6 Understanding PharmaCare Benefit Status

6.1 Benefit Status Types

General Policy Description

PharmaCare uses an evidence-informed approach to drug policy development. By confirming that clinical evidence supports a drug's effectiveness before considering it for coverage, PharmaCare ensures that program resources are wisely spent.

Policy Details

Benefit status definitions

- Each prescription drug or eligible medical supply or device is assigned one of four PharmaCare benefit status types:

Benefit status	Coverage details	Notes
Regular benefit	Eligible for full reimbursement subject to PharmaCare price limits and subject to the rules of a patient's PharmaCare plan.	
Partial benefit	Eligible for limited reimbursement under the Low Cost Alternative Program or the Reference Drug Program or other maximum and subject to the rules of a patient's PharmaCare plan.	In some situations, PharmaCare may grant full coverage to a drug that would otherwise be only a partial benefit.
Limited Coverage drug	Eligible for reimbursement only in certain medical circumstances and subject to the rules of a patient's PharmaCare plan. Before a patient can get PharmaCare coverage, their medical practitioner must submit a Special Authority request to PharmaCare.	The drug is usually a second-, third- or fourth-line treatment. Drug is subject to LCA Program rules if a low-cost alternative exists.
Non-benefit	Not eligible for PharmaCare coverage under any circumstances. Special Authority is not available for these drugs. If the drug subsequently becomes a benefit, PharmaCare cannot provide retroactive coverage.	For a list of non-benefits, see the Examples of Items/Services that PharmaCare Does Not Cover.

- A prescription medication or medical supply may have a different benefit status under different PharmaCare plans.
- Patients wishing to take a partial benefit will be required to pay the difference between the low-cost alternative (LCA) or Reference Drug Program (RDP) price and the full cost of the prescription. For Fair PharmaCare patients, only the lower amount counts toward the annual deductible and family maximum, unless Special Authority has been provided by PharmaCare.

Procedures for pharmacists

Determining Benefit Status

- There are several ways to determine the benefit status of a drug or supply:
  - Use the online PharmaCare Formulary Search.
  - The PharmaCare Newsletter routinely provides information on the completion of reviews, new benefits, and changes in benefit status.
  - Use the Drug Review Results web page for drugs under review.
  - Pharmacists can send the transaction through on PharmaNet to determine coverage and reverse the claim if necessary.
  - Pharmacists may contact the PharmaNet Help Desk and choose:
    - the **PharmaCare Information Line**—*This interactive* voice-response system can provide information regarding the benefit status and benefit plans for a given drug.
    - to speak to a service representative.

    >>> For more information, see Contacting PharmaCare.
  - Some in-pharmacy software provides the ability to store benefit/non-benefit information.

Tools and Resources

- PharmaCare Formulary Search
- Drug Review Results

6.2 Health Canada's Special Access Programme Drugs

General Policy Description

Physicians occasionally treat patients with medications not approved for sale in Canada in cases of serious or life-threatening illness when conventional therapies have failed, are unsuitable, are unavailable, or offer limited options.

The Therapeutic Products Programme (TPP) of Health Canada is mandated to authorize the sale of these medications to physicians. The Special Access Programme (SAP) of the TPP administers this mandate. SAP is responsible for authorizing the sale of pharmaceutical, biologic and radio-pharmaceutical products that are not approved for sale in Canada.

The prescribing physician is required to submit an application to the SAP for approval to use a SAP drug for a patient. Once approved, the SAP authorizes release of the drug to the physician.

Policy Details

PharmaCare Coverage of SAP drugs

- PharmaCare coverage for SAP drugs is available only under exceptional circumstances through the Special Authority process.
- PharmaCare otherwise does not cover non-approved indications or drugs that have not been approved for sale in Canada.
- Special Authority approval must be in place **before** the drug is dispensed to the patient. Retroactive coverage cannot be provided.

