# SmartPA Criteria Proposal

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| **Drug/Drug Class:** | Hepatitis C Agents PDL Edit |
| **First Implementation Date:** | October 2, 2014 |
| **Proposed Date:** | April 18, 2023 |
| **Prepared For:** | MO HealthNet |
| **Prepared By:** | MO HealthNet/Conduent |
| **Criteria Status:** | ☒Existing Criteria<br>☐Revision of Existing Criteria<br>☐New Criteria |

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** Hepatitis C (HCV) infection has recently been referred to as a "Silent Epidemic" because it usually progresses slowly over many years. HCV is the most common cause of chronic liver disease in the United States. Many people who are infected are not aware of any noticeable symptoms for as long as 10 to 20 years after they are infected. Often by the time symptoms appear, the virus has already begun to damage the liver. Approximately 5-30% of chronically infected individuals develop cirrhosis 20-30 years after exposure. HCV is a blood-borne virus spread through the blood or blood products. Common routes of infections include blood transfusions, needle stick accidents, recreational drug use, tattooing, body piercing, and unprotected sexual activity. The goals of hepatitis C therapy are to clear the virus from the blood and slow the progression of the disease, preventing further liver damage. Currently no vaccine is available to prevent people from getting this disease. There has been a steady and significant increase in new HCV infections over the previous 10 years, which has been attributed to an increase in needle sharing due to the opioid epidemic. It is estimated that 4.1 million Americans have been infected with HCV, with approximately 40,000 new cases occurring in the U.S. each year.

It is the State of Missouri's goal to eliminate HCV in the MO HealthNet population. In the past few years, new therapies such as direct-acting antivirals (DAAs) have become available to effectively treat and cure HCV patients with shorter treatment times and fewer side effects. MO HealthNet has partnered with AbbVie in a modified subscription model from July 2021 to June 2024 to utilize the medication Mavyret® with a goal to eliminate HCV in the MO HealthNet population that 3 year period. This partnership allows MO HealthNet to remove the prior authorization requirement for Mavyret and ensure access to Mavyret for all MO HealthNet participants infected with HCV.

Total program savings for the PDL classes will be regularly reviewed.

**Program-Specific Information:**

| Preferred Agents | Non-Preferred Agents |
|---|---|
| • Mavyret® | • Epclusa®<br>• Harvoni®<br>• Ledipasvir-Sofosbuvir<br>• Sofosbuvir-Velpatasvir<br>• Sovaldi® |

| | |
|---|---|
| | • Viekira Pak™<br>• Vosevi®<br>• Zepatier® |

**Type of Criteria:** ☒ **Increased risk of ADE** ☒ **Preferred Drug List**
☒ **Appropriate Indications** ☐ **Clinical Edit**

**Data Sources:** ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

## Setting & Population

- Drug class for review: Hepatitis C Agents
- Age range: All appropriate MO HealthNet participants aged 3 years or older

## Approval Criteria

- For Mavyret tablets: No Prior Authorization is required
- For Mavyret pellets:
  - Participant aged 3 to 11 years **OR**
  - Documented inability to swallow tablets

- All other HCV DAA treatments require Prior Authorization and Clinical Consultant Review based on the following criteria:
  - Clinical Documentation for why Mavyret cannot be utilized for the participant **AND**
  - Documented diagnosis of hepatitis C (HCV) in the past year **AND**
  - Baseline viral load and fibrosis score submitted – note fibrosis score of F4 also requires a Child-Pugh score to be submitted **AND**
  - For Vosevi:
    - Participant aged 18 years or older **AND**
    - Prescribing provider confirmed therapy is for retreatment – note retreatment is at the discretion of MO HealthNet
  - For Zepatier:
    - Participant aged 18 years or older **AND**
    - NS5A RAV polymorphism test results submitted
  - For Viekira Pak: participant aged 18 years or older
  - Viral load must be submitted upon completion of treatment for non-preferred products and 12 weeks post treatment. FAILURE TO SUBMIT THESE LAB REPORTS OR IN A TIMELY FASHION MAY RESULT IN DENIAL OF RE-TREATMENT SHOULD THAT SITUATION ARISE.
  - Occasionally duration of treatment of 24 weeks is necessary, a viral load must be obtained and submitted at week 10 of treatment with any results of > 25 International Units resulting in possible discontinuance of treatment. Not submitting this viral load in a timely fashion may result in patient having difficulty getting medication to begin week 13 of treatment.
  - Retreatment is at the discretion of MO HealthNet.
  - MO HealthNet uses three resources for drug interaction information, Facts and Comparisons, Micromedex, and University of Liverpool Hepatitis C Drug Interaction tool. Provider resources other than the three listed will not supersede MO HealthNet's resources.

## Denial Criteria

- Greater than a 14 day gap between prior claim and incoming claim with a 168 day look back (excluding claims for Mavyret)
- Lack of adequate trial on required preferred agents

- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

| Drug Description | Generic Equivalent | Max Dosing Limits |
|---|---|---|
| EPCLUSA 200 MG-50 MG TABLET | SOFOSBUVIR/VELPATASVIR | 28 tablets for 28 days |
| EPCLUSA 400 MG-100 MG TABLET | SOFOSBUVIR/VELPATASVIR | 28 tablets for 28 days |
| HARVONI 33.75-150 MG PELLET PK | LEDIPASVIR/SOFOSBUVIR | 28 packets for 28 days |
| HARVONI 45-200 MG PELLET PK | LEDIPASVIR/SOFOSBUVIR | 28 packets for 28 days |
| HARVONI 45-200 MG TABLET | LEDIPASVIR/SOFOSBUVIR | 28 tablets for 28 days |
| HARVONI 90-400 MG | LEDIPASVIR AND SOFOSBUVIR | 28 tablets for 28 days |
| SOVALDI 150 MG PELLET PACKET | SOFOSBUVIR | 28 packets for 28 days |
| SOVALDI 200 MG PELLET PACKET | SOFOSBUVIR | 28 packets for 28 days |
| SOVALDI 200 MG TABLET | SOFOSBUVIR | 28 tablets for 28 days |
| SOVALDI 400 MG | SOFOSBUVIR | 28 tablets for 28 days |
| VIEKIRA PAK | DASABUVIR/OMBITASVIR/ PARITAPREVIR/RITONAVIR | 112 tablets for 28 days |
| VOSEVI 400-100-100 MG TABLET | SOFOSBUVIR/VELPATAS/ VOXILAPREV | 28 tablets for 28 days |
| ZEPATIER 50-100 MG TABLET | ELBASVIR/ GRAZOPREVIR | 28 tablets for 28 days |

## Required Documentation

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|---|---|---|---|
| Laboratory Results: | X | Progress Notes: | X |
| MedWatch Form: | | Other: | X |

## Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

## Default Approval Period

3 months

## References


- Evidence-Based Medicine and Fiscal Analysis: “Therapeutic Class Review: ANTI-INFECTIVES: Hepatitis C Agents, Oral Direct Acting Antivirals”, Gainwell Technologies; Last updated February 27, 2023.
- Evidence-Based Medicine Analysis: “Hepatitis C Agents – Direct-Acting Antiviral Agents (DAAVs)”, UMKC-DIC; April 2020.
- USPDI, Micromedex; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.
- HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (accessed February 2023). https://www.hcvguidelines.org/.