Texas Children's	Monoclonal Antibodies for Asthma and Allergic Conditions Guideline	
Guideline # 11062	***Categories*** Clinical →Care Coordination	***This Guideline Applies To:*** Texas Children's Health Plan ***Document Owner*** Lisa Fuller

GUIDELINE STATEMENT: Texas Children's Health Plan performs authorizations for certain monoclonal antibodies.

DEFINITIONS:

Omalizumab (Xolair, procedure code J2357): injectable FDA-approved drug indicated for members 6 years of age and older with **moderate to severe persistent asthma** as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and Management of Asthma with a positive skin test or in vitro reactivity to a perennial aeroallergen AND symptoms that are inadequately controlled with inhaled corticosteroids. It is also FDA-approved for members 12 years of age or older with **chronic idiopathic urticaria (CIU)** who remain symptomatic despite H1 antihistamine treatment.

Benralizumab (Fasenra, procedure code J0517): injectable FDA-approved drug indicated for members 12 years of age and older with **severe asthma** with an eosinophilic phenotype.

Reslizumab (Cinqair®, procedure code J2786): injectable FDA-approved drug indicated for members 18 years of age and older with **severe asthma** as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and Management of Asthma with an eosinophilic phenotype.

Mepolizumab (Nucala, procedure code J2182): injectable FDA-approved drug indicated for members:

- 6 years of age or older with **severe asthma** with an eosinophilic phenotype
- 18 years or older with eosinophilic granulomatosis with polyangitis
- 12 years or older with hypereosinophilc symptoms
- 18 years or older as add-on maintenance of chronic rhinosinusits with nasal polyps

Tezepelumab-ekko (Tezspire, procedure code J2356): injectable drug that is a human monoclonal antibody indicated as an add-on maintenance therapy treatment for **severe asthma** in pediatric and adult clients 12 and older.

1. All requests for prior authorization for monoclonal antibody treatment are received via fax, mail, or electronically by the Utilization Management Department and processed during normal business hours.

2. The Utilization Management professional receiving the request evaluates the submitted information to determine if the documentation supports the requested medication as an eligible service.

3. Documentation supporting the medical necessity of the requested treatment must be provided including:

   - Special Medical Prior Authorization (SMPA) form
   - Exact dosage of the requested monoclonal antibody treatment

4. Requests are reviewed against:

   - TCHP Monoclonal Antibodies Guideline
   - Texas Medicaid Provider and Procedures Manual, Outpatient Drug Services Handbook guideline criteria and all referenced information about Texas Medicaid's benefits, policies and procedures applicable to outpatient drugs.

Requirements for Initial Therapy

5. Prior authorization for **Omalizumab** will be considered for the following:

   5.1 **Moderate to Severe asthma**
   - Member is 6 years of age and older
   - Member has a diagnosis of moderate to severe asthma (as defined by the National Blood Institute's Guidelines for the Diagnosis and management of asthma) (diagnosis codes J4540 and J4550)
   - Member has a positive skin test or radioabsorbent assay test (RAST) to a perennial (not seasonal) aseroallergen within the past 36 months
   - Member has a total IgE level greater than 30 IU/mL but less than 1300 IU/mL within the past 12 months
   - Meet additional criteria defined in Section 9 *Additional medical necessity criteria for prior authorization for Asthma: Moderate to Severe (Omalizumab) and Severe (Benralizumab, Mepolizumab, Reslizuma, and Tezepepelumab-ekko)*.

   5.2 **Chronic Idiopathic Urticaria**
   - Member is 12 years of age or older
   - Member has a diagnosis of chronic idiopathic urticaria with symptoms despite H1 antihistamine treatment (diagnosis code L501)
   - Documented failure of, or contraindication to, antihistamine

- Evidence of an evaluation that excludes other medical diagnosis associated with chronic urticaria

5.3 **Add-on Maintenance treatment of nasal polyps**

- Member is 18 years of age or older
- Member has a diagnosis of nasal polyps (diagnosis codes J330, J331, J338, J339) with inadequate response to nasal corticosteroids
- Member has bilateral nasal polyposis confirmed by physical examination or nasal endoscopy
- Documented failure of, or contraindication to, prior corticosteroids as monotherapy
- Documented inadequate response to prior corticosteroid treatments

6. Prior authorization for **benralizumab** (Fasenra) will be considered for members who are 12 years of age or older with **severe asthma with an eosinophilic phenotype** (diagnosis codes J4450, J4451, and J4452) and the following:

   6.1 Meet additional criteria defined in Section 9 *Additional medical necessity criteria for prior authorization for Asthma: Moderate to Severe (Omalizumab) and Severe (Benralizumab, Mepolizumab, Reslizuma, and Tezepepelumab-ekko)*.

