed treatment with 2 preferred products in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions). • Rhinocort AQ will be approved for pregnant members without failure of preferred products. • Brand name Flonase will require a letter of medical necessity
LEUKOTRIENE MODIFIERS *Effective 4/1/2016*	**No PA Required** Montelukast (tab, chewable)	**PA Required** ACCOLATE (zafirlukast) SINGULAIR (montelukast) (tab, chewable tab)	Non-preferred Leukotrienes will be approved if **both** of the following criteria are met: • Member failed treatment with montelukast in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) • Member has a diagnosis of Asthma

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
		ZAFIRLUKAST ZYFLO (zileuton) ZYFLO CR (zileuton)	
MULTIPLE SCLEROSIS AGENTS *Effective 4/1/2016*	**No PA Required (unless indicated)** AVONEX (interferon beta 1a) BETASERON (interferon beta 1b) *GILENYA (fingolimid) (2^{nd} line) REBIF (interferon beta 1a) COPAXONE 20MG INJECTION (glatiramer)	**PA Required** AUBAGIO (teriflunomide) AMPYRA (dalfampridine) COPAXONE 40MG INJECTION (glatiramer) EXTAVIA (interferon beta 1b) GLATOPA (glatiramer) PLEGRIDY (peg-interferon beta 1a) TECFIDERA (dimethyl fumarate) ZINBRYTA (daclizumab)	Non-preferred **Interferon** products will be approved if the member has failed treatment with three preferred products in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions). Copaxone® 40mg will be approved for members who have a severe intolerable injection site reactions (e.g, pain requiring local anesthetic, oozing, lipoatrophy, swelling, or ulceration) to Copaxone 20mg. For treatment of EARLY disease, Gilenya will be approved for members that meet the following criteria: • Documented, diagnosis of multiple sclerosis made by neurologist in the last 3 years AND • Documentation provided by prescribing neurologist, or is prescribed in conjunction with a neurologist, for marked functional decline as demonstrated by two of the following: ○ MRI, EDSS scale OR medical chart notes that specify increased burden of disease AND • Provider attests to shared decision making with respect to risks versus benefits of medical treatment AND • Does not have a recent history of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or New York Heart Association Class III-IV heart failure within six months of initiating therapy AND • Does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome unless patient has a pacemaker AND • Has a baseline QTc interval < 500 ms prior to starting therapy AND • Is not receiving treatment with a Class Ia or Class III anti-arrhythmic medication AND

<table>
<tr><th>Therapeutic Drug Class</th><th>Preferred Agents</th><th>Non-preferred Agents</th><th>Prior Authorization Criteria
(All Non-preferred Products will be approved for one year unless otherwise stated.)</th></tr>
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Has no active infections AND
Had an ophthalmologic evaluation (ocular coherence test) prior to starting therapy and within 3-4 months follow-up after starting therapy AND
Had baseline complete blood count with differential and liver function tests.

For the treatment of <u>EARLY</u> disease,
Tecfidera and Aubagio may be approved for members that meet the following criteria:

Member has failed Gilenya. Failure will be defined as intolerable side effects, drug-drug interaction, contraindication to, or lack of efficacy AND
Documented, diagnosis of multiple sclerosis made by neurologist in the last 3 years AND
Documentation provided by prescribing neurologist, or is prescribed in conjunction with a neurologist, for marked functional decline as demonstrated by two of the following: AND

MRI, EDSS scale OR medical chart notes that specify increased burden of disease

Provider attests to shared decision making with respect to risks versus benefits of medical treatment AND
Appropriate safety criteria for Tecfidera and Aubagio are met below:

<table>
<tr><th colspan="2">Safety Criteria</th></tr>
<tr><th>Tecfidera</th><th>Aubagio</th></tr>
<tr><td>Has no active infections AND
Had a complete blood count with differential within the six months prior to initiating therapy</td><td>Has no active infections AND
If a female patient of child bearing age, has a negative pregnancy test at baseline and is using a form of highly effective contraceptive AND
Had transaminase and bilirubin levels with ALT < 2 times the upper limit of normal within the</td></tr>
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Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
			6 months prior to initiating therapy AND • Had a complete blood count with differential within the six months prior to initiating therapy AND • Has a documented baseline blood pressure AND • Has been evaluated for active or latent tuberculosis infection by documented test results (purified protein derivative test) or blood test. **AUBAGIO** will be approved if member met all the following criteria: • In members **without** a contraindication to GILENYA, member has failed COPAXONE or a preferred interferon product **AND** GILENYA. [Failure will be defined as intolerable side effects drug-drug interaction, or lack of efficacy] OR • In members **with** a contraindication to GILENYA, has failed COPAXONE or a preferred interferon product. Failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy. Lack of efficacy will be defined as one of the following: • On MRI: presence of any new spinal lesions, cerebellar or brain stem lesions, or change in brain atrophy. • On clinical exam, signs and symptoms consistent with functional limitations that last one month or longer AND • Has a diagnosis of a relapsing form of MS AND • Is being prescribed by a neurologist or is prescribed in conjunction with a neurologist AND • Has no active infections AND • If a female patient of child bearing age, has a negative pregnancy test at baseline and is using a form of highly effective contraceptive AND • Had transaminase and bilirubin levels with ALT<2 times the upper limit of normal within the 6 months prior to initiating therapy AND • Had a complete blood count with differential within the six months prior to initiating therapy AND

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
			• Has a documented baseline blood pressure AND • Has been evaluated for active or latent tuberculosis infections by documented test results (purified protein derivative test) or blood test. **TECFIDERA** will be approved if the member has met all the following criteria: • In members without a contraindication to GILENYA, member has failed COPAXONE or a preferred interferon product and GILENYA. Failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy OR • In members with a contraindication to GILENYA, has failed COPAXONE or a preferred interferon product. Failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy. Lack of efficacy will be defined as one of the following: • One of the following on MRI: presence of any new spinal lesions, cerebellar or brain stem lesions, or change in brain atrophy • On clinical exam, signs and symptoms consistent with functional limitations that last one month or longer AND • Has a diagnosis of a relapsing form of MS AND • Is being prescribed by a neurologist or is prescribed in conjunction with a neurologist AND • Has no active infections AND • Had a complete blood count with differential within the six months prior to initiating therapy. ***GILENYA** will be approved if the member has met all the following criteria: • Has failed COPAXONE or a preferred interferon product. Failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy. Lack of efficacy will be defined as one of the following: • One of the following on MRI: presence of any new spinal lesions, cerebellar or brain stem lesions, or change in brain atrophy • On clinical exam, signs and symptoms consistent with functional limitations that last one month or longer AND

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
			• Has a diagnosis of a relapsing form of MS AND • Is being prescribed by a neurologist or is prescribed in conjunction with a neurologist AND • Does not have a recent history of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or New York Heat Association Class III-IV heart failure within six months of initiating therapy AND • Does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome unless patient has a pacemaker AND • Has a baseline QTc interval <500 ms prior to starting therapy AND • Is not receiving treatment with a Class Ia or Class III anti-arrhythmic medication AND • Has no active infections AND • Had an ophthalmologic evaluation (ocular coherence test) prior to starting therapy within 3-4 months after starting therapy AND • Had a baseline complete blood count with differential and liver function tests. **AMPYRA** – Up to a 90 day supply of Ampyra will be approved if all of the following criteria are met: • Member has a diagnosis of MS; • Member is ambulatory and has established a baseline which is defined as ambulating between 8-45 seconds Timed 25-foot Walk (T25FW) assessment; • Member has no history of seizure disorder; • Member has no history of moderate to severe renal dysfunction (CrCl > 50 ml/min); • Prescriber is a neurologist or is prescribed in conjunction with a neurologist; • The prescribed dose does not exceed 10 mg twice daily. Extended coverage of Ampyra (up to one year) will be approved if documentation shows improvement in ambulation (measured by T25FW assessment) or improvement in ADLs after three months of therapy.

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
			Grandfathering: Members currently stabilized on GILENYA, TECFIDERA, and AUBAGIO may receive approval to continue on that agent.
OPHTHALMIC ALLERGY *Effective 4/1/2016*	**No PA Required** Cromolyn Olopatadine 0.1% PATADAY (olopatadine) PAZEO (olopatadine) ZADITOR (ketotifen)	**PA Required** ALAMAST (pemirolast) ALAWAY (ketotifen) ALOCRIL (nedocromil) ALOMIDE (lodoxamide) Azelastine BEPREVE (bepotastine) ELESTAT (epinastine) EMADINE (emedastine) LASACRAFT (alcaftadine) Ketotifen OPTICROM (sodium cromoglicate) PATANOL (olopatadine)	Non-preferred Ophthalmic Allergy medications will be approved if the member has failed treatment with two preferred products in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)
OPIOIDS **Long Acting – Oral Opioids** *Effective 7/1/2016*	**No PA Required** **FIRST LINE** Fentanyl patches Methadone (generic Dolophine) Morphine ER (generic MS Contin)	**PA Required** BELBUCA (buprenorphine) buccal film *BUTRANS (buprenorphine) patch CONZIP (TRAMADOL ER)	Non-preferred, long-acting oral opioids will be approved for members who have failed treatment with two preferred agents in the last six months. (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.) Fentanyl patches (Duragesic) will require a PA for doses of more than 1 patch/2 days. *Butrans patches will be approved for members who have failed treatment with ONE preferred agent in the last 6 months. (Failure is

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
	Tramadol ER	DOLOPHINE (methadone) DURAGESIC (fentanyl patch) EMBEDA (morphine/naltrexone) EXALGO (hydromorphone ER) Hydromorphone ER HYSINGLA (hydrocodone ER) KADIAN (morphine ER) MS CONTIN (morphine ER) MORPHABOND (morphine ER) NUCYNTA ER (tapentadol ER) OPANA ER (oxymorphone ER) OXYCONTIN (oxycodone ER) XARTEMIS XR (oxycodone/acetaminophen) ZOHYDRO ER (hydrocodone ER)	defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.) ZOHYDRO ER and HYSINGLA® ER and OXYCONTIN (new starts) will be approved for members who have failed treatment with two preferred products, AND at least one other long acting opiate in the past year. OXYCONTIN®, OPANA ER®, NUCYNTA ER®, and ZOHYDRO ER® will only be approved for twice daily dosing. HYSINGLA ER® will only be approved for once daily dosing. No more than one long-acting oral opioid will be approved at one time. Medicaid is not mandating that a patient switch from a non-preferred drug to methadone. Methadone requires special training due to its complex pharmacokinetic profile. However, if a patient has tried and failed methadone in the past, it can be considered a trial of one preferred drug. Use of opioid analgesics during pregnancy has been associated with neonatal abstinence syndrome. Providers MUST counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of neonatal abstinence syndrome. Providers should offer access to contraceptive services when necessary. For all prior authorization requests for opiate agents, provider must attest to counseling provided to women of childbearing age. The total daily limit of milligrams of morphine equivalents is 300mg effective 2/17/2016. This includes opioid-containing products where conversion calculations are applied. Prescriptions that cause the member's drug regimen to exceed the maximum daily limit of 300 milligrams of morphine equivalents (MME) will be denied. This does not currently include methadone prescriptions. Prior authorizations will be granted to allow for tapering.

