



Medicare Advantage Medical Utilization Review Policy

Policy:	Immunologicals – Xolair Utilization Management Medical Policy <ul style="list-style-type: none"> Xolair® (omalizumab subcutaneous injection – Genentech/Novartis)
Date:	03/22/2023
Applicable Lines of Business:	Medicare Advantage - Medical
Applicable States:	NGS, J6: Wisconsin, Minnesota, Illinois NGS, JK: New York, Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont

OVERVIEW

Xolair, an anti-immunoglobulin E (IgE) monoclonal antibody, is indicated for the following uses:¹

- **Asthma**, in patients ≥ 6 years of age with moderate to severe persistent disease who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids (ICSs). Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Limitations of Use: Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus. It is also not indicated for the treatment of other allergic conditions.
- **Chronic idiopathic urticaria**, in patients ≥ 12 years of age who remain symptomatic despite H1 antihistamine treatment. Limitation of Use: Xolair is not indicated for the treatment of other forms of urticaria.
- **Nasal polyps**, as add-on maintenance treatment in patients ≥ 18 years of age with an inadequate response to nasal corticosteroids.

Dosing of Xolair for the treatment of asthma or nasal polyps is based on body weight and the serum total IgE level measured before the start of treatment.¹ Dosing for these indications is only provided for patients with a pretreatment serum IgE level ≥ 30 IU/mL. Dosing of Xolair in patients with chronic idiopathic urticaria is not dependent on serum IgE level or body weight.

Clinical Efficacy

Timing of efficacy assessments varied by indication across the numerous pivotal studies in which Xolair demonstrated benefit. In the majority of the asthma trials, efficacy with Xolair was assessed as early as 16 weeks.¹⁻¹¹ In chronic idiopathic urticaria, one of the studies included a 12-week double-blind treatment period, while the other was longer with 24 weeks of double-blind treatment.^{12,13} Across both studies evaluating Xolair in nasal polyps, efficacy was evaluated at Week 24.¹⁴ Patients continued treatment with intranasal corticosteroids throughout the study.

Guidelines*Asthma Guidelines*

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention (2022) proposes a step-wise approach to asthma treatment.¹⁵ Xolair is listed as an option for add-on therapy in patients ≥ 6 years of age with difficult-to-treat, severe eosinophilic asthma (i.e., asthma that cannot be managed by therapy with an inhaled corticosteroid [ICS]/long-acting beta₂-agonist [LABA] combination with or without an additional controller). Higher blood eosinophil levels, elevated fractional exhaled nitric oxide, allergy-driven symptoms, and childhood-onset asthma may predict a good asthma response to Xolair.

According to the European Respiratory Society/American Thoracic Society guidelines (2014; updated in 2020), severe asthma is defined as asthma which requires treatment with a high-dose ICS in addition to a second controller medication (and/or systemic corticosteroids) to prevent it from becoming uncontrolled, or asthma which remains uncontrolled despite this therapy.^{16,17} Uncontrolled asthma is defined as asthma that worsens upon tapering of high-dose ICS or systemic corticosteroids or asthma that meets one of the following four criteria:

- 1) Poor symptom control: Asthma Control Questionnaire consistently ≥ 1.5 or Asthma Control Test < 20 ;

- 2) Frequent severe exacerbations: two or more bursts of systemic corticosteroids in the previous year;
- 3) Serious exacerbations: at least one hospitalization, intensive care unit stay, or mechanical ventilation in the previous year;
- 4) Airflow limitation: $FEV_1 < 80\%$ predicted after appropriate bronchodilator withholding.

Chronic Urticaria Guidelines

A Practice Parameter on the Diagnosis and Management of Acute and Chronic Urticaria (2014) from the Joint Task Force on Practice Parameters (JTFPP) and guideline from the European Academy of Allergy and Clinical Immunology/Global Allergy and Asthma European Network/European Dermatology Forum/World Allergy Organization (2018) define chronic urticaria as urticaria that has been continuously or intermittently present for at least 6 weeks.^{18,19} Continuous therapy with antihistamines (second generation H1-antagonists) is generally recommended as first-line pharmacologic treatment for urticaria following trigger avoidance. If symptoms persist following 2 to 4 weeks of initial therapy, the dose of the second generation H1-antagonist should be increased to up to 4-fold. For patients with refractory chronic urticaria, the addition of Xolair may be considered.

