Exhibit 1

AGREEMENT TO SETTLE CLAIMS

Jamie Harper, et al. v. Jeff Andersen, et al.
United States District Court for the District of Kansas
Case No. 5:18-cv-4008-DDC-GEB

This Agreement to Settle Claims ("Agreement") is between Plaintiffs Jamie Harper and Jessica Owens, on their own behalf and on behalf of the "Medicaid HCV Class" (as defined in ¶1.13), Jeff Andersen, in his official capacity as Secretary of the Kansas Department of Health and Environment ("KDHE," as defined in ¶1.19), and Jon Hamdorf, in his official capacity as the Director of the Kansas Division of Health Care Finance ("KDHCF," as defined in ¶1.20). Jamie Harper, Jessica Owens, KDHE, and KDHCF, (and "KanCare" as defined in ¶1.18) are referred to collectively as the "Parties." This Agreement is a full expression of the agreements between the Parties.

RECITALS

This Agreement is made with reference to the following facts:

A. ***Harper, et al. v. Andersen, et al***. On February 15, 2018, Plaintiffs challenged the then existing policies of the Kansas Department of Health and Environment, and exemplar of which for Harvoni® is attached as Exhibit A, that resulted in the denial of medically necessary treatment—direct-acting antiviral ("DAA") drugs, including Harvoni®, and/or other drugs to treat Hepatitis C—for Plaintiffs and other Medicaid beneficiaries infected with the Hepatitis C Virus ("HCV"). The action, brought by Plaintiffs in the United States District Court for the District of Kansas, sought injunctive relief both on their own behalf and on behalf of a class of similarly situated individuals.

B. ***Plaintiffs' Claims.*** In the Complaint, Plaintiffs assert three separate claims: (1) improper exclusion of qualified individuals from covered medical assistance under the Medicaid Act; (2) violations of Medicaid comparability; and (3) violations of reasonable promptness. Compl. ¶¶ 64-72; Am. Compl. ¶¶ 64-72. The claims all arose out of a coverage policy that Defendants applied to Kansas Medicaid enrollees seeking coverage of DAAs ("HCV Policy"). Plaintiffs alleged that the HCV Policy excluded care that was medically necessary, and that the exclusion was inappropriately imposed based on the cost of DAAs. Specifically, Plaintiffs challenged the HCV Policy's exclusion of coverage for certain HCV-infected enrollees based on fibrosis scores.

C. ***Agreement to Settle Claims.*** After Plaintiffs filed their Complaint, the Parties engaged in discussions in an effort to resolve all claims, including mediations with Judge Gale on June 19, 2018 and July 10, 2018, which included the filing of an amended class action complaint to define the settlement class and an agreed class certification order to implement the settlement for the benefit of the class. These discussions resulted in this Agreement.

AGREEMENT

I. Definitions.

1.1 "Action" shall mean: *Harper, et al. v. Andersen, et al.*, United States District Court for the District of Kansas, Case No. 5:18-cv-4008-DDC-GEB.

1.2 "Agreement Execution Date" shall mean: the date on which this Agreement is fully executed.

1.3 "Class Counsel" shall mean: J. Stan Sexton, Andrew Carpenter and Russell Shankland of SHOOK, HARDY & BACON L.L.P., and Lauren Bonds of the AMERICAN CIVIL LIBERTIES UNION OF KANSAS.

1.4 "Class Members" shall mean: those individuals who comprise the Medicaid HCV Settlement Class defined in ¶ 1.13.

1.5 "Class Period" shall mean: individuals who were, are, or will be enrolled in the Kansas Medicaid Program on or after October 31, 2016.

1.6 "Court" shall mean: the United States District Court for the District of Kansas.

1.7 "Defendants" shall mean: Jeff Andersen, in his official capacity as Secretary of the Kansas Department of Health and Environment ("KDHE"), and Jon Hamdorf, in his official capacity as the Director of the Kansas Division of Health Care Finance ("KDHCF").

1.8 "Effective Date of Settlement" shall mean: the date on which all of the conditions to settlement have been fully satisfied or waived.

1.9 "Final" or "Finality" shall mean: with respect to any judicial ruling or order in the Action, that the period for any appeals, petitions, motions for reconsideration, rehearing or certiorari or any other proceeding for review ("Review Proceeding") has expired without the initiation of a Review Proceeding, or, if a Review Proceeding has been timely initiated, that there has occurred a full and final disposition of any such Review Proceeding, including the exhaustion of proceedings in any remand and/or subsequent appeal on remand.

1.10 "Final Decision" shall mean: a decision of the United States Supreme Court or of any federal Court of Appeals that is not appealed within the time permitted for such appeals or that, if appealed, is not accepted for review.

1.11 "HCV" shall mean: infection with the Hepatitis C virus.

1.12 "Medicaid HCV Class Released Claims" shall mean: any and all claims, demands, and causes of action, known or unknown, for injunctive and declaratory relief relating to Defendants' exclusion of coverage for Mavyret®, Harvoni® and other similar DAAs for the treatment of HCV due to fibrosis score for the class

that were brought by the Named Plaintiffs against Defendants in the Action on behalf of a class, including but not limited to claims for injunctive and declaratory relief under the Medicaid Act, attorney's fees, and costs. Medicaid HCV Class Released Claims shall not include a release of claims for damages to the extent those exist outside this Action or of any claims that could have been brought under state law. This Release shall be binding on Plaintiffs, the class and all their lawful guardians, heirs, beneficiaries, representatives, assigns, attorneys and agents.

