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ENVIRONMENTAL SCAN

# Coverage Categories at Public Drug Plans in Canada


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**Funding:** CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

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## Abbreviations

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| **AB** | Alberta |
| **BC** | British Columbia |
| **CAF** | Canadian Armed Forces |
| **CSC** | Correctional Services Canada |
| **ES** | Environmental Scan |
| **MB** | Manitoba |
| **NIHB** | Non-Insured Health Benefits |
| **NL** | Newfoundland and Labrador |
| **NS** | Nova Scotia |
| **ON** | Ontario |
| **PE** | Prince Edward Island |
| **QC** | Quebec |
| **RAMQ** | Régie de l'assurance maladie du Québec |
| **SK** | Saskatchewan |
| **VAC** | Veterans Affairs Canada |
| **YT** | Yukon |

## Summary


- Drugs that are listed in the public drug plan formularies are assigned various coverage categories taking into consideration the limitations and restrictions (if applicable) for the reimbursement of the drugs. This Environmental Scan (ES) provides information on the various coverage categories under which drugs are listed at the 15 Canadian federal, provincial, and territorial drug plans' formularies.
- All of the 15 public drug plans have one or more form of restricted coverage category, which can be divided into three groups. Five public drug plans formularies list drugs that are reimbursed when prescribed/dispensed as per the limits and restrictions or terms and conditions stated in the formulary. Four drug plans formularies list drugs that are reimbursed when prescribed/dispensed as per the limits and restrictions stated in the formulary; and require the prescriber to write a pre-specified code for the drug in the prescription. There are 14 drug plans formularies that list drugs that are reimbursed when prescribed/dispensed as per the limits and restrictions stated in the formulary; and require prior approval / special authorization through an established application processes. A variety of terminologies are used to refer to the three types of restricted coverage category, with little consistency across drug plans.
- Nine drug plans have provision for a case-by-case review process for non-formulary drugs, that is, drugs that do not fall under unrestricted or restricted benefit; thereby requiring an individualized medical review.


## Background

Publicly funded federal, provincial, and territorial drug plans provide coverage for eligible drugs to eligible populations within their jurisdictions. These eligible drugs, listed in the public drug plans' formularies, are assigned various coverage categories; that is, the formulary benefit status terminology used by jurisdictions that can be broadly classified as unrestricted or restricted benefits.[1,2]

Unrestricted benefit refers to drugs that are covered by a drug plan without any limits or restriction for reimbursement. Depending on the drug plan, this type of formulary benefit status is referred to as benefit, open benefit, full benefit, general benefit, standard benefit, or regular benefit.[1,2]

Restricted benefit refers to drugs that are covered with certain limits or restrictions for reimbursement, such as quantity or frequency limits, specific clinical criteria limits, or defined patient subgroup or prescriber/specialist limits. Restricted benefit can be divided into three groups:[1,3-27]

- Drugs that are reimbursed when prescribed/dispensed as per the limits and restrictions stated in the formulary.
- Drugs that are reimbursed when prescribed/dispensed as per the limits and restrictions stated in the formulary and require the prescriber to write a pre-specified code for the drug in the prescription.
- Drugs that are reimbursed when prescribed/dispensed as per the limits and restrictions stated in the formulary; and require prior approval /special authorization. There is a requirement to apply for reimbursement, with the required clinical details by the authorized prescriber using established application processes (e.g., use of specific authorization forms). Each request is subject to a medication review by staff responsible for claims adjudication at the public drug plan before approval for coverage is granted.

Depending on the level of limit or restriction and requirement for prior approval, drug plans refer to the restricted benefit status as special authorization, exceptional access program, exceptional drug status, limited use, limited coverage drug, or prior authorization.

Under certain circumstances, some drug plans may also consider covering certain drugs that are not routinely covered (through restricted or unrestricted benefit) on a case-by-case basis; that is, it requires an individualized medical review.[3-5,7-9,12-14,20,21,24,25]

## Objectives

This ES provides information on the various coverage categories under which drugs are listed in the Canadian federal, provincial, and territorial drug plans' formularies for reimbursement.

## Methods

The findings of this ES are based on information obtained from the Canadian public drug plan formulary websites. No bibliographic literature searches were performed. Official websites of the Canadian public drug plans were searched between October 10, 2020 and October 30, 2020. Information was gathered from the following 15 publicly funded drug plans (10 provincial, one territorial, and four federal drug plans) listed below:

**Provincial/territorial plans**

- Alberta (AB) Drug Benefit List
- British Columbia (BC) Pharmacare Formulary
- Manitoba (MB) Pharmacare Drug Formulary
- New Brunswick (NB) Drug Plan Formulary
- Newfoundland and Labrador (NL) Prescription Drug Program Formulary
- Nova Scotia (NS) Pharmacare Formulary
- Ontario (ON) Drug Benefit Formulary
- Régie de l'assurance maladie du Québec (RAMQ in QC)
- Prince Edward Island (PE) Pharmacare Formulary
- Saskatchewan (SK) Formulary
- Yukon (YT) Drug Formulary

**Federal plans**

- Canadian Armed Forces (CAF) Drug Benefit List
- Correctional Services Canada (CSC) National Formulary
- Non-Insured Health Benefits (NIHB) Drug Benefit List
- Veterans Affairs Canada (VAC) Drug Formulary

It should be noted that publicly reimbursed medications for residents of Nunavut and the Northwest Territories follow the coverage category and reimbursement criteria of the NIHB program.[28,29]

## Research Questions

The following research question was addressed:

- What are the various coverage categories and the respective terminologies, under which reimbursed drugs are categorized by the Canadian federal, provincial, and territorial drug plans

## Consultations

- Representatives from the federal, provincial, and territorial health ministries were consulted to validate the information gathered from the public drug plans' websites.[30] The consultation period ended on November 17, 2020; therefore, the information summarized in this report is up-to-date as of November 17, 2020. The information regarding coverage categories was validated by representatives from 10 provincial and territorial drug plans (AB, BC, MB, NB, NL, NS, ON, QC, PE, and SK); and from the four federal drug plans (CAF, CSC, NIHB, and VAC).
- Some information presented in this report was not available in the public domain and was obtained through personal communication with representatives from the federal, provincial, and territorial health ministries. When this occurred, permission was obtained to publish this information in this report and all details obtained through personal communication were referenced accordingly.