Nasal Polyp Guidelines

A 2014 Practice Parameter on the Diagnosis and Management of Rhinosinusitis (2014) and a Practice Parameter for the Management of Rhinitis from the JTFPP (2020), and a 2015 Clinical Practice Guideline update on Adult Sinusitis from the American Academy of Otolaryngology (AAO), make similar recommendations regarding the diagnosis and management of chronic rhinosinusitis with nasal polyposis (CRSwNP).²⁰⁻²⁴ The presence of two or more signs and symptoms of chronic rhinosinusitis (e.g., rhinorrhea, postnasal drainage, anosmia, nasal congestion, facial pain, headache, fever, cough, and purulent discharge) that persist for an extended period of time makes the diagnosis CRS likely. However, this requires confirmation of sinonasal inflammation, which can either be done via direct visualization or computed tomography scan. Nasal corticosteroids are recommended for the management of CRSwNP, as they decrease nasal polyp size, prevent regrowth of nasal polyps following surgical removal, and improve nasal symptoms. Short courses of oral corticosteroids are also recommended. Endoscopic surgical intervention may be considered as an adjunct to medical therapy in patients with chronic rhinosinusitis that is not responsive or is poorly responsive to medical therapy. The JTFPP parameter lists Xolair as a therapy that may be considered for the treatment of nasal polyps based on the limited data available at the time of publication. The AAO guidelines do not address Xolair.

The European Forum for Research and Education in Allergy expert board on uncontrolled severe CRSwNP and biologics (2021) recommends that these agents, including Xolair, only be used for severe uncontrolled CRSwNP when Type 2 inflammation is present.⁴⁹ Severe CRSwNP is defined as bilateral CRSwNP with a nasal polyp score ≥ 4 and persistent symptoms (e.g., loss of smell/taste, nasal obstruction, secretion or postnasal drip, facial pain or pressure) with the need for add-on treatment to supplement intranasal corticosteroids. Severe CRSwNP is considered to be uncontrolled if the patient has received continuous treatment with an intranasal corticosteroid and has needed at least one course of systemic corticosteroids in the previous 2 years (or has a medical contraindication or intolerance) and/or has a previous sinonasal surgery.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Xolair. Approval is recommended for those who meet the **Criteria** and **Dosing** the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. All approvals are provided for the durations noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the References section of this policy. In some cases,



EmblemHealth®

ConnectiCare

this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xolair is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. Asthma.

Criteria. Approve Xolair for the duration noted if the patient meets one of the following conditions (A or B):

A) **Initial Therapy.** Approve for 4 months if the patient meets the following criteria (i, ii, iii, and iv):

- i. The patient is ≥ 6 years of age; AND
- ii. The patient has a baseline positive skin test or *in vitro* test (i.e., a blood test) for allergen-specific immunoglobulin E (IgE) for one or more perennial aeroallergens and/or for one or more seasonal aeroallergens; AND

Note: “Baseline” is defined as prior to receiving any Xolair or another monoclonal antibody therapy that may interfere with allergen testing (e.g., Dupixent and Tezspire). Examples of perennial aeroallergens are house dust mite, animal dander, cockroach, feathers, and mold spores. Examples of seasonal aeroallergens are grass, pollen, and weeds.

- iii. Patient has received at least 3 consecutive months of therapy with an inhaled corticosteroid; AND

Note: Use of a combination inhaler containing an inhaled corticosteroid would fulfill this requirement. Examples of inhaled corticosteroids include Aerospan, Alvesco, ArmonAir RespiClick, Arnuity Ellipta, Asmanex Twisthaler/HFA, Flovent Diskus/HFA, Pulmicort Flexhaler, Qvar/Qvar RediHaler, and budesonide suspension for inhalation (Pulmicort Respules, generics). Examples of combination inhalers containing an inhaled corticosteroid include Advair Diskus (generic Wixela Inhub; authorized generics), Advair HFA, AirDuo RespiClick (authorized generics), Breo Ellipta, Dulera, and Symbicort.

