Texas Children's	Monoclonal Antibodies Guideline	
Guideline # 11062	***Categories*** Clinical →Care Management CM	***This Guideline Applies To:*** Texas Children's Health Plan ***Document Owner*** Bhavana Babber

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.

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 (diagnosis codes J4540 and J4550).

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).
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).
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).
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 of monoclonal antibodies (Omalizumab, 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 beta2--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

14. 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.

15. 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:

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Peer Reviewed Publications:

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Texas Medicaid Provider Procedures Manual Accessed February 28, 2021

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Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention 2020. https://ginasthma.org/wp-content/uploads/2020/04/GINA-2020-full-report_-final-_wms.pdf [accessed March 10, 2021]

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 [accessed March 10, 2021]

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Status	Date	Action
Approved	1/13/2022	Clinical & Administrative Advisory Committee Reviewed and Approved for Implementation

Original Creation Date: No Date Set	Version Creation Date: 12/17/2021	Effective Date: 01/27/2022