UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

DORENA COLEMAN, CURTIS JACKSON, and FEDERICO PEREZ, on behalf of themselves and all others similarly situated, Plaintiffs, v. PHIL WILSON, Acting Executive Commissioner, VICTORIA FORD, Chief Policy and Regulatory Officer, MAURICE MCCREARY, Chief Operating Officer, and MICHELLE ALLETTO, Chief Program and Services Officer, in their official capacities with the Texas Health and Human Services Commission, Defendants.	No. 1:20-cv00847-RP

MOTION FOR CERTIFICATION OF CLASS, APPROVAL OF CLASS REPRESENTATIVES, AND APPOINTMENT OF CLASS COUNSEL

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

RULES

TREATISES

REGULATIONS

CONSTITUTIONAL PROVISIONS

OTHER AUTHORITIES

Plaintiffs Dorena Coleman, Curtis Jackson, and Federico Perez ("Plaintiffs"), move for class certification under Federal Rules of Civil Procedure 23(a) and 23(b)(2).[1] For the reasons that follow, class certification is warranted.

I. INTRODUCTION

Plaintiffs are certain Texas Medicaid enrollees who are diagnosed as chronically infected with the Hepatitis C Virus ("HCV"), a widespread contagious disease of the liver. More than 17,000 people in the United States die each year due to HCV, making it the deadliest infectious disease in the United States (prior to the COVID-19 pandemic). *See* Decl. of Dr. Stacey Trooskin, M.D., PhD, M.P.H. ("Trooskin Decl."), ¶ 4 (July 24, 2020) (attached as Exhibit A to the Appendix of Exhibits filed concurrently herewith in support of this motion).[2,3] The Center for Disease Control and Prevention ("CDC") estimates that more than 2 million people in the United States have chronic HCV, *id.*, while the Texas Health and Human Services Commission ("HHSC") and Texas Department of State Health Services estimate that over 500,000 Texans suffer from the disease, *id.* at ¶ 15 & n.7.

[1] At the time this motion was filed, Defendants had not entered an appearance, and thus conference could not take place. Plaintiffs will confer with defense counsel regarding this motion as soon as Defendants enter an appearance, or Plaintiffs' counsel otherwise learns the appropriate attorneys to confer with.

[2] All exhibits referenced herein as Exhibits A thru G are attached to the Appendix of Exhibits filed concurrently herewith in support of this motion.

[3] *See* TEX. HEALTH & HUMAN SERVS., *2020 State Plan for Hepatitis C: As Required by Texas Health & Safety Code Section 94.001* ("TEX. HHS, *2020 State Plan for HCV*") 1, 4 (Aug. 2019), https://www.dshs.state.tx.us/legislative/2019-Reports/2020-State-Plan-for-Hepatitis-C.pdf (*also available via* https://dshs.texas.gov/legislative/Reports-2019.aspx).

A curative "breakthrough" treatment for HCV – called direct-acting antivirals ("DAAs") – has been available since 2013.[4] Ex. A, Trooskin Decl. ¶ 8. Unlike prior treatments for HCV, DAAs have success rates for treating HCV over 90%. *Id.* The clinical standard of care is DAA treatment for nearly everyone living with chronic HCV, regardless of the extent to which the virus has damaged their liver. *Id.* at ¶ 9, 16; Ex. B, Decl. of Dr. Benjamin P. Linas ("Linas Decl."), ¶ 6 (July 24, 2020). Medicare, the United States Department of Veterans Affairs, and the majority of commercial health insurers cover DAA treatment to all patients living with chronic HCV, without respect to the patient's disease stage or amount of liver damage. Ex. A, Trooskin Decl. ¶ 16.

In addition, the federal agency responsible for administering Medicaid, the Centers for Medicare and Medicaid Services ("CMS"), has issued guidance concerning state Medicaid programs' restrictive HCV coverage policies ("the Guidance").[5] The Guidance warns that federal law prohibits policies that result in the denial of access to effective, clinically appropriate, and medically necessary treatment, specifically citing the type of disease severity restriction imposed by HHSC as an example of a policy that is "contrary to [] statutory requirements." *See id.*

Despite CMS's Guidance and the medical consensus that DAA treatment is the standard of care for HCV, HHSC – the agency responsible for managing the Texas Medicaid Program –

---

[4] The FDA defines a breakthrough therapy as a drug "intended alone or in combination with one or more other drugs to treat a serious or life threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development." FOOD & DRUG ADMIN. SAFETY & INNOVATION ACT (FDASIA), *Fact Sheet: Breakthrough Therapies* (Mar. 28, 2018), https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDASIA/ucm329491.htm.

[5] *See* CMS, *Medicaid Drug Rebate Program Notice, Release No.* 172 (Nov. 5, 2015), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf.

has illegally limited access to this cure for thousands of individual currently living with chronic HCV. HHSC's discriminatory coverage policy and practice (the "Policy") treats putative class members differently from other similarly situated Medicaid enrollees.[6] The Policy makes a categorical distinction by fibrosis score (one measure of liver damage) that arbitrarily rations DAA treatment, both among those who have HCV and when comparing putative class members to other Medicaid enrollees suffering from other chronic illnesses. Texas's policy will not cover treatment for putative class members that would *cure* their chronic HCV until they have become so sick that they suffer potentially irreversible damage to their bodies. HSSC's refusal to treat thousands of Medicaid recipients infected with HCV contravenes the medical standard of care and is not supported by any medical literature. It is driven solely by short-term cost concerns. The short-sightedness of such a restrictive policy is plain: significant evidence indicates that DAAs are a cost-effective treatment at all stages of disease severity because early treatment saves individuals from requiring costlier medical interventions down the line (including organ transplants), and slows the spread of the virus among the population. *See* Ex. A, Trooskin Decl. ¶ 9 & n.5; Ex. B, Linas Decl. ¶ 3. HHSC's policy is thus not only illegal, it is also poor fiscal strategy.

The key facts relevant to this motion for class certification are straightforward: the Defendants prohibit access to curative treatment by imposing the common Policy on thousands of putative class members, each diagnosed with the same disease and seeking the same treatment but refused coverage because they did not have a fibrosis score of F3 or F4 as required by Texas's unlawful Policy.

---

[6] Ex. G, TEX. HEALTH & HUMAN SERVS., *Vendor Drug Program: Antiviral Agents for Hepatitis C Virus Initial Authorization Request (Medicaid) Form 1335* ("TEX. HHS, *Vendor Drug Program, (Medicaid) Form*") (Mar. 2018-E), https://paxpress.txpa.hidinc.com/hepc_initial_request.pdf (*also available via* https://www.txvendordrug.com/formulary/prior-authorization/ffs-clinical-pa).

This is an ideal case for class certification.[7] The Plaintiffs seek declaratory and injunctive relief: specifically, a judgment declaring that HHSC's Policy violates federal law and an injunction forbidding HHSC from relying on fibrosis score (a measure of liver damage), as grounds for denying DAA treatment to qualified Medicaid beneficiaries. Federal Rule of Civil Procedure 23(b)(2) is designed to address, in a single proceeding, precisely this type of uniform and systemic violation of the law because a judicial finding that HHSC's challenged restrictions do not comply with the law will apply equally to all members of the proposed class.

II. FACTUAL BACKGROUND

A. The Medicaid Act Requires that State Medicaid Programs Treat Similarly Situated Enrollees Similarly

The Medicaid Program is a cooperative federal-state program serving the health care needs of low-income Texans. According to Title XIX of the Social Security Act of 1965 ("Medicaid Act"), 42 U.S.C. §§ 1396–1396w-5, Medicaid's purpose is to "furnish [] medical assistance on behalf of" certain groups of individuals, including "families with dependent children and aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services[.]" 42 U.S.C. § 1396-1. Such groups are deemed "categorically

[7] Federal district courts from around the country have certified virtually identical classes. *See M.R. v. Lyon*, No. 17-11184, 2018 WL 8801418, slip op. at *3–4 (E.D. Mich. May 29, 2018) (certifying class of Michigan Medicaid enrollees as part of settlement); *B.E. v. Teeter* ("*Teeter II*"), No. C16-0227-JCC, 2016 WL 3939674 (W.D. Wash. July 21, 2016) (granting contested certification motion for class of Washington Medicaid enrollees); *Ryan v. Birch*, No. 17-cv-00904-KLM, 2017 WL 3896440 (D. Colo. Sept. 5, 2017) (denying motion to dismiss in litigation where contested class of Colorado Medicaid enrollees was subsequently certified in an unpublished opinion); *see also* Order on Final Approval of Class Action Settlement ("*Harper*, Order Approving Class Settlement"), at 2–5, *Harper v. Andersen*, No. 18-CV-04008-DDC-GEB (D. Kan. Apr. 29, 2019), ECF No. 43 (certifying class of Kansas Medicaid enrollees as part of settlement); Order Certifying Cause as Class Action, *Jackson v. Sec'y of the Ind. Family & Soc. Servs. Admin.*, No. 1:15-CV-01874-SEB-MPB (S.D. Ind. Nov. 9, 2018), ECF No. 159 (certifying class of Indiana Medicaid enrollees as part of settlement).

needy" under 42 U.S.C. § 1396a(a)(10)(A)(ii). States are also able to further expand Medicaid coverage to other groups, such as individuals with breast and cervical cancer and independent foster care youth, who are also categorically needy. 42 U.S.C. § 1396a(a)(10)(A)(ii); *see also* TEX. HUM. RES. CODE § 32.024(y); *id.* at § 32.0247. "Medically needy" individuals, whose income is too high to otherwise qualify for Medicaid under the Medicaid Act, but who have significant health needs, can also receive medical assistance if they meet certain income thresholds. 42 U.S.C. § 1396a(a)(10)(C)(i); *see also Blum v. Caldwell*, 446 U.S. 1311, 1312 (1980); TEX. HUM. RES. CODE § 32.0247. Although participation in the Medicaid Program is optional for states, once a state "opts in" to participation, it is subject to the requirements in the Medicaid Act and the regulations promulgated by the Secretary of the Department of Health & Human Services ("HHS"). *See Romano v. Greenstein*, 721 F.3d, 374–75 (5th Cir. 2013).