- iv. The patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by ONE of the following (a, b, c, d, e, f, g, h, or i):

Note: “Baseline” is defined as prior to receiving Xolair or another monoclonal antibody therapy for asthma. Examples of monoclonal antibody therapies for asthma include Cinqair, Dupixent, Fasentra, Nucala, Tezspire, and Xolair.

- a. Daily symptoms or symptoms throughout the day;⁵⁰ OR
- b. Daily use of inhaled short-acting beta₂-agonist or use of inhaled short-acting beta 2-agonist several times per day;⁵⁰ OR
- c. Some limitation with normal activity or extremely limited normal activity;⁵⁰ OR
- d. The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
- e. The patient experienced one or more asthma exacerbation requiring a hospitalization, an emergency department (ED) visit, or an urgent care visit in the previous year; OR
- f. Nighttime symptoms greater than 1 time a week but not nightly or nighttime symptoms often 7x/week;⁵⁰ OR
- g. Patient has a forced expiratory volume in 1 second (FEV₁) < 80% predicted; OR



- A) Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii and iv):
- i. Patient is ≥ 18 years of age; AND
 - ii. Patient has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan; AND
 - iii. Patient will receive therapy with an intranasal corticosteroid concomitantly with Xolair; AND
 - iv. Patient meets ONE of the following (a, b or c):
 - a. Patient has had an inadequate response to an intranasal corticosteroid;⁵¹ OR
 - b. Patient has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; OR
 - c. Patient has a contraindication to systemic corticosteroid therapy; OR
 - d. Patient has had prior surgery for nasal polyps.
- B) Patient is currently receiving Xolair. Approve for 1 year if the patient meets the following criteria (i, ii and iii):
- i. Patient has already received at least 6 months of therapy with Xolair; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Xolair should be considered under criterion 3A [Nasal Polyps, Initial Therapy].
 - ii. Patient continues to receive therapy with an intranasal corticosteroid; AND
 - iii. Patient has responded to Xolair therapy as determined by the prescriber.
Note: Examples of a response to Xolair therapy are reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal symptoms, and/or improved sense of smell.

Dosing. Approve up to a maximum dose of 600 mg administered subcutaneously (SC) not more frequently than once every 2 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Xolair is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Xolair[®] subcutaneous injection [prescribing information]. South San Francisco, CA and East Hanover, NJ: Genentech and Novartis; April 2021.
2. Busse W, Corren J, Lanier BQ, et al. Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. *J Allergy Clin Immunol.* 2001;108(2):184-190.
3. Finn A, Gross G, van Bavel J, et al. Omalizumab improves asthma-related quality of life in patients with severe allergic asthma. *J Allergy Clin Immunol.* 2003;111(2):278-284.
4. Lanier BQ, Corren J, Lumry W, et al. Omalizumab is effective in the long-term control of severe allergic asthma. *Ann Allergy Asthma Immunol.* 2003;91:154-159.
5. Bousquet J, Wenzel S, Holgate S, et al. Predicting response to omalizumab, an anti-IgE antibody, in patients with allergic asthma. *Chest.* 2004;125(4):1378-1386.
6. Solèr M, Matz J, Townley R, et al. The anti-IgE antibody omalizumab reduces exacerbations and steroid requirement in allergic asthmatics. *Eur Respir J.* 2001;18:254-261.
7. Buhl R, Solèr M, Matz J, et al. Omalizumab provides long-term control in patients with moderate-to-severe allergic asthma. *Eur Respir J.* 2002;20:73-78.
8. Buhl R, Hanf G, Solèr M, et al. The anti-IgE antibody omalizumab improves asthma-related quality of life in patients with allergic asthma. *Eur Respir J.* 2002;20:1088-1094.
9. Holgate S, Chuchalin A, Herbert J, et al. Efficacy and safety of a recombinant anti-immunoglobulin E antibody (omalizumab) in severe allergic asthma. *Clin Exp Allergy.* 2004;34:632-638.
10. Kulus M, Hebert J, Garcia E, et al. Omalizumab in children with inadequately controlled severe allergic (IgE-mediated) asthma. *Curr Med Res Opin.* 2010;26:1285-1293.



