CELLTRION CONNECT™
PATIENT SUPPORT PROGRAM

SEND COMPLETED ENROLMENT FORM TO

1-855-966-2223 support@celltrionconnect.ca

Questions? 1-855-966-1648

Pr Omlyclo™ omalizumab

The CELLTRION CONNECT™ Patient Support Program (the "Program") is sponsored and offered by Celltrion Healthcare Canada Limited ("Celltrion") in conjunction with its third-party providers ("Program Administrators"), to support patients who have been prescribed Omlyclo™ (omalizumab) ("Support Services"). Information contained in this document is used by the Program to facilitate access to Omlyclo™.

PATIENT INFORMATION

First name: _____ Last name: _____ Date of birth: _____ Female ☐ Male ☐ Non-binary ☐

Address: _____ Email: _____

Cellphone: _____ Okay to leave message: Yes ☐ No ☐ Best time to be contacted: AM ☐ PM ☐

Tel. (home): _____ Known allergies: Yes ☐ No ☐ If yes, please specify: _____

Preferred language: English ☐ French ☐ Other ☐ Please specify: _____ Personal health number (PHN): _____

FOR MINOR PATIENT

_____ _____

Legal guardian name **Relationship to patient**

PHYSICIAN INFORMATION

Name: _____

Specialty: _____

License number: _____

Office contact name: _____

Address: _____

Tel (office): _____ Fax (office): _____

Email: _____

PHARMACY

Do you have a preferred pharmacy that you are working with? Yes ☐ No ☐

Pharmacy name: _____

Address: _____

Tel: _____

Fax: _____

PHYSICIAN PRESCRIBING SECTION FOR OMLYCLO™

☐ Patient is already on Xolair®

☐ Patient is eligible to begin self-injection of pre-filled syringe

☐ Patient is new to omalizumab

☐ Patient is eligible for self-injection of pre-filled syringe **after 3rd dose:**
- **Patients naïve to omalizumab treatment must receive the first 3 doses of Omlyclo™ either by or under the supervision of a healthcare professional**

Requested start date: _____

Eligible patients for self-injection:
- Must have no known history of anaphylaxis to either Omlyclo™ or other agents (e.g., foods, drugs, biologics, etc.)
- The patient and/or caregiver will receive proper training on the preparation and administration of Omlyclo™
- The patient and/or caregiver must be trained to recognize early signs and symptoms of serious allergic reactions, and be able to treat anaphylactic reactions appropriately

DIAGNOSIS ☐ Allergic asthma ☐ Chronic rhinosinusitis with nasal polyps ☐ Chronic idiopathic urticaria (chronic spontaneous urticaria)

DOSAGE: Please ☑ and complete the required information.

Refer to the back for dose calculations for Asthma and Chronic Rhinosinusitis with Nasal Polyps.

Allergic Asthma

SC q 2 weeks

☐ 225 mg ☐ 300 mg ☐ 375 mg

SC q 4 weeks

☐ 75 mg ☐ 150 mg ☐ 225 mg

☐ 300 mg

Patient's weight (kg): _____

☐ IgE level test result: _____

☐ Positive skin prick or *in vitro* reactivity allergen test result: _____

☐ Pulmonary function test result: _____

Chronic Rhinosinusitis with Nasal Polyps

SC q 2 weeks

☐ 300 mg ☐ 375 mg ☐ 450 mg

☐ 525 mg ☐ 600 mg

SC q 4 weeks

☐ 75 mg ☐ 150 mg ☐ 225 mg

☐ 300 mg ☐ 450 mg ☐ 600 mg

Patient's weight (kg): _____

☐ IgE level test result: _____

Chronic Idiopathic Urticaria

SC q 4 weeks

☐ 150 mg ☐ 300 mg

UAS7 score: _____

Previous therapy: _____

Duration: _____

Quantity and refills authorized: _____

Other instructions: _____

Provincial formulary code (if applicable): _____

My signature acknowledges that:
- The above prescription parameters comply with the indications set forth in the Product Monograph.
- I consent to the patient being enrolled in the CELLTRION CONNECT™ Patient Support Program (the "Program").
- I have the patient's consent to share with the Program the patient's information in this form and as needed to provide the Program's services.
- I consent to Celltrion contacting me with respect to the enrolment of this patient as may be required to administer or deliver the Program or the Support Services, or in the event of an adverse drug event relating to Omlyclo™. This prescription is the original prescription that will be sent to the pharmacy chosen by the patient.
- I consent to the Program Administrator designated agent for the purposes of forwarding the prescription to the Program and to the pharmacy. I consent to the Program Administrator collecting, using and disclosing my information for the purpose of delivering the Support Services, or for contacting me to improve the quality of the Support Services offered under the Program.