Procedures

Procedures for Physicians and Pharmacists

Applying for Coverage of an SAP Drug

- A prescribing physician must submit an application to the SAP for approval to use a SAP drug for a patient. Once approved, the SAP sends a notification to the manufacturer and a copy to the physician, authorizing the release of the drug to the physician. The manufacturer then supplies the drug directly to the physician or to a hospital pharmacy. (Manufacturers cannot release SAP drugs directly to community pharmacies.)
- Because SAP medications are not approved for sale in Canada, they do not have drug identification numbers (DINs). In order for a pharmacy to dispense a SAP drug, PharmaCare will assign a Product Identification Number (PIN).
- The pharmacist can request a PIN by providing the drug information (including manufacturer, generic name, brand name and dosage form) to PharmaCare.
- When PharmaCare grants an individual patient Special Authority coverage for an SAP drug, a confirmation letter is sent to the patient's physician indicating the PIN for that drug. If the physician does not advise the pharmacist of the PIN to be used, the pharmacist can call the PharmaNet Help Desk to obtain it.

- If PharmaCare has a granted Special Authority coverage for an SAP drug, a claim must be entered on PharmaNet by a community or hospital pharmacy.
- Physicians are advised to make arrangements with the hospital pharmacy or local community pharmacy **before** the SAP drug is received.
- For instance, the hospital or community pharmacy may agree to purchase the drug from the physician. The pharmacy can then dispense the drug and enter the prescription details on PharmaNet. In addition to ensuring appropriate coverage by PharmaCare, this also ensures that the prescription information is included on the patient's medication profile. Please note that the physician would remain responsible for the manufacturer's invoice and should remit payment directly to the manufacturer. PharmaCare cannot reimburse physicians or patients directly.

Tools and Resources

Special Access Programme Contact Information

Special Access Programme
Therapeutic Products Directorate
Finance Building
2nd Floor PL 0202C1, Tunney's Pasture
Ottawa ON K1A 1B9

Telephone: 613 941 2108 (08:30-16:30 hours EST)

Fax: 613 941 3194

E-mail:
SAPdrugs@hc-sc.gc.ca

6.3 Special Authority Coverage

General Policy Description

For some drugs, PharmaCare requires the patient's health care provider to submit a request for Special Authority approval in order to be eligible for coverage.

PharmaCare coverage is applicable only to prescriptions purchased **after** Special Authority has been granted and entered in PharmaNet. No retroactive coverage is available.

Policy Details

Patient Special Authorities

- Special Authority (SA) approval grants full or partial PharmaCare coverage for a drug that might otherwise not be covered or be covered only partially.
- The rules of a patient's plan, including any deductible and co-payment requirement, apply even if the patient is granted Special Authority coverage.
- Special Authority approval does not exempt the drug from PharmaCare pricing policies such as the PharmaCare Maximum Pricing Policy, the Low Cost Alternative Program or the Reference Drug Program, unless the Special Authority has been specifically granted for that purpose.
- Special Authority coverage cannot be provided retroactively. Special Authority approval must be in effect on PharmaNet when the patient purchases the prescription.
- Special Authority may be granted for:
    - a Limited Coverage medication, or
    - an alternate product for patients unable to use the low-cost alternative (due to allergy) or reference drug product (due to adverse reaction or treatment failure).
    - drugs that are not marketed in Canada (i.e., Health Canada "Special Access Programme Drugs"), in exceptional circumstances only.
- Although PharmaCare Special Authority Requests are normally approved only for patients who meet established criteria, under exceptional circumstances, PharmaCare may cover patients who do not meet the pre-defined criteria when a request is made by an appropriate health care practitioner.

Special Authority Approval for Groups of Similar Medications

- PharmaCare applies the same coverage criteria to certain groups of similar medications. When PharmaCare approves Special Authority coverage for one medication in the group, coverage is automatically provided for all the drugs in that group. If the patient later requires another medication in the same group, no additional Special Authority request is necessary.
- When a medical practitioner prescribes a medication similar to one the patient has taken before, the practitioner or pharmacist can contact the PharmaNet HelpDesk to see if the drug is part of a "super category" for which the patient already has Special Authority coverage. If it is, another Special Authority request will not be required for the new medication.

Products Not Eligible for Special Authority coverage

- Items not generally available for Special Authority coverage include drugs and medical supplies and devices listed as Examples of Items/Services that PharmaCare Does Not Cover.