EmblemHealth[®]

ConnectiCare

11. Milgrom H, Berger W, Nayak A, et al. Treatment of childhood asthma with anti-immunoglobulin E antibody (omalizumab). *Pediatrics*. 2001;108(2).
12. Saini SS, Bindeslev-Jensen C, Maurer M, et al. Efficacy and safety of omalizumab in patients with chronic idiopathic/spontaneous urticaria who remain symptomatic on H1 antihistamines: a randomized, placebo-controlled study. *J Invest Dermatol*. 2015;135:67-75.
13. Maurer M, Rosen K, Hsieh HJ, et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria. *N Engl J Med*. 2013;368:924-935.
14. Gevaert P, Omachi TA, Corren J, et al. Efficacy and safety of omalizumab in nasal polyposis; 2 randomized phase 3 trials. *J Allergy Clin Immunol*. 2020;146(3):595-605.
15. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2021. Available at: <http://www.ginasthma.org>. Accessed on: March 1, 2022.
16. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014;43:343-373.
17. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European Respiratory Society/American Thoracic Society Guideline. *Eur Respir J*. 2020;55:1900588.
18. Zuberbier T, Aberer W, Asero R, et al. EAACI/GA²LEN/EDF/WAO guideline for the definition, classification, diagnosis, and management of urticaria. *Allergy*. 2018;73:1393-1414.
19. Joint Task Force on Practice Parameters: American Academy of Allergy, Asthma and Immunology; the American College of Allergy, Asthma and Immunology; and the Joint Council of Allergy, Asthma and Immunology. The diagnosis and management of acute and chronic urticaria: 2014 update. *J Allergy Clin Immunol*. 2014;133(5):1270-1277.e66.
20. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. *Ann Allergy Asthma Immunol*. 2014;347-385.
21. Joint Task Force on Practice Parameters: American Academy of Allergy, Asthma and Immunology; the American College of Allergy, Asthma and Immunology; and the Joint Council of Allergy, Asthma and Immunology. The diagnosis and management of rhinitis: An updated practice parameter. *J Allergy Clin Immunol*. 2008;122(2):S1-S84.
22. Dykewicz MS, Wallace DV, Baroody F, et al. Treatment of seasonal allergic rhinitis: an evidenced-based focused 2017 guideline update. *Ann Allergy Asthma Immunol*. 2017;119(6):489-511.
23. Joint Task Force on Practice Parameters: American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology. Rhinitis 2020: a practice parameter update. *J Allergy Clin Immunol*. 2020;146:721-767.
24. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. *Otolaryngol Head Neck Surg*. 2015;152(2S):S1-S39.
25. Chan S, Cornelius V, Cro S, et al. Treatment effect of omalizumab on severe pediatric atopic dermatitis: the ADAPT randomized clinical trial. *JAMA Pediatr*. 2019;174(1):29-37.
26. Holm JG, Agner T, Sand C, et al. Omalizumab for atopic dermatitis: case series and a systematic review of the literature. *Int J Dermatol*. 2017;56(1):18-26.
27. Wang HH, Li YC, Huang YC, et al. Efficacy of omalizumab in patients with atopic dermatitis: a systematic review and meta-analysis. *J Allergy Clin Immunol*. 2016;138(6):1719-1722.
28. Sidbury R, et al. Guidelines of care for the management of atopic dermatitis Section 3. Management and treatment with phototherapy and systemic agents. *J Am Acad Dermatol*. 2014;71(2): 327-349.
29. Wollenberg A, Barbarot S, Bieber T, et al. Consensus-based European guidelines for the treatment of atopic eczema (atopic dermatitis) in adults and children: part II. *J Eur Acad Dermatol Venereol*. 2018;32(6):850-878.
30. Altman MC, Lenington J, Bronson S, et al. Combination omalizumab and mepolizumab therapy for refractory allergic bronchopulmonary aspergillosis. *J Allergy Clin Immunol Pract*. 2017;5(4):1137-1139.
31. Han D, Lee JK. Severe asthma with eosinophilic gastroenteritis effectively managed by mepolizumab and omalizumab. *Ann Allergy Asthma Immunol*. 2018;121(6):742-743.
32. Dedaj R, Unsel L. Case study: a combination of mepolizumab and omalizumab injections for severe asthma. *J Asthma*. 2019;56(5):473-474.
33. Froughi S, Foster B, Young Kim N, et al. Anti-IgE treatment of eosinophil-associated gastrointestinal disorders. *J Allergy Clin Immunol*. 2007;120(3):594-601.
34. Clayton F, Fang JC, Gleich GJ, et al. Eosinophilic esophagitis in adults is associated with IgG4 and not mediated by IgE. *Gastroenterology*. 2014;147:602-609.
35. Fang JC, Hilden K, Gleich GJ, et al. A pilot study of the treatment of eosinophilic esophagitis with omalizumab. *Gastroenterology*. 2011;140(5):S-235.
36. Dellon ES, Gonsalves N, Hirano I, et al. ACG clinical guideline: evidenced based approach to the diagnosis and management of esophageal eosinophilia and eosinophilic esophagitis. *Am J Gastroenterol*. 2013;108(5):679-692.
37. Hirano I, Chan ES, Rank MA, et al. AGA Institute and Joint Task Force on Allergy-Immunology Practice Parameters Clinical Guidelines for the Management of Eosinophilic Esophagitis. *Gastroenterology*. 2020;158(6):1776-1786.
38. Leynadier F, Doudou O, Gaouar H, et al. Effect of omalizumab in health care workers with occupational latex allergy [letter]. *J Allergy Clin Immunol*. 2004;113(2):360-361.
39. Sampson HA, Leung DYM, Burks AW, et al. A phase II, randomized, double-blind, parallel-group, placebo-controlled oral food challenge trial of Xolair (omalizumab) in peanut allergy. *J Allergy Clin Immunol*. 2011;127:1309-1310.e1.