1.13 "Medicaid HCV Class" shall mean: the class certified by the Court in the Action, specifically defined as

All individuals who:

(i) were, are, or will be enrolled in the Kansas Medicaid Program on or after October 31, 2016;

(ii) require or are expected to require treatment for Hepatitis C with Mavyret® or other similar direct acting antiviral under the current guidelines adopted by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America; and

(iii) did not meet the coverage criteria for HCV medication adopted by Defendants prior to the initial filing of this action, an exemplar for which is the Prior Authorization for Harvoni® attached as Exhibit A, except those Medicaid enrollees denied coverage based upon a history of illicit intravenous (IV) substance use within the 3 month period of their request for Mavyret® or other similar direct acting antiviral treatment for Hepatitis C.

1.14 "Named Plaintiffs" shall mean: Plaintiffs Jamie Harper and Jessica Owens.

1.15 "Parties" shall mean: Plaintiffs and Defendants.

1.16 "Releasees" shall mean: Defendants Jeff Andersen, in his official capacity as Secretary of the Kansas Department of Health and Environment, and Jon Hamdorf, in his official capacity as the Director of the Kansas Division of Health Care Finance.

1.17 "Settlement" shall mean: the settlement to be consummated under this Agreement.

1.18 "Kansas Medicaid Program" shall mean the Kansas Medicaid program administered by KDHE and KDHCF, and shall include the managed care program (commonly known as "KanCare") and the Fee-For Services program.

1.19 "KDHE" shall mean: Defendant Jeff Andersen, in his official capacity as Director of the Kansas Department of Health and Environment, and his successors in interest.

1.20 "KDHCF" shall mean: Defendant Jon Hamdorf, in his official capacity as the Director of the Kansas Division of Health Care Finance, and his successors in interest.

2. Conditions to Effectiveness of the Settlement.

2.1 General. The Settlement provided for in this Agreement shall not become binding unless and until each and every one of the conditions in sections 2.2 through 2.4 have been satisfied or waived.

2.2 In conjunction with filing the executed Agreement with the Court, Plaintiffs shall file a motion for leave to file an Amended Class Action Complaint to amend their class definition and seek certification of the Settlement Class.

2.3 Court Approval. The Settlement contemplated under this Agreement must be approved by the Court, as provided herein and pursuant to Fed. R. Civ. P. 23. The Parties agree jointly to recommend to the Court that it approve the terms of the Agreement and the Settlement contemplated hereunder. The Parties agree to promptly take all steps and efforts contemplated by the Agreement, including the following:

2.3.1 Motions for Preliminary Approval and Notices. The Court shall have preliminarily approved the Agreement ("Preliminary Approval Order"). Class Counsel shall make a motion for preliminary approval and authorization to send notice. The Court must conclude that the notice to be sent fairly and adequately describes the terms of the Agreement, gives notice of the time and place of the hearing for final approval of the Settlement, and describes how a Class Member may comment on, object to, or support the Settlement. The Court must also conclude that the manner of providing the notice to Class Members is the best notice practicable under the circumstances.

2.3.2 Issuance of Class Notice.

2.3.2.1 On the date set by the Court in its Preliminary Approval Order, KDHE, at its sole expense, shall have caused the Court-approved notice to be delivered to the relevant Class Members as follows: (1) All class members who KDHE identifies as potentially having a diagnosis of HCV, including specifically those diagnosed with HCV and denied treatment based upon application of the previous Prior Authorization, Exhibit A, shall receive notice by direct first class United States mail, forwarding requested, and (2) Defendants shall prominently post, on its webpage, a link to the Agreement and class notice. If the Court requires additional, different, or

expanded notice, then any such ordered notice must be provided by Defendants.

2.3.2.2 Class Counsel shall create a webpage that includes at least the following material:

a. A brief description of the case;

b. Identification of the class;

c. A summary of the proposed settlement derived from the class notice;

d. A timeline and schedule of events, including deadlines for supporting or objecting to the Agreement; and

e. How to contact Class Counsel for additional information;

f. Settlement documents, or links to documents, including:

i. class notice;

ii. motions for preliminary approval; and

iii. all court orders on preliminary approval.

g. Updates. The webpage created by Class Counsel shall be updated as the following become available:

i. Class Counsel's application(s) for attorney's fees, costs and incentive awards (with all supporting materials);

ii. Motion(s) for Final Approval of the settlement (including any objections and Class Counsel's response to those objections); and

iii. Frequently asked questions.

2.3.3 Fairness Hearing. On the date set by the Court in its Preliminary Approval Order, the Parties shall participate in the hearings ("Fairness Hearings") during or after which the Court will determine by order (the "Final Order"): (i) the proposed Settlement between the Parties is fair, reasonable and adequate and should be approved by the Court; and (ii) the requirements of Fed. R. Civ. P. 23 and due process have been satisfied in connection with the distribution of the notice.

