



SmartPA Criteria Proposal

Drug/Drug Class:	Hepatitis C Agents PDL Edit
First Implementation Date:	October 2, 2014
Revised Date:	July 7, 2022
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> 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 some 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 over the next 3 years. 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
	<ul style="list-style-type: none"> • Mavyret® 	<ul style="list-style-type: none"> • Eplclusa® • Harvoni® • Ledipasvir-Sofosbuvir • Sofosbuvir-Velpatasvir • Sovaldi® • Viekira Pak™ • Vosevi® • Zepatier®

Type of Criteria: Increased risk of ADE
 Appropriate Indications

Preferred Drug List
 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	SOFOBUVIR/VELPATASVIR	28 tablets for 28 days
EPCLUSA 400 MG-100 MG TABLET	SOFOBUVIR/VELPATASVIR	28 tablets for 28 days
HARVONI 33.75-150 MG PELLET PK	LEDIPASVIR/SOFOBUVIR	28 packets for 28 days
HARVONI 45-200 MG PELLET PK	LEDIPASVIR/SOFOBUVIR	28 packets for 28 days
HARVONI 45-200 MG TABLET	LEDIPASVIR/SOFOBUVIR	28 tablets for 28 days
HARVONI 90-400 MG	LEDIPASVIR AND SOFOBUVIR	28 tablets for 28 days
SOVALDI 150 MG PELLET PACKET	SOFOBUVIR	28 packets for 28 days
SOVALDI 200 MG PELLET PACKET	SOFOBUVIR	28 packets for 28 days
SOVALDI 200 MG TABLET	SOFOBUVIR	28 tablets for 28 days
SOVALDI 400 MG	SOFOBUVIR	28 tablets for 28 days
VIEKIRA PAK	DASABUVIR/OMBITASVIR/ PARITAPREVIR/RITONAVIR	112 tablets for 28 days
VOSEVI 400-100-100 MG TABLET	SOFOBUVIR/VELPATAS/ VOXILAPREV	28 tablets for 28 days
ZEPATIER 50-100 MG TABLET	ELBASVIR/ GRAZOPREVIR	28 tablets for 28 days

Required Documentation

Laboratory Results:
MedWatch Form:

X

Progress Notes:
Other:

X
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: "Hepatitis C Therapy: Direct-Acting Antiviral Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; April 2020.
- Evidence-Based Medicine Analysis: "Hepatitis C Agents – Direct-Acting Antiviral Agents (DAAVs)", UMKC-DIC; April 2020.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 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 March 2022). <https://www.hcvguidelines.org/>.
- Mavyret® (glecaprevir and pibrentasvir) [package insert]. North Chicago, IL: AbbVie Inc; June 2021.
- Sovaldi® (sofosbuvir) [package insert]. Foster City, CA: Gilead Sciences Inc; March 2020.

SmartPA PDL Proposal Form

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- Zepatier® (elbasvir and grazoprevir) [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; December 2021.
- Epclusa® (sofosbuvir and velpatasvir) [package insert]. Foster City, CA: Gilead Sciences Inc; April 2022.
- Harvoni® (ledipasvir and sofosbuvir) [package insert]. Foster City, CA: Gilead Sciences Inc; March 2020.
- Viekira Pak® (ombitasvir, paritaprevir, ritonavir, and dasabuvir) [package insert]. North Chicago, IL; AbbVie Inc; December 2019.