Clinical Policy: Omalizumab (Xolair)

Reference Number: ERX.SPA.141
Effective Date: 03.01.14
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Omalizumab (Xolair®) is an anti-immunoglobin E (IgE) antibody.

FDA Approved Indication(s)
Xolair is indicated for:

- Moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
- Nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment
- Chronic idiopathic urticaria (CIU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment

Limitation(s) of use: Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus, treatment of other allergic conditions, or treatment of other forms of urticaria.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Xolair is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Moderate to Severe Persistent Asthma (must meet all)**:**

1. Diagnosis of asthma;
2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist;
3. Age ≥ 6 years;
4. Member has experienced ≥ 2 exacerbations within the last 12 months, requiring any of the following despite adherent use of controller therapy (i.e., medium- to high-dose inhaled corticosteroid [ICS] plus either a long acting beta-2 agonist [LABA] or leukotriene modifier [LTRA] if LABA contraindication/intolerance):
   a. Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid);
   b. Urgent care visit or hospital admission;
   c. Intubation;
5. Positive skin test or in vitro reactivity to a perennial aeroallergen (see *Appendix D*);
6. Immunoglobulin (IgE) level ≥ 30 IU/mL;
7. Xolair is prescribed concurrently with an ICS plus either a LABA or LTRA;
8. Xolair is not prescribed concurrently with Cinqair®, Fasenra®, Nucala®, or Dupixent®;
9. Dose does not exceed 375 mg administered every 2 weeks (*see Appendix E and F for dosing based on pre-treatment IgE level, weight, and age*).

Approval duration: 6 months

B. Chronic Idiopathic Urticaria (must meet all)**:**
1. Diagnosis of CIU;
2. Prescribed by or in consultation with a dermatologist, immunologist, or allergist;
3. Age ≥ 12 years;
4. Failure of both of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
   a. Two antihistamines (including one second generation antihistamine – e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) at maximum indicated doses, each used for ≥ 2 weeks;
   b. A LTRA in combination with an antihistamine at maximum indicated doses for ≥ 2 weeks;
5. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala, or Dupixent;
6. Dose does not exceed 300 mg every 4 weeks.

Approval duration: 6 months

C. Nasal Polyps (must meet all)**:**
1. Diagnosis of chronic rhinosinusitis with documentation of all of the following (a, b, and c):
   a. Presence of nasal polyps;
   b. Disease is bilateral;
   c. Member has experienced signs and symptoms (e.g., nasal congestion/blockage/ obstruction, loss of smell, rhinorrhea) for ≥ 12 weeks;
2. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist;
3. Age ≥ 18 years;
4. Member has required the use of systemic corticosteroids for symptom control within the last 2 years, unless contraindicated or clinically significant adverse effects are experienced *(see Appendix B for examples)*;
5. Failure of maintenance therapy with at least three intranasal corticosteroids, one of which must be Xhance™, each used for ≥ 4 weeks, unless contraindicated or clinically significant adverse effects are experienced *(see Appendix B for examples)*;
6. Xolair is prescribed concurrently with an intranasal corticosteroid, unless contraindicated or clinically significant adverse effects are experienced *(see Appendix B for examples)*;
7. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala, or Dupixent;
8. Dose does not exceed 600 mg every 2 weeks (see *Appendix G* for dosing based on pre-treatment IgE level and weight).

Approval duration: 6 months

D. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Moderate to Severe Persistent Asthma (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Demonstrated adherence to asthma controller therapy that includes an ICS plus either a LABA or LTRA;
3. Member is responding positively to therapy (examples may include but are not limited to: reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume over one second since baseline, reduction in the use of rescue therapy);
4. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala, or Dupixent;
5. If request is for a dose increase, new dose does not exceed 375 mg administered every 2 weeks (*see Appendix E and F for dosing based on pre-treatment IgE level, weight, and age*).

Approval duration: 12 months

B. Chronic Idiopathic Urticaria (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala, or Dupixent;
4. If request is for a dose increase, new dose does not exceed 300 mg every 4 weeks.

Approval duration: 12 months

C. Nasal Polyps (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Demonstrated adherence to an intranasal corticosteroid, unless contraindicated or clinically significant adverse effects are experienced;
3. Member is responding positively to therapy (examples may include but are not limited to: reduced nasal polyp size, reduced need for systemic corticosteroids, improved sense of smell, improved quality of life);
4. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala, or Dupixent;
5. If request is for a dose increase, new dose does not exceed 600 mg every 2 weeks (see *Appendix G* for dosing based on pre-treatment IgE level and weight).

