Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Administrative Information | References | Other Notes | Disclaimer

A - Regimen Name

CYTA(HD)+GEMT Regimen

Cytarabine (high dose)-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:

cytarabine	3000 mg /m²	IV	q12h Days 1, 3, 5

If patient is **≥60 years of age**, give **cytarabine 1000 to 1500 mg/m^2 q12h** days 1, 3, 5

gemtuzumab ozogamicin*	3 mg /m²	IV	Day 1

**up to a maximum of 4.5 mg per dose

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C - Cycle Frequency

For up to 2 cycles

Gemtuzumab ozogamicin is given in **consolidation cycles 1 and 2** only.

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J - Administrative Information

Approximate Patient Visit	3.5 hours
Pharmacy Workload (average time per visit)	23.771 minutes
Nursing Workload (average time per visit)	99.167 minutes

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K - References

Burnett AK, Russell NH, Hills RK, et al. Optimization of chemotherapy for younger patients with acute myeloid leukemia: results of the medical research council AML15 trial. J Clin Oncol 2013 Sep 20;31(27):3360-8. doi: 10.1200/JCO.2012.47.4874

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.

Mayer RJ, Davis RB, Schiffer CA, et al. Intensive postremission chemotherapy in adults with acute myeloid leukemia. Cancer and Leukemia Group B. N Engl J Med 1994;331(14):896-903.

pCODR expert review committee final recommendation: gemtuzumab ozogamicin. April 2020.

Princess Margaret Cancer Centre Clinical Practice Guideline: Acute Myeloid