# Findings

The following section presents a summary of the findings relating to coverage categories for eligible drugs at the 15 public drug plans. Public drug plans provide coverage for drugs under various programs, which are based on age (e.g., seniors), income (pre-specified income threshold), or a medical condition (e.g., cystic fibrosis, cancer) among others. The formularies listed below may be applicable to more than one drug program for a given drug plan. Of note, Canadian provincial and territorial abbreviations are used to refer to the respective jurisdictional drug plan formularies. It should be noted that publicly reimbursed medications for residents of Nunavut and the Northwest Territories follow the coverage category and reimbursement criteria of the NIHB program.[28,29]

Table 1 provides an overview of the coverage categories at the 15 public drug plan formularies, and the respective terminologies used by the drug plans to refer to these categories.

### 1. Unrestricted Benefit

Unrestricted benefit, which is one of the benefit status categories, is defined as the following across the 15 public drug plans:

- benefit (QC, NS, PE, YT)
- regular benefit (BC, AB, SK, NB, CAF)
- open benefit (NL, NIHB, CSC)
- general benefit (ON)

- standard benefit (VAC)
- part 1 benefit (MB).

There are no limits or restriction for reimbursement for drugs that are assigned this status. Overall, the majority of the drugs within each drug plan fall under the unrestricted benefit coverage category.[3-27]

**2. Restricted Benefit**

There is one or more forms of restricted benefit category at all of the 15 public drug plans. Details on the restricted coverage categories at each drug plan is provided in Appendix 1.

a) AB, MB, QC, NL, and NIHB formularies list drugs that are reimbursed when prescribed/dispensed as per the limits and restrictions or terms and conditions stated in the formulary. These limits and restrictions could be in terms of quantity limits, frequency limits, limited to certain patient subgroups (e.g., specific age group), or prescribed by a certain specialist. When prescribed within the limits and restrictions or terms and conditions — as specified in the formularies — further approval is not required.[4,9,15,21,27] This benefit status is referred as the following:

   - restricted benefit (AB, QC)
   - limited restricted benefit (AB)
   - part 2 benefit (MB)
   - open benefit with limitations (NL)
   - limited Use – no prior authorization required (NIHB).

   AB also has a process for step therapy, whereby if a patient has made a claim for the first-line drug product(s) within the preceding 12 months, the claim for the step therapy drug product will be approved. A first-line drug product includes any drug(s) or drug product(s) that, under the Drug Products Special Authorization criteria, are required to be utilized before reimbursement for the step therapy drug product is permitted.[26]

   AB may allow optional special authorization for some drugs (within the prior approval/special authorization category as noted later in this document), where prior approval is not needed if certain clinical and/or prescriber criteria are met.[26]

Some drugs are covered only under special medical circumstances to ensure its appropriate use, and access to these drugs are limited through the following two mechanisms.

b) ON, QC, NS, and CSC formularies list drugs that are reimbursed when prescribed/dispensed as per the limits and restrictions stated in the formulary; and require the prescriber to write a pre-specified code for the drug in the prescription.[6,9,13,24] In ON and CSC, the pre-specified code that is written on the prescription is known as RFU code.[13,24] A specific terminology used to refer to the pre-specified code written on the prescription was not identified for QC, and it was referred to as code. In NS, the pre-specified code that is written on the prescription is known as criteria code. In NS, some exception status drugs are assigned such criteria code to allow the drugs to be prescribed /dispensed without SA, as long as the criteria code is stated in the prescription.[6]

This benefit status is referred to as the following:

- limited use (ON), — RFU code required
- exceptional medication — coded (QC) — code required
- exception status drug with criteria code (NS) — criteria code required
- benefit with criteria (CSC) RFU code required.

c) Except for CSC, all other 14 drug plans (AB, BC, SK, MB, ON, QC, NB, NS, NL, PE, YT, NIHB, VAC, and CAF) formularies list drugs that are reimbursed when prescribed/dispensed as per the limits and restrictions stated in the formulary; and require prior approval/SA. There is a requirement to apply for reimbursement, with the required clinical details by the authorized prescriber using established application processes (e.g., use of specific authorization forms). Each request is subject to a medication review by staff responsible for claims adjudication at the public drug plan before approval for coverage.[5-12,16,18,19,21-23,25,26] This benefit status is referred to as the following:

   - special authorization (AB, NB, NL, PE, VAC, CAF)
   - exception drug status (SK, YT)
   - exception status drugs (NS)
   - part 3 exception drug status (MB)
   - exceptional access program (ON)
   - exceptional medication — uncoded (QC)
   - limited use — prior authorization required (NIHB)
   - special authority/limited coverage drug (BC).

   Depending on the drug plan, the medication and the condition being treated, the duration of approval may range from a one time only fill to coverage with no end date. Some drug plans may provide retroactive coverage, that is coverage may be provided for a specified period of time after the application is received (but under review, that is, before a decision has been made) to ensure immediate access to the drugs. For example, in YT, the Formulary Working Group reviews applications noted as Exception Drug coverage on a monthly basis; hence, to provide coverage until the application is reviewed, a 30-day approval for the patient may be requested. If a 30-day approval was granted and the exception application was approved, the client will continue to be covered. If declined, the program will discontinue payment after 30 days.

