SmartPA Criteria Proposal

Drug/Drug Class:	HBV Nucleotide Analog Reverse Transcriptase Inhibitors Fiscal Edit
First Implementation Date:	November 4, 2021
Proposed Date:	December 15, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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 prodrug 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:

Date Range FFS 10-01-2021 to 9-30-2022			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
VEMLIDY 25 MG TABLET	101	$106,299.77	$1,052.47
VIREAD 150 MG TABLET	0	-	-
VIREAD 200 MG TABLET	0	-	-
VIREAD 250 MG TABLET	0	-	-
VIREAD 300 MG TABLET	601	$16,967.48	$28.23

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: 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

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

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

Default Approval Period

1 year

References

- VEMLIDY (tenofovir alafenamide) [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2021.
- VIREAD (tenofovir disoproxil fumarate) [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2019.
- Tang LSY, Covert E, Wilson E, Kottilil S. Chronic Hepatitis B Infection: A Review. JAMA. 2018;319(17):1802–1813. doi:10.1001/jama.2018.3795
- Terrault, N.A., Lok, A.S., McMahon, B.J., Chang, K.-M., Hwang, J.P., Jonas, M.M., Brown, R.S., Jr., Bzowej, N.H. and Wong, J.B. (2018), Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. Hepatology, 67: 1560-1599. https://doi.org/10.1002/hep.29800
- IPD Analytics. Hepatitis B Virus: Overview of Disease and Management. October 2019.