



Billing and Coding Guide

OMLYCLO® is the first and only biosimilar to XOLAIR® (omalizumab)^{1,2}



INDICATIONS

OMLYCLO® (omalizumab-igec) injection, is an anti-IgE antibody indicated for:

- **Moderate to severe persistent asthma** in adults and pediatric patients ≥ 6 years of age with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
- **Chronic rhinosinusitis with nasal polyps (CRSwNP)** in adult patients ≥ 18 years of age with inadequate response to nasal corticosteroids, as add-on maintenance treatment
- **IgE-mediated food allergy** in adult and pediatric patients ≥ 1 year of age for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance
- **Chronic spontaneous urticaria (CSU)** in adults and adolescents ≥ 12 years of age who remain symptomatic despite H1 antihistamine treatment

Limitations of Use: Not indicated for acute bronchospasm or status asthmaticus; emergency treatment of allergic reactions, including anaphylaxis and other forms of urticaria.

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 omalizumab products. Anaphylaxis has occurred as early as after the first dose of omalizumab products, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, initiate OMLYCLO therapy in a healthcare setting and closely observe patients for an appropriate period of time after OMLYCLO administration. Healthcare providers administering OMLYCLO should be prepared to manage anaphylaxis, which can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur. Selection of patients for self-administration of OMLYCLO should be based on criteria to mitigate risk from anaphylaxis.

Overview of Biosimilars

Biosimilars are biologics

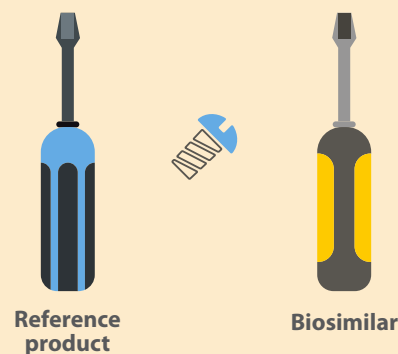
OMLYCLO® (omalizumab-igec) is a biosimilar to XOLAIR® (omalizumab).¹ Biosimilars—like OMLYCLO—are biologics that are highly similar versions of existing US Food and Drug Administration (FDA)–approved biologics (generally referred to as *reference products*). They are safe and effective, with **no clinically meaningful differences from reference products**.^{1,3}

Biosimilars are designed to be as similar as possible to reference products. That's why, compared to reference products, biosimilars³:

- Have the same treatment benefits and potential side effects
- Are created with the same types of living sources (such as bacteria, yeast, or animal cells)
- Are administered the same way
- Have the same strength and dosage

However, biosimilars cannot be considered identical to their reference products because biologics are made from living sources. All biologics have inherent variability from batch to batch.^{3,4}

Reference products and biosimilars are like slightly different versions of the same tool...



The Value of Biosimilars

Biosimilars can help provide patients with additional treatment options, improve access to lifesaving medications, and may lower healthcare costs via competition.³

IMPORTANT SAFETY INFORMATION (continued)

Contraindications: Severe hypersensitivity reaction to omalizumab products or any ingredient of OMLYCLO.

Anaphylaxis. Life-threatening anaphylaxis has occurred after use of omalizumab products, with signs/symptoms including bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue; it can occur as early as the first dose, beyond 1 year after starting, and has been reported up to 4 days after administration. Initiate OMLYCLO in a healthcare setting equipped to manage anaphylaxis and observe patients for an appropriate period after dosing; educate patients on signs/symptoms and the need for immediate medical care. Risk is increased in patients with a history of anaphylaxis to foods, medications, or other causes. After therapy is safely established, self-administration of the OMLYCLO prefilled syringe may be appropriate for selected patients/caregivers based on risk mitigation (including no prior history of anaphylaxis, at least 3 supervised doses without hypersensitivity, ability to recognize and appropriately treat anaphylaxis, and ability to perform SC injections correctly). Discontinue OMLYCLO in patients who experience a severe hypersensitivity reaction.

Malignancy. Malignant neoplasms have been observed in clinical studies; the impact of longer exposure and use in patients at higher baseline risk is not known, and limitations of longer-term observational data preclude definitively ruling out a malignancy risk with omalizumab products.

Acute Asthma Symptoms and Deteriorating Disease. Omalizumab products have not been shown to relieve acute asthma exacerbations; do not use OMLYCLO to treat acute bronchospasm or status asthmaticus. Advise patients to seek medical care if asthma remains uncontrolled or worsens after starting OMLYCLO.

Corticosteroid Reduction. Do not abruptly discontinue systemic or inhaled corticosteroids when starting OMLYCLO for asthma or CRSwNP; taper gradually under physician supervision. In CSU patients, use of omalizumab products in combination with corticosteroids has not been evaluated.

Biosimilar Pricing and Reimbursement

Biosimilars provide substantial cost savings

Biosimilars are held to the same rigorous standards as reference products. However, an abbreviated approval pathway can allow biosimilar manufacturers to avoid repeating certain costly studies required for reference biologics.⁵⁻⁷ As a result, biosimilars can be offered with wholesale acquisition costs (WACs) and average sales prices (ASPs) that are **discounted** as compared to reference products.⁸

Reimbursement expectations for in-office administration

For patients with commercial insurance, if OMLYCLO® is covered, there should be no reason to anticipate reimbursement issues. Reimbursement will vary by payer.

For patients with Medicare, OMLYCLO is covered under Medicare Part B if administered in the office. Medicaid coverage and reimbursement are determined on a state-by-state basis.^{9,10}

OMLYCLO is a relatively new product, and it will take time to establish an ASP.⁸ To determine reimbursement for a new biosimilar when ASP has not been established, the Centers for Medicare & Medicaid Services (CMS) uses the biosimilar's WAC plus a percentage.¹¹

Below are the anticipated OMLYCLO reimbursement scenarios. Initial reimbursement may be higher until ASP is established.^{8,11}

OMLYCLO has an established Q code (Q5154) and is reimbursed at its own biosimilar-specific rate.^{11,12}

Immediately after launch¹¹

- No ASP established—only WAC available
- CMS uses WAC to calculate Part B reimbursement
- Standard payment limit is WAC + 3%

After establishing market presence^{11,13}

- CMS has calculated an ASP
- CMS uses ASP to calculate Part B reimbursement
- Payment calculated as OMLYCLO ASP + 8% of the reference product's ASP*

For patients who self-administer OMLYCLO, reimbursement is provided to private insurers based on CMS arrangements.^{9,14}

Celltrion Reimbursement Support

A dedicated team of Field Reimbursement Managers (FRMs) assists providers in navigating all aspects of medication access for patients. Call 1-877-812-6662 to be connected with your dedicated FRM.

*For new qualifying biosimilars, the ASP + 8% reimbursement applies for 5 years starting on the first day of the calendar quarter during which Medicare payment is first made using ASP. Thereafter, reimbursement changes to ASP + 6% of the reference biological product's ASP or WAC (whichever is lower).

IMPORTANT SAFETY INFORMATION (continued)

Eosinophilic Conditions. In rare cases, patients with asthma on omalizumab products have developed serious systemic eosinophilia, sometimes with vasculitis consistent with Churg-Strauss syndrome, often in the setting of oral corticosteroid reduction. Be alert for eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy; a causal association has not been established.

Introduction to OMLYCLO^{®1,2}

OMLYCLO injection, for subcutaneous use only, is an anti-IgE antibody biosimilar to XOLAIR[®] (omalizumab). OMLYCLO is interchangeable with XOLAIR.

Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a *reference product*, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of OMLYCLO has been demonstrated for the condition(s) of use (eg, indication[s], dosing regimen[s]), strength(s), dosage form(s), and route(s) of administration described in its full Prescribing Information.

This guide is provided for informational purposes only. Correct coding is the responsibility of the provider who is submitting the claim for the item or service. Please check with the payer to verify codes and specific billing requirements. Celltrion does not make any representation or guarantees concerning reimbursement or coverage for any service or item, nor does Celltrion guarantee patient assistance to the limits described.

OMLYCLO Formulation¹

FOR SUBCUTANEOUS INJECTION



75 mg/0.5 mL single-dose
prefilled syringe with a
27-gauge staked needle syringe
Carton of 1 syringe*
NDC 72606-035-01



150 mg/mL single-dose
prefilled syringe with a
27-gauge staked needle syringe
Carton of 1 syringe*
NDC 72606-036-01



300 mg/2 mL (150 mg/mL)
single-dose prefilled syringe with
a 27-gauge staked needle syringe
Carton of 1 syringe*
NDC 72606-054-01
Multipack of 2 syringes*
NDC 72606-054-02

*Please note that the above images may differ from the actual product images.

FDA, US Food and Drug Administration; IgE, immunoglobulin E; NDC, National Drug Code.

IMPORTANT SAFETY INFORMATION (continued)

Fever, Arthralgia, and Rash. In post-approval use, a serum sickness-like constellation (arthritis/arthralgia, rash, fever, lymphadenopathy) has occurred 1 to 5 days after injections and may recur with additional doses; stop OMLYCLO if this constellation develops.

Indications¹

OMLYCLO® (omalizumab-igec) injection, is an anti-IgE antibody indicated for:

- **Moderate to severe persistent asthma** in adults and pediatric patients ≥ 6 years of age with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
- **Chronic rhinosinusitis with nasal polyps (CRSwNP)** in adult patients ≥ 18 years of age with inadequate response to nasal corticosteroids, as add-on maintenance treatment
- **IgE-mediated food allergy** in adult and pediatric patients ≥ 1 year of age for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance
- **Chronic spontaneous urticaria (CSU)** in adults and adolescents ≥ 12 years of age who remain symptomatic despite H1 antihistamine treatment

Limitations of Use: Not indicated for acute bronchospasm or status asthmaticus; emergency treatment of allergic reactions, including anaphylaxis and other forms of urticaria.

IMPORTANT SAFETY INFORMATION (continued)

Parasitic (Helminth) Infection. Monitor patients at high risk of geohelminth infection during OMLYCLO therapy; available data are insufficient to define the duration of monitoring needed after stopping treatment. A clinical trial in a high-risk setting observed more infections with omalizumab than placebo; response to appropriate anti-geohelminth treatment was not different between groups.

Laboratory Tests. Total serum IgE increases after dosing and may remain elevated for up to 1 year after discontinuation due to drug:IgE complexes; do not use total IgE levels obtained less than 1 year after discontinuation to reassess dosing regimen for asthma, CRSwNP, or IgE-mediated food allergy because these levels may not reflect steady-state free IgE levels.

Potential Medication Error Related to Emergency Treatment of Anaphylaxis. OMLYCLO should not be used for the emergency treatment of allergic reactions, including anaphylaxis. Instruct patients that OMLYCLO is for maintenance use to reduce allergic reactions, including anaphylaxis, while avoiding food allergens.

Most Common Adverse Reactions

- Asthma: In patients ≥ 12 years, reported in $\geq 1\%$: arthralgia, general pain, leg pain, fatigue, dizziness, fracture, arm pain, pruritus, dermatitis, and earache. In pediatric patients (6 to <12 years), reported in $\geq 3\%$: nasopharyngitis, headache, pyrexia, upper abdominal pain, streptococcal pharyngitis, otitis media, viral gastroenteritis, arthropod bites, and epistaxis.
- CRSwNP: In $\geq 3\%$ of adult patients: headache, injection site reactions, arthralgia, upper abdominal pain, and dizziness.
- IgE-Mediated Food Allergy: In $\geq 3\%$ of patients: injection site reactions and pyrexia.
- CSU: In $\geq 2\%$ of patients: nausea, nasopharyngitis, sinusitis, upper respiratory tract infections (viral and non-viral), arthralgia, headache, and cough.

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 omalizumab products. Anaphylaxis has occurred as early as after the first dose of omalizumab products, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, initiate OMLYCLO therapy in a healthcare setting and closely observe patients for an appropriate period of time after OMLYCLO administration. Healthcare providers administering OMLYCLO should be prepared to manage anaphylaxis, which can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur. Selection of patients for self-administration of OMLYCLO should be based on criteria to mitigate risk from anaphylaxis.

Contraindications: Severe hypersensitivity reaction to omalizumab products or any ingredient of OMLYCLO.

Dosage and Administration¹

General administration and dosing information

OMLYCLO® is for subcutaneous (SC) administration only.

When used to treat moderate to severe persistent asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), or IgE-mediated food allergy, dosing is based on serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). Please refer to the respective dosing determination charts for these indications in Section 2 of the OMLYCLO Prescribing Information. Dosing for chronic spontaneous urticaria (CSU) is not dependent on serum IgE level or body weight.

Indication	Recommended Dosing
Moderate to Severe Persistent Asthma	- OMLYCLO 75 mg 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)*
CRSwNP	- OMLYCLO 75 mg 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)[†]
IgE-Mediated Food Allergy	- OMLYCLO 75 mg 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)[‡]
CSU	- OMLYCLO 150 mg or 300 mg SC every 4 weeks - Dosing in CSU is not dependent on serum IgE level or body weight

IgE, immunoglobulin E.

*Refer to dose determination charts in Section 2.2 of the OMLYCLO Prescribing Information.

[†]Refer to dose determination charts in Section 2.3 of the OMLYCLO Prescribing Information.

[‡]Refer to dose determination charts in Section 2.4 of the OMLYCLO Prescribing Information.

IMPORTANT SAFETY INFORMATION (continued)

Anaphylaxis. Life-threatening anaphylaxis has occurred after use of omalizumab products, with signs/symptoms including bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue; it can occur as early as the first dose, beyond 1 year after starting, and has been reported up to 4 days after administration. Initiate OMLYCLO in a healthcare setting equipped to manage anaphylaxis and observe patients for an appropriate period after dosing; educate patients on signs/symptoms and the need for immediate medical care. Risk is increased in patients with a history of anaphylaxis to foods, medications, or other causes. After therapy is safely established, self-administration of the OMLYCLO prefilled syringe may be appropriate for selected patients/caregivers based on risk mitigation (including no prior history of anaphylaxis, at least 3 supervised doses without hypersensitivity, ability to recognize and appropriately treat anaphylaxis, and ability to perform SC injections correctly). Discontinue OMLYCLO in patients who experience a severe hypersensitivity reaction.

Malignancy. Malignant neoplasms have been observed in clinical studies; the impact of longer exposure and use in patients at higher baseline risk is not known, and limitations of longer-term observational data preclude definitively ruling out a malignancy risk with omalizumab products.

Sample Coding

This section serves as an educational reference for coding that may be appropriate for reporting OMLYCLO® and related services. Medical record documentation must support the codes reported on the claim. These codes may be appropriate when OMLYCLO is administered to patients in the physician's office or a hospital setting.

Diagnosis codes (ICD-10-CM codes)¹⁵

This list is for informational purposes only. One or more codes may be appropriate on a claim. Please review payer policy requirements for guidance on diagnosis codes.

Code	Description
Moderate to Severe Persistent Asthma	
J45.40	Moderate persistent asthma, uncomplicated
J45.41	Moderate persistent asthma with (acute) exacerbation
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
Chronic Rhinosinusitis with Nasal Polyps	
J32.0	Chronic maxillary sinusitis
J32.1	Chronic frontal sinusitis
J32.2	Chronic ethmoidal sinusitis
J32.3	Chronic sphenoidal sinusitis
J32.4	Chronic pansinusitis
J32.8	Other chronic sinusitis
J32.9	Chronic sinusitis, unspecified
J33.0	Polyp of nasal cavity
J33.1	Polypoid sinus degeneration
J33.8	Other polyp of sinus
J33.9	Nasal polyp, unspecified

Code	Description
IgE-Mediated Food Allergy	
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
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
Z91.014	Allergy to mammalian meats
Z91.018	Allergy to other foods
Z91.02	Food additives allergy status
K52.21	Food protein-induced enterocolitis syndrome
K52.29	Other allergic and dietetic gastroenteritis and colitis
Chronic Spontaneous Urticaria	
L50.0	Allergic urticaria
L50.1	Idiopathic urticaria
L50.8	Other (chronic, recurrent) urticaria
L50.9	Urticaria, unspecified

Note: Allowable diagnosis codes may vary by payer.

ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification.

IMPORTANT SAFETY INFORMATION (continued)

Acute Asthma Symptoms and Deteriorating Disease. Omalizumab products have not been shown to relieve acute asthma exacerbations; do not use OMLYCLO to treat acute bronchospasm or status asthmaticus. Advise patients to seek medical care if asthma remains uncontrolled or worsens after starting OMLYCLO.

Corticosteroid Reduction. Do not abruptly discontinue systemic or inhaled corticosteroids when starting OMLYCLO for asthma or CRSwNP; taper gradually under physician supervision. In CSU patients, use of omalizumab products in combination with corticosteroids has not been evaluated.

Sample Coding (continued)

National drug code (NDC)

The NDC is required on the claim form. This is a unique identifier assigned by the FDA to drugs in the US. The FDA assigns 10-digit NDCs, but some government agencies and payers require the NDC in an 11-digit format. The 11-digit format is created by adding a leading zero to the correct part of the 10-digit format.¹⁶ The NDC unit of measure qualifier and quantity may also be required. Check payer-specific reporting requirements.

Subcutaneous Injection^{1,16,17}

OMLYCLO®		Carton Size	10-Digit NDC	11-Digit NDC	WAC
Prefilled syringes	75 mg/0.5 mL single-dose prefilled syringe	1 unit	72606-035-01	72606-0035-01	\$660.35
	150 mg/mL single-dose prefilled syringe	1 unit	72606-036-01	72606-0036-01	\$1,320.70
	300 mg/2 mL (150 mg/mL) single-dose prefilled syringe	1 unit	72606-054-01	72606-0054-01	\$2,641.40
	300 mg/2 mL (150 mg/mL) single-dose prefilled syringe	2 units (multipack)	72606-054-02	72606-0054-02	\$5,282.80

FDA, US Food and Drug Administration; WAC, wholesale acquisition cost.

IMPORTANT SAFETY INFORMATION (continued)

Eosinophilic Conditions. In rare cases, patients with asthma on omalizumab products have developed serious systemic eosinophilia, sometimes with vasculitis consistent with Churg-Strauss syndrome, often in the setting of oral corticosteroid reduction. Be alert for eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy; a causal association has not been established.

Fever, Arthralgia, and Rash. In post-approval use, a serum sickness-like constellation (arthritis/arthralgia, rash, fever, lymphadenopathy) has occurred 1 to 5 days after injections and may recur with additional doses; stop OMLYCLO if this constellation develops.

Parasitic (Helminth) Infection. Monitor patients at high risk of geohelminth infection during OMLYCLO therapy; available data are insufficient to define the duration of monitoring needed after stopping treatment. A clinical trial in a high-risk setting observed more infections with omalizumab than placebo; response to appropriate anti-geohelminth treatment was not different between groups.

Laboratory Tests. Total serum IgE increases after dosing and may remain elevated for up to 1 year after discontinuation due to drug:IgE complexes; do not use total IgE levels obtained less than 1 year after discontinuation to reassess dosing regimen for asthma, CRSwNP, or IgE-mediated food allergy because these levels may not reflect steady-state free IgE levels.

Administration and Billing Codes

This section reviews general coding guidelines for drug administration services coded by physician offices using the CMS-1500 claim form and by hospital outpatient departments using the CMS-1450 (UB-04) claim form (or the electronic equivalent).

CPT® code¹⁸⁻²¹

Drug administration services are reported on claim forms in both the physician office and hospital outpatient sites of care using the Current Procedural Terminology (CPT®) coding system.

Code Set	Code and Description	Location on CMS-1500 Form	Location on CMS-1450 (UB-04) Form
CPT®	96372 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	Field 24D	Field 44

Note: CPT® is a registered trademark of the American Medical Association.
CMS, Centers for Medicare & Medicaid Services.

IMPORTANT SAFETY INFORMATION (continued)

Potential Medication Error Related to Emergency Treatment of Anaphylaxis. OMLYCLO should not be used for the emergency treatment of allergic reactions, including anaphylaxis. Instruct patients that OMLYCLO is for maintenance use to reduce allergic reactions, including anaphylaxis, while avoiding food allergens.

Most Common Adverse Reactions

- **Asthma:** In patients ≥ 12 years, reported in $\geq 1\%$: arthralgia, general pain, leg pain, fatigue, dizziness, fracture, arm pain, pruritus, dermatitis, and earache. In pediatric patients (6 to <12 years), reported in $\geq 3\%$: nasopharyngitis, headache, pyrexia, upper abdominal pain, streptococcal pharyngitis, otitis media, viral gastroenteritis, arthropod bites, and epistaxis.
- **CRSwNP:** In $\geq 3\%$ of adult patients: headache, injection site reactions, arthralgia, upper abdominal pain, and dizziness.
- **IgE-Mediated Food Allergy:** In $\geq 3\%$ of patients: injection site reactions and pyrexia.
- **CSU:** In $\geq 2\%$ of patients: nausea, nasopharyngitis, sinusitis, upper respiratory tract infections (viral and non-viral), arthralgia, headache, and cough.

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Contraindications: Severe hypersensitivity reaction to omalizumab products or any ingredient of OMLYCLO.

Administration and Billing Codes (continued)

HCPCS level II codes^{12,20-22}

Drugs are typically reported using product-specific Healthcare Common Procedure Coding System (HCPCS) codes, which are assigned by CMS. Effective October 1, 2025, providers may use HCPCS code Q5154 (Injection, omalizumab-igec [OMLYCLO], biosimilar, 5 mg) to report OMLYCLO® on claims. Note that providers should not report the HCPCS code for the reference product when billing for a biosimilar.

Code Set	Code and Description	Location on CMS-1500 Form	Location on CMS-1450 (UB-04) Form
HCPCS	Q5154 Injection, omalizumab-igec (OMLYCLO), biosimilar, 5 mg	Field 24D	Field 44

CMS, Centers for Medicare & Medicaid Services.

IMPORTANT SAFETY INFORMATION (continued)

Anaphylaxis. Life-threatening anaphylaxis has occurred after use of omalizumab products, with signs/symptoms including bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue; it can occur as early as the first dose, beyond 1 year after starting, and has been reported up to 4 days after administration. Initiate OMLYCLO in a healthcare setting equipped to manage anaphylaxis and observe patients for an appropriate period after dosing; educate patients on signs/symptoms and the need for immediate medical care. Risk is increased in patients with a history of anaphylaxis to foods, medications, or other causes. After therapy is safely established, self-administration of the OMLYCLO prefilled syringe may be appropriate for selected patients/caregivers based on risk mitigation (including no prior history of anaphylaxis, at least 3 supervised doses without hypersensitivity, ability to recognize and appropriately treat anaphylaxis, and ability to perform SC injections correctly). Discontinue OMLYCLO in patients who experience a severe hypersensitivity reaction.

Malignancy. Malignant neoplasms have been observed in clinical studies; the impact of longer exposure and use in patients at higher baseline risk is not known, and limitations of longer-term observational data preclude definitively ruling out a malignancy risk with omalizumab products.

Acute Asthma Symptoms and Deteriorating Disease. Omalizumab products have not been shown to relieve acute asthma exacerbations; do not use OMLYCLO to treat acute bronchospasm or status asthmaticus. Advise patients to seek medical care if asthma remains uncontrolled or worsens after starting OMLYCLO.

Corticosteroid Reduction. Do not abruptly discontinue systemic or inhaled corticosteroids when starting OMLYCLO for asthma or CRSwNP; taper gradually under physician supervision. In CSU patients, use of omalizumab products in combination with corticosteroids has not been evaluated.

Eosinophilic Conditions. In rare cases, patients with asthma on omalizumab products have developed serious systemic eosinophilia, sometimes with vasculitis consistent with Churg-Strauss syndrome, often in the setting of oral corticosteroid reduction. Be alert for eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy; a causal association has not been established.

Fever, Arthralgia, and Rash. In post-approval use, a serum sickness-like constellation (arthritis/arthralgia, rash, fever, lymphadenopathy) has occurred 1 to 5 days after injections and may recur with additional doses; stop OMLYCLO if this constellation develops.

Administration and Billing Codes (continued)

Modifiers^{1,20,21,23}

Modifier	Description	Location on CMS-1500 Form	Location on CMS-1450 (UB-04) Form
JZ	Zero drug amount discarded/ not administered to any patient	Field 24D	Field 44

Note on Product and Administration Coding

If you order OMLYCLO® through a specialty pharmacy or the Celltrion CONNECT® Patient Assistance Program, you should not seek reimbursement for the product; however, your patient's health plan may still require that you include the HCPCS code on the claim with a zero or nominal charge in order for them to reimburse the drug administration procedure.

Remember to submit a claim for reimbursement for services associated with OMLYCLO.

CMS, Centers for Medicare & Medicaid Services.

IMPORTANT SAFETY INFORMATION (continued)

Parasitic (Helminth) Infection. Monitor patients at high risk of geohelminth infection during OMLYCLO therapy; available data are insufficient to define the duration of monitoring needed after stopping treatment. A clinical trial in a high-risk setting observed more infections with omalizumab than placebo; response to appropriate anti-geohelminth treatment was not different between groups.

Laboratory Tests. Total serum IgE increases after dosing and may remain elevated for up to 1 year after discontinuation due to drug:IgE complexes; do not use total IgE levels obtained less than 1 year after discontinuation to reassess dosing regimen for asthma, CRSwNP, or IgE-mediated food allergy because these levels may not reflect steady-state free IgE levels.

Potential Medication Error Related to Emergency Treatment of Anaphylaxis. OMLYCLO should not be used for the emergency treatment of allergic reactions, including anaphylaxis. Instruct patients that OMLYCLO is for maintenance use to reduce allergic reactions, including anaphylaxis, while avoiding food allergens.

Most Common Adverse Reactions

- Asthma:** In patients ≥12 years, reported in ≥1%: arthralgia, general pain, leg pain, fatigue, dizziness, fracture, arm pain, pruritus, dermatitis, and earache. In pediatric patients (6 to <12 years), reported in ≥3%: nasopharyngitis, headache, pyrexia, upper abdominal pain, streptococcal pharyngitis, otitis media, viral gastroenteritis, arthropod bites, and epistaxis.
- CRSwNP:** In ≥3% of adult patients: headache, injection site reactions, arthralgia, upper abdominal pain, and dizziness.
- IgE-Mediated Food Allergy:** In ≥3% of patients: injection site reactions and pyrexia.
- CSU:** In ≥2% of patients: nausea, nasopharyngitis, sinusitis, upper respiratory tract infections (viral and non-viral), arthralgia, headache, and cough.

Sample CMS-1500 Claim Form—Physician Office²⁰

The sample claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE ☐ MEDICAID ☒ TRICARE ☐ CHAMPVA ☐ GROUP HEALTH PLAN ☐ FECA BLK LUNG ☐ OTHER ☐
(Medicare#) (Medicaid#) (ID# DoD#) (Member ID#) (ID#) (ID#)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)
Doe, Jane S.

3. PATIENT'S BIRTH DATE
MM DD YY
02 12 70

4. INSURED'S NAME (Last Name, First Name, Middle Initial)
Doe, Jane S.

5. PATIENT'S ADDRESS (No., Street)
123 Main Street

6. PATIENT RELATIONSHIP TO INSURED
Self ☒ Spouse ☐ Child ☐ Other ☐

7. INSURED'S ADDRESS (No., Street)
123 Main Street

8. RESERVED FOR NUCC USE

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:
a. EMPLOYMENT? (Current or Previous) YES ☐ NO ☐
b. AUTO ACCIDENT? YES ☐ NO ☐ PLACE (State) _____
c. OTHER ACCIDENT? YES ☐ NO ☐

11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits due to myself or to the party who accepts assignment below.
John Smith, MD

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.
John Smith, MD

14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP)
MM DD YY
QUAL _____

15. OTHER DATE
MM DD YY
QUAL _____

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION
FROM MM DD YY TO MM DD YY

17. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES
FROM MM DD YY TO MM DD YY

18. OUTSIDE LAB? YES ☐ NO ☐ \$ CHARGES _____

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
ONLYCLO 75 MG SC NDC: 72606-0035-01

20. RESUBMISSION CODE
ORIGINAL REF. NO. _____

21. PRIOR AUTHORIZATION NUMBER

22. DATE(S) OF SERVICE
From MM DD YY To MM DD YY

23. PLACE OF SERVICE
EMG _____

24. PROCEEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)
CPT/HCPCS MODIFIER
Q5156

25. DIAGNOSIS POINTER
A

26. \$ CHARGES
XX

27. DAYS OR UNITS
1

28. NDC
321 654 7890

29. RENDERING PROVIDER ID #
321 654 7890

30. FEDERAL TAX ID NUMBER
SSN EIN

31. PATIENT'S ACCOUNT NO.

32. ACCEPT ASSIGNMENT? YES ☐ NO ☐

33. TOTAL CHARGE
\$ _____

34. AMOUNT PAID
\$ _____

35. Rev'd for NUCC Use

36. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)
John Smith, MD

37. SERVICE FACILITY LOCATION INFORMATION
a. NPI b. _____

38. BILLING PROVIDER INFO & PH #
a. NPI b. _____

39. SIGNATURE
DATE

40. NUCC Instruction Manual available at: www.nucc.org

41. PLEASE PRINT OR TYPE

42. APPROVED OMB-0938-1197 FORM 1500 (02-12)

Field 19: Payers require drug name, route of administration, NDC, and total dosage. Check with your payer to verify specific requirements, including use of the 10-digit or 11-digit NDC.

Note: Some payers may also request the wholesale acquisition cost (WAC) price to be included.

Field 21: Indicate the most medically appropriate diagnosis code (ICD-10-CM).

Field 23: If required, report the prior authorization number here.

Field 24A: If line item NDC information is required, enter it in the shaded portion of Field 24A. NDCs must be billed with the N4 qualifier before the NDC.

Field 24D: Indicate appropriate HCPCS as required by the payer (eg, Q5154). Include the appropriate CPT® code (eg, 96372 for subcutaneous administration) to report the administration procedure. Make sure to include the JZ modifier to indicate no wastage.

Field 24E: Enter the diagnosis code reference letter as shown in Field 21. Enter only 1 diagnosis pointer.

Field 24G: Enter the number of HCPCS units.

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, National Drug Code.

CMS-1450 (UB-04) Claim Form—Hospital Outpatient Departments²¹

The sample claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

1 Facility Name Street Address City, State Zip		2 Pay-to name Street Address City, State Zip		3a PAY. CONT. # b. MEX. RES. # c. FED. TAX NO.		4. CODE OF BEL.	
8 PATIENT NAME a. Jane S. Doe		9 PATIENT ADDRESS a. 123 Main Street		c. AZ d. 12333		e. US	
10 BIRTHDAY 03/23/970		11 SEX F		12 DATE 03/23/970		13 ADMISSION 13 HPI 14 TYPE 15 SEC 16 DHR	
17 STAT 18 19 20 21 22 23 24 25 26 27 28		19 ACCT 20 STATE		21 ACCT 22 STATE		23 ACCT 24 STATE	
25 ACCT 26 STATE		27 ACCT 28 STATE		29 ACCT 30 STATE		31 ACCT 32 STATE	
33 ACCT 34 STATE		35 ACCT 36 STATE		37 ACCT 38 STATE		39 ACCT 40 STATE	
41 ACCT 42 STATE		43 ACCT 44 STATE		45 ACCT 46 STATE		47 ACCT 48 STATE	
49 ACCT 50 STATE		51 ACCT 52 STATE		53 ACCT 54 STATE		55 ACCT 56 STATE	
57 ACCT 58 STATE		59 ACCT 60 STATE		61 ACCT 62 STATE		63 ACCT 64 STATE	
65 ACCT 66 STATE		67 ACCT 68 STATE		69 ACCT 70 STATE		71 ACCT 72 STATE	
73 ACCT 74 STATE		75 ACCT 76 STATE		77 ACCT 78 STATE		79 ACCT 80 STATE	
81 ACCT 82 STATE		83 ACCT 84 STATE		85 ACCT 86 STATE		87 ACCT 88 STATE	
89 ACCT 90 STATE		91 ACCT 92 STATE		93 ACCT 94 STATE		95 ACCT 96 STATE	
97 ACCT 98 STATE		99 ACCT 100 STATE		101 ACCT 102 STATE		103 ACCT 104 STATE	
105 ACCT 106 STATE		107 ACCT 108 STATE		109 ACCT 110 STATE		111 ACCT 112 STATE	
113 ACCT 114 STATE		115 ACCT 116 STATE		117 ACCT 118 STATE		119 ACCT 120 STATE	
121 ACCT 122 STATE		123 ACCT 124 STATE		125 ACCT 126 STATE		127 ACCT 128 STATE	
129 ACCT 130 STATE		131 ACCT 132 STATE		133 ACCT 134 STATE		135 ACCT 136 STATE	
137 ACCT 138 STATE		139 ACCT 140 STATE		141 ACCT 142 STATE		143 ACCT 144 STATE	
145 ACCT 146 STATE		147 ACCT 148 STATE		149 ACCT 150 STATE		151 ACCT 152 STATE	
153 ACCT 154 STATE		155 ACCT 156 STATE		157 ACCT 158 STATE		159 ACCT 160 STATE	
161 ACCT 162 STATE		163 ACCT 164 STATE		165 ACCT 166 STATE		167 ACCT 168 STATE	
169 ACCT 170 STATE		171 ACCT 172 STATE		173 ACCT 174 STATE		175 ACCT 176 STATE	
177 ACCT 178 STATE		179 ACCT 180 STATE		181 ACCT 182 STATE		183 ACCT 184 STATE	
185 ACCT 186 STATE		187 ACCT 188 STATE		189 ACCT 190 STATE		191 ACCT 192 STATE	
193 ACCT 194 STATE		195 ACCT 196 STATE		197 ACCT 198 STATE		199 ACCT 200 STATE	
201 ACCT 202 STATE		203 ACCT 204 STATE		205 ACCT 206 STATE		207 ACCT 208 STATE	
209 ACCT 210 STATE		211 ACCT 212 STATE		213 ACCT 214 STATE		215 ACCT 216 STATE	
217 ACCT 218 STATE		219 ACCT 220 STATE		221 ACCT 222 STATE		223 ACCT 224 STATE	
225 ACCT 226 STATE		227 ACCT 228 STATE		229 ACCT 230 STATE		231 ACCT 232 STATE	
233 ACCT 234 STATE		235 ACCT 236 STATE		237 ACCT 238 STATE		239 ACCT 240 STATE	
241 ACCT 242 STATE		243 ACCT 244 STATE		245 ACCT 246 STATE		247 ACCT 248 STATE	
249 ACCT 250 STATE		251 ACCT 252 STATE		253 ACCT 254 STATE		255 ACCT 256 STATE	
257 ACCT 258 STATE		259 ACCT 260 STATE		261 ACCT 262 STATE		263 ACCT 264 STATE	
265 ACCT 266 STATE		267 ACCT 268 STATE		269 ACCT 270 STATE		271 ACCT 272 STATE	
273 ACCT 274 STATE		275 ACCT 276 STATE		277 ACCT 278 STATE		279 ACCT 280 STATE	
281 ACCT 282 STATE		283 ACCT 284 STATE		285 ACCT 286 STATE		287 ACCT 288 STATE	
289 ACCT 290 STATE		291 ACCT 292 STATE		293 ACCT 294 STATE		295 ACCT 296 STATE	
297 ACCT 298 STATE		299 ACCT 300 STATE		301 ACCT 302 STATE		303 ACCT 304 STATE	
305 ACCT 306 STATE		307 ACCT 308 STATE		309 ACCT 310 STATE		311 ACCT 312 STATE	
313 ACCT 314 STATE		315 ACCT 316 STATE		317 ACCT 318 STATE		319 ACCT 320 STATE	
321 ACCT 322 STATE		323 ACCT 324 STATE		325 ACCT 326 STATE		327 ACCT 328 STATE	
329 ACCT 330 STATE		331 ACCT 332 STATE		333 ACCT 334 STATE		335 ACCT 336 STATE	
337 ACCT 338 STATE		339 ACCT 340 STATE		341 ACCT 342 STATE		343 ACCT 344 STATE	
345 ACCT 346 STATE		347 ACCT 348 STATE		349 ACCT 350 STATE		351 ACCT 352 STATE	
353 ACCT 354 STATE		355 ACCT 356 STATE		357 ACCT 358 STATE		359 ACCT 360 STATE	
361 ACCT 362 STATE		363 ACCT 364 STATE		365 ACCT 366 STATE		367 ACCT 368 STATE	
369 ACCT 370 STATE		371 ACCT 372 STATE		373 ACCT 374 STATE		375 ACCT 376 STATE	
377 ACCT 378 STATE		379 ACCT 380 STATE		381 ACCT 382 STATE		383 ACCT 384 STATE	
385 ACCT 386 STATE		387 ACCT 388 STATE		389 ACCT 390 STATE		391 ACCT 392 STATE	
393 ACCT 394 STATE		395 ACCT 396 STATE		397 ACCT 398 STATE		399 ACCT 400 STATE	
401 ACCT 402 STATE		403 ACCT 404 STATE		405 ACCT 406 STATE		407 ACCT 408 STATE	
409 ACCT 410 STATE		411 ACCT 412 STATE		413 ACCT 414 STATE		415 ACCT 416 STATE	
417 ACCT 418 STATE		419 ACCT 420 STATE		421 ACCT 422 STATE		423 ACCT 424 STATE	
425 ACCT 426 STATE		427 ACCT 428 STATE		429 ACCT 430 STATE		431 ACCT 432 STATE	
433 ACCT 434 STATE		435 ACCT 436 STATE		437 ACCT 438 STATE		439 ACCT 440 STATE	
441 ACCT 442 STATE		443 ACCT 444 STATE		445 ACCT 446 STATE		447 ACCT 448 STATE	
449 ACCT 450 STATE		451 ACCT 452 STATE		453 ACCT 454 STATE		455 ACCT 456 STATE	
457 ACCT 458 STATE		459 ACCT 460 STATE		461 ACCT 462 STATE		463 ACCT 464 STATE	
465 ACCT 466 STATE		467 ACCT 468 STATE		469 ACCT 470 STATE		471 ACCT 472 STATE	
473 ACCT 474 STATE		475 ACCT 476 STATE		477 ACCT 478 STATE		479 ACCT 480 STATE	
481 ACCT 482 STATE		483 ACCT 484 STATE		485 ACCT 486 STATE		487 ACCT 488 STATE	
489 ACCT 490 STATE		491 ACCT 492 STATE		493 ACCT 494 STATE		495 ACCT 496 STATE	
497 ACCT 498 STATE		499 ACCT 500 STATE		501 ACCT 502 STATE		503 ACCT 504 STATE	
505 ACCT 506 STATE		507 ACCT 508 STATE		509 ACCT 510 STATE		511 ACCT 512 STATE	
513 ACCT 514 STATE		515 ACCT 516 STATE		517 ACCT 518 STATE		519 ACCT 520 STATE	
521 ACCT 522 STATE		523 ACCT 524 STATE		525 ACCT 526 STATE		527 ACCT 528 STATE	
529 ACCT 530 STATE		531 ACCT 532 STATE		533 ACCT 534 STATE		535 ACCT 536 STATE	
537 ACCT 538 STATE		539 ACCT 540 STATE		541 ACCT 542 STATE		543 ACCT 544 STATE	
545 ACCT 546 STATE		547 ACCT 548 STATE		549 ACCT 550 STATE		551 ACCT 552 STATE	
553 ACCT 554 STATE		555 ACCT 556 STATE		557 ACCT 558 STATE		559 ACCT 560 STATE	
561 ACCT 562 STATE		563 ACCT 564 STATE		565 ACCT 566 STATE		567 ACCT 568 STATE	
569 ACCT 570 STATE		571 ACCT 572 STATE		573 ACCT 574 STATE		575 ACCT 576 STATE	
577 ACCT 578 STATE		579 ACCT 580 STATE		581 ACCT 582 STATE		583 ACCT 584 STATE	
585 ACCT 586 STATE		587 ACCT 588 STATE		589 ACCT 590 STATE		591 ACCT 592 STATE	
593 ACCT 594 STATE		595 ACCT 596 STATE		597 ACCT 598 STATE		599 ACCT 600 STATE	
601 ACCT 602 STATE		603 ACCT 604 STATE		605 ACCT 606 STATE		607 ACCT 608 STATE	
609 ACCT 610 STATE		611 ACCT 612 STATE		613 ACCT 614 STATE		615 ACCT 616 STATE	
617 ACCT 618 STATE		619 ACCT 620 STATE		621 ACCT 622 STATE		623 ACCT 624 STATE	
625 ACCT 626 STATE		627 ACCT 628 STATE		629 ACCT 630 STATE		631 ACCT 632 STATE	
633 ACCT 634 STATE		635 ACCT 636 STATE		637 ACCT 638 STATE		639 ACCT 640 STATE	
641 ACCT 642 STATE		643 ACCT 644 STATE		645 ACCT 646 STATE		647 ACCT 648 STATE	
649 ACCT 650 STATE		651 ACCT 652 STATE		653 ACCT 654 STATE		655 ACCT 656 STATE	
657 ACCT 658 STATE		659 ACCT 660 STATE		661 ACCT 662 STATE		663 ACCT 664 STATE	
665 ACCT 666 STATE		667 ACCT 668 STATE		669 ACCT 670 STATE		671 ACCT 672 STATE	
673 ACCT 674 STATE		675 ACCT 676 STATE		677 ACCT 678 STATE		679 ACCT 680 STATE	
681 ACCT 682 STATE		683 ACCT 684 STATE		685 ACCT 686 STATE		687 ACCT 688 STATE	
689 ACCT 690 STATE		691 ACCT 692 STATE		693 ACCT 694 STATE		695 ACCT 696 STATE	
697 ACCT 698 STATE		699 ACCT 700 STATE		701 ACCT 702 STATE		703 ACCT 704 STATE	
705 ACCT 706 STATE		707 ACCT 708 STATE		709 ACCT 710 STATE		711 ACCT 712 STATE	
713 ACCT 714 STATE		715 ACCT 716 STATE		717 ACCT 718 STATE		719 ACCT 720 STATE	
721 ACCT 722 STATE		723 ACCT 724 STATE		725 ACCT 726 STATE		727 ACCT 728 STATE	
729 ACCT 730 STATE		731 ACCT 732 STATE		733 ACCT 734 STATE		735 ACCT 736 STATE	
737 ACCT 738 STATE		739 ACCT 740 STATE		741 ACCT 742 STATE		743 ACCT 744 STATE	
745 ACCT 746 STATE		747 ACCT 748 STATE		749 ACCT 750 STATE		751 ACCT 752 STATE	
753 ACCT 754 STATE		755 ACCT 756 STATE		757 ACCT 758 STATE		759 ACCT 760 STATE	
761 ACCT 762 STATE		763 ACCT 764 STATE		765 ACCT 766 STATE		767 ACCT 768 STATE	
769 ACCT 770 STATE		771 ACCT 772 STATE		773 ACCT 774 STATE		775 ACCT 776 STATE	
777 ACCT 778 STATE		779 ACCT 780 STATE		781 ACCT 782 STATE		783 ACCT 784 STATE	
785 ACCT 786 STATE		787 ACCT 788 STATE		789 ACCT 790 STATE		791 ACCT 792 STATE	
793 ACCT 794 STATE		795 ACCT 796 STATE		797 ACCT 798 STATE		799 ACCT 800 STATE	
801 ACCT 802 STATE		803 ACCT 804 STATE		805 ACCT 806 STATE		807 ACCT 808 STATE	
809 ACCT 810 STATE		811 ACCT 812 STATE		813 ACCT 814 STATE		815 ACCT 816 STATE	
817 ACCT 818 STATE		819 ACCT 820 STATE		821 ACCT 822 STATE		823 ACCT 824 STATE	
825 ACCT 826 STATE		827 ACCT 828 STATE		829 ACCT 830 STATE		831 ACCT 832 STATE	
833 ACCT 834 STATE		835 ACCT 836 STATE		837 ACCT 838 STATE		839 ACCT 840 STATE	
841 ACCT 842 STATE		843 ACCT 844 STATE		845 ACCT 846 STATE		847 ACCT 848 STATE	
849 ACCT 850 STATE		851 ACCT 852 STATE		853 ACCT 854 STATE		855 ACCT 856 STATE	
857 ACCT 858 STATE		859 ACCT 860 STATE		861 ACCT 862 STATE		863 ACCT 864 STATE	
865 ACCT 866 STATE		867 ACCT 868 STATE		869 ACCT 870 STATE		871 ACCT 872 STATE	
873 ACCT 874 STATE		875 ACCT 876 STATE		877 ACCT 878 STATE		879 ACCT 880 STATE	
881 ACCT 882 STATE		883 ACCT 884 STATE		885 ACCT 886 STATE		887 ACCT 888 STATE	
889 ACCT 890 STATE		891 ACCT 892 STATE		893 ACCT 894 STATE		895 ACCT 896 STATE	
897 ACCT 898 STATE		899 ACCT 900 STATE		901 ACCT 902 STATE		903 ACCT 904 STATE	
905 ACCT 906 STATE		907 ACCT 908 STATE		909 ACCT 910 STATE		911 ACCT 912 STATE	
913 ACCT 914 STATE		915 ACCT 916 STATE		917 ACCT 918 STATE		919 ACCT 920 STATE	
921 ACCT 922 STATE		923 ACCT 924 STATE		925 ACCT 926 STATE		927 ACCT 928 STATE	
929 ACCT 930 STATE		931 ACCT 932 STATE		933 ACCT 934 STATE		935 ACCT 936 STATE	
937 ACCT 938 STATE		939 ACCT 940 STATE		941 ACCT 942 STATE		943 ACCT 944 STATE	
945 ACCT 946 STATE		947 ACCT 948 STATE		949 ACCT 950 STATE		951 ACCT 952 STATE	
953 ACCT 954 STATE		955 ACCT 956 STATE		957 ACCT 958 STATE		959 ACCT 960 STATE	
961 ACCT 962 STATE		963 ACCT 964 STATE		965 ACCT 966 STATE		967 ACCT 968 STATE	
969 ACCT 970 STATE		971 ACCT 972 STATE		973 ACCT 974 STATE		975 ACCT 976 STATE	
977 ACCT 978 STATE		979 ACCT 980 STATE		981 ACCT 982 STATE		983 ACCT 984 STATE	
985 ACCT 986 STATE		987 ACCT 988 STATE		989 ACCT 990 STATE		991 ACCT 992 STATE	
993 ACCT 994 STATE		995 ACCT 996 STATE		997 ACCT 998 STATE		999 ACCT 1000 STATE	

