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 preforms authorizations for certain monoclonal antibodies.

DEFINITIONS:

Omalizumab (Xolair procedure code J2357) is an injectable drug that is FDA-approved for the treatment of members who are 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) who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.

Omalizumab is also FDA-approved for the treatment of members who are 12 years of age or older and have chronic idiopathic urticaria (CIU) who remain symptomatic despite H1 antihistamine treatment.

Benralizumab (Fasenra procedure code J0517) is an injectable drug that is FDA-approved and indicated for the treatment of members who are 12 years of age and older and have severe asthma with an eosinophilic phenotype.

Reslizumab (Cinqair procedure code J2786) is an injectable drug that is FDA-approved and indicated for the treatment of members who are 18 years of age and older and have 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) is an injectable drug that is approved by the FDA for the treatment of members who are 6 years of age or older and have 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.

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

GUIDELINE

1. All requests for prior authorization for monoclonal antibody treatment are received via fax, phone or mail 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. To request prior authorization documentation supporting the medical necessity of the requested treatment must be provided.

    3.1 Prior authorization requests must be submitted with the Special Medical Prior Authorization (SMPA) form.

4. Prior authorization for **Omalizumab** will be considered for members who are 12 years of age or older with **chronic idiopathic urticaria** (CIU) who have symptoms despite H1 antihistamine treatment (diagnosis code L501). Documentation supporting medical necessity for treatment of CIU with omalizumab must be submitted with the request and include all of the following:

    4.1 Documented failure of, or contraindication to, antihistamine and leukotriene inhibitor therapies

    4.2 Evidence of an evaluation that excludes other medical diagnoses associated with chronic urticaria.

5. Prior authorization for **Omalizumab** will be considered for members who are 6 years of age or older with moderate or severe asthma (as defined by the National Heart, Lung, and Blood I Institute's Guidelines for the Diagnosis and management of Asthma) (diagnosis codes J4540 and J4550) and meet additional criteria defined in Section 13.

6. Prior authorization for **Omalizumab** will be considered for members who are 18 years of age or older who have a diagnosis of nasal polyps (diagnosis codes J330, J331, J338, and J339) with inadequate response to nasal corticosteroids.

    6.1 Documentation of medical necessity must include:

        6.1.1 Diagnosis of bilateral nasal polyposis confirmed by physical examination or nasal endoscopy

        6.1.2 Documented failure of or contraindication to prior intranasal corticosteroids as monotherapy

6.1.3 Documented inadequate response to prior intranasal corticosteroid treatments

7. Prior authorization for **Benralizumab** 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 meet additional criteria defined in Section 13.

8. Prior authorization for **Reslizumab** will be considered for members who are 18 years of age or older with severe asthma (diagnosis codes J4450, J4451, and J4452) and meet additional criteria defined in Section 13.

9. Prior authorization for **Mepolizumab** will be considered for members who are 6 years of age or older with severe asthma with eosinophilic phenotype (diagnosis codes J4450, J4451, and J4452) and meet additional criteria defined in Section 13.

10. Prior authorization for **Mepolizumab** will be considered for members who are 18 years of age or older with Eosinophilic granulomatosis with polyangiitis (EGPA) (diagnosis code M301) with documentation supporting medical necessity including the following:

    10.1 Diagnosis of EGPA

    10.2 Medical history of asthma

    10.3 Presence of at least 2 of the following EGPA characteristics:

        10.3.1 Histopathological findings of eosinophilic vasculitis:

            10.3.1.1 Perivascularitis eosinophilic infiltration

            10.3.1.2 Eosinophil-rich granulomatous inflammation

        10.3.2 Neuropathy

        10.3.3 Pulmonary infiltrates, non-fixed; sino-nasal abnormality

        10.3.4 Cardiomyopathy

        10.3.5 Glomerulonephritis

        10.3.6 Alveolar hemorrhage

        10.3.7 Palpable purpura

        10.3.8 Anti-neutrophils cytoplasmic antibody

    10. 4 Refractory disease or a history of EGPA relapse

11. Prior authorization for **Mepolizumab** will be considered for members who are 12 years of age or older with 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) and with documentation supporting medical necessity for treatment including:

    11.1 Diagnosis of HES for 6 months or longer without any non-hematologic secondary cause

11.2 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

11.3 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.

