



| Policy: | 201420 | Initial Effective Date: 07/30/2014 |
|----------|---|------------------------------------|
| Code(s): | HCPCS J2357 | Annual Review Date: 03/21/2024 |
| SUBJECT: | Xolair® (omalizumab injection for subcutaneous [SC] use – Genentech/Novartis) | Last Revised Date: 01/16/2025 |

⊠Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed annually, unless otherwise specified.

 Management of Immune Checkpoint Inhibitor-Related Toxicity: Coverage will be provided for 6 months and may NOT be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Xolair 75 mg single-dose prefilled syringe/autoinjector: 1 syringe/autoinjector every 14 days
- Xolair 150 mg single-dose prefilled syringe/autoinjector: 4 syringes/autoinjectors every 14 days
- Xolair 150 mg single-dose vial for injection: 4 vials every 14 days
- Xolair 300 mg single-dose prefilled syringe/autoinjector: 2 syringes/autoinjectors every 14 days

B. Max Units (per dose and over time) [HCPCS Unit]:

Allergic Asthma

• 75 billable units every 14 days

CRSwNP and IgE-Mediated Food Allergy

• 120 billable units every 14 days

All other indications

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• 60 billable units every 28 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

Patient is at least 18 years of age (unless otherwise specified); AND

Universal Criteria ¹

• Will not be used in combination with another anti-IL4, anti-IL5 or IgG2 lambda monoclonal antibody agents (e.g., benralizumab, mepolizumab, reslizumab, dupilumab, tezepelumab etc.); **AND**

Moderate to Severe Persistent Allergic Asthma † 1-3,20,25,29

- Patient is at least 6 years of age; AND
- Will not be used for treatment of acute bronchospasm, status asthmaticus, or allergic conditions (other than indicated); AND
- Patient has a positive skin test or in vitro reactivity to a perennial aero-allergen; AND
- Patient must weigh between 20 kg (44 lbs.) and 150 kg (330 lbs.); AND
- Patient has a serum total IgE level, measured before the start of treatment, of either [documentation required]:
 - \geq 30 IU/mL and \leq 700 IU/mL in patients age \geq 12 years; **OR**
 - \geq 30 IU/mL and \leq 1300 IU/mL in patients age 6 to \leq 12 years; **AND**
- Patient has documented ongoing symptoms of moderate-to-severe asthma* with a minimum (3) month trial on
 previous combination therapy including medium- or high-dose inhaled corticosteroids PLUS another controller
 medication (e.g., long-acting beta-2 agonist, leukotriene receptor antagonist, theophylline, etc.); AND
- Baseline measurement of at least one of the following for assessment of clinical status:
 - Use of systemic corticosteroids
 - Use of inhaled corticosteroids
 - o Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
 - o Forced expiratory volume in 1 second (FEV₁)

Chronic Idiopathic Urticaria/Chronic Spontaneous Urticaria (CIU/CSU) † 1,4-6,8,28

- Patient is at least 12 years of age; **AND**
- The underlying cause of the patient's condition is NOT considered to be any other allergic condition(s) or other form(s) of urticaria; **AND**

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- Patient is avoiding triggers (e.g., NSAIDs, etc.); AND
- Documented baseline score from an objective clinical evaluation tool, such as: urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AEQOL), urticaria control test (UCT), angioedema control test (AECT), or Chronic Urticaria Quality of Life Questionnaire (CU-Q2OL) [documentation required]; AND
- Patient had an inadequate response to a one or more-month trial on previous therapy with scheduled dosing of a second-generation H1-antihistamine product**; **AND**
- Patient had an inadequate response to a one or more-month trial on previous therapy with scheduled dosing of at least one of the following:
 - o Up-dosing/dose advancement (up to 4-fold) of a second generation H1-antihistamine**
 - o Add-on therapy with a leukotriene antagonist (e.g., montelukast, zafirlukast, etc.)
 - Add-on therapy with another H1-antihistamine**
 - o Add-on therapy with a H2-antagonist (e.g., ranitidine, famotidine, etc.)

