XHALE+ PROGRAM Patient Enrollment and Consent Form

Pr Xolair® omalizumab

For patients prescribed PrXOLAIR® for chronic idiopathic urticaria (CIU), moderate to severe allergic asthma (AA), or severe chronic rhinosinusitis with nasal polyps (CRSwNP).
All sections **MUST** be completely filled out (PLEASE PRINT).
Unless encrypted, be mindful that email communications may not be safe. ***One form per email.***

Phone: 1-866-9XOLAIR (1-866-996-5247)
Fax: 1-833-9XOLAIR (1-833-996-5247)
Email: xhale@xhaleprogram.ca

PATIENT INFORMATION

First name _____ Last name _____

Date of birth (DD/MM/YYYY) _____ ☐ Female ☐ Male ☐ Non-binary

Mobile phone _____ Other phone _____

Preferred time to call: ☐ Morning ☐ Afternoon ☐ Evening

☐ I authorize the Program to leave a voicemail message at the above phone number(s).

Email _____

Address _____

City _____ Province _____ Postal code _____

FOR MINOR PATIENT

Legal guardian name _____

Relationship to patient _____

I would like to be enrolled in the Novartis XHALE+ program for XOLAIR® (omalizumab). I have read and agree to the patient consent on the reverse side of this document.

☐ I accept that representatives of the Program may contact me via electronic means, such as email or text message.

I consent to the Program collecting, using and disclosing my personal information (contact information) for purposes related to administration of Program services.

The Program may wish to contact you via electronic means; you will have the opportunity to opt-out from such communications.

Patient signature _____

Name _____ Date (DD/MM/YYYY) _____

TREATING PHYSICIAN

First name _____ Last name _____

Specialty _____ License # _____

Address _____

City _____ Province _____ Postal code _____

Office contact _____ Email _____

Office phone _____ Office fax _____

PRESCRIPTION INFORMATION

DIAGNOSIS

☐ Chronic idiopathic urticaria (CIU)
☐ Allergic asthma (moderate)
☐ Allergic asthma (severe)
☐ Severe chronic rhinosinusitis with nasal polyps

PRESCRIPTION & DISPENSING INSTRUCTIONS

XOLAIR® (omalizumab) for subcutaneous injection:

☐ New Rx ☐ Continued Tx

Duration of treatment (months): _____ (from 1st injection)

☐ Patient eligible for self-injection of pre-filled syringe after 3rd dose

Eligible patients for self-injection:

- Must have no prior history of anaphylaxis to either XOLAIR® or other agents (e.g., foods, drugs, biologics, etc.)
- Will need to receive the first 3 doses of XOLAIR® either by or under the supervision of a healthcare professional
- Will receive proper training on the preparation and administration of XOLAIR®
- Must have been trained to recognize early signs and symptoms of serious allergic reactions, and be able to treat anaphylactic reactions appropriately

DOSAGE

CIU

SC q 4 weeks ☐ 150 mg ☐ 300 mg

Medical history for reimbursement validation:

UAS7 score: _____

Previous therapy: _____

ALLERGIC ASTHMA (moderate to severe)

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: _____ lbs _____ 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: _____ lbs _____ kg

☐ IgE level test result: _____

SPECIAL INSTRUCTIONS

I certify that this prescription order is an original prescription. The designated pharmacy is the only recipient. The original will not be reissued. The above prescription parameters comply with the indications set forth in the Product Monograph.

I have read and agree to the Physician Declaration on the reverse side of this form.

Physician signature _____ Date (DD/MM/YYYY) _____

PLEASE COMPLETE ALL SECTIONS ENTIRELY TO ENSURE PROMPT REVIEW AND PROCESSING.

SC=subcutaneous; UAS7=urticaria activity score

Patient Enrollment and Consent Form

Section A

XOLAIR® (omalizumab) 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 (CRSwNP) inadequately controlled by intranasal corticosteroids alone.
- The treatment of adults and adolescents (12 years of age and above) with chronic idiopathic urticaria (CIU) who remain symptomatic despite H1 antihistamine treatment.

Consult the Product Monograph at www.novartis.ca/XolairMonograph for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monograph is also available by calling 1-800-363-8883.