Field 42: Include appropriate revenue code corresponding with the HCPCS code in Field 44. Then, enter the appropriate revenue code corresponding with the CPT® code in Field 44.

Field 43: Provide drug product name, strength, NDC, and quantity.

Field 44: Indicate appropriate HCPCS codes (eg, Q5154) and CPT® codes (eg, 96372 for subcutaneous administration) and modifiers (eg, JZ), as required by the payer.

Field 46: Enter the number of HCPCS units.

Field 47: Indicate total charges.

Field 56: Indicate the appropriate NPI number.

Field 66: Indicate the most medically appropriate diagnosis code.

Field 80: Payers require drug name, route of administration, NDC, and total dosage. Check with your payer to verify specific requirements, including use of the 10-digit or 11-digit NDC. This is a necessary field.

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code; NPI, National Provider Identifier.

Patient Support Programs Created to Provide Treatment Access to as Many Eligible Patients as Possible



Celltrion CONNECT® helps hub-enrolled patients understand and navigate their insurance coverage and identify resources that may help them afford their treatment



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A dedicated team of Field Reimbursement Managers assists patients and providers in navigating all aspects of medication access

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- Patient insurance benefit verifications
- Prior authorization assistance
- Appeal support
- Co-pay Assistance Program (Celltrion CARES) for your commercially insured patients
- Financial support for qualified eligible patients



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- Sample Letters of Medical Exception and Appeal
- Downloadable brochures
- Downloadable Enrollment Form
- Downloadable Billing and Coding Guide

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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 omalizumab products. Anaphylaxis has occurred as early as after the first dose of omalizumab products, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, initiate OMLYCLO therapy in a healthcare setting and closely observe patients for an appropriate period of time after OMLYCLO administration. Healthcare providers administering OMLYCLO should be prepared to manage anaphylaxis, which can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur. Selection of patients for self-administration of OMLYCLO should be based on criteria to mitigate risk from anaphylaxis.

Contraindications: Severe hypersensitivity reaction to omalizumab products or any ingredient of OMLYCLO.

Anaphylaxis. Life-threatening anaphylaxis has occurred after use of omalizumab products, with signs/symptoms including bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue; it can occur as early as the first dose, beyond 1 year after starting, and has been reported up to 4 days after administration. Initiate OMLYCLO in a healthcare setting equipped to manage anaphylaxis and observe patients for an appropriate period after dosing; educate patients on signs/symptoms and the need for immediate medical care. Risk is increased in patients with a history of anaphylaxis to foods, medications, or other causes. After therapy is safely established, self-administration of the OMLYCLO prefilled syringe may be appropriate for selected patients/caregivers based on risk mitigation (including no prior history of anaphylaxis, at least 3 supervised doses without hypersensitivity, ability to recognize and appropriately treat anaphylaxis, and ability to perform SC injections correctly). Discontinue OMLYCLO in patients who experience a severe hypersensitivity reaction.

Malignancy. Malignant neoplasms have been observed in clinical studies; the impact of longer exposure and use in patients at higher baseline risk is not known, and limitations of longer-term observational data preclude definitively ruling out a malignancy risk with omalizumab products.

Acute Asthma Symptoms and Deteriorating Disease.

Omalizumab products have not been shown to relieve acute asthma exacerbations; do not use OMLYCLO to treat acute bronchospasm or status asthmaticus. Advise patients to seek medical care if asthma remains uncontrolled or worsens after starting OMLYCLO.

Corticosteroid Reduction. Do not abruptly discontinue systemic or inhaled corticosteroids when starting OMLYCLO for asthma or CRSwNP; taper gradually under physician supervision. In CSU patients, use of omalizumab products in combination with corticosteroids has not been evaluated.

Eosinophilic Conditions. In rare cases, patients with asthma on omalizumab products have developed serious systemic eosinophilia, sometimes with vasculitis consistent with Churg-Strauss syndrome, often in the setting of oral corticosteroid reduction. Be alert for eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy; a causal association has not been established.

Fever, Arthralgia, and Rash. In post-approval use, a serum sickness-like constellation (arthritis/arthralgia, rash, fever, lymphadenopathy) has occurred 1 to 5 days after injections and may recur with additional doses; stop OMLYCLO if this constellation develops.

Parasitic (Helminth) Infection. Monitor patients at high risk of geohelminth infection during OMLYCLO therapy; available data are insufficient to define the duration of monitoring needed after stopping treatment. A clinical trial in a high-risk setting observed more infections with omalizumab than placebo; response to appropriate anti-geohelminth treatment was not different between groups.

Laboratory Tests. Total serum IgE increases after dosing and may remain elevated for up to 1 year after discontinuation due to drug:IgE complexes; do not use total IgE levels obtained less than 1 year after discontinuation to reassess dosing regimen for asthma, CRSwNP, or IgE-mediated food allergy because these levels may not reflect steady-state free IgE levels.

Potential Medication Error Related to Emergency Treatment of Anaphylaxis. OMLYCLO should not be used for the emergency treatment of allergic reactions, including anaphylaxis. Instruct patients that OMLYCLO is for maintenance use to reduce allergic reactions, including anaphylaxis, while avoiding food allergens.

Most Common Adverse Reactions

- **Asthma:** In patients ≥ 12 years, reported in $\geq 1\%$: arthralgia, general pain, leg pain, fatigue, dizziness, fracture, arm pain, pruritus, dermatitis, and earache. In pediatric patients (6 to < 12 years), reported in $\geq 3\%$: nasopharyngitis, headache, pyrexia, upper abdominal pain, streptococcal pharyngitis, otitis media, viral gastroenteritis, arthropod bites, and epistaxis.
- **CRSwNP:** In $\geq 3\%$ of adult patients: headache, injection site reactions, arthralgia, upper abdominal pain, and dizziness.
- **IgE-Mediated Food Allergy:** In $\geq 3\%$ of patients: injection site reactions and pyrexia.
- **CSU:** In $\geq 2\%$ of patients: nausea, nasopharyngitis, sinusitis, upper respiratory tract infections (viral and non-viral), arthralgia, headache, and cough.

Please see the full [Prescribing Information](#) for complete details. To report suspected adverse reactions, contact CELLTRION USA INC. at 1-800-560-9414 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.com

References

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