The Medicaid Act's "comparability" requirement necessitates that services made available to categorically needy individuals "shall not be less in amount, duration, and scope" than to any other Medicaid enrollee, including any other categorically or medically needy individual. 42 U.S.C. § 1396a(a)(10)(B); Med. Assistance Programs Servs.: Comparability of services for groups, 42 C.F.R. § 440.240; *see also Blanchard v. Forrest*, 71 F.3d 1163, 1167 (5th Cir. 1996) (striking down Louisiana's Medicaid policy that offered greater benefits to retroactive enrollees who failed to pay their medical bills compared to those who did); *Equal Access for El Paso, Inc. v. Hawkins*, 428 F. Supp. 2d 585, 616 (W.D. Tex. 2006), *rev'd on other grounds*, 509 F.3d 697 (5th Cir. 2007). The comparability provision "guarantees that medical service to the 'categorically needy' be equal to or better than care provided to any other individual funded by Medicaid." *Women's Hosp. Found. v. Townsend*, No. 07-711-JJB-DLD, 2008 WL 2743284, at *6 (M.D. La. July 10, 2008). Stated differently, under the comparability requirement, states may not treat Medicaid recipients

differently from others where they have similar levels of need. *See, e.g.*, *Pashby v. Cansler*, 279 F.R.D. 347, 355 (E.D.N.C. 2011), *aff'd and remanded sub nom*., *Pashby v. Delia*, 709 F.3d 307 (4th Cir. 2013); *see also Davis v. Shah*, 821 F.3d 231, 255–56 (2d Cir. 2016) ("[T]he comparability provision does not protect categorically needy beneficiaries simply by prohibiting states from treating them less favorably than the medically needy. It also prohibits states from discriminating *among* the categorically needy by 'provid[ing] benefits to some categorically needy individuals but not to others.'") (quoting *Rodriguez v. City of N.Y.*, 197 F.3d 611, 615 (2d Cir. 1999)). All putative class members have HCV and have a medical need for DAA treatment, but may not have yet experienced the scope of liver scarring the Policy requires before it will cover treatment. The Policy does not treat putative class members comparably to other individuals with HCV with a higher fibrosis score, despite the fact that the standard of care requires treatment without regard to fibrosis score and despite the fact that HCV can wreak havoc on the body in ways not represented by a person's fibrosis score.

Two additional Medicaid Act requirements are relevant in this case. First, states must furnish medical assistance to all eligible individuals "with reasonable promptness." 42 U.S.C. § 1396a(a)(8); *see also Romano*, 721 F.3d at 377; *Steward v. Abbott*, 189 F. Supp. 3d 620, 634 (W.D. Tex. 2016). By creating a policy that delays coverage for Medicaid enrollees for whom DAA treatment is medically necessary until they test at an arbitrary threshold of liver scarring, Defendants violate the reasonable promptness provision. Second, the Act mandates that states make certain categories of care and services available to Medicaid-eligible individuals. *See* 42 U.S.C. § 1396a(a)(10)(A). Prescription drugs are among the categories of services that Texas has

chosen to make available to its Medicaid enrollees.[8] Services made available must be "sufficient in amount, duration, and scope to reasonably achieve [their] purpose," *see* Med. Assistance Programs Servs.: Sufficiency of amount, duration, and scope, 42 C.F.R. § 440.230(b), and a state cannot "arbitrarily deny or reduce the amount, duration, or scope" of such services "to an otherwise eligible beneficiary solely because of diagnosis, type of illness, or condition," *see id.* at § 440.230(c); *see also White v. Beal*, 555 F.2d 1146, 1152 n.6 (3d Cir. 1977). The Policy violates this provision as well.

B. Nearly All Individuals with Chronic HCV Need DAA Treatment

HCV is an increasingly common, potentially deadly infectious disease.[9] Generally speaking, HCV is an infection of the liver resulting from the Hepatitis C Virus. An individual infected with HCV sometimes clears the virus naturally – if not, and the virus persists in their body for more than six months after infection, the infection is considered "chronic."[10] New cases of HCV have increased rapidly since 2010,[11] and the Centers for Disease Control and Prevention

---

[8] Under 42 U.S.C. § 1396d(a)(12), prescription drugs are identified as a service that the state is not required to cover, but may choose to do so. Texas has chosen to cover prescription drugs. *See* TEX. HHS, *2020 State Plan for HCV* at 9, https://www.dshs.state.tx.us/legislative/2019-Reports/2020-State-Plan-for-Hepatitis-C.pdf (*also available via* https://dshs.texas.gov/legislative/Reports-2019.aspx). If states elect to provide an optional service, they are required to comply with applicable requirements in the Medicaid Act and related regulations. *See Montoya v. Johnston*, 654 F. Supp. 511, 514 (W.D. Tex. 1987) (citing *Meyers ex rel. Walden v. Reagan*, 776 F.2d 241 (8th Cir. 1985)).

[9] *See* CDC, *Press Release: Hepatitis C Kills More Americans than Any Other Infectious Disease* ("CDC, *Press Release*") (CDC last reviewed May 4, 2016), https://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html.

[10] *See* CDC, *Hepatitis C Questions and Answers for the Public* ("CDC, *HCV Q's & A's*") at Overview & Statistics (CDC last reviewed July 28, 2020), https://www.cdc.gov/hepatitis/hcv/cfaq.htm#D5.

[11] *See* CDC, *Press Release*, https://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html.

("CDC") estimates that 2.7 to 3.9 million individuals in the U.S. are HCV-positive.[12] HCV is transmitted through infected blood.[13] As such, individuals at high-risk of contracting HCV include recipients of blood transfusions or organ transplants prior to 1992, current or former injection drug users, health care workers exposed to needle sticks containing HCV-infected blood, and children born to mothers with HCV.[14] In 2018, the Texas Department of State Health Services reported that over 500,000 Texans were living with HCV.[15]

Chronic HCV progressively damages the liver—thereby inhibiting its ability to function effectively—and can lead to fibrosis (liver scarring), cirrhosis (liver impairment due to scarring), liver cancer, need for a liver transplant, and death.[16] HCV is the most common reason for liver transplantation in the United States. *See id*. South Texas has one of the highest liver cancer death rates in the U.S., in part due to high HCV prevalence in the area.[17]

---

[12] AM. LIVER FOUND., *Hepatitis C Information Center*, https://liverfoundation.org/for-patients/about-the-liver/diseases-of-the-liver/hepatitis-c/#faqs (last visited Aug. 7, 2020).

[13] CDC, *HCV Q's & A's* at Transmission/Exposure, https://www.cdc.gov/hepatitis/hcv/cfaq.htm#D5; WORLD HEALTH ORG., *Factsheet: Hepatitis C* (July 27, 2020), https://www.who.int/news-room/fact-sheets/detail/hepatitis-c.

[14] CDC, *HCV Q's & A's* at Transmission/Exposure, https://www.cdc.gov/hepatitis/hcv/cfaq.htm#D5.

[15] *See* TEX. HHS, *2020 State Plan for HCV* at 4, https://www.dshs.state.tx.us/legislative/2019-Reports/2020-State-Plan-for-Hepatitis-C.pdf (*also available via* https://dshs.texas.gov/legislative/Reports-2019.aspx).

[16] CDC, *HCV Q's & A's* at Overview & Statistics, https://www.cdc.gov/hepatitis/hcv/cfaq.htm#D5.

[17] *See generally* Laura Tenner, et al., *The Cost of Cure: Barriers to Access for Hepatitis C Virus Treatment in South Texas*, 15 J. ONCOLOGY PRAC. 61 (2019), https://ascopubs.org/doi/full/10.1200/JOP.18.00525.

Progression of liver scarring is measured by an individual's Metavir Fibrosis Score ("fibrosis score"), which ranges from F0 to F4.[18] A score of F0 indicates liver inflammation with no scarring; F1 indicates minimal scarring; F2 indicates an intermediate stage of scarring; F3 indicates severe fibrosis; and F4 indicates cirrhosis. *See id*. A 2015 study based on unpublished data from the CDC concluded that, at initial diagnosis, approximately 70 percent of individuals with HCV have a fibrosis score of F0, F1, or F2, while only 30 percent have a fibrosis score of F3 or F4.[19] A significant number of persons with chronic HCV and no or mild fibrosis will progress to cirrhosis without treatment. Ex. A, Trooskin Decl. ¶ 11. There is no way, currently, to predict who in this cohort will develop advanced liver disease. *Id.*

HCV is also a *systemic* inflammatory disease.[20] At all stages of disease progression, HCV can cause serious medical conditions and effects, independent of and not reflected by an individual's degree of liver scarring.[21] Chronic HCV is associated with various complications outside the liver, including kidney disease, hypertension, lymphoma, intractable fatigue, joint pain,

---

[18] Elizabeth C. Verna, *Perspective: Management of Advanced Fibrosis in the Context of Hepatitis C Virus* Infection, 25 TOPICS ANTIVIRAL MED. 1 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5677038/pdf/tam-25-007.pdf.

