Appendix D – Special Authorization Criteria

Special Authorization is a process whereby Beneficiaries of the Program may obtain coverage for drug products not offered as regular benefits under the Program. The purpose of the Special Authorization process is to ensure optimal, cost-effective and evidence-based drug utilization.

The Special Authorization process is one means the government of NL has of ensuring patients continue to have access to needed medications while being responsible and accountable for the expenditure of public funds. Drugs listed in this category are available to Beneficiaries who meet certain defined criteria.

The Special Authorization criteria are based on extensive review processes (CDR, ACDR and pCODR). The criteria are posted on the Program's web site at http://www.health.gov.nl.ca/health/prescription/special_auth_drug_products.pdf

As part of our special authorization process, a physician has the option of appealing a decision by the Pharmaceutical Services Division to not provide coverage of a drug through the Non-Funded Process. Under the Non-Funded Review Policy, the Medical Consultant will also consider requests for drugs without a Notice of Compliance (NOC) and Drug Identification Number (DIN) issued by Health Canada if the physician indicates in the request that approval has been obtained through the Health Canada Special Access Program (SAP). This would require the physician to apply in writing providing *detailed* documentation as outlined below:

- **Diagnosis**
  - The Provider must provide detailed information outlining specific diagnosis, noting any relevant severity of symptoms, patient comorbidities, allergies, or other relevant patient specific information to indicate a rare clinical situation.

  - The severity of the disease/condition

- **Supporting Clinical Evidence**
  - The Provider must provide published evidence to support the request. The minimum acceptable level of evidence is case-series or multiple case reports where n > 25 in total.

  - The evidence of efficacy must be overwhelmingly in favor of the drug. Ideally randomized controlled trial data (RCT) should be available, individual case reports, Phase I and II trials and expert opinion provide the lowest level of evidence and may be considered insufficient data to support non-funded requests.

- Safety evidence to support the potential benefits outweigh the risks.

- **Clinical Alternatives**
  - The Provider must provide detailed information outlining failure of ALL available and appropriate alternatives available on the NLPDP Formulary AND all appropriate non-pharmacological alternatives. Failure of other clinically appropriate and/or less expensive alternatives not funded by NLPDP that may be considered through this Non-Funded process must also be considered.

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

The senior medical consultant 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.

The Special Authorization Criteria is updated as deemed necessary. Please refer to most recent criteria located on the website at:
http://www.health.gov.nl.ca/health/prescription/special_auth_drug_products.pdf