Special Authorities and Third-Party Insurers

- Some third-party insurers cover a product only if PharmaCare has granted a Special Authority for the product and the Special Authority was granted before the prescription was filled (i.e., they do not provide retroactive coverage). All enquiries regarding retroactive coverage by a third-party insurer should be directed to the specific insurer, not to PharmaCare.

Prescriber (Medical Practitioner) and Specialty Special Authority Exemptions

- On occasion, PharmaCare grants a Special Authority exemption to a medical practitioner or specialty.
- A Special Authority exemption applied to *a specific medical practitioner* provides coverage for identified drugs for all the patients of that practitioner.
- A Special Authority exemption applied to *a specialty group of medical practitioners* provides coverage for identified drugs for all the patients of all the practitioners in that specialty group.
- Although PharmaCare carefully reviews requests for such exemptions, only a limited number of requests can be approved.

Assumed Special Authorities

- Assumed SAs reduce the number of SA requests medical practitioners are required to submit. The resulting decrease in workload improves processing times for other requests.
- For specific medications, if the medication is initially prescribed by a medical practitioner who has a Special Authority exemption, in most cases, the patient is automatically granted indefinite Special Authority (SA) approval. If so, a general practitioner or other medical practitioners will not need to submit a Special Authority request to maintain the patients' coverage.
- Before issuing a prescription for medications eligible for an Assumed SA, a medical practitioner can **check the patient's chart to verify that the medication was initially prescribed by a specialist**. If it was the practitioner can choose not to submit a Special Authority request.
- Each criteria page indicates whether or not an SA exemption exists for a specific medication.

Pharmacy Special Authority Exemptions

- Some pharmacies, usually hospital pharmacies, deal with patients in specialty areas. Occasionally such a pharmacy (e.g., British Columbia's Children's Hospital's) is granted a Special Authority exemption.
- When dispensing a particular drug that would otherwise not be a full benefit, a Pharmacy Special Authority exempts patients of that pharmacy from requiring individual Special Authority approval.

- A drug dispensed under a Pharmacy Special Authority becomes a full benefit for all patients of that pharmacy, subject to PharmaCare pricing policies and the usual rules of each patient's PharmaCare plan, including any deductible requirements.

Special Authorities for Exceeding Maximum Days' Supply

Rural/Remote Areas

- *[Amended August 24, 2016]* Pharmacists can call the PharmaNet HelpDesk to request Special Authority Exemptions to PharmaCare 30-day maximum supply limit for patients residing in rural or remote areas for whom travel to the pharmacy is a significant barrier.
- The exemption will be entered into PharmaNet as a one-day Special Authority.

Chronic Conditions

- Medical practitioners can submit a Special Authority, requesting that a patient be exempted from the 30-day maximum supply policy for 'short-term' drugs if the patient has a chronic condition.
- Short-term drugs include all narcotics, all antibiotics, antifungals, sedatives, sleeping pills, barbiturates and all medications in the Palliative Care Plan formulary.
- Approval may be granted to allow a maximum 100-day supply.

Procedures

Procedures for medical practitioners

Obtaining Special Authority for drug coverage for an individual patient

- A medical practitioner submits information outlining the exceptional needs of the patient by:
  - submitting a Special Authority Request form by fax; or,
  - by telephone, using the Practitioner Special Authority phone line.

Obtaining Special Authority Exemption for Patients Chronic Conditions

- If a patient has a chronic condition requiring repeated treatment with a short-term drug, their medical practitioner can submit a Special Authority asking that the patient be exempted from the 30-day maximum supply policy for 'short-term' drugs.
- If granted Special Authority coverage is granted, an entry is made in PharmaNet allowing a maximum 100-day supply of the specified drug.

Procedures for Pharmacists

Obtaining Special Authority Exemption for Patients in Rural/Remote Areas

- *[Amended August 24, 2016]* Pharmacists can call the PharmaNet HelpDesk to request Special Authority Exemptions to PharmaCare 30-day maximum supply limit for patients in rural or remote areas for whom travel to the pharmacy is a significant barrier.
- The exemption will be entered into PharmaNet as a one-day Special Authority.

Tools and Resources

- For specific criteria for individual products, visit the Special Authority section of the PharmaCare website or can use the PharmaCare Formulary Search.
- Pharmacists can phone the automated PharmaCare Information Line or speak to a PharmaNet Help Desk representative to enquire about Special Authorities for specific patients.
- Contacts for Health Care Practitioners and Providers.