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
			• A one year PA will be granted for diagnosis of sickle cell anemia or admission to or diagnosis of hospice or end of life care. • A one year PA will be granted for pain associated with cancer. Medicaid provides guidance on the treatment of pain, including tapering, on our website Pain Management Resources and Opioid Use at www.Colorado.gov/hcpf then search Pain Management. Only one long-acting oral opioid agent (including different strengths) and one short-acting opioid agent (including different strengths) will be considered for a prior authorization.
OVERACTIVE BLADDER AGENTS *Effective 10/1/16*	**No PA Required** Oxybutynin tablets (generic) Oxybutynin ER tablets (generic) TOVIAZ (fesoterodine ER)	**PA Required** DETROL (tolterodine) DETROL LA (tolterodine ER) DITROPAN (brand) DITROPAN XL (brand) ENABLEX (darifenacin) Flavoxate GELNIQUE (oxbutynin gel) MYRBETRIQ (mirabegron) Oxybutynin syrup OXYTROL (oxybutynin patch) SANCTURA (trospium) SANCTURA XL (trospium ER)	Non-preferred products will be approved for members who have failed treatment with two preferred products. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.). Members with hepatic failure can receive approval to receive trospium or trospium extended-release (Sanctura XR) products without a trial on a Preferred product.

<table>
<tr><th>Therapeutic Drug Class</th><th>Preferred Agents</th><th>Non-preferred Agents</th><th>Prior Authorization Criteria
(All Non-preferred Products will be approved for one year unless otherwise stated.)</th></tr>
<tr><td></td><td></td><td>Tolterodine

VESICARE (solifenacin)</td><td></td></tr>
<tr><td>PANCREATIC ENZYMES
Effective 1/1/2016</td><td>No PA Required

CREON (pancrelipase)

ZENPEP (pancrelipase)</td><td>PA Required

PANCREAZE (pancrelipase)

PANCRELIPASE (pancrelipase)

PERTZYE (pancrelipase)

ULTRESA (pancrelipase)

VIOKACE (pancreatin)</td><td>Non-preferred products will be approved for members who have failed an adequate trial (4 weeks) with at least two preferred products. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.)

Grandfathering: Members currently stabilized on a Non-preferred pancreatic enzyme can receive approval to continue on that agent for one year if medically necessary.</td></tr>
<tr><td>PROTON PUMP INHIBITORS
Effective 1/1/2016</td><td>*Must meet eligibility criteria

NEXIUM (esomeprazole) capsules and packets BNR

Omeprazole generic capsules

Pantoprazole tablets

PREVACID solutab BNR (lansoprazole)
(for members under 2)</td><td>PA Required

ACIPHEX tab, sprinkles (rabeprazole)

DEXILANT (dexlansoprazole)

KAPIDEX (dexlansoprazole)

Esomeprazole (generic Nexium)

Esomeprazole strontium

Lansoprazole capsules

Lansoprazole 15mg OTC (currently available as PREVACID 24HR)

NEXIUM 24 hour

PREVACID (lansoprazole) capsules & suspension

PRILOSEC OTC (omeprazole)</td><td>*PA will be required for therapy beyond 60 days of treatment per year for all agents. For members treated for GERD, once 60 days of therapy per year has been exceeded, members must fail an adequate trial of a histamine 2 receptor antagonist (H2A) before PPI therapy can be reconsidered. An adequate trial is defined as 8 weeks of histamine 2 receptor antagonist at optimal doses listed in the table below.

<table><tr><th>Drug</th><th>Optimal Dose</th></tr><tr><td>Erbrotidine</td><td>800 mg once daily</td></tr><tr><td>Famotidine</td><td>20 mg twice daily</td></tr><tr><td>Nizatidine</td><td>150 mg twice daily</td></tr><tr><td>Ranitidine</td><td>150 mg twice daily</td></tr><tr><td>Ranitidine</td><td>** For children less than 30 kg, maximum dose is 10mg/kg per day divided in 2 doses</td></tr><tr><td>Roxatidine</td><td>150 mg once daily or 75mg twice daily</td></tr></table>
Long-term therapy, without a H2A trial, will be approved for members with Barrett’s Esophagus, Erosive Esophagitis, GI Bleed, post-bariatric surgery; Hypersecretory Conditions (Zollinger Ellison), Recurrent Aspiration Syndrome, chronic NSAID or prednisone therapy, Spinal Cord Injury members with an acid reflux diagnosis, or children (< 18 years of age) with Cystic Fibrosis, on mechanical ventilation or who have a feeding tube.</td></tr>
</table>

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
		PROTONIX (pantoprazole) tablets and suspension Rabeprazole (generic Aciphex) ZEGERID (omeprazole/Na bicarbonate)	In addition, members with continuing, symptomatic GERD or recurrent peptic ulcer disease who have documented failure on step-down therapy to an H2-receptor antagonist will be approved for up to one year of daily PPI therapy. Non-preferred proton pump inhibitors will be approved if all of the following criteria are met: • Member failed treatment with three Preferred Products within the last 24 months, • Member has a qualifying diagnosis, AND • Member has been diagnosed by an appropriate diagnostic method. **The Qualifying Diagnoses are:** Barrett's Esophagus, Duodenal Ulcer, Erosive Esophagitis, Gastric Ulcer, GERD, GI Bleed, H. pylori, Hypersecretory Conditions (Zollinger-Ellison), NSAID-Induced Ulcer, Pediatric Esophagitis, Recurrent Aspiration Syndrome or Ulcerative GERD **The Appropriate Diagnostic Methods are:** GI Specialist, Endoscopy, X-Ray, Biopsy, Blood test, or Breath test **Quantity Limits:** Non-preferred agents will be limited to once daily dosing except for the following diagnoses: Barrett's Esophagus, GI Bleed, H. pylori, Hypersecretory Conditions, or Spinal Cord Injury patients with any acid reflux diagnosis. **Age Limits:** Aciphex, Protonix, and Zegerid will not be approved for members less than 18 years of age. Prevacid Solutab will be approved for members less than 2 years old and ≥ 2 years with a feeding tube.
H. Pylori Treatments	NONE	OMECLAMOX-PAK (amoxicillin/ omeprazole/ clarithromycin) PREVPAC (amoxicillin/lansoprazole/ clarithromycin)	H. Pylori treatments should be used as individual products unless one of the individual products is not commercially available then a PA for the combination product will be given.

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
		Amoxicillin/lansoprazole/ clarithromycin PYLERA (bismuth subcitrate/ metronidazole/tetracycline)	
PULMONARY ARTERIAL HYPERTENSION THERAPIES **Phosphodiesterase Inhibitors** *Effective 1/1/2016*	***Must meet eligibility criteria** Sildenafil **(**generic Revatio)	**PA Required** ADCIRCA (tadalafil) REVATIO (sildenafil)	***Eligibility Criteria for all agents in the class** Approval will be granted for a diagnosis of pulmonary hypertension. **Grandfathering**: Members currently stabilized on Adcirca can receive approval to continue on that agent.
Endothelin Antagonists *Effective 1/1/2016*	**No PA Required** LETAIRIS (ambrisentan)	**PA Required** OPSUMIT (macitentan) TRACLEER (bosentan)	Non-preferred products will be approved for members who have failed treatment with Letairis or for members requiring a dose preparation not available with a preferred product. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **Grandfathering:** Members who have been previously stabilized on a Non-preferred product can receive approval to continue on the medication.
Prostanoids *Effective 1/1/2016*	**No PA Required** Epoprostenol (generic) VENTAVIS (iloprost)	**PA Required** FLOLAN (brand) (epoprostenol) ORENITRAM (treprostinil) REMODULIN (treprostinil) TYVASO (treprostinil) VELETRI (epoprostenol) UPTRAVI (selexipag)	Non-preferred products will be approved for members who have failed treatment with a Preferred Product. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, contraindication to IV therapy or significant drug-drug interaction) **Grandfathering:** Members who have been previously stabilized on a non-preferred product can receive approval to continue on the medication.

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
Guanylate Cyclase (sGC) Stimulator *Effective 1/1/2016*	**No PA Required**	**PA Required** ADEMPAS (riociguat)	**Adempas** will be approved for patients who meet the following criteria: • Patient is not a pregnant female and is able to receive monthly pregnancy tests while taking Adempas and one month after stopping therapy. AND • Women of childbearing potential and their male partners must use one of the following contraceptive methods during treatment and one month after stopping treatment (e.g, IUD, contraceptive implants, tubal sterilization, a hormone method with a barrier method, two barrier methods, vasectomy with a hormone method, or vasectomy with a barrier method). AND • Patient is not receiving dialysis or has severe renal failure (e.g, Crcl < 15 ml/min). AND • Patient does not have severe liver impairment (e.g, Child Pugh C). AND • Prescriber must be enrolled with the Adempas REMS Program. AND • Female patients, regardless of reproductive potential, must be enrolled in the Adempas REMS program prior to starting therapy. AND • Patient has a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment or has inoperable CTEPH OR • Patient has a diagnosis of pulmonary hypertension and has failed treatment with a preferred product for pulmonary hypertension. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions).
RESPIRATORY INHALANTS **Inhaled Anticholinergics & Anticholinergic Combinations** *Effective 7/1/2016*	**No PA Required** **Solutions** Albuterol/ipratropium solution Ipratropium (generic Atrovent) solution **Short-Acting Inhalers** ATROVENT HFA (ipratropium)	**PA Required** **Solutions** ATROVENT (ipratropium) solution **Short-Acting Inhalers** **Long-Acting Inhalers** ANORO ELLIPTA (umeclininium/vilanterol)	Non-preferred anticholinergic inhalants and anticholinergic combination inhalants will require a brand-name PA stating medical necessity. ATROVENT® solution and DUONEB ® will require a brand-name prior authorization stating medical necessity. SPIRIVA RESPIMAT ® will be approved for members with a diagnosis of asthma requiring the use of this drug for maintenance therapy

