Pharmacy Medical Necessity Guidelines: Non-Sedating Antihistamines

Effective: October 22, 2018

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:

**Pharmacy Medical Necessity Guidelines: Non-Sedating Antihistamines**

- **Communication 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
  - CareLinkSM – 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**

**FDA-APPROVED INDICATIONS**

Cetirizine is indicated for the temporary relief of symptoms associated with upper respiratory allergies, and for the relief of itching due to urticaria.

Desloratadine is indicated for the relief of the nasal and non-nasal symptoms of perennial allergic rhinitis in patients 6 months of age and older, for the relief of the nasal and non-nasal symptoms of seasonal allergic rhinitis in patients 2 years of age and older, and for the symptomatic relief of pruritus and reduction in the number and size of hives in patients 6 months of age and older.

Levocetirizine is indicated for the relief of symptoms associated with perennial allergic rhinitis in patients 6 months of age and older, for the relief of symptoms of seasonal allergic rhinitis in patients 2 years of age and older, and for the treatment of uncomplicated skin manifestations of chronic idiopathic urticarial in patients 6 months of age and older.

**COVERAGE GUIDELINES**
The plan may authorize coverage of a non-preferred non-sedating antihistamine for Members when one of the following criterions is met and limitations do not apply:

- **Desloratadine (Clarinex), levocetirizine (Xyzal)**
  1. The Member tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with both a loratadine- and a cetirizine-containing agent.
     OR
  2. The Member is between 6 months and 2 years of age and has tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with a cetirizine-containing agent.

- **Cetirizine oral syrup or solution (Rx)**
  1. The Member tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with over-the-counter (OTC) cetirizine syrup or solution

**LIMITATIONS**

1. Requests for brand-name products, with AB-rated generics, will also be reviewed according to Brand Name criteria.

**CODES**
None

**REFERENCES**

7. Clarinex (desloratadine) [prescribing information]. Whitehouse Station, NJ: Merck & Co, Inc; April 2014.

**APPROVAL HISTORY**
February 10, 2015: Reviewed by Pharmacy & Therapeutics Committee; approval duration is limited to one year; criteria modified to a single trial with OTC cetirizine for prescription cetirizine.

Subsequent endorsement date(s) and changes made:
2. January 1, 2016: Administrative change to rebranded template.
3. January 12, 2016: No changes.
5. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template

**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.