6.4 Collaborative Prescribing Agreements

General Policy Description

For some Limited Coverage drugs, PharmaCare invites physicians to sign a Collaborative Prescribing Agreement (CPA).

A CPA may be offered to specialists who commonly prescribe a medication for patients who meet PharmaCare coverage criteria.

Policy Details

About Collaborative Prescribing Agreements

- Physicians who enter into a CPA are exempt from completing Special Authority requests for a specific drug and are subject to the terms of the CPA.
- The CPA indicates the specified criteria for prescribing the drug.
- If a patient does not meet the criteria set out in the CPA, the CPA requires the physician to either:
  - write 'Submit as zero cost to PharmaCare'/"PharmaCare pays zero" on prescriptions, or
  - submit a Special Authority request for exceptional coverage.
- Pharmacists filling prescriptions annotated with the words "Submit as zero cost to PharmaCare" must enter the intervention code **DE Adjudicate to $0.00 as requested** to ensure PharmaCare does not cover the cost.
- When a pharmacist sees "Submit as zero cost to PharmaCare" on a prescription, the pharmacist **must** submit the claim using the intervention code **DE Adjudicate to $0.00 as requested** (the same code used when a patient is not eligible for PharmaCare coverage).

Procedures

Procedures for Pharmacists

Processing prescriptions for that state "Submit as zero cost to PharmaCare"

- When you receive a prescription with this note, submit the claim with the intervention code **DE Adjudicate to $0.00 as requested**.

This ensures appropriate PharmaCare coverage and accurate prescribing feedback to physicians.

Tools and Resources

- Coverage criteria, forms and Collaborative Prescribing Agreements for Limited Coverage drugs are provided on the drug coverage criteria pages accessible from the List of Limited Coverage Drugs.

6.5 Drug Review Process

General Policy Description

Under the PharmaCare program, the Ministry of Health seeks to provide coverage for drugs that support the health and well-being of British Columbians and provide value for money.

Before a drug can be included in the PharmaCare formulary, it undergoes a thorough review to determine whether it meets these two requirements. The review process helps ensure that the PharmaCare program remains fair, effective, and continues into the future.

Policy Details

National and Provincial Drug Reviews Processes

- In Canada, the drug review processes take place in three stages.

Stage 1 – Health Canada (federal government)

- All drugs sold in Canada must have received a Health Canada Notice of Compliance (NOC). Before issuing an NOC, Health Canada reviews the:
  - drug's safety,
  - effect of the drug when compared to taking no drug at all, and
  - quality of the manufacturing process used to make the drug.

>> For more information on Health Canada's drug review process, visit www.hc-sc.gc.ca/dhp-mps/prodpharma/index-eng.php.

Stage 2 – Common Drug Review (national review)

- To have their patented drugs (including new drugs, new combination drugs, subsequent entry biologics (SEBs) and new uses for existing drugs) covered by public sector drug plans, drug sponsors must send a submission to the Common Drug Review (CDR), a process administered by Canadian Agency for Drugs and Technologies in Health (CADTH).
- Drug submissions reviewed by the CDR include new drugs introduced in Canada or new Health Canada approved uses of existing drugs.
- The CDR process reviews:
  - how well the drug works when compared to similar drugs that are used to treat the same condition, and
  - whether the drug provides value for money.
- A team of independent experts is assembled to review each drug; based on their findings, a recommendation on whether or not drug plans should cover the drug is issued.

>> Learn more about CADTH and the CDR on their website at www.cadth.ca/en/products/cdr/cdr-overview.

Stage 3 – Ministry of Health Drug Review (B.C. review)

- The ministry conducts its own review before making its coverage decision. This review builds on the work done by Health Canada and the CDR process. The ministry does not duplicate the work of the CDR.

>> See the PharmaCare website for more information on patented drug submission requirements.

Review Process in British Columbia

- The review process in B.C. involves two entities: the Drug Benefit Council (DBC) and the Ministry of Health.

>> Learn more about the DBC on the PharmaCare website.

- The DBC is an independent advisory committee made up of nine professional members with expertise in critical appraisal, medicine, ethics, pharmacy and health economics, and three members from the public. Their task is to review drug submissions and make recommendations to the ministry.

