Preferred Drug List Criteria Proposal

Drug/Drug Class:	**Hepatitis C (HCV) Therapy**
Date:	**November 1, 2017**
Prepared for:	
Prepared by:	MO HealthNet

☐ **New Criteria** ☒ **Revision of Existing Criteria**

Executive Summary

Purpose:

The MO HealthNet Pharmacy Program will implement a state specific preferred drug list.

Why was this Issue Selected:

Hepatitis C (HCV) infection has been recently been referred to as a "Silent Epidemic" because it usually progresses slowly over many years. 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. Hepatitis C (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. It is estimated that some 3.9 million Americans have been infected with HCV, with approximately 35,000 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 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 new DAAs were approved, competition has helped lower the costs of treatment.

Total program savings for the PDL classes will be regularly reviewed. MO HealthNet after careful consideration has taken a new approach in their Hepatitis C PDL. With the availability of two pan-genotypic DAA products, MO HealthNet has elected to select preferred agents on the basis of treatment duration and not based on genotype. MO HealthNet will continue to require Metavir Fibrosis Score as part of the clinical information necessary for approval. Clinically and financially, the shortest duration of treatment will drive the PDL and must always be used. A 12 week duration of treatment cannot be used when an 8 week duration of treatment is available and appropriate, based upon FDA approved prescribing information.

Agents are listed in alphabetical order

Program-specific information:

Preferred Agents for 8 Weeks Duration of Treatment	Non-Preferred Agents for 8 Weeks Duration of Treatment
• **Mavyret®**	• Daklinza® • Epclusa® • Harvoni® • Olysio® • Sovaldi® • Technivie® • Viekira Pak® • Viekira XR® • Vosevi® • Zepatier®

Preferred Agents for 12 Weeks Duration of Treatment	Non-Preferred Agents for 12 Weeks Duration of Treatment
• **Mavyret®** • **Vosevi® (for retreatment only)** • Zepatier®	• Daklinza® • **Epclusa®** • **Harvoni®** • Olysio® • Sovaldi® • Viekira Pak® • Viekira XR® • Technivie®

Preferred Agents for 16 Weeks Duration of Treatment	Non-Preferred Agents for 16 Weeks Duration of Treatment
• Mavyret® • Zepatier®	• Daklinza® • Epclusa® • Harvoni® • Olysio® • Sovaldi® • Technivie® • Viekira Pak® • Viekira XR® • Vosevi®

Approval for duration of treatment greater than those listed above requires approval by MHD clinical consultant.

Approval for non-preferred agent requires approval by MHD clinical consultant. A letter of medical necessity indicating why no preferred agents are clinically appropriate based upon FDA approved prescribing information should be submitted.

Setting & Population: All patients

Data Sources: ☐ **Only administrative databases** ☒ **Databases + Prescriber-supplied**

Setting & Population

- Drug/drug class for review: Hepatitis C Therapy
- Age range: All patients

Approval Criteria and Required Information

- **Diagnosis of Chronic Hepatitis C (HCV) Infection**
- **Adult patients age 18 years and older**
- **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.**
- **Baseline Viral Load**
- **Baseline Fibrosis Score**
- **Fibrosis score of F4 requires a CP Score to be submitted**
- **NS5A RAV polymorphism test results must be submitted if prescribing Zepatier**

Approval Criteria and Required Information (continued)

- **Prescriber required to attest that the member demonstrates treatment readiness.**
- **Prescribing provider is responsible for addressing ongoing misuse of alcohol and/or continued use of illicit IV drugs (if appropriate)**
- **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.**
- **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.**
- **Retreatment is at the discretion of MO HealthNet.**
- **Prescription claim for Epclusa® with billed units = 28 tablets for 28 day supply**
- **Prescription claim for Mavyret® with billed units = 84 tablets for 28 day supply**
- **Prescription claim for Zepatier® with billed units = 28 tablets for 28 day supply**
- **Prescription claim for Vosevi® with billed units = 28 tablets for 28 day supply**
- **Prescription claim for non-preferred agents with billed units should equal number of tablets in a daily dose x 28 for 28 day supply**
- **No more than a 7 day gap between prior claim and incoming claim with a 168 day look back**

DRUG PRIOR AUTHORIZATION HOTLINE: (800) 392-8030

References

1. AASLD/IDSA. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. Last Updated September 21, 2017. www.hcvguidelines.org
2. Glecaprevir/Pibrentasvir (Mavyret™) New Drug Update. Magellan Rx Management, August 2017.
3. Glecaprevir/Pibrentasvir (Mavyret™) Clinical Criteria. Magellan Rx Management, August 2017.
4. Evidence-Based Medicine Analysis: "Hepatitis C Agents", UMKC-DIC; March 2015 – Updated August 2017.
5. Evidence-Based Medicine and Fiscal Analysis: "Hepatitis C Agents", Provider Synergies, L.L.C., Mason, OH; March 2017.
6. Medicaid Evidence-based Decisions Project (MED) Participant Request: "Cost-Effectiveness of Direct-Acting Antivirals to Treat Chronic Hepatitis C". Center for Evidence-based Policy, Oregon Health & Science University; February 2017 – updated September 2017.
7. Medicaid Evidence-based Decisions Project (MED) Participant Request: "Treating Hepatitis C at Liver Fibrosis Stage F2 versus F3". Center for Evidence-based Policy, Oregon Health & Science University; December 2016.
8. Medicaid Evidence-based Decisions Project (MED) Participant Request: "Association of Metavir Fibrosis Scores and Clinical Outcomes". Center for Evidence-based Policy, Oregon Health & Science University; August 2016.
9. Drug Effectiveness Review Project – Drug Class Review: "Direct-Acting Antiviral Agents for Chronic Hepatitis C Infection." Center for Evidence-Based Policy, Oregon Health & Science University; December 2014; Update 2 Report April 2016.
10. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2017.
11. USPDI, Micromedex; 2017.
12. eFacts and Comparisons; 2017.