2.3.4 Motions for Final Approval. On the date set by the Court in its Preliminary Approval Order, Plaintiffs shall have filed a motion ("Final Approval

Motion") for an order giving final approval to this settlement ("Approval Order").

2.4 No Termination. The Settlement shall not have terminated pursuant to section 7.

3. Releases.

3.1 Releases of the Releasees. Upon the Effective Date of Settlement, Plaintiffs on behalf of themselves and, to the full extent permitted by law on behalf of the Medicaid HCV Class, absolutely and unconditionally release and forever discharge Releasees from any and all Medicaid HCV Released Claims that Plaintiffs or the Medicaid HCV Class has directly, indirectly, derivatively, or in any other capacity ever had or now have. This Release shall be binding on Plaintiffs, the Medicaid HCV Class, and all their lawful heirs, beneficiaries, representatives, assigns, attorneys and agents.

3.2 Release of Personal Injury Claims. Upon the Effective Date of Settlement, Plaintiffs on behalf of themselves only, absolutely and unconditionally release and forever discharge Releasees from the personal injury claims that they filed on their own behalf in Case No. 5:18-cv-4008-DDC-GEB.

3.2 Defendants' Release of Named Plaintiffs, the Class and Class Counsel. Upon the Effective Date of Settlement, Defendants, to the full extent permitted by law, absolutely and unconditionally release and forever discharge the Plaintiffs, the Medicaid HCV Class, and Class Counsel from any and all claims relating to the Medicaid HCV Class Released Claims.

4. Representations and Warranties. The Parties, and each of them, represent and warrant that they are voluntarily entering into this Agreement as a result of arm's-length negotiations and in executing this Agreement they are relying upon their own judgment, belief and knowledge, and the advice and recommendations of their own counsel, concerning the nature, extent and duration of their rights and claims hereunder and regarding all matters which relate in any way to the subject matter hereof. The Parties, and each of them, represent and warrant that they have carefully read the contents of this Agreement; they have made such investigation of the facts pertaining to the Settlement, this Agreement and all of the matters pertaining thereto as they deem necessary; and this Agreement is signed freely by each person executing this Agreement on behalf of each party. Each individual executing this Agreement on behalf of any other person does hereby represent and warrant to the other parties that he or she has the authority to do so.

5. Coverage Modifications and Agreements.

5.1 HCV Coverage Modifications and Agreements.

5.1.1 Coverage of DAAs for Individuals with HCV. The parties agree that the Kansas Medicaid Program will treat Medicaid HCV patients with DAA drugs regardless of fibrosis score in accordance with the HCV guidelines adopted by the AASLD/IDSA (except as provided for below relating to IV

drug usage in the 3 month period prior to seeking Prior Authorization) as more fully specified by the Drug Utilization Review Board-approved treatment guidelines dated July 11, 2018, attached as Exhibit B to this Agreement. KanCare will also ensure that all MCOs authorized to provide Medicaid services for the State of Kansas under KanCare will be notified to follow the new Drug Utilization Review Board protocol adopted July 11, 2018, attached as Exhibit B. The pre-July 11, 2018 exclusion based on a history of alcohol or non-intravenous illicit drug abuse within the past 6 months will be removed. The Parties agree that the only drug or alcohol abstinence requirement shall now state: "Patient must not have a history of using IV needles to inject any illicit substance within 90 days of being authorized to receive DAA Drug Therapy," as set out in Exhibit B.

KDHE shall require a drug screen for Prior Authorizations for DAA treatment. In the event the drug screen is positive for any illicit substance (e.g., THC, amphetamines, or opioids), the prescribing physicians must certify that such drugs were not ingested by intravenous drug use to satisfy Prior Authorization requirements. If such drugs were ingested by intravenous method, the 90-day abstinence requirement must be met before DAA therapy is authorized.

5.1.2 KDHE also agrees to provide data to Class Counsel on a quarterly basis that specifies the number of requests and approvals for treatment of HCV by MCO until December 31, 2020.

5.1.3 Appeal Rights. Nothing herein shall be construed to limit or affect a Medicaid HCV Class Member's right to appeal a claims determination under applicable law.

6. Effective Date of Settlement.

6.1 Effective Date. This Agreement shall be fully effective and binding on the date on which all of the conditions to settlement set forth in section 2 have been fully satisfied or waived.

6.2 Disputes Concerning the Effective Date of Settlement. If Parties disagree as to whether each and every condition set forth in section 2 has been satisfied or waived, they shall promptly confer in good faith and, if unable to resolve their differences within ten (10) business days thereafter, shall present their dispute to the Court for resolution.

7. Termination of Agreement to Settle Claims.

7.1 Court Rejection. If the Court declines to preliminarily or finally approve the Settlement, then this Agreement shall automatically terminate, and thereupon become null and void. The Court must both preliminarily and finally approve the Agreement for it to be effective and binding.

7.2 Court of Appeals Reversal. If the Tenth Circuit Court of Appeals reverses the Court's order approving the Settlement, then, provided that no appeal is then pending from such a ruling, this Agreement shall automatically terminate and thereupon become null and void, on the 31st day after issuance of the order referenced in this section.

