Regimen Monograph

A - Regimen Name

CYTADAUN+GEMT Regimen

DAUNOrubicin-Cytarabine-Gemtuzumab Ozogamicin

Disease Site

Hematologic
Leukemia - Acute Myeloid (AML)

Intent

Curative

Regimen Category

evidence-informed :

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

This **Regimen Abstract** is an **abbreviated** version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

The information provided in this document is intended for use only in the management of adults with leukemia, and for cancer centres with expertise in treating acute leukemia.

Rationale and Uses	For consolidation after completion of induction treatment in patients with *de novo* CD33-positive acute myeloid leukemia (AML), who have good performance status and have favourable, intermediate, or unknown cytogenetics
Supplementary Public Funding	**gemtuzumab ozogamicin** New Drug Funding Program (Gemtuzumab Ozogamicin (Outpatient) - Previously Untreated Acute Myeloid Leukemia) (NDFP Website)

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B - Drug Regimen

After complete remission following induction, give consolidation (for up to 2 cycles):

DAUNOrubicin†	60 mg /m²	IV	Day 1 (First course)*
*or on days 1 to 2 (second course)			
cytarabine†	1000 mg /m²	IV	Q12 hours on Days 1 to 4
gemtuzumab ozogamicin**	3 mg /m²	IV	Day 1

† CYTADAUN regimen based on Castaigne et al.

**up to a maximum of 4.5 mg per dose

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C - Cycle Frequency

For up to 2 cycles

CYTADAUN consolidation regimens may vary. Refer to local protocols for details.

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J - Administrative Information

Approximate Patient Visit	4 hours
Pharmacy Workload (average time per visit)	25.817 minutes
Nursing Workload (average time per visit)	79.167 minutes

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K - References

Castaigne S, Pauras C, Terre C, et al. Effect of gemtuzumab ozogamicin on survival of adult patients with de-novo acute myeloid leukemia (ALFA-0701): a randomised, open-label, phase 3 study. Lancet 2012;379:1508-16.

Lambert J, Pautas C, Terre C, et al. Gemtuzumab ozogamicin for de novo acute myeloid leukemia: final efficacy and safety updates from the open-label, phase III ALFA-0701 trial. Haematologica 2019;104(1):113-119.

November 2021 Added NDFP form and Cycle frequency section; Modified Rationale and uses section

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M - Disclaimer

Regimen Abstracts

A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis,

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Regimen Monographs

Refer to the New Drug Funding Program or Ontario Public Drug Programs websites for the most up-to-date public funding information.

The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.

Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.

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