



TO: Hospitals
Regional Cancer Programs
Heads of Medical Oncology
Ontario Cancer Leads and Drug Advisory Committees
Chairs of Disease Site Groups
Regional Vice Presidents

FROM: Scott Gavura, Director, Provincial Drug Reimbursement Programs

CC: Dr. Leta Forbes, Provincial Head, Systemic Treatment Program
Dr. Kelvin Chan, Clinical Lead, Provincial Drug Reimbursement Programs
David Schachow, Director, Drug Programs Delivery Branch, Ontario Public Drug Programs Division

DATE: June 7, 2019

SUBJECT: **Fludarabine Supply Status & Conservation Strategies**

PLEASE DISTRIBUTE TO ALL CANCER CARE PROVIDERS

A. Fludarabine Supply Status

Fludarabine is a cancer drug that is Health Canada approved for chronic lymphocytic leukemia and low-grade non-Hodgkin's lymphoma. Fludarabine is also used across other hematology sub-diseases, and as part of the preparative regimen prior to allogeneic stem cell transplantation. While this product is available as both an oral and intravenous preparation, Cancer Care Ontario (CCO) has been notified of a **supply interruption affecting the intravenous (IV) formulation (allocation in place at up to 50%)**. Please refer to the attached 'Dear Healthcare Provider' letter from Teva Canada dated June 6, 2019 for more information. Teva Canada is the sole source supplier of the IV product. Please also refer to *Appendix 1* for the current supply status from available manufacturers for all fludarabine products.

CCO will be engaging in discussions with the Ministry, Health Canada, Group Purchasing Organizations (GPOs) and the manufacturers with the overall goal of minimizing patient impact of this supply interruption.

B. Conservation Strategies

CCO has consulted with cancer experts and other provincial cancer agencies to develop evidence-informed guidance that may assist your institution in prioritizing patients and conserving existing supply. To ensure use of available product is fair, equitable and transparent, it is **strongly suggested that sites refrain from starting any new patients on IV fludarabine for non-curative regimens** until the supply status is fully restored. Consideration should also be given towards switching patients on existing non-curative fludarabine-based regimens to oral fludarabine as a means of conservation. Please refer to the attached document entitled "*Conservation Strategies for Fludarabine in Oncology Care*" for suggested strategies.

C. Resources

Drug Shortages Canada Website

As of March 14, 2017, regulations require drug manufacturers to publicly report drug shortages and product discontinuations. Specifically, manufacturers must report an anticipated drug shortage, a discontinuation of a drug six months in advance, and any previously unreported shortage within five days of learning about it. This information will be reported on the *Drug Shortages Canada* website at: <https://www.drugshortagescanada.ca>.

Drug Shortages and Medication Safety Concerns. ISMP Canada Safety Bulletin. 20 March 2012

https://www.ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-03_Drug_Shortages.pdf

Ethical Framework for Resource Allocation during a Drug Supply Shortage

http://www.health.gov.on.ca/en/pro/programs/drugs/supply/docs/ethical_framework.pdf

Drug Shortages Guide. A Guide for Assessment and Patient Management. Canadian Pharmacists Association

<http://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/DrugShortagesGuide.pdf>

Multi-Stakeholder Steering Committee on Drug Shortages Toolkit

https://www.drugshortagescanada.ca/files/MSSC_Toolkit_2017.pdf

Multi-Stakeholder Steering Committee on Drug Shortages Protocol

https://www.drugshortagescanada.ca/files/MSSC_Protocol_2017.pdf

D. Drug Shortage Questions?

Please direct any questions for CCO on drug shortages to Ron Fung, Clinical Program Manager, Provincial Drug Reimbursement Programs at ron.fung@cancercare.on.ca.

Appendix 1

Table 1: Supply Status of Fludarabine Products as of June 6, 2019*

Brand	DIN	Vial Size	Dosage Form	Availability	Estimated Resupply Date
Teva Canada Limited	02283859	2 mL	25 mg / mL solution for injection	On allocation at up to 50%	October 2019
Sanofi Genzyme Canada	02246226	Not applicable	10 mg oral tablet	In stock	Not applicable

*For the most up-to-date information on supply status and ordering procedures, please contact the manufacturer and/or your distributor directly.