Immunomodulators: Asthma and Allergy
Utilization Management Criteria

Therapeutic Class:	Immunomodulators: Asthma and Allergy
Non-Preferred Agents:	Cinqair (reslizumab), Nemluvio (nemolizumab), Nucala (mepolizumab)
Preferred Agents:	Adbry (tralokinumab), Dupixent (dupilumab), Ebglyss (lebrikizumab), Fasenra (benralizumab), Tezspire (tezepelumab), Xolair (omalizumab)
Implementation Date:	1/1/2026
Prepared For:	CT
PDL Status:	Non-preferred
Purpose:	The following criteria covers various monoclonal antibodies used to treat asthma and other type 2 inflammatory diseases. The agents covered include reslizumab, benralizumab, mepolizumab, omalizumab, dupilumab, tezepelumab, tralokinumab, lebrikizumab, and nemolizumab. Each agent targets specific immune system components, offering therapeutic benefits for various conditions. Reslizumab, benralizumab, and mepolizumab all target interleukin (IL)-5 or its receptor, while omalizumab targets immunoglobulin E (IgE), dupilumab targets IL-4 receptors, tezepelumab targets thymic stromal lymphopoietin, tralokinumab and lebrikizumab targets IL-13 receptors, and nemolizumab targets IL-31 receptors. All agents, except tralokinumab, lebrikizumab, and nemolizumab are indicated for use in severe asthma. Additionally, omalizumab, mepolizumab, and dupilumab are indicated for chronic rhinosinusitis with nasal polyps. Other indications for these agents include chronic spontaneous urticaria (omalizumab and dupilumab), IgE-mediated food allergies (omalizumab), atopic dermatitis (dupilumab, tralokinumab, nemolizumab, and lebrikizumab), eosinophilic esophagitis (dupilumab), prurigo nodularis (dupilumab,nemolizumab), Eosinophilic chronic obstructive pulmonary disease (mepolizumab, dupilumab), eosinophilic granulomatosis with polyangiitis (mepolizumab, benralizumab), and hypereosinophilic syndrome (mepolizumab).

Table 1. Immunomodulators: Asthma and Allergy

Generic Name	Brand Name	Approved Indications	Route of Administration	Biosimilar Availability
Benralizumab	Fasenra®	Severe EoS asthma, EGPA	SC	N
Dupilumab	Dupixent®	AD, Bullous Pemphigoid, moderate to severe EoS asthma or oral corticosteroid dependent asthma, EoS COPD, CRSwNP, EoE, PN, CSU	SC	N
Lebrikizumab	Ebglyss™	AD	SC	N
Mepolizumab	Nucala®	Severe EoS asthma, CRSwNP, EoS COPD, EGPA, HES	SC	N
Nemolizumab	Nemluvio®	AD, PN	SC	N
Omalizumab	Xolair®	Moderate to severe asthma, CRSwNP, CSU, IgE-mediated food allergies	SC	N
Reslizumab	Cinqair®	Severe EoS asthma	IV	N
Tezepelumab	Tezspire™	Severe asthma, CRSwNP	SC	N
Tralokinumab	Adbry™	AD	SC	N

Abbreviations: AD, atopic dermatitis; CRSwNP, chronic rhinosinusitis with nasal polyps; COPD, chronic obstructive pulmonary disease; CSU, chronic spontaneous urticaria; EGPA, eosinophilic granulomatosis with polyangiitis; EoE, eosinophilic esophagitis; EoS, eosinophilic; HES, hypereosinophilic syndrome; IgE, immunoglobulin E; IV, intravenous; PN, prurigo nodularis; SC, subcutaneous.

All authorizations must be prescribed in accordance with FDA approved labeling. Use of samples to initiate therapy does not meet step therapy and/or continuation of therapy prior authorization requirements. Prior therapies will be verified through pharmacy claims and/or submitted chart notes

General Approval Criteria

- Prescribed by or in consultation with a pulmonologist, allergist, immunologist, dermatologist, rheumatologist or any specialist familiar with the treated disease state
- Requested quantity in accordance with FDA approved product labelling

Initial Therapy for Non-preferred Agents (Cinqair, Nemluvio, Nucala) – All of the following must be met:

For the Diagnosis of Moderate to Severe Atopic Dermatitis (Nemluvio)