Approval duration: 12 months

D. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents;

B. Acute bronchospasm or status asthmaticus.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CIU: chronic idiopathic urticarial
FDA: Food and Drug Administration
FEV: forced expiratory volume
GINA: Global Initiative for Asthma
ICS: inhaled corticosteroid
IgE: immunoglobin E
LABA: long acting beta-2 agonist
LTRA: leukotriene modifier

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Asthma – ICS (medium – high dose)		
Qvar® (beclomethasone)	> 100 mcg/day 40 mcg, 80 mcg per actuation 1-4 actuations BID	4 actuations BID
budesonide (Pulmicort®)	> 200 mcg/day 90 mcg, 180 mcg per actuation 2-4 actuations BID	2 actuations BID
Alvesco® (ciclesonide)	> 80 mcg/day 80 mcg, 160 mcg per actuation	2 actuations BID

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	1-2 actuations BID	
Aerospan® (flunisolide)	≥ 320 mcg/day 80 mcg per actuation 2-4 actuations BID	2 actuations BID
Flovent® (fluticasone propionate)	>176 mcg/day 44-250 mcg per actuation 2-4 actuations BID	2 actuations BID
Arnuity Ellipta® (fluticasone furoate)	200 mcg/day (≥ 12 years only) 100 mcg, 200 mcg per actuation 1 actuation QD	1 actuation QD
Asmanex® (mometasone)	≥ 220 mcg/day HFA: 100 mcg, 200 mcg per actuation Twisthaler: 110 mcg, 220 mcg per actuation 1-2 actuations QD to BID	2 inhalations BID
Asthma - LABA		
Serevent® (salmeterol)	50 mcg per dose 1 inhalation BID	1 inhalation BID
Asthma - Combination Products (ICS + LABA)		
Dulera® (mometasone/ formoterol)	100/5 mcg, 200/5 mcg per actuation 2 actuations BID	4 actuations/day
Breo Ellipta® (fluticasone/vilanterol)	100/25 mcg, 200/25 mcg per actuation 1 actuation QD	1 actuation QD
Advair® (fluticasone/ salmeterol)	Diskus: 100/50 mcg, 250/50 mcg, 500/50 mcg per actuation HFA: 45/21 mcg, 115/21 mcg, 230/21 mcg per actuation 1 actuation BID	1 actuation BID
fluticasone/salmeterol (Airduo RespiClick®)	55/13 mcg, 113/14 mcg, 232/14 mcg per actuation 1 actuation BID	1 actuation BID
Symbicort® (budesonide/ formoterol)	80 mcg/4.5 mcg, 160 mcg/4.5 mcg per actuation 2 actuations BID	2 actuations BID
Asthma - LTRA		
montelukast (Singulair®)	4 to 10 mg PO QD	10 mg per day
zafirlukast (Accolate®)	10 to 20 mg PO BID	40 mg per day
zileuton ER (Zyflo® CR)	1200 mg PO BID	2400 mg per day
Zyflo® (zileuton)	600 mg PO QID	2400 mg per day
CIU - 1st Generation Antihistamine		
hydroxyzine (Vistaril®)	CIU ≥ 6 years: 25 mg PO TID-QID < 6 years: 50 mg PO in divided doses	100 mg/day
CIU - 2nd Generation Antihistamine		
cetirizine (Zyrtec®)	CIU 5-10 mg PO QD	10 mg/day
levocetirizine (Xyzal®)	CIU 2.5-5 mg PO QD	5 mg/day
fexofenadine (Allegra®)	CIU ≥ 12 years: 60 mg PO BID or 180 mg PO QD 2-11 years: 30 mg PO BID 6-23 months: 15 mg PO BID	180 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
loratadine (Claritin®)	CIU 10 mg PO QD	10 mg/day
desloratadine (Clarinex®)	CIU ≥ 12 years: 5 mg PO QD 6-11 years: 2.5 mg PO QD 1-5 years: 1.25 mg PO QD 6-11 months: 1 mg PO QD	5 mg/day
Nasal Polyps		
Oral corticosteroids		
dexamethasone (Decadron®)	0.75 to 9 mg/day PO in 2 to 4 divided doses	Varies
methylprednisolone (Medrol®)	4 to 48 mg PO in 1 to 2 divided doses	Varies
prednisolone (Millipred®, Orapred ODT®)	5 to 60 mg PO in 1 to 2 divided doses	Varies
prednisone (Deltasone®)	5 to 60 mg PO in 1 to 2 divided doses	Varies
Intranasal corticosteroids		
beclomethasone (Beconase AQ®, Qnasl®)	1-2 sprays IN BID	2 sprays/nostril BID
budesonide (Rhinocort® Aqua, Rhinocort®)	128 mcg IN QD or 200 mcg IN BID	1-2 inhalations/nostril/ day
flunisolide	2 sprays IN BID	2 sprays/nostril TID
fluticasone propionate (Flonase®)	1-2 sprays IN BID	2 sprays/nostril BID
mometasone (Nasonex®)	2 sprays IN BID	2 sprays/nostril BID
Omnaris®, Zetonna® (ciclesonide)	Omnaris: 2 sprays IN QD Zetonna: 1 spray IN QD	Omnaris: 2 sprays/ nostril/day Zetonna: 2 sprays/ nostril/day
triamcinolone (Nasacort®)	2 sprays IN QD	2 sprays/ nostril/day
Xhance™ (fluticasone propionate)	1 to 2 sprays (93 mcg/spray) to nostril IN BID	744 mcg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity
- Boxed warning(s): anaphylaxis

