

Patient Support Program

ENROLLMENT FORM



Monday - Friday, 8 AM - 8 PM ET | Phone: (877) 812-6662 | Fax: (877) 431-6444 | www.CelltrionConnect.com

Instructions for Enrollment - Celltrion CONNECT® offers 3 options for enrollment:

Option 1: Submit through the Portal

At www.CelltrionConnect.com/hcpportal, a healthcare provider can:

- Enroll a patient in Celltrion CONNECT
- Instruct the patient to complete electronic consent as applicable
- Inform the patient a Celltrion CONNECT Case Coordinator will contact them by phone with the next steps and to verify their information

Option 2: Complete this form

- Attach both sides of the patient's insurance card(s)
- Attach the patient's demographics, chart notes, and clinical documentation
- Have the patient and prescriber sign the form
- Fax the completed form, along with attachments, to (877) 431-6444

OR

Option 3: Send an ePrescription

- Select ePrescribe to Phyz via the pharmacy drop-down menu: NCPDP: 5928809 | Phone: 844-590-5792
- Phyz will facilitate the enrollment process in Celltrion CONNECT
- Send this completed enrollment form along with the patient's insurance card(s), demographics, chart notes, and clinical documentation through your EMR or via fax to (877) 431-6444
- Celltrion CONNECT will forward the OMLYCLO® prescription to the appropriate pharmacy, if necessary

OR

Complete and sign the patient consent online at www.celltrionconnect.hipaa.com

Requested Services - Please check all that apply:

☐ All Services

☐ Benefits Verification

☐ Prior Authorization Support

☐ Co-pay Support for Commercially Insured Patients

☐ Appeals Support

☐ Medical Claims Support

☐ Nurse Connector™ Support Only*

For co-pay assistance only, visit www.CelltrionCARES.com to enroll

*Nurse Connectors can assist patients with medication and adherence communications, offer medication dispensing support, and provide disease state education. Nurse Connectors are provided by Celltrion and do not work under the direction of the patient's healthcare provider. Nurse Connectors will direct patients to their healthcare provider for treatment-related inquiries and medical decision-making.

Patient Information - All fields marked with an * are required.

*First Name MI *Last Name
*Address *City *State *ZIP
*Date of Birth Sex ☐ Male ☐ Female ☐ Prefer Not to Answer Weight lb or kg
*Email Preferred Language ☐ English ☐ Other
*Primary Phone ☐ Cell ☐ Home Secondary Phone ☐ Cell ☐ Home
Preferred Contact ☐ Patient ☐ Alternate Contact (By providing alternate contact information, I hereby authorize the release of my protected health information to the authorized alternate contact.)
Alternate Contact Name Relationship to Patient
Primary Phone ☐ Cell ☐ Home Secondary Phone ☐ Cell ☐ Home

Provide required patient/authorized representative signature on page 3 or at www.celltrionconnect.hipaa.com

Patient Insurance Information - All fields marked with an * are required.

Please attach a copy of the patient's insurance card(s) (both front and back). If not available, please complete the following:

❗ If the patient is uninsured, please complete the Patient Assistance Program application at www.CelltrionConnect.com/Omlyclo or call (877) 812-6662

*Primary Insurance *Policyholder Name
*Primary Policy # *Primary Group # *Policyholder Date of Birth
Secondary Insurance Policyholder Name
Secondary Policy # Secondary Group # Policyholder Date of Birth
*Does the patient have a separate pharmacy benefit card? ☐ Yes ☐ No
Cardholder Name Pharmacy Benefit Name Policy/Identification #

Please see Important Safety Information, including BOXED WARNING, on page 4 and full Prescribing Information.

Celltrion CONNECT does not guarantee coverage or reimbursement. Coverage and reimbursement decisions are made by insurance companies following the receipt of claims.

Patient Name Patient Date of Birth

Prescriber Information - All fields marked with an * are required.

*Prescriber First Name MI *Prescriber Last Name *Prescriber NPI
*Tax ID # Medicare PTAN Prescriber Address
*City *State *ZIP *Phone *Fax
*Practice Name Practice Contact Name
Practice Contact Title Phone Practice Contact Email Address

Clinical Information - Complete to the highest level of specificity for diagnosis codes. At least one code is required.

IgE-mediated Food Allergy	Chronic Spontaneous Urticaria (CSU)	Allergic Asthma	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
☐ Z91.010 Allergy to peanuts	☐ L50.0 Allergic urticaria	☐ J45.40 Moderate persistent asthma, uncomplicated	☐ J33.0 Polyp of nasal cavity
☐ Z91.011 Allergy to milk products	☐ L50.1 Idiopathic urticaria	☐ J45.50 Severe persistent asthma, uncomplicated	☐ J33.1 Polypoid sinus degeneration
☐ Z91.012 Allergy to eggs	☐ L50.8 Other (chronic, recurrent) urticaria		☐ J33.8 Other polyp of sinus
☐ Z91.013 Allergy to seafood	☐ L50.9 Urticaria, unspecified		☐ J33.9 Nasal polyp, unspecified
☐ Z91.018 Allergy to other foods			
Other Diagnosis Code:			

Acquisition and Administration Information - All fields marked with an * are required.

*Acquire OMLYCLO® through: ☐ Buy & Bill ☐ Specialty Pharmacy Preferred Specialty Pharmacy: *Anticipated Date of Treatment:
*Place of Administration/Ship to: ☐ Physician's Office ☐ Hospital Outpatient Department ☐ Alternate Injection Center ☐ Patient's Address
If shipping address is not the patient's address, please complete below:
Place of Administration Name Place of Administration Tax ID#
Street Suite City State ZIP

OMLYCLO® (omalizumab-igec) Prescribing Information - All fields marked with an * are required.

*Prescription Type: ☐ New Start ☐ Transition ☐ Last Injection Date (if applicable):
*Dispense: ☐ Single-dose prefilled syringe *Days Supply: ☐ 1 month ☐ 3 months *Refills:
*Frequency & Dose (mg): Please select one of the doses below.
Every 2 weeks: ☐ 150 mg ☐ 225 mg ☐ 300 mg ☐ 375 mg ☐ 450 mg ☐ 525 mg ☐ 600 mg Every 4 weeks: ☐ 75 mg ☐ 150 mg ☐ 225 mg ☐ 300 mg ☐ 450 mg ☐ 525 mg ☐ 600 mg
*Pretreatment serum IgE level IU/mL (1.0 kU/L=1.0 IU/mL; 2.4 ng/mL=1.0 IU/mL): IgE level: Patient weight: lb or kg *Not required for CRSwNP patients*
Dosage of OMLYCLO in patients with chronic spontaneous urticaria (CSU) is not dependent on serum IgE (free or total) level or body weight.

Prescriber Attestation/Authorization

I certify that the information provided in this OMLYCLO Enrollment Form is complete and accurate to the best of my knowledge. I have prescribed OMLYCLO based on my judgment of medical necessity. I certify that I have obtained my patient's written authorization in accordance with applicable state and federal law, including the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations to provide the individually identifiable health information on this form to agents and service providers of Celltrion Inc. and to the Celltrion CONNECT program for benefits eligibility, coverage authorization, coordination and dispensing of OMLYCLO, and providing my patient and me with other educational and support services associated with OMLYCLO. I agree that the Celltrion CONNECT program may contact me for additional information relating to OMLYCLO, including but not limited to via email, fax, and telephone. I authorize the Celltrion CONNECT program to transmit the above prescription to the pharmacy.

 **SIGN & DATE** *Prescriber Signature and Date (no stamps) Dispense as Written/Brand Medically Necessary Date
May Substitute/Product Selection Permitted Date
CA, MA, NC, and PR: Interchange is mandated unless the prescriber writes the words "No Substitution" here
ATTN: Please submit the electronic prescription as required by your state law.

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Patient Name

Patient Date of Birth

Patient Authorization to Share Health Information

By signing this form, the patient gives their permission for their physicians, pharmacies, laboratories, and other healthcare providers ("Healthcare Providers") and their health insurers to share their individually identifiable health information with Celltrion USA, Inc., the Celltrion Patient Assistance Foundation, and Celltrion affiliates and its vendors (collectively, "Celltrion").

The patient understands that their individually identifiable health information may include their full name, address, date of birth, demographic information, financial information, insurance information, and information related to their medical condition, treatment, care management, medication history, and prescriptions (collectively, "Health Information"), whether in written or verbal form, including portions of their medical record.

The patient's Health Information will be shared with Celltrion so that Celltrion may provide them with various support and information to help them access a Celltrion medicine, which may include the following, depending on the program (collectively, "Patient Support Activities"):

- Processing this application
- Verifying the information provided in this application
- Providing benefit investigation/verification and reimbursement support, including:
 - Assisting with identification of prior authorization requirements
 - Assisting with the identification of requirements of their insurer for appeal of a denied claim
- Determining their eligibility for and helping them access co-pay support or free drug programs
- Communicating with their Healthcare Providers about a Celltrion medicine and Patient Support Activities
- Coordinating the dispensing and delivery of medication
- Providing them with financial assistance resources and information if they are eligible
- Providing them with disease management and other educational materials, as well as information about Celltrion's products, services, and programs, which may include sending them surveys about their experience with Celltrion products, services, and programs
- Providing them with access to a Nurse Connector™, who can assist in educational support communications

Celltrion also may use their Health Information for auditing for compliance with Program requirements, for quality assurance purposes, and to evaluate and improve our operations and services.