- Documentation of diagnosis (listed above) **AND** provider attests that disease is not adequately controlled with topical prescriptions therapies or topical therapies are not advisable
- Trial and failure of **ONE** preferred injectable Asthma and Allergy Immunomodulator agent (defined as a 30 day trial) indicated for atopic dermatitis (Adbry, Ebglyss, or Dupixent) **OR** documented adverse reaction/adverse event or contraindication to Adbry, Ebglyss, and Dupixent
- Age limitations:
    - Nemluvio: 12 years and older

For the Diagnosis of Asthma (Cinqair, Nucala)

- Documentation of diagnosis of severe asthma with an eosinophilic subtype
    - Claim is for Cinqair, Nucala
    - Blood eosinophils greater than or equal to 150 cells/microL
    - Patient must have experienced at least one exacerbation in the previous 12 months despite compliance to maintenance therapies that required either oral or injectable corticosteroids, office visit for worsening asthma, hospitalization or ER visit
- Trial and failure of **ONE** preferred injectable Asthma and Allergy Immunomodulator agent (defined as a 30 day trial) indicated for the diagnosis of eosinophilic asthma (Dupixent, Fasenra, or Tezspire) **OR** documented adverse reaction/adverse event or contraindication to Dupixent, Fasenra, and Tezspire
- Will be used as add-on maintenance therapy in conjunction with maximally tolerated guideline directed therapy in patients experiencing ongoing exacerbations (i.e. inhaled corticosteroid in combination with a long-acting beta adrenergic (LABA) or long-acting muscarinic antagonist (LAMA)
    - Claims will be reviewed to confirm patient received inhaled asthma maintenance treatments for 90 in the past 120 days
- Age limitations:
    - Cinqair: 18 years and older
    - Nucala: 6 years and older

For the Diagnosis of Eosinophilic Granulomatosis with Polyangiitis (Nucala)

- Documentation of diagnosis (listed above)
- Trial and failure of **ONE** preferred injectable Asthma and Allergy Immunomodulator agent (defined as a 30 day trial) indicated for the diagnosis of eosinophilic granulomatosis with polyangiitis (Fasenra) **OR** documented adverse reaction/adverse event or contraindication to Fasenra
- Age limitations: 18 years and older

For the Diagnosis of COPD (Nucala)

- Documentation of diagnosis (listed above) with an eosinophilic subtype (blood eosinophils greater than or equal to 300cells/microL)
- History of ≥2 moderate or ≥1 severe exacerbations in past year
- Will be used as add-on maintenance therapy in conjunction with maximally tolerated guideline directed inhaler therapy in patients experiencing ongoing exacerbations
- Trial and failure of **ONE** preferred injectable Asthma and Allergy Immunomodulator agent (defined as a 30 day trial) indicated for the diagnosis of COPD (Dupixent) **OR** documented adverse reaction/adverse event or contraindication to Dupixent
- Age limitations: 18 years and older

For the Diagnosis of Chronic Rhinosinusitis with Nasal Polyps (Nucala)

- Documentation of diagnosis (listed above) **AND** provider attests that patient has symptoms of nasal obstruction
- Patient has had an inadequate response to nasal corticosteroids (defined as an 8 week trial) **OR** documented adverse reaction/adverse event or contraindication to nasal corticosteroids
- Trial and failure of **ONE** preferred injectable Asthma and Allergy Immunomodulator agent (defined as a 30 day trial) indicated for the diagnosis of chronic rhinosinusitis with nasal polyps (Dupixent, Tezspire, or Xolair) **OR** documented adverse reaction/adverse event or contraindication to Dupixent, Tezspire, and Xolair

- Age limitations: 18 years and older

For the Diagnosis of Prurigo Nodularis (Nemluvio)

- Documentation of diagnosis (listed above) **AND** both of the following
    - Provider attests disease is widespread (defined as greater than or equal to 20 lesions) **OR** recalcitrant to other therapies
    - Patient is experiencing severe itching
- Trial and failure of **ONE** preferred injectable Asthma and Allergy Immunomodulator agent (defined as a 30 day trial) indicated for the diagnosis of prurigo nodularis (Dupixent) **OR** documented adverse reaction/adverse event or contraindication to Dupxient
- Age limitations: 18 years and older

For the Diagnosis of Hypereosinophilic Syndrome (Nucala)

- Claim is for Nucala
- Patient has a diagnosis of hypereosinophilic syndrome for greater than or equal to 6 months without an identifiable non-hematologic secondary cause
- Age limitations: 12 years and older

Initial PA length: 1 year

Exclusion Criteria: Approval Criteria not met

Continuation Therapy: Documented compliance on current therapy regimen **AND** Documented continued clinical benefit

Continuation Length: 1 year

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Revision History

Date	Version	Revisions
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