Appendix D: General Information

- Allergic asthma:
  - The definition of moderate to severe allergy varied among the clinical trials. The definition most often used was a patient who required oral systemic steroid bursts or unscheduled physician office visits for "uncontrolled" asthma exacerbations despite maintenance inhaled steroid use. Patients in the clinical trials most often were required to have an FEV1 between 40% and 80% of predicted. No patients were enrolled with an FEV1 greater than 80% of predicted.

- Xolair has been shown to be marginally effective in decreasing the incidence of asthma exacerbations in patients who have met all the criteria described above.
- Xolair provides little therapeutic benefit over existing therapies. Use in patients on inhaled corticosteroids or chronic oral steroids plus or minus a second controller agent decreased asthma exacerbation by 0.5 to 1 per year. Use of rescue beta-agonists declined by 1 inhalation per day. Small changes in pulmonary function tests were also seen. An analysis of unpublished data indicated that hospital admissions declined by 3 per hundred patient years, emergency department (ED) visits by 2 per hundred patient years, and unscheduled physician office visits by 14 per one hundred patient years.
- The 2007 National Heart, Lung and Blood Institute's Expert Panel Report 3 (EPR3) Guidelines for the Diagnosis and Management of Asthma recommend Xolair may be considered as adjunct therapy for patients 12 years and older with allergies and Step 5 or 6 (severe) asthma whose symptoms have not been controlled by ICS and LABA.
- The 2019 Global Initiative for Asthma (GINA) guidelines for difficult-to-treat and severe asthma recommend Xolair be considered as adjunct therapy for patients 6 years of age and older with exacerbations or poor symptom control despite taking at least high dose ICS/LABA and who have allergic or eosinophilic biomarkers or need maintenance oral corticosteroids. Per 2020 GINA guidelines, Xolair may also be considered if the patient is uncontrolled on Step 4 treatment (medium dose ICS/LABA).
- The four perennial aeroallergens most commonly tested for in the clinical trials were dog dander, cat dander, cockroach, and house dust mite.
- Serious and life-threatening allergic reactions (anaphylaxis) in patients after treatment with Xolair have been reported. Usually these reactions occur within two hours of receiving a Xolair subcutaneous injection. However, these new reports include patients who had delayed anaphylaxis—with onset two to 24 hours or even longer-after receiving Xolair treatment. Anaphylaxis may occur after any dose of Xolair (including the first dose), even if the patient had no allergic reaction to the first dose.
- Patients could potentially meet asthma criteria for both Xolair and Nucala, though there is insufficient data to support the combination use of multiple asthma biologics. The combination has not been studied. Approximately 30% of patients in the Nucala MENSA study also were candidates for therapy with Xolair.

