Drug/Drug Class: HBV Nucleotide Analog Reverse Transcriptase Inhibitors

First Implementation Date: November 4, 2021

Revised Date: N/A

Prepared for: MO HealthNet

Prepared by: MO HealthNet/Conduent

Criteria Status: ☒ New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of HBV Nucleotide Analog Reverse Transcriptase Inhibitors

Why Issue Selected: Hepatitis B Virus (HBV) infection is the world’s most common serious liver infection. It is estimated that over 300 million people are infected with chronic HBV worldwide, of whom approximately 600,000 die annually from HBV-related liver disease. Most persons with chronic HBV infection are asymptomatic and have no evidence of liver disease; however, some persons may develop chronic hepatitis, cirrhosis, or hepatocellular carcinoma. Viread® (tenofovir disoproxil fumarate) and Vemlidy® (tenofovir alafenamide) are both nucleotide analog reverse transcriptase inhibitors for the treatment of chronic HBV, and both are preferred therapies per the American Association for the Study of Liver Diseases 2018 Guidelines on Prevention, Diagnosis, and Treatment of Chronic Hepatitis B. Vemlidy is a produg of Viread, allowing treatment at a lower dose than Viread. Generic versions of Viread are also now available. MO HealthNet desires to provide therapy for chronic HBV to all qualifying participants, and as such, it is clinically and fiscally advantageous for MO HealthNet to establish guidelines for chronic HBV therapy.

Program-Specific Information:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Date Range FFS 4-01-2020 to 3-31-2021</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Claims</td>
</tr>
<tr>
<td>VEMLIDY 25 MG TABLET</td>
<td>340</td>
</tr>
<tr>
<td>VIREAD 150 MG TABLET</td>
<td>0</td>
</tr>
<tr>
<td>VIREAD 200 MG TABLET</td>
<td>0</td>
</tr>
<tr>
<td>VIREAD 250 MG TABLET</td>
<td>0</td>
</tr>
<tr>
<td>VIREAD 300 MG TABLET</td>
<td>354</td>
</tr>
</tbody>
</table>

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

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

Setting & Population:

- Drug class for review: HBV Nucleotide Analog Reverse Transcriptase Inhibitors
• Age range: All appropriate MO HealthNet participants

**Approval Criteria**

• Claim is for Viread (tenofovir disoproxil) **OR**
• Clinical Consultant review required for use of Vemlidy (tenofovir alafenamide)

**Denial Criteria**

• Therapy will be denied if all approval criteria are not met

**Required Documentation**

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>Progress Notes:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>MedWatch Form:</td>
<td>Other:</td>
</tr>
<tr>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

**Disposition of Edit**

Denial: Exception code “0683” (Fiscal Edit)
Rule Type: CE

**Default Approval Period**

1 year

**References**

• IPD Analytics. Hepatitis B Virus: Overview of Disease and Management. October 2019.