7. Prior authorization for **reslizumab** (Cinqair®) will be considered for members who are 18 years of age or older with **severe asthma** (diagnosis codes J4450, J4451, and J4452) with an eosinophilic phenotype and the following:

   7.1 Meet additional criteria defined in Section 9 *Additional medical necessity criteria for prior authorization for Asthma: Moderate to Severe (Omalizumab) and Severe (Benralizumab, Mepolizumab, Reslizuma, and Tezepepelumab-ekko)*.

8. Prior authorization for **mepolizumab** (Nucala) will be considered for the following:

   8.1 Severe asthma with eosinophilic phenotype

   - Member is 6 years of age or older
   - Member has a diagnosis of severe asthma with eosinophilic phenotype (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and management of Asthma) (diagnosis codes J4550, J4551, J4552)
   - One of the following blood eosinophil counts in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection: Greater than or equal to 150 cells/microliter at initiation of therapy or Greater than or equal to 300 cells/microliter within 12 months prior to initiation of therapy

- Meet additional criteria defined in Section 9 *Additional medical necessity criteria for prior authorization for Asthma: Moderate to Severe (Omalizumab) and Severe (Benralizumab, Mepolizumab, Reslizuma, and Tezepepelumab-ekko)*.

8.2 Eosinophilic granulomatosis with polyangiitis (EGPA)

- Member is 18 years of age or older
- Confirmed diagnosis of eosinophilic granulomatosis with polyangiitis (diagnosis code M301)
- Medical history of asthma
- Presence of at least 2 of following EGPA characteristics: histopathological findings of eosinophilic vascularitis, perivascularitis eosinophilic infiltration or eosinophil-rich granulomatous inflammation, neuropathy, pulmonary infiltrates, cardiomyopathy, glomerulonephritis, alveolar hemorrhage, palpable purpura, antineutrophils cytoplasmic antibody
- Member use of an oral glucocorticoid and/or cyclophosphamide, azathioprine, methotrexate, or leflunomide
- Refractory disease or has had a history of EGPA relapse

8.3 Hypereosinophilic Symptoms (HES)

- Member is 12 years of age or older
- Member has a diagnosis of **hypereosinophilic symptoms (HES)** who have had symptoms for 6 months or longer without identifiable non-hematologic secondary cause (diagnosis codes D72110, D72111, D72118, and D72119)
- History of 2 or more HES flares (defined as worsening clinical symptoms or blood eosinophil counts requiring an increase in prior therapy) within the past 12 months prior to the initiation on mepolizumab therapy
- The prescribing physician's attestation that the member has been on a stable dose of HES therapy that includes but is not limited to corticosteroids, immunosuppressive, and cytotoxic therapy.

8.4 **Chronic rhinosinusitis with nasal polyps (CRSwNP)**

- Member is 18 years of age or older
- Confirmed diagnosis of chronic rhinosinusitis with nasal polyps (diagnosis codes J330, J331, J338, and J339)
- Evidence of inadequate response to nasal corticosteroid

9. Additional medical necessity criteria for prior authorization for Asthma: **Moderate to Severe** (Omalizumab) and **Severe** (Benralizumab, Mepolizumab, Reslizuma, and Tezepepelumab-ekko)

9.1 Symptoms are inadequately controlled with the use of either combination therapy:

- A minimum of 3 months of controller medication (which includes but is not limited to long-acting beta 2-agonist (LABA), an inhaled or oral corticosteroid, leukotriene receptor antagonist (LTRA), or theophylline), unless the individual is intolerant of or has a medical contraindication

9.2 Pulmonary function tests must have been performed within a three-month period and be documented

9.3 Member is not currently smoking

9.4 A client with preexisting helminth infections should be treated prior to receiving omalizumab, benralizumab, mepolizumab, reslizumab, or tezepelumab-ekko therapy.

9.5 Exceptions to the criteria will be considered on a case-by-case basis, which will require a letter from the prescribing provider stating the medical necessity for omalizumab, benralizumab, mepolizumab, or reslizumab, the client's asthma severity level, and the duration of current and past therapies and lack of asthma control.

10. Prior authorization for initiation of **Tezepelumab-ekko** will be considered for members 12 years of age or older when all of the following criteria are met:

10.1 Confirmed diagnosis of severe asthma (diagnosis code: J45.50 and J45.51).

10.2 Tezepelumab-ekko is requested as an add-on maintenance therapy.

- Tezepelumab-ekko is not to be used as a single or primary therapy.