- CIU:
  - CIU is classified as spontaneous onset of wheals, angioedema, or both, for more than 6 weeks due to an unknown cause.
  - Clinical studies have shown that Xolair 150 mg and 300 mg significantly improved the signs and symptoms of chronic idiopathic urticaria compared to placebo in patients who had remained symptomatic despite the use of approved dose of H_1- antihistamine.
  - The Joint Task Force on Practice Parameters representing various American allergy organizations include Xolair in combination with H1-antihistamines as a fourth line treatment option following a stepwise approach starting with a second generation antihistamine. This is followed by one or more of the following: a dose increase of the second generation antihistamine, or the addition of another second generation antihistamine, H2-antagonist, LTRA, or first generation antihistamine. Treatment with hydroxyzine or doxepin can be considered in patients whose symptoms remain poorly controlled.
  - The EAACI/GA2LEN/EDF/AAAAI/WAO Guideline for the Management of Urticaria include Xolair in combination with H_1-antihistamines as a third line treatment option in patients who have failed to respond to higher doses of H_1-Antihistamines.
  - Xolair is the first medicine in its class approved for CIU since non-sedating antihistamines.
  - The use of over-the-counter H_1 antihistamines may not be a benefit to the treatment of chronic idiopathic urticaria. Credit will be given for its use, but will not be covered under plan.
  - Anaphylaxis has occurred as early as after the first dose of Xolair, but also occurred beyond 1 year after beginning regularly administered treatment.
- Nasal polyps: Both pivotal studies evaluating the use of Xolair in nasal polyps (NCT03280550, NCT03280537) were performed in patients with chronic rhinosinusitis.

- Idiopathic anaphylaxis: A randomized, double-blind, placebo-controlled study in 19 patients with frequent episodes (≥ 6/year) of idiopathic anaphylaxis found Xolair to have no significant difference compared to placebo in the number of anaphylactic episodes at 6 months (Carter MC et al).

Appendix E: Age ≥ 12 Years: Asthma Dosing Based on Pre-treatment IgE and Body Weight†

Pre-treatment serum IgE IU/mL	Dosing Frequency	Body Weight			
		30-60 kg	> 60-70 kg	> 70-90 kg	> 90-150 kg
≥ 30-100	Q 4 weeks	150 mg	150 mg	150 mg	300 mg
> 100-200		300 mg	300 mg	300 mg	225 mg
> 200-300		300 mg	225 mg	225 mg	300 mg
> 300-400	Q 2 weeks	225 mg	225 mg	300 mg	
> 400-500		300 mg	300 mg	375 mg	
> 500-600		300 mg	375 mg	Insufficient Data to Recommend a Dose	
> 600-700		375 mg			

†The manufacturer recommends dose adjustments for significant body weight changes during treatment.

Appendix F: Age 6 to < 12 Years: Asthma Dosing Based on Pre-treatment IgE and Body Weight†

Pre-treatment serum IgE IU/mL	Dosing Freq-uency	Body Weight									
		20-25 kg	> 25-30 kg	> 30-40 kg	> 40-50 kg	> 50-60 kg	> 60-70 kg	> 70-80 kg	>80-90 kg	>90-125 kg	>125-150 kg
≥ 30-100	Q 4 weeks	75	75	75	150	150	150	150	150	300	300
> 100-200		150	150	150	300	300	300	300	300	225	300
> 200-300		150	150	225	300	300	225	225	225	300	375
> 300-400		225	225	300	225	225	225	300	300		
> 400-500		225	300	225	225	300	300	375	375		
> 500-600		300	300	225	300	300	375				
> 600-700		300	225	225	300	375					
> 700-800	Q 2 weeks	225	225	300	375						
> 800-900		225	300	375							
> 900-1,000		225	300	375							
> 1,100-1,200		300	300								
> 1,200-1,300		300	375								

Insufficient Data to Recommend a Dose

†The manufacturer recommends dose adjustments for significant body weight changes during treatment.

Appendix G: Age ≥ 18 Years: Nasal Polyps Dosing Based on Pre-treatment IgE and Body Weight†

Pre-treatment serum IgE IU/mL	Dosing Frequency	Body Weight							
		> 30-40 kg	> 40-50 kg	> 50-60 kg	> 60-70 kg	> 70-80 kg	> 80-90 kg	> 90-125 kg	> 125-150 kg
≥ 30-100	Q 4 weeks	75	150	150	150	150	150	300	300
> 100-200		150	300	300	300	300	300	450	600
> 200-300		225	300	300	450	450	450	600	375
> 300-400		300	450	450	450	600	600	450	525
> 400-500		450	450	600	600	375	375	525	600
> 500-600		450	600	600	375	450	450	600	
> 600-700		450	600	375	450	450	525		

Pre-treatment serum IgE IU/mL	Dosing Frequency	Body Weight							
		> 30-40 kg	> 40-50 kg	> 50-60 kg	> 60-70 kg	> 70-80 kg	> 80-90 kg	> 90-125 kg	> 125-150 kg
> 700-800	Q 2 weeks	300	375	450	450	525	600		
> 800-900		300	375	450	525	600			
> 900-1,000		375	450	525	600				
> 1,000-1,100		375	450	600					
> 1,100-1,200		450	525	600					
> 1,200-1,300		450	525						
> 1,300- 1,500		525	600						