### 3. Non-Formulary Review Process

Under certain circumstances, some drug plans may also consider coverage for certain drugs that is not routinely provided through restricted or unrestricted benefit on a case-by-case basis**,** that is, it requires individualized medical review.[3,7-9,12-14,21,24,25] BC, SK, ON, QC, NB, NS, NL, NIHB, and CSC have provision for non-formulary case-by case review process for drugs that are not currently a benefit with the drug plan. This provision is referred to as the following:

- exceptional case-by-case review (SK)
- compassionate review policy (ON)

- exception patient program (QC)
- formulary exception review process (NB)
- exception review process (NL)
- exception (NIHB)
- exception benefit (CSC).

NS may also consider coverage for non-benefit drugs in exceptional circumstances with a written request from a prescriber.[31] BC does not have an official provision for a case-by case review, but the drug plan does complete case-by-case reviews of drugs that are non-benefit through the general Special Authority mechanism. (Clifford Lo, BC Pharmacare Formulary: personal communication, Nov 2020). NIHB also has an appeals process available in circumstances when coverage for a benefit through the NIHB program is denied.[20]

Table 1 presents information on the coverage category (grouped as unrestricted benefit, restricted benefit, and provision for case-by-case review of non-formulary drugs) for each public drug plan. Appendix 1 provides a detailed overview of the restricted coverage category, that is the formulary benefit status terminology used by jurisdictions.

## Table 1: Coverage Categories at Canadian Public Drug Plan Formularies and Provision for Case-By-Case Review of Non-Formulary Drugs

| Public drug plan formulary | Unrestricted benefit | Restricted benefit[a] | | | Provision for a case-by-case review of non-forumary drugs |
|---|---|---|---|---|---|
| | | Reimbursed when prescribed /dispensed as per the limits and restrictions stated in the formulary | Reimbursed when prescribed /dispensed as per the limits and restrictions stated in the formulary | Reimbursed when prescribed /dispensed as per the limits and restrictions stated in the formulary | |
| **British Columbia Pharmacare Formulary** | Regular benefit | NA | NA | Special authority/ limited coverage drug | Case-by case review available[c] |
| **Alberta Drug Benefit List** | Regular benefit | • Restricted benefit<br>• Limited restricted benefit<br>• Step therapy<br>• Optional special authorization | NA | Special Authorization | NA |
| **Saskatchewan Formulary** | Regular benefit | NA | NA | Exception drug status | Exceptional case-by-case review |
| **Manitoba Drug Benefits and Interchangeability Formulary** | Part 1 benefit | Part 2 Benefit | NA | Part 3 (exception drug status) | NA |
| **Ontario Drug Benefit Formulary** | General benefit | NA | Limited Use -*RFU code required* | Exceptional Access Program | Compassionate Review Policy |
| **RAMQ List of Medication** | Benefit | Restricted Benefit | Exceptional Medication —Coded — code required | Exceptional Medication — uncoded | Exception Patient Program |
| **New Brunswick Drug Plans Formulary** | Regular benefit | NA | NA | Special Authorization | Formulary Exception Review Process |
| **Nova Scotia Pharmacare Formulary** | Benefit | NA | Exception Status Drug with criteria code – *criteria code required* | Exception status drug | Case-by case review available |
| **The Newfoundland and Labrador Prescription Drug Program Formulary** | Open benefit | Open Benefit with limitations | NA | Special authorization | Exception review process |

| Public drug plan formulary | Unrestricted benefit | Restricted benefit[a] | | | Provision for a case-by-case review of non-forumary drugs |
|---|---|---|---|---|---|
| | | Reimbursed when prescribed /dispensed as per the limits and restrictions stated in the formulary | Reimbursed when prescribed /dispensed as per the limits and restrictions stated in the formulary | Reimbursed when prescribed /dispensed as per the limits and restrictions stated in the formulary | |
| **Prince Edward Island Pharmacare Formulary** | Benefit | NA | NA | Special authorization | NA |
| **Yukon Pharmacare Formulary** | Benefit | NA | NA | Exception drug status | NA |
| **Non-Insured Health Benefits Formulary[b]** | Open benefit | • Limited use (no PA required)<br>• Limited use (no PA required; quantity/ frequency limits) | NA | Limited use (PA required) | • Exception<br>• Appeals |
| **Correctional Services Canada Formulary** | Open benefit | NA | Benefit with criteria – *RFU code required* | NA | Exception benefit |
| **Veterans Affairs Canada Formulary** | Standard benefit | NA | NA | Special authorization | NA |
| **Canadian Armed Forces Formulary** | Regular benefit | NA | NA | Special authorization | NA |

NA = not applicable; PA = prior authorization; RAMQ = Régie de l'assurance maladie du Québec; RFU = reason for use.

[a] See Appendix 1 for details on various categories of restricted benefits at each drug plan.

[b] Also applicable to Nunavut and the Northwest Territories.

[c] Clifford Lo, BC Pharmacare Formulary: personal communication, Nov 2020.

Source: Canadian public drug plan formularies.[3-29,31]

## Conclusions

Publicly funded federal, provincial, and territorial drug plans provide coverage for eligible drugs to eligible populations within their jurisdictions. However, some drugs have restricted access, primarily to ensure their appropriate use. As such, drug plans assign drugs listed in their formularies various benefit statuses taking into consideration the limitations and restrictions (if applicable) for the reimbursement of the drugs. This ES provides information on the various coverage categories under which drugs are listed at the 15 Canadian federal, provincial, and territorial drug plans' formularies for reimbursement. The information in this report was collected from the public domain — namely, the public drug plan websites — and subsequently validated by 14 drug plans.

The coverage categories can be broadly classified as unrestricted and restricted benefit. Overall, the majority of the drugs within each drug plan fall under the unrestricted benefit category, where there are no limits or restrictions for reimbursement for drugs that are assigned this status.