British Columbian Drug Review Process

1 – Drug Review Resource Committee (DRRC)

- When the patented drug has gone through the necessary Health Canada and CDR reviews, the ministry starts its review process. The ministry sends the drug submission to the DRRC, a subcommittee of the DBC.
- The DRRC establishes the review requirements, including requesting reports or other inputs required for each drug submission. The DRRC also assigns expert review teams, called Drug Review Resource Teams (DRRTs), to complete the required review reports for each drug submission.
- Depending on what reviews have been done to date, requested reports may include clinical evidence, clinical practice and pharmacoeconomic reviews.

2 – Drug Review Resource Teams (DRRT)

- Each DRRT produces written reports on their assigned drug and forwards them to the drug sponsor for review. The drug sponsor can submit written comments for the DBC to consider during their review.

This is one of the four points at which stakeholders can become engaged in the review process; see Sponsor Engagement in the Drug Review Process for details.

3 – Patient Input through the "Your Voice" website

- The ministry has implemented a process that lets British Columbia patients, caregivers and patient advocacy groups submit input on specific drug reviews.

>> Learn more at the Your Voice webpage.

4 – Drug Benefit Council (DBC) review

- All DRRT reports, drug sponsor written comments, patient input and other review documents are forwarded to DBC members for review at their meetings.

>> See the PharmaCare website for more information on the DBC.

- The DBC reviews all the documents and makes a recommendation to the ministry about covering the drug under the PharmaCare program. The DBC recommendation includes:
  - whether or not to cover the drug,
  - how to cover the drug (i.e., a regular benefit for everyone or covered only under certain circumstances as a Limited Coverage benefit).
- The DBC considers the following when making a recommendation:
  - available information on the clinical effect of the drug and health outcomes
  - whether it is good value for the people of British Columbia
  - whether PharmaCare already covers a drug or drugs that work as well as this one
  - clinical practice and ethical considerations
  - patient input
  - the sponsor's written comments on the DRRT review reports
  - the recommendations of the national Common Drug Review, when applicable

5 – Ministry Decision

- In making its drug listing decision, the ministry considers:
  - the DBC's recommendation
  - PharmaCare policy for this type of drug and other programs that exist in the ministry
  - which PharmaCare plans would cover the drug
  - whether PharmaCare has the resources to cover the cost of the drug

Conflict of Interest Guidelines

- The ministry is committed to a fair, independent, objective, and unbiased drug review process. All people who take part in the review of a drug submission, including members of the DBC, the DRRC, and the DRRTs, are held to the highest ethical standards when conducting their activities.
- For this reason, all persons involved in the drug review process must declare any relationship they, or their immediate family, have that creates—or could appear to create – a conflict of interest. The need to disclose conflict of interest information is ongoing and is the responsibility of all involved in the review process.

  Ministry guidelines for the drug review process state that "a conflict of interest may exist whenever a Participant or an Immediate Family Member of a Participant has a direct or indirect interest or relationship, financial or otherwise, with an Entity that may affect or reasonably appear to affect the objectivity or fairness of the Participant in the Drug Benefit Review Process."
- Examples of information that need to be disclosed include: payments or research funds received from a company that may benefit from the drug review decision; financial ownership in such a company; being employed by such a company; and any arrangement or relationship through which the participant could either earn or lose money because of a ministry drug coverage decision.
- Individuals who declare possible conflict of interest information are not automatically excluded from participating in the drug review process.

- Whether an individual is selected to participate or not depends upon the particular drug submission under review and is determined by the DBC and/or the DRRC. To select drug reviewers, the DRRC assesses the review requirements of the particular drug submission, the expertise of the potential reviewers, and the conflict of interest information declared by the reviewers. It is up to the DRRC to select the best reviewer without conflict of interest whenever possible. As such, the DRRC may select a reviewer with an identified conflict of interest after weighing the potential benefits and risks of including the participant in the review.

>> For full details see the Ministry's Conflict of Interest Guidelines and forms.

