SmartPA Criteria Proposal

Drug/Drug Class:	Hepatitis C Agents PDL Edit
First Implementation Date:	October 2, 2014
Proposed Date:	June 18, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐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. Previous therapy with pegylated interferon plus ribavirin was characterized by major adverse drug reactions and at best a 50-60% success rate. HCV treatment changed with the advent of new Direct Acting Agents (DAAs). In 2014, Olysio™ and Sovaldi® were FDA approved for Hepatitis C therapy with treatment success rates in the 90% range. Then came Harvoni®, Viekira Pak™ (and later Viekira XR™), Daklinza®, Technivie®, Zepatier™, Epclusa®, Vosevi® and Mavyret™. Epclusa and Mavyret are pan-genotypic, and along with Vosevi, received FDA approval for retreatment of patients who were treated previously. Originally a 12 week treatment with the early agents was quite expensive, approximately $93,000 wholesale acquisition cost. Because of the high cost of these agents, having clinical criteria in place for approval of these drugs was necessary. As more DAAs were approved competition has helped lower the costs of treatment. Current clinical practice guidelines favor oral, ribavirin-free treatment regimens for all genotypes.

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

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	• Epclusa® • Mavyret™ • **Sofosbuvir-Velpatasvir** • Vosevi® (Retreatment Only)	• Harvoni® • Ledipasvir-Sofosbuvir • Sovaldi® • Viekira Pak™ • 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

Approval Criteria

- Documented diagnosis of hepatitis C (HCV) in the past year **AND**
- Prescribing provider is responsible for addressing ongoing misuse of alcohol and continued use of illicit IV drugs **AND**
- Prescriber required to attest that the participant demonstrates treatment readiness **AND**
- Baseline viral load and fibrosis score submitted – note fibrosis score of F4 also requires a Child-Pugh score to be submitted **AND**
- For Mavyret:
  - Participants aged 12 years of age or older **AND**
  - Approvable for an 8-week dosing regimen for treatment in naïve participants with compensated cirrhosis (Child-Pugh A) **OR**
- **For Epclusa: participants aged 6 years of age or older OR**
- For Vosevi:
  - Participants aged 18 years of age or older **AND**
  - Prescribing provider confirmed therapy is for retreatment – note retreatment is at the discretion of MO HealthNet **OR**
- Failure to achieve desired therapeutic outcomes with trial on 1 or more preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents **AND**
- For Zepatier: NS5A RAV polymorphism test results submitted **OR**
- For Harvoni: participants aged **3** years of age or older **OR**
- For Sovaldi: participants aged **3** years of age or older **OR**
- For Viekira Pak: participants aged 18 years of age or older
- Viral load must be submitted upon completion of treatment, 12 weeks post treatment, and 24 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 7 day gap between prior claim and incoming claim with a 168 day look back
- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
EPCLUSA 400 MG-100 MG TABLET	SOFOSBUVIR/ VELPATASVIR	28 tabs for 28 days
HARVONI 90-400 MG	LEDIPASVIR AND SOFOSBUVIR	28 tabs for 28 days
MAVYRET 100-40 MG TABLET	GLECAPREVIER/ PIBRENTASVIR	84 tabs for 28 days
SOVALDI 400 MG	SOFOSBUVIR	28 tabs for 28 days
VIEKIRA PAK	DASABUVIR/OMBITASVIR /PARITAPREVIR/RITONAVIR	112 tabs for 28 days
VOSEVI 400-100-100 MG TABLET	SOFOSBUVIR/ VELPATAS/ VOXILAPREV	28 tabs for 28 days
ZEPATIER 50-100 MG TABLET	ELBASVIR/ GRAZOPREVIR	28 tabs for 28 days

Required Documentation

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

1. 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.
2. Evidence-Based Medicine Analysis: “Hepatitis C Agents – Direct-Acting Antiviral Agents (DAAVs)”, UMKC-DIC; April 2020.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
4. USPDI, Micromedex; 2020.
5. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
6. 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 April 2019). https://www.hcvguidelines.org/.
7. Mavyret [package insert]. North Chicago, IL: AbbVie Inc; 2020.
8. Sovaldi [package insert]. Foster City, CA: Gilead Sciences Inc; 2020.
9. Zepatier [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; 2019.
10. Epclusa [package insert]. Foster City, CA: Gilead Sciences Inc; 2020.
11. Harvoni [package insert]. Foster City, CA: Gilead Sciences Inc; 2020.
12. Viekira Pak [package insert]. North Chicago, IL; AbbVie Inc; 2019.