All of the 15 public drug plans have one or more types of restricted benefit category, whereby drugs are covered with certain limits or restrictions for reimbursement, such as quantity or frequency limits, limited by specific clinical criteria, or limited to a defined patient subgroup or prescriber/specialist. Five drug plans (AB, MB, QC, NL, and NIHB) formularies list drugs that are reimbursed when prescribed and dispensed as per the limits and restrictions or terms and conditions stated in the formulary. Four drug plans' (ON, QC, NS, and CSC) formularies list drugs that are reimbursed when prescribed/dispensed as per the limits and restrictions stated in the formulary; *and* require the prescriber to write a pre-specified code for the drug in the prescription. There are 14 drug plans' (AB, BC, SK, MB, ON, QC, NB, NS, NL, PE, YT, NIHB, VAC, and CAF) formularies that list drugs that are reimbursed when prescribed/dispensed as per the limits and restrictions stated in the formulary; *and* require prior approval/special authorization. For this benefit status, there is a requirement to apply for reimbursement, with the required clinical details by the authorized prescriber using established application processes (e.g., use of specific authorization forms).

Nine drug plans (BC, SK, ON, QC, NB, NS, NL, NIHB, and CSC) have provision for a case-by-case review process for non-formulary drugs, that is, drugs that do not fall under unrestricted or restricted benefit; thereby requiring an individualized medical review.

There are different terminologies used to refer to the unrestricted coverage category; the most common terms used by drug plans are regular benefit, open benefit, or benefit. A variety of terminologies are used to refer to the three types of restricted coverage category, with little consistency between drug plans; except for special authorization or exception drug that are used by 10 drug plans to identify drugs that require prior authorization. Similarly, there is a lack of consistency across the terms used to refer to the case-by-case review process for non-formulary drugs used by drug plans.

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# Appendix 1: Details of Restricted Benefit Categories

## BC Pharmacare Formulary

### Special Authority/Limited Coverage Drug

- "These include drugs that are covered only under specific medical circumstances. This is because some drugs only work for certain patients or are more costly than others, but are equally safe and effective drug treatments.
- Drugs in the following categories require Special Authority approval to be eligible for full PharmaCare coverage. To be eligible for coverage, Special Authority approval must be in place before the prescription is filled (that is, before a patient pays for a prescription). Coverage cannot be provided retroactively.
  - Limited Coverage: Medications that generally are not first-line therapies or that have more cost-effective alternatives.
  - Non-reference (partially covered): For patients who experience an adverse reaction or treatment failure on the reference drug.
  - Alternative products: For patients unable to use the low-cost alternative drug due to an allergy.
  - Drugs not marketed in Canada: For instance, Health Canada "Special Access Program" drugs are covered in exceptional circumstances only.
  - Biologics and biosimilars: Most biologics require Special Authorization approval. Those that have biosimilars are generally covered on an exceptional basis only, for patients who cannot take a biosimilar for documented medical reasons."[17,18]

### Case-By-Case Review

BC does not have an official provision for a case-by case- review, but the drug plan does complete case-by-case reviews of drugs that are non-benefit through the general Special Authority mechanism. (Clifford Lo, BC Pharmacare Formulary: personal communication, Nov 2020).

## Alberta Drug Benefit List

### Restricted Benefits or Limited Restricted Benefits

"Some drugs are restricted to certain criteria, for example, specific age groups or when prescribed by certain specialist. When prescribed within the limits and restrictions prior approval is not required. Some drugs may be reimbursed if prescribed outside these restrictions, but they will require Special Authorization.

- Restricted Benefits: Selected devices or drug products are eligible benefits with restrictions in the Alberta Drug Benefit List.
- Limited Restricted Benefits: Selected drug products are eligible benefits with limits and restrictions in the Alberta Drug Benefit List."[27]

## Step Therapy Benefits

"Step Therapy is a mechanism to provide access to select drug products that are eligible for coverage according to the step therapy process, as outlined below.

- If a patient has made a claim for the First-Line* Drug Product(s) within the preceding 12 months, the claim for the step therapy drug product will be approved.
- The automated re-time adjudication system will read the patient's claims history to determine if the required First-Line* Drug Product(s) have been claimed within the preceding 12 months.
- Subsequent claims for Drug Product(s) permitted by step therapy will continue to be approved as long as the Drug Product has been claimed within the preceding 12 months.
- The regular special authorization approval process will continue to be available for step therapy approvals for those patients whose First-Line* drug claims cannot be adjudicated through the automated real-time claims adjudication system.

Note: *A First-Line Drug Product includes any drug(s) or drug product(s) that, under the Drug Products Special Authorization criteria, are required to be utilized before reimbursement for the Step Therapy drug product is permitted."[26]

## Special authorization benefits

"Special authorization is a mechanism to provide access to certain drugs according to defined clinical criteria. Special authorization request forms are completed by physicians and reviewed by clinical pharmacists. Prior approval must be granted to ensure coverage by special authorization. Drug Products Eligible for Consideration by Special Authorization Drug Products may be considered for coverage by special authorization under one or more of the following circumstances, unless a specific product falls under the criteria for Drug Products not eligible for consideration by special authorization.

- The drug is covered by Alberta Health under specified criteria. Drug Products and indications other than those specified are not eligible for consideration by special authorization.
- The Drug Product is normally covered by another government program or agency for a specific approved clinical condition, but is needed for the treatment of a clinical condition that is not covered by that government program or agency.
- The Drug Product is required because other Drug Products listed in the Alberta Drug Benefit List are contraindicated or inappropriate because of the clinical condition of the patient.
- The particular brand of Drug Product is considered essential in the care of a patient, where the least cost alternative (LCA) price policy would otherwise apply. Coverage of a specific brand may be considered where a patient has experienced significant allergic reactions or documented untoward therapeutic effects with alternate brands in an interchangeable grouping. Coverage of a brand name product will not be considered in situations where the interchangeable grouping includes a pseudo-generic to the brand name Drug Product.
- A particular Drug Product or dosage form of a Drug Product is essential in the care of a patient where the maximum allowable price (MAC) price policy would otherwise apply. Exceptions may occur at the Drug Product level. Coverage may be considered only where a patient has experienced significant allergic reactions or documented untoward therapeutic effects with the Drug Product which establishes the MAC pricing.

Prior approval must be granted by Alberta Blue Cross to ensure coverage by special authorization. For those special authorization requests that are approved, the effective date for authorization is the beginning of the month in which the physician's request is received by Alberta Blue Cross. Special authorization is granted for a defined period as indicated in each applicable special authorization Drug Product criteria (the "Approval Period"). If continued treatment is necessary beyond the Approval Period, it is the responsibility of the patient and physician to re-apply for coverage prior to the expiration date of the Approved Period, unless the Auto-Renewal Process or Step Therapy Approval Process apply.

**Optional Special Authorization** of select drug products: Some drug products may be considered for coverage by optional special authorization for patients covered under Alberta Health-sponsored drug programs, provided they meet the official optional special authorization criteria, as recommended by the Alberta Health Expert Committee on Drug Evaluation and Therapeutics, and approved by the Minister of Health."[26]

*Role of the Prescribers:* "In conjunction with the criteria, prescribers have two options by which patients may be eligible for coverage of these select optional special authorization drug products.

- Prescribers can register to be a designated prescriber. Registration allows for patients to receive coverage of select drug products without special authorization as long as the prescription is written for one of the criteria for coverage set out in this section. Should a designated prescriber wish to prescribe one of the select drug products outside the coverage criteria, they may do so but must indicate this on the prescription; however, patients will not be eligible for payment under the Alberta government-sponsored program for such prescription and the patient may choose to receive the product at their expense. The registration form may be found on the previous page.
- Prescribers who choose not to register will be considered non-designated prescribers. Such prescribers will be required to apply for special authorization on the patient's behalf."[26]

## Saskatchewan Formulary

### Exception Drug Status (EDS)

"Certain drugs are reviewed and recommended by the Drug Advisory Committee of Saskatchewan (DACS) for coverage under the EDS Program. All recommendations must be approved by the Minister of Health. The drugs usually fall into one of the following categories:

- The drug is ordinarily administered only to hospital in-patients, but is being administered outside of a hospital because of unusual circumstances.
- The drug is not ordinarily prescribed or administered in Saskatchewan, but is being prescribed because it is required in the diagnosis or treatment of an illness, disability, or condition rarely found in Saskatchewan.
- The drug is infrequently used because Formulary products are usually effective but are contraindicated or found to be ineffective due to the clinical condition of the patient.
- The drug has been deleted from the Formulary but is required by patients previously stabilized on the drug.
- The drug has potential for use in other than approved indications.
- The drug has potential for the development of widespread inappropriate use.

- The drug is more expensive than listed alternatives and offers an advantage in only a limited number of indications.

Drugs approved for EDS coverage are subject to the same deductible and co-payment as the patient's Formulary drugs."[7,8]

### Exceptional Case-by-Case Review

"On rare occasions drugs are required for non-approved indications on a case by case basis. In order to conduct a timely review of these requests, the drug review committee requests the following information be provided by the prescriber:

- the disease or problem being treated
- list of previous therapies tried and the response achieved
- other non-exception options available and why not appropriate
- name of the drug being requested
- clinical evidence to strongly support the use of the drug for the condition being treated
- outcome measures that will be followed to assess the effect of the drug
- dose of the drug and length of time to be used."[7]

## Manitoba Drug Benefits and Interchangeability Formulary

### Part 2 Benefit

"Includes drug products that are eligible for Pharmacare benefits only when prescribed for the terms and conditions indicated in the Formulary."[15]

### Part 3 Exception Drug Status (EDS)

"Certain drugs are approved for coverage under the Exception Drug Status (EDS) Program when they meet specific criteria and upon review and recommendation of the Manitoba Drug Standards and Therapeutics Committee (MDSTC). The drugs usually fall into one of the following categories:

- The drug is ordinarily administered only to hospital in-patients but is being administered outside of a hospital because of unusual circumstances.
- The drug is not ordinarily prescribed or administered in Manitoba but is being prescribed because it is required in the diagnosis or treatment of an illness, disability, or condition rarely found in Manitoba.
- Evidence, including therapeutic and economic evidence, provided to the minister in accordance with the criteria established by him or her, supports a specific treatment regime which includes use of the drug or other item. [16]

The doctor must make an application to the Exception Drug Status office. Individuals are notified in writing of the decision.[16]

When an EDS drug is approved as a benefit, the cost will be covered through the Pharmacare Program during the time period authorized by the EDS Program and after the clients Pharmacare deductible has been met."[16]

## Ontario Drug Benefit Formulary

### Limited Use (LU) drugs

"These drugs are covered only under special medical circumstances. The prescribing doctor or nurse practitioner must confirm that the patient's circumstances require treatment with a LU drug by writing a three-digit code on the prescription, called the Reason for Use code. Some LU drugs are covered for days or weeks, some for a year or years, while some are approved for lifetime coverage."[13]

### Exceptional Access Program (EAP)

"The EAP may help pay for a drug that's not currently covered by the Ontario Drug Benefit (ODB) program, if the patient qualifies for the EAP and the drug is covered through the EAP.[12,14]

To qualify for the EAP, including applications through the Compassionate Review Policy, the patient must:

- already qualify — and have applied — for the ODB program
- be prescribed the drug by an Ontario doctor licensed through the College of Physicians and Surgeons of Ontario or an Ontario nurse practitioner licensed through the College of Nurses of Ontario
  - a Quebec or Manitoba doctor may prescribe the drug if you live on the border with either of these provinces
- get the prescription filled at a pharmacy in Ontario that is specially licensed to dispense drugs under the ODB program
  - doctors specially licensed as dispensing physicians may also fill prescriptions in their office.[12,14]

Only a doctor or nurse practitioner can apply for coverage through the EAP or Compassionate Review Policy. Pharmacists who specialize in the EAP consider each application. In some cases, applications are sent out for medical expert review. Once an application is submitted, and if it's approved, the cost of the drug will be covered for up to 30 days prior to the date the application is received. Coverage usually lasts for two weeks to a lifetime, depending on the type of drug."[12,14]

### Compassionate Review Policy (CRP):

"Where there are rare clinical circumstances in immediately life-, limb-, or organ-threatening conditions, the Executive Officer will also consider requests for drugs or indications in the absence of a Committee to Evaluate Drugs (CED) review. Requests must be submitted by authorized prescribers (i.e., physicians or nurse practitioners) and meet the criteria for the Compassionate Review Policy.[12,14]

Note: Requests for cancer drugs are considered under the Case-by-Case Review Program (CBCRP) which is administered by Cancer Care Ontario (CCO) on behalf of the Ministry of Health. Information on the application process, FAQs, eligibility criteria and program policies can be found on the CCO website (www.cancercare.on.ca/cbcrp)."[12,14]

## RAMQ List of Medication

### Restricted Benefits

In Quebec, selected devices or drug products are eligible benefits with restrictions stated in the List of Medications.[9]

### Exceptional Medication

"The public plan covers, under certain conditions, the prescription drugs indicated in the Exceptional medications section of the List of Medications. There are two types of exceptional medications:

- Coded**:** The health professional writes a code on the prescription so that it will be covered. The prescription drug can be obtained at the pharmacy without delay.
- Uncoded**:** The health professional must send the public plan an authorization request before the prescription drug can be covered. The beneficiary is able to obtain it at the pharmacy once authorization has been granted."[9]

### Exception Patient Program (case-by-case review)

"The public plan also covers certain prescription drugs, notably those not on the List of Medications for insured persons with an exceptional need. The health professional will send the public plan an authorization request so that the beneficiary may qualify for the program. If authorization is granted, the prescription drug will be covered, and the patient can obtain it at the pharmacy."[9]

## New Brunswick Drug Plan Formulary

### Special Authorization

"Certain drugs are eligible for coverage under the New Brunswick Drug Plans through special authorization. Drugs listed as special authorization benefits have specific criteria that must be met before they are approved for reimbursement. The criteria are developed by the expert advisory committees based on the evidence considered in the Drug Review Process. To request coverage through special authorization, the requestor must provide all of the required information in the general request form or the specific request form.[25]

All drugs approved through special authorization may be subject to a renewal process. Additional information may be required to ensure that the drug is having the expected effect and is still needed.[25]

### Formulary Exception Review Process

Under exceptional circumstances, requests for drugs not listed in the Formulary or for an indication not included in the special authorization criteria, may be reviewed on a case-by-case basis. This does not include drugs that are ineligible for consideration through special authorization.

Requests must be in writing and include the following information:

- dose and administration frequency of the requested drug
- diagnosis or description of the patient's medical condition

- relevant previous therapies tried along with duration, dose, and results and rationale for why an alternative drug listed on the plan Formulary cannot be used
- substantial scientific evidence for the requested use supporting the clinical effectiveness of the drug
- risk assessment of serious harm to the member's life, health, or recovery without the drug
- relevant clinical measures and laboratory results supporting the request
- clinical outcome measures to determine when the drug should be stopped or continued."[25]

## The Nova Scotia Pharmacare Formulary

### Exception Status Drug

"Coverage of exception status drugs will be approved according to the criteria specified in the formulary, and upon review of a prescriber's written request (through the Forms for Exception Status Drug request)."[6]

### Criteria Code

"As an alternative to sending a written request to the Pharmacare office, certain exception status drugs have been assigned criteria codes. To allow for online payment of these drugs, the criteria code may be provided by the prescriber on the prescription or confirmed by the pharmacist. The use of these codes offers the prescriber and the pharmacist access to immediate coverage for patients who clearly meet the exception status criteria. The criteria codes are indicated within the exception criteria in the formulary."[6]

### Request for Coverage (for non-benefit drug)

"NS may also consider coverage for non-benefit drugs in exceptional circumstances following a written request from the prescriber. Prescribers may also contact Pharmacare and speak directly to a pharmacist consultant to request coverage."[31]

## The Newfoundland and Labrador Prescription Drug Program Formulary

### Open Benefit Drug Products With Limitations

Drugs listed in this category are available to beneficiaries if their submissions for reimbursement meet the specified limitations.[4]

### Special Authorization and Exceptional Review

Drugs listed in categories, Special Authorization and Exceptional Review are available to beneficiaries if their submissions for reimbursement meet the specified limitations. Section 18 of The Pharmaceutical Services Act entitled Special Authorization Review outlines the Special Authorization Review and Exceptional Review Process (formerly known as Non-funded Process)[3,5]

- *" A prescriber may, on behalf of a beneficiary, request a drug for which special authorization is required under the program.*

- *A request shall be considered in accordance with criteria developed by*
  - *the National Common Drug Review or the Joint Atlantic Common Drug Review or their successor organizations;*
    *(a.1) the pan-Canadian Oncology Drug Review; or*
  - *other committees or processes as determined by the minister and adopted by the minister.*
- *If a request for special authorization has been declined based on the criteria referred to in subsection (2), a prescriber may request an internal review of the matter.*
- *If, after consideration in an internal review the request for special authorization is again denied, a prescriber may apply to the medical practitioner designated by the minister for a review of the decision and the decision of that medical practitioner with respect to the special authorization is final." [3,5]*

Subsection (4) above provides the authority for the Exceptional Review Process.[3,5]

## Special Authorization

"The Newfoundland and Labrador Prescription Drug Program (NLPDP) uses evidence-based decision-making processes to consider coverage of drugs under the program. Therefore, all drugs are reviewed by one of the committees noted above. These committees make recommendations on whether a drug should be listed under a public drug program with or without restrictions meaning if a beneficiary must meet certain criteria before the drug can be considered.[3,5]

Coverage of special authorization drugs will be assessed:

- according to defined criteria
- upon receipt of the required clinical information from a health care provider involved in the patient's care
- subject to a drug review by staff of the Pharmaceutical Services Division.[3,5]

Drugs listed in this category are available to beneficiaries who meet certain defined criteria. Special authorization request forms have been prepared at the request of health care providers that may be used to facilitate the special authorization assessment process. The use of the form, while not mandatory, is encouraged to expedite the assessment process. Special Authorization request must be made by a health care professional on behalf of the beneficiary documenting medical need. The beneficiary and the requesting prescriber will receive written notification of the program's decision."[3,5]

## Exceptional Review Process

"The Exceptional Review Process is intended to be a mechanism for a final appeal to the Newfoundland and Labrador Prescription Drug Program (NLPDP) for a drug that is considered under Special Authorization, but has not been reviewed for the requested indication (diagnosis).[3,5]

Under the Exceptional Review rocess (formerly known as Non-Funded Process), the medical practitioner designated by the minister will consider requests for drugs with a notice of compliance from Health Canada and are considered under the NLPDP special authorization process. This would require the health care provider to apply in writing providing detailed documentation, including diagnosis, supporting clinical evidence; safety evidence to support the potential benefits must outweigh the risks; clinical alternatives and

funding alternatives. In cases where a health care provider does not provide supporting clinical evidence as well as clinical and funding alternatives, the request will not be reviewed or considered under the Exceptional Review Process. 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.[3,5]

Exceptional Review requests will not be accepted:

- if the drug requested is not listed on the NLPDP benefit list under Special Authorization. Only drugs designated as Special Authorization are considered under the Exceptional Review Process
- if the drug requested is listed on the NLPDP benefit list under Special Authorization, but the beneficiary has already been denied coverage, it will not be considered for exceptional review and it will be denied.[3,5]

Note: Exceptions may apply when additional compelling evidence is presented that was not provided with the original request. Once an Exceptional Review request is finalized it is forwarded to the medical practitioner for assessment and decision.[3,5]

- If the drug will not be reviewed by one of the expert committees it will not be considered for the Exceptional Review process and denied.
- If a drug is undergoing review by one of the expert committees utilized by the program it will not be considered for the exceptional review process and will be denied.
- If the drug has been reviewed by one of the expert committees and is not recommended for coverage it will not be considered for the Exceptional Review process and denied."[3,5]

## Prince Edward Island Pharmacare Formulary

### Special Authorization

"Some medications in the Prince Edward Island Pharmacare Formulary are approved on a special authorization basis only. If your physician prescribes a drug in this category, they will have to submit a Standard Special Authorization request form to have a medication considered for coverage.[11]

Under the AIDS/HIV, Diabetes, Family Health Benefit, Financial Assistance, High-Cost Drugs, Institutional Pharmacy, Nursing Home, Seniors, and Transplant Drugs programs, certain drug products may be considered for SA coverage under the following circumstances:

- therapeutic alternatives listed in the Formulary are contraindicated or have been found to be ineffective
- drugs for which there is no alternative listed in the Formulary."[11]

Special Authorization coverage will not be considered for medications that have not yet been reviewed for coverage by either the Atlantic Expert Advisory Committee (AEAC), CADTH's Canadian Expert Drug Advisory Committee (CEDAC) or CADTH's pan-Canadian Oncology Drug Review (pCODR) or that have received a negative recommendation from one of these expert advisory committees.[11]

"Special Authorization coverage will normally only be approved for the treatment of indications and in dosages listed in the official product monograph approved by Health

Canada and published in the most recent edition of the Compendium of Pharmaceuticals and Specialities (CPS).[11]

The duration of approval of Special Authorization coverage may range from a one time only fill to coverage with no end date. This will be based upon the medication requested and the condition being treated.[11]

Medications approved through the Special Authorization process are limited to a maximum 30 day supply per fill unless otherwise noted in drug criteria."[11]

## Yukon Pharmacare Formulary

### Exception Drug Status

"Certain drugs are listed under Exception Drug Status, and the drug must be prescribed in accordance to the criteria stated in the formulary for reimbursement. Prior approval is required. Yukon physicians only may apply for Exception Drug Status. Application must be submitted in writing and must provide sufficient details to permit thorough objective assessment. Comprehensive supporting information must be provided.[10]

An Exception Drug Status application must be submitted when a physician prescribes such a drug. To provide coverage until the application is reviewed, a 30-day approval for the patient may be requested by the pharmacist. The pharmacist must phone the respective drug program advising them. If the patient is active, the Exception drug will be covered for 30 days providing the drug is listed in the Formulary. All new drugs will be reviewed according to the CADTH Common Drug Review process before listing in the Formulary.[10]

The Formulary Working Group will review application for Exception drug coverage on a monthly basis. The Formulary Working Group's decision will be communicated to the physician and the patient. Only the physician will be informed as to the therapeutic reason for non-approval.[10]

If a 30-day approval was granted and the Exception application was approved, the client will continue to be covered. If declines, the program will discontinue payment after 30 days.[10]

Exception Drug Status coverage will remain in effect until such time as the physician requests a change in the status, or until reassessment is required. There are some Exception drugs that have specific time periods for coverage listed with criteria."[10]