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
	COMBIVENT RESPIMAT (albuterol/ipratropium) **Long-Acting Inhalers** SPIRIVA Handihaler (tiotropium)	BEVESPI AEROSPHERE (glycopyrrolate/formoterol fumarate) INCRUSE ELLIPTA (umeclindinium) SEEBRI Neohaler (glycopyrrolate) SPIRIVA RESPIMAT (tiotropium) STIOLTO Respimat (tiotropium/olodaterol) TUDORZA Pressair (aclidinium) UTIBRON Neohaler (glycopyrrolate/indacaterol)	Non-preferred anticholinergic agents will be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema who have failed treatment with Spiriva Handihaler® (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) or who have a contraindication to Spiriva Handihaler. Non-preferred combination anticholinergic agents will be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema AND has failed treatment with Combivent Respimat® (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction), OR who have a contraindication to Combivent Respimat®.
RESPIRATORY INHALANTS **Inhaled Beta2 Agonists (short acting)** *Effective 7/1/2016*	**No PA Required** **Solutions** Albuterol (generic) solution **Inhalers** PROAIR (albuterol) HFA	**PA Required** **Solutions** Metaproterenol Levalbuterol solution PROVENTIL (albuterol) solution XOPENEX (levalbuterol) solution **Inhalers** Metaproterenol inhaler Pirbuterol PROAIR Respiclick PROVENTIL (albuterol) HFA inhaler VENTOLIN (albuterol) HFA inhaler	Non-preferred, short acting beta2 agonists will be approved for members who have failed treatment with one preferred agent. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction). **Proair HFA, Proventil HFA, Ventolin HFA**: Quantity limits: 2 inhalers / 30 days

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
		XOPENEX (levalbuterol) Inhaler	
RESPIRATORY INHALANTS Inhaled Beta2 Agonists (long acting) *Effective 7/1/2016*	**No PA Required* (if dx restrictions met)** SEREVENT DISKUS* (salmeterol) inhaler	**PA Required** **Solutions** BROVANA (Arformoterol) solution PERFOROMIST (formoterol) solution **Inhalers** ARCAPTA (indacaterol) neohaler FORADIL (formoterol) STRIVERDI RESPIMAT (olodaterol)	SEREVENT ® will be approved for members with moderate to very severe COPD. Non-preferred agents will be approved for members with moderate to severe COPD, AND members must have failed a trial of SEREVENT (Failure is defined as: lack of efficacy, allergy, contraindication to, intolerable side effects, or significant drug-drug interaction). **For treatment of members with diagnosis of asthma needing add-on therapy, please refer to preferred agents in combination Long-Acting Beta Agonist/Inhaled Corticosteroid. SEREVENT will not be approved for treatment of asthma in members needing add-on therapy due to safety risks associated with monotherapy.
RESPIRATORY INHALANTS Inhaled Corticosteroids *Effective 7/1/2016*	**No PA Required** **Solutions** Budesonide nebules 0.25mg and 0.5mg PULMICORT (budesonide) nebules 1mg **Inhalers** ASMANEX twisthaler (mometasone) FLOVENT (fluticasone) diskus FLOVENT (fluticasone) HFA QVAR (beclomethasone)	**PA Required** **Solutions** PULMICORT (budesonide) nebules 0.25mg and 0.5mg **Inhalers** AEROSPAN HFA (flunisolide) inhaler ALVESCO (ciclesonide) inhaler ARNUITY ELLIPTA (fluticasone furoate) ASMANEX HFA (mometasone furoate) inhaler PULMICORT (budesonide) flexhaler	Non-preferred inhaled corticosteroids will be approved in members with asthma who have failed an adequate trial of two preferred agents. An adequate trial is defined as at least 6 weeks. (Failure is defined as: lack of efficacy, allergy, contraindication to, intolerable side effects, or significant drug-drug interactions.) Pulmicort Flexhaler will only be approved for female members with asthma who have a new diagnosis of pregnancy. Budesonide nebulizer solution will only be approved for a maximal dose of 2mg/day.

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
RESPIRATORY INHALANTS Inhaled Corticosteroid Combinations *Effective 7/1/2016*	**No PA Required** ADVAIR Diskus (fluticasone/salmeterol) DULERA (mometasone/ formoterol)	**PA Required** ADVAIR HFA (fluticasone/salmeterol) BREO Ellipta (vilanterol/fluticasone furoate) SYMBICORT (budesonide/formoterol) inhaler	Non-preferred inhaled corticosteroid combinations will be approved for members meeting both of the following criteria: • Member has a qualifying diagnosis of asthma or COPD; AND • Member (with a diagnosis of asthma) has failed two preferred agents due to lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction. Members with a diagnosis of COPD will only have to fail one preferred agent due to lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.
SEDATIVE- HYPNOTICS (non-benzodiazepine) *Effective 4/1/2016*	**No PA Required* (unless duplication criteria apply)** Eszopiclone Zaleplon Zolpidem	**PA Required** AMBIEN (zolpidem) AMBIEN CR (zolpidem) BELSOMRA (suvorexant) EDLUAR (zolpidem) (sublingual) INTERMEZZO (zolpidem) (sublingual) LUNESTA (eszopiclone) ROZEREM (ramelteon) SONATA (zaleplon) ZOLPIMIST (zolpidem)	Non-preferred sedative hypnotics will be approved for members who have failed treatment with two preferred agents in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) BELSOMRA (suvorexant) will be approved for members that meet the following criteria: • Members who have failed treatment with two preferred agents in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND** • Member is not receiving strong inhibitors (e.g, erythmromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, delavirdine, and milk thistle) or inducers (e.g, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifabutin, rifapentine, dexamethasone, efavirenz, etravirine, nevirapine, darunavir/ritonavir, ritonavir, and St John's Wort) of CYP3A4 **AND** • Member does not have a diagnosis of narcolepsy Sedative hypnotics will require PA for member's ≥65 years of age exceeding 90 days of therapy. Rozerem will be approved for members with a history/concern of substance abuse or for documented concern of diversion within the household without failed treatment on a preferred agent

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
			Children: PAs will be approved for members 18 years of age and older. ***Duplications:** Only one agent in this drug class will be approved at a time. Approval will not be granted for members currently taking a long-acting benzodiazepine such as clonazepam or temazepam.
SKELETAL MUSCLE RELAXANTS *Effective 7/1/2016*	**No PA Required (if under 65 years of age)*** Baclofen (generic Lioresal) Cyclobenzaprine (generic Flexeril) 5mg and 10mg tablet Tizanidine (generic Zanaflex) 2mg and 4mg tablet	**PA Required** AMRIX ER (cyclobenzaprine ER) Carisoprodol Chlorzoxazone Cyclobenzaprine 7.5mg tabs DANTRIUM (dantrolene) Dantrolene FEXMID (cyclobenzaprine) LORZONE (chlorzoxazone) METAXALL (metaxolone) Metaxolone Methocarbamol Orphenadrine PARAFON FORTE (chlorzoxazone) ROBAXIN (methocarbamol)	All agents in this class will require a PA for members 65 years of age and older. Approval will only be given if the member has had at least a 7 day trial with an opiate or has a diagnosis of spasticity. The maximum allowable approval will be for a 7-day supply. Non-preferred skeletal muscle relaxants will be approved for members who have failed two preferred agents in the last 6-months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.) Authorization for any CARISOPRODOL product will be given for a maximum 3-week one-time authorization for members with acute, painful musculoskeletal conditions who have failed treatment with three preferred products.

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
		SKELAXIN (metaxalone) SOMA (carisoprodal) Tizanidine 2, 4, 6mg caps ZANAFLEX (tizanadine)	
STATINS *Effective 4/1/2016*	**No PA Required** Atorvastatin CRESTOR (rosuvastatin) Pravastatin Simvastatin*	**PA Required** ALTOPREV (lovastatin ER) LESCOL (fluvastatin) LESCOL XL (fluvastatin ER) LIPITOR (atorvastatin) LIVALO (pitavastatin) Lovastatin (generic Mevacor) MEVACOR (lovastatin) Pitavastatin PRAVACHOL (pravastatin) Rosuvastatin ZOCOR* (simvastatin)	Non-preferred Statin/Statin combinations will be approved if the member has failed treatment with two preferred products in the last 24 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) **Children:** Altoprev, Advicor, Livalo and Vytorin will be approved for members 18 years of age and older. Caduet, fluvastatin and lovastatin will be approved for members 10 years of age and older. *Simvastatin 80mg dose products will only be covered for members who have been stable for more than 12 months at that dose. Providers should consider alternate preferred statins in members who have not met cholesterol goals on simvastatin at doses up to 40mg per day. Please refer to the FDA communication titled, "FDA Drug Safety Communication: New restrictions, contraindications and dose limitations for Zocor (simvastatin) to reduce the risk of muscle injury" for updated guidance on contraindications, dose limits and relative LDL lowering doses of alternatives.

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
STATIN COMBINATIONS *Effective 4/1/2016*		ADVICOR (niacin ER / lovastatin) CAUDET (amlodipine /atorvastatin) JUVISYNC (sitagliptin/ simvastatin) LIPTRUZET (ezetimibe/ atorvastatin) SIMCOR (niacin/simvastatin) VYTORIN* (ezetimibe/simvastatin.)	
STIMULANTS and other ADHD agents *Effective 10/1/2016*	**No PA Required (if age, daily dose, dx restrictions met)** ADDERALL IR (mixed-amphetamine salts) ADDERALL XR *BNR* (mixed amphetamine salts ER) FOCALIN IR *BNR* (brand name dexmethylphenidate) FOCALIN XR *BNR* (dexmethylphenidate ER) Guanfacine ER Methylphenidate IR (generic Ritalin IR) Methylphenidate ER (generic Concerta)	**PA Required** ADZENYS XR ODT (amphetamine) APTENSIO XR (methylphenidate XR) CONCERTA (methylphenidate ER) D-amphetamine spansule DAYTRANA (methylphenidate transdermal) DESOXYN (methamphetamine) DEXEDRINE (dextroamphetamine) DEXTROSTAT (dextroamphetamine) Dexmethylphenidate (generic Focalin IR) Dexmethylphenidate (generic Focalin XR)	For beneficiaries with ADD/ADHD or narcolepsy warranting treatment with a stimulant or non-stimulant (either preferred or non-preferred), a diagnosis of ADD/ADHD or narcolepsy must be documented in the beneficiaries medical record at the time of diagnosis and annually. For patients with ADD/ADHD, prior to receiving pharmacotherapy, the beneficiary must have additional documentation through a validated ADHD/ADD instrument. For beneficiaries with ADD/ADHD who are currently receiving a stimulant or non-stimulant but does not have an official diagnosis of ADD/ADHD, the beneficiary will have six months to obtain a diagnosis otherwise the medication will be discontinued. Non-preferred agents will be approved for members who have documented failure with two preferred products in the last 12 months (age six years or older) or documented failure with one preferred products in the last 12 months if ages 3 – 5 years (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction). However, certain exceptions exist for Daytrana, Intuniv, Methylin solution, Quillivant XR, Nuvigil and Provigil. Please see the criteria below. **In addition:** Non-preferred agents will only be approved for FDA and official compendium indications. • Provigil will only be approved for Narcolepsy, Obstructive Sleep Apnea/Hypopnea Syndrome, Shift Work Sleep Disorder,

