Ontario

Ministry of Health

Exceptional Access Program (EAP) – Biosimilar Exemption Request

Instructions

Consider using the Special Authorization Digital Information Exchange (SADIE) at ontario.ca/sadie to submit exemption requests electronically to enable faster processing.

Fax the completed form and/or any additional/relevant information to 416-327-7526 or toll-free to 1-866-811-9908; or send your request Delivery and Eligibility Review Branch, Exceptional Access Program, 3rd Floor, 5700 Yonge Street, Toronto ON M2M 4K5.

This form is only for prescribers to request an exemption for Ontario's Biosimilar Switch Policy for a patient who **has been using an originator (innovator) biologic reimbursed through the Ontario Drug Benefit (ODB) program** previously authorized through the Exceptional Access Program. **True allergies to the comparative non-medicinal ingredients and pharmaceutical features of every biosimilar version are rare**. If a patient is deemed to be intolerant to the biosimilar used, refer to the product monograph on the Health Canada website to ensure that they have used a biosimilar version that has the most similar non-medicinal ingredients and features to the originator (innovator) product to justify exemptions due to intolerances and allergies.

This form is only to be used by prescribers to request an exemption for Ontario's Biosimilar Switch Policy for a patient who **has been using an originator (innovator) biologic reimbursed through the Ontario Drug Benefit (ODB) program** previously authorized through the Exceptional Access Program and is unable to switch from an originator (innovator) biologic or who is requesting to switch back to the originator following biosimilar switch. Sufficient clinical information must be provided to support a temporary exemption or a long-term medically necessary exemption. Please note, if you are requesting an exemption that requires Health Canada Side effect forms to be submitted, copies of the form are not required by the pharmacy.

Do not use this form if your patient does not have an existing EAP approval. These may include patients new to the ODB program who have been stabilized on their originators through another funding mechanism; patients on insulin who do not meet the LU biosimilar exemption criteria; patients on an originator for plaque psoriasis on the ODB formulary. For such requests full clinical details must be submitted for assessment of the request by EAP to ensure that the Ministry funding criteria for initials and approvals under met. You may wish to consider SADIE to facilitate new requests for EAP approvals.

Section 1 – Prescriber Information

First Name	Initial	Last Name

Street Number	Street Name

City	Postal Code

Office Fax Number	Office Telephone Number

Section 2 – Patient Information

First Name	Initial	Last Name

Ontario Health Insurance Number

Date of Birth (yyyy/mm/dd)

Section 3 – Drug Requested

Originator (Innovator) Biologic Requested	Diagnosis for which the biologic is used	How long has patient used the Originator (Innovator)? years

Dosage and Frequency	Duration of Exemption Requested months years	EAP Request number for current approval of Originator (Innovator)

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Section 4 – Clinical Information

Reason for exemption (check all that apply)	Required information - attach consult notes and additional detail as applicable to support the request for exemption
☐ Current pregnancy	Expected delivery date (yyyy/mm/dd)
☐ Palliative end-of-life care	Approximate date when palliative end-of-life care was initiated (yyyy/mm/dd)
☐ Needs more time to switch	Reason for the delay to switch to a biosimilar and the date when a new prescription is expected
☐ Side effects to 2 Biosimilar versions and wish to resume use of Originator (Innovator)	**Must** attach the copies of completed Health Canada Side Effect forms describing the adverse effect(s) experienced with each biosimilar product. These must also be submitted to Health Canada. May attach additional information about how other causes of symptoms were ruled out.
☐ Pediatric patient using etanercept for weight-based dosing	Weight of the patient and approximate duration of requested exemption before a biosimilar version may be suitable for dosing needs. kg months **or** years
☐ Cannot switch to biosimilar version for medical reasons	Provide a detailed summary of the clinical rationale to explain why a biosimilar version of the biologic cannot be used. Include applicable clinical scores associated with the condition, relevant surgical procedures, and responses to all medications that have been used to manage their condition. Attach additional information, consult notes and other relevant information regarding the patient's complex clinical course.
☐ Other	Provide the reason that a patient cannot switch to originator (innovator) and submit additional clinical details.

Prescriber Name	Prescriber Signature	License number	Date (yyyy/mm/dd)