## Non-Insured Health Benefits Formulary

### Limited use benefits

"These Limited use drugs are drug products listed on the Non-Insured Health Benefits Drug Benefit List that may be inappropriate for general listing but have value in specific circumstances. These products will have specific criteria for provision as a benefit under the NIHB program. A product will be designated for limited use when:

- it has the potential for widespread use outside the indications for which benefit has been demonstrated
- it has proven effectiveness, but is associated with predictable severe adverse effects
- it is usually a second- or third-line choice for treatment and is required because of allergies, intolerance, treatment failure, or non-compliance with a first-line alternative

- it is very costly and a therapeutically effective alternative is available as a benefit.[21]

There are three types of limited use benefits:

1. Limited use benefits that do not require prior approval. These include but are not limited to:
    - multivitamins (which are benefits for children up to 19 years of age)
    - prenatal and postnatal vitamins (which are benefits for women of childbearing age, 12 to 50 years old).[21]
2. **Benefits, which have a quantity and/or frequency limit.** A maximum quantity of drug is allowed within a specified period of time. No prior approval is required for the recipient to obtain the allowable quantity of drug within the specified period. An example of a category of drugs with a quantity and frequency limit is smoking cessation products. Recipients are eligible to receive up to three treatment courses of nicotine replacement therapy (NRT) within a 12-month period with quantity limits, which include two courses of NRT patches and one course of NRT products used PRN (i.e., gums, lozenges, inhalers).[21]
3. **Limited use benefits which require prior approval** (using the "Limited Use Drugs Request Form"). Limited use benefits and the criteria for their coverage are identified in the Drug Benefit List. The criteria are also listed on the forms faxed to prescribers for completion."[21]

### Exceptions (case by case review)

"Exception drugs are drug products which are not listed in the DBL. These drug products may be approved in special circumstances upon receipt of a completed "Exception Drugs Request Form" from the attending licensed practitioner.[21]

- When the prescription is for a recognized clinical indication and dose that is supported by published evidence or authoritative opinion.
- When there is significant evidence that the requested drug is superior to drugs already listed as program benefits.
- When a patient has experienced an adverse reaction with a best-price alternative drug, and a higher cost alternative is requested by the prescriber.
- When there is supporting evidence that available alternatives are ineffective, toxic, or contraindicated (personal preference alone does not justify an exception)."[21]

### Appeals

"NIHB also has an appeals process available in circumstances when coverage for a benefit through the NIHB program is denied. The following documents must be provided when an appeal for a drug benefit is submitted:

- condition for which the drug is being requested
- diagnosis and prognosis (including what other drugs have been tried)
- relevant diagnostic test results
- reason for the proposed treatment
- any additional supporting information, such as case notes from your health provider."[20]

## Correctional Services Canada National Formulary

### Benefits With Criteria

"Certain drug products may be inappropriate for general listing, but have value in specific circumstances. These products may be recommended as "benefits with criteria" and are detailed in Appendix C: Criteria Medications.

A product may be designated for criteria listing when it meets any of the following conditions:

- Has the potential for widespread use outside the indications for which benefit has been demonstrated.
- Has proven effectiveness, but is associated with predictable severe adverse effects.
- Is usually a second- or third-line choice for treatment and is required because of allergies, intolerance, treatment failure or non-compliance with a first-line alternative.
- Is considered to be one of many drugs in a specific therapeutic class and having similar therapeutic response that it is considered only upon unsuccessful trial of other "preferred" medications in the class.
- Is very costly and a therapeutic effective alternative is available as a benefit.[24]

A Reason for Use (RFU) code is assigned to each criteria. The medications will be provided by the pharmacy when prescribed in accordance with the criteria and when accompanied by a valid, fully completed prescription with the appropriate RFU code on the prescription. The RFU code verifies that the patient meets the criteria. The RFU code can be communicated by one of the following methods:

- writing on Doctor's Order form or Medication Reconciliation
- verbally during a verbal or telephoned order by a prescriber or by a nurse.[24]

The authorization is valid for the duration indicated by the listed criteria.[24]

If an applicable code could not be found, the request will require the completion of the Correctional Services Canada form Benefit with Criteria and Non-Formulary Medication Request."[24]

### Exception Benefits (case-by-case review)

"Drugs that are not openly listed or do not meet all Formulary criteria may be approved in special circumstances. Requests for exceptions will require the Benefits with Criteria and Non-Formulary Medication Request form from the attending physician. These requests will be reviewed on a case-by-case basis.[24]

Requests for exceptions will be considered when the following criteria are met:

- The prescription is for a recognized clinical indication and dose which is supported by published evidence or authoritative opinion.
- There is supporting evidence that available formulary alternatives are ineffective, toxic, or contraindicated (personal preference alone does not justify an exception).
- There is significant evidence that the requested drug is superior to drugs already listed as program benefits."[24]

## Veterans Affairs Canada Drug Formulary

### Special Authorization Benefits

"These benefits provide eligible clients with higher level or higher cost therapies approved by Veterans Affairs Canada as part of a managed health care approach. To access benefits on this formulary, clients will need a prescription and must be able to demonstrate a medical need that is most appropriately met with the requested therapy."[19]

## Canadian Armed Forces Drug Benefit List

### Special Authorization

"Certain medications are only approved for use in specific conditions, generally because their therapeutic potential may be limited or their side effects are more significant: these medications require Special Authorization to confirm that criteria for use have been met, and to thereby ensure optimal drug therapy."[22,23]

### Case-by-Case Review

"Other medications which are not routinely provided may be considered for use when the Canadian Armed Forces Drug Benefit alternatives are not well tolerated or are ineffective. The use of these medications must be consistent with an evidence-based approach and must be approved through the CF Drug Exception Centre."[22,23]