[19] David B. Rein, et al., *The Cost-effectiveness, Health Benefits, and Financial Costs of New Antiviral Treatments for Hepatitis C Virus* ("D.B. Rein, *New Antiviral Treatments for HCV*"), 61 CLINICAL INFECTIOUS DISEASES 157, Table 2 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5759765/pdf/nihms929766.pdf.

[20] Zeynel A. Sayiner, et al., *Hepatitis C Virus Infection and Its Rheumatologic Implications*, 10 GASTROENTEROLOGY & HEPATOLOGY 287 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4076875/pdf/GH-10-287.pdf.

[21] *See generally* Kirat Gill, et al., *Hepatitis C virus as a systemic disease: reaching beyond the liver*, 9 HEPATOLOGY INT'L 415 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4819925/pdf/12072_2015_Article_9684.pdf.

arthritis, vasculitis, thyroid disease, depression, memory loss, muscle soreness, mental changes, heart attacks, diabetes, nerve damage, jaundice, and various cancers.[22]

Beginning about 2011, a cure for HCV was developed and approved by the FDA, with the potential to relieve the suffering of individuals with HCV and prevent further risk of spread to uninfected populations. DAA treatment has been shown to eliminate the virus in more than 90% of HCV-positive individuals. Where that elimination has occurred, it is referred to as Sustained Virologic Response ("SVR").[23] Not only does SVR represent a *de facto* cure of the HCV infection, it can also prevent further transmission of the virus – an important step in eradication of the HCV epidemic.[24] DAA treatment consists of a once-daily pill taken over the course of 8–12 weeks. Ex. B, Linas Decl. ¶ 3. DAAs cause minimal side effects.[25] There is no other treatment for chronic HCV recognized under the standard of care. Ex. A, Trooskin Decl. ¶¶ 9, 13. Because DAA treatment is such a substantial improvement over prior treatments for HCV, the FDA deemed DAA treatment a "breakthrough therapy." *See* Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 356(a). Curative treatment remains quite rare in modern medicine. Ex. B, Linas Decl. ¶ 3. There is no

---

[22] See Amy C. Sherman & Kenneth E. Sherman, *Extrahepatic Manifestations of Hepatitis C Infection: Navigating CHASM*, 12 CURRENT HIV/AIDS REP. 353 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4554601/pdf/nihms-710942.pdf; Patrice Cacoub, et al., *Extrahepatic manifestations of chronic hepatitis C virus infection* ("P. Cacoub, *Extrahepatic manifestations of chronic HCV*"), 3 THERAPEUTIC ADVANCES IN INFECTIOUS DISEASE 3 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4735500/pdf/10.1177_2049936115585942.pdf.

[23] *See* U.S. DEP'T OF VET. AFFAIRS, VET. HEALTH ADMIN., *FAQs about Sustained Virologic Response to Treatment for Hepatitis C* (July 2020), https://www.hepatitis.va.gov/pdf/sustained-virological-response.pdf.

[24] *Id.*

[25] *See* Brian P. Lam, et al., *The changing landscape of hepatitis C virus therapy: focus on interferon-free treatment*, 8 THERAPEUTIC ADVANCES IN GASTROENTEROLOGY 298 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4530432/pdf/10.1177_1756283X15587481.pdf.

medical cure for HIV, diabetes, heart disease, nor rheumatic diseases like rheumatory arthritis, but there is a cost-effective cure for HCV. *See id.* Treating HCV at all stages of liver disease progression plays an important role in reducing the incidence of HCV in Texas generally. *See id.* at ¶ 9. When individuals are no longer HCV-infected, they cannot transmit the disease to others. *Id*. The Texas Department of State Health Services recognizes that addressing the incidence of HCV among Texans requires "a coordinated approach to expand prevention, testing, and treatment."[26] Texas's State Plan expressly concedes that lack of treatment contributes to prevalent transmission and that "[e]ffective treatment of hepatitis C requires timely diagnosis."[27]

Due to the individual and public health benefits of DAAs, the standard of care now dictates that all individuals who are HCV-positive should receive DAA treatment, regardless of fibrosis score, with extremely limited exceptions.[28] The expert guidelines published by the American Association for the Study of Liver Diseases ("AASLD") and the Infectious Diseases Society of America ("IDSA") establish that DAAs are the standard of care for all individuals with HCV, regardless of fibrosis score, unless they have a short life expectancy which "cannot be remediated by treating HCV, by transplantation, or by other directed therapy." *Id*. This is the case in Texas as it is across the United States. In 2018, a cross-section of Texas doctors and other medical

---

[26] *See* TEX. HEALTH & HUMAN SERVS., TEX. DEP'T OF STATE HEAHT SERVS., *2018 State Plan for Hepatitis C: As Required by Texas Health & Safety Code Section 94.001* 1 (Nov. 2018), https://www.dshs.state.tx.us/legislative/2018-Reports/2018-State-Plan-for-Hepatitis-C.pdf.

[27] *Id*. at 5.

[28] *See* AM. ASS'N FOR THE STUDY OF LIVER DISEASES & THE INFECTIOUS DISEASES SOC'Y OF AM., *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C* at When and in Whom to Initiate HCV Therapy ("AASLD & IDSA, *HCV Guidance*"), 1–2/11 (updated Nov. 6, 2019), https://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/200206_HCVGuidance_November_06_2019_a.pdf (*also available at* https://www.hcvguidelines.org).

professionals wrote to HHSC urging abandonment of the Policy based on its extant conflict with the national standard of care. *See* Ex. F, Letter from Alliance for Patient Access and National Viral Heptatis Roundtable to Executive Commissioner Charles Smith, Texas Health & Human Services, et al. The CMS, CDC, U.S. Department of Veterans Affairs, and most commercial health insurers recognize or cover DAA treatment for individuals with HCV, regardless of disease severity, in accordance with the standard of care.[29]

Untreated chronic HCV—at any stage of liver disease progression—can cause serious suffering as a result of medical complications and effects, such as heart attacks, diabetes, impaired cognitive function, fatigue, arthritis, decreased kidney function, and autoimmune disease.[30] Consequently, an individual with an F1 score could experience equally or more serious complications associated with her HCV infection than an individual with an F3 score. Ex. A, Trooskin Decl. ¶¶ 11–12, 17–18. The Guidance also reflects the unpredictability of liver disease progression as a result of HCV, as there is currently no way to foresee the pace or course of liver damage.

Delaying DAA treatment until an individual is at a more advanced stage of liver damage ignores the risk of severe medical consequences in at least two principal ways. First, where treatment is delayed to a more advanced stage of liver damage, there is risk of permanent consequences, even after SVR is achieved. Damage to the liver and other effects of HCV are not

---

[29] *See* HEPATITIS C: STATE OF MEDICAID ACCESS, *Hepatitis C: State of Medicaid Access Report Card – Texas* 1–4, https://stateofhepc.org/wp-content/themes/infinitie-child/reports/HCV_Report_Texas.pdf (last visited Aug. 11, 2020).

[30] *See* AASLD & IDSA, *HCV Guidance* at 10/11, https://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/200206_HCVGuidance_November_06_2019_a.pdf (*also available at* https://www.hcvguidelines.org); *see also* Ex. A, Trooskin Decl. ¶ 12.

always wholly (or reliably) mediated by SVR; at a minimum, individuals who experienced severe scarring prior to being cured must be monitored for liver cancer and other adverse consequences for the remainder of their lives. Ex. A, Trooskin Decl. ¶ 12.

Second, deferring treatment of individuals at an earlier stage of fibrosis ignores the potentially serious extrahepatic effects that individuals living with HCV can experience regardless of their fibrosis score.[31] For individuals experiencing such extrahepatic effects, the Policy withholds coverage of effective medical treatment in a manner that prolongs their suffering without any medical justification whatsoever. The Policy categorically excludes treatment coverage based on a liver damage assessment that is causally unconnected from these individuals' manifestations of HCV.

Thus, there is no medical justification for delaying coverage of DAA treatment for HCV-positive patients unless their life expectancy is too short to be remedied by treatment, liver transplant, or another directed therapy. Any restriction of coverage for DAA treatment based on a patient's fibrosis score cannot be grounded in her medical need for such treatment. The primary driver behind Texas HHSC's decision to erect unreasonable fibrosis score restrictions on DAA treatment is the state's ill-considered fiscal concerns.

C. Treatment of Chronic HCV with DAA Treatment is Cost Effective—and Even Cost Saving

There is also a consensus among scientists and physicians that the treatment of hepatitis C with DAAs is cost-effective. Ex. B, Linas Decl. ¶ 3. In recent years, the wholesale cost of DAA treatment has significantly decreased, which has drastically changed the cost-effectiveness

[31] *See* P. Cacoub, *Extrahepatic manifestations of chronic HCV*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4735500/pdf/10.1177_2049936115585942.pdf.

calculus.[32] Costs are even lower for the Texas Medicaid program, which is entitled to a rebate of at least 23.1% of the average manufacturer price of DAAs. *See id.* This pricing trend underscores the point that it makes no economic sense to allow treatment coverage for some patients while withholding it from others. *See id.* Studies that have compared "treatment-for-all" HCV regimes with regimes that restrict treatment in various ways routinely have determined that "treatment-for-all" is a cost-effective approach. *Id.* Further, treating all patients provides better population-level outcomes than restricting therapy, and it provides those better outcomes at a lower cost per QALY (quality-adjusted-life-years) gained. *Id.* In other words, with any available budget, ensuring treatment for all patients provides better health outcomes at better value than restricting treatment to those with advanced disease. *Id*.

