TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Respiratory Interleukins: Cinqair® (reslizumab), Fasenra™ (benralizumab), Nucala® (mepolizumab)

Effective: January 1, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED /RX	Department to Review	PRECERT /MM / RXUM

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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
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Fax Numbers:

Cinqair, Fasenra, Nucala vials:
All plans except Tufts Health Public Plans:
PRECERT: 617.972.9409

Tufts Health Public Plans only:
MM: 888.415.9055

Fasenra and Nucala pre-filled autoinjector and/or syringe
RXUM: 617.673.0988
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Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Cinqair (reslizumab) is an interleukin-5 antagonist monoclonal antibody (IgG4 kappa) indicated for:

- **Maintenance treatment of severe asthma**
  Add-on maintenance treatment of patients with severe asthma aged 18 years and older and with an eosinophilic phenotype. Cinqair (reslizumab) is not indicated for treatment of other eosinophilic conditions or for relief of acute bronchospasm or status asthmaticus.

Fasenra (benralizumab) is an interleukin-5 alpha directed cytolytic monoclonal antibody (IgG1, kappa) indicated for:

- **Maintenance treatment of severe asthma**
  Add-on maintenance treatment of patients with severe asthma aged 18 years and older and with an eosinophilic phenotype. Fasenra (benralizumab) is not indicated for treatment of other eosinophilic conditions or for relief of acute bronchospasm or status asthmaticus.

Nucala (mepolizumab) is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa) indicated for:

- **Eosinophilic granulomatosis with polyangiitis**
  The treatment of adult patients with eosinophilic granulomatosis with polyangiitis
- **Maintenance treatment of severe asthma**
  Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. Nucala (mepolizumab) is not indicated for the relief of acute bronchospasm or status asthmaticus

COVERAGE GUIDELINES

Asthma

The plan may authorize coverage of Cinqair, Fasenra, or Nucala for Members when all of the following criteria are met:

1. Documented diagnosis of moderate to severe eosinophilic asthma

   AND

2. Member age is **one (1)** of the following:
   a. 18 years for Cinqair
   b. 12 years for Fasenra
   c. 6 years for Nucala

   AND

3. Prescribing physician is an asthma specialist (e.g., allergist, immunologist, pulmonologist)

   AND

4. Documentation the Member is symptomatic despite receiving **one (1)** of the following:
   a. Combination inhaler
   b. Combination of an inhaled corticosteroid and a long-acting beta-agonist inhaler
   c. Chronic oral corticosteroids (defined as ≥90 days of therapy within the last 120 days)

   AND

5. Documentation of evidence of an eosinophilic phenotype (i.e., peripheral blood eosinophil count ≥150 cells/uL [for Nucala and Fasenra] or ≥400 cells/uL [for Cinqair], elevated sputum eosinophils or FeNO)

Eosinophilic Granulomatosis with Polyangiitis

The plan may authorize coverage of **Nucala (mepolizumab)** for Members when all of the following criteria are met:

1. Documented diagnosis of eosinophilic granulomatosis with polyangiitis

   AND

2. Member is at least 18 years of age

   AND

3. The prescribing physician is a specialist (e.g., allergist, immunologist, pulmonologist, rheumatologist)

   AND

4. Documented inadequate response (defined as ≥30 days of therapy), adverse reaction or contraindication to **one (1)** systemic glucocorticoid

   AND

5. Documented inadequate response (defined as ≥30 days of therapy), adverse reaction or contraindication to **one (1)** of the following
   a. azathioprine
   b. methotrexate

LIMITATIONS

- None

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J2182	Injection, mepolizumab, 1 mg
J2786	Injection, reslizumab, 1 mg
J0517	Injection, benralizumab, 1 mg

Note: Medical billing codes may not be used for Fasenra autoinjector and Nucala pre-filled autoinjectors and glass syringes for self-administration. These formulations must be obtained via the Member's pharmacy benefit.

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APPROVAL HISTORY

November 24, 2020: Reviewed by Pharmacy & Therapeutics Committee for an effective date of January 1, 2021 for implementation of MassHealth ACPP/MCO Partial Unified Formulary. Coverage criteria update and reauthorization criteria removed.

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.