

SmartPA Criteria Proposal

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|-----------------------------------|--|
| Drug/Drug Class: | HBV Nucleotide Analog Reverse Transcriptase Inhibitors Fiscal Edit |
| First Implementation Date: | TBD |
| Proposed Date: | June 17, 2021 |
| Prepared for: | MO HealthNet |
| Prepared by: | MO HealthNet/Conduent |
| Criteria Status: | <input type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input checked="" type="checkbox"/> 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 4-01-2020 to 3-31-2021 | | | |
|-------------------------------|---------------------------------------|--------|--------------|---------------------|
| | Drug | Claims | Spend | Avg Spend per Claim |
| | VEMLIDY 25 MG TABLET | 340 | \$354,641.57 | \$1,043.06 |
| | VIREAD 150 MG TABLET | 0 | - | - |
| | VIREAD 200 MG TABLET | 0 | - | - |
| | VIREAD 250 MG TABLET | 0 | - | - |
| | VIREAD 300 MG TABLET | 354 | \$14,046.74 | \$39.68 |

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: 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:
MedWatch Form:

Progress Notes:
Other:

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, Kottlil 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.