Cosentyx® secukinumab

XPOSE® Program enrollment form – DERMATOLOGY

Please email or fax completed form. Fax: 1-866-872-5771 Email: cosentyx@xposeprogram.ca
Telephone: 1-844-27XPOSE (1-844-279-7673)
Unless encrypted, be mindful that email communications may not be safe. ***One form per email.***

XPOSE by Novartis

Clear

Patient information

First name _____ Last name _____

Date of birth (DD/MMM/YYYY) _____ ☐ Male ☐ Female ☐ Other Weight (kg): _____

Health card number _____ Language: ☐ English ☐ French Other: _____

Address _____

City _____ Province _____ Postal code _____

Mobile phone _____ Other phone _____

Email: _____

Type of coverage: ☐ Public ☐ Private ☐ Other

Medical history for reimbursement

I=Intolerance; CI=Contraindication; F=Failure		Start – Stop Dates/Notes
☐ **Topicals (specify)** _____	☐ I ☐ CI ☐ F	_____ (MMM/YYYY) _____ (MMM/YYYY)
☐ **Phototherapy**	☐ I ☐ CI ☐ F	_____ (MMM/YYYY) _____ (MMM/YYYY)
☐ **Methotrexate**	☐ I ☐ CI ☐ F	_____ (MMM/YYYY) _____ (MMM/YYYY)
☐ **Acitretin**	☐ I ☐ CI ☐ F	_____ (MMM/YYYY) _____ (MMM/YYYY)
☐ **Cyclosporine**	☐ I ☐ CI ☐ F	_____ (MMM/YYYY) _____ (MMM/YYYY)
☐ **Biologic(s) (specify)** _____	☐ I ☐ CI ☐ F	_____ (MMM/YYYY) _____ (MMM/YYYY)
☐ **Other(s) (specify)** _____	☐ I ☐ CI ☐ F	_____ (MMM/YYYY) _____ (MMM/YYYY)

Tuberculosis (TB) screening*†

☐ **Completed** | **Requested:** ☐ QuantiFERON ☐ Skin test | ☐ **Pending** (no support req.)

Patient consent

I would like to be enrolled in the Novartis XPOSE® Program. I have read and agree to the collection, use and disclosure of my personal information as explained in the consent section (page 2).

Furthermore, I hereby request that the PSP administrator provide my prescription to my designated pharmacy, and I appoint the PSP administrator as my agent or, if I reside in Quebec, as my mandatary, to perform any acts necessary to have my prescription filled by my designated pharmacy.

I understand that Novartis reserves the right to modify or terminate the Program without prior notice.

I understand that I am solely responsible for: (i) verifying with my financial advisor(s) and public or private drug benefit providers the impact of accepting financial assistance through the Program; and (ii) complying with all applicable laws, policies, or guidance from government agencies and public or private drug benefit providers if I choose to accept such assistance.

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

Consent obtained by the prescriber from: ☐ Patient ☐ Legal guardian

Name _____ Relationship _____

X _____ _____

Signature Date (DD/MMM/YYYY)

IMPORTANT: If written consent cannot be obtained from patient/legal representative, please document when verbal consent was obtained and by whom. This will allow the XPOSE® Program to proceed with enrollment.

Verbal consent obtained by:

Name of HCP _____ Date (DD/MMM/YYYY) _____

Prescriber information

First name _____ Last name _____

Address _____

City _____ Province _____ Postal code _____ License # _____

Office contact name _____ Preference: ☐ Phone ☐ Email ☐ Fax

Telephone _____ Fax _____

Email: _____

Assessment details

Plaque Psoriasis (PsO)

BSA (%): _____

PASI: _____

DLQI: _____

☐ Face ☐ Palms ☐ Nails
☐ Plantar ☐ Genitals ☐ Scalp

Hidradenitis Suppurativa (HS)

Continuous 3-month trial of oral antibiotics with inadequate response? ☐ Yes ☐ No

Adalimumab trial? ☐ Yes ☐ No: _____

Lesions in ≥2 distinct anatomic areas? ☐ Yes ☐ No

Hurley Stage: ☐ II ☐ III

Total # abscesses: _____ Total # nodules: _____

Prescription information

COSENTYX® format:
☐ Auto-injector Pen (SensoReady® or UnoReady®, not available in 75 mg)
☐ Pre-filled syringe

Samples given: # _____

Plaque Psoriasis (PsO) - See page 2 for dosing information

Induction: ☐ 75 mg ☐ 150 mg ☐ 300 mg s.c. at Weeks 0, 1, 2, 3, and 4

Maintenance: ☐ 75 mg ☐ 150 mg ☐ 300 mg s.c. taken ☐ Monthly ☐ Every 2 wks (≥90 kg)

Duration: ☐ 12 months ☐ Other: _____ months

FOR ONTARIO USE ONLY: ☐ Meets LU476 criteria ☐ Does not meet LU476 criteria

See Ontario Drug Benefit formulary for full criteria. Formulary Search – Limited Use Note(s).