Treating all stages of HCV with DAA treatments is not only cost-effective but actually cost-*saving* compared to the option of restricting access. *See* Ex. B, Linas Decl. ¶ 5. That is, they are both more medically effective and *less costly* than the previously recommended course of treatment. *See id.* A Medicaid policy that treated all patients rather than treating only those with advanced liver disease would lead to savings of upwards of $3.5 billion to the health care system. *See id.*

Limiting access to HCV treatment until patients experience severe liver scarring is the bluntest, most restrictive, and least thoughtful means of controlling cost – in addition to cruelly denying patients necessary drug therapies for a potentially deadly illness. *See id.* at ¶ 7. More

[32] Available reported costs of certain DAA medications are, for example, $13,200 per month for an 8-week course of Glecaprevir/pibrentasvir (Mavyret) and $22,920 per month for a 12-week course of sofosbuvir/velpatasvir (Epclusa). Ex. B, Linas Decl. ¶ 4 n.3.

reasonable alternatives to controlling cost exist, especially as less-expensive competitor DAAs continue to lower the cost of DAA treatment. *Id.*

D. Texas HHSC's Prior Authorization Criteria and Policy Prevents Categorically Needy Beneficiaries with Fibrosis Scores Lower Than F3 From Accessing DAA Treatment

According to Defendants' current Prior Authorization Criteria and Policy for Antiviral Agents for Hepatitis C Virus ("Prior Authorization Criteria and Policy"),

> Immediate [DAA] treatment is assigned the highest priority for patients with advanced fibrosis (Metavir stage F3) or cirrhosis (Metavir stage F4), liver transplant recipients, and patients with hepatocellular carcinoma. Patients with Metavir scores less than stage 3 may not be approved.[33]

As a result of this policy, individuals with a fibrosis score of F0, F1, or F2 are denied coverage for curative DAA treatment. Estimates based on general distributions suggest that the Policy leaves approximately 70 percent of Texas Medicaid beneficiaries with HCV without access to effective medical treatment for their condition, regardless of the serious health consequences they may be facing.[34]

Defendants' Policy applies to all putative class members uniformly: it prohibits HCV-positive, categorically needy[35] beneficiaries with fibrosis scores of F0–F2 from accessing curative DAA treatment, but allows categorically needy and medically needy beneficiaries with fibrosis scores of F3 to F4 to receive it. Moreover, the Policy applies an unjustified disease severity

---

[33] Ex. G, TEX. HHS, *Vendor Drug Program, (Medicaid) Form* § I, https://paxpress.txpa.hidinc.com/hepc_initial_request.pdf (*also available via* https://www.txvendordrug.com/formulary/prior-authorization/ffs-clinical-pa).

[34] *See supra* n.9.

[35] In Texas, categorically needy groups include pregnant women, adults caring for dependent children, Supplemental Security Income ("SSI") recipients, women with breast or cervical cancer, and independent foster care adolescents. Putative class members are categorically needy beneficiaries that belong to one or more of the aforementioned groups.

methodology to Medicaid enrollees with HCV that is not applied to enrollees with any similar chronic illness.

E. Plaintiffs are Categorically Needy Medicaid Beneficiaries with HCV Who Have Been Denied Coverage for DAA Treatment Based on Insufficient Fibrosis Score

Defendants' Policy unjustifiably prevents categorically needy beneficiaries, like Plaintiffs Dorena Coleman, Curtis Jackson, and Federico Perez, from accessing DAA treatment while allowing beneficiaries with fibrosis scores of F3–F4 to receive coverage for such treatment *and* beneficiaries with comparable chronic illnesses to receive coverage for medically necessary prescription drugs without regard to their disease severity. The Comparability requirement of the Medicaid Act prohibits such a Policy.

1. Dorena Coleman

Plaintiff Dorena Coleman is enrolled in Texas Medicaid. Decl. of Dorena Coleman in Supp. of Pls.' Mot. for Class Certification ("Coleman Decl."), ¶ 3 (July 29, 2020) (attached as Exhibit 1 to the Declaration of Jeffrey S. Edwards in Support of Class Certification ("Edwards Decl.") (Aug. 12, 2020), Appendix of Exhibits, Ex. D). Ms. Coleman is eligible for Medicaid through Texas's Medicaid for Breast and Cervical Cancer Program, *id.*, which designates her as a categorically needy beneficiary under 42 U.S.C. § 1396a(a)(10)(A).[36] Ms. Coleman has been diagnosed with chronic HCV since 2016. Ex. A, Trooskin Decl. ¶ 21. Consistent with the medical standard of care, Ms. Coleman has been prescribed DAA treatment to cure her chronic HCV. Ex.

[36] *See* TEX. HHSC, *Texas Medicaid and CHIP Reference Guide* ("TEX. HHSC, *Medicaid & CHIP Ref. Guide*"), 18–19 (12th ed. 2018), https://hhs.texas.gov/sites/default/files/documents/laws-regulations/reports-presentations/2018/medicaid-chip-perspective-12th-edition/12th-edition-complete.pdf.

D at Ex. 1 (Coleman Decl.) ¶ 5. Ms. Coleman's treating physician prescribed DAA medication for Ms. Coleman and submitted a request to the Texas Medicaid Program to provide Ms. Coleman with coverage for DAA treatment. *Id.* at ¶¶ 5–6. On July 16, 2019, Ms. Coleman's application for DAA treatment was denied because she did not meet Texas HHSC's fibrosis score requirements for approval. Ex. A, Trooskin Decl. ¶ 22. The initial denial stated that DAA treatment is "given to patients who have a certain degree of liver damage such as advanced liver fibrosis (Metavir stage F3), cirrhosis (Metavir stage F4), liver transplant recipient, or type of cancer such as hepatocellular carcinoma." Denial Letter for Dorena Coleman (July 16, 2019) (attached as Exhibit 2 to the Edwards Decl., Ex. D). Ms. Coleman sought a formal appeal of this denial on September 16, 2019. Her appeal was denied on September 30, 2019, because she did not have "advanced liver scarring (stage 3 or higher)." *Id.* (Denial Letter for Dorena Coleman (Oct. 4, 2019)). Ms. Coleman remains ineligible for DAA treatment coverage under Defendants' Prior Authorization Criteria and Policy, 14 months after she first applied for coverage in June 2019. *Id.* (Denial Letters for Dorena Coleman (July 16, 2019; Oct. 4, 2019)).

Ms. Coleman suffers from diabetes, asthma, sleep apnea, depression, chronic back pain, and a history of breast cancer. Ex. A, Trooskin Decl. ¶ 21. Ms. Coleman experiences ongoing symptoms from her Hepatitis C. Ex. D at Ex. 1 (Coleman Decl.) ¶¶ 4–5.

Counsel has discussed and thoroughly explained to Ms. Coleman the nature of a class action and the potential advantages and disadvantages of proceeding in a class action rather than individually. *Id.* at ¶¶ 10–12.

2. Curtis Jackson

Plaintiff Curtis Jackson is enrolled in Texas Medicaid. Decl. of Curtis Jackson in Supp. of Pls.' Mot. for Class Certification ("Jackson Decl."), ¶ 3 (Aug. 13, 2020) (attached as Exhibit 3 to

the Edwards Decl., Ex. D). Mr. Jackson is eligible for Medicaid because he receives SSI benefits, *see id.*, and thus qualifies as a categorically needy beneficiary under 42 U.S.C. § 1396a(a)(10)(A).[37] Mr. Jackson has been diagnosed with chronic HCV since approximately 2017. Ex. A, Trooskin Decl. ¶ 26. Mr. Jackson's treating physician prescribed DAA medication for Mr. Jackson and submitted a request to the Texas Medicaid Program to provide Mr. Jackson with coverage for DAA treatment. Ex. D at Ex. 3 (Jackson Decl.) ¶¶ 5–6; Ex. A, Trooskin Decl. ¶ 28. On October 31, 2018, Mr. Jackson's application for DAA treatment was denied because he did not meet the fibrosis score requirements for approval. Ex. A, Trooskin Decl. ¶ 28. Mr. Jackson remains ineligible for DAA treatment coverage under Defendants' Prior Authorization Criteria and Policy, 22 months after he first applied for coverage in October 2018. Denial Letter for Curtis Jackson (Oct. 31, 2018) (attached as Exhibit 4 to the Edwards Decl., Ex. D).

Mr. Jackson experiences ongoing symptoms from his Hepatitis C. *Id.* at Ex. 3 (Jackson Decl.) ¶¶ 4, 8.

Counsel has discussed and thoroughly explained to Mr. Jackson the nature of a class action and the potential advantages and disadvantages of proceeding in a class action rather than individually. *Id.* at ¶¶ 10–12.

3. Federico Perez

Plaintiff Federico Perez is enrolled in Texas Medicaid. Decl. of Federico Perez in Supp. of Pls.' Mot. for Class Certification ("Perez Decl."), ¶ 3 (Aug. 6, 2020) (attached as Exhibit 5 to the Edwards Decl., Ex. D). Mr. Perez is eligible for Medicaid because he receives SSI benefits,

[37] *See* TEX. HHSC, *Medicaid & CHIP Ref. Guide* at 10, https://hhs.texas.gov/sites/default/files/documents/laws-regulations/reports-presentations/2018/medicaid-chip-perspective-12th-edition/12th-edition-complete.pdf.

id., and thus qualifies as a categorically needy beneficiary under 42 U.S.C. § 1396a(a)(10)(A).[38] Mr. Perez has been diagnosed with chronic HCV in 2017. Ex. A, Trooskin Decl. ¶ 32. Mr. Jackson's treating physician prescribed DAA medication for Mr. Jackson and submitted a request to the Texas Medicaid Program to provide Mr. Perez with coverage for DAA treatment. Ex. D at Ex. 5 (Perez Decl.) ¶¶ 5–6; Ex. A, Trooskin Decl. ¶ 34. Between November 2017 and September 2019, Mr. Perez's application for DAA treatment was denied multiple times because he did not meet the fibrosis score requirements for approval. Ex. A, Trooskin Decl. ¶ 34. Mr. Perez remains ineligible for DAA treatment coverage under Defendants' Prior Authorization Criteria and Policy, 33 months after he first applied for coverage in November 2017. Denial Letter for Federico Perez (Sept. 12, 2019) (attached as Exhibit 6 to the Edwards Decl., Ex. D).

Mr. Perez experiences ongoing symptoms from his Hepatitis C. *Id.* at Ex. 5 (Perez Decl.) ¶¶ 4, 8. Counsel has discussed and thoroughly explained to Mr. Perez the nature of a class action and the potential advantages and disadvantages of proceeding in a class action rather than individually. *Id.* at ¶¶ 10–12.

F. The Proposed Class

Plaintiffs propose a class of individuals who:

a. are or will in the future be enrolled in the Texas Medicaid Program as categorically needy individuals, as defined by 42 U.S.C. 1396a(a)(10)(A);

b. have been or will be diagnosed as having an infection of the Hepatitis C Virus;

[38] *See* TEX. HHSC, *Medicaid & CHIP Ref. Guide* at 10, https://hhs.texas.gov/sites/default/files/documents/laws-regulations/reports-presentations/2018/medicaid-chip-perspective-12th-edition/12th-edition-complete.pdf.

c. have been or will be prescribed DAA treatment by a qualified prescriber; and

d. would be eligible for DAA treatment coverage but for the Prior Authorization Criteria and Policy's fibrosis score threshold.[39]

G. Local Rule 23 – Additional Certification Matters

In accordance with Local Court Rule 23, Plaintiff addresses the following additional matters:

1. Settlement. No settlement negotiations have occurred between any Plaintiff and Defendants. Plaintiffs are unable to assess the likelihood of individual settlements with any named Plaintiff as it depends solely on whether Defendants will modify their policy and agree to provide any named Plaintiff with DAA medication.

2. Similar Actions. There are no similar actions against these Defendants, but the Edwards Law Group is currently representing a putative class of Texas Department of Criminal Justice prisoners diagnosed with HCV against other state employees in their official capacities seeking similar relief – provision of DAA medication to all prisoners with HCV regardless of fibrosis score. The style of the case is *Roppolo*

[39] This definition mirrors other classes certified in similar matters across the country. *See, e.g.*, *M.R. v. Lyon*, No. 17-11184, 2018 WL 4179635, at *6 (E.D. Mich. Aug. 31, 2018) (certifying as class: "All individuals that are or will be enrolled in Michigan's Medicaid Program at the time this Order is entered; have been or will be diagnosed with a chronic infection of the Hepatitis C Virus; are 18 years of age or older; require, or in the future will require, treatment for Hepatitis C with direct-acting antiviral medication; and do not meet the Michigan Department of Health and Human Services' current treatment criteria, which restricts direct-acting antiviral treatment to individuals with a minimum metavir fibrosis score criteria of F-2."); *Teeter II*, 2016 WL 3939674, at *1 (certifying class defined as: "All individuals who: (1) Were, are, or will be enrolled in WHCA's Medicaid Program on or after October 10, 2014; (2) Require, or are expected to require treatment for HCV with Harvoni/ledipasvir-sofosbuvir or other similar DAAs under the current guidelines adopted by the [AASLD] and the [IDSA]; and (3) Do not meet the coverage criteria for HCV medication adopted by WHCA, as reflected in Appendix 1 to Plaintiffs' Complaint.").

v. Linthicum, No. 2:19-cv-00262 (S.D. Tex. Jan. 9, 2020) (Ramos, J., presiding), and a motion to certify the class is pending.

3. No Notice Required in Connection with Certification. As Plaintiffs seek certification under Federal Rule of Civil Procedure 23(b)(2), and no monetary damages are sought (other than attorneys' fees), notice at the certification stage is not required and Plaintiffs request that the Court not order notice in connection with a decision to certify the class (as opposed to later notice upon a proposed settlement or judgment in the event the class is certified). *See, e.g.*, *Bolton v. Murray Envelope Corp.*, 553 F.2d 881, 883 (5th Cir. 1977) (affirming trial court's decision not to require notice in connection with certification proceedings a Rule 23(b)(2) class: "Rule 23 does not require notice for (b)(2) type actions") (citation omitted).

III. ARGUMENT

A. The Rule 23 Standard for Class Certification

Class certification under Rule 23(a) requires that a proposed class satisfies all four requirements under Rule 23(a) of the Federal Rules of Civil Procedure and at least one of the three additional requirements under Rule 23(b). *Gene & Gene LLC v. BioPay LLC*, 541 F.3d 318, 325 (5th Cir. 2008). This Court must "look beyond the pleadings to understand the claims, defenses, relevant facts, and applicable substantive law in order to make a meaningful determination of the certification issues." *M.D. ex rel. Stukenberg v. Perry* ("*Perry I*"), 675 F.3d 832, 837 (5th Cir. 2012) (internal quotation marks and citation omitted).

Rule 23(a) requires plaintiffs seeking class certification to meet the following requirements: (1) "the class is so numerous that joinder of all members is impracticable"; (2) "there are questions of law or fact common to the class"; (3) "the claims or defenses of the

representative parties are typical of the claims or defenses of the class"; and (4) "the representative parties will fairly and adequately protect the interests of the class." FED. R. CIV. P. 23(a); *Ward v. Hellerstedt*, 753 F. App'x 236, 243 (5th Cir. 2018). "The existence of an ascertainable class of persons to be represented by the proposed class representative is an implied prerequisite of [Rule 23]." *John v. Nat'l Sec. Fire & Cas. Co.*, 501 F.3d 443, 445 (5th Cir. 2007) (footnote omitted). The Plaintiffs seeks class certification pursuant to Rule 23(b)(2), which is appropriate when the defendant "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." FED. R. CIV. P. 23(b)(2); *Ward*, 753 F. App'x at 243.

B. The Proposed Class Meets the Requirements of Rule 23(a)

1. Ascertainability

To maintain a class action, "the class sought to be represented must be adequately defined and clearly ascertainable." *DeBremaecker v. Short*, 433 F.2d 733, 734 (5th Cir. 1970) (collecting authorities). An identifiable class exists "'if its members can be ascertained by reference to objective criteria.'" *DeOtte v. Azar*, 332 F.R.D. 188, 195 (N.D. Tex. 2019) (quoting *Conrad v. Gen. Motors Acceptance Corp. (GMAC)*, 283 F.R.D. 326, 328 (N.D. Tex. 2012)). Every potential member need not be readily identified. *Mitchell v. State Farm Fire & Cas. Co. ("Mitchell I")*, 327 F.R.D. 552, 560 (N.D. Miss. 2018), *aff'd*, 954 F.3d 700 (5th Cir. 2020). The key inquiry is whether "it is administratively feasible for the court to determine whether a particular individual is a member." *McGuire v. Int'l Paper Co.*, No. 1:92-CV-593BRR, 1994 WL 261360, at *3 (S.D. Miss. Feb. 18, 1994) (quoting 7A Wright, Miller & Kane, FED. PRAC. & PROC. § 1760, at 121 (2d ed. 1986)).

The class proposed here is easily ascertainable. There are objective standards to determine membership of the proposed class. Records of enrollment in the Texas Medicaid Program are maintained by the Defendant and its contractors, which provide the basis for eligibility. Where a HCV infection has been diagnosed, the Defendant or its contractors will have claim and coverage records reflecting the diagnosis, as well as associated fibrosis score testing necessary to determine DAA treatment coverage eligibility under the Policy. Further, the business and medical records of the Defendants and its contractors will likewise reflect where a qualified prescriber has submitted a request for coverage and been denied.[40]

These specific, objective criteria will obviate the need for the Court to "resort[] to intensive, individualized factual inquiries." *Pfeffer v. HSA Retail, Inc.*, No. SA-11–CV–959-XR, 2012 WL 1910034, at *3 (W.D. Tex. May 24, 2012) (internal quotation marks and citation omitted). Thus, it is "administratively feasible for the Court to determine whether a particularly individual is a member." *Morrow v. Washington*, 277 F.R.D. 172, 187 (E.D. Tex. 2011) (citations omitted); *see also Mitchell I*, 327 F.R.D. at 560–61 ("sorting and working through [Defendant's claims] records is a feasible process by which to identify the class members"). The proposed class's inclusion of *future* Texas Medicaid enrollees and those who *will* be diagnosed as having chronic HCV does not defeat ascertainability. *See Steward v. Janek* ("*Janek*"), 315 F.R.D. 472, 488 & n.15 (W.D. Tex. 2016); *Pederson v. La. State Univ.*, 213 F.3d 858, 868–69 & n.11 (5th Cir. 2000) ("In [*Pederson*],

[40] *See* Ex. G, TEX. HHS, *Vendor Drug Program, (Medicaid) Form*, https://paxpress.txpa.hidinc.com/hepc_initial_request.pdf (*also available via* https://www.txvendordrug.com/formulary/prior-authorization/mco-clinical-pa) (showing that a prior authorization request for HCV treatment contains the patient's Medicaid ID number, the prescriber's information, and the prescriber's diagnosis).

the fact that the class include[d] unknown, unnamed future members also weigh[ed] in favor of certification.").

2. Numerosity

Plaintiffs who seek class certification must demonstrate that "the class is so numerous that joinder of all members is impracticable[.]" FED. R. CIV. P. 23(a)(1). "The proper focus [of the numerosity requirement] is not on numbers alone, but on whether joinder of all members is practicable in view of the numerosity of the class." *Zeidman v. J. Ray McDermott & Co., Inc.*, 651 F.2d 1030, 1038 (5th Cir. 1981) (internal quotation marks and citations omitted). A number of factors are relevant to determining whether "it is difficult or inconvenient to join all members of the class[,]" *Ledet v. Fischer*, 548 F. Supp. 775, 781–82 (M.D. La. 1982) (citing *Republic Nat'l Bank of Dall., Tr. v. Denton & Anderson Co.*, 68 F.R.D. 208 (N.D. Tex. 1975)), including "the geographical dispersion of the class, the ease with which class members may be identified, the nature of the action, and the size of each plaintiff's claim." *Mullen v. Treasure Chest Casino, LLC*, 186 F.3d 620, 624–25 (5th Cir. 1999) (citation omitted).

Plaintiffs' proposed class is sufficiently numerous. As of 2018, over 500,000 Texans were estimated to be living with HCV.[41] By September 2014, over 4 million individuals were enrolled in Medicaid and CHIP in Texas, a population that is by definition low-income and therefore disproportionately affected by HCV.[42] Among the Medicaid enrollees living with HCV, about 70

[41] TEX. HHS, *2020 State Plan for HCV* at 4, https://www.dshs.state.tx.us/legislative/2019-Reports/2020-State-Plan-for-Hepatitis-C.pdf (*also available via* https://dshs.texas.gov/legislative/Reports-2019.aspx).

[42] CMS, Medicaid & CHIP in Texas, https://www.medicaid.gov/state-overviews/stateprofile.html?state=Texas (last visited Aug. 11, 2020). According to an HHSC report in 2017, less than 1 percent of the Texas full beneficiary caseload in 2015 comes from medically needy spend down programs. TEX. HHSC, TEXAS MEDICAID AND CHIP IN PERSPECTIVE

percent have a fibrosis score of F0, F1, or F2.[43] Thus, the proposed class likely consists of hundreds or thousands of individuals currently denied DAA treatment for HCV. The size of the proposed class here is clearly sufficient to satisfy the numerosity requirement. *See Mullen*, 186 F.3d at 624 (stating that "any class consisting of more than forty members 'should raise a presumption that joinder is impracticable'") (quoting 1 NEWBERG ON CLASS ACTIONS § 3.05, at 3-25 (3d ed. 1992)); *Ledet*, 548 F. Supp. at 781–82 (noting that Plaintiffs seeking class certification need not show the "exact number of potential members").

Joinder of all members in the proposed class is impracticable, "especially in light of the fact that Medicaid recipients are indigent[,]" *Chisholm ex rel. Chisholm v. Jindal*, No. CIV. A. 97-3274, 1998 WL 92272, at *3 (E.D. La. Mar. 2, 1998), and that "there are countless potential future members" who will be enrolled in Texas Medicaid Program, *Pitts v. Greenstein*, No. 10-635-JJB-SR, 2011 WL 2193398, at *3–4 (M.D. La. June 6, 2011); *see also Jack v. Am. Linen Supply Co.*, 498 F.2d 122, 124 (5th Cir. 1974) ("[J]oinder of unknown individuals is certainly impracticable."). The individuals included in the proposed class are also located across the state of Texas, making joinder nearly impossible. *See Garcia v. Gloor*, 618 F.2d 264, 267 (5th Cir. 1980) (listing "geographic dispersion" among the factors that determine the practicability of joinder).

---

35 (11th ed. 2017), https://hhs.texas.gov/sites/default/files/documents/laws-regulations/reports-presentations/2017/medicaid-chip-perspective-11th-edition/11th-edition-complete.pdf; *see also* Barbara J. Turner, et al., *High Priority for Hepatitis C Screening in Safety Net Hospitals: Results From a Prospective Cohort of 4582 Hospitalized Baby Boomers*, 62 HEPATOLOGY 1388, 1388 (2015), https://aasldpubs.onlinelibrary.wiley.com/doi/full/10.1002/hep.28018 ("Low-income populations are disproportionately affected by hepatitis C virus (HCV) infection.").

[43] D.B. Rein, *New Antiviral Treatments for HCV* at Table 2, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5759765/pdf/nihms929766.pdf; MD. DEP'T OF HEALTH, *2017 Joint Chairmen's Report on Hepatitis C Treatment* 1, 5–6 (2018), https://mmcp.health.maryland.gov/Documents/JCRs/2017/hepcJCRfinal10-17.pdf.

3. Commonality

Rule 23(a) also requires that "there are questions of law or fact common to the class[.]" FED. R. CIV. P. 23(a)(2). Plaintiffs must show that the class's claims "depend upon a common contention . . . of such a nature that it is capable of classwide resolution — which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011). "[F]or purposes of Rule 23(a)(2), [e]ven a single [common] question will do," *id.* at 359 (internal quotation marks and citation omitted), and the key determination is "whether there is a need for combined treatment and a benefit to be derived therefrom," *Jenkins v. Raymark Indus., Inc.*, 782 F.2d 468, 472 (5th Cir. 1986) (internal quotation marks and citation omitted). In general, a plaintiff seeking class certification "must identify a unified common policy, practice, or course of conduct that is the source of their alleged injury[,]" *M.D. ex rel. Stukenberg v. Perry* ("*Perry II*"), 294 F.R.D. 7, 26 (S.D. Tex. 2013), that "provides a class-wide basis for deciding significant common issues of fact and law," *Frey v. First Nat'l Bank Sw.*, 602 F. App'x 164, 172 (5th Cir. 2015) (unpublished) (citation omitted).

Here, Plaintiffs and putative class members seek adjudication of the same legal question: whether Defendant's restriction on access to coverage for DAA treatment based on fibrosis score is illegal under the Medicaid Act. The range of legal and factual questions inherent in this ultimate inquiry are common to all members of the class. Among these common questions are:

- What constitutes the standard of care for treatment of HCV;
- Whether withholding DAA treatment coverage to Medicaid enrollees with HCV violates such standard of care or medical necessity;
- Whether putative class members are similarly situated to other Medicaid enrollees with respect to medical need;

- Whether Texas Medicaid employs any other disease severity threshold for approval of a cure for any other similar chronic illness;
- Whether a denial of coverage until suffering a qualifying fibrosis score is permissible under the reasonable promptness provision of 42 U.S.C. § 1396a(a)(8);
- Whether the Policy is in place for cost reasons, rather than medical reasons.

Resolution of these factual and legal questions is central to the validity of each class member's ultimate claims about Defendants' violation of the Medicaid Act. Indeed, these common contentions among all individuals in the class result from the Policy – the Defendants' unified express policy or practice of disallowing DAA treatment to HCV patients with "[fibrosis] scores less than stage 3."[44] The proposed class is tightly drawn to include only individuals suffering from chronic HCV, all of whom are suffering a common risk of harm if this Policy remains in place. Untreated HCV poses a significantly higher risk of liver damage, and may cause each of them to miss the opportunity to treat their HCV due to the significant (and possibly rapid) deterioration of their medical condition. *See Janek*, 315 F.R.D. at 489 (holding that commonality was satisfied because plaintiffs presented "[s]ubstantial evidence suggest[ing] that the State's policies and practices have created a systemic deficiency in the availability of community-based mental health services, and that that deficiency is the source of the harm alleged by all class members").

Indeed, district courts across the country have certified classes of Medicaid enrollees with chronic HCV who seek declaratory and injunctive relief to enforce the standard of care in their states. *See, e.g.*, *B.E. v. Teeter* ("*Teeter I*"), No. C16-227-JCC, 2016 WL 3033500 (W.D. Wash.

[44] Ex. G, TEX. HHS, *Vendor Drug Program, (Medicaid) Form* § I ¶ 4, https://paxpress.txpa.hidinc.com/hepc_initial_request.pdf (*also available via* https://www.txvendordrug.com/formulary/prior-authorization/ffs-clinical-pa).

May 27, 2016); *Ryan v. Birch*, No. 17-CV-00904-KLM, 2017 WL 3896440 (D. Colo. Sept. 5, 2017); *Jackson v. Sec'y of the Ind. Family & Soc. Servs. Admin.*, No. 1:15-CV-01874-SEB-MPB (S.D. Ind. Feb. 12, 2019) (Order Finding Settlement Agreement to be Fair, Reasonable, and Adequate, and Approving Settlement Agreement (ECF No. 167)); *Harper v. Andersen et al.*, No. 18-CV-04008-DDC-GEB (D. Kan. Apr. 29, 2019) (Order Approving Class Settlement (ECF No. 43)); *M.R. v. Lyon*, No. 17-CV-11184, 2018 WL 4179635 (E.D. Mich. Aug. 31, 2018). Other courts have found commonality and certified classes of prisoners with chronic HCV challenging the same types of DAA-restriction policies implemented by state prison systems. *See*, *e.g.*, *Postawko v. Mo. Dep't of Corr.*, 910 F.3d 1030, 1037–38, 1041 (8th Cir. 2018) (affirming the district court's decision of class certification for inmates with chronic Hepatitis C), *rehr'g & rehr'g en banc denied* (Jan. 11, 2019); *West v. Gobeille*, No. 2:19-cv-81, — F. Supp. 3d —, 2020 WL 1505677, at **1, 8 (D. Vt. Mar. 30, 2020) (district court granting motion to certify class of inmates and detaines diagnosed with chronic HCV); *Hoffer v. Jones*, 323 F.R.D. 694, 700 (N.D. Fla. 2017) (class certification granted for "all current and future prisoners . . . who have been diagnosed, or will be diagnosed, with chronic [HCV]"), *appeal filed* (11th Cir. May 17, 2019); *Hilton v. Wright*, 235 F.R.D. 40, 54–55 (N.D.N.Y. 2006) (granting plaintiff's motion for class certification).

Cases with similar fact situations to this one are routinely certified as Rule 23(b)(2) class actions in the Fifth Circuit. *See, e.g.*, *Yates v. Collier*, 868 F.3d 354, 358, 371 (5th Cir. 2017) (certification of a class of inmates at Texas prison alleging violations of Eighth Amendment due to high temperatures in prison housing areas); *Morrow v. Washington*, 277 F.R.D. 172, 178–79 (E.D. Tex. 2011) (class of motorists alleging violations of Fourth and Fourteenth Amendments); *Ledet v. Fischer*, 548 F. Supp. 775, 782 (M.D. La. 1982) (class of Medicaid enrollees certified to challenge state regulations limiting provision of free eyeglasses); *Davis v. Weir*, 497 F.2d 139 (5th

Cir. 1974) (civil rights class certified against city water department to secure declaration that utility termination procedures were unconstitutional).

The fact that plaintiffs may suffer individualized injury as a practical matter "is not fatal to [a finding of] commonality[,]" *Perry I*, 675 F.3d at 839–40 (internal quotation marks and citation omitted), analysis here, because these common questions are dispositive of plaintiff's claims, and this Court will not need to conduct "individualized inquiries to determine [whether] liability would be needed[.]" *Perry II*, 294 F.R.D. at 28 (quoting *Ahmad v. Old Republic Nat'l Title Ins. Co.*, 690 F.3d 698, 704 (5th Cir. 2012)). In *Yates*, the Fifth Circuit specifically addressed this issue, and affirmed the District Court's finding that differences in underlying medical conditions did not defeat the commonality requirement for class certification in a case challenging prison conditions related to extremely high indoor temperatures. *Yates*, 868 F.3d at 362–66. In that case, the defendants argued that due to a population that is diverse in age and health, the court could not decide whether all prisoners were at a substantial risk of harm "in one stroke[.]" *Id*. at 362–63 (citation omitted). But in *Yates*, the Fifth Circuit held that the question was whether extremely high temperatures posed a substantial risk of harm to *all* inmates, even the young and healthy. *Id*. at 363–65. That the sick and disabled were at an even greater risk did not defeat the commonality of the general risk to everyone. *Id.* at 365–66. While acknowledging that "no two individuals have the exact same risk," the Fifth Circuit affirmed that differences in underlying medical conditions "does not destroy commonality." *Id*. at 363 (alterations omitted). Here, this is not a close call, because *all* HCV patients, regardless of the disease's progression or the patient's underlying health, require treatment with DAA medications.[45]

[45] Ex. A, Trooskin Decl. ¶ 16 ("There is consensus among medical professionals and organizations responsible for the . . . treatment standards for HCV that *all* individuals with chronic HCV should

Relying upon this reasoning in *Yates*, the Eighth Circuit affirmed certification in the *Postawko* prison HCV class action despite the defendants' argument regarding individualized medical conditions. 910 F.3d at 1038. The prison system defendants in *Postawko* specifically argued that "the unique medical condition of each member of the class means that resolving their claims will require a 'highly individualized' inquiry"—but the Eighth Circuit rejected this, reasoning that it "misunderstands the nature of the class's claims." *Id.* "Here the physical symptoms eventually suffered by each class member may vary, but the question asked by each class member is susceptible to common resolution." *Id.* at 1038–39 (citing *Yates*, 868 F.3d at 363). Here, regardless of whether various class members ultimately suffer the same symptoms, they all have the same common question: Is it illegal for Texas HHSC to withhold coverage for DAA treatment until after they suffer significant liver damage?

Because there are common factual and legal questions among all members of the proposed class, "maintenance of a class action is economical," and all plaintiffs' claims "can productively be litigated at once." *Wal-Mart*, 564 U.S. at 349 & n.5. The proposed class here satisfies the commonality requirement under Rule 23(a)(2).

4. Typicality

The claims or defenses of proposed class representatives must be "typical of the claims or defenses of the class[.]" FED. R. CIV. P. 23(a)(3). To satisfy typicality, the class representatives must "possess the same interest and suffer the same injury" as the prospective class members. *Gen. Tel. Co. of the Sw. v. Falcon*, 457 U.S. 147, 156 (1982) (citations omitted). The requirement

---

be provided DAAs *regardless* of disease progression. Agreement on this standard of care exists among the AASLD, IDSA, the CDC, and . . . is established practice of Medicare, the Veterans Administration and other providers of medical care and coverage.") (emphasis added).

"focuses on the similarity between the named plaintiffs' legal and remedial theories and the legal and remedial theories of those whom they purport to represent." *Lightbourn v. Cty. of El Paso*, 118 F.3d 421, 426 (5th Cir. 1997) (citing *In re Asbestos Litig.*, 90 F.3d 963, 976 (5th Cir. 1996)). The representatives' claims and those of all class members, however, "need not be completely co-extensive or identical." *Ledet*, 548 F. Supp. at 782 (citing *Vuyanich v. Republic Nat'l Bank of Dall.*, 505 F. Supp. 224 (N.D. Tex. 1980)). This Court has discretion to choose "the appropriate level of generality at which to compare Plaintiffs to members of the proposed class." *Janek*, 315 F.R.D. at 489.

The test for typicality "is not demanding." *Chisholm*, 1998 WL 92272, at *4 (citations omitted). Both commonality and typicality "serve as guideposts for determining whether under the particular circumstances maintenance of a class action is economical and whether the named plaintiff's claim and the class claims are so interrelated that the interests of the class members will be fairly and adequately protected in their absence." *Wal-Mart*, 564 U.S. at 349 n.5. In a sense, typicality is "commonality addressed from the perspective of the named plaintiffs." *Bridges v. Freese*, No. 3:13CV457TSL-JCG, 2015 WL 1401513, at *4 (S.D. Miss. Mar. 26, 2015) (citation omitted). "Often, once commonality is shown typicality will follow as a matter of course." *Perry II*, 294 F.R.D. at 29 (citing *Frey v. First Nat'l Bank Sw.*, No. 3:11-CV-3093-N, 2013 U.S. Dist. LEXIS 37153 (N.D. Tex. Feb. 20, 2013)).

Dorena Coleman, Curtis Jackson, and Federico Perez are typical of the class. They (i) are all enrolled in the Texas Medicaid Program as a categorically needy individuals under 42 U.S.C. § 1396a(a)(10)(A)(ii)(XVIII); (ii) have all been diagnosed as having an infection of HCV; (iii) all were prescribed DAA treatment by a qualified prescriber; and (iv) are all ineligible for DAA

treatment coverage on the basis of the Defendants' illegal Prior Authorization Criteria and Policy's fibrosis score threshold.

Variations on how HCV manifests itself in each class member's body "are not relevant to the Court's assessment of typicality because they do not shed light on meaningful differences between Plaintiffs and prospective class members." *Janek*, 315 F.R.D. at 490; *see also DeOtte*, 332 F.R.D. at 200 (finding "no legally significant difference[]" in typicality among class members who oppose contraceptive mandate under the Patient Protection and Affordable Care Act differently because in the end, the legal inquiry under RFRA was the same). Regardless of individual differences, each proposed class representative is challenging the legality of the same Policy. Each has suffered the same legal injury as all members of the proposed class: categorical exclusion from medically necessary curative treatment for HCV, resulting in substantially higher risk of poor health outcomes. Dorena Coleman, Curtis Jackson, and Federico Perez do not seek individualized relief, but have the same interest as all members of the class — the elimination of the fibrosis score restriction in the DAA treatment coverage Policy widely applicable to every categorically eligible Medicaid enrollee who has or may develop chronic HCV. Indeed, Plaintiffs' claims "arise[] out of the same . . . course of conduct that gives rise to the claims of other class members' claims and [are] based on the same legal theory." *Tex. Grain Storage, Inc. v. Monsanto Co.*, No. SA-07-CA-673-OG, 2019 WL 4087430, at *2 (W.D. Tex. June 24, 2019) (citing *Durret v. John Deere Co.*, 150 F.R.D. 555, 558 (N.D. Tex. 1993)).

The typicality requirement for proposed class representatives are met.

5. Adequacy

Rule 23(a) also requires that "the representative parties will fairly and adequately protect the interests of the class." FED. R. CIV. P. 23(a)(4). The adequacy inquiry can be broken up into

three subcategories: (1) "the zeal and competence of the representative[s'] counsel"; (2) "the willingness and ability of the representative[s] to take an active role in and control the litigation and to protect the interests of absentees"; and (3) the risk of "conflicts of interest between the named plaintiffs and the class they seek to represent." *Regmund v. Talisman Energy USA, Inc.*, No. 4:16-CV-02960, 2019 WL 2863926, slip op. at *4 (S.D. Tex. July 2, 2019) (quoting *Slade v. Progressive Sec. Ins. Co.*, 856 F.3d 408, 412 (5th Cir. 2017)). With respect to the putative class representatives, it is sufficient that they "have a general understanding of their position as plaintiffs with respect to the cause of action and the alleged wrongdoing perpetrated against them by the defendants." *Janek*, 315 F.R.D. at 490–91 (citing *Hamilton v. First Am. Title Ins. Co.*, 266 F.R.D. 153, 164 (N.D. Tex. 2010), *vacated on other grounds*, 423 F. App'x 425 (5th Cir. 2011)). Additionally, the court must find that class counsel is "qualified, experienced, and generally able to conduct the proposed litigation[]" in order to certify a class. *N. Am. Acceptance Corp. Sec. Cases v. Amall, Golden & Gregory*, 593 F.2d 642, 644 (5th Cir. 1979) (footnote omitted) (citing *Johnson v. Ga. Highway Express, Inc.*, 417 F.2d 1122, 1125 (5th Cir. 1969)).