<u>Note</u>: renewals will require a documented score from an objective clinical evaluation tool (e.g., UAS7, AAS, DLQI, AE-QoL, UCT, AECT, CU- Q_2 oL, etc.) recorded within the previous 6 months.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) † 1,22,23, 26-27

- Patient has bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 12 weeks; AND
- Patient has failed at least 4 weeks of daily intranasal corticosteroid therapy; AND
- Patient has at least three (3) of the following indicators for biologic treatment:
 - O Patient has evidence of type 2 inflammation (e.g., tissue eosinophils \geq 10/hpf, blood eosinophils \geq 150 cells/ μ L, or total IgE \geq 100 IU/mL)
 - o Patient has required ≥2 courses of systemic corticosteroids per year or >3 months of low dose corticosteroids, unless contraindicated
 - o Disease significantly impairs the patient's quality of life
 - Patient has experienced significant loss of smell
 - Patient has a comorbid diagnosis of asthma; AND
- Patient does not have any of the following:
 - Antrochoanal polyps
 - Nasal septal deviation that would occlude at least one nostril
 - o Disease with lack of signs of type 2 inflammation

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- Cystic fibrosis
- o Mucoceles; AND
- Other causes of nasal congestion/obstruction have been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis, etc.); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Therapy will be used in combination with intranasal corticosteroids unless not able to tolerate or use is contraindicated

IgE-Mediated Food Allergic Reactions (Type 1) 1,30

- Patient is at least 1 year of age; **AND**
- Patient is avoiding known food allergens; AND
- Patient is allergic to at least two foods (e.g., peanut, milk, egg, wheat, tree nuts, etc.); **AND**
- Patient's allergy must be confirmed by all of the following [documentation required]:
 - o Positive skin prick test (SPT), defined as wheal ≥4 mm larger than saline control; **AND**
 - Positive peanut and food specific IgE, defined as ≥6 IU/mL at screening or within three months of screening; AND
- Patient meets one of the following [documentation required]:
 - o Patient has a positive response oral food challenge defined as experiencing dose-limiting symptoms at a single dose of ≤100 mg of peanut protein or ≤300 mg of food protein; **OR**
 - According to the prescriber, the patient has a history of an allergic reaction to a food and the patient has demonstrated all the following:
 - Patient demonstrated signs and symptoms of a significant systemic allergic reaction and this
 reaction occurred within a short period of time following a known ingestion of the food. Note:
 Signs and symptoms of a significant systemic allergic reaction include hives, swelling, wheezing,
 hypotension, and gastrointestinal symptoms.; AND
 - The prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector; **AND**
- Will not be used for the emergency treatment of allergic reactions, including anaphylaxis

Management of Immune Checkpoint Inhibitor-Related Toxicity ‡ 9,10

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- Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, dostarlimab, tremelimumab, nivolumab/relatlimabrmbw, retifanlimab etc.);
- Patient has refractory and severe (i.e., grade 3: intense or widespread, constant, limiting self-care activities of daily living or sleep) pruritus; **AND**
- Patient has an increased serum IgE level above the upper limit of normal of the laboratory reference value

Systemic Mastocytosis ‡ 9,11

- Used for the prevention of one of the following:
 - Chronic mast cell mediator-related cardiovascular (e.g., pre-syncope, tachycardia, etc.) or pulmonary (e.g., wheezing, throat-swelling, etc.) symptoms insufficiently controlled by conventional therapy (e.g., H1 or H2 blockers or corticosteroids); OR
 - Unprovoked anaphylaxis; OR
 - Hymenoptera or food-induced anaphylaxis in patients with a negative test for specific IgE antibodies or a negative skin test; OR
- Used to improve tolerance while on immunotherapy (i.e., venom immunotherapy [VIT])

*Components of severity for classifying asthma as <u>moderate</u> may include any of the following (not all inclusive): ^{2,25}

- Daily symptoms
- Nighttime awakenings > 1x/week but not nightly
- SABA use for symptom control occurs daily
- Some limitation to normal activities
- Lung function (percent predicted FEV₁) >60%, but <80%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to mild asthma

