Xolair PA Criteria

1. Is the patient being treated for an OHP funded condition?
   a. If Yes, Go to question #2.
   b. If No, Review documentation for relevant comorbid conditions that are funded by OHP. If there are relevant comorbid conditions, move to question #2. If there are no relevant comorbid conditions, Cat. 1 denial.
   Cat 1: Not a covered benefit. Provider submitted diagnosis code is not for an OHP funded condition. No relevant comorbid conditions found in the provider submitted documentation.

2. Is the member diagnosed with severe asthma?
   a. If Yes, Go to question #3.
   b. If No, Cat 3 denial.
   Cat 3: Not a covered benefit. Xolair is only FDA approved for the treatment of asthma or chronic urticaria.

3. Is the prescriber a pulmonologist or an allergist who specializes in management of severe asthma?
   a. If Yes, Go to question #4.
   b. If No, forward to Medical Director for medical appropriateness evaluation (Cat 5).

4. Has the patient required at least 2 hospitalizations or ED visits in the past 12 months while receiving a maximally-dosed inhaled corticosteroid (Table 1) AND long-acting beta-agonist with at least 80% adherence to therapy?
   a. If Yes, Go to question #5 and document in MMC notes the number of hospitalizations or ED visits for asthma exacerbation in the past 12 months. This will be the baseline value to compare to in renewal criteria.
   b. If No, forward to Medical Director for medical appropriateness evaluation (Cat 5).

5. Has the patient been adherent to current asthma therapy (80% or greater) in the past 12 months?
   a. If Yes, Go to question #6.
   b. If No, forward to Medical Director for medical appropriateness evaluation (Cat 5).

6. Is the patient currently receiving another monoclonal antibody for asthma (e.g., omalizumab, mepolizumab or reslizumab)?
   a. If Yes, deny Cat 5 – medical appropriateness, medication is not indicated for use in combination with another monoclonal antibody.
   b. If No, Go to question #7.

7. Can the prescriber provide documentation of allergic IgE-mediated asthma diagnosis, confirmed by a positive skin test or in vitro reactivity to perennial allergan?
    a. If Yes, Go to question #8.
    b. If No, deny Cat 5 – medical appropriateness, dose and frequency of this medication is determined by serum total IgE level measured before the start of treatment, and body weight.

8. Is the dose appropriate for members Serum IgE level and body weight based upon chart at end of this criteria?
    a. If Yes, Approve once every 2-4 weeks for up to 12 months. Document test and result in MMC notes.
    b. If No, forward to Medical Director for medical appropriateness evaluation (Cat 5).

Renewal Criteria

1. Is the patient currently taking a maximally-dosed inhaled corticosteroid and 2 additional controller drugs (i.e., long-acting inhaled beta-agonist, montelukast, theophylline)?
    a. If Yes, Go to question #2.
    b. If No, forward to Medical Director for medical appropriateness evaluation (Cat 5).

2. Has the number of ED visits or hospitalizations in the last 12 months been reduced from baseline, or has the patient reduced their systemic corticosteroid dose by >/=50% compared to baseline?
    a. If Yes, approve for up to 12 months.
    b. If No, forward to Medical Director for medical appropriateness evaluation (Cat 5).

Maximum Adult Doses for Inhaled Corticosteroids

High Dose Corticosteroids:	Maximum Dose
Qvar (beclomethasone)	320 mcg BID
Pulmicort Flexhaler (budesonide)	720 mcg BID
Alvesco (ciclesonide)	320 mcg BID
Aerospan (flunisolide)	320 mcg BID
Arnuity Ellipta (fluticasone furoate)	200 mcg daily
Flovent HFA (fluticasone propionate)	880 mcg BID
Flovent Diskus (fluticasone propionate)	1000 mcg BID
Asmanex Twisthaler (mometasone)	440 mcg BID
Asmanex HFA (mometasone)	400 mcg BID
High Dose Corticosteroid/Long-acting Beta-agonists	Maximum Dose
Symbicort (budesonide/formoterol)	320/9 mcg BID
Advair Diskus (fluticasone/salmeterol)	500/50 mcg BID
Advair HFA (fluticasone/salmeterol)	460/42 mcg BID
Breo Ellipta (fluticasone/vilanterol)	200/25 mcg daily
Dulera (mometasone/formoterol)	400/10 mcg BID