7.3 Supreme Court Reversal. If the Supreme Court reverses the Court's order approving the Settlement, then, provided that no appeal is then pending from such a ruling, this Agreement shall automatically terminate and thereupon become null and void, on the 31st day after issuance of the order referenced in this section.

7.4 Pending Appeal. If an appeal is pending of an order declining to approve the Settlement, this Agreement shall not be terminated until final resolution of dismissal of any such appeal, except by written agreement of the Parties.

8. Consequences of Termination. If the Agreement is terminated and rendered null and void for any reason, then the following shall occur:

8.1 Reversion of Action. The Action shall revert to its status as of July 9, 2018.

8.2 Releases and Terms Void. All Releases given or executed pursuant to this Agreement shall be null and void and none of the terms of the Agreement shall be effective or enforceable.

9. Attorney's Fees, Litigation Expenses and Case Contribution Awards.

9.1 Attorney's Fees and Litigation Expenses. Defendants agree to pay Class Counsel's reasonable attorney's fees and costs that are associated with this Action as approved by the Court not to exceed $68,000.

9.2 Case Contribution Awards. Upon Finality, Defendants agree to pay named Plaintiffs incentive awards in an amount not to exceed $7,500 each. These incentive awards must be presented to and approved by the Court. This Agreement is not contingent upon an award of incentive payments, and shall not terminate by reason of the Court awarding less than the amount requested. Defendants will take no position with respect to the application for incentive awards provided that the requests do not exceed the amounts set forth herein.

10. Miscellaneous

10.1 Governing Law. This Agreement shall be governed by the laws of the State of Kansas without regard to conflict of law principles.

10.2 Severability. The provisions of this Agreement are not severable.

10.3 Amendment. Before entry of any Preliminary Approval Order, this Agreement may be modified or amended only by written agreement signed by or on behalf of all Parties.

10.4 Waiver. The provisions of this Agreement may be waived only by an instrument in writing executed by the waiving party. The waiver by any party of any breach of this Agreement shall not be deemed to be or construed as a waiver of any other breach, whether prior, subsequent, or contemporaneous, of this Agreement.

10.5 Construction. None of the Parties hereto shall be considered to be the drafter of this Agreement or any provision thereof for the purpose of any statute, case law or rule of interpretation or construction that would or might cause the provision to be construed against the drafter thereof.

10.6 Principles of Interpretation. The following principles of interpretation apply to this Agreement:

10.6.1 Headings. The headings herein are for reference purposes only and do not affect in any way the meaning or interpretation of this Agreement.

10.6.2 Singular and Plural. Definitions apply to the singular and plural forms of each term defined.

10.6.3 References to a Person. References to a person include references to an entity, and include successors and assigns.

10.7 Survival. All representations, warranties and covenants set forth herein shall be deemed continuing and shall survive the Effective Date of Settlement.

10.8 Entire Agreement. This Agreement contains the entire agreement between the Parties relating to this Settlement.

10.9 Counterparts. This Agreement may be executed by exchange of executed faxed or PDF signature pages, and any signature transmitted in such a manner shall be deemed an original signature. This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original, but all of which, when taken together, shall constitute one and the same instrument.

10.10 Binding Effect. This Agreement binds and inures to the benefit of the parties hereto, their assigns, heirs, administrators, executors, and successors-in-interest, affiliates, benefit plans, predecessors, and transferees, and their past and present shareholders, officers, directors, agents, and employees.

10.11 Further Assurances. Each of the Parties agree, without further consideration, and as part of finalizing the Settlement hereunder, that they will in good faith promptly execute and deliver such other documents and take such other actions as may be necessary to consummate the subject matter and purpose of this Agreement.

SIGNATURE OF PLAINTIFF:

Jamie Harper on his own behalf and on behalf of the "Medicaid HCV Class"

Jamie R. Harper
Signature

11/3/2018
Date

SIGNATURE OF PLAINTIFF:

Jessica Owens, on her own behalf and on behalf of the "Medicaid HCV Class"

Jessica Owens
Signature

11/5/2018
Date

SIGNATURES:

Jamie Harper on his own behalf and on behalf of the "Medicaid HCV Class"

_____
Signature

_____
Date

Jessica Owens, on her own behalf and on behalf of the "Medicaid HCV Class"

_____
Signature

_____
Date

Jeff Andersen, in his official capacity as Secretary of the Kansas Department of Health and Environment

Andersen
Signature

11/15/18
Date

Jon Hamdorf, in his official capacity as the Director of the Kansas Division of Health Care Finance

Signature

11/19/18
Date

Exhibit A

Initial Approval: November 14, 2014
Revised Dates: January 11, 2017; April 13, 2016
January 13, 2016; October 14, 2015; January 14, 2015

CRITERIA FOR PRIOR AUTHORIZATION

Fixed Combination Direct Acting Hepatitis C Agent

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Ledipasvir/Sofosbuvir (Harvoni®)

CRITERIA FOR INITIAL APPROVAL OF LEDIPASVIR/SOFOSBUVIR: (must meet all of the following)

Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 24 weeks of Sofosbuvir/Ledipasvir therapy total)

- Patient must have a diagnosis of chronic hepatitis C (CHC)
- Patient must have genotype 1, 4, 5, or 6 hepatitis C
- Patient must not have severe renal impairment (eGFR<30mL/min/1.73m^2) or currently require hemodialysis
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Patient must not have been on previous or concurrent direct acting hepatitis C agents
- If patient was on a previous course of treatment with Incivek or Victrelis it must have included an interferon-based regimen
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
- Dose must not exceed 1 capsule per day
- Patient must have one of the following:
    - Advanced fibrosis (Metavir F3)
    - Compensated cirrhosis
    - Organ transplant
    - Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis)
    - Proteinuria
    - Nephrotic syndrome
    - Membranoproliferative glomerulonephritis
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with ledipasvir/sofosbuvir therapy
- For Genotypes 1 and/or 4: the PDL preferred drug, which covers Genotypes 1 and 4, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines

RENEWAL CRITERIA FOR LEDIPASVIR/SOFOSBUVIR:

- Prescriber must document adherence by patient of greater than or equal to 90% and meet one of the following:
  - Genotype 1 (one of the following)
    - Treatment-naïve, without cirrhosis, and a pre-treatment HCV RNA < 6 million IU/mL – **8 weeks total therapy**
    - Treatment-naïve, with or without cirrhosis, and a pre-treatment HCV RNA ≥ 6 million IU/mL – **12 weeks total therapy**
    - Treatment-naïve, with cirrhosis– **12 weeks total therapy**
    - Treatment-experienced, without cirrhosis – **12 weeks total therapy**
    - Treatment-experienced, with cirrhosis:
      - **24 weeks total therapy alone**
      - **12 weeks total therapy if used with Ribavirin**
  - Genotype 4, 5, or 6
    - **12 weeks total therapy**

LENGTH OF APPROVAL FOR LEDIPASVIR/SOFOSBUVIR: 4 weeks

_____

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

_____

DATE

_____

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

_____

DATE

Exhibit B

Initial Approval: July 11, 2018

CRITERIA FOR PRIOR AUTHORIZATION

Hepatitis C Agents

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES All dosage forms of the medications listed in Table 1 below will require prior authorization.

CRITERIA FOR NON-REFRACTORY, INITIAL APPROVAL (MUST MEET ALL OF THE FOLLOWING):

**Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to the duration listed below)*

- Patient must have a diagnosis of chronic hepatitis C virus (HCV)
- Patient must have a confirmed genotype of 1a, 1b, 2, 3, 4, 5 or 6.
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist
- Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
- Treatment regimen and duration of treatment must be prescribed in accordance with FDA-approved product labeling (defined in table 2)
- Requested medication must be prescribed for an FDA-approved age (defined in table 1)
- Dose must not exceed the medication-specific quantity limits (defined in table 1).
- Patient must not have a history of illicit intravenous (IV) substance use within the past 3 months
- Prescriber must attest that the patient will be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment
- If the requested medication will be used in combination with ribavirin, female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly thereafter until treatment completion.
- Patient must not have been on previous or concurrent direct-acting hepatitis C agents.
- Prescriber must attest that the patient's drug profile will be reviewed and monitored for potential clinically significant drug interactions (defined in table 1) with the requested medication prior to therapy initiation and throughout treatment duration.
- Prescriber must attest that all additional medication-specific safety criteria, as defined in table 1, is met.
- Prescriber must attest that the patient has demonstrated readiness to begin treatment for hepatitis C per the Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C) free interactive online tool (https://prepc.org), completed by the prescriber.
- For all genotypes: the PDL preferred drug, which covers that specific genotype, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label.

LENGTH OF INITIAL APPROVAL: 4 weeks

CRITERIA FOR RENEWAL FOR NON-REFRACTORY TREATMENT: (must meet all of the following)

- Prescriber must document adherence by patient of greater than or equal to 90%.

LENGTH OF RENEWAL APPROVALS: 4 weeks, up to the total number of approved weeks based upon FDA labeling.

APPROVED PA Criteria

CRITERIA FOR REFRACTORY, INITIAL APPROVAL: (must meet all of the following)

- Patient must meet all criteria for non-refractory, initial approval above.
- MCO claims data must indicate greater than or equal to 90% adherence to the previous direct-acting antiviral regimen (the MCO reviewer should verify this by the MCO claims data)
- Prescriber has submitted documentation showing that the patient has a documented presence of detectable HCV RNA at/up to 12 weeks after the last treatment was given
    - An assessment of viral response, including documentation of Sustained Viral Response (SVR), using an FDA-approved quantitative or qualitative nucleic acid test (NAT) with a detection level of greater than (>) 25 IU/mL at/up to 12 weeks after the last treatment was given (https://www.hcvguidelines.org/evaluate/when-whom)

LENGTH OF INITIAL APPROVAL: 4 weeks

CRITERIA FOR RENEWAL FOR REFRACTORY TREATMENT: (must meet all of the following)

- Prescriber must document adherence by patient of greater than or equal to 90% for both agents.

