# PROCESS FOR COVERAGE DETERMINATION FOR NEW DRUG THERAPIES UNDER THE NEWFOUNDLAND AND LABRADOR PRESCRIPTION DRUG PROGRAM ( NLPDP)

**Subject to Revision**
**Updated June, 2002**

## PROGRAM DESCRIPTION

The Newfoundland and Labrador Prescription Drug Program is administered by the Department of Health and Community Services and comprises two programs, the Senior Citizens Drug Subsidy Program and the Social Services Drug Program. The Program also provides coverage for persons who meet financial eligibility as determined by the Department of Human Resources and Employment.

## OVERVIEW

When a new drug is introduced to the Canadian market, the manufacturer may submit a request to NLPDP that it be considered for possible coverage by the Drug Program. A drug manufacturer may submit a request to NLPDP at any time. Reviews are conducted in the order they are received and are added as they are approved. Only drug products which are valid therapeutic agents, with proven clinical effectiveness will be considered for coverage under the Program. The cost of therapy and clinical efficacy relative to other drug therapies is considered; an increased cost may be justified if the drug produces better clinical results in the patient population.

Coverage status under NLPDP is listed under two categories:

**1. OPEN BENEFIT**:
(a). Open benefit without limitations. Drugs listed in this category are available to recipients without any restrictions. They must however demonstrate:

- cost-effectiveness
- a low potential for inappropriate prescribing
- meaningful therapeutic benefits to program clients

(b). Open Benefit with limitations. Drugs listed in this category are available to recipients providing submissions for reimbursement meet the set limitations.

**2. SPECIAL AUTHORIZATION**:
Drugs listed in this category are available to recipients who meet certain defined criteria. Request must be made by a physician, dentist, nurse practioner, or pharmacist on behalf of the patient.

## DRUG REVIEW PROCESS:

Currently the province of Newfoundland and Labrador in participating in two initiatives related to the sharing of resources in reviewing submissions for coverage, the Atlantic Pharmacare Review Committee and the National Common Drug Review Committee.

### INDIVIDUAL PRODUCTS

- Manufacturers should submit requests for drug coverage according to national minimum submission requirements for brand name and single source drugs as follows:
  1. Evidence of approval from Health Canada - NOC, DIN, Product Monograph.
  2. Proposed Drug Benefit Price and evidence of the manufacturer's ability to supply.
  3. Clinical data on therapeutic use, safety and adverse drug reactions.
  4. Pharmacoeconomic evaluation.
  5. Letter authorizing communication with Health Canada, other provinces, territories, federal drug programs, Patent Medicine Prices Review Board (PMPRB), expert committees and CCOHTA.

  Additional details of these requirements are supplied in Appendix 1.

- The new drug submission is initially screened for completeness by the Secretariat of the Atlantic Pharmacare Review Committee (APRC). If all requirements are met, it is placed on the agenda for the next meeting of the APRC who will prioritize the submission and place it in the review queue.

- The APRC Secretariat will issue a notice of receipt to the manufacturer, referencing the drug name and the date the submission was received. The letter will indicate the status of the submission i.e, complete or incomplete.If a submission is incomplete, the letter will indicate what additional information is required.

- The product will be reviewed based on the priority set by the APRC and, if not already reviewed by the National Common Drug Review Committee, a reviewer will be chosen. Once the product review is complete it will be shared with the four participating provinces and placed on the agenda for the next Atlantic Expert Committee (AEC) meeting.

- The EAC will make recommendations with respect to appropriate criteria for the cost-effective use of the medication based on the review and each provincial departmental representative will bring these recommendations back to their own jurisdiction

- Our Newfoundland and Labrador APRC member prepares a summary of the recommendations and forwards them to the executive committee of the Department of Health and Community Services. Once a decision is made by the Department the Pharmaceutical Services Division will notify the manufacuter of the listing decision.

- In the case of a negative decision, issues or concerns raised will be outlined in this communication. Appeals must contain new evidence-based supplementary information to address the issues or concerns that formed the basis of the negative recommendation. Appeals submitted will be reviewed in the normal process.

- If the decision is to list under special authorization the established approval criteria will be communicated to the manufacturer in their notification letter from the division.

- All pharmacy providers are notified of approved benefits and/or amendments by NLPDP via web site postings, email and surface mail as appropriate. All approved benefits are listed on the web site at **www.gov.nf.ca/health/nlpdp. Note: Criteria for drugs designated as requiring special authorization will be available on the web site**.

# Appendix 1

**Manufacturer Submission Requirements:** (in accordance with guidelines set by the Atlantic Pharmacare Review Committee)

- Only one copy of a submission of a drug product is required. Submissions in CD ROM format are encouraged.

- Submissions must include:

1. Executive Summary (2 copies)
2. Notice of Compliance (NOC)
3. Product Monograph
4. Therapeutic classifications:
    - American Hospital Formulary Service, Pharmacologic-Therapeutic Classification (PTC) and
    - World Health Organization's Anatomical Therapeutic Chemical (ATC) classification
5. Clinical evidence on efficacy, effectiveness and safety.
    - Double-blind randomized, controlled trials (RCTs) published in peer-reviewed journals are given the most weight
    - If unpublished/abstract data is submitted, it must be indicated why it is unpublished.
    - List all studies submitted in one table and specify the study name, date, authors and whether it is published or unpublished.
    - Published articles supporting the validity of outcome measures in studies (if available)
6. Economic Evaluation:
    - Pharmacoeconomic analysis in agreement with the Canadian Coordinating Office for Health Technology Assessment (CCOHTA): *Guidelines for Economic Evaluation of Pharmaceuticals:* Canada is encouraged.
    - Marker share information and projection of incremental financial impact to NLPDP and the healthcare system.
7. Pricing and availability
    - Current price for all strengths and dosage forms
    - Method of distribution to pharmacies (wholesale, direct, or other arrangements)
    - Evidence of ability to supply anticipated demand
8. A letter authorizing unrestricted communication regarding the drug product between Nova Scotia, New Brunswick, Prince Edward Island, and Newfoundland and Labrador drug programs and
    - Other federal, provincial, and territorial (F/P/T) drug programs
    - F/P/T health authorities and related facilities
    - Health Canada

- Patented Medicine Prices Review Board (PMPRB)
- Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

9. A letter specifying the current or intended Compendium of Pharmaceuticals and Specialties (CPS) listing status.
10. A copy of the Pharmaceutical Advertising Advisory Board (PAAB) approved promotional materials.

- All submissions should be sent to:

**Newfoundland and Labrador Prescription Drug Program**
**Department of Health and Community Services**
**P. O. Box 8700**
**St. John's, NF A1B 4J6**

# Appendix 2

## THERAPEUTIC CLASS REVIEWS

Many new drugs released to the market are similar in classification and are intended for treatment of a specific disease state. As such, therapuetic class reviews are often conducted and involve extensive consultation via ad hoc therapeutic class review committees, comprising members with expertise in the treatment of the disease for which the drugs are intended.

Reviews are conducted with emphasis on clinical literature such as reports of scientific studies comparing the new product with existing therapeutic alternatives. Material discussed include utilization data from the Drug Program, information available from other provincial drug programs, Federal Provincial Territorial (FTP) agencies, as well as scientific and clinical literature pertaining to the drug and drug category. If there are no significant additional clinical benefits, decisions will be made by the department based on the comparative costs of available therapies.

The Drug Program also utilizes data from the Patient Research Center at Memorial University as a source of reference when making decisions with respect to coverage status. This information includes cost benefit analysis of a drug product to determine effectiveness in real life situations versus controlled clinical trials.