Insufficient Data to Recommend a Dose

†The manufacturer recommends dose adjustments for significant body weight changes during treatment.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CIU	150 or 300 mg SC every 4 weeks	300 mg/4 weeks
Asthma	75 to 375 mg SC every 2 or 4 weeks based on serum total IgE level (IU/mL) measured before the start of treatment, and body weight (kg) Xolair is not approved for use in patients weighing more than 150 kg (*see Appendix E and F*). Do not administer more than 150 mg (contents of one vial) per injection site. Divide doses of more than 150 mg amongst two or more injection sites.	375 mg/2 weeks
Nasal polyps	75 to 600 mg SC every 2 or 4 weeks based on serum total IgE level (IU/mL) measured before the start of treatment, and body weight (kg)	600 mg/2 weeks

VI. Product Availability

- Single-dose vial: 150 mg
- Single-dose prefilled syringes: 75 mg/0.5 mL, 150 mg/mL

VII. References

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13. ClinicalTrials.gov. A clinical trial of omalizumab in participants with chronic rhinosinusitis with nasal polyps (POLYP 2). Available at: https://clinicaltrials.gov/ct2/show/NCT03280537. Accessed January 4, 2021.
14. Carter MC, Maric I, Brittain EH, et al. A randomized double-blind, placebo-controlled study of omalizumab for idiopathic anaphylaxis. J Allergy Clin Immunol. 2021; 147(3): 1004-1010.e2.
15. Han JK, Bosson JV, Cho SH, et al. Multidisciplinary consensus on a stepwise treatment algorithm for management of chronic rhinosinusitis with nasal polyps. Int Forum Allergy Rhinol. 2021;1-10. Available at: https://onlinelibrary.wiley.com/doi/10.1002/alr.22851. Accessed June 16, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy converted to new template. All documentation requests removed; modified requirement for 3 months of adherent use to requirement for at least 2 exacerbations in the last 12 months despite adherent use of controller medication; changed "RAST" to "immunoassay." Changed requirement for nonsmoker and nonsmoking home to engaged in smoking cessation efforts if smoker. Added requirement for concomitant use of maintenance therapy in asthma. Added failure or contraindication to step therapy for CIU. Removed criteria regarding response to therapy and rescuer inhaler use from asthma renewal criteria; removed questions about adverse reaction to Xolair for continuation of therapy requirement for both asthma and CIU; added maximum allowed dose to asthma and CIU criteria; added "positive response" to CIU continuation criteria; added definition of positive response to asthma continuation criteria. Modified age restriction in asthma from ≥ 12 years to ≥ 6 years based on FDA labeling update.	08.16	09.16
Modified initial/continued approval durations from 3/6 months to 6/12 months. Asthma step therapy edited to require LABAs before LTRAs unless contraindicated or intolerant. Added positive response to therapy under continued approval. CIU: Examples of second-generation antihistamines added. Initial criteria: IgE level between 30-700 IU/mL is edited to read "between 30-1300 IU/mL" per PI.	06.17	08.17
Policy converted to new template. FEV1 < 80% is removed from the asthma criteria leaving a history of at least 2 exacerbations despite step 5 therapy as evidence of moderate to severe persistent asthma that is not well controlled. References updated.	07.17	08.17
1Q18 annual review: Removed smoking cessation program requirements as this cannot be enforced. Added "Acute bronchospasm or status asthmaticus" to section III as indications for which coverage is not authorized per PI. For CIU, modified length of trials from 4 to 2 weeks each.	11.08.17	02.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2019 annual review: modified ICS requirement to include medium dose ICS per GINA 2018 recommendations; added option for immunologist prescribing; references reviewed and updated.	10.11.18	02.19
1Q 2020 annual review: added requirement that Xolair is not prescribed concurrently with other biologic therapies for asthma; references reviewed and updated.	11.07.19	02.20
1Q 2021 annual review: criteria added for new FDA approved indication: nasal polyps; references reviewed and updated.	01.04.21	02.21
Updated Appendix D to include information about idiopathic anaphylaxis.	03.09.21	
For nasal polyps, specified that one of the trialed intranasal steroids must be Xhance and modified trial duration from 8 weeks to 4 weeks per 2021 consensus panel treatment algorithm.	06.16.21	08.21

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.