Pharmacy Medical Necessity Guidelines:
Vemlidy (tenofovir alafenamide)

Effective: March 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Vemlidy (tenofovir alafenamide) is a nucleoside analog reverse transcriptase inhibitor indicate for the treatment of chronic hepatitis B infection in patients 6 years of age and older and weighing at least 25 kg with compensated liver disease. Prior to initiating Vemlidy, patients should be tested for HIV, as Vemlidy should not be used alone in patients with an HIV infection. Vemlidy is not recommended in patients with decompensated (Child-Pugh B or C) hepatic impairment.

Per the American Association for the Study of Liver Disease (AASLD), preferred treatment options for chronic hepatitis B include entecavir (Baraclude), tenofovir disoproxil fumarate (Viread) and tenofovir alafenamide (Vemlidy). Tufts Health RITogether covers entecavir tablet and Viread tablet and oral powder without prior authorization; quantity limits do apply.

COVERAGE GUIDELINES

The plan may authorize coverage when **ALL** of the following criteria are met and limitations do not apply:

1. The member has a diagnosis of chronic hepatitis B

AND

2. The member is 6 years of age and older and weighing at least 25 kg

AND

3. The member meets one of the following:
   a. **If member has not previously been treated with a nucleoside analog:** documentation of clinical rationale for use of Vemlidy instead of entecavir

   OR

   b. Documentation the member has a history of prior treatment with a nucleoside analog (e.g., entecavir, tenofovir disoproxil fumarate).

LIMITATIONS

- Vemlidy is limited to 1 tablet per day.

CODES

None

REFERENCES

1. Terrault NA, Lok ASF, McMahon BJ, et al. Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. *Hepatology*. 2018;67(4):1560-1599.
2. Vemlidy (tenofovir alafenamide) [prescribing information]. Foster City, CA: Gilead Sciences, Inc; October 2022.

APPROVAL HISTORY

October 11, 2023: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 13, 2023: Effective August 1, 2023, updated age requirement from 18 years of age to 12 years of age due to updated indication. Administrative update: added "documentation" to previous trial requirements.
2. March 12, 2024: Effective April 1, 2024, updated RxUM fax number.

3. March 11, 2025: Effective April 1, 2025, Updated overview and criteria to include Vemlidy expanded indication in pediatric patients 6 years of age and older and weighing at least 25 kg with compensated liver disease.
4. March 10, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services