LENGTH OF RENEWAL APPROVALS: 4 weeks, up to a total of 12 weeks based on approved treatment regimen and duration

TABLE 1: MEDICATION-SPECIFIC CRITERIA

MEDICATION	MEDICATION-SPECIFIC CRITERIA	
Daklinza® (daclatasvir)	Indication/Use	Hepatitis C virus (HCV) NS5A inhibitor indicated for use with sofosbuvir, with or without ribavirin, for the treatment of chronic HCV genotype 1 or 3 infection.
	Age (years)	≥ 18
	Quantity Limit	1 tablet/day
	Safety Criteria	➢ Patient must not be concurrently prescribed a strong CYP3A inducer (e.g. phenytoin, carbamazepine, rifampin, St. John's wort) ➢ Patient must not be on concurrent moderate CYP3A inducers (e.g. bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, rifapentine)
Epclusa® (sofosbuvir/velpatasvir)	Indication/Use	Fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adult patients with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection: • without cirrhosis or with compensated cirrhosis • with decompensated cirrhosis for use in combination with ribavirin
	Age (years)	≥ 18
	Quantity Limit	1 tablet/day
	Safety Criteria	➢ Patient must not have severe renal impairment (eGFR < 30 mL/min/1.73m^2) or currently require hemodialysis ➢ Patient must not be on concurrent: • Amiodarone • Moderate to strong inducers of CYP2B6 (e.g., carbamazepine, fosphenytoin, nevirapine, phenobarbital, phenytoin, primidone, rifampin) • Moderate to strong inducers of CYP2C8 (e.g., rifampin) • Moderate to strong inducers of CYP3A4 (e.g., avasimibe, carbamazepine, dexamethasone, ethosuximide, griseofulvin, phenytoin, primidone, progesterone, rifabutin, rifampin, nafcillin, nelfinavir, nevirapine, oxcarbazepine, phenobarbital, phenylbutazone, St John's wort, sulfadimidine, sulfinpyrazone, troglitazone) • Inducers of P-gp (e.g., avasimibe, carbamazepine, phenytoin, rifampin, St John's wort, tipranavir/ritonavir)
Harvoni® (ledipasvir/sofosbuvir)	Indication/Use	Fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis C virus (HCV) in: • Adults with genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis • Adults with genotype 1 infection with decompensated cirrhosis, in combination with ribavirin • Adults with genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin • Pediatric patients 12 years of age and older or weighing at least 35 kg with genotype 1, 4, 5, or 6 without cirrhosis or with compensated cirrhosis
	Age (years)	≥ 12 years of age or weighing at least 35 kg
	Quantity Limit	1 tablet/day
	Safety Criteria	➢ Patient must not have severe renal impairment (eGFR < 30 mL/min/1.73m^2) or currently require hemodialysis ➢ If patient was on a previous course of treatment with Incivek or Victrelis it must have included an interferon based regimen ➢ Coadministration with amiodarone is not recommended. If alternative, viable treatment options are unavailable, cardiac monitoring is recommended
Mavyret® (glecaprevir/pibrentasvir)	Indication/Use	1. Fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is indicated for the treatment of patients with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A). 2. HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.
	Age (years)	≥ 18
	Quantity Limit	1 daily dose pack/day
	Safety Criteria	➢ Patient must not have moderate or severe hepatic impairment (Child-Pugh class B or C) ➢ Patient must not be concurrently prescribed atazanavir or rifampin ➢ Patient must not be on a concurrent direct acting hepatitis C agent or ribavirin