10.3 Current management includes regular treatment for severe asthma and is compliant with the therapy defined as:

- Medium or high-dose inhaled corticosteroid therapy, **AND**
- An additional asthma controller

11. **Tezepelumab-ekko** should not be used and is not medically necessary:

- For relief of acute bronchospasm or status asthmaticus.
- In combination with anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody agents (i.e., benralizumab, omalizumab, mepolizumab, reslizumab, dupilumab, etc.)
- When member has active, untreated helminth infection
- Concurrent administration with live attenuated vaccination

Requirements for Continuation of Therapy

12. **Continuation** of therapy with omalizumab, benralizumab, mepolizumab, reslizumab, or Tezepelumab-ekko after 6 consecutive months requires documentation of compliance and satisfactory clinical response:

12.1 Documentation of clinical improvement must include one or more of the following:

- Decreased utilization of rescue medications; or
- Increase in predicted FEV1 (forced expiratory volume) from pretreatment baseline; or
- Reduction in reported asthma-related symptoms, as evidenced by decreases in frequency or magnitude of one or more of the following symptoms:
  - Asthma attacks
  - Chest tightness or heaviness
  - Coughing or clearing throat

- Difficulty taking deep breath or difficulty breathing out
- Shortness of breath
- Sleep disturbance, night wakening, or symptoms upon awakening
- Tiredness
- Wheezing/heavy breathing/fighting for air, and

○ No symptoms of hypersensitivity or anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema) after administration of omalizumab, benralizumab, mepolizumab, or reslizumab.

13. Requests that do not meet the criteria established by this procedure will be referred to a TCHP Medical Director/Physician Reviewer for review and the Denial Policy will be followed.

14. Preauthorization is based on medical necessity and not a guarantee of benefits or eligibility. Even if preauthorization is approved for treatment or a particular service, that authorization applies only to the medical necessity of treatment or service. All services are subject to benefit limitations and exclusions. Providers are subject to State and Federal Regulatory compliance and failure to comply may result in retrospective audit and potential financial recoupment.

RELATED DOCUMENTS:

REFERENCES:

Government Agency, Medical Society, and Other Publications:

Texas Medicaid Provider Procedures Manual, Accessed February 6, 2025. https://www.tmhp.com/sites/default/files/file-library/resources/provider-manuals/tmppm/archives/2025-01-TMPPM.pdf

National Heart, Lung, and Blood Institute Guidelines for the Diagnosis and Management of Asthma https://www.nhlbi.nih.gov

Texas Medicaid and Healthcare Partnership Memo: Updated Prior Authorization Criteria for Monoclonal Antibodies Effective August 1 2023. **https://www.tmhp.com/news/2023-06-23-updated-prior-authorization-criteria-monoclonal-antibodies-effective-august-1-2023**

Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention Updated 2023. https://ginasthma.org/wp-content/uploads/2023/07/GINA-2023-Full-report-23_07_06-WMS.pdf

NICE: National Institute for Health and Care Excellence (United Kingdom). Omalizumab for treating severe persistent allergic asthma Technology appraisal guidance [TA278] Published date: 24 April

2013 https://www.nice.org.uk/guidance/ta278/resources/omalizumab-for-treating-severe-persistent-allergic-asthma-pdf-82600619176645

NICE: National Institute for Health and Care Excellence (United Kingdom). Mepolizumab for treating severe eosinophilic asthma. Technology appraisal guidance [TA671] Published date: 03 February 2021 https://www.nice.org.uk/guidance/ta671/resources/mepolizumab-for-treating-severe-eosinophilic-asthma-pdf-82609314548677

NICE: National Institute for Health and Care Excellence (United Kingdom). Benralizumab for treating severe eosinophilic asthma Technology appraisal guidance [TA565] Published date: 06 March 2019 Last updated: 03 September 2019 https://www.nice.org.uk/guidance/ta565/resources/benralizumab-for-treating-severe-eosinophilic-asthma-pdf-82607084018629

NICE: National Institute for Health and Care Excellence (United Kingdom). Reslizumab for treating severe eosinophilic asthma Technology appraisal guidance [TA479] Published date: 04 October 2017 Reviewed 2021 https://www.nice.org.uk/guidance/ta479

Peer Reviewed Publications:

Kardas G, Panek M, Kuna P, Damiański P, Kupczyk M. Monoclonal antibodies in the management of asthma: Dead ends, current status and future perspectives. Front Immunol. 2022 Dec 6;13:983852.

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