The putative class representatives have no interest that is now or may potentially be antagonistic to the interests of the class. Their interests are wholly aligned with all individuals in the putative class; all challenge the legal validity of the Policy, and gain coverage of DAA treatment for their HCV by HHSC. The claims of the class also do not require subclasses, neither presently nor in the future.

The proposed class representatives will fairly and adequately protect the interests of the class as a whole. Dorena Coleman, Curtis Jackson, and Federico Perez are committed to and passionate about the case and fully understand their responsibilities as class representatives. They have expressed their intent to respond to discovery, appear for deposition, and travel to courts to

testify for this case. *See Haley v. Merial, Ltd.*, 292 F.R.D. 339, 349 (N.D. Miss. 2013). Their declarations clearly demonstrate that they understand their role in the litigation. Ex. D at Ex. 1 (Coleman Decl.) ¶¶ 10–11; *id.* at Ex. 3 (Jackson Decl.) ¶¶ 10–11; *id.* at Ex. 5 (Perez Decl.) ¶¶ 10–11. *Cf. Berger v. Compaq Comput. Corp.*, 257 F.3d 475, 483 (5th Cir. 2001) (finding that the named plaintiffs did not adequately represented the class because they knew nothing "more than that they were involved in a bad business deal") (footnote omitted) (quoting *Kelley v. Mid–America Racing Stables, Inc.*, 139 F.R.D. 405, 410 (W.D. Okla. 1990)). They have also specifically described the outcomes they wish to achieve and expressed their willingness to represent the class. Ex. D at Ex. 1 (Coleman Decl.) ¶¶ 10–12; *id.* at Ex. 3 (Jackson Decl.) ¶¶ 10–12; *id.* at Ex. 5 (Perez Decl.) ¶¶ 10–12; *see Janek*, 315 F.R.D. at 491. All these elements demonstrate "a general understanding of their position as plaintiffs with respect to the cause of action and the alleged wrongdoing perpetrated against" them by the Defendants. *Hamilton*, 266 F.R.D. at 164 (internal quotation marks omitted) (quoting *Rubenstein v. Collins*, 162 F.R.D. 534, 538 (S.D. Tex. 1995)).

Plaintiffs are represented by highly competent attorneys with extensive experience in litigating class action cases in federal court.[46] Each of the attorneys in this case has extensive experience with civil rights and healthcare-related litigation. *See id.* Specifically, among the proposed counsel are lawyers who have successfully certified classes of inmates who brought Eighth Amendment claims against state facilities, *see, e.g.*, *Cole v. Livingston*, No. 4:14-C1698, 2016 WL 3258345, at *1 (S.D. Tex. June 14, 2016), *aff'd by Yates v. Collier*, 858 F.3d 354 (5th Cir. 2017), as well as statewide classes of Medicaid beneficiaries seeking access to chronic HCV

[46] *See* Ex. D, Edwards Decl.; Ex. C, Decl. of David C. Tolley in Supp. of Class Certification ("Tolley Decl.") (Aug. 12, 2020); Ex. E, Decl. of Kevin Costello in Supp. of Pls.' Mot. for Class Certification ("Costello Decl.") (July 16, 2020).

treatment under the same standard of care at issue here, *see, e.g.*, *Ryan*, 2017 WL 3896440; *Teeter I*, 2016 WL 3033500. Moreover, counsel from the Edwards Law Group represent Plaintiffs and a putative class of Texas inmates with chronic HCV in an action seeking the same relief here – injunctive relief ending a fibrosis threshold requirement and instead requiring DAA treatment for all TDCJ inmates with chronic HCV. *See* Ex. D, Edwards Decl. ¶ 16. Each attorney proposed as class counsel has filed a declaration outlining their specific experience and qualifications. *See* Ex. D, Edwards Decl.; Ex. C, Tolley Decl.; Ex. E, Costello Decl. Because both the named Plaintiffs and Plaintiffs' counsel will adequately represent the interests of the proposed class, the adequacy requirement of Rule 23(a) is satisfied.

C. The Proposed Class Meets All of the Requirements of 23(b)(2)

Rule 23(b)(2) requires plaintiffs seeking class certification to show that "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[.]" FED. R. CIV. P. 23(b)(2). The Fifth Circuit has identified two requirements when a proposed class seeks classwide injunctive relief: (1) class members must have been harmed in essentially the same way, *i.e.*, that there was "common behavior by the defendant towards the class," *Haley*, 292 F.R.D. at 350 (citing *Casa Orlando Apartments, Ltd. v. Fed. Nat'l Mortg. Ass'n*, 624 F.3d 185, 198 (5th Cir. 2010)); and (2) the injunctive relief sought must be specific, *Maldonado v. Ochsner Clinic Found.*, 493 F.3d 521, 524 (5th Cir. 2007); *see also* FED. R. CIV. P. 65(d)(1)(A)–(C). In addition, "injunctive or declaratory relief must be the predominant form of relief." *Corley v. Entergy Corp*., 222 F.R.D. 316, 322 (E.D. Tex. 2004) (citation omitted), *aff'd sub nom.*, *Corley v. Orangefield Indep. Sch. Dist.*, 152 F. App'x 350 (5th Cir. 2005). To satisfy

this prong, plaintiffs generally need to show that there was "common behavior by the defendant towards the class." *Casa Orlando Apartments*, 624 F.3d at 198 (citing FED. R. CIV. P. 23(b)(2)).

All individuals in the putative class are subject to the Policy challenged here, such that "the [injunctive or declaratory] relief sought [would] perforce affect the entire class at once[.]" *Wal-Mart*, 564 U.S. at 361–62. Plaintiffs do not ask the Court to make individualized determinations of class members' medical need. Rather, plaintiffs ask the Court to strike down Defendant's categorical policy or practice towards Medicaid enrollees with HCV that prevents coverage of DAA treatment for patients with fibrosis levels F0, F1, or F2 in contravention of the prevailing standard of care. In this way, the single injunction of Defendant's policy or practice Plaintiffs are seeking "would provide relief to each member of the class[,]" who are systematically harmed by Defendant's current policy or practice. *Id.* at 360.

The injunctive relief sought by plaintiffs is sufficiently specific. Plaintiffs ask this Court for a permanent injunction enjoining Defendant from denying treatment coverage for curative DAAs to those with a fibrosis score less than a specified minimum. This request is "specific in its terms" and "describe[s] in reasonable detail the act or acts" that are to be enjoined. *Ala. Nursing Home Ass'n v. Harris*, 617 F.2d 385, 387–88 (5th Cir. 1980) (citation omitted). Moreover, Plaintiffs seek only injunctive and declaratory relief in this case, not monetary damages. *Cf. Allison v. Citgo Petroleum Corp.*, 151 F.3d 402, 418 (5th Cir. 1998) (denying Rule 23(b)(2) class certification because monetary relief predominated).

Therefore, class action is an appropriate vehicle for the type of claims raised here, and the proposed class satisfies Rule 23(b)(2).

IV. CONCLUSION

For all the reasons stated above, the proposed class satisfies the prerequisites of Federal Rules of Civil Procedure 23(a) and 23(b)(2). Plaintiffs respectfully request that this Court grant Plaintiffs' Motion, certify the class proposed by the Plaintiffs, appoint the named Plaintiffs as class representatives, and appoint the undersigned as class counsel. Specifically, Plaintiffs move for an order:

A. Certifying a class defined as all individuals:

1. who are or will in the future be enrolled in the Texas Medicaid Program as categorically needy individuals, as defined by 42 U.S.C. 1396a(a)(10)(A);

2. who have been or will be diagnosed as having a chronic infection of the Hepatitis C Virus;

3. who have been or will be prescribed DAA treatment by a qualified prescriber; and

4. who would be granted coverage for DAA treatment but for application of the Policy's fibrosis score threshold.

B. Approving Plaintiffs as the class representatives;

C. Approving Jeff Edwards, Mike Singley, Scott Medlock and David James of Edwards Law Group, David Tolley and Allison Turner of Latham & Watkins LLP; and Kevin Costello of the Harvard Law School Center for Health Law & Policy Innovation as counsel for the class; and,

D. Ordering that this action proceeds as a class action under Federal Rules of Civil Procedure 23(a) and 23(b)(2).

Dated: August 13, 2020

Respectfully submitted,

EDWARDS LAW
1101 East 11th Street
Tel. 512-623-7727
Fax. 512-623-7729

By /s/ Jeff Edwards
JEFF EDWARDS
State Bar No. 24014406
jeff@edwards-law.com
SCOTT MEDLOCK
State Bar No. 24044783
scott@edwards-law.com
MICHAEL SINGLEY
State Bar No. 00794642
mike@edwards-law.com
DAVID JAMES
State Bar No. 24092572
david@edwards-law.com

Kevin Costello (*pro hac vice* filed concurrently)
Harvard Law School Center for Health Law & Policy Innovation
1585 Massachusetts Avenue
Cambridge, MA 02138
(617) 496-0901
kcostello@law.harvard.edu

David C. Tolley (*pro hac vice* filed concurrently)
Allison Lukas Turner (*pro hac vice* filed concurrently)
Amanda Barnett (*pro hac vice* filed concurrently)
Avery E. Borreliz (*pro hac vice* filed concurrently)
Latham & Watkins LLP
200 Clarendon Street, 27th Floor
Boston, MA 02116
(617) 880-4610
david.tolley@lw.com
allison.turner@lw.com
amanda.barnett@lw.com
avery.borreliz@lw.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I certify, by my signature below, that a true and correct copy of this document was delivered to all counsel of record through the Western District of Texas' electronic filing system.

/s/ Jeff Edwards
JEFF EDWARDS