TABLE 1 (CONT.). MEDICATION-SPECIFIC CRITERIA

MEDICATION	MEDICATION-SPECIFIC CRITERIA	
Olysio® (simeprevir)	Indication/Use	Hepatitis C virus (HCV) NS3/4A protease inhibitor indicated for the treatment of adults with chronic hepatitis C virus (HCV) infection: • in combination with sofosbuvir in patients with HCV genotype 1 without cirrhosis or with compensated cirrhosis • in combination with peginterferon alfa (Peg-IFN-alfa) and ribavirin (RBV) in patients with HCV genotype 1 or 4 without cirrhosis or with compensated cirrhosis
	Age (years)	≥ 18
	Quantity Limit	1 capsule/day
	Safety Criteria	➢ If patient has subtype 1a they must have a negative test for NS3-Q80k polymorphism ➢ The patient must not have advanced and/or decompensated cirrhosis (moderate or severe hepatic impairment)
Sovaldi® (sofosbuvir)	Indication/Use	Hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of: • Adult patients with genotype 1, 2, 3 or 4 chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen. • Pediatric patients 12 years of age and older or weighing at least 35 kg with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin.
	Age (years)	≥ 18 (genotype 1, 2, 3, 4) ≥ 12 years of age or weighing at least 35 kg (genotype 2 or 3)
	Quantity Limit	1 tablet/day
	Safety Criteria	➢ Coadministration with amiodarone is not recommended. If alternative, viable treatment options are unavailable, cardiac monitoring is recommended
Technivie® (ombitasvir/paritaprevir/ ritonavir)	Indication/Use	Fixed-dose combination of ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor and is indicated in combination with ribavirin for the treatment of patients with genotype 4 chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis.
	Age (years)	≥ 18
	Quantity Limit	2 tablets/day
	Safety Criteria	➢ Patient must not have moderate or severe hepatic impairment or cirrhosis (Metavir score of F4 and Child-Pugh class B or C) ➢ Patient must not be concurrently prescribed a moderate or strong CYP3A inducer
Viekira Pak™, Viekira XR™ (ombitasvir/paritaprevir/ ritonavir and dasabuvir)	Indication/Use	Treatment of adult patients with chronic hepatitis C virus (HCV): • genotype 1b without cirrhosis or with compensated cirrhosis • genotype 1a without cirrhosis or with compensated cirrhosis for use in combination with ribavirin. (VIEKIRA PAK includes ombitasvir, a HCV NS5A inhibitor, paritaprevir, a HCV NS3/4A protease inhibitor, ritonavir, a CYP3A inhibitor and dasabuvir, a HCV non-nucleoside NS5B palm polymerase inhibitor)
	Age (years)	≥ 18
	Quantity Limit	1 daily dose pack/day
	Safety Criteria	➢ Patient must not have underlying moderate to severe hepatic impairment (Child-Pugh class B or C)
Zepatier® (elbasvir/grazoprevir)	Indication/Use	Fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor, and is indicated for treatment of chronic HCV genotype 1 or 4 infection in adults. ZEPATIER is indicated for use with ribavirin in certain patient populations.
	Age (years)	≥ 18
	Quantity Limit	1 tablet/day
	Safety Criteria	➢ Patient must not be concurrently prescribed a strong CYP3A inducer (e.g. phenytoin, carbamazepine, rifampin, St. John's Wort), efavirenz, or OATP1B1/3 inhibitor (e.g. cyclosporine, eltrombopag, lapatinib, lopinavir, rifampin, ritonavir) ➢ If the patient has genotype 1a, patient must be tested for the presence of virus with NS5A resistance-associated polymorphisms prior to initiation of therapy ➢ Patient must not have moderate or severe hepatic impairment (Child-Pugh class B or C)

TABLE 1 (CONT.). MEDICATION-SPECIFIC CRITERIA

MEDICATION	MEDICATION-SPECIFIC CRITERIA	
Vosevi™ (sofosbuvir/velpatasvir/ voxilaprevir)	Indication/Use	Fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, velpatasvir, an HCV NS5A inhibitor, and voxilaprevir, an HCV NS3/4A protease inhibitor, and is indicated for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have: • Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor. • Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.
	Age (years)	≥ 18
	Quantity Limit	1 tablet/day
	Safety Criteria	➢ Patient must not have severe renal impairment (eGFR < 30 mL/min/1.73m^2) or currently require hemodialysis ➢ Patient must not be on concurrent rifampin ➢ Patient should not be on concurrent: P-gp inducers, moderate to potent CYP2B6, 2C8, or 3A4 inducers, amiodarone (if alternative, viable treatment options are unavailable, cardiac monitoring is recommended)

TABLE 2. TREATMENT REGIMEN AND DURATION

MEDICATION	GENOTYPE	PATIENT POPULATION	TREATMENT AND DURATION
Daklinza® (daclatasvir)	1	Without cirrhosis	Daklinza + Sofosbuvir for 12 weeks
		Compensated (Child-Pugh A) cirrhosis	Daklinza + Sofosbuvir for 12 weeks
		Decompensated (Child-Pugh B or C) cirrhosis	Daklinza + Sofosbuvir + Ribavirin for 12 weeks
		Post-transplant	Daklinza + Sofosbuvir + Ribavirin for 12 weeks
	3	Without cirrhosis	Daklinza + Sofosbuvir for 12 weeks
		Compensated (Child-Pugh A) cirrhosis	Daklinza + Sofosbuvir + Ribavirin for 12 weeks
		Decompensated (Child-Pugh B or C) cirrhosis	Daklinza + Sofosbuvir + Ribavirin for 12 weeks
		Post-transplant	Daklinza + Sofosbuvir + Ribavirin for 12 weeks
Epclusa® (sofosbuvir/velpatasvir)	1, 2, 3, 4, 5, 6	Treatment-naïve and treatment-experienced[a], without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Epclusa for 12 weeks
		Treatment-naïve and treatment-experienced[a], with decompensated cirrhosis (Child-Pugh B or C)	Epclusa + Ribavirin for 12 weeks
Harvoni® (ledipasvir/sofosbuvir)	1	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni for 12 weeks
		Treatment-experienced[b] without cirrhosis	Harvoni for 12 weeks
		Treatment-experienced[b] with compensated cirrhosis (Child-Pugh A)	Harvoni for 24 weeks
		Treatment-naïve and treatment-experienced[b] with decompensated cirrhosis (Child-Pugh B or C)	Harvoni + Ribavirin for 12 weeks
	1 or 4	Treatment-naïve and treatment-experienced[b] liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	Harvoni + Ribavirin for 12 weeks
	4, 5 or 6	Treatment-naïve and treatment-experienced[b], without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Harvoni for 12 weeks