The patient understands that Celltrion may de-identify their Health Information and use it in performing research, education, business analytics, marketing studies, or for other commercial purposes, including linkage with other de-identified data Celltrion receives from other sources.

The patient understands that they do not have to sign this form, and choosing not to sign will not affect their ability to receive treatment from their Healthcare Providers or payment from their health insurer. However, if they do not sign this form, Celltrion may not be able to provide them with assistance.

The patient understands that once their Health Information is shared, it may no longer be protected by federal privacy law. However, Celltrion agrees to protect their Health Information and to use it for the purposes described in this form or as required or permitted by law. Select pharmacies may receive remuneration from Celltrion in exchange for their Health Information and/or for any Patient Support Activities provided to them. The patient understands that this form will remain in effect for six (6) years from the date of their signature or shall otherwise expire at a shorter duration as required under applicable state law unless they provide written notice that they would like to withdraw their approval to share their Health Information sooner. If the patient would like to withdraw their approval, they may contact Celltrion at (877) 812-6662. This withdrawal will not affect the use or sharing of their Health Information that took place before they withdraw their approval. The patient understands that they may receive a copy of this form.

 **SIGN & DATE**

Patient or Patient Authorized Representative Signature

Date

Patient Representative First and Last Name (print):

Relationship to Patient

By checking this box, the patient elects to opt out of Nurse Connectors educational support communications. ☐

Patient Authorization to Telephone Consumer Protection Act (TCPA) Information

By signing up for text messages from Celltrion, the patient agrees that they are the primary owner of the phone number(s) provided and consent to receiving promotional communications in the form of phone calls or text messages relating to Celltrion products and services and/or their condition or treatment at the phone number(s) provided. These communications may be sent from an automated system for the selection and dialing of telephone numbers, including an automatic telephone dialing system, or may use an artificial or pre-recorded voice, including recording messages or pre-recorded voicemails.

Your agreement and consent are not required as a condition for the purchase of any goods or services. Message and data rates may apply. Unsubscribe at any time by replying STOP or clicking the unsubscribe link (where available). Text HELP for help. Message frequency varies. To the maximum extent permitted by law: (i) all information contained in SMS text messages is provided "as is" without warranty of any kind, either expressed or implied, including but not limited to the implied warranties of merchantability, fitness for a particular purpose, or noninfringement; and (ii) Celltrion expressly excludes any liability for any direct, indirect, or consequential loss or damage incurred by any user in connection with the receipt, use, failure of, or inability to use SMS text messages.

The patient also gives their permission to receive communications from Celltrion and parties acting on its behalf, including calls or messages made with an automated system for the selection and dialing of telephone numbers, including an automatic telephone dialing system, or may use an artificial or pre-recorded voice, including recorded messages or prerecorded voicemails at the phone number(s) provided to determine their eligibility and provide benefits verification, prior authorization/appeals assistance, and financial assistance resources and information, such as co-pay support or free drug programs, Nurse Connector™ educational support communications, and/or other nonmarketing purposes. The patient understands that they can opt out of these telephonic communications concerning Patient Support Activities at any time by contacting Celltrion at (877) 812-6662, Monday - Friday, 8 AM - 8 PM ET.

Celltrion CONNECT®: View our privacy policy: <https://www.celltrionconnect.com/patient-privacy-policy> | View our terms of use: <https://www.celltrionconnect.com/terms-of-use/>

By signing below, the patient expressly consents to the terms of this section.



☐ By checking this box, the patient accepts receiving SMS messages with the cell phone number(s) provided in the Patient Information section.

 **SIGN & DATE**

Patient or Patient Authorized Representative Signature

Date

Patient Representative First and Last Name (print)

Relationship to Patient

Please see Important Safety Information, including BOXED WARNING, on page 4 and full Prescribing Information.

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Indication and Important Safety Information for OMLYCLO® (omalizumab-igec)

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.

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

Anaphylaxis. Life-threatening anaphylaxis has occurred after 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 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. Rarely, 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 ≥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 patients ≥3% of adults: 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.

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



Please see full [Prescribing Information](#), including BOXED WARNING, by scanning the QR Code.

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