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
	Mixed-amphetamine salts (generic Adderall IR) RITALIN IR (methylphenidate) STRATTERA (atomoxetine) *BNR* VYVANSE (lisdexamfetamine)	DYANAVEL XR solution (amphetamine) EVEKEO (amphetamine) Guanfacine ER INTUNIV (guanfacine ER) KAPVAY (clonidine ER) METADATE CD (methylphenidate ER) METADATE ER (methylphenidate ER) Methylphenidate ER (generic Metadate CD, ER, generic Ritalin LA) METHYLIN SUSPENSION (methylphenidate) Mixed-amphetamine salts ER (generic for Adderall XR) Modafanil (generic PROVIGIL) NUVIGIL (armodafinil) PROCENTRA (dextroamphetamine liquid) PROVIGIL (modafinil) QUILLICHEW (methylphenidate) QUILLIVANT XR suspension (methylphenidate)	Traumatic Brain Injury, Multiple Sclerosis related fatigue or ADHD. Only a maximum of 400mg per day will be approved. • Nuvigil will be approved for obstructive sleep apnea/hypopnea syndrome, narcolepsy and shift work sleep disorder. Beneficiaries with ADD/ADHD must fail a 4 week trial of a preferred stimulant before the use of Nuvigil® will be approved. Only one tablet per day will be approved. • All other Non-preferred products will be approved for members with a diagnosis of ADD, ADHD, Narcolepsy, Multiple Sclerosis related fatigue, traumatic brain injury or severe autism. • **Daytrana, Methylin solution, Quillichew and Quillivant XR**: Members with documented difficulty swallowing that are unable to utilize alternative dosing with FOCALIN XR, VYVANSE or ADDERALL XR can receive approval without failure on preferred products. Provider must document contraindications. **And** Non-preferred agents will only be approved for FDA approved age limitations. • Provigil will be approved for members 16 years of age and older. • Nuvigil will be approved for members 17 years of age and older. • Adderall IR, Dexedrine and Dextrostat will be approved for members 3 years of age and older. • All other medications in this class will be approved for members 6 years of age and older. Below are the FDA recommended maximum daily doses:

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
		RITALIN LA (methylphenidate ER (LA)) ZENZEDI (dextroamphetamine)	

Drug	Maximum Daily Dose
Preferred	
ADDERALL ®	40 mg/day
ADDERALL XR®	40mg/day
AMPHETAMINE SALTS mixed	40 mg/day
DESOXYN ®	25mg/day
FOCALIN ®	20 mg/day
FOCALIN XR ®	40 mg/day
INTUNIV ER®	4 mg/day or 7mg/day > age 12
METHYLPHNIDATE IR	60 mg/day
METHYLPHNIDATE LA (ER)	60 mg/day
METHYLPHNIDATE ER	54 mg/day or 72 mg/day > age 12
RITALIN® IR	60 mg/day
RITALIN LA ®	60 mg/day
STRATTERA®	100 mg/day
VYVANSE ®	70 mg/day
Non preferred	
ADZENYS XR ODT ®	18.8mg or 12.5mg > age 12
AMPHETAMINE SALTS ER mixed	30mg/day
APTENSIO XR ®	60 mg/day
CONCERTA ER ®	54 mg/day or 72 mg/day > age 12
D-AMPHETAMINE ER spansule	40 mg/day
DESOXYN ®	25mg/day
DAYTRANA ®	30 mg/day
DEXEDRINE ®	40mg/day
DEXMETHYLPHENIDATE IR	20 mg/day
DEXMETHYLPHENIDATE ER	40 mg/day
DEXTROSTAT ®	40mg/day
DYANAVEL XR ODT ®	20 mg/day
EVEKEO ®	40 mg/day
GUANFACINE ER	4mg/day or 7mg/day > age 12
KAPVAY ER®	0.4 mg/day
METADATE CD ®	60 mg/day
METADATE ER ®	60 mg/day
METHYLIN ER ®	60 mg/day
METHYLIN SUSPENSION®	60 mg/day

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
			METHYLPHENIDATE ER: 60 mg/day Modafanil: 400mg/day NUVIGIL ®: 250 mg/day PROCENTRA ®: 40 mg/day PROVIGIL ®: 400 mg/day QUILLICHEW ®: 60 mg/day QUILLIVANT XR®: 60 mg/day ZENZEDI ®: 40 mg/day
TARGETED IMMUNE MODULATORS *Effective 1/1/2016*	**No PA Required** ENBREL (etanercept) HUMIRA (adalimumab)	**PA Required** ACTEMRA (tocilizumab) CIMZIA (certolizumab) COSENTYX (secukinumab) KINERET (anakinra) ORENCIA (abatacept) Subcutaneous OTEZLA (apremilast) SIMPONI (golimumab) STELARA (ustekinumab) TALTZ (ixekizumab) XELJANZ (tofacitinib) XELJANZ XR (tofacitinib) ***for information on IV infused Targeted Immune Modulators for Rheumatoid Arthritis please see Appendix P**	**The Department would like to remind providers that many products have patient support programs that assist patients in drug administration, education, and emotional support for our member's diseases.** **Actemra** (SQ) will be approved for treatment of RA in members who have had treatment failure with at least one conventional DMARD (e.g, methotrexate, leflunomide, and sulfasalazine), Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects or significant drug-drug interaction.) **Cimzia** (all dosage forms) will be approved for treatment of Crohn's disease in members who have had treatment failure with Humira (Failure is defined as: lack of efficacy of a 3 month trial, allergy, intolerable side effects, or significant drug-drug interaction.) **Cimzia** (all dosage forms) will be approved for treatment of RA in members who have had treatment failure with Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects, or significant drug-drug interaction.) **Cimzia** (all dosage forms) will be approved for treatment of Ankylosing Spondylitis or Psoriatic Arthritis in members who have had treatment failure with Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects, or significant drug-drug interaction.) **Cosentyx** will be approved for moderate to severe plaque psoriasis in members who have tried and failed methotrexate, Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects or significant drug-drug interaction).

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
			Cosentyx will be approved for adults with psoriatic arthritis in members who have tried and failed Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects or significant drug-drug interaction). **Cosentyx** will be approved for adults with active ankyloses spondylitis in members who have tried and failed Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects or significant drug-drug interaction). **Kineret** will be approved for treatment of RA in members who have had treatment failure with Enbrel and Humira (Failure is defined as: lack of efficacy of a 3 month trial, allergy, intolerable side effects, or significant drug-drug interaction). **Kineret** will be approved without PA for members with documented neonatal-onset multisystem inflammatory disease (NOMID). **Orencia** will be approved for the treatment of RA in members who have tried and failed Enbrel and Humira (Failure is defined as: lack of efficacy of a 3 month trial, allergy, intolerable side effects, or significant drug-drug interaction). **Orencia** will be approved for the treatment juvenile idiopathic arthritis who have tried and failed Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects, or significant drug-drug interaction). **Otezla** will be approved for treatment of plaque psoriasis in members who have had treatment failure at least one conventional DMARD (e.g, methotrexate, leflunomide, and sulfasalazine), Enbrel and Humira (Failure is defined as: lack of efficacy of a 3 month trial, allergy, intolerable side effects or significant drug-drug interaction.) **Simponi** will be approved (in combination with methotrexate) for treatment of RA in members who have tried and failed Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects, or significant drug-drug interaction).

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
			Simponi will be approved with or without methotrexate for the treatment of Ankylosing Spondylitis or Psoriatic Arthritis in members who have tried and failed Enbrel and Humira (Failure is defined as: lack of efficacy of a 3 month trial, allergy, intolerable side effects or significant drug-drug interaction). **Simponi** will be approved for treatment of ulcerative colitis in members who have tried and failed Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects, or significant drug-drug interaction). **Stelara** will be approved with or without methotrexate for the treatment of Psoriatic Arthritis in members who have tried and failed Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects, or significant drug-drug interaction.) **Stelara** will be approved for moderate to severe plaque psoriasis in members who have tried and failed Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects, or significant drug-drug interaction.) **Taltz** will be approved for members with diagnosis of moderate to severe plaque psoriasis who have tried and failed methotrexate, Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction) **Taltz** approval will be given for an initial 12 weeks and further authorization will be provided based on clinical response **Xeljanz** will be approved for the treatment of RA in members who have had treatment failure with methotrexate, Humira, and Enbrel (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects, or significant drug-drug interaction.) **Xeljanz** will be not be approved for combination therapy with a biologic disease modifying agent.

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
			Quantity Limits: 2 tablets per day or 60 tablets for a 30 day supply
TESTOSTERONE PRODUCTS *Effective 7/1/2016*	**Must meet criteria** ANDROGEL 1.62% (testosterone topical) ANDRODERM (testosterone patch) DEPO TESTOSTERONE (testosterone cypionate) IM Testosterone Cypionate IM	**PA Required** ANDROGEL 1% **BNR** (testosterone) ANDROID (methyltestosterone) ANDROXY (fluoxymesterone) AXIRON solution (testasterone) DELATESTRYL (testosterone enanthate) IM injection FORTESTA gel (testosterone) Methyltestosterone NATESTO nasal gel (testosterone) STRIANT buccal (testosterone) TESTIM gel (testosterone) Testosterone gel TESTRED (methyltestosterone) Testosterone enanthate IM injection VOGELXO gel	*Hypogonadotropic or Primary Hypogonadism* Preferred androgenic drugs will be approved for members meeting the following: 1. Male patient > 18 years of age AND 2. Has a documented diagnosis of hypogonadotropic or primary hypogonadism (Patients with other diagnoses will require a manual review by a state pharmacist) AND 3. Has two documented low serum testosterone levels below the lower limit of normal range for testing laboratory prior to initiation of therapy AND 4. Does not have a diagnosis of breast or prostate cancer AND 5. Does not have a palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL AND 6. Has normal liver function tests prior to initiation of therapy *Gender Transition* Preferred androgenic drugs will be approved for members meeting the following: 1. Biologically born female patient > 18 years of age* AND 2. Is undergoing female to male transition AND 3. Has a negative pregnancy test prior to initiation AND 4. Has normal liver function tests prior to initiation of therapy *For members < 18 years of age, a manual review will be required. Non-preferred androgenic drugs will be approved for patients meeting the above criteria with documented failure with an 8 week trial of a preferred androgenic drug (Failure is defined as lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction) **Grandfathering:** Members may be grandfathered on preferred agents without requirement of updated low serum testosterone laboratory testing that meet the following criteria: • Male patient > 18 years of age AND

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
			• Has at least one past documented low serum testosterone levels below the lower limit of normal range for testing laboratory prior to initiation of therapy AND • Has documented diagnosis of hypogonadotropic or primary hypogonadism AND • Does not have a diagnosis of breast or prostate cancer AND • Does not have a palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL AND • Has normal liver function tests prior to initiation of therapy
TOPICAL IMMUNOMODULATORS *Effective 7/1/2016*	**Must meet criteria** ELIDEL (pimecrolimus)*	**PA Required** PROTOPIC (tacrolimus) Tacroliumus (generic Protopic)	Manual review will be required for members needing ≥ 6 weeks of therapy. *ELIDEL® will only be approved for a member who had an adequate trial (e.g, one month or longer) of a topical steroid and failed treatment. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.) Tacrolimus will only be approved for a member who had an adequate trial (e.g, one month or longer) of a topical steroid and ELIDEL® and failed treatment. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.) For members under 18 years of age, must be prescribed by or in conjunction with a dermatologist.
TRIPTANS *Effective 1/1/2016*	**No PA Required (monthly quantity limits may apply)** IMITREX **BNR** (sumatriptan) nasal spray and injection Naratriptan tablets RELPAX **BNR** (eletriptan)	**PA Required** AMERGE (naratriptan) AXERT (almotriptan) FROVA (frovatriptan) IMITREX (sumatriptan) tablets MAXALT MLT tablets (rizatriptan)	Non-preferred products will be approved for members who have failed treatment with two Preferred Products within the last 6 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions.) **Quantity Limits:** Amerge, Frova, Imitrex, Treximet and Zomig: Max 9 tabs / 30 days. Axert and Relpax: Max 6 tabs / 30 days. Imitrex injection: Max 4 injectors / 30 days Maxalt: Max 12 tabs / 30 days.