TABLE 2 (CONT.). TREATMENT REGIMEN AND DURATION

MEDICATION	GENOTYPE	PATIENT POPULATION	TREATMENT AND DURATION
Mavyret® (glecaprevir/pibrentasvir)	1, 2, 3, 4, 5, 6	Treatment-naïve, without cirrhosis	Mavyret for 8 weeks
		Treatment-naïve, with compensated cirrhosis (Child-Pugh A)	Mavyret for 12 weeks
	1	Treatment-experienced, previously treated with regimen containing an NS5A inhibitor[c] without prior treatment with an NS3/4A protease inhibitor, without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	Mavyret for 16 weeks
		Treatment-experienced, previously treated with regimen containing an NS3/4A PI[d] without prior treatment with an NS5A inhibitor, without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	Mavyret for 12 weeks
	1, 2, 4, 5, 6	Treatment-experienced, previously treated with regimen containing PRS[e], without cirrhosis	Mavyret for 8 weeks
		Treatment-experienced, previously treated with regimen containing PRS[e], with compensated cirrhosis (Child-Pugh A)	Mavyret for 12 weeks
	3	Treatment-experienced, previously treated with regimen containing PRS[e], without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	Mavyret for 16 weeks
Olysio® (simeprevir)	1	Treatment-naïve and treatment-experienced, without cirrhosis	Olysio + Sofosbuvir for 12 weeks
		Treatment-naïve and treatment-experienced, with compensated cirrhosis (Child-Pugh A)	Olysio + Sofoxbuvir for 24 weeks
	1, 4	Treatment-naïve and treatment-experienced, without cirrhosis or with compensated cirrhosis (Child-Pugh A), with or without HIV-1 co-infection	Olysio + Peg-IFN-alfa + Ribavirin for 12 weeks (followed by 12 or 36 additional weeks of Peg-IFN-alfa + Ribavirin depending on prior response status and presence of HIV-1 infection)
Sovaldi® (sofosbuvir)	1, 4	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + Peg-IFN-alfa + Ribavirin for 12 weeks
	2	Treatment-naïve and treatment-experienced[b] without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + Ribavirin for 12 weeks
	3	Treatment-naïve and treatment-experienced[b] without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + Ribavirin for 24 weeks
Technivie® (ombitasvir/paritaprevir/ ritonavir)	4	Without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Technivie + Ribavirin for 12 weeks (Technivie without ribavirin for 12 weeks may be considered for treatment-naïve patients without cirrhosis who cannot take or tolerate ribavirin)
Viekira Pak™, Viekira XR™ (ombitasvir/paritaprevir/ ritonavir and dasabuvir)	1a	Treatment-naïve or interferon-experienced, without cirrhosis	Viekira Pak + Ribavirin for 12 weeks
		Treatment-naïve or interferon-experienced, with compensated cirrhosis (Child-Pugh A)	Viekira Pak + Ribavirin for 24 weeks (Viekira Pak + ribavirin for 12 week may be considered for some patients based on prior treatment history)
	1b	Treatment-naïve or interferon-experienced, without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Viekira Pak for 12 weeks
	*Follow genotype 1a dosing recommendations in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection		

TABLE 2 (CONT.). TREATMENT REGIMEN AND DURATION

MEDICATION	GENOTYPE	PATIENT POPULATION	TREATMENT AND DURATION
Zepatier® (elbasvir/grazoprevir)	1a	Treatment-naïve or Peg-IFN/Ribavirin-experienced without baseline NS5A polymorphisms, without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	Zepatier for 12 weeks
		Treatment-naïve or Peg-IFN/Ribavirin-experienced with baseline NS5A polymorphisms, without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	Zepatier + Ribavirin for 16 weeks
	1b	Treatment-naïve or Peg-IFN/Ribavirin-experienced without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	Zepatier for 12 weeks
	1a or 1b	Peg-IFN/Ribavirin/NS3/4A protease inhibitor-experienced, without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	Zepatier + Ribavirin for 12 weeks
	4	Treatment-naïve, without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	Zepatier for 12 weeks
		Peg-IFN/Ribavirin/NS3/4A protease inhibitor-experienced, without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	Zepatier + Ribavirin for 16 weeks
Vosevi™ (sofosbuvir/velpatasvir/ voxilaprevir)	1, 2, 3, 4, 5, 6	Treatment-experienced, previously treated with regimen containing an NS5A inhibitor[g], without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Vosevi for 12 weeks
	1a or 3	Treatment-experienced, previously treated with regimen containing sofosbuvir without an NS5A inhibitor[h], without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Vosevi for 12 weeks

[a] – In clinical trials, regimens contained peginterferon alfa/ribavirin with or without an HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir)

[b] – Treatment-experienced patients have failed an interferon based regimen with or without ribavirin

[c] – In clinical trials, subjects were treated with prior regimens containing ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin

[d] – In clinical trials, subjects were treated with prior regimens containing simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin

[e] – PRS = Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor

[f] – Treatment-experienced patients include prior relapsers, prior partial responders and prior null responders who failed prior IFN-based therapy

[g] – In clinical trials, prior NS5A inhibitor experience included daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir

[h] – In clinical trials, prior treatment experience included sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir)