



**NON-FUNDED PROCESS REQUEST FORM**  
**The Newfoundland and Labrador Prescription Drug Program (NLPDP)**

Pharmaceutical Services  
 Department of Health and Community Services  
 P.O. Box 8700, Confederation Bldg.  
 St. John's, NL A1B 4J6

Phone: (709) 729-6507  
 Toll Free Line: 1-888-222-0533  
 Fax: (709) 729-2851

**Patient Information**

<b>Patient Name</b>	<b>Date of Birth</b>	<b>NLPDP Drug Card/MCP Number</b>
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<b>Address</b>	<b>Patient Weight (kg)</b>
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**Drug Requested**

Please check one:  Non-benefit drug     Special authorization drug, unapproved use     Special Access drug

<b>Drug</b>	<b>DIN</b>
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<b>Strength/Dosage form</b>	<b>Frequency of administration</b>
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<b>Expected start date</b>	<b>Duration of therapy</b>
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**Diagnosis and Reason for Use**

**Diagnosis**

**Rationale for Therapy**

**Published evidence (attach copy)**

**Reason for use over benefit alternatives**

**If patient is currently taking the requested product, please provide start date & objective evidence of its efficacy**

**Current and/or Previous Medications**

<b>Drug</b>	<b>Dose</b>	<b>Duration</b>	<b>Outcome</b>
<input type="checkbox"/> current <input type="checkbox"/> previous			
<input type="checkbox"/> current <input type="checkbox"/> previous			
<input type="checkbox"/> current <input type="checkbox"/> previous			
<input type="checkbox"/> current <input type="checkbox"/> previous			

**Provide patient's current drug therapies for other conditions:**

**Clinical Information**

**Please provide relevant medical data (e.g. diagnostic testing results, laboratory results)**

**Funding Alternatives**

Patient cannot enroll in clinical trial  
 Compassionate Program is not available

**Prescriber Information/Requested by:**

Prescriber Name: \_\_\_\_\_ License Number: \_\_\_\_\_ Phone Number: \_\_\_\_\_  
 Address: \_\_\_\_\_ Fax Number: \_\_\_\_\_  
 Pharmacist \_\_\_\_\_ Pharmacy \_\_\_\_\_  
 Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## **NON-FUNDED PROCESS**

Under the Non Funded Review Policy, the Medical Practitioner designated by the Minister will consider requests for drugs with a Notice of Compliance (NOC) but is not covered under NLPDP, and also for drugs without an NOC and Drug Identification Number (DIN) issued by Health Canada if the physician indicates in the request that approval has been obtained through the Health Canada Special Access Program (SAP). This would require the physician to apply in writing providing *detailed* documentation as outlined below:

### **Diagnosis**

- Please provide detailed information outlining specific diagnosis noting any relevant severity of symptoms, patient co-morbidities, allergies, or other relevant patient specific information to indicate a rare clinical situation.
- The severity of the disease/condition

### **Supporting Clinical Evidence**

- Please provide published evidence to support the request. The minimum acceptable level of evidence is case-series or multiple case reports where  $n > 25$  in total.
- The evidence of efficacy must be overwhelmingly in favour of the drug. Ideally randomized controlled trial data (RCT) should be available, individual case reports, Phase I and II trials and expert opinion provide the lowest level of evidence and may be considered insufficient data to support non-funded requests.
- Safety evidence to support the potential benefits outweigh the risks.

### **Clinical Alternatives**

- Please provide detailed information outlining failure of ALL available and appropriate alternatives available on the NLPDP Formulary AND all appropriate non-pharmacological alternatives. Failure of other clinically appropriate and/or less expensive alternatives not funded by NLPDP that may be considered through this Non-Funded process or those funded through other agencies (i.e. Regional Health Authority) must also be considered.

### **Funding Alternatives**

- Before consideration for funding is considered, documentation must be supplied outlining that the patient cannot enrol in a clinical trial AND no other funding options (including compassionate supply through the manufacturer, funding under other programs etc.) are available.

The medical practitioner designated by the minister would then review the information and make a decision. The decision of that consultant with respect to the special authorization is final.

**Please note:** The Non-Funded Process is not available for drug therapies that are awaiting NOC and/or review through an established expert review process (e.g. CDR, pCODR or ACDR). These therapies will not be funded until there is an implementable funding recommendation from the expert review committee and a listing decision from the Department.

## **Definitions**

**Benefit Drugs:** Drugs that are covered through NLPDP as either regular benefits or through Special Authorization

**Non-benefit Drugs:** Drugs that are not covered through NLPDP

**Special Access Drugs:** Drugs that are not marketed in Canada that are made available to practitioners through the Special Access Program, Health Canada

**Special Authorization Drugs:** Drugs covered through NLPDP with pre-defined reimbursement criteria based on recommendations from an expert review committee