_____

Physician name

_____

Physician signature

_____

Date†

†Effective date. Order(s) expire one year from the date of signature.
Prescriber certification: I certify that this prescription is an original prescription and this pharmacy is the only receiver. The original will not be reused.

IgE: immunoglobulin E; UAS7: weekly urticaria activity score; SC: subcutaneous.

NOTES

Omlyclo™'s Indications

Indications have been granted on the basis of similarity between Omlyclo™ and the reference biologic drug Xolair®.

Omlyclo™ is indicated for:

- Adult and pediatric patients (6 years of age and above) with moderate to severe persistent asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.
- Add-on maintenance treatment with intranasal corticosteroids in adult patients with severe chronic rhinosinusitis with nasal polyps inadequately controlled by intranasal corticosteroids alone.
- Treatment of adults and adolescents (12 years of age and above) with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment.

Consult the Product Monograph at https://pdf.hres.ca/dpd_pm/00077971.PDF for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The product monograph is also available by calling 1-855-914-2021.

Recommended Dose for Asthma Patients

Adults and adolescents ≥12 years of age

Omlyclo™ doses (mg) administered by subcutaneous injection every 4 weeks (light-grey area) or 2 weeks (white area)

Baseline IgE (IU/mL)*	Dosing Freq.	Body weight (kg)								
		≥20–30	>30–40	>40–50	>50–60	>60–70	>70–80	>80–90	>90–125	>125–150
		Dose (mg)								
≥30-100	Every 4 weeks	150	150	150	150	150	150	150	300	300
>100–200		150	150	300	300	300	300	300	225	300
>200–300		150	300	300	300	225	225	225	300	375
>300–400		300	300	225	225	225	300	300		
>400–500		300	225	225	300	300	375	375		
>500–600		300	225	300	300	375	DO NOT DOSE			
>600–700	Every 2 weeks	225	225	300	375	DO NOT DOSE				

Children 6 to <12 years of age

Omlyclo™ doses (mg) administered by subcutaneous injection every 4 weeks (light-grey area) or 2 weeks (white area)

Baseline IgE (IU/mL)*	Dosing Freq.	Body weight (kg)									
		20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
		Dose (mg)									
30-100	Every 4 weeks	75	75	75	150	150	150	150	150	300	300
>100-200		150	150	150	300	300	300	300	300	225	300
>200-300		150	150	225	300	300	225	225	225	300	375
>300-400		225	225	300	225	225	225	300	300		
>400-500		225	300	225	225	300	300	375	375		
>500-600		300	300	225	300	300	375				
>600-700		300	225	225	300	375	DO NOT DOSE				
>700-800	Every 2 weeks	225	225	300	375	DO NOT DOSE					
>800-900		225	225	300	375	DO NOT DOSE					
>900-1000		225	300	375	DO NOT DOSE						
>1000-1100		225	300	375	DO NOT DOSE						
>1100-1200		300	300	DO NOT DOSE							
>1200-1300		300	375	DO NOT DOSE							

Adult Patients with Chronic Rhinosinusitis with Nasal Polyps

Omlyclo™ doses (mg) administered by subcutaneous injection every 4 weeks (light-grey area) or 2 weeks (white area)

Pretreatment Serum IgE (IU/mL)*	Dosing Freq.	Body weight (kg)							
		>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
		Dose (mg)							
30-100	Every 4 weeks	75	150	150	150	150	150	300	300
>100-200		150	300	300	300	300	300	450	600
>200-300		225	300	300	450	450	450	600	375
>300-400		300	450	450	450	600	600	450	525
>400-500		450	450	600	600	375	375	525	600
>500-600		450	600	600	375	450	450	600	
>600-700		450	600	375	450	450	525		
>700-800	Every 2 weeks	300	375	450	450	525	600		
>800-900		300	375	450	525	600			
>900-1000		375	450	525	600				
>1000-1100		375	450	600	INSUFFICIENT DATA TO RECOMMEND A DOSE				
>1100-1200		450	525	600	INSUFFICIENT DATA TO RECOMMEND A DOSE				
>1200-1300		450	525	INSUFFICIENT DATA TO RECOMMEND A DOSE					
>1300-1500		525	600	INSUFFICIENT DATA TO RECOMMEND A DOSE					