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
	Rizatriptan MLT tablets Sumatriptan tablets	Maxalt tablets (rizatriptan) Rizatriptan tablets ONZETRA nasal powder (sumatriptan) SUMAVEL DOSEPRO (sumtriptan) TREXIMET (sumatriptan/ naproxen) Sumatriptan nasal spray and injection ZECUITY patch (sumatriptan) ZEMBRACE SYMTOUCH injection (sumatriptan) ZOMIG (zolmitriptan)	Zomig nasal spray and Imitrex Nasal Spray: Max 6 inhalers / 30 days. Zecuity patch: Max 4 patches /30 days

COLORADO MEDICAID PROGRAM

1400
721-3947

December 08, 2016

PHARM2-12092016-270 T6 SN270
MICHAEL P. RYAN
PO BOX 3572
ESTES PARK, CO 80517-3572

THIS IS NOT A BILL.

This pharmacy prior authorization has been denied.

CLIENT ID:	Y406764
CLIENT NAME (L/F/M):	RYAN MICHAEL P
PROVIDER NAME:	FREESE, DANIEL J (DO)
EFFECTIVE DATE OF PRIOR AUTHORIZATION:	12/07/16
EXPIRATION DATE OF PRIOR AUTHORIZATION:	12/07/16
DRUG NAME:	EPCLUSA 400 MG-100 MG TABLE

DENIAL REASON
This prior authorization was denied because the client does not meet the criteria for approval. See Prior Authorization criteria on the Preferred Drug List (PDL) or APPENDIX P at www.colorado.gov/hcpf/provider-forms. (10 CCR 2505-10 □8.800.16.C)

If you have questions regarding this prior authorization denial, please contact your prescribing doctor or dentist.

FREESE 1ST VISIT OCT 26

FIBRA TEST REQUEST 11-21

PROVIDER LINE

Nếu bạn cần thông dịch hoặc có gì thắc mắc về lá thư nầy, xin liên lạc văn phòng y khoa hay người phụ trách hồ sơ của quận nơi bạn cư ngụ.
Si usted necesita la traducción o tienes preguntas con respecto a este aviso - por favor entre en contacto con su trabajador médico o a la oficina del Departamento de Servicios Social en el condado. If you need translation or have questions regarding this notice - please contact your medical office or county worker.

EXHIBIT D

Facsimile

xerox

To:	Prescriber	From:	Colo Denied
Fax:	7204943114	Pages:	23
Phone:		Date:	1/24/2017 5:42:54 PM

Rx Delivery Services

Xerox State Healthcare, LLC.
145 Technology Lane
Henderson, NC 27537

tel 800.365.4944
fax 888.772.9696

EPCLUSA PAR FOR MEMBER Y406764 DENIAL UPHELD. NO NEW INFORMATION PRES ENTED TO OVERTURN DENIAL. NO EVIDENCE OF MINIMUM METAVIR F2. YOU MAY ASSIST MEMBER WITH FORMAL APPEAL PER INSTRUCTIONS IN DENIAL LETTER. M SUTTON 012417 1742

#3286023

EXHIBIT E

Colorado Medicaid Hepatitis C Prior Authorization Request Form

Fax completed form and supporting documentation to: 888-772-9696 -for requests sent 10/1/16-2/28/17
Fax completed form and supporting documentation to: 800-424-5881 –for requests sent 3/1/17 and later

Please fill in ALL areas on form to avoid a delay in processing. Determinations for benefit coverage will not be able to be completed until the form is complete including submission of all required lab values/documentation. See the Preferred Drug List (PDL) page 22 -25 for full Hepatitis C PA criteria at: https://www.colorado.gov/hcpf/provider-forms under Pharmacy tab.

Note: The Department will only cover a once per lifetime treatment with any Direct Acting Antiviral

Member name: Michael Ryan DOB: 11/14/57 Medicaid ID: Y4006764 Gender: male ☐ female ☐

1-Has the member previously been treated for chronic Hepatitis C? ☒No ☐ Yes
1a-If yes, please list previous treatment regimen received: _____
- Approximate dates of therapy: _____
- If early discontinuation occurred, please describe: _____

2-Provider attests that member is ready to be compliant to the medication regimen ☐ No ☒Yes
- Prescribers should utilize assessment tools to evaluate readiness of the patient for treatment, some examples are available at: http://www.interqual.com/clinicalpractice/screening-tools#drugs or Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C) is available at: https://prepc.org/

3-Planned start date of Hepatitis C treatment (week 0): ASAP Please note, HCV RNA levels must be submitted at week 4 (Please use today's date if request is for treatment start date of as soon as possible)

4-Provider attests that SVR12 and SVR24 will be submitted timely via fax to 303-866-3590 ☐ No ☒Yes
- Hepatitis C Treatment Outcomes form is accessible at: https://www.colorado.gov/hcpf/provider-forms under Pharmacy tab

5-Member's complete current medication list is attached ☐ No ☒Yes
- Provider attests that significant drug-drug interactions have been screened for and addressed ☐ No ☐ Yes

6-Is the member abusing/misusing controlled substances and/or alcohol? ☒No ☐ Yes
6a-If yes, Provider attests that the member been enrolled in counseling or substance use treatment program for at least one month? ☐ No ☐ Yes
- Provider referrals can be requested from the member's Behavioral Health Organization by calling customer service, which is accessible at: https://www.colorado.gov/pacific/hcpf/behavioral-health-organizations under "Where is my BHO?"

6b-If yes, please describe: Provider/Facility/Treatment Program AND provide dates that member received services:
Name/Type: _____ Dates: _____

7-Is the member female and of childbearing potential? ☒No ☐ Yes
7a-If yes, is pregnancy test attached (must be dated not more than 30 days prior to beginning therapy)? ☒No ☐ Yes
- Is the member planning to become pregnant in the next 12 months? ☒No ☐ Yes

Physician: Daniel Freese Phone: 7204943123 Fax: 7204943114 NPI: 1144200296
Prescriber or prescriber agent signature (required): _____ Date: 1/24/17

Is the prescriber an infectious disease specialist, gastroenterologist, or hepatologist? ☐ No ☒ Yes

If no, is the requested drug being prescribed by a primary care provider in consultation with (**CIRCLE one**) an infectious disease specialist, gastroenterologist, or hepatologist? ☐ No ☐ Yes
If yes, please provide provider first and last name: _____

8-Genotype: ☐ 1a ☐ 1b ☒2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
8a-Has documentation been submitted confirming genotype within one year of start date? ☐ No ☐ Yes

9-Pre-treatment/baseline HCV RNA: IU/mL: 6.9million Date taken: 10/14/16
10-Hep A&B* vaccination series or immunity (please submit documentation/records) ☐ Completed ☒In Progress
(Or if Hepatitis B* co-infected, please indicate in diagnosis box #13)
11-Fibrosis (check one) ☐ F0 ☐ F1 ☒F2 ☐ F3 ☐ F4
11a- Cirrhosis (check one): ☒No cirrhosis ☐ Compensated Cirrhosis ☐ Decompensated Cirrhosis
- **Attach results for fibrosis level via FibroSure / FibroMeter / FibroTest / Imaging / Shear Wave Elastography**

12-Documentation/Score: **Biopsy**_____ **FibroScan** _____ (>7.1 kPa) **FibroMeter/Test/Sure** ✓ (>0.48 kPa)
APRI_____ (> 0.7) **FIB-4**_____ (> 1.5) **Shear Wave** _____ (>8.29kPa)
12a-If FibroTest/FibroMeter/Fibrosure was used, calculation for APRI or FIB-4 for concordance is required See Result
12b-If F4, Child-Pugh Score (number): _____

This form must be used for criteria effective October 1, 2016 Page 1

UNIVERSITY
of COLORADO HEALTH

To: Medicaid

From: Dr. Freese Gastro Longmont Clinic

Fax Number: 8668772969 6

Date: 1/24/17

Company:

Total No. of Pages Including Cover: 02

☑ Urgent ☐ For Review ☑ Please Comment ☐ Please Reply

NOTES

Michael Ryan
11/14/1957

Hep C prior authorization

DENIED

Colorado Medicaid Hepatitis C Prior Authorization Request Form

Fax completed form and supporting documentation to: 888-772-9696 –for requests sent 10/1/16-2/28/17
Fax completed form and supporting documentation to: 800-424-5881 –for requests sent 3/1/17 and later

13-Please indicate (by checking boxes below) and provide documentation of any applicable diagnoses:

☒ Chronic Hepatitis C	☐ Post-transplant	☐ Cirrhosis: ☐ CTP A (5-6) ☐ CTP B (7-9)	☐ CTP C (on transplant list)
☐ HIV/AIDS	☐ Hepatitis B+	☐ On transplant list with less than 1 year on the list projected	
☐ Ascites	☐ Variceal bleed	☐ Hepatic encephalopathy	☐ Leukocytoclastic vasculitis
☐ Membranoproliferative glomerulonephritis		☐ Severe renal impairment (eGFR< 30)	☐ Fibrosing cholestatic HCV
☐ Hepatocellular carcinoma meeting Milan criteria		☐ Symptomatic cryoglobulinemia	☐ Life expectancy < 1 year

+ Due to risk of HBV reactivation with DAAs FDA is directing health care professionals to screen and monitor for HBV in all patients receiving DAA treatment.

