NHP Pharmacy Department
Drug Protocol Management

Xolair® (omalizumab)
Coverage for Xolair® (omalizumab) will be granted given all of the following conditions are met:

Asthma Criteria:
- a. Age ≥ 12 years and < 65 years. Requests for patients under the age of 12 will be reviewed on a case-by-case basis.
- b. Patient must be under the active care of a pulmonologist or allergist and prescription must be written by pulmonologist or allergist.
- c. Patient must not be an active smoker.
- d. Patient must have moderate/severe persistent allergy-related asthma.

Note: Not indicated for acute asthma exacerbations, acute bronchospasms or status asthmaticus

Labs:
- a. Must submit total IgE level & specific allergy testing results conducted within past 2 years to allergens (RAST or SPT).
- b. IgE levels – must be between 30-1300 IU/mL for children and between 30-700 IU/mL for adults. IgE levels outside of these ranges will be reviewed on a case-by-case basis.
- c. Patient has a positive skin test or in vitro testing (i.e., a blood test for allergen-specific IgE antibodies such as the radioallergosorbent test (RAST)) for one or more perennial Aeroallergens.
- d. Patient must have pre-bronchodilator FEV1 performed within the past 6 months.

Medications:
- a. Patient must be maintained on and adherent to (taking at least 80% of daily doses) high dose inhaled steroids for a minimum of 6 weeks such as the following:

<table>
<thead>
<tr>
<th>Steroid</th>
<th>Adult Dose</th>
<th>Adult Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beclomethasone</td>
<td>&gt;480 mcg/d</td>
<td>&gt;1080 mcg/d</td>
</tr>
<tr>
<td>(QVAR®, Beclovent®, Vanceril®)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Budesonide</td>
<td>&gt;2000 mcg/d</td>
<td>&gt;660 mcg/d</td>
</tr>
<tr>
<td>(Pulmicort®, AroSpän)</td>
<td>440</td>
<td></td>
</tr>
<tr>
<td>Flunisolide</td>
<td>&gt;640 mcg/d</td>
<td>&gt;640 mcg/d</td>
</tr>
<tr>
<td>(AeroBID®, AreoSpan)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluticasone</td>
<td>&gt;440 mcg/d</td>
<td>&gt;640 mcg/d</td>
</tr>
<tr>
<td>(Flovent®, Arnity)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mometasone</td>
<td>&gt;1080 mcg/d</td>
<td>&gt;1080 mcg/d</td>
</tr>
<tr>
<td>(Asmanex®, Alvesco)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PLUS
- a long-acting bronchodilator (e.g., Serevent®, Foradil®, Arcapta® Neohaler®, etc.) and/or
- a leukotriene modifier (e.g., Singular®, Accolate®, or Zyflo®)

OR
- high dose Advair Diskus® (≥ 500/50; twice daily) or
- high dose Advair HFA® (≥ 115/21; 2 puffs twice daily) or
- high dose Symbicort® (≥ 160/4.5; 2 puffs twice daily) or
- high dose Dulera® (≥ 200/5; 2 puffs twice daily) or
- high dose Breo® (≥ 200/25; 1 puff daily)

OR
- daily systemic steroid therapy
b. Patient has at least 1 claim in the last 6 months for a bronchodilator to control acute symptoms (such as albuterol, Alupent®, Maxair®, Proventil®, Ventolin®, Xopenex®, etc.)

**Symptomatic:**
Despite adequate adherence to above therapy, patient must be actively symptomatic as evidenced by:

a. Daily use of bronchodilator therapy OR
b. An asthma-related hospitalization or emergency room visit within the past 12 months OR
c. More than 2 systemic steroid bursts within the past 6 months for an asthma exacerbation.

**Appropriate Dosing:**

**ADMINISTRATION EVERY 4 WEEKS (Milligrams of omalizumab)**

<table>
<thead>
<tr>
<th>Pre-treatment Serum IgE (IU/mL)</th>
<th>Body Weight (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>30-60</td>
</tr>
<tr>
<td>30-100</td>
<td>150</td>
</tr>
<tr>
<td>101-200</td>
<td>300</td>
</tr>
<tr>
<td>201-300</td>
<td>300</td>
</tr>
</tbody>
</table>

Refer to table below

**ADMINISTRATION EVERY 2 WEEKS (Milligrams of omalizumab)**

<table>
<thead>
<tr>
<th>Pre-treatment Serum IgE (IU/mL)</th>
<th>Body Weight (kg)</th>
</tr>
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<tr>
<td></td>
<td>30-60</td>
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</tr>
<tr>
<td>201-300</td>
<td></td>
</tr>
<tr>
<td>301-400</td>
<td>225</td>
</tr>
<tr>
<td>401-500</td>
<td>300</td>
</tr>
<tr>
<td>501-600</td>
<td>300</td>
</tr>
<tr>
<td>601-700</td>
<td>375</td>
</tr>
</tbody>
</table>

X = DO NOT DOSE*

*dosing that is not recommended by the manufacturer (Refer to Reference section for additional resources)

**Initial Approval Duration & Administration Requirement:**
If patient meets all of the above criteria, authorization for Xolair will be granted for 6 months (initial approval). Xolair should only be administered in a healthcare setting by healthcare providers prepared to manage anaphylaxis that can be life-threatening. Providers must confirm that Xolair will be administered only in a healthcare setting.

**Recertification:**
Documentation of improvement in FEV1, PEF, PFTs and decreased steroid requirement must be provided for continuation of therapy. Approve for 12 months. Providers must confirm that Xolair will be administered only in a healthcare setting.

**OR**

Documentation of improvement in symptoms or a reduction in the frequency of exacerbations (especially hospital-based) even in the absence of PFTs or steroid requirement improvements. Approve for 12 months. Providers must confirm that Xolair will be administered only in a healthcare setting.
Chronic Idiopathic Urticaria (CIU) Criteria:

Coverage for Xolair® (omalizumab) will be granted for chronic idiopathic urticaria (CIU) when all of the following conditions are been met:

a. Diagnosis is chronic idiopathic urticaria (CIU) (also referred to as chronic urticaria)
   Note: Not indicated for other allergic conditions or other forms of urticaria
b. Age ≥ 12 years
   Note: Requests for patients under the age of 12 will be reviewed on a case-by-case basis.
c. The prescriber is an allergist, immunologist, dermatologist, or practitioner specializing in the treatment of CIU.
d. Patient has had a documented inadequate response* with two (2) different histamine (H₁) blockers despite adherence to therapy:
   - Nonsedating antihistamines (e.g., cetirizine, fexofenadine, loratadine, desloratadine, levocetirizine, etc.);
   - First-generation antihistamines (e.g., brompheniramine, clemastine, chlorpheniramine, cyproheptadine, diphenhydramine, hydroxyzine, etc.)
   *Note: Maximum tolerated doses (up to 4 times recommended doses)
e. Patient has had a documented inadequate response with an antihistamine (H₂) blocker (e.g., ranitidine, famotidine, cimetidine, etc.) used in combination with a histamine (H₁) blocker despite adherence to therapy
f. Patient has had a documented inadequate response with montelukast used in combination with a histamine (H₁) blocker despite adherence to therapy

Dosing:
Xolair® (omalizumab) is administered as 150mg or 300mg by subcutaneous injection every 4 weeks.

Approval duration:
Initial requests will be approved for 3 months.

Recertification requests: must include documentation of improvement in the signs and symptoms of CIU per provider assessment and/or, if applicable, a decrease/discontinuation of any steroid therapy requirement. May be approved for 6 months.

Reference:


19. de Silva et al Leukotriene receptor antagonists for chronic urticaria: a systematic review. Allergy, Asthma & Clinical Immunology 2014, 10:24


21. Khan, David A, MD.; Chronic urticaria: Standard management and patient education, UpToDate (online), accessed 9/14/15

22. Estimated Comparative Daily Doses for Inhaled Corticosteroids (Adults and Children ≥ 12 Years Chart, UpToDate (online), accessed 9/12/16