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 Subject: Non-covered Drugs with Suggested Alternatives
 Effective Date: March 9, 2010

Clinical Documentation and Prior Authorization Required	√	Type of Review - Case Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX and MED	Administrative Process (Internal Use Only)	LPN

Note: This pharmacy medical necessity guideline applies to commercial products. For Tufts Health Plan Medicare Preferred members, please refer to the Tufts Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

Overview

To promote clinically appropriate and cost-effective prescription drug use, Tufts Health Plan has several programs in place, one of which is the Non-Covered Drugs with Suggested Alternatives Program described below:

Non-Covered Drugs with Suggested Alternatives (NC)

The drugs on the non-covered list are not covered because there are safe, comparably effective alternatives available or there are generic versions of the brand-name product available. The alternatives listed are approved by the U.S. Food and Drug Administration (FDA) and are widely used and accepted by the medical community to treat the same condition as the medications that are on the non-covered list.

Pharmacy Coverage Guidelines

Tufts Health Plan may authorize coverage of prescription medications included on the Non-covered Drug list for Members, when **one** of the following criteria is met:

1. The requesting physician has documented that the Member has had a treatment failure of 2 or more formulary alternative medications (when available).
 - For non-covered combination medications, the Member has had a trial of the individual ingredients used together (when available).
2. The requesting physician has documented that the Member is unable to tolerate 2 or more formulary alternative medications because of significant clinical adverse effects.
3. The requesting physician has documented that the Member has been successfully maintained on their current medication regimen and that a change to a formulary alternative could result in instability of the medical condition.

Limitations

1. For non-covered drugs that are included on a step therapy program, the member must meet the criteria above AND fulfill the requirements of the step therapy as outlined in the respective step therapy guidelines.

Codes

None.

References

None.

Approval History

Reviewed by the Pharmacy and Therapeutics Committee on October 11, 2001.

Subsequent Endorsement Date(s) and Changes Made:

4. October 12, 2004: No changes.
5. September 13, 2005: No changes.
6. August 8, 2006: No changes.
7. July 10, 2007:
 - Added limitation that “For non-covered drugs that are included on a step therapy program, the member must meet the criteria above AND fulfill the requirements of the step therapy as outlined in the respective step therapy guidelines.”
8. July 8, 2008: No changes.
9. July 14, 2009:
 - Added criteria for non-covered combination medications: the Member has had a trial of the individual ingredients used together (when available).
10. September 8, 2009:
 - Added criterion that the requesting physician has documented that the Member has been successfully maintained on their current medication regimen and that a change to a formulary alternative could result in instability of the medical condition.
11. January 1, 2010:
 - Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred).
12. March 9, 2010:
 - Removed attachment A: Sporanox (itraconazole) Capsules from Medical Necessity Guidelines for Non-covered Drugs with Suggested Alternatives.
 - Changed criterion #2 from requiring inability to tolerate the formulary alternative medications to inability to tolerate 2 or more formulary alternative medications because of significant clinical adverse effects.
 - Removed note that the Non-Covered Drugs with Suggested Alternatives program is also referred to as the Prescription Alternative Program.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). Tufts Health 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 Tufts Health Plan

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 revises and updates 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 offerings unless otherwise noted in this policy or the Member's benefit document. Check the applicable formulary in the Pharmacy section of our Website at www.tuftshealthplan.com to determine if the drug requires you to get prior authorization. This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Medicare Preferred, please refer to Tufts Medicare Preferred Prior Authorization Criteria.

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.