**SmartPA Criteria Proposal**

<table>
<thead>
<tr>
<th>Drug/Drug Class:</th>
<th>Hepatitis C Agents PDL Edit</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Implementation Date:</td>
<td>October 2, 2014</td>
</tr>
<tr>
<td>Revised Date:</td>
<td>October 1, 2020</td>
</tr>
<tr>
<td>Prepared For:</td>
<td>MO HealthNet</td>
</tr>
<tr>
<td>Prepared By:</td>
<td>MO HealthNet/Conduent</td>
</tr>
<tr>
<td>Criteria Status:</td>
<td>☒ Revision of Existing Criteria</td>
</tr>
<tr>
<td></td>
<td>☐ New Criteria</td>
</tr>
</tbody>
</table>

**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:**

<table>
<thead>
<tr>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epclusa®</td>
<td>Harvoni®</td>
</tr>
<tr>
<td>Mavyret™</td>
<td>Ledipasvir-Sofosbuvir</td>
</tr>
<tr>
<td><strong>Sofosbuvir-Velpatasvir</strong></td>
<td>Sovaldi®</td>
</tr>
<tr>
<td>Vosevi® (Retreatment Only)</td>
<td>Viekira Pak™</td>
</tr>
<tr>
<td></td>
<td>Zepatier™</td>
</tr>
</tbody>
</table>

**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:
  - Participants aged 18 years of age or older AND
  - 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.

*SmartPA PDL Proposal Form*

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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:

<table>
<thead>
<tr>
<th>Drug Description</th>
<th>Generic Equivalent</th>
<th>Max Dosing Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPCLUSA 400 MG-100 MG TABLET</td>
<td>SOFOSBUVIR/VELPATASVIR</td>
<td>28 tabs for 28 days</td>
</tr>
<tr>
<td>HARVONI 33.75-150 MG PELLET PK</td>
<td>LEDIPASVIR/SOFOSBUVIR</td>
<td>28 packets for 28 day</td>
</tr>
<tr>
<td>HARVONI 45-200 MG PELLET PACKT</td>
<td>LEDIPASVIR/SOFOSBUVIR</td>
<td>28 packets for 28 day</td>
</tr>
<tr>
<td>HARVONI 45-200 MG TABLET</td>
<td>LEDIPASVIR/SOFOSBUVIR</td>
<td>28 tabs for 28 day</td>
</tr>
<tr>
<td>HARVONI 90-400 MG</td>
<td>LEDIPASVIR AND SOFOSBUVIR</td>
<td>28 tabs for 28 days</td>
</tr>
<tr>
<td>MAVYRET 100-40-40 MG TABLET</td>
<td>GLECAPREVIR/PIBRENTASVIR</td>
<td>84 tabs for 28 days</td>
</tr>
<tr>
<td>SOVALDI 150 MG PELLET PACKET</td>
<td>SOFOSBUVIR</td>
<td>28 packets for 28 day</td>
</tr>
<tr>
<td>SOVALDI 200 MG PELLET PACKET</td>
<td>SOFOSBUVIR</td>
<td>28 packets for 28 day</td>
</tr>
<tr>
<td>SOVALDI 200 MG TABLET</td>
<td>SOFOSBUVIR</td>
<td>28 tabs for 28 day</td>
</tr>
<tr>
<td>SOVALDI 400 MG</td>
<td>SOFOSBUVIR</td>
<td>28 tabs for 28 days</td>
</tr>
<tr>
<td>VIEKIRA PAK</td>
<td>DASABUVIR/OMBITASVIR/PARITAPREVIR/RITONAVIR</td>
<td>112 tabs for 28 days</td>
</tr>
<tr>
<td>VOSEVI 400-100-100 MG TABLET</td>
<td>SOFOSBUVIR/VELPATAS/VOXILAPREV</td>
<td>28 tabs for 28 days</td>
</tr>
<tr>
<td>ZEPATIER 50-100 MG TABLET</td>
<td>ELBASVIR/ GRAZOPREVIR</td>
<td>28 tabs for 28 days</td>
</tr>
</tbody>
</table>

**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**

4. USPDI, Micromedex; 2020.
5. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.