Hidradenitis Suppurativa (HS) - See page 2 for dosing information

Induction: ☐ 300 mg s.c. at Weeks 0, 1, 2, 3, and 4

Maintenance: ☐ 300 mg s.c. taken ☐ Monthly (every 4 weeks) ☐ Every 2 weeks

Duration: ☐ 12 months ☐ Other: _____ months

Medical clearance

Patient is cleared to start therapy: ☐ Yes ☐ No

Notes: _____

If samples provided, PSP to assume patient is medically cleared

Prescriber consent (MANDATORY)

X _____ _____

Prescriber signature Date (DD/MMM/YYYY)

ACKNOWLEDGEMENTS AND UNDERTAKINGS: 1) The above prescription parameters comply with the indications set forth in the Product Monograph. I represent, certify and warrant that I can legally order a prescription of the drug product in focus for this PSP. **2)** I have discussed the Patient Support Program ("PSP") with the patient who wishes to enroll and has consented that I share their personal information (name, email, contact number, prescription information) in this form with the PSP to contact patient and confirm enrollment. Additionally, I have explained the uses and communication of the patient's personal information to the patient, as described in the consent section (page 2). **3)** This prescription represents the original prescription drug order. I appoint the PSP to be my designated agent to forward this prescription by fax, or other mode of delivery, to the pharmacy chosen by the patient, which is the only intended recipient.

PERSONAL INFORMATION: I have read and agree to the collection, use and disclosure of my personal information for the purpose of managing the PSP, as set out in the consent section (page 2).

*This service will only be offered in provinces where there is no provincial access.
†Specific TB QuantiFERON results will be reported back to the Prescriber and the Program by the diagnostic laboratory. Any follow-up on positive TB is at the discretion/responsibility of the Prescriber.

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Have your patients take a photo to access **COSENTYX.ca** for more information. The Drug Identification Number (DIN) 02438070 is needed to sign in.

Recommended dose:

- **PsO adult with moderate to severe PsO:**
  - The recommended dose is 300 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4, followed by monthly maintenance dosing.
  - A maintenance dose of 300 mg every 2 weeks may provide additional benefit for adult patients with a body weight of 90 kg or higher.
- **PsO pediatric (≥6 years) with moderate to severe PsO:**
  - The recommended dose is **75 mg for patients weighing <50 kg** and **150 mg for patients weighing ≥50 kg** by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4, followed by monthly maintenance dosing.
  - Maintenance dose may be increased to 300 mg in pediatric patients (≥6 years, ≥50 kg), as they may derive additional benefit from the higher dose.
- **HS adult with moderate to severe HS:**
  - The recommended dose is 300 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing (every 4 weeks).
  - Maintenance dose of 300 mg every 2 weeks may be prescribed based on clinical response.

COSENTYX® is intended for use under the guidance of a healthcare professional. Patients may self-inject after proper training and when deemed appropriate. Prescribers are advised to periodically reassess the need for continued therapy.

Consent

Welcome to the Novartis Pharmaceuticals Canada Inc. ("Novartis", "we") XPOSE® for COSENTYX®.

The PSP services are available to any patient meeting the eligibility requirements for enrollment, which typically consist at minimum in a prescription for a drug treatment from an HCP as well as current eligibility under a federal or provincial health insurance plan.

CONSENT TO THE COLLECTION, USE AND DISCLOSURE OF PERSONAL INFORMATION (for more information, see the "Details" section)

Why do we collect personal information for the PSP?

We collect personal information to provide our services. This information can directly identify you (like your name) or indirectly identify you (with enough details). We may also use personal information to comply with regulatory reporting requirements, and for analytical purposes. We will ask for your specific consent if we need to use it for other reasons, unless the law allows us to use it without your consent.

I understand that Novartis reserves the right to modify or terminate the Program without prior notice.

What type of personal information is collected?

Patients: We collect your name, address, phone number, date of birth, health information, such as disease information and test results, and caregiver's name.

HCPs: We will collect your name, address, and information about your patients in the PSP, including the number of patients enrolled.

Caregivers or legal guardians: We collect your name, address, and phone number.

Who collects and has access to personal information?

Novartis or its appointed company manages the PSP. They collect and store your information securely and may share with HCPs, insurance companies, or other organizations, such as pharmacies, labs, and clinics that provide a service as part of the program.

