

 Texas Children's®	<b>Monoclonal Antibodies Guideline</b>	
<b>Guideline #</b> 11062	<b>Categories</b> Clinical → Care Management CM	<b>This Guideline Applies To:</b> Texas Children's Health Plan
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**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 clients 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 genetic testing 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.
4. Prior authorization for **Omalizumab** will be considered for members who are 12 years of age or older with **chronic idiopathic urticaria** (CIU). Requests must be submitted with the Special Medical Prior Authorization (SMPA) form. 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. Documentation supporting medical necessity for treatment with **Omalizumab for asthma** must be submitted with the request and must indicate the following:
  - 5.1 Symptoms are inadequately controlled with use of one of the following combination therapies:
    - 5.1.1 12 months of high-dose inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of an additional 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; **Or**
    - 5.1.2 6 months of inhaled corticosteroid (ICS) with daily oral glucocorticoids given in combination with a minimum of 3 months of an additional controller medication (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
  - 5.2 Pulmonary function tests (spirometry) must have been performed within a three-month period prior to the start of this medication and be documented.
  - 5.3 Omalizumab dose is not greater than 375 mg every 2 weeks.
  - 5.4 Positive skin test or in vitro (allergen specific IgE) test to a perennial (not seasonal) aeroallergen within the past 36 months.
  - 5.5 Total IgE level greater than 30 IU/ml but less than 1300 IU/ml within the past 12 months.

5.6 Member must not be currently smoking, using electronic cigarettes/electronic nicotine delivery systems, or using heated tobacco product (ex IQOS®) devices.

5.6 Exceptions to the criteria above will be considered on a case-by-case basis, which will require a letter from the prescribing provider stating the medical necessity for omalizumab, the member's asthma severity level, and the duration of current and past therapies and lack of asthma control. Consideration for these exceptions will be reviewed by a TCHP medical director/physician reviewer.

5.7 Providers may not bill for an office visit if the only reason for the visit is an Omalizumab injection.

5.8 Prior authorization for **Benralizumab** will be considered for members who are 12 years of age or older with severe asthma with an eosinophilic phenotype. Requests must be submitted with the Special Medical Prior Authorization (SMPA) form. Documentation supporting medical necessity for treatment of asthma with Benralizumab must be submitted with the request and include all of the following:

5.9.1 Symptoms are inadequately controlled with use of one of the following combination therapies:

5.9.1.1 12 months of high-dose inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of an additional 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; **Or**

5.9.1.2 6 months of inhaled corticosteroid ICS with daily oral glucocorticoids 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.

5.10 Pulmonary function tests (spirometry) must have been performed within a three-month period prior to the start of this medication and be documented.

5.11 Documented diagnosis of severe asthma with eosinophilic phenotype.

5.12 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.

5.14 Member must not be currently smoking, using electronic cigarettes/electronic nicotine delivery systems, or using heated tobacco product (ex. IQOS®) devices.

5.16 Providers may not bill for an office visit if the only reason for the visit is a Benralizumab injection.

5.17 Benralizumab may be approved for a maximum of 30 mg every 4 weeks x 3 doses (12 weeks), after which Benralizumab may be approved for use only once every 8 weeks.

- 5.18 Treatment of benralizumab may not be used concurrently with omalizumab or any other interleukin-5 or interleukin-4 antagonist
- 5.19 Exceptions to the criteria above will be considered on a case-by-case basis, which will require a letter from the prescribing provider stating the medical necessity for Benralizumab, the member's asthma severity level, and the duration of current and past therapies and lack of asthma control. Consideration for these exceptions will be reviewed by a TCHP medical director/physician reviewer.
6. Prior authorization for **Reslizumab** will be considered for members who are 18 years of age or older with chronic severe asthma. Requested must be submitted with the Special Medical Prior Authorization (SMPA) form. Documentation supporting medical necessity for treatment of asthma with reslizumab must be submitted with the request and include all of the following:
- 6.1 Symptoms are inadequately controlled with use of one of the following combination therapies:
    - 6.1.1 12 months of high-dose inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of another 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; **Or**
    - 6.1.2 6 months of high-dose inhaled corticosteroid (ICS) with daily oral glucocorticoids 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.
  - 6.2 Pulmonary function tests (spirometry) must have been performed within a three-month period and be documented for all members.
  - 6.3 Has an eosinophilic phenotype as determined by blood eosinophils of 400 cells/microliter or higher prior to initiation of therapy (within 1 month of initiation)
  - 6.4 Member must not be currently smoking, using electronic cigarettes/electronic nicotine delivery systems, or using heated tobacco product (ex. IQOS®) devices.
  - 6.5 Providers may not bill for an office visit if the only reason for the visit is a Reslizumab injection.
  - 6.6 Treatment of Reslizumab may not be used concurrently with Omalizumab or any other interleukin-5 or interleukin-4 antagonist
  - 6.7 Exceptions to the criteria above will be considered on a case-by-case basis, which will require a letter from the prescribing provider stating the medical necessity for Benralizumab, the member's asthma severity level, and the duration of current and past therapies and lack of asthma control. Consideration for these exceptions will be reviewed by a TCHP medical director/physician reviewer.
7. Prior authorization for **Mepolizumab** will be considered for members who are 6 years of age or older with severe asthma with Requests must be submitted with the Special Medical Prior Authorization (SMPA) form. Documentation supporting medical necessity for treatment of asthma with Mepolizumab must be submitted with the request and include all of the following:

