XPOSE® Program enrolment and consent form:

For patients prescribed PrCOSENTYX® (secukinumab) for psoriatic arthritis, ankylosing spondylitis, or the juvenile idiopathic arthritis (JIA) categories of enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA)

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

All sections MUST be completely filled out

Patient information (please print)

The XPOSE® Program will contact you to assist with your insurance/reimbursement needs and provide you with information about the medication and your illness.

First name _____ Last name _____

Date of birth (DD/MM/YYYY) _____ ☐ Male ☐ Female ☐ Other

Address _____ City _____ Province _____ Postal code _____

Mobile phone (____) ____ - _____ Other (____) ____ - _____

Preferred time to call: ☐ Morning ☐ Afternoon ☐ Evening

Mode of communication: ☐ Phone ☐ Email ☐ Text message

Language: ☐ English ☐ French

Email _____ ☐ I consent to receive emails related to the Program.

Tuberculosis (TB) evaluation*†

☐ Pending

☐ Negative result Date (DD/MM/YYYY) _____

Comments: _____

Chest X-ray† (CXR)

☐ Required ☐ Not required

Test results†

☐ Positive ☐ Negative

Previous therapies

Please list any previous therapies: _____

Pharmacy services (optional)

Pharmacy services: indicate if the patient has a preferred pharmacy provider

_____

Patient signature

I have read and agree to the patient consent on the reverse side of this form.

X _____ Date (DD/MM/YYYY) _____

Patient signature

Physician signature

I certify that this prescription order is an original prescription. The designated pharmacy is the sole recipient. The original will not be reused.

X _____ Date (DD/MM/YYYY) _____

Physician signature

Referring physician (please print or stamp)

First name _____ Last name _____

License # _____

Address _____ City _____ Province _____ Postal code _____

Office contact name _____

(____) ____ - _____ (____) ____ - _____

Telephone Fax

Email _____

Preferred mode of communication: ☐ Phone ☐ Email ☐ Fax

Rx

COSENTYX® format: ☐ **SensoReady® pen** ☐ **Prefilled syringe**

Psoriatic arthritis

The recommended dose for psoriatic arthritis is 150 mg by subcutaneous injection, with initial dosing at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing.

Consider using the 300-mg dose for psoriatic arthritis patients with moderate to severe plaque psoriasis or who are anti-TNFα inadequate responders and who continue to have active psoriatic arthritis. Each 300-mg dose is given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg.

New Rx ☐ 150 mg s.c. ☐ 300 mg s.c. **Duration of treatment:** _____ (months)

Renewal ☐ 150 mg s.c. ☐ 300 mg s.c.

Induction dose at weeks 0, 1, 2, 3 and 4. Maintenance dose monthly.

PsA assessment details

HAQ: _____

CRP: _____

BASDAI: _____

DAS-28: _____

Radiographic evidence: _____

Swollen joint count: _____

For payer purposes: has the patient had previous biologic exposure?

☐ Yes ☐ No

If yes, specify which one(s): _____

Ankylosing spondylitis

The recommended dose for ankylosing spondylitis is 150 mg by subcutaneous injection, with initial dosing at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. If a patient continues to have active ankylosing spondylitis, consider a monthly maintenance dosage of 300 mg. Each 300-mg dose is given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg.

New Rx ☐ 150 mg s.c. **Duration of treatment:** _____ (months)

Renewal ☐ 150 mg s.c. ☐ 300 mg s.c.

Induction dose at weeks 0, 1, 2, 3 and 4. Maintenance dose monthly.

AS assessment details

BASDAI: _____

BASFI: _____

HAQ: _____

Spinal pain VAS (cm): _____

Radiographic evidence: _____

For payer purposes: has the patient had previous biologic exposure?

☐ Yes ☐ No

If yes, specify which one(s): _____

Juvenile idiopathic arthritis categories: Enthesitis-Related Arthritis (ERA) and Juvenile Psoriatic Arthritis (JPsA)

The recommended dose is based on body weight. For patients weighing <50 kg, the dose is 75 mg, and for patients weighing ≥50 kg, the dose is 150 mg. It is administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing (every 4 weeks). Each 75-mg dose is given as one subcutaneous injection of 75 mg. Each 150-mg dose is given as one subcutaneous injection of 150 mg.

New Rx ☐ 75 mg s.c. ☐ 150 mg s.c.

Renewal ☐ 75 mg s.c. ☐ 150 mg s.c.

Induction dose at weeks 0, 1, 2, 3 and 4. Maintenance dose monthly.

ERA and JPsA assessment details

Body weight (lb): _____

JADAS: _____

Disease activity VAS (mm): _____

Number of joints with active arthritis: _____

Number joints with limited range of motion: _____

C-reactive protein standardized value: _____

For payer purposes: has the patient had previous biologic exposure?

☐ Yes ☐ No

If yes, specify which one(s): _____

Directives from the prescriber

I confirm the prescription and permit start at the time indicated below.

Therapy initiation ☐ I approve to start the patient

☐ Initiate therapy at a later date: _____ (DD/MM/YYYY)

Other instructions: _____

* This service will only be offered in provinces where there is no provincial access.

† Specific TB results will be reported back to the requester by the Program. Any follow-up on positive TB results is at the discretion/responsibility of the requester.

Cosentyx® secukinumab

XPOSE by Novartis

Recommended dose for PsA

1.	Psoriatic arthritis	150 mg s.c.
2.	Psoriatic arthritis patients with moderate to severe plaque psoriasis or who are anti-TNFα inadequate responders and who continue to have active psoriatic arthritis	300 mg s.c.

Recommended dose for AS

1.	Ankylosing spondylitis	150 mg s.c.
2.	Patients who continue to have active ankylosing spondylitis following treatment with 150-mg dose	300 mg s.c.

Recommended dose for ERA and JPsA (Based on body weight)

1.	Patients <50 kg	75 mg s.c.
2.	Patients ≥50 kg	150 mg s.c.

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.

Physician declaration

I have read the Patient Consent and (1) agree to my patient being enrolled in the XPOSE® Program (the "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 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 enrol and has agreed that I share their personal information with the Program to contact the patient and confirm enrolment.

Patient consent

XPOSE® is a patient support program (the "Program") provided by Novartis Pharmaceuticals Canada Inc. and/or its affiliates (collectively "Novartis", "we," "us," "our") to provide Canadian patients who have been prescribed COSENTYX® 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.

Information such as your date of birth, contact information, drug/medical and insurance/financial information (collectively "Personal Information") is collected to communicate with you, 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 will have access to your Personal Information.

Novartis and/or its agents may de-identify (replace your identifying data with a code or label), aggregate (combine with other data) or anonymize data from the Program to conduct analyses for commercial, research or publication purposes. Analyses are performed to help us improve our offers and services such as this Program, other programs, treatment reimbursement, disease educational campaigns and online communications, and may be conducted using digital capabilities.

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 Program at 1-844-279-7673.

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 https://www.novartis.ca/en/privacy-policy.

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

- moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy;
- 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.ca/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.

For program-related inquiries, please call or email the XPOSE® Program at:

- **1-844-27XPOSE (1-844-279-7673)**
- **cosentyx@xposeprogram.ca**

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Printed in Canada 230181E

REVIEWED BY PAAB

MEMBER OF INNOVATIVE MEDICINES CANADA

Cosentyx® secukinumab

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