Recommended XOLAIR® dose and dosage adjustment

1. Allergic asthma
Children 6 to <12 years of age

	BODY WEIGHT (kg)*									
Baseline IgE†	20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
≥30-100 IU/mL ≥72-240 ng/mL	75	75	75	150	150	150	150	150	300	300
≥100-200 IU/mL ≥240-480 ng/mL	150	150	150	300	300	300	300	300	225	300
≥200-300 IU/mL ≥480-720 ng/mL	150	150	225	300	300	225	225	225	300	375
≥300-400 IU/mL ≥720-960 ng/mL	225	225	300	225	225	225	300	300		
≥400-500 IU/mL ≥960-1,200 ng/mL	225	300	225	225	300	300	375	375		
≥500-600 IU/mL ≥1,200-1,440 ng/mL	300	300	225	300	300	375				
≥600-700 IU/mL ≥1,440-1,680 ng/mL	300	225	225	300	375					
≥700-800 IU/mL ≥1,680-1,920 ng/mL	225	225	300	375						
≥800-900 IU/mL ≥1,920-2,160 ng/mL	225	225	300	375						
≥900-1,000 IU/mL ≥2,160-2,400 ng/mL	225	300	375							
≥1,000-1,100 IU/mL ≥2,400-2,640 ng/mL	225	300	375							
≥1,100-1,200 IU/mL ≥2,640-2,880 ng/mL	300	300								
≥1,200-1,300 IU/mL ≥2,880-3,120 ng/mL	300	375								

Adult and adolescents 12 years of age and older

	BODY WEIGHT (kg)*								
Baseline IgE†	>20-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
≥30-100 IU/mL ≥72-240 ng/mL	150	150	150	150	150	150	150	300	300
≥100-200 IU/mL ≥240-480 ng/mL	150	150	300	300	300	300	300	225	300
≥200-300 IU/mL ≥480-720 ng/mL	150	300	300	300	225	225	225	300	375
≥300-400 IU/mL ≥720-960 ng/mL	300	300	225	225	225	300	300		
≥400-500 IU/mL ≥960-1,200 ng/mL	300	225	225	300	300	375	375		
≥500-600 IU/mL ≥1,200-1,440 ng/mL	300	225	300	300	375				
≥600-700 IU/mL ≥1,440-1,680 ng/mL	225	225	300	375					

2. Chronic rhinosinusitis with nasal polyps (18 years of age and older)

	BODY WEIGHT (kg)*							
Pretreatment serum IgE	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
30-100 IU/mL 72-240 ng/mL	75	150	150	150	150	150	300	300
>100-200 IU/mL >240-480 ng/mL	150	300	300	300	300	300	450	600
>200-300 IU/mL >480-720 ng/mL	225	300	300	450	450	450	600	375
>300-400 IU/mL >720-960 ng/mL	300	450	450	450	600	600	450	525
>400-500 IU/mL >960-1,200 ng/mL	450	450	600	600	375	375	525	600
>500-600 IU/mL >1,200-1,440 ng/mL	450	600	600	375	450	450	600	
>600-700 IU/mL >1,440-1,680 ng/mL	450	600	375	450	450	525		
>700-800 IU/mL >1,680-1,920 ng/mL	300	375	450	450	525	600		
>800-900 IU/mL >1,920-2,160 ng/mL	300	375	450	525	600			
>900-1,000 IU/mL >2,160-2,400 ng/mL	375	450	525	600				
>1,000-1,100 IU/mL >2,400-2,640 ng/mL	375	450	600					
>1,100-1,200 IU/mL >2,640-2,880 ng/mL	450	525	600					
>1,200-1,300 IU/mL >2,880-3,120 ng/mL	450	525						
>1,300-1,500 IU/mL >3,120-3,600 ng/mL	525	600						

Administration every 4 weeks
Administration every 2 weeks
Do not dose

* 1 kg=2.2 lb; 1 lb=0.45 kg
† 1 IU/mL=2.4 ng/mL=2.4 mcg/L

Chronic idiopathic urticaria (12 years of age and older):

150 or 300 mg administered every 4 weeks

- The efficacy of XOLAIR® in CIU patients is dose-dependent
- Dosing is not dependent on serum IgE (free or total) level or body weight

Prescribers are advised to periodically reassess the need for continued therapy.
Clinical trial experience in long-term treatment (>6 months) of CIU is limited.