14-Preferred: Please check the requested preferred treatment regimen in left column below:

	Genotype	Patient Population	Preferred Treatment Regimen	Length of Authorization
☐	1a	No cirrhosis	Viekira* + ribavirin	12 weeks
☐		Treatment naïve and with compensated cirrhosis	Viekira* + ribavirin	12 weeks
☐		Treatment experienced and with compensated cirrhosis	Viekira* + ribavirin	24 weeks
☐	1b	With compensated cirrhosis or no cirrhosis	Viekira*	12 weeks
☒	2	No cirrhosis or with compensated cirrhosis	Epclusa	12 weeks
☐		With decompensated cirrhosis	Epclusa + ribavirin	12 weeks
☐	3	No cirrhosis or with compensated cirrhosis	Epclusa	12 weeks
☐		With decompensated cirrhosis	Epclusa + ribavirin	12 weeks
☐	4	With or without compensated cirrhosis	Technivie* + ribavirin	12 weeks

14a-Non-preferred: If requested regimen is not checked above, then list full Hep C medication regimen (+/- ribavirin) including length of treatment requested AND fill out 14b below:

Drug* (indicate strength if drug is available in more than one strength)	Requested Length of Treatment

14b-Please provide documentation below indicating sound rationale for prescribing a non-preferred treatment regimen (this may include, for example, patient specific medical contraindications to a preferred treatment). Note, if request is for a ribavirin ineligible member, documentation and medical notes must be provided for consideration of approval.

*Viekira/Technivie: Provider attests member will be enrolled in Abbvie proCead Nurse Connector Program ☐ No ☐ Yes
To enroll by Phone: 1-855-984-3547 or Fax: 1-866-299- 1687

All approved treatment regimens will be authorized for an initial approval of 6 weeks. Reauthorizations for refills will not be granted until required documentation is received (week 4 HCV RNA).

- If the week 4 HCV RNA is detectable (>25 copies) while on therapy, HCV RNA will be reassessed in 2 weeks. If the repeated HCV RNA level has not decreased (i.e., >1 log10 IU/ml from nadir) all treatment will be discontinued unless documentation is provided which supports continuation of therapy
- The member MUST receive refills within one week of completing the previous fill. Please allow ample time for reauthorization to occur after HCV RNA levels are submitted.

Please include a cover page and/or indicate number of pages being faxed to ensure complete processing of this request

This form must be used for criteria effective October 1, 2016

Facsimile

CONDUENT

To:	Prescriber	From:	Colo Denied
Fax:	3034424866	Pages:	24
Phone:		Date:	2/13/2017 10:56:30 AM

Rx Delivery Services
145 Technology Lane
Henderson, NC 27537
tel 800.365.4944
fax 888.772.9696

SM (P449829)
EPCLUSA DENIED: FIBROTEST .68= F3; APRI 0.223; FIB4 0.86; NONCONCO
RDANCE.
FIBROTEST IS NOT SUPPORTED BY EITHER APRI OR FIB4. DO YOU HAVE EITHER
IMAGING, BIOPSY, OR FIBROSCAN?
BPOTTER

TA OK

EXHIBIT F

23 pages

Colorado Medicaid Hepatitis C Prior Authorization Request Form

Fax completed form and supporting documentation to: 888-772-9696 -for requests sent 10/1/16-2/28/17
Fax completed form and supporting documentation to: 800-424-5881 -for requests sent 3/1/17 and later

Please fill in ALL areas on form to avoid a delay in processing. Determinations for benefit coverage will not be able to be completed until the form is complete including submission of all required lab values/documentation. See the Preferred Drug List (PDL) page 22 -25 for full Hepatitis C PA criteria at: https://www.colorado.gov/hcpf/provider-forms under Pharmacy tab.

Note: The Department will only cover a once per lifetime treatment with any Direct Acting Antiviral

Member name: Jaxon Molina DOB: 9/ [illegible] Medicaid ID: [illegible] Gender: ☐ male ☐ female

1-Has the member previously been treated for chronic Hepatitis C? ☒ No ☐ Yes
1a-If yes, please list previous treatment regimen received: _____
- Approximate dates of therapy: _____
- If early discontinuation occurred, please describe: _____

2-Provider attests that member is ready to be compliant to the medication regimen ☐ No ☒ Yes
- Prescribers should utilize assessment tools to evaluate readiness of the patient for treatment, some examples are available at: http://www.integration.samhsa.gov/clinicalpractice/screening-tools#drugs or Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C) is available at: https://prepc.org/

3-Planned start date of Hepatitis C treatment (week 0): 12/ [illegible] /16 Please note, HCV RNA levels must be submitted at week 4. (Please use today's date if request is for treatment start date of as soon as possible)

4-Provider attests that SVR12 and SVR24 will be submitted timely via fax to 303-866-3590 ☐ No ☒ Yes
- Hepatitis C Treatment Outcomes form is accessible at: https://www.colorado.gov/hcpf/provider-forms under Pharmacy tab

5-Member's complete current medication list is attached ☐ No ☒ Yes
- Provider attests that significant drug-drug interactions have been screened for and addressed ☐ No ☒ Yes

6-Is the member abusing/misusing controlled substances and/or alcohol? ☐ No ☒ Yes
6a-If yes, Provider attests that the member been enrolled in counseling or substance use treatment program for at least one month? ☐ No ☐ Yes N/A
- Provider referrals can be requested from the member's Behavioral Health Organization by calling customer service, which is accessible at: https://www.colorado.gov/pacific/hcpf/behavioral-health-organizations under "Where is my BHO?"

6b-If yes, please describe: Provider/Facility/Treatment Program AND provide dates that member received services:
Name/Type: _____ Dates: _____ _____

7-Is the member female and of childbearing potential? ☒ No ☐ Yes
7a-If yes, is pregnancy test attached (must be dated not more than 90 days prior to beginning therapy)? ☐ No ☐ Yes
- Is the member planning to become pregnant in the next 12 months? ☐ No ☐ Yes

Physician: Richard Moseley Phone: 303-[illegible] Fax: 303-443-[illegible] NPI: 1467345843
Prescriber or prescriber agent signature (required): [signature] Date: 12/9/16

Is the prescriber an infectious disease specialist, gastroenterologist, or hepatologist? ☐ No ☒ Yes

If no, is the requested drug being prescribed by a primary care provider in consultation with (CIRCLE one) an infectious disease specialist, gastroenterologist, or hepatologist? ☐ No ☐ Yes
If yes, please provide provider first and last name: _____

8-Genotype: ☐ 1a ☐ 1b ☐ 2 ☒ 3a ☐ 4 ☐ 5 ☐ 6
8a-Has documentation been submitted confirming genotype within one year of start date? ☐ No ☒ Yes

9-Pre-treatment/baseline HCV RNA: IU/mL: 1429100 Date taken: 10/25/16
10-Hep A&B* vaccination series or immunity (please submit documentation/records) ☐ Completed ☒ In Progress
(Or if Hepatitis B* co-infected, please indicate in diagnosis box #13)
11-Fibrosis (check one) ☐ F0 ☐ F1 ☐ F2 ☒ F3 ☐ F4
11a- Cirrhosis (check one): ☐ No cirrhosis ☐ Compensated Cirrhosis ☐ Decompensated Cirrhosis
- Attach results for fibrosis level via FibroSure / FibroMeter / FibroTest / Imaging / Shear Wave Elastography

12-Documentation/Score: Biopsy: _____ FibroScan _____ (>7.1 kPa) FibroMeter/Test/Score 0.60 (>0.48 kPa)
APRI 0.334 (>0.7) FIB-4 0.83 (>1.5) Shear Wave _____ (>8.39kPa)
12a-If FibroTest/FibroMeter/Fibrosure was used, calculation for APRI or FIB-4 for concordance is required
12b-If F4, Child-Pugh Score (number): _____

This form must be used for criteria effective October 1, 2016

Colorado Medicaid Hepatitis C Prior Authorization Request Form

Fax completed form and supporting documentation to: 888-772-9896 –for requests sent 10/1/16-2/28/17
Fax completed form and supporting documentation to: 800-424-5881 –for requests sent 3/1/17 and later

13-Please indicate (by checking boxes below) and provide documentation of any applicable diagnoses:

- ☐ Chronic Hepatitis C
- ☐ HIV/AIDS
- ☐ Ascites
- ☐ Membranoproliferative glomerulonephritis
- ☐ Hepatocellular carcinoma meeting Milan criteria
- ☐ Post-transplant
- ☐ Hepatitis B*
- ☐ Variceal bleed
- ☐ Cirrhosis: ☐ CTP A (5-6) ☐ CTP B (7-9) ☐ CTP C (on transplant list)
- ☐ On transplant list with less than 1 year on the list projected
- ☐ Hepatic encephalopathy
- ☐ Severe renal impairment (eGFR< 30)
- ☐ Symptomatic cryoglobulinemia
- ☐ Leukocytoclastic vasculitis
- ☐ Fibrosing cholestatic HCV
- ☐ Life expectancy < 1 year

* Due to risk of HBV reactivation with DAAs FDA is directing health care professionals to screen and monitor for HBV in all patients receiving DAA treatment.

14-Preferred: Please check the requested preferred treatment regimen in left column below:

	Genotype	Patient Population	Preferred Treatment Regimen	Length of Authorization
☐	1a	No cirrhosis	Viekira* + ribavirin	12 weeks
☐		Treatment naive and with compensated cirrhosis	Viekira* + ribavirin	12 weeks
☐		Treatment experienced and with compensated cirrhosis	Viekira* + ribavirin	24 weeks
☐	1b	With compensated cirrhosis or no cirrhosis	Viekira*	12 weeks
☐	2	No cirrhosis or with compensated cirrhosis	Epclusa	12 weeks
☐		With decompensated cirrhosis	Epclusa + ribavirin	12 weeks
☒	3	No cirrhosis or with compensated cirrhosis	Epclusa	12 weeks
☐		With decompensated cirrhosis	Epclusa + ribavirin	12 weeks
☐	4	With or without compensated cirrhosis	Technivie* + ribavirin	12 weeks

14a-Non-preferred: If requested regimen is not checked above, then list full Hep C medication regimen (+/- ribavirin) including length of treatment requested AND fill out 14b below:

Drug* (indicate strength if drug is available in more than one strength)	Requested Length of Treatment

14b-Please provide documentation below indicating sound rationale for prescribing a non-preferred treatment regimen (this may include, for example, patient specific medical contraindications to a preferred treatment). Note, if request is for a ribavirin ineligible member, documentation and medical notes must be provided for consideration of approval.

***Viekira/Technivie:** Provider attests member will be enrolled in Abbvie proCeed Nurse Connector Program ☐ No ☐ Yes
To enroll by Phone: 1-855-984-3547 or Fax: 1-866-299-1687 or online at: https://www.viekira.com/proceed-program

All approved treatment regimens will be authorized for an initial approval of 8 weeks. Reauthorizations for refills will not be granted until required documentation is received (week 4 HCV RNA).

- If the Week 4 HCV RNA is detectable (>25 copies) while on therapy, HCV RNA will be reassessed in 2 weeks. If the repeated HCV RNA level has not decreased (i.e., >1 log10 IU/ml from nadir) all treatment will be discontinued unless documentation is provided which supports continuation of therapy
- The member MUST receive refills within one week of completing the previous fill. Please allow ample time for reauthorization to occur after HCV RNA levels are submitted.