*Components of severity for classifying asthma as <u>severe</u> may include any of the following (not all inclusive): ^{2,25}

- Symptoms throughout the day
- Nighttime awakenings, often 7x/week
- SABA use for symptom control occurs several times daily
- Extremely limited in normal activities
- Lung function (percent predicted FEV₁) <60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

**H1 Antihistamine Products (not all inclusive) 5,8

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| First Generation H1 | Second Generation H1 |
|---|---|
| bromphineramine carbinoxamine clorpheniramine clemastine cyproheptadine dexchlorpheniramine diphenhydramine doxepin hydroxyzine triprolidine | cetirizine desloratadine fexofenadine levocetirizine loratadine |

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria ¹

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III;
 AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of
 anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema), malignancy, symptoms similar
 to serum sickness (fever, arthralgia, and rash), parasitic (helminth) infection, eosinophilic conditions (e.g.,
 vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy, especially upon
 reduction of oral corticosteroids), etc.; AND

Moderate to Severe Persistent Allergic Asthma 1-3,20,25

- Patient must weigh between 20 kg (44 lbs.) and 150 kg (330 lbs.); AND
- Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
 - Use of systemic corticosteroids
 - Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
 - Hospitalizations
 - ER visits
 - Unscheduled visits to healthcare provider; **OR**
- Improvement from baseline in forced expiratory volume in 1 second (FEV₁)

Chronic Idiopathic Urticaria/Chronic Spontaneous Urticaria (CIU/CSU) 1,4-6,8,28

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- Provider attests that the patient has been reassessed and continued therapy is necessary for the maintenance treatment of this condition; AND
- Treatment has resulted in clinical improvement as documented by improvement from baseline using objective clinical evaluation tools such as the urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), urticaria control test (UCT), angioedema control test (AECT), or Chronic Urticaria Quality of Life Questionnaire(CU-Q₂oL); **AND**
- Provider has current UAS7, AAS, DLQI, AE-QoL, UCT, AECT, or Cu-Q20L recorded within the past 6 months

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) 1,22,23, 26-27

- Disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool (e.g., nasal polyposis score (NPS), nasal congestion (NC) symptom severity score, sino-nasal outcome test-22 (SNOT-22), etc.); **OR**
- Patient had an improvement in at least one (1) of the following response criteria:
 - Reduction in nasal polyp size
 - Reduction in need for systemic corticosteroids
 - Improvement in quality of life
 - Improvement in sense of smell
 - Reduction of impact of comorbidities

IgE-Mediated Food Allergic Reactions (Type 1) 1,30

- Provider attests that the patient has been reassessed and continued therapy is necessary for the maintenance treatment of this condition; AND
- Patient has had a reduction in allergic reaction, including anaphylaxis, and/or symptoms (e.g., moderate to severe skin, respiratory or gastrointestinal symptoms) associated with accidental exposure of known food allergens

Management of Immune Checkpoint Inhibitor-Related Toxicity 9,10

May not be renewed

Systemic Mastocytosis 9,11

 Disease response as indicated by improvement in signs and symptoms compared to baseline or a decreased frequency of exacerbations

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V. Dosage/Administration 1,11-13

| Indication | Dose |
|--|---|
| Allergic Asthma | 75 to 375 mg administered subcutaneously by a health care provider§§ every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See tables below. |
| Chronic Idiopathic Urticaria/Chronic Spontaneous Urticaria | 150 or 300 mg administered subcutaneously by a health care provider§§ every 4 weeks. Dosing is not dependent on serum IgE (free or total) level or body weight. |
| Chronic Rhinosinusitis with Nasal Polyps | 75 to 600 mg administered subcutaneously by a health care provider§§ every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See table below. |
| IgE-Mediated Food Allergy | 75 to 600 mg administered subcutaneously by a health care provider§§ every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See table below. |
| Management of Immune Checkpoint Inhibitor- Related Toxicity & Systemic Mastocytosis | 150 or 300 mg administered subcutaneously every 4 weeks. Dosing is not dependent on serum IgE (free or total) level or body weight. **Must ONLY be administered by a health care provider. |

