Exceptional Review Process – Frequently Asked Questions – Health Care Providers

1. **When can a healthcare professional request an Exceptional Review?**

   An Exceptional Review can be requested when prescribing a drug for an NLPDP beneficiary which is listed on the NLPDP benefit list as requiring Special Authorization **BUT** is being prescribed for an **off label** indication or an indication that is not considered under Special Authorization.

2. **What type of documentation is required to request an Exceptional Review?**

   Requests for Exceptional Review can be faxed to the Pharmaceutical Services Division at 709-729-2851 and must include a detailed letter from the requesting healthcare professional outlining:

Diagnosis

- Detailed information outlining the specific diagnosis, severity of disease/condition, symptoms, co-morbidities, allergies, and any other relevant information to indicate a rare clinical situation.

Supporting Clinical Evidence

- 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 however it may be considered to support Exceptional Review for rare diseases or medical conditions.
- Safety evidence to support the potential benefits must outweigh the risks.

Clinical Alternatives

- Detailed information outlining failure of ALL appropriate alternatives available in the NLPDP benefit list 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 Exceptional Review process) or those funded through other agencies (i.e. Regional Health Authority) must be considered.

Funding Alternatives

- Before funding is considered, documentation must be supplied outlining that the patient cannot enroll in a clinical trial AND other funding options (including compassionate supply through the manufacturer, funding under other programs etc.) are have been exhausted.

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. **Can an Exceptional Review be completed for a drug authorized by Health Canada under its Special Access Program?**

   No. NLPDP, a public drug plan, does not reimburse for Special Access drugs authorized by Health Canada. (Any costs associated with special access drugs is the responsibility of the patient, patient's family, the hospital, or the patient's private insurer, such as Medavie Blue Cross).

4. **What is required by the NLPDP to consider off label use of a drug?**

   Only drugs that are considered under the Special Authorization process may be considered for off label uses. In addition, there is the requirement for adequate evidence to support the off label indication, including detailed information outlining the specific diagnosis noting the severity of symptoms, patient co-morbidities, allergies, or other patient specific information.

5. **If a Health Care Provider only has phase I and II trials, is this enough clinical evidence?**

   No. Phase I and II trials and expert opinion provide the lowest level of evidence and may be considered insufficient data to support an Exceptional Review request.

6. **Why does a patient have to try clinical alternatives and/or standard therapies of adequate duration before requesting a drug for an off label indication?**

   The NLPDP is an evidence based program. Prior to considering off label funding all available and appropriate clinical evidence must be considered before moving to a non-funded therapy.

7. **What happens if the clinical evidence provided is inadequate to support the use of the requested drug for an off label use?**

   The Exceptional Review request will be denied.

8. **Do all funding alternatives have to be exhausted?**

Before funding can be considered, documentation must be supplied outlining that the patient cannot enroll in a clinical trial **AND** other funding options (including compassionate supply through the manufacturer, funding under other programs, etc.) are not available.

9. **Is there an appeal process if the medical practitioner designated by the minister denies an Exceptional Review request?**

   No. The review of an Exceptional Review request by the medical practitioner is the final level of appeal.

10. **If an Exceptional Review request is submitted for a drug for an off label use but does not include any clinical alternatives, could it be denied?**

    The NLPDP is an evidence based program. Prior to considering off label funding all available and appropriate clinical evidence alternatives must be considered before moving to an off label therapy.

11. **What is the processing time for an Exceptional Review request?**

    It depends on the complexity of the request. Detailed information provided with the request must be analyzed and additional research may be required before the medical practitioner is able to review the request. Given these factors, an exceptional review could take anywhere from a few weeks to a couple of months to reach a final decision.