Please include a cover page and/or indicate number of pages being faxed to ensure complete processing of this request

This form must be used for criteria effective October 1, 2016

Molina, Sharon 48y F
DOB: 09/16/68

Patient Chart Report

10/28/16 1:24 pm

GASTROENTEROLOGY OF THE ROCKIES

Patient Information

Demographics

Patient Number	183781
Chart Number	
Age/Sex	48y F
Marital Status	Legally Separated
Emp. Status	Not Employed
Assigned Prov	
Primary Care Prov	Scanlon, Jennifer NP
Care Coordinator	
Referring Prov	Scanlon, Jennifer NP (303) 650-4480
Rel. to Guarantor	Self
Date of Birth	09/16/1968
Race	Race Not Reported - Refusal
Language	English
Mother's Maiden	
Social Security #	
Became Patient	09/13/16
Last Visit	10/03/16
Home Phone	(720) 296-2358
Work Phone	
Mobile Phone	
Address	3003 Valmont #30 Pt is Homeless Boulder, CO 80301
Patient Consent	Yes
Rx History Consent	Rx Hx Consent Given for Any Prescriber
Date Set	10/05/16
Consent Notes	

Additional Information

Name pt Prefers	Sharon
Previous Endo	N
Proc Type	n
Proc Year	n
Reason For Appt	LIVNEW -chronic viral hepatitis C
Past Surg/ Health HX	lump on back (2016)
Added HX	hbp
Fam Hx Colon Ca	n
FHX Polyps	N
PHX of Polyps	N
HEME Test	N
Diabetic	n
Pills	N
Diet	N
Insulin	N
Constipation	N
Pacemaker	N
Defibrillator	N
Heart Attack/Stroke	n
Bmell	n/a
Blood Thinner	N
Managing MD (Blood	n
Wheelchair/Need	n
Allergy	morphine
Recall Method	Paper
Exempt from Reports	
Patient Exempt	No
Hx of Renal/Kidney	N
Hx of Congestive	N
HX of Conscious	Y
Tolerated Well	Y
HX of General	Y
Tolerated Well	Y
MiraLAX	n
NuLYTELY	n
Prepopio	n
SUPREP	n
Other	n
Height	5.3
Weight	150
Taken By	MDavis
Date	9/13/2016

Colorado Medicaid Prior Authorization Request Form

2 pages

PREFERRED: Viekira Pak (ombitasvir, paritaprevir, ritonavir, dasabuvir)

NONPREFERRED: Daklinza (daclatisvir), Harvoni (sofosbuvir and ledipasvir), Sovaldi (sofosbuvir), Technivie (ombitasvir, paritaprevir, ritonavir), Olysio (simeprevir), Zepatier (elbasvir/grazoprevir)

This form must be signed by prescriber or prescriber's agent to request prior authorization for treatment agents for Hepatitis C beginning March 1, 2016. See the Preferred Drug List (PDL) for details at: https://www.colorado.gov/hcpf/provider-forms. Certain documentation is required to accompany this form for approval consideration. Prescriber must be a physician who is a hepatologist, infectious disease specialist, or gastroenterologist or a physician working in consultation with one of these specialists.

Please fill in ALL areas on form to avoid a delay in processing. Requests cannot be approved if the form is incomplete or there are missing required lab values/documentation.

Select requested drug(s) and co-administration drugs: ☐ Viekira Pak ☒ Sovaldi ☐ Harvoni ☐ Daklinza ☐ Technivie (noncirrhotic only) ☐ Olysio ☐ Zepatier ☒ Ribavirin ☐ Peg-Interferon

Member name: [redacted] DOB: 1/3/1953

Medicaid ID: [redacted] Gender: M BMI: 24.1 CrCl ml/min: 51 Baseline ALT 41

Genotype: ☐ 1a ☐ 1b ☒ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Child-Pugh Score: 5 (5-9, not A, B) Prevx HCV RNA IU/mL: 1,490,000 Hep A&B vaccination series ☐ Completed ☒ In Progress (provide lab/immunization record)

Any fibrosis? (must provide labs and show calculation for APRI/FIB-4/FibroSure/FibroMeter/FibroTest) ☐ No ☒ Yes

Provide scores: Biopsy ____ (Applicable scores) FibroScan ____ (F3-4 >9.6kPa) FibroMeter/Test/Sure 1.19 (>0.90kPa) APRI 2.16 (>1) FIB-4 6.53 (>2.2) Imaging ____

Viekira/Technivie: Provider attests member will be enrolled in Abbvie proCaad Nurse Connector Program ☐ Yes

Provider attests that member is ready to be compliant to the medication regimen ☒ Yes

Provider attests that SVR12 and SVR24 will be submitted timely via fax to **888-772-9696** ☒ Yes

History of drug/alcohol misuse/abuse? ☐ No ☒ Yes

Has member been drug/alcohol free for at least 6 months? ☐ No ☒ Yes

Attached screens (not more than 30 days old) ☒ Marijuana ☒ Toxicology ☐ ETOH

ALL members must provide initial drug/alcohol screen documentation which must include marijuana. For members that have a recent history of misuse/abuse (within last 2 years), random monthly screens should be provided during treatment.

Prior Treatment: ☒ No ☐ Yes **Describe with approximate dates:** ____

Indicate member's diagnosis(es) (provide documentation):

- ☒ Chronic Hepatitis C
- ☐ HIV/AIDS
- ☐ Ascites
- ☐ Membranoproliferative glomerulonephritis
- ☐ Hepatocellular carcinoma meeting Milan criteria
- ☐ Post-transplant
- ☐ Hepatitis B
- ☐ Variceal bleed
- ☐ Cirrhosis: ☒ CTP A (5-6) ☐ CTP B (7-9) ☐ CTP C (on transplant list)
- ☐ On transplant list with less than 1 year on the list projected
- ☐ Hepatic encephalopathy
- ☐ Severe renal impairment (eGFR< 30)
- ☐ Symptomatic cryoglobulinemia despite mild liver disease
- ☐ Leukocytoclastic vasculitis
- ☐ Fibrosing cholestatic HCV

Sovaldi and Olysio: If Peginterferon alfa ineligible (circle): Platelet count <75,000mm³; CTP Class B/C; Uncontrolled mood disorder or history of psychosis; Autoimmune hepatitis and another autoimmune disorder; Documented interferon-related adverse event - (provide documentation)

Olysio and Zepatier: If GT1a: NS3 Q80K or NS5A resistance polymorphism? (provide documentation) ☐ No ☐ Yes

Complete current medication list required. Attached? ☒ Yes

Provider attests that significant drug-drug interactions have been addressed ☐ No ☒ Yes

Female members: Is member of childbearing potential? ☒ No ☐ Yes (provide pregnancy test)

Is requested drug being prescribed in conjunction with (CIRCLE) an infectious disease specialist, gastroenterologist, or hepatologist?

☐ No ☒ Yes Identify provider first and last name and specialty (circle above): [redacted]

Initial approval: 8 week supply. Refills: not granted unless required documentation is received.

Physician: [redacted] Phone: 303-604-5000 Fax: 720-870-0324 NPI: 1447 3438438

Physician signature: [redacted] Date: 3/29/16

(Must be signed by physician or physician's agent for attestation)

Effective March 1, 2016 **Please fax completed form and supporting documentation to 888-772-9696**

10 Pages

Colorado Medicaid Hepatitis C Prior Authorization Request Form

Fax completed form and supporting documentation to: 888-772-9696 -for requests sent 10/1/16-10/30/16
Fax completed form and supporting documentation to: 800-624-5881 -for requests sent 10/31/16 and later

Please fill in ALL areas on form to avoid a delay in processing. Determinations for benefit coverage will not be able to be completed until the form is complete including submission of all required lab values/documentation. See the Preferred Drug List (PDL) page 22 -25 for full Hepatitis C PA criteria at: https://www.colorado.gov/hcpf/provider-forms under Pharmacy tab.

Note: The Department will only cover a once per lifetime treatment with any Direct Acting Antiviral

Member name: Earl [illegible] DOB: 1/31/1952 Medicaid ID: 188[illegible]31 Gender: male ☒ female ☐

1-Has the member previously been treated for chronic Hepatitis C? ☒ No ☐ Yes
1a-If yes, please list previous treatment regimen received: _____
- Approximate dates of therapy: _____
- If early discontinuation occurred, please describe: _____

2-Provider attests that member is ready-to be compliant to the medication regimen ☐ No ☒ Yes
- Prescribers should utilize assessment tools to evaluate readiness of the patient for treatment, some examples are available at: http://www.integration.samhsa.gov/clinicalpractice/screening-tools#drugs or Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C) is available at: https://prepc.org/

3-Planned start date of Hepatitis C treatment (week 0): _____ Please note, HCV RNA levels must be submitted at week 4 (Please use today's date if request is for treatment start date of as soon as possible)

4-Provider attests that SVR12 and SVR24 will be submitted timely via fax to 303-866-3599 ☐ No ☒ Yes
- Hepatitis C Treatment Outcomes form is accessible at: https://www.colorado.gov/hcpf/provider-forms under Pharmacy tab

5-Member's complete current medication list is attached ☐ No ☒ Yes
- Provider attests that significant drug-drug interactions have been screened for and addressed ☐ No ☒ Yes

6-Is the member abusing/misusing controlled substances and/or alcohol? ☒ No ☐ Yes
6a-If yes, Provider attests that the member been enrolled in counseling or substance use treatment program for at least one month? ☐ No ☐ Yes
- Provider referrals can be requested from the member's Behavioral Health Organization by calling customer service, which is accessible at: https://www.colorado.gov/pacific/hcpf/behavioral-health-organizations under "Where is my BHO?"