Section B

Physician Declaration

I have read the Patient Consent and (1) agree to my patient being enrolled in the XHALE+ program ("Program"); (2) have prescribed the drug specified on this form in accordance with its product monograph; and (3) 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 accept that my information, including personal information, may be used by Novartis or its agents for reasons related to improving, monitoring and auditing its programs, for commercial or market research purposes and as otherwise required or permitted by law. Details about how my file will be maintained, shared and how to access/correct my information, are as set out in the Patient Consent.

I acknowledge that adverse events may be reported about my patients participating in the Program and understand I may be contacted by Novartis or its agents to provide follow-up information. As adverse event reports may need to be processed in and outside of Canada and forwarded to Canadian and foreign regulatory authorities,I understand that my information may be stored or processed outside of Canada.

I have discussed the Program with the patient who wishes to enroll and has agreed that I share their personal information with the Program for the purpose of contacting the patient and confirming enrollment.

Section C

Patient Consent

What is the XHALE+ program?

The XHALE+ program is a patient support program ("Program") provided by Novartis Pharmaceuticals Canada Inc. and/or its affiliates (collectively "Novartis", we, us, our) to provide Canadian patients who have been prescribed XOLAIR® patient support services. Your healthcare professional believes you could benefit from the Program. The Program services may include health/disease/product information, insurance reimbursement assistance or treatment services (the "Services").

A third-party service provider is the administrator of the Program: its employees and/or agents handle your Personal Information, which is processed in accordance with privacy laws and Novartis privacy/data protection standards. You will be notified should the administrator of the Program change, including in the case of administration by a Novartis department; your Personal Information will continue to be protected with equivalent safeguards.

Your participation in the Program is voluntary. If you choose not to participate, neither your medical treatment nor your insurance coverage eligibility will be impacted. However, if you do not participate, you cannot receive assistance or Services from the Program. The Program is not intended to provide medical advice or medical diagnoses. You agree to seek the advice of your physician or other qualified healthcare professional if you have health concerns, and not to disregard professional medical advice based on information obtained from the Program. Novartis reserves the right to modify or terminate the Program at any time without prior notice.

In the event that you elect to benefit from any external support referral service offered by the Program to help you locate available resources in your community, you understand that the third-parties to whom you may be referred by the Program are in no way affiliated with, or monitored by, Novartis. You understand that you are solely responsible for your interactions with these third-parties and Novartis cannot be held responsible for the information or services that these third-parties may offer to you.

Why is personal information collected, for which purposes and to whom could it be shared with?

Information, such as your date of birth, contact information, drug/medical, and insurance/financial information (collectively "Personal Information") is collected to communicate with you and provide you with the Program's Services, audit or monitor the Program, and perform certain activities as required or permitted by law, including to process and report adverse events ("AEs"). We may contact you at the contact information you have provided; email, phone or other (if via cellular, we will not assume any resulting cellular phone charges). Only relevant personnel will have access to your Personal Information.

Your Personal Information may be collected from and disclosed to healthcare professionals, insurance providers or other third-parties, as needed for the Program's administration and Services. Our third-party providers are contractually obliged to strict data protection and security requirements.

In the case of AE processing and reporting to regulatory authorities, if monitoring or auditing is performed, or if required and/or permitted by law, it may be that Novartis employees or agents not assigned to the Program will have access to your Personal Information.

Your Personal Information may be de-identified (replacing your identifying data with a code or label), aggregated (combined with other data) or anonymized to conduct analyses for commercial, research or publication purposes. Analyses are performed to help us improve our offers and services such as this Program, others, treatment reimbursement, disease educational campaigns, online communications and, may be conducted using digital capabilities.

Your Personal Information may be stored or processed outside of Canada, including for AEs processing and reporting requirements. In such case, Novartis ensures that your Personal Information is protected. Your Personal Information may be subject to the laws of foreign jurisdictions, with a different level of protection than your country of residence.

What happens if I withdraw from the Program?

You may revoke your consent at any time. Withdrawing your consent will result in the termination of your participation in the Program and its Services; no new personal information will be collected, the file containing your Personal Information will be maintained during the term of the Program for monitoring and regulatory purposes, de-identified, aggregated or anonymized data may continue to be used as described above.

You may request access or correction to your file by contacting the Innomar Privacy Officer at 3470 Superior Court, Oakville, ON, L6L 0C4 or Privacy.Officer@innomar-strategies.com.

By signing the consent, you agree to the collection, use and disclosure of your Personal Information as described herein. You can learn more about how Novartis protects privacy at www.novartis.ca/en/privacy-policy.

NOVARTIS

Pr Xolair® omalizumab

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