OVERVIEW

Generic drug products must demonstrate pharmaceutical equivalence and bioequivalence to be considered therapeutic equivalents.

For a generic drug product to gain FDA approval, it must:
• be therapeutically equivalent to the innovator (brand) product
• meet the same batch requirements for identity, strength, purity, and quality
• be manufactured under the same strict standards of the FDA’s manufacturing practice regulations required for innovator products.

The FDA formulates a list of all marketed prescription drug products approved by the FDA for safety and efficacy, commonly known as the Orange Book. The Orange Book is the definitive reference guide on bioequivalence for FDA-approved prescription drugs.

In the Orange Book, “A” rated products are considered therapeutically equivalent to other pharmaceutically equivalent products. Products with a “B” rating are considered not therapeutically equivalent to other pharmaceutical products.

PHARMACY COVERAGE GUIDELINES

Tufts Health Plan – Network Health may authorize coverage of a brand name drug with an A-rated generic for members when the following criteria for a particular regimen are met and limitations do not apply:

• There is a drug shortage of the generic product

OR

• Provider documentation that a change to the generic could result in instability of the member’s medical condition provided the medication is not in schedule II, III or IV (i.e. narrow therapeutic index medications and non-controlled substances)

OR

• The following criteria:
  o The member had a treatment failure with two or more formulary alternative medications (when available), including the A-rated generic AND
  o Provider documentation that the member had an allergic reaction to an ingredient in the A-rated generic that is not contained in the brand-name product

In addition to the above, for controlled substances used for pain management,
• Member signed pain management agreement consistent with the American Academy of Pain Management guidelines is in place

LIMITATIONS

• Approval duration will be limited to 3 months for drugs with shortage or availability issues.
• Approval duration will be limited to 6 months for schedule II, III and IV medications.

Clinical Documentation and Prior Authorization Required

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Pharmacy (RX) or Medical (MED) Benefit

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- Drugs on the Preferred Drug List with restrictions must additionally meet drug- or class-specific Medical Necessity Guidelines.
- Non-covered drugs must additionally meet Non-Covered Medical Necessity Guidelines.
- Requests that exceed quantity limits must additionally meet Quantity Limit Medical Necessity Guidelines.

**CODES**

None

**REFERENCES**


**APPROVAL HISTORY**

- 10/7/14: Reviewed by the Pharmacy and Therapeutics Committee. For controlled substances, a pain management agreement must be in place. Changes in approval durations.

**BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). 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 Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan – Network Health offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable product formulary in the Pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

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.