6b-If yes, please describe: Provider/Facility/Treatment Program AND provide dates that member received services:
Name/Type: _____ Dates: _____ _____ _____ _____

7-Is the member female and of childbearing potential? ☒ No ☐ Yes
7a-If yes, is pregnancy test attached (must be dated not more than 30 days prior to beginning therapy)? ☐ No ☐ Yes
- Is the member planning to become pregnant in the next 12 months? ☐ No ☐ Yes

Physician: Richard Moseley Phone: 303-[illegible] Fax: 720-[illegible] NPI: 1447343843[illegible]
Prescriber or prescriber agent signature (required): [signature] MD Date: 10/6/16

Is the prescriber an infectious disease specialist, gastroenterologist, or hepatologist? ☐ No ☒ Yes

If no, is the requested drug being prescribed by a primary care provider in consultation with (CIRCLE one) an infectious disease specialist, gastroenterologist, or hepatologist? ☐ No ☐ Yes
If yes, please provide provider first and last name: _____

8-Genotype: ☐ 1a ☐ 1b ☒ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
8a-Has documentation been submitted confirming genotype within one year of start date? ☐ No ☒ Yes

9-Pre-treatment/baseline HCV RNA: IU/mL: 9860000 Date taken: 9/20/16
10-Hep A&B vaccination series or immunity (please submit documentation/records) ☒ Completed ☐ Progress
(Or if Hepatitis B co-infected, please indicate in diagnosis box #13)

11-Fibrosis (check one): ☐ F0 ☐ F1 ☒ F2 ☐ F3 ☐ F4
11a- Cirrhosis (check one): ☒ No cirrhosis ☐ Compensated Cirrhosis ☐ Decompensated Cirrhosis
- Attach results for fibrosis level via FibroSure / FibroMeter / FibroTest / Imaging / Shear Wave Elastography

12-Documentation/Score: Biopsy _____ FibroScan _____ (>7.1 kPa) FibroMeter/Test/Sure iD 3.3 (>0.48 kPa)
APRI 0.1853 (> 0.7) FIB-4 0.85 (> 1.5) Shear Wave _____ (>8.29kPa)

12a-If F2 or F3, provide documentation of FibroTest/FibroMeter PLUS calculation for APRI or FIB-4 for concordance
12b-If F4, Child-Pugh Score (number): 5

This form must be used for criteria effective October 1, 2016 Page 1

Colorado Medicaid Hepatitis C Prior Authorization Request Form

Fax completed form and supporting documentation to: 855-772-9696 -for requests sent 10/1/16-10/30/16
Fax completed form and supporting documentation to: 800-424-2881 -for requests sent 10/31/16 and later

13-Please indicate (by checking boxes below) and provide documentation of any applicable diagnoses:

- ☒ Chronic Hepatitis C
- ☐ HIV/AIDS
- ☐ Ascites
- ☐ Membranoproliferative glomerulonephritis
- ☐ Hepatocellular carcinoma meeting Milan criteria
- ☐ Post-transplant
- ☐ Hepatitis B
- ☐ Variceal bleed
- ☐ Cirrhosis: ☒ CTP A (5-6) ☐ CTP B (7-9) ☐ CTP C (on transplant list)
- ☐ On transplant list with less than 1 year on the list projected
- ☐ Hepatic encephalopathy
- ☐ Severe renal impairment (eGFR< 30)
- ☐ Symptomatic cryoglobulinemia
- ☐ Leukocytoclastic vasculitis
- ☐ Fibrosing cholestatic HCV
- ☐ Life expectancy < 1 year

14-Please check the requested preferred treatment regimen in left column below:

	Genotype	Patient Population	Treatment Regimen	Length of Authorization
☐	1a	No cirrhosis	Viekira* + ribavirin	12 weeks
☐		Treatment naive and with compensated cirrhosis	Viekira* + ribavirin	12 weeks
☐		Treatment experienced and with compensated cirrhosis	Viekira* + ribavirin	24 weeks
☐	1b	With compensated cirrhosis or no cirrhosis	Viekira*	12 weeks
☐	2	No cirrhosis or with compensated cirrhosis	Epclusa	12 weeks
☐		With decompensated cirrhosis	Epclusa + ribavirin	12 weeks
☐	3	No cirrhosis or with compensated cirrhosis	Epclusa	12 weeks
☐		With decompensated cirrhosis	Epclusa + ribavirin	12 weeks
☐	4	With or without compensated cirrhosis	Technivie* + ribavirin	12 weeks

14a-If requested regimen is not checked above, then list full Hep C medication regimen (+/- ribavirin) including length of treatment requested AND fill out 14b below:

Drug* (indicate strength if drug is available in more than one strength)	Requested Length of Treatment

14b-Please provide documentation below indicating sound rationale for prescribing a non-preferred treatment regimen (this may include, for example, patient specific medical contraindications to a preferred treatment). Note, if request is for a ribavirin ineligible member, documentation and medical notes must be provided for consideration of approval.

*Viekira/Technivie: Provider attests member will be enrolled in Abbvie proCeed Nurse Connector Program ☐ No ☐ Yes
To enroll by Phone: 1-855-984-3547 or Fax: 1-866-299-1687

All approved treatment regimens will be authorized for an initial approval of 8 weeks. Reauthorizations for refills will not be granted until required documentation is received (week 4 HCV RNA).

- If the week 4 HCV RNA is detectable (>25 copies) while on therapy, HCV RNA will be reassessed in 2 weeks. If the repeated HCV RNA level has not decreased (i.e., >1 log10 IU/ml from nadir) all treatment will be discontinued unless documentation is provided which supports continuation of therapy
- The member MUST receive refills within one week of completing the previous fill. Please allow ample time for reauthorization to occur after HCV RNA levels are submitted.

Please include a cover page and/or indicate number of pages being faxed to ensure complete processing of this request

This form must be used for criteria effective October 1, 2016

EXHIBIT G

Facsimile

To:	See Cover Sheet Notes	From:	Colo Denied
Fax:	7208900364	Pages:	27
Phone:		Date:	10/11/2016 10:27:26 AM

Rx Delivery Services

Xerox State Healthcare, LLC.
145 Technology Lane
Henderson, NC 27537

tel 800.365.4944
fax 888.772.9696

EM (J881431)
EPCLUSA DENIED: FIBROTEST 0.33= F1-F2; APRI 0.185; FIB4 0.83;
NONCONCORDANCE
BP

EXHIBIT H

JS 44 (Rev. 11/15) District of Colorado Form

CIVIL COVER SHEET

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.)*

I. (a) PLAINTIFFS

MICHAEL RYAN, EARBY MOXON, and SHARON MOLINA, on behalf of themselves and all others similarly situated

(b) County of Residence of First Listed Plaintiff Larimer County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
See Attachment

DEFENDANTS

SUSAN E. BIRCH, in her official capacity only as Executive Director of the COLORADO STATE DEPARTMENT OF HEALTH CARE POLICY & FINANCING

County of Residence of First Listed Defendant Denver County
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ❒ 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)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
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- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

CIVIL RIGHTS
- ☒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
42 U.S.C. § 1983; 42 U.S.C. §1396; 42 C.F.R. § 440.240

Brief description of cause:
Violations of Title XIX of the Social Security Act of 1965

☐ AP Docket

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ Declaratory Judgment and Injunction

CHECK YES only if demanded in complaint:
JURY DEMAND: ❒ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
04/13/2017

SIGNATURE OF ATTORNEY OF RECORD
/s/ Paul G. Karlsgodt

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

Print Save As... Reset

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked**.** (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service; **OR "AP Docket."**

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. _____

MICHAEL RYAN, and
EARBY MOXON, and
SHARON MOLINA,
on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

SUSAN E. BIRCH, in her official capacity only as
Executive Director of the COLORADO STATE DEPARTMENT OF HEALTH
CARE POLICY& FINANCING,

Defendant.

CIVIL COVER SHEET ATTACHMENT:

ATTORNEYS APPEARING ON BEHALF OF PLAINTIFFS

Mark Silverstein, #26979
Sara R. Neel, #36904
ACLU FOUNDATION OF COLORADO
303 E. Seventeenth Ave., Suite 350
Denver, CO 80203
Phone: 720.402.3107
Email: msilverstein@aclu-co.org
sneel@aclu-co.org

Kevin Costello
HARVARD LAW SCHOOL CENTER FOR
HEALTH LAW & POLICY INNOVATION
122 Boylston Street
Jamaica Plain, MA 02130
Tel. (617) 390-2578
Email: kcostello@law.harvard.edu

Paul G. Karlsgodt, #29004
BAKER & HOSTETLER LLP
1801 California Street, Suite 4400
Denver, CO 80202-2662
Tel. (303) 861-0600
Email: pkarlsgodt@bakerlaw.com

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. _____

MICHAEL RYAN, and
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on behalf of themselves and all others similarly situated,

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SUSAN E. BIRCH, in her official capacity only as
Executive Director of the COLORADO STATE DEPARTMENT OF HEALTH
CARE POLICY& FINANCING,

Defendant.

PLAINTIFFS' NOTICE OF RELATED CASE

Under Local Rule 3.2, "[a] party to a case shall file a notice identifying all cases *pending* in this or any other federal, state, or foreign jurisdiction that are related to the case." Related cases include "cases that have common facts and claims and (1) have at least one party in common; or (2) are filed serially or collectively as a group by the same attorney or law firm." D.C.COLO.LCivR 3.2. Plaintiffs are not aware of any cases meeting the requirements of Local Rule 3.2. Nonetheless, Plaintiffs file this notice to apprise this Court of a previously-dismissed case involving common facts and claims as well as a party in common with the instant suit:

(1) *Cunningham v. Birch*, Case No. 1:16-cv-02353-NYW, U.S. District Court for the District of Colorado (the "*Cunningham* case").

On February 17, 2017, Magistrate Judge Nina Wang entered a Memorandum Opinion and Order dismissing the *Cunningham* case without prejudice. Final judgment was entered by the Clerk of the Court on February 17, 2017.

Dated: April 13, 2017

/s/ Paul G. Karlsgodt
Paul G. Karlsgodt, #29004

BAKER & HOSTETLER LLP (CO)
1801 California Street, Suite 4400
Denver, CO 80202
Phone: 303.861.0600
Email: pkarlsgodt@bakerlaw.com
dmcmillan@bakerlaw.com
stillotson@bakerlaw.com

In cooperation with the ACLU Foundation of Colorado

/s/ Mark Silverstein
Mark Silverstein, #26979
Sara R. Neel, #36904

ACLU FOUNDATION OF COLORADO
303 E. Seventeenth Ave., Suite 350
Denver, CO 80203
Phone: 720.402.3107
Fax: 303.777.1773
Email: msilverstein@aclu-co.org
sneel@aclu-co.org

Kevin Costello

HARVARD LAW SCHOOL
CENTER FOR HEALTH LAW & POLICY INNOVATION
122 Boylston Street
Jamaica Plain, MA 02130
Phone: 617.390.2578
Email: kcostello@law.harvard.edu

ATTORNEYS FOR PLAINTIFFS

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Colorado

MICHAEL RYAN, EARBY MOXON, and SHARON MOLINA, on behalf of themselves and all others similarly situated

Plaintiff(s)

v.

SUSAN E. BIRCH, in her official capacity only as Executive Director of the COLORADO STATE DEPARTMENT OF HEALTH CARE POLICY & FINANCING

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* SUSAN E. BIRCH, COLORADO STATE DEPARTMENT OF HEALTH CARE POLICY& FINANCING, 1570 Grant Street, Denver, CO 80203-1818

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: Mark Silverstein, Sara R. Neel, ACLU FOUNDATION OF COLORADO, 303 E. Seventeenth Ave., Suite 350, Denver, CO 80203; Paul G. Karlsgodt, BAKER & HOSTETLER LLP, 1801 California Street, Suite 4400, Denver, CO 80202; Kevin Costello, HARVARD LAW SCHOOL CENTER FOR HEALTH LAW & POLICY INNOVATION 122 Boylston Street, Jamaica Plain, MA 02130

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: _____

_____

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