Pharmacy Medical Necessity Guidelines:
Firvanq™ (vancomycin hydrochloride oral solution)

Effective: Jun 15, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Firvanq™ (vancomycin hydrochloride oral solution) is a glycopeptide antibacterial indicated in adults and pediatric patients less than 18 years of age for the treatment of:

- *Clostridium difficile*-associated diarrhea
- Enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains)

Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections.

In order to reduce the development of drug-resistant bacteria and maintain the effectiveness of Firvanq and other antibacterial drugs, Firvanq should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Per the 2018 Infectious Diseases Society of America (IDSA) guidelines for the treatment of *C. difficile*, vancomycin is considered first-line for initial and recurrent episodes.

COVERAGE GUIDELINES

The plan may authorize coverage of Firvanq (vancomycin hydrochloride oral solution) for Members when the following criteria are met:

1. Member has a diagnosis of *Clostridium difficile*-associated diarrhea or enterocolitis caused by *Staphylcoccus aureus* (including methicillin-resistant strains)

AND

2. Clinical rationale why the member is not able to take generic vancomycin capsules

LIMITATIONS

1. Firvanq is limited to two bottles per 10 days.

CODES

None

REFERENCES

1. Firvanq (vancomcin hydrochloride oral solution) [prescribing information]. Wilmington, MA: Cutis Pharma; February 2018.
2. McDonald LC, Gerding DN, Johnson S, Bakken JS, Carroll KC, Coffin SE, et al. Clinical practice guidelines for Clostridium difficile infection in adults and children: 2017 update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). CID. 2018;66:e1-e48.

APPROVAL HISTORY

April 10, 2018: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. March 12, 2019: Administrative changes made to template.
2. June 9, 2020: Effective 6/15/2020, MNG is retired, as Firvanq oral solution is covered.

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.