12. Prior authorization for **Mepolizumab** will be considered for members who are 18 years of age or older with Chronic rhinosinusitis with nasal polyps (CRSwNP) when the following criteria are met:

12.1 Confirmed diagnosis of chronic rhinosinusitis with nasal polyps (diagnosis codes J330, J331, J338, and J339)

12.2 Evidence of inadequate response to nasal corticosteroid

13. Additional medical necessity criteria for prior authorization for Asthma:
Moderate to Severe (Omalizumab) and Severe (Benralizumab, Mepolizumab, Reslizumab):

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

13.1.1 Twelve months of high-dose inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of controller medication (either a long-acting beta 2-agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline) unless the member is intolerant of or has a medical contraindication to these agents

13.1.2 Six months of ICS with daily oral glucocorticoids given in combination with a minimum of 3 months of controller medication (a LABA, LTRA, or theophylline) unless the member is intolerant of or has a medical contraindication to these agents

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

13.2 Mepolizumab

The following additional documentation for treatment with mepolizumab must also be submitted:

13.2.1 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:

13.2.2 Greater than or equal to 150 cells/microliter at initiation of therapy; or

13.2.3 Greater than or equal to 300 cells/microliter within 12 months prior to initiation of therapy

13.3 Omalizumab

The following additional documentation for treatment with omalizumab also must be submitted:

13.3.1 Positive skin test or RAST to a perennial (not seasonal) aeroallergen within the past 36 months

13.3.2 Total IgE level greater than 30 IU/ml but less than 1300 IU/ml within the past 12 months

13.4 Benralizumab

The following additional documentation for treatment with benralizumab must also be submitted with the initial prior authorization request:

13.4.1 Documented diagnosis of severe eosinophilic asthma

13.4.2 Blood eosinophil count greater than or equal to 150 cells/microliter before the initiation of therapy, in the absence of other potential causes of eosinophilia including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection

13.5 Resilzumab

The following additional documentation for treatment with reslizumab must also be submitted:

13.5.1 Has an eosinophilic phenotype as determined by blood eosinophils of 400 cells/microliter or higher prior to initiation of therapy (within 3-4 weeks of dosing).

13.5.2 When requesting prior authorization, the exact dosage must be included with the request.

13.6 Requirements for Continuation of Therapy

For continuation of therapy with omalizumab, benralizumab, mepolizumab, or reslizumab after 6 continuous months, the requesting provider must submit the following documentation of the client's compliance and satisfactory clinical response to omalizumab, benralizumab, mepolizumab, or reslizumab:

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

13.6.2 Decreased utilization of rescue medications; or

13.6.3 Increase in predicted FEV1 (forced expiratory volume) from pretreatment baseline; or

13.6.4 Reduction in reported asthma-related symptoms, as evidenced by decreases in frequency or magnitude of one or more of the following symptoms:

13.6.4.1 Asthma attacks

13.6.4.2 Chest tightness or heaviness

13.6.4.3 Coughing or clearing throat

13.6.4.4 Difficulty taking deep breath or difficulty breathing out

13.6.4.5 Shortness of breath

13.6.4.5 Sleep disturbance, night wakening, or symptoms upon awakening

13.6.4.6 Tiredness

13.6.4.7 Wheezing/heavy breathing/fighting for air, and

13.6.5 Member has not exhibited symptoms of hypersensitivity or anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema) after administration of omalizumab, benralizumab, mepolizumab, or reslizumab.

13.6.6 After lapses in treatment of 3 months or greater, prior authorization requests submitted with documentation will be reviewed by the TMHP medical director.

13.6.7 Requests for clients who do not meet the above criteria will be reviewed for medical necessity by the TMHP medical director.

14. 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:

14.1 confirmed diagnosis of severe asthma (diagnosis code: J45.50 and J45.51).
14.2 Tezepelumab-ekko is requested as an add-on maintenance therapy.
14.2.1 Tezepelumab-ekko is not to be used as a single or primary therapy.
14.3 Current management includes regular treatment for severe asthma and is compliant with the therapy defined as:
14.3.1 Medium or high-dose inhaled corticosteroid therapy, **AND**
14.3.2 An additional asthma controller

15. **Tezepelumab-ekko** should not be used and is not medically necessary:
15.1 for relief of acute bronchospasm or status asthmaticus.
15.2 in combination with anti-IgE, anti_IL4, or anti-IL5 monoclonal antibody agents (i.e., benralizumab, omalizumab, mepolizumab, reslizumab, dupilumab, etc.)

16. **Tezepelumab-ekko** should not be used and will not be approved with
16.1 active, untreated helminth infection
16.2 concurrent administration with live attenuated vaccination

17. Prior authorization for renewal or continuation therapy of **Tezepelumab-ekko** will be considered when all the following criteria are met:
17.1 Initial authorization approval criteria continue to be met
17.2 Positive clinical response to therapy as demonstrated by no increase in asthma exacerbations or improvement in asthma symptoms

18. 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.

19. 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:

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Normansell R, Walker S, Milan SJ, Walters EH, Nair P. Omalizumab for asthma in adults and children. Cochrane Database Syst Rev. 2014 Jan 13;(1):CD003559

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MCO Notices- 6/13/22- Tezspire (Tezepelumab-ekko) Update Effective July 1

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