40. Schneider LC, Rachid R, LeBovidge J, et al. A pilot study of omalizumab to facilitate rapid oral desensitization in high-risk peanut-allergic patients. *J Allergy Clin Immunol.* 2013;132(6):1368-1374.
41. Nadeau KC, Schneider LC, Hoyte L, et al. Rapid oral desensitization in combination with omalizumab therapy in patients with cow’s milk allergy. *J Allergy Clin Immunol.* 2011;127(6):1622-1624.
42. Nilsson C, Nordvall L, Johansson SGO, et al. Successful management of severe cow’s milk allergy with omalizumab treatment and CD-sens monitoring. *Asia Pac Allergy.* 2014;4:257-260.
43. Takahashi M, Taniuchi S, Soejima K, et al. Successful desensitization in a boy with severe cow’s milk allergy by a combination therapy using omalizumab and rush oral immunotherapy. *Allergy Asthma Clin Immunol.* 2015;11(1):18.
44. Wood RA, Kim JS, Lindblad R, et al. A randomized, double-blind, placebo-controlled study of omalizumab combined with oral immunotherapy for the treatment of cow’s milk allergy. *J Allergy Clin Immunol.* 2016;137(4):1103-1110.
45. Begin P, Domingues T, Wilson SP, et al. Phase 1 results of safety and tolerability in a rush oral immunotherapy protocol to multiple foods using omalizumab. *Allergy Asthma Clin Immunol.* 2014;10(1):7.
46. Andorf S, Purington N, Kumar D, et al. A phase 2 randomized controlled multisite study using omalizumab-facilitated rapid desensitization to test continued vs discontinued dosing in multifood allergic individuals. *EClinicalMedicine.* 2019;7:27-38.
47. Boyce JA, Assa’ad A, Burks AW, et al. Guidelines for the diagnosis and management of food allergy in the United States: summary of the NIAID-sponsored expert panel report. *J Allergy Clin Immunol.* 2010;126:1105-1118.
48. Joint Task Force on Practice Parameters: American Academy of Allergy, Asthma and Immunology; the American College of Allergy, Asthma and Immunology; and the Joint Council of Allergy, Asthma and Immunology. Food allergy: a practice parameter update – 2014. *J Allergy Clin Immunol.* 2014.
49. Bachert C, Han JK, Wagenmann, et al. EUFOREA expert board meeting on uncontrolled severe chronic rhinosinusitis with nasal polyps (CRS_{wNP}) and biologics: definitions and management. *J Allergy Clin Immunol.* 2021;147(1):29-36.
50. Centers for Medicare and Medicaid Services, National Government Services, Inc, Local Coverage Article: Billing and Coding: Omalizumab (e.g., Xolair®) – Related to LCD L33394 (A52448) [original date 10/01/2015; revision effective date 3/10/2022]. Accessed on December 12, 2023.
51. Centers for Medicare and Medicaid Services, National Government Services, Inc, Local Coverage Determination (LCD): Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394) [original date 10/01/2015; revision effective date 11/1/2022]. Accessed on December 12, 2023.

