Pharmacy Medical Necessity Guidelines: Non-Sedating Antihistamines

Effective: October 13, 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

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 pediatric patients 6 months to 2 years of age, 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.

Acrivastatine-pseudoephedrine (Semprex-D) is approved for the relief of symptoms associated with seasonal allergic rhinitis such as sneezing, rhinorrhea, pruritis, lacrimation, and nasal congestion. The efficacy of acrivastatine-pseudoephedrine beyond 14 days of continuous treatment in patients with seasonal allergic rhinitis has not been adequately investigated in clinical trials. Safety and effectiveness of acrivastatine-pseudoephedrine in patients under the age of 12 years have not been established.

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.

Acrivastine-Pseudoephedrine (Semprex-D)

1. The Member tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with a generic non-sedating antihistamine (e.g., loratadine, certizine) in combination with pseudoephedrine.

LIMITATIONS

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

CODES

None

REFERENCES

1. Zyrtec (cetirizine) [prescribing information]. Pfizer: New York, NY; July 2004.
2. Zyrtec Allergy (cetirizine) [prescribing information]. Fort Washington, PA: McNeil Consumer Healthcare; received May 20, 2014.
3. Cetirizine hydrochloride syrup [prescribing information]. Carmel, NY: Silarx Pharmaceuticals; May 2014.
4. Xyzal (levocetirizine) [package insert]. Bridgewater, NJ: Sanofi-Aventis; April 2019.
5. Clarinex (desloratadine) [prescribing information]. Whitehouse Station, NJ: Merck & Co, Inc; May 2020.
6. Semprex-D (acrivastine-pseudoephedrine) [prescribing information]. Malvern, PA: Endo Pharmaceuticals; January 2019.

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:

1. September 16, 2015: Approval duration approved for life of plan.
2. January 1, 2016: Administrative change to rebranded template.
3. January 12, 2016: No changes.
4. January 10, 2017: No changes.
5. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template
6. October 16, 2018: Administrative update to template.
7. June 11, 2019: Effective October 1, 2019, added criteria for Semprex-D
8. October 13, 2020: 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.