Ministry of Health and Long-Term Care **Ministère de la Santé et des Soins de longue durée**

Ontario

Exceptional Access Program (EAP)

NOTICE OF APPROVAL

Ontario Public Drug Programs Division
Drug Programs Delivery Branch
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This letter contains privileged and confidential information and is intended only for the use of the Addressee(s) named below. If you are not the intended recipient or the employee or agent responsible for delivering it to the intended recipient, you are hereby notified that any dissemination or copying of this facsimile is strictly prohibited. If you have received this letter in error, please notify us immediately by telephone and further instructions will be provided.

In order to facilitate processing, please fax requests to the ministry. Responses are faxed back to the requesting prescriber's office. Please include your fax number on all correspondence. To ensure confidentiality, ministry replies will identify the patient by first name and the initial of the last name and date of birth.

To: **Dr. Curtis, Margaret Anne**
Fax: **(416) 922-4358**

Re: **Sonja G** (**Date of Birth:** 1954-05-20)

The Exceptional Access Program (EAP) facilitates access to drugs that are not listed on the Ontario Drug Benefit (ODB) Formulary for requests that meet specified criteria.

Ontario has an established process for determining the drug products which are funded through the Ontario Public Drug Programs (OPDP). In general, new brand drugs and new indications that are approved by Health Canada are first reviewed under the national Common Drug Review (CDR) process, with overall assessment of the evidence by the Canadian Drug Expert Committee (CDEC). CDEC then issues a funding recommendation to provincial and territorial drug plans, recommending whether or not to fund and to include the circumstances for which the drug may be considered for funding by public drug plans. Following the release of the final CDEC recommendation, and if there is a recommendation for consideration of funding to the provinces and territories, the pan-Canadian pharmaceutical alliance (pCPA) becomes involved in the process to negotiate costs and criteria for funding with the manufacturer.

Since 2010, provinces and territories have been working together through the pCPA to conduct joint provincial/territorial negotiations for brand name drugs in Canada with the goal of achieving greater value to the broader health care systems of participating organizations and to improve patient care by negotiating drug reimbursement collectively. There is membership from every province, Yukon, and the Federal Non-insured Health Benefits (NIHB) program. Although negotiations with the manufacturer are conducted on behalf of all jurisdictions, each jurisdiction still decides whether to fund the drug product as a benefit under its own provincial drug plan(s) and manufacturers are still required to make a submission to Ontario for listing within the province's

public drug program. The pan-Canadian Oncology Drug Review (pCODR) and the pCODR Expert Review Committee (pERC) perform the same function for cancer drugs.

Ontario-specific drug submissions for funding, i.e. drugs not reviewed by CDR or pCODR, are evaluated by the ministry's drug expert advisory committee, the Committee to Evaluate Drugs (CED), which provides a funding recommendation to the ministry. It should be noted that the reimbursement criteria for EAP drugs has generally involved the recommendations of the CED until 2016 when the office of the pCPA became formally established to coordinate the national process.

The Executive Officer (EO) of the OPDP makes a final funding decision for the listing of drug products in Ontario utilizing recommendations from national and provincial review processes and negotiations, and taking into account budgetary and pharmacoeconomic considerations for fiscal sustainability, and the public interest. It should be noted that not all products approved by Health Canada can be funded by the provincial public drug programs.

The request has been reviewed in accordance with the guidelines approved by the EO and approval of funding has been granted. The coverage period begins as of the effective date and extends to the specified expiry date and includes the backdated period of coverage explained in further detail below. In order to receive coverage, the patient must be eligible to receive benefits under the ODB program.

Should an extension of coverage be requested, please provide information to ensure that criteria for renewal of funding are addressed. Renewal of funding generally requires objective information demonstrating that a patient is benefitting from the drug and is expected to continue to do so. This may include a clear description of the patient's response to treatment, and information pertaining to current medications, dosages, adverse effects, quality of life, improvement of laboratory markers or measures of disease, as well as any specific information requested below. Renewal requests should be submitted on a timely basis to avoid any gap in therapy. The physician is asked to note that requests for certain drugs and indications may take up to 6 weeks to process.

Drug Request Number: 00494159-01
Generic Drug: acyclovir

DIN/PIN	Brand Name	Effective Date	Expiry Date
02207648	Apo-Acyclovir 400mg tab	2017-03-20	2022-08-02

If and when an extension is requested, the requesting physician is asked to provide an update on this patient's clinical status and details of response to treatment with the requested medication, including the dose, frequency of administration, adverse reactions, and number of recurrences while on prophylactic therapy. Also for renewal, please specify whether prophylaxis is being utilized on a continuous or intermittent basis.