Will we collect other personal information outside of the PSP?

No, we will ask for your additional consent to collect personal information not related to the PSP services. For example, we may ask for your permission to participate in market research.

How can you request access or corrections to your personal information in the PSP?

For questions, access or corrections to your information, or to withdraw consent, you can reach the Novartis Privacy Officer at global.privacy_operations@novartis.com or the Novartis XPOSE® Program for COSENTYX® at 1-844-279-7673.

For more information on our privacy practices, you may also consult our Canadian Privacy Notice at: https://www.novartis.com/ca-en/privacy.

How can you withdraw consent from the PSP?

You can withdraw consent anytime. Without it, we may not be able to provide services. Withdrawal stops future use of your information and new collection, but already collected information will remain in our database or adverse events database until it can be deleted as per health authorities' guidelines.

We may contact you by email or text to inform you about the PSP services. For SMS, message frequency varies and standard messaging rates may apply. You can opt out of these messages, but this may limit your use of the PSP services.

DETAILS ON HOW WE COLLECT, USE AND SHARE PERSONAL INFORMATION FOR THE PSP

Why do we collect personal information to run the PSP?

We collect personal information to:

- Confirm and manage prescriptions.
- Communicate with HCPs, patients or legal guardians/caregivers about treatment, patient care, and where applicable, regarding adverse events.
- Ensure we are connecting with the right patient or caregiver.
- Process insurance claims.
- Coordinate with service providers*
- Provide program services, like injection training, lab test coordination, and sending medical tests results.
- Arrange travel if the PSP offers travel assistance.
- Confirm patient prescriptions.
- Monitor the program's performance and service quality.
- Support business planning, optimization and strategy development.
- Compile information on treatment usage and disease management.

These analyses help us improve our services, create awareness campaigns, patient brochures, and provide drug information for HCPs. Most analyses use de-identified (replacing identifying data with a code or label) or anonymized data.

*In the event that you opt to benefit from any external service provider, referred by the Program, you understand that these are third parties who are in no way affiliated with Novartis. Novartis cannot be held responsible for the information or services these third parties may provide to you.

Do we collect any other personal information not connected to a PSP service?

No, unless we have obtained additional consent to collect and use personal information for research to advance the knowledge and data on drug, treatment or disease. These analyses conducted may not benefit you directly but are valuable to the healthcare community.

Who collects the personal information, and how is it protected?

The program administrator, Novartis or a company acting on behalf of Novartis, collects and stores personal information in a secure database using:

Encryption (converting personal information into a secret code).

Restricted access (individual usernames and passwords).

Only authorized personnel can access your information, including:

- Call center agents managing PSP requests.
- PSP HCPs providing treatment training.
- PSP staff overseeing program activities or handling complaints.
- Patient safety agents for managing adverse events.

External service providers, including drug reimbursement specialists, travel agencies, pharmacies, labs, and clinics, must protect personal information similarly.

Novartis personnel may access your information for supervision, audits, or reporting adverse events.

Also, any entity who the law allows could have access to your personal information.

Can personal information be transferred outside your province or Canada?

Personal information may be transferred outside of your province of residence or of Canada when:

- it is stored in a database outside your province or country of residence.
- it must be reported to health authorities worldwide in case of an adverse event.

The privacy laws that apply where we store or process your personal information may differ from those that apply in your location. While personal information is stored in another location, it may be accessed by courts, law enforcement, and national security authorities. For more information about our policies and practices regarding international transfers of personal information, contact us at global.privacy_operations@novartis.com.

What happens if you withdraw your consent?

Without your consent, we may not be able to provide the services. Withdrawal stops future use and new collection of your information, but already collected information will remain in our database or adverse events database until it can be deleted as per legal requirements and health authority guidelines.

COSENTYX® (secukinumab injection) is indicated for the treatment of:

- Moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy;
- Adult patients with moderate to severe hidradenitis suppurativa (acne inversa) who have responded inadequately to conventional systemic hidradenitis suppurativa therapy;
- Active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. COSENTYX® can be used alone or in combination with methotrexate;
- Active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy;
- Active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs);
- Moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy;
- Active enthesitis-related arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy;
- Active juvenile psoriatic arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.

Consult the Product Monograph at www.novartis.com/ca-en/CosentyxMonograph 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.

NOVARTIS

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MEMBER OF INNOVATIVE MEDICINES CANADA

For program-related inquiries, please call or email the XPOSE® Program at:
1-844-27XPOSE (1-844-279-7673)
cosentyx@xposeprogram.ca