Ontario

Ministry of Health and Long-Term Care

Ontario Public Drug Programs (OPDP)
c/o Compassionate Review Policy
Drug Programs Delivery Branch
5700 Yonge Street 3rd floor
Toronto ON M2M 4K5

Initial Request for Compassionate Review Policy

This Form Is Intended For New Requests Only.
Refer to your approval letter for information required for extension of previously granted CRP funding.

Fax the completed form and/or any additional relevant information to our expedited fax line 416 327-0981 ***or*** send to Compassionate Review Policy (CRP), 3rd floor, 5700 Yonge Street, Toronto ON M2M 4K5.

For copies of this form, visit http://www.health.gov.on.ca/en/public/forms/odb_fm.aspx.

Ministry may request additional documentation to support the request.
Ensure that all appropriate information for each section is provided to avoid delays.

Section 1 - Prescriber Information			**Section 2 - Patient Information**		
First Name	Initial	Last Name	First Name	Initial	Last Name
Mailing address Street Number / Street Name			Ontario Health Insurance Number		
City		Postal Code	Gender ◯Male ◯Female		
Treatment Centre			Body Weight (kg)		
Fax Number	Telephone Number		Date of Birth *(yyyy/mm/dd)*		

***Request will not be processed unless correct fax number OR an accurate and complete address is provided.**

Screening Checklist: Review the following eligibility questions

If you answer NO to any of the following questions, your request is NOT eligible:

1. Does your patient have an immediately life, limb, or organ threatening condition?
2. Is the patient's disease or clinical circumstance rare and unusual *(less than 25 similar cases per year in Ontario anticipated)*?
3. Is there published evidence demonstrating that this drug has a clinical benefit?
   (The minimum level of evidence required is a case series, or multiple case-reports where n ≥ 25 in total.)
4. Has the patient failed all other appropriate alternatives available on the Ontario Drug Benefit Formulary or through the Exceptional Access Program?
5. Has the patient failed all appropriate non-pharmacological alternatives?

If you answer YES to any of the following questions, your request is NOT eligible:

1. Is the requested drug to be used for cancer therapy?
   (Note that Cancer Care Ontario's Case-by-Case Review Program considers funding requests for oral and injectable cancer drugs for cancer patients who have rare clinical circumstances that are immediately life threatening. Refer to: https://www.cancercare.on.ca/toolbox/drugs/cbcrp)
2. Is the drug the standard of care or standard regimen for the requested indication?
3. Can a supply of the drug be obtained by other means *(i.e. from a manufacturer's compassionate access program or through a clinical trial)*?
4. Does the drug have a Notice of Compliance in Canada or recently received approval from the U.S. Food and Drug Administration for the indication requested?

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Section 3 - Requested Drug Product

Drug Name

DIN(s) *(if known)*

Dosage and Frequency of administration requested

Anticipated start date of treatment *(yyyy/mm/dd)*

* The patient must meet the CRP criteria in full even when ongoing funding is required to continue on therapy the patient has already started.

Planned duration of therapy & rationale

If the drug is not approved for sale in Canada, has the release of the drug for this patient been granted by Health Canada's Special Access Program (SAP)?

◯Yes ◯No *(how will drug be obtained?)*▶

Discuss results of alternative funding requests made *(e.g., to manufacturer program, private insurance, etc.)*

Discuss whether funding of this drug is available through a clinical trial

Section 4 - Diagnosis/ Clinical Information

Attach any clinical notes, consultations, laboratory and test results *(e.g., radiology, culture and sensitivity, bloodwork genetics, etc.)* that support your request submission.

Diagnosis for which the drug is required

Incidence and prevalence of disease *(or of patient's clinical presentation)*

Details of the patient's clinical presentation

Details of co-morbidities

Describe how the patient's condition is immediately life, limb or organ threatening

Current medications *(with dosing regimens)*

Treatment goals

Section 5 - Evidence

Attach additional notes, citations, or full references as necessary to support your request submission.

Level of evidence to use the requested medication in this clinical setting *(check all that apply)*

◯Randomized controlled trials ◯Prospective studies ◯Observational studies ◯Case Series ◯Case Reports

◯Other*(specify)*

Summary of effectiveness

Summary of safety data

Monitoring parameters

Section 6 - Treatment History

Describe *(or attach)* treatment guidelines for the above diagnosis

Details of all pharmacological alternatives tried OR rationale why appropriate alternatives cannot be tried

Name	Dosing Regimen	Start Date	End Date	Contraindication or Response to Therapy

Details of all non-pharmacological alternatives *(e.g., surgical procedures, behavioural therapy, etc.)*

Description	Treatment Date(s)	Contraindication or Response to Therapy

Discuss whether the patient is eligible for any clinical trials for novel therapies for this clinical condition

The information on this form is collected under the authority of the *Personal Health Information Protection Act*, 2004, S.O. 2004, c.3, Sched. A (PHIPA) and Section 13 of the *Ontario Drug Benefit Act*, R.S.O. 1990c.O.10 and will be used in accordance with PHIPA, as set out in the Ministry of Health and Long Term Care "Statement of Information Practices", which may be accessed at www.health.gov.on.ca.

If you have any questions about the collection or use of this information, call Ontario Public Drug Programs at 1 866 811–9893 or contact the Director, Exceptional Access Program, 5700 Yonge St., 3rd Floor, Toronto ON M2M 4K5.

CPSO Number	Prescriber Signature	Date (yyyy/mm/dd)