Omalizumab

Adjudication Guideline

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Approved by:	Responsible:	Related Adjudication Guidelines:
Daman	Pharmacy Standards & Governance	

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1. Abstract

1.1 For Members

Omalizumab, is a monoclonal antibody, a type of protein (man-made), designed to attach to IgE, which is produced in large quantities in patients with allergies and triggers an allergic reaction in response to an allergen. By attaching to IgE, it 'mops up' the free IgE in the blood.

Omalizumab is indicated for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients **aged 1 year and older** with IgE-mediated food allergy

In patients from **6 years of age**, Omalizumab must only be used to improve the control of severe persistent asthma caused by an allergy. It is used as an add-on to asthma treatment in patients from 6 years of age when an antibody called immunoglobulin E (IgE) causes the asthma. It must only be used in patients who:

- Have had a require result for an allergy caused by an allergen in the air, such as house dust mites, pollen, or mold.
- Have frequent symptoms during the day or waking up during the night.
- Have had many severe asthma attacks (that require rescue treatment with other medicines) despite treatment with high doses of inhaled corticosteroids plus a long-acting inhaled beta2 agonist.

In patients **aged 12 years or over**, Omalizumab must only be used if the lung function is less than 80% of normal. Omalizumab is also used to treat:

- Chronic (long-term) spontaneous urticaria (itchy rash). It is used as an add-on to existing treatment in patients aged 12 years or over in whom treatment with an antihistamine does not work well enough.

In adults, **18 years and above,** Omalizumab is used to treat:

- Severe chronic rhinosinusitis with nasal polyps (inflamed lining of the nose and sinuses with swellings in the nose) in adults, 18 years and above. It is used with a corticosteroid given into the nose when the corticosteroid alone does not work well enough.

1.2 For Medical Professionals

DOSAGE AND ADMINISTRATION

For subcutaneous (SC) administration only. Divide doses of more than 150 mg among more than one injection site to limit injections to not more than 150 mg per site.

- **Moderate and Severe persistent Asthma:** Recommended dose **75 to 375 mg** SC 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).

- **Chronic Rhinosinusitis with Nasal Polyps: Recommended dose 75 to 600 mg SC 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).

- **Chronic Spontaneous Urticaria:** Recommended dose **150 or 300 mg** SC every 4 weeks.

Dosing in CSU is not dependent on serum IgE level or body weight.

- **IgE-mediated food allergy:** Recommended dose **75 to 600 mg** SC 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.

Treatment discontinuation

1. Total IgE levels are elevated during treatment and remain elevated for up to one year after the discontinuation of treatment. Therefore, re-testing of IgE levels during treatment cannot be used as a guide for dose determination.
2. If Interruptions / treatment discontinuation is lasting less than one year then the dose will be based on serum IgE levels obtained at the initial dose determination.
3. Interruptions lasting one year or more: Re-test total serum IgE levels for dose determination based on patients age and weight.

CONTRAINDICATIONS

Omalizumab is contraindicated in patients with severe hypersensitivity reaction to it or any ingredient.

2. Scope

This Adjudication Rule highlights the coverage and payment requirements by Daman as per policy terms and conditions for Omalizumab. It also highlights the medical criteria for coverage and refill.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

- It is intended for use under the guidance of a healthcare provider.
- Patient should have no prior history of anaphylaxis, to other agents, such as foods, drugs, biologics, etc. including Omalizumab.
- Omalizumab is stopped at or before the fourth dose if the condition has not improved.
- Urticaria Activity Score 7 (UAS7) scores should be weekly assessed objectively, and the score reports should be submitted for review.
- The endoscopic nasal polyp score (NPS) reports should be submitted pre-treatment.
- The patient's pre-treatment serum total immunoglobulin E (IgE) level (IU/mL), and body weight (lb or kg) should be mentioned in the report.
- One or more injections are administered subcutaneously, once every 2 or 4 weeks.
- The minimum duration and frequency of prescribing the medication should be 14 days.
- Not indicated for children under 6 years.

- A positive allergy skin test or RAST test, the use of inhaled or intranasal corticosteroids should be coded in the claims and IgE levels, use of other antihistamines should be documented in the reports.
- There should be a history of at least one or more exacerbations that required hospitalizations, or urgent care or ER visits before administering Omalizumab.
- Failure to other conservative therapies with second generation antihistamines.
- Documentation mentioning the reduction of symptoms and dosage should be submitted before the re-fill.
- There will be a quarterly evaluation of the requests for re-fill.

3.2 Requirements for Coverage

- Failure to submit the medical reports upon request or when requesting a clinical history, indication for the need for refill will result in rejection of claim.
- Kindly code the ICD-10 and the drug codes to the highest level of specificity.
- Eligible clinician specialties are as follows: -

Eligible clinical specialities	
Internal Medicine	Allergology
Otolaryngology	Immunology and Allergy
Pulmonology	Respiratory Medicine
Immunology	Dermatologist
Pediatric Pulmonology	Family medicine

3.3 Non-Coverage

- Not covered for visitor plan and Basic plan.
- For less than 1 year of age.
- Claims without additional diagnosis indicating the concurrent use of other medications (antihistamines, corticosteroids etc.,)
- As a first line therapy.
- Ineligible ordering or prescribing clinicians.
- For atopic dermatitis, acute bronchospasm, status asthmaticus, mild asthma and other forms of urticaria with known etiology or for other allergic conditions.
- Re-fill requests with incomplete reports on UAS7 score, NPS, other medications.

3.4 Payment and Coding Rules

- Kindly apply DOH payment rules and regulations and relevant coding manuals for ICD, Drugs.
- The condition Omalizumab is indicated for should be coded along with supporting diagnosis that addresses the concurrently use of other medications, allergy status, etc.,

4. Denial Codes

Regulator denial codes with description are elaborated for reference. These are specialized codes directed by regulator, that explains the reason of rejection of the service by DAMAN to the providers.

Code	Code Description
CODE-010	Activity/diagnosis inconsistent with clinician specialty
MNEC-004	Service is not clinically indicated based on good clinical practice
MNEC-003	Diagnoses are not covered
AUTH-001	Prior approval is required and was not obtained

5. Appendices

5.1 References

https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/103976s5225lbl.pdf
https://www.ema.europa.eu/en/medicines/human/EPAR/Omalizumab
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https://www.type2inflammation.com/resources/pdf/measures-of-disease-severity-in-crswnp.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/103976s5245lbl.pdf

5.2 Revision History

Date	Version No.	Change(s)
28/01/2024	V1.0	New version
13/11/2024	V2.0	Age revised, Indication added (IgE-Mediated Food Allergy)