***1 IU/mL = 2.4 ng/mL = 2.4 mcg/L**
≥30-100 IU/mL = ≥72-240 ng/mL; >100-200 IU/mL = >240-480 ng/mL;
>200-300 IU/mL = >480-720 ng/mL; >300-400 IU/mL = >720-960 ng/mL;
>400-500 IU/mL = >960-1200 ng/mL; >500-600 IU/mL = >1200-1440 ng/mL;
>600-700 IU/mL = >1440-1680 ng/mL; >700-800 IU/mL = >1680-1920 ng/mL;
>800-900 IU/mL = >1920-2160 ng/mL; >900-1000 IU/mL = >2160-2400 ng/mL;
>1000-1100 IU/mL = >2400-2640 ng/mL; >1100-1200 IU/mL = >2640-2880 ng/mL;
>1200-1300 IU/mL = >2880-3120 ng/mL; >1300-1500 IU/mL = >3120-3600 ng/mL.

Refer to the Omlyclo™ Product Monograph for complete dosing and administration information including dosing adjustments.

PATIENT CONSENT

The CELLTRION CONNECT™ Patient Support Program (the "**Program**") is designed to support patients in Canada who have been prescribed a Celltrion product. Celltrion administers this Program via third-party service providers appointed by Celltrion ("**Program Administrators**"), and offers various support services for individuals. Depending on eligibility, these services may include education and training, product information, insurance reimbursement assistance, treatment services, or financial assistance (collectively called "**Support Services**").

Any information collected and shared to administer the Support Services may include personally identifiable information ("Personal Information") about me. This includes my contact information, date of birth, sensitive health information (such as medical conditions, treatments, care management, health insurance, and prescription details), and any other information disclosed in connection with the Support Services.

I understand and agree that the Program does not provide medical advice or replace the need for me to speak with my treating healthcare provider for medical-related inquiries. I also recognize that my participation in the Program is voluntary.

I understand that Program Administrator employees and/or agents will handle my Personal Information to provide Support Services. This information will be processed in accordance with privacy laws and Celltrion's privacy/data protection standards (available at https://www.celltrionhealthcare.ca/contactus/law/).

I agree to Celltrion and the Program Administrators collecting information from and sharing information with my healthcare providers and their staff, pharmacies, pharmacists, insurance companies, provincial public payers, or other healthcare and service providers (collectively referred to as "**Providers**") as necessary to provide me with the Support Services. Celltrion will not use or share my Personal Information for any purpose other than for the Program, unless required or permitted by law.

The Program Administrators may anonymize and aggregate my Personal Information with that of other patients and provide it to Celltrion and its service providers for the purposes of reporting, assessing, auditing, monitoring, improving, or evaluating the Program for the benefit of patients. My anonymized statistical and aggregated information may also be collected, shared, and published with healthcare providers and third parties for reimbursement, publication, or commercial purposes.

I agree to be contacted by the Program Administrators through various means (e.g., phone, fax, email, mail, SMS/text message, etc.) to coordinate Program services or inquire about my experience with the Program to improve the Support Services.

I agree that my de-identified Personal Information may be shared with Celltrion and my Providers for the purpose of reporting adverse events (side effects). Such information may be provided to Health Canada or to another regulatory agency to report any adverse drug events or as otherwise required by law.

I understand that my Personal Information may be stored or processed outside of Canada. If this is the case, then my information would be subject to the laws of the country where it is stored. That country may have laws that require my Personal Information be disclosed to the government under different circumstances than would Canada.

I understand and agree that Celltrion has the right without notice to (1) make changes to the scope of Support Services offered; (2) make changes to the eligibility requirements for the Support Services; or (3) discontinue the Program or any of the Support Services. If at any time Celltrion appoints a new Program Administrator, I will be notified of same and I hereby authorize Celltrion to transfer my Personal Information to the new Program Administrator for the purposes of continuing my participation in the Program. I understand that I have the right to have access to or to correct my Personal Information held by Program Administrators by contacting the Program at support@celltrionconnect.ca, or by telephone at: 1-855-966-1648. I understand that I have the right at any time to withdraw my consent to the use of my Personal Information but if I do decide to do so, I will no longer be participating in the Program or have access to the services.

In signing this form, I consent to the above.

☐ In addition to the above consent, I agree to the Program Administrator contacting me by electronic or other means for the purposes of market research. I acknowledge that I may at any time opt-out from such communications by advising Program Administrator by email at: support@celltrionconnect.ca.

Patient name (please print): _____

Patient signature: _____

Date: _____

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