Ministry Drug Review Timelines

- When a drug needs a CDR review, the ministry starts its own review process when the CDR process is complete, (i.e., **on the date when the CDR issues its final recommendation**).
- All other patented drug submissions, start on the date the complete submission is received by the ministry.
- The ministry's target timeline to a decision (time-to-decision) is defined as the time from which the ministry begins its review to the time that the ministry publicly communicates its decision and usually includes completing all implementation steps.
- The target timeline to a decision for a **standard review** is nine (9) months. The timeline for a **complex review** is twelve (12) months. A complex review usually includes extra requirements, such as having to develop clinical coverage criteria, develop a Special Authority form, complete discussions with a pharmaceutical manufacturer, and/or complete other implementation steps as required.

Priority Reviews

- A drug submission may be given priority status if it:
  - was granted priority review status by CDR, or
  - meets a significant clinical need and shows major therapeutic benefit, or
  - shows substantial economic benefit
- Priority drug reviews will be completed within six (6) months for standard submissions or nine (9) months for complex submissions.

>> See further details about priority reviews on the PharmaCare website.

Sponsor Engagement in the Drug Review Process

Upon receipt of a drug submission, the ministry provides the sponsor with the following four points of engagement during the drug review process:

A. when the Drug Review Resource Team (DRRT) reports are ready for comment (Pre Drug Benefit Council (DBC);
B. when the embargoed DBC Recommendation and Reasons for Recommendation are ready for review (Post Drug Benefit Council (DBC) ;
C. once the DBC recommendation becomes final but prior to implementation (Pre MOH Decision); and

D. after the ministry has implemented the decision (Post MOH decision).

>> See the sections below for additional details on each point of engagement.

>> You may also want to see the sponsor engagement diagram.

A. Pre Drug Benefit Council (DBC)

- The sponsor may review the reports of the Drug Review Resource Teams (DRRT) and submit written DRRT report comments to the ministry **within ten (10) business days** of receiving the reports. These comments will be included in the documentation forwarded to the DBC for review. The comments should:
  - indicate whether there is agreement or disagreement with the reviewers report;
  - be evidence-based and referenced, citing material from the original drug submission; and
  - not introduce new clinical evidence.
- New clinical evidence included in Manufacturer comments will **not** be considered by the DBC. If the manufacturer would like new clinical evidence considered by the DBC, the Manufacturer will need to resubmit the drug submission to the Common Drug Review (CDR) for a CDR submission or to the ministry for a non-CDR submission.

B. Post Drug Benefit Council (DBC)

- The sharing of the embargoed DBC Recommendation and Reasons for Recommendation is intended to improve the dialogue between the ministry and the sponsor. The sponsor will be provided with an embargoed copy of the DBC Recommendation & Reasons for Recommendation after the DBC meeting subject to requirements of a confidentiality agreement.
- At the time the embargoed DBC recommendation is released, the sponsor may file a Request for Reconsideration based on grounds that either:
  - the ministry and/or the DBC did not follow the proper process; or
  - the DBC recommendation is not supported by the evidence or input reviewed.
- This written request, directed to the Director of Formulary Management, must be filed **within five (5) business days** of receiving the embargoed copy of the DBC Recommendation and Reasons for Recommendation.
- The request for reconsideration will comprise the reason and grounds for the request, the relief sought, and supporting evidence. A Request for Reconsideration cannot be made solely because the sponsor disagrees with the recommendation. The request must identify the aspect(s) of the DBC recommendation with which the sponsor disagrees.
- No new information will be considered in the reconsideration as new information requires a resubmission.
- Requests are examined by the ministry DBC Secretariat in consultation with the DBC Chair to determine whether the issue(s) raised can be resolved in discussions with the sponsor. If the ministry is unable to address the issues, the request will be forwarded to the DBC for reconsideration.

- If the ministry does not receive a request for reconsideration **after five (5) business days**, the embargoed Recommendation and Reasons for Recommendation will become final.

C. Pre Ministry of Health Decision

- Once a DBC Recommendation and Reasons for Recommendation document is made final, a sponsor may engage the ministry **within ten (10) business days** of this final document being issued by submitting a written statement to pharma@gov.bc.ca requesting a meeting with the ministry before the listing decision and its implementation occurs.
- The ministry, at its discretion, may also initiate discussions with the sponsor.
- If and when discussions are initiated, the target time frame to complete discussions is within 25 business days after the final DBC recommendation is released. The target timeline may be adjusted upon mutual agreement.

