# Omalizumab
# Omlyclo®; Xolair®
## (Subcutaneous)

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## I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months (365 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

## II. Dosing Limits

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

- **Moderate to Severe Persistent Asthma:** 75 billable units every 14 days
- **CRSwNP and IgE-Mediated Food Allergy:** 120 billable units every 14 days
- **Chronic Spontaneous Urticaria:** 60 billable units every 28 days

## III. Initial Approval Criteria

**Target Agent(s)** will be approved when ALL of the following are met:

1. ONE of the following
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

| Agents Eligible for Continuation of Therapy |
|---|
| All target agents are eligible for continuation of therapy |

      1. The member has been treated with the requested agent (starting on samples is not approvable); **OR**
      2. The prescriber states the member has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed; **OR**
   B. BOTH of the following:
      1. ONE of the following:
         A. The member has a diagnosis of moderate to severe persistent asthma AND ALL of the following:

1. If the member is 6 to less than 12 years of age, then BOTH of the following:
    A. The member's pretreatment IgE level is 30 IU/mL to 1300 IU/mL; **AND**
    B. The member's weight is 20 kg to 150 kg; **AND**
2. If the member is 12 years of age or over, then BOTH of the following:
    A. The member's pretreatment IgE level is 30 IU/mL to 700 IU/mL; **AND**
    B. The member's weight is 30 kg to 150 kg; **AND**
3. Allergic asthma has been confirmed by a positive skin test or in vitro reactivity test to a perennial aeroallergen; **AND**
4. ONE of the following:
    A. The member has a history of uncontrolled asthma while on asthma control therapy (e.g., inhaled corticosteroid [ICS]/long-acting beta-2 agonist [LABA] combination therapy) as demonstrated by ONE of the following:
        1. Two or more severe asthma exacerbations (i.e., required treatment with a systemic corticosteroid [steroid burst]) within the past 12 months; **OR**
        2. One or more serious asthma exacerbation(s) (i.e., required hospitalization, mechanical ventilation, or visit to the emergency room or urgent care) within the past 12 months; **OR**
        3. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered; **OR**
        4. Baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted; **OR**
    B. The member's medication history (excluding sample use) indicates use of a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma within the past 12 months; **OR**

B. The member has a diagnosis of chronic spontaneous urticaria (CSU) AND ALL of the following:
1. The member has had hives and itching for more than 6 weeks; **AND**
2. The prescriber has evaluated the member to determine if the member is currently treated with medications known to cause or

worsen urticaria (e.g., NSAIDs) in order to reduce urticaria risk; **AND**

3. The member has ONE of the following:
    A. Tried and had an inadequate response to the FDA labeled maximum dose of ONE second-generation H1-antihistamine (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine,) AND ONE of the following:
        1. The member has tried and had an inadequate response to a maximally tolerated dose of ONE second-generation H1-antihistamine titrated to up to 4 times above the FDA labeled maximum dose after at least a 2-week duration of therapy; **OR**
        2. There is support that the member cannot be treated with a second-generation H1-antihistamine at a dose above the FDA labeled maximum dose; **OR**
    B. An intolerance or hypersensitivity to ONE second-generation H1-antihistamine; **OR**
    C. An FDA labeled contraindication to ALL second-generation H1-antihistamines; **OR**

C. The member has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND ALL of the following:
1. BOTH of the following:
    A. The member's pretreatment IgE level is 30 IU/mL to 1500 IU/mL; **AND**
    B. The member's weight is 30 kg to 150 kg; **AND**
2. The member has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS):
    A. Nasal discharge (rhinorrhea or post-nasal drainage)
    B. Nasal obstruction or congestion
    C. Loss or decreased sense of smell (hyposmia)
    D. Facial pressure or pain; **AND**
3. The member has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks; **AND**
4. The member's diagnosis was confirmed by ONE of the following:
    A. Anterior rhinoscopy; **OR**
    B. Nasal endoscopy; **OR**
    C. Computed tomography (CT) of the sinuses; **AND**
5. The member has ONE of the following:

A. Tried and had an inadequate response to ONE intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva) after at least a 4-week duration of therapy; **OR**

B. An intolerance or hypersensitivity to ONE intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva); **OR**

C. An FDA labeled contraindication to ALL intranasal corticosteroids; **OR**

D. The member has a diagnosis of IgE-mediated food allergy AND ALL of the following:

1. BOTH of the following:

A. The member's pretreatment IgE level is 30 IU/mL to 1850 IU/mL; **AND**

B. The member's weight is 10 kg to 150 kg; **AND**

2. The member has an IgE-mediated food allergy confirmed by an allergy diagnostic test (e.g., skin prick test, serum specific IgE test, oral food challenge); **AND**

3. The requested agent will NOT be used for the emergency treatment of allergic reactions, including anaphylaxis; **OR**

E. The member has another FDA labeled indication for the requested agent and route of administration; **AND**

2. If the member has an FDA labeled indication, then ONE of the following:

A. The member's age is within FDA labeling for the requested indication for the requested agent; **OR**

B. There is support for using the requested agent for the member's age for the requested indication; **OR**

C. The member has an indication that is supported in compendia for the requested agent and route of administration; **AND**

2. If the member has a diagnosis of moderate to severe persistent asthma, then ALL of the following:

A. ONE of the following:

1. The member is NOT currently treated with a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma (including the requested agent) AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months AND has been adherent for 90 days within the past 120 days; **OR**

2. The member is currently treated with a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma (including the requested agent) AND ONE of the following:
    A. The member is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms AND has been adherent for 90 days within the past 120 days; **OR**
    B. The member is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months AND has been adherent for 90 days within the past 120 days; **OR**
3. The member has an intolerance or hypersensitivity to ONE inhaled corticosteroid; **OR**
4. The member has an FDA labeled contraindication to ALL inhaled corticosteroids; **AND**

B. ONE of the following:
1. The member is currently treated for at least 3 months AND has been adherent for 90 days within the past 120 days with ONE of the following:
    A. A long-acting beta-2 agonist (LABA); **OR**
    B. A long-acting muscarinic antagonist (LAMA); **OR**
    C. A leukotriene receptor antagonist (LTRA); **OR**
    D. Theophylline; **OR**
2. The member has an intolerance or hypersensitivity to ONE long-acting beta-2 agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist (LTRA), or theophylline; **OR**
3. The member has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA); **AND**

C. The member will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND**

3. If the member has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP), then ALL of the following:
    A. The member is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva]); **AND**
    B. The member will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva]) in combination with the requested agent; **AND**
4. If the member has a diagnosis of chronic spontaneous urticaria (CSU) , then BOTH of the following:
    A. ONE of the following:
        1. BOTH of the following:

A. The member is currently treated with second-generation H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine); **AND**

B. The member will continue second-generation H1-antihistamine therapy in combination with the requested agent; **OR**

2. The member has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL second-generation H1-antihistamines; **AND**

5. If the member has a diagnosis of IgE-mediated food allergy, then ALL of the following:
   A. The member will avoid known food allergens while treated with the requested agent; **AND**
   B. The member has epinephrine on hand for emergency treatment; **AND**
6. The prescriber is a specialist in the area of the member's diagnosis (e.g., asthma: allergist, immunologist, pulmonologist; CRSwNP: otolaryngologist, allergist, immunologist, pulmonologist; CSU: allergist, dermatologist, immunologist; IgE-mediated food allergy: allergist, immunologist), or the prescriber has consulted with a specialist in the area of the member's diagnosis; **AND**
7. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
   A. The member will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors); **OR**
   B. The member will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
      1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent; **AND**
      2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required); **AND**
8. The member does NOT have any FDA labeled contraindications to the requested agent

**Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

## IV. Renewal Criteria

**Target Agent(s)** will be approved when ALL of the following are met:

1. The member has been previously approved for the requested agent through the plan's Prior Authorization process (Note: members not previously approved for the requested agent will require initial evaluation review); **AND**
2. ONE of the following:
   A. The member has a diagnosis of moderate to severe persistent asthma AND ALL of the following:
      1. The member has had clinical benefit with the requested agent; **AND**

2. The member is currently treated within the past 90 days and is compliant with asthma control therapy (e.g., inhaled corticosteroids [ICS], ICS/long-acting beta-2 agonist [ICS/LABA], leukotriene receptor antagonist [LTRA], long-acting muscarinic antagonist [LAMA], theophylline); **OR**

B. The member has a diagnosis of chronic spontaneous urticaria (CSU) AND ALL of the following:
   1. The member has had clinical benefit with the requested agent; **AND**
   2. ONE of the following:
      A. The member will continue second-generation H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) in combination with the requested agent; **OR**
      B. The member has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL second-generation H1-antihistamines; **OR**

C. The member has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND ALL of the following:
   1. The member has had clinical benefit with the requested agent; **AND**
   2. The member will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva]) in combination with the requested agent; **OR**

D. The member has a diagnosis of IgE-mediated food allergy AND ALL of the following:
   1. The member will avoid known food allergens while treated with the requested agent; **AND**
   2. The member has epinephrine on hand for emergency treatment; **OR**

E. The member has a diagnosis other than moderate to severe persistent asthma, CSU, CRSwNP, or IgE-mediated food allergy; **AND**
   1. The member has had clinical benefit with the requested agent; **AND**

3. The prescriber is a specialist in the area of the member's diagnosis (e.g., asthma: allergist, immunologist, pulmonologist; CRSwNP: otolaryngologist, allergist, immunologist, pulmonologist; CSU: allergist, dermatologist, immunologist; IgE-mediated food allergy: allergist, immunologist), or the prescriber has consulted with a specialist in the area of the member's diagnosis; **AND**
4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
   A. The member will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors); **OR**
   B. The member will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
      1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent; **AND**
      2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required); **AND**

5. The member does NOT have any FDA labeled contraindications to the requested agent

**Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

| **Contraindicated as Concomitant Therapy** |
|---|
| **Agents NOT to be used Concomitantly**<br><br>Abrilada (adalimumab-afzb)<br>Actemra (tocilizumab)<br>Adalimumab<br>Adbry (tralokinumab-ldrm)<br>Amjevita (adalimumab-atto)<br>Anzupgo (delgocitinib)<br>Arcalyst (rilonacept)<br>Avsola (infliximab-axxq)<br>Avtozma (tocilizumab-anoh)<br>Benlysta (belimumab)<br>Bimzelx (bimekizumab-bkzx)<br>Cibinqo (abrocitinib)<br>Cimzia (certolizumab)<br>Cinqair (reslizumab)<br>Cosentyx (secukinumab)<br>Cyltezo (adalimumab-adbm)<br>Dupixent (dupilumab)<br>Ebglyss (lebrikizumab-lbkz)<br>Enbrel (etanercept)<br>Entyvio (vedolizumab)<br>Exdensur (depemokimab-ulaa)<br>Fasenra (benralizumab)<br>Hadlima (adalimumab-bwwd)<br>Hulio (adalimumab-fkjp)<br>Humira (adalimumab)<br>Hyrimoz (adalimumab-adaz)<br>Icotyde (icotrokinra)<br>Idacio (adalimumab-aacf)<br>Ilaris (canakinumab)<br>Ilumya (tildrakizumab-asmn)<br>Imuldosa (ustekinumab-srlf)<br>Inflectra (infliximab-dyyb)<br>Infliximab<br>Kevzara (sarilumab)<br>Kineret (anakinra)<br>Leqselvi (deuruxolitinib)<br>Litfulo (ritlecitinib)<br>Nemluvio (nemolizumab-ilto) |

| Contraindicated as Concomitant Therapy |
| --- |
| Nucala (mepolizumab) |
| Olumiant (baricitinib) |
| Omlyclo (omalizumab-igec) |
| Omvoh (mirikizumab-mrkz) |
| Opzelura (ruxolitinib) |
| Orencia (abatacept) |
| Otezla (apremilast) |
| Otezla XR (apremilast extended-release) |
| Otulfi (ustekinumab-aauz) |
| Pyzchiva (ustekinumab-ttwe) |
| Remicade (infliximab) |
| Renflexis (infliximab-abda) |
| Rhapsido (remibrutinib) |
| Riabni (rituximab-arrx) |
| Rinvoq (upadacitinib) |
| Rituxan (rituximab) |
| Rituxan Hycela (rituximab/hyaluronidase human) |
| Ruxience (rituximab-pvvr) |
| Saphnelo (anifrolumab-fnia) |
| Selarsdi (ustekinumab-aekn) |
| Siliq (brodalumab) |
| Simlandi (adalimumab-ryvk) |
| Simponi (golimumab) |
| Simponi ARIA (golimumab) |
| Skyrizi (risankizumab-rzaa) |
| Sotyktu (deucravacitinib) |
| Spevigo (spesolimab-sbzo) subcutaneous injection |
| Starjemza (ustekinumab-hmny) |
| Stelara (ustekinumab) |
| Steqeyma (ustekinumab-stba) |
| Taltz (ixekizumab) |
| Tezspire (tezepelumab-ekko) |
| Tofacitinib |
| Tofidence (tocilizumab-bavi) |
| Tremfya (guselkumab) |
| Truxima (rituximab-abbs) |
| Tyenne (tocilizumab-aazg) |
| Tyruko (natalizumab-sztn) |
| Tysabri (natalizumab) |
| Ustekinumab |
| Velsipity (etrasimod) |
| Wezlana (ustekinumab-auub) |
| Xeljanz (tofacitinib) |

| Contraindicated as Concomitant Therapy |
|---|
| Xeljanz XR (tofacitinib extended release)<br>Xolair (omalizumab)<br>Yesintek (ustekinumab-kfce)<br>Yuflyma (adalimumab-aaty)<br>Yusimry (adalimumab-aqvh)<br>Zeposia (ozanimod)<br>Zymfentra (infliximab-dyyb) |

## V. Dosage/Administration

| Indication | Dose |
|---|---|
| Moderate to Severe Persistent Asthma | 75 to 375 mg administered subcutaneously 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 Spontaneous Urticaria | 150 or 300 mg administered subcutaneously 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 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 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. |

| Asthma Omalizumab Doses Administered Every 4 Weeks (mg) in members ≥ 12 years | | | | |
|---|---|---|---|---|
| **Pre-treatment serum IgE (IU/mL)** | **Body weight (kg)** | | | |
| | **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 members ≥ 12 years | | | | |
|---|---|---|---|---|
| **Pre-treatment serum IgE (IU/mL)** | **Body weight (kg)** | | | |
| | **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 | |
| > 400 to 500 | 300 | 300 | 375 | |
| > 500 to 600 | 300 | 375 | | |
| > 600 to 700 | 375 | Do Not Dose | | |

**Asthma Omalizumab Doses Administered Every 2 or 4 Weeks (mg) for Pediatric Members Who Begin Omalizumab Between the Ages of 6 to <12 Years**

| Pre-treatment serum IgE (IU/mL) | Dosing Freq. (weeks) | Body Weight (kg) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 20-25 | >25-30 | >30-40 | >40-50 | >50-60 | >60-70 | >70-80 | >80-90 | >90-125 | >125-150 |
| 30-100 | 4 | 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 | | | | | |
| >700-900 | 2 | 225 | 225 | 300 | 375 | | | | | | |
| >900-1100 | | 225 | 300 | 375 | | | Do Not Dose | | | | |
| >1100-1200 | | 300 | 300 | | | | | | | | |
| >1200-1300 | | 300 | 375 | | | | | | | | |

**CRSwNP Omalizumab Doses Administered Every 2 or 4 Weeks (mg)**

| Pre-treatment serum IgE (IU/mL) | Dosing Freq. (weeks) | Body Weight (kg) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | >30-40 | >40-50 | >50-60 | >60-70 | >70-80 | >80-90 | >90-125 | >125-150 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 30-100 | 4 | 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 | | |
| >700-800 | 2 | 300 | 375 | 450 | 450 | 525 | 600 | | |
| >800-900 | | 300 | 375 | 450 | 525 | 600 | | | |
| >900-1000 | | 375 | 450 | 525 | 600 | Do Not Dose | | | |
| >1000-1100 | | 375 | 450 | 600 | | | | | |
| >1100-1200 | | 450 | 525 | 600 | | | | | |
| >1200-1300 | | 450 | 525 | | | | | | |
| >1300-1500 | | 525 | 600 | | | | | | |

| IgE-Mediated Food Allergy Omalizumab Doses Administered Every 2 or 4 Weeks (mg) | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Pre-treatment serum IgE (IU/mL)** | **Dosing Freq. (weeks)** | **Body Weight (kg)** | | | | | | | | | | | | |
| | | **≥10-12** | **>12-15** | **>15-20** | **>20-25** | **>25-30** | **>30-40** | **>40-50** | **>50-60** | **>60-70** | **>70-80** | **>80-90** | **>90-125** | **>125-150** |
| ≥30-100 | 4 | 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 | | 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 | 2 | 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 | | 150 | 150 | 225 | 300 | 300 | 450 | 525 | 600 | | | |
| >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 | | | | | |

Do Not Dose

## VI. Billing Code/Availability Information

HCPCS Code(s):

- J2357 – Injection, omalizumab, 5 mg; 1 billable unit = 5 mg (*Xolair Only*)
- Q5154 – Injection, omalizumab-igec (omlyclo), biosimilar, 5mg (*Omlyclo Only*)

NDC(s):

- 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
- Omlyclo 75 mg single-dose prefilled syringe: 72606-0035-xx
- Omlyclo 150 mg single-dose prefilled syringe: 72606-0036-xx
- Omlyclo 300 mg single-dose prefilled syringe: 72606-0054-xx

## VII. References


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## Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

| Factor | Conclusion |
|---|---|
| Indication | Yes: Consider for PA |
| Safety and efficacy | Yes: Consider for PA |
| Potential for misuse/abuse | No: PA not a priority |
| Cost of drug | Yes: Consider for PA |

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|---|---|
| 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 |
| L29.89 | Other pruritus |
| L29.9 | Pruritus, unspecified |
| L50.0 | Allergic urticaria |
| L50.1 | Idiopathic urticaria |
| L50.8 | Other (chronic, recurrent) urticaria |
| L50.9 | Urticaria, unspecified |
| Z91.010 | Allergy to peanuts |
| Z91.0110 | Allergy to milk products, unspecified |
| Z91.0111 | Allergy to milk products with tolerance to baked milk |
| Z91.0112 | Allergy to milk products with reactivity to baked milk |
| Z91.0120 | Allergy to eggs, unspecified |

| ICD-10 | ICD-10 Description |
|---|---|
| Z91.0121 | Allergy to eggs with tolerance to baked egg |
| Z91.0122 | Allergy to eggs with reactivity to baked egg |
| Z91.013 | Allergy to seafood |
| Z91.018 | Allergy to other foods |

## 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 | | |
|---|---|---|
| **Jurisdiction** | **NCD/LCA/LCD Document (s)** | **Contractor** |
| 6, K | A52448 | Wellpoint Federal |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| 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 | Wellpoint Federal |
| 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 |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | Wellpoint Federal |
| 15 | KY, OH | CGS Administrators, LLC |