EXHIBIT 1

Normal ranges by age for FEV₁/FVC are as follows (National Heart, Lung, and Blood Institute [NHLBI]):

- 8-19 years of age – 85%;
- 20-39 years of age – 80%;
- 40-59 years of age – 75%;
- 60-80 years of age – 70%

HISTORY

Type of Revision	Summary of Changes	Date
Policy created	New Medicare Advantage Medical Policy	07/11/2018
Policy revision	Reviewed and revised original policy created 07/11/2018 in accordance with Local Coverage Article A52448.	02/20/2019
Policy revision	Completion of 2019 monthly monitoring process in accordance with Local Coverage Determination L33394, Local Coverage Article A52448.	12/11/2019
Policy revision	Non-clinical update to policy to add the statement “This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10	1/30/2020



EmblemHealth®



	code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does <u>not</u> necessarily mean that the applicable condition or diagnosis is excluded from coverage.”	
Policy revision	Reviewed and revised original policy created 07/11/2018 in accordance with Local Coverage Determination L33394, Local Coverage Article A52448.	02/12/2020
Policy revision	<ul style="list-style-type: none"> Asthma – changed wording for the indication, simplified to asthma. Also changed “moderate to severe requirement” to “uncontrolled or was uncontrolled prior to receiving any Xolair or anti-IL-4/13 therapy (Dupixent) therapy” and added additional options to meet that criteria, Added criteria requiring patient to continue therapy with an ICS or ICS-containing product for continuation of coverage. All indications – removed requirement that Xolair be administered by a physician or incident to a physician’s service in office/clinic setting. Removed Allergic rhinitis as a covered condition Removed self-administration of Xolair and acute bronchospasm or status asthmaticus from conditions not recommended for approval 	3/26/2020
Policy revision	New indication - Nasal Polyps: criteria for this indication – for initial therapy includes an age requirement, current intranasal corticosteroid therapy, previous systemic therapy (or contraindication) or surgery for nasal polyps or previous inadequate response to an intranasal corticosteroid. For continuation therapy, requires patient has already received at least 6 months of therapy with Xolair, patient continues to receive therapy with an intranasal corticosteroid, and that pt has had a response to therapy.	01/06/2021
Policy revision	Nasal Polyps: Added criteria requiring patient have chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan. Changed criteria requiring patient be currently receiving a nasal corticosteroid to Patient will receive therapy with an intranasal corticosteroid concomitantly with Xolair. Clarified the systemic corticosteroid criteria to require that the patient has received at least one course of systemic corticosteroids for at least 5 days in the previous 2 years.	07/20/2021
Policy revision	Asthma: Notes were also updated to include Xolair, Cinqair, Fasenna, Nucala, and Tezspire as examples of monoclonal antibody therapies for asthma. Criteria requiring the patient to have experienced one or more asthma exacerbation(s) requiring a hospitalization or an emergency department visit in the previous year, were updated to include an urgent care visit as well.	08/03/2022
Policy review	No criteria changes	03/22/2023



EmblemHealth®

ConnectiCare

03/22/2023

© 2023. All Rights Reserved.