D. Post Ministry of Health Decision

- The sponsor may file a resubmission if new information becomes available that addresses the reasons for the decision. The resubmission should be made to the Common Drug Review (CDR) process for CDR drug submissions.
- For non-CDR drug submissions, the ministry has the discretion to determine whether the drug review reports will be made publicly available (i.e. posted on the ministry website) once a listing decision has been made. Prior to posting publicly the submission sponsor will have **15 business days** to review the final reports to request the non-disclosure of any specific portions that it deems to be of a confidential or proprietary nature. The time frame may be adjusted on mutual agreement.
- If the submission sponsor requests the confidential information be deleted, the ministry will remove the confidential information by using "blacking out" redaction techniques.

Patient Engagement in the Drug Review Process

- Through the Your Voice website, patients, caregivers, and patient groups can add their voice to the BC PharmaCare drug review process.

Who is eligible to give input?

- B.C. residents who can answer "yes" to any of the following questions for a drug available for input through the Your Voice website can give their input:
    - Do you have the medical condition for which the drug would be used?
    - Are you a caregiver to someone who has that medical condition?
    - Does your patient group represent patients who have that medical condition AND have you registered with PharmaCare to give input?

      >>Learn more about registering your organization.

Drug Submission Requirements

Patented Drug Products

- Drug submission sponsors (sponsors) are required to apply to the Ministry of Health (the ministry) to have their drug product considered as a PharmaCare benefit. The following information outlines the submission requirements for patented drug products that must be submitted to the ministry.
- The ministry makes PharmaCare coverage decisions based on a range of considerations including existing PharmaCare policies, programs, therapeutic options, resources and the evidence-informed recommendations of an independent advisory body called the Drug Benefit Council (DBC). The DBC's advice to the ministry is based upon a review of many considerations, as well as available clinical and pharmacoeconomic evidence, clinical practice, patient and ethical considerations, and the recommendations of the national Common Drug Review (the CDR), when applicable.
- In order for **patented drug product submissions for new drugs, new combination products, and drugs with new indications** to be considered by the ministry, the submission must undergo an initial review by the CDR. Drug products that are designated as Subsequent Entry Biologics (SEBs) are also required to go through the national CDR process.
- **All other submissions,** including those for line extensions and modification of criteria should be submitted directly to the ministry.
- For detailed drug submission requirements for patented drug products, please see:
  - Patented drug products reviewed by the CDR—including new drugs, new combination products and drugs with new indications
  - Modification of Coverage Criteria
  - Line Extensions – New Strengths

Generic Products

>> For information, see the Section 5.6 to 5.12 of this manual.

Review timelines

- The target timeline to a decision (time-to-decision) is defined as the time from when the ministry begins its review to the time the ministry publicly communicates its decision.
- The target timeline to a decision for a **standard review is nine (9) months** and for a **complex review is twelve (12) months**. Complex reviews may involve the need to develop clinical coverage criteria and/or a Special Authority form, to complete a Product Listing Agreement or other implementation steps.
- For submissions reviewed by the CDR, the review start date is the issue date of the final Canadian Drug Expert Committee (CDEC) Recommendation and Reasons for Recommendation.
- For other patented drug submissions (including line extensions and modification of criteria), the review start date is the **date the complete submission is received by the ministry**.

For information on review periods for recently patented drugs, refer to the Quarterly Report on Drug Review Timelines.

Submitting the documents

- Sponsors are required to submit copies of their submissions to:

  Director, Formulary Management
  Medical Beneficiary & Pharmaceutical Services Division
  Ministry of Health
  PO Box 9652 Stn Prov Govt
  1515 Blanshard St
  Victoria BC V8W 9P4

- Submissions that are e-mailed to the ministry will **not** be accepted for review.
- If a drug submission has incomplete information, PharmaCare will contact the manufacturer with a request to complete the submission. Incomplete submissions cannot be reviewed.

Tools and Resources

- Drug Submission Requirements for Patented Drug Products
- Drug Benefit Council
- Conflict of Interest Guidelines
- Sponsor Engagement in the Drug Review Process
- Drug Review Process & Results