7.1. Symptoms are inadequately controlled with use of one of the following combination therapies:

7.1.1. 12 months of high-dose inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of additional 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; **Or**

7.1.2 6 months of ICS with daily oral glucocorticoids given in combination with a minimum of 3 months of an additional controller medication (a LABA, LTRA, or theophylline), unless the member is intolerant of, or has a medical contraindication to these agents.

7.2 Pulmonary function tests (spirometry) must have been performed within a three-month period and be documented for all members.

7.3 One of the following blood eosinophil counts in the absence of other potential causes of eosinophilia, including, neoplastic disease, and known or suspected parasitic infection:

- 7.3.1 Greater than or equal to 150 cells/microliter within 1 month prior to initiation of therapy;
- 7.3.2 Greater than or equal to 300 cells/microliter within 12 months prior to initiation of therapy

7.4 Member is not currently smoking, using electronic cigarettes/electronic nicotine delivery systems, or using heated tobacco product (ex. IQOS®) evices.

7.5 Providers may not bill for an office visit if the only reason for the visit is a Mepolizumab injection.

7.6 Treatment with Mepolizumab may not occur concurrently with Omalizumab or any other interleukin-5 or interleukin-4 antagonist.

7.7 Exceptions to the criteria above will be considered on a case-by-case basis, which will require a letter from the prescribing provider stating the medical necessity for Mepolizumab, the member's asthma severity level, and the duration of current and past therapies and lack of asthma control. Consideration for these exceptions will be reviewed by a TCHP medical director/physician reviewer.

8 Renewal of authorization. For continued therapy with Omalizumab, Benralizumab, Mepolizumab, or Reslizumab after 6 continuous months, the requesting provider must submit the following documentation of the member's compliance and satisfactory clinical response:

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

- 8.1.1 Decreased utilization of rescue medications; or
- 8.1.2 Increase in predicted FEV1 (forced expiratory volume) from pretreatment baseline
- 8.1.3 Reduction in asthma-related symptoms, as evidenced by decreases in frequency or magnitude of one or more of the following symptoms:
  - 8.1.3.1 Asthma attacks
  - 8.1.3.2 Chest tightness or heaviness
  - 8.1.3.3 Coughing or clearing throat
  - 8.1.3.4 Difficulty taking deep breath or difficulty breathing out

- 8.1.3.5 Shortness of breath
- 8.1.3.6 Sleep disturbance, night waking, or symptoms upon awakening
- 8.1.3.7 Tiredness
- 8.1.3.8 Wheezing/heavy breathing/fighting for air
- 8.2 Member has not exhibited symptoms of hypersensitivity or anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema) after administration of )malizumab, Benralizumab, Mepolizumab, or Reslizumab.
- 8.3 Documentation from provider that member has been compliant with their Omalizumab, Benralizumab, Mepolizumab, or Reslizumab regimen.

9. 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.

10. 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:

### Peer Reviewed Publications:

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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

### Government Agency, Medical Society, and Other Publications:

Texas Medicaid Provider Procedures Manual [Accessed February 28, 2021](#)

[https://www.tmhp.com/sites/default/files/file-library/resources/provider-manuals/tmppm/pdf-chapters/2021/2021-03-march/2\\_Outpatient\\_Drug.pdf](https://www.tmhp.com/sites/default/files/file-library/resources/provider-manuals/tmppm/pdf-chapters/2021/2021-03-march/2_Outpatient_Drug.pdf)

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](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]

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> [accessed March 10, 2021]

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> [accessed March 10, 2021]

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 <https://www.nice.org.uk/guidance/ta479/resources/reslizumab-for-treating-severe-eosinophilic-asthma-pdf-82604974420933> [accessed March 10, 2021]

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