Dosing Table Adults

Pretreatment serum IgE levels	Patient Weight	Dose
≥30 to 100 units/mL	30-90 kg	150 mg every 4 weeks
≥30 to 100 units/mL	>90 to 150 kg	300 mg every 4 weeks
>100 to 200 units/mL	30 to 90 kg	300 mg every 4 weeks
>100 to 200 units/mL	>90 to 150 kg	225 mg every 2 weeks
>200 to 300 units/mL	30 to 60 kg	300 mg every 4 weeks
>200 to 300 units/mL	>60 to 90 kg	225 mg every 2 weeks
>200 to 300 units/mL	>90 to 150 kg	300 mg every 2 weeks
>300 to 400 units/mL	30 to 70 kg	225 mg every 2 weeks
>300 to 400 units/mL	>70 to 90 kg	300 mg every 2 weeks
>300 to 400 units/mL	>90 kg	Do not administer dose
>400 to 500 units/mL	30 to 70 kg	300 mg every 2 weeks
>400 to 500 units/mL	>70 to 90 kg	375 mg every 2 weeks
>400 to 500 units/mL	>90 kg	Do not administer dose
>500 to 600 units/mL	30 to 60 kg	300 mg every 2 weeks
>500 to 600 units/mL	>60 to 70 kg	375 mg every 2 weeks
>500 to 600 units/mL	>70 kg	Do not administer dose
>600 to 700 units/mL	30 to 60 kg	375 mg every 2 weeks
>600 to 700 units/mL	>60 kg	Do not administer dose

Dosing Table Pediatrics (6 to 12 yo)

Pretreatment serum IgE levels	Patient Weight	Dose
≥30 to 100 units/mL	20 to 40 kg	75 mg every 4 weeks
≥30 to 100 units/mL	>40 to 90 kg	150 mg every 4 weeks
≥30 to 100 units/mL	>90 to 150 kg	300 mg every 4 weeks
>100 to 200 units/mL	20 to 40 kg	150 mg every 4 weeks
>100 to 200 units/mL	>40 to 90 kg	300 mg every 4 weeks
>100 to 200 units/mL	>90 to 125 kg	225 mg every 2 weeks
>100 to 200 units/mL	>125 to 150 kg	300 mg every 2 weeks
>200 to 300 units/mL	20 to 30 kg	150 mg every 4 weeks
>200 to 300 units/mL	>30 to 40 kg	225 mg every 4 weeks
>200 to 300 units/mL	>40 to 60 kg	300 mg every 4 weeks
>200 to 300 units/mL	>60 to 90 kg	225 mg every 2 weeks
>200 to 300 units/mL	>90 to 125 kg	300 mg every 2 weeks
>200 to 300 units/mL	>125 to 150 kg	375 mg every 2 weeks
>300 to 400 units/mL	20 to 30 kg	225 mg every 4 weeks
>300 to 400 units/mL	>30 to 40 kg	300 mg every 4 weeks
>300 to 400 units/mL	>40 to 70 kg	225 mg every 2 weeks
>300 to 400 units/mL	>70 to 90 kg	300 mg every 2 weeks
>300 to 400 units/mL	>90 kg	Do not administer dose
>400 to 500 units/mL	20 to 25 kg	225 mg every 4 weeks
>400 to 500 units/mL	>25 to 30 kg	300 mg every 4 weeks
>400 to 500 units/mL	>30 to 50 kg	225 mg every 2 weeks

Pretreatment serum IgE levels	Patient Weight	Dose
>400 to 500 units/mL	>50 to 70 kg	300 mg every 2 weeks
>400 to 500 units/mL	>70 to 90 kg	375 mg every 2 weeks
>400 to 500 units/mL	>90 kg	Do not administer dose
>500 to 600 units/mL	20 to 30 kg	300 mg every 4 weeks
>500 to 600 units/mL	>30 to 40 kg	225 mg every 2 weeks
>500 to 600 units/mL	>40 to 60 kg	300 mg every 2 weeks
>500 to 600 units/mL	>60 to 70 kg	375 mg every 2 weeks
>500 to 600 units/mL	>70 kg	Do not administer dose
>600 to 700 units/mL	20 to 25 kg	300 mg every 4 weeks
>600 to 700 units/mL	>25 to 40 kg	225mg every 2 weeks
>600 to 700 units/mL	>40 to 50 kg	300 mg every 2 weeks
>600 to 700 units/mL	>50 to 60 kg	375 mg every 2 weeks
>600 to 700 units/mL	>60 kg	Do not administer dose
>700 to 900 units/mL	20 to 30 kg	225 mg every 2 weeks
>700 to 900 units/mL	>30 to 40 kg	300 mg every 2 weeks
>700 to 900 units/mL	>40 to 50 kg	375 mg every 2 weeks
>700 to 900 units/mL	>50 kg	Do not administer dose
>900 to 1,100 units/mL	20 to 25 kg	225 mg every 2 weeks
>900 to 1,100 units/mL	>25 to 30 kg	300 mg every 2 weeks
>900 to 1,100 units/mL	>30 to 40 kg	375 mg every 2 weeks
>900 to 1,100 units/mL	>40 kg	Do not administer dose
>1,100 to 1,200 units/mL	20 to 25 kg	300 mg every 2 weeks
>1,100 to 1,200 units/mL	>30 kg	Do not administer
>1,200 to 1,300 units/mL	20 to 25 kg	300 mg every 2 weeks
>1,200 to 1,300 units/mL	>25 to 30 kg	375 mg every 2 weeks
>1,200 to 1,300 units/mL	>30 kg	Do not administer dose