§§ Criteria for Selection of Patients for Self-Administration of Xolair Prefilled Syringe or Autoinjector

The pre-filled syringe or autoinjector formulation may be self-administered after the initial 3 doses are administered in the healthcare setting AND the healthcare provider determines that self-administration is appropriate based on assessment of risk for anaphylaxis and mitigation strategies criteria below:

- Asthma, CRSwNP and CIU/CSU: Patient should have no prior history of anaphylaxis to Xolair or other agents, such as foods, drugs, biologics, etc.
- **IgE-Mediated Food Allergy:** Patient should have no prior history of anaphylaxis to Xolair or other agents (except foods), such as drugs, biologics, etc.
- Patient should receive at least 3 doses of Xolair under the guidance of a healthcare provider with no hypersensitivity reactions; **AND**
- Patient or caregiver is able to recognize symptoms of anaphylaxis; AND
- Patient or caregiver is able to treat anaphylaxis appropriately; AND
- Patient or caregiver is able to perform subcutaneous injections with Xolair prefilled syringe or autoinjector with proper technique according to the prescribed dosing regimen and Instructions for Use

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Note: Xolair prefilled syringes for patients under 12 years of age should be administered by a caregiver. Xolair autoinjectors (all doses) are not intended for use in pediatric patients under 12 years of age.

| Asthma Omalizumab Doses Administered Every 4 Weeks (mg) in patients ≥ 12 years | | | | | | | | | |
|--|------------------|--------------------------|--------------------------|--------------------------|--|--|--|--|--|
| Pre-treatment serum IgE | Body weight (kg) | | | | | | | | |
| (IU/mL) | 30 to 60 | > 60 to 70 | > 70 to 90 | > 90 to 150 | | | | | |
| ≥ 30 to 100 | 150 | 150 | 150 | 300 | | | | | |
| > 100 to 200 | 300 | 300 | 300 | See the following table. | | | | | |
| > 200 to 300 | 300 | See the following table. | See the following table. | See the following table. | | | | | |

| Asthma Omalizumab Doses Administered Every 2 Weeks (mg) in patients ≥ 12 years | | | | | | | | | |
|--|---------------------|---------------------|---------------------|--------------|--|--|--|--|--|
| Pre-treatment serum IgE | Body weight (kg) | | | | | | | | |
| (IU/mL) | 30 to 60 | > 60 to 70 | > 70 to 90 | > 90 to 150 | | | | | |
| > 100 to 200 | See previous table. | See previous table. | See previous table. | 225 | | | | | |
| > 200 to 300 | See previous table. | 225 | 225 | 300 | | | | | |
| > 300 to 400 | 225 | 225 | 300 | Do not dose. | | | | | |
| > 400 to 500 | 300 | 300 | 375 | Do not dose. | | | | | |
| > 500 to 600 | 300 | 375 | Do not dose. | Do not dose. | | | | | |
| > 600 to 700 | 375 | Do not dose. | Do not dose. | Do not dose | | | | | |

| Asthma Oma | alizumab Doses A | Administered Every 2 or 4 Weeks (mg) for Pediatric Patients Who Begin | | | | | |
|--------------|---|---|--|--|--|--|--|
| Xolair Betwo | Xolair Between the Ages of 6 to <12 Years | | | | | | |
| | | Body Weight (kg) | | | | | |
| | | | | | | | |

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| Dosing | 20-25 | >25- | >30- | >40- | >50- | >60- | >70- | >80- | >90- | >125- |
|---------|---------------|---|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---|
| Freq. | | 30 | 40 | 50 | 60 | 70 | 80 | 90 | 125 | 150 |
| (weeks) | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | 75 | 75 | 75 | 150 | 150 | 150 | 150 | 150 | 300 | 300 |
| | 150 | 150 | 150 | 300 | 300 | 300 | 300 | 300 | 225 | 300 |
| | 150 | 150 | 225 | 300 | 300 | 225 | 225 | 225 | 300 | 375 |
| 4 | 225 | 225 | 300 | 225 | 225 | 225 | 300 | 300 | | |
| | 225 | 300 | 225 | 225 | 300 | 300 | 375 | 375 | | |
| | 300 | 300 | 225 | 300 | 300 | 375 | | | | |
| | 300 | 225 | 225 | 300 | 375 | | | | | |
| | 225 | 225 | 300 | 375 | | | | | | |
| | 225 | 300 | 375 | | | | | | | |
| | | | | | | | | _ | | |
| 2 | 300 | 300 | | | | | Do Not | Dose | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | 300 | 375 | | | | | | | | |
| | | | | | | | | | | |
| | Freq. (weeks) | Freq. (weeks) 75 150 150 225 225 300 300 225 225 | Freq. (weeks) 75 | Freq. (weeks) 75 | Freq. (weeks) 75 | Freq. (weeks) 75 | Freq. (weeks) 30 | Freq. (weeks) 30 | Freq. (weeks) 30 | Freq. (weeks) 30 40 50 60 70 80 90 125 4 75 75 75 150 150 150 150 300 150 150 150 300 300 300 300 300 300 225 150 150 225 300 300 225 225 225 300 300 300 300 300 300 300 300 300 300 300 375 375 375 375 375 375 375 300 300 375 375 375 300 300 375 300 300 375 300 300 375 300 |

| Nasal Polyps | Omalizum | ab Doses | Administe | red Every | 2 or 4 W | Veeks (mg) | | | | | |
|-----------------------------------|---------------|------------------|-----------|-----------|------------|------------|--------|----------|----------|--|--|
| Pre- | Dosing | Body Weight (kg) | | | | | | | | | |
| treatment serum IgE (IU/mL) | Freq. (weeks) | >30-40 | >40-50 | >50-60 | >60- 70 | >70-80 | >80-90 | >90-125 | >125-150 | | |
| 30-100 | | 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 | 4 | 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 | | | | |
| >700-800 | | 300 | 375 | 450 | 450 | 525 | 600 | | | | |
| >800-900 | | 300 | 375 | 450 | 525 | 600 | | | | | |
| >900-1000 | 2 | 375 | 450 | 525 | 600 | | Do l | Not Dose | | | |
| >1000-1100 | | 375 | 450 | 600 | | | | | | | |
| >1100-1200 | | 450 | 525 | 600 | | | | | | | |
| >1200-1300 | | 450 | 525 | | | | | | | | |

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| IgE-Media | | Allergy | Omali | izumab | Doses | Admir | | | | Weeks | s (mg) | | | |
|----------------|---------|---------|-------|--------|-------|-------|------|-------|---------|-------|--------|---------|------|-------|
| Pre- | Dosing | | | | | | Body | Weigl | ht (kg) | | | | | |
| treatment | Freq. | ≥10- | >12- | >15- | >20- | >25- | >30- | >40- | >50- | >60- | >70- | >80- | >90- | >125- |
| serum IgE | (weeks) | 12 | 15 | 20 | 25 | 30 | 40 | 50 | 60 | 70 | 80 | 90 | 125 | 150 |
| (IU/mL) | | | | | | | | | | | | | | |
| ≥30-100 | | 75 | 75 | 75 | 75 | 75 | 75 | 150 | 150 | 150 | 150 | 150 | 300 | 300 |
| >100-200 | | 75 | 75 | 75 | 150 | 150 | 150 | 300 | 300 | 300 | 300 | 300 | 450 | 600 |
| >200-300 | | 75 | 75 | 150 | 150 | 150 | 225 | 300 | 300 | 450 | 450 | 450 | 600 | 375 |
| >300-400 | 4 | 150 | 150 | 150 | 225 | 225 | 300 | 450 | 450 | 450 | 600 | 600 | 450 | 525 |
| >400-500 | | 150 | 150 | 225 | 225 | 300 | 450 | 450 | 600 | 600 | 375 | 375 | 525 | 600 |
| >500-600 | | 150 | 150 | 225 | 300 | 300 | 450 | 600 | 600 | 375 | 450 | 450 | 600 | |
| >600-700 | | 150 | 150 | 225 | 300 | 225 | 450 | 600 | 375 | 450 | 450 | 525 | | |
| >700-800 | | 150 | 150 | 150 | 225 | 225 | 300 | 375 | 450 | 450 | 525 | 600 | | |
| >800-900 | | 150 | 150 | 150 | 225 | 225 | 300 | 375 | 450 | 525 | 600 | | | |
| >900- 1000 | | 150 | 150 | 225 | 225 | 300 | 375 | 450 | 525 | 600 | | | | |
| >1000- 1100 | | 150 | 150 | 225 | 225 | 300 | 375 | 450 | 600 | | | | | |
| >1100- 1200 | 2 | 150 | 150 | 225 | 300 | 300 | 450 | 525 | 600 | | De | o Not D | Oose | |
| >1200- 1300 | | 150 | 225 | 225 | 300 | 375 | 450 | 525 | | | | | | |
| >1300- 1500 | | 150 | 225 | 300 | 300 | 375 | 525 | 600 | | | | | | |
| >1500- 1850 | | | 225 | 300 | 375 | 450 | 600 | | | | | | | |

VI. Billing Code/Availability Information

HCPCS Code:

• J2357 – Injection, omalizumab, 5 mg; 1 billable unit = 5 mg

NDC:

- Xolair 75 mg single-dose prefilled syringe or autoinjector: 50242-0214-xx
- Xolair 150 mg single-dose prefilled syringe or autoinjector: 50242-0215-xx
- Xolair 150 mg single-dose vial powder for injection: 50242-0040-xx
- Xolair 300 mg single-dose prefilled syringe or autoinjector: 50242-0227-xx

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VII. References

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Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description | | | | | |
|---------|--|--|--|--|--|--|
| C94.30 | Mast cell leukemia not having achieved remission | | | | | |
| C94.31 | Mast cell leukemia, in remission | | | | | |
| C94.32 | Mast cell leukemia, in relapse | | | | | |
| C96.20 | Malignant mast cell neoplasm, unspecified | | | | | |
| C96.21 | Aggressive systemic mastocytosis | | | | | |
| C96.22 | Mast cell sarcoma | | | | | |
| C96.29 | Other malignant mast cell neoplasm | | | | | |
| D47.02 | Systemic mastocytosis | | | | | |
| J33.0 | Polyp of nasal cavity | | | | | |
| J33.1 | Polypoid sinus degeneration | | | | | |
| J33.8 | Other polyp of sinus | | | | | |
| J33.9 | Nasal polyp, unspecified | | | | | |
| J45.40 | Moderate persistent asthma, uncomplicated | | | | | |
| J45.50 | Severe persistent asthma, uncomplicated | | | | | |
| L29.8 | Other pruritus | | | | | |
| L29.9 | Pruritus, unspecified | | | | | |
| L50.1 | Idiopathic urticaria | | | | | |
| Z91.010 | Allergy to peanuts | | | | | |
| Z91.011 | Allergy to milk products | | | | | |
| Z91.012 | Allergy to eggs | | | | | |
| Z91.013 | Allergy to seafood | | | | | |
| Z91.018 | Allergy to other foods | | | | | |

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Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

| Jurisdictio | NCD/LCA/LCD | Contractor |
|-------------|--------------|-----------------------------------|
| n | Document (s) | |
| 6, K | A52448 | National Government Services, Inc |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|--|
| Jurisdictio | Applicable State/US Territory | Contractor |
| n | | |
| E(1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp. (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp. (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA, LLC |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |

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| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | | |
|---|--|--|--|
| Jurisdictio | Applicable State/US Territory | Contractor | |
| n | | | |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & | Novitas Solutions, Inc. | |
| | Fairfax counties and the city of Alexandria in | | |
| | VA) | | |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) | |
| 15 | KY, OH | CGS Administrators, LLC | |

Edits and Denials:

Prior approval: Prior approval is required for Xolair (**HCPCS Code J2357**). Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician consultant for review if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Code J2357** will edit with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary. A provider may bill a member for charges denied as investigational.

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