XOLAIR Sample Coding

Moderate to Severe Persistent Allergic Asthma

<table>
<thead>
<tr>
<th>TYPE</th>
<th>CODE</th>
<th>DESCRIPTION</th>
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<tr>
<td>Diagnosis: ICD-10-CM</td>
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<tr>
<td>J45.40</td>
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<td>Moderate persistent asthma, uncomplicated</td>
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<td>J45.50</td>
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<td>Severe persistent asthma, uncomplicated</td>
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<tr>
<td>Drug: NDC</td>
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<td>Note: Payer requirements regarding use of a 10-digit or 11-digit NDC may vary. Both formats are listed here for your reference.</td>
<td>11-digit</td>
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<td>75 mg Prefilled Syringe</td>
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<td>Administration procedures: CPT</td>
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<td>Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular</td>
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<tr>
<td>96401</td>
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<td>Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic</td>
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HCPCS=Healthcare Common Procedure Coding System.
ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.
NDC=National Drug Code.

Chronic Idiopathic Urticaria

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Important Safety Information & Indication

Indication

XOLAIR® (omalizumab) IS INDICATED FOR:

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, at www.xolair.com for additional Important Safety Information.
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- Moderate to severe persistent asthma in patients 6 years of age and older who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. XOLAIR has been shown to decrease the incidence of asthma exacerbations in these patients.
- Chronic idiopathic urticaria in patients 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

Limitations of Use:

- XOLAIR is not indicated for treatment of other allergic conditions or other forms of urticaria.
- XOLAIR is not indicated for the relief of acute bronchospasm or status asthmaticus.

Important Safety Information

WARNING: Anaphylaxis

Anaphylaxis presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of XOLAIR. Anaphylaxis has occurred as early as after the first dose of XOLAIR, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, observe patients closely for an appropriate period of time after XOLAIR administration. Health care providers administering XOLAIR should be prepared to manage anaphylaxis that can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur.

CONTRAINDICATIONS

The use of XOLAIR is contraindicated in patients with a severe hypersensitivity reaction to XOLAIR or to any ingredient of XOLAIR.

WARNINGS AND PRECAUTIONS

Anaphylaxis

Anaphylaxis has been reported to occur after administration of XOLAIR in asthma premarketing clinical trials and in postmarketing spontaneous reports. The frequency of anaphylaxis attributed to XOLAIR use was estimated to be 0.1% and at least 0.2% (based on an estimated exposure of about 57,300 patients from June 2003 through December 2006), respectively.

A case-control study showed that among XOLAIR users, patients with a history of anaphylaxis to foods, medications, or other causes were at increased risk of anaphylaxis associated with XOLAIR, compared to those with no prior history of anaphylaxis.

Observe patients closely for an appropriate period of time after administration of XOLAIR, taking into account the time to onset of anaphylaxis seen in premarketing clinical trials and postmarketing spontaneous reports. Anaphylaxis occurred with the first dose of XOLAIR in 2 patients and with the fourth dose in 1 patient; the time to onset of anaphylaxis was 90 minutes after administration in 2 patients and 2 hours after administration in 1 patient. Discontinue XOLAIR in patients who experience a severe hypersensitivity reaction.

Malignancy

Malignant neoplasms were observed in 20 of 4127 (0.5%) XOLAIR-treated patients compared with 5 of 2236 (0.2%) control patients in clinical studies of adults and adolescents (≥12 years of age) with asthma and other allergic disorders. The observed malignancies in XOLAIR-treated patients were a variety of types, with breast, non-melanoma skin, prostate, melanoma, and parotid occurring more than once, and five other types occurring once each. The majority of patients were observed for less than 1 year. The impact of longer exposure to XOLAIR or use in patients at higher risk for malignancy (eg, elderly, current smokers) is not known.

A subsequent 5-year observational study of 5007 XOLAIR-treated and 2829 non–XOLAIR-treated adolescent and adult patients with moderate to severe persistent asthma and a positive skin test reaction or in vitro reactivity to a perennial aeroallergen found that the incidence rates of primary malignancies (per 1000 patient years) were similar in both groups (12.3 vs 13.0, respectively). Study limitations which include the observational study design, the bias introduced by allowing enrollment of patients previously exposed to XOLAIR (88%), enrollment of patients (56%) while a history of cancer or a premalignant condition were study exclusion criteria, and the high study discontinuation rate (44%) preclude definitively ruling out a malignancy risk with XOLAIR.

Acute Asthma Symptoms

XOLAIR has not been shown to alleviate asthma exacerbations acutely. Do not use XOLAIR to treat acute bronchospasm or status asthmaticus.

Corticosteroid Reduction

Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of XOLAIR therapy for asthma. Decrease corticosteroids gradually under the direct supervision of a physician. In CIU patients, the use of XOLAIR in combination with corticosteroids has not been evaluated.

Eosinophilic Conditions

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, at www.xolair.com for additional Important Safety Information.
In rare cases, patients with asthma on therapy with XOLAIR may present with serious systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome. These events usually, but not always, have been associated with the reduction of oral corticosteroid therapy. Physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. A causal association between XOLAIR and these underlying conditions has not been established.

**Fever, Arthralgia, and Rash**

In post-approval use, some patients have experienced a constellation of signs and symptoms, including arthritis/arthralgia, rash, fever, and lymphadenopathy with an onset 1 to 5 days after the first or subsequent injections of XOLAIR. These signs and symptoms have recurred after additional doses in some patients. Physicians should stop XOLAIR if a patient develops this constellation of signs and symptoms.

**Parasitic (Helminth) Infection**

Monitor patients at high risk of geohelminth infection while on XOLAIR therapy. Insufficient data are available to determine the length of monitoring required for geohelminth infections after stopping XOLAIR treatment.

**Laboratory Tests**

Due to formation of XOLAIR:IgE complexes, serum total IgE levels increase following administration of XOLAIR and may remain elevated for up to 1 year following discontinuation of XOLAIR. Do not use serum total IgE levels obtained less than 1 year following discontinuation to reassess the dosing regimen for asthma patients, because these levels may not reflect steady state free IgE levels.

**ADVERSE REACTIONS**

**Indication-Specific Adverse Reactions**

**Asthma:**

In patients ≥12 years of age, the most commonly observed adverse reactions (≥1% more frequent in XOLAIR-treated patients) from 4 placebo-controlled asthma studies were: arthralgia (8%), pain (general) (7%), leg pain (4%), fatigue (3%), dizziness (3%), fracture (2%), arm pain (2%), pruritus (2%), dermatitis (2%), and earache (2%).

In pediatric patients 6 to 12 years of age, the most commonly observed adverse reactions (≥3% more frequent in XOLAIR-treated pediatric patients) were: nasopharyngitis, headache, pyrexia, upper abdominal pain, pharyngitis streptococcal, otitis media, viral gastroenteritis, arthropod bite, and epistaxis.

**Injection Site Reactions**

In adults and adolescents, injection site reactions of any severity occurred at a rate of 45% in XOLAIR-treated patients compared with 43% in placebo-treated patients. The types of injection site reactions included: bruising, redness, warmth, burning, stinging, itching, hive formation, pain, indurations, mass, and inflammation. Severe injection site reactions occurred more frequently in XOLAIR-treated patients compared with patients in the placebo group (12% vs 9%, respectively).

**Chronic Idiopathic Urticaria:**

In patients ≥12 years of age, the most commonly observed adverse reactions: (≥2% XOLAIR-treated patients and more frequent than in placebo) from 3 placebo-controlled CIU studies (Day 1 to Week 12) for XOLAIR 150 mg and 300 mg, respectively, were: headache (12%, 6%), nasopharyngitis (9%, 7%), arthralgia (3%, 3%), viral upper respiratory infection (2%, 1%), nausea (1%, 3%), sinusitis (1%, 5%), upper respiratory tract infection (1%, 3%), and cough (1%, 2%).

**Injection Site Reactions**

Injection site reactions of any severity occurred during the trials in more XOLAIR-treated patients (11 patients [2.7%] at 300 mg, 1 patient [0.6%] at 150 mg) compared with 2 placebo-treated patients (0.8%). The types of injection site reactions included: swelling, erythema, pain, bruising, itching, bleeding, and urticaria. None of the events resulted in study discontinuation or treatment interruption.

**Cardiovascular and Cerebrovascular Events from Clinical Studies in Patients with Asthma**

A 5-year observational study was conducted in 5007 XOLAIR-treated and 2829 non-XOLAIR-treated patients ≥12 years of age with moderate to severe persistent asthma and a positive skin test reaction to a perennial aeroallergen to evaluate the long term safety of XOLAIR, including the risk of malignancy. Similar percentages of patients in both cohorts were current (5%) or former smokers (29%). Patients had a mean age of 45 years and were followed for a mean of 3.7 years. More XOLAIR-treated patients were diagnosed with severe asthma (50%) compared to the non-XOLAIR-treated patients (23%). A higher incidence rate (per 1000 patient-years) of overall cardiovascular and cerebrovascular serious adverse events (SAEs) was observed in XOLAIR-treated patients (13.4) compared to non-XOLAIR-treated patients (8.1). Increases in rates were observed for transient ischemic attack (0.7 vs 0.1), myocardial infarction (2.1 vs 0.8), pulmonary hypertension (0.5 vs 0), pulmonary embolism/venous thrombosis (3.2 vs 1.5), and unstable angina (2.2 vs 1.4), while the rates observed for ischemic stroke and cardiovascular death were similar among both study cohorts. The results suggest a potential increased risk of serious cardiovascular and cerebrovascular
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events in patients treated with XOLAIR, however the observational study design, the inclusion of patients previously exposed to XOLAIR (88% for a mean of 8 months), baseline imbalances in cardiovascular risk factors between the treatment groups, an inability to adjust for unmeasured risk factors, and the high study discontinuation rate (44%) limit the ability to quantify the magnitude of the risk.

Pregnancy

The data with XOLAIR use in pregnant women are insufficient to inform on drug associated risk

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555 or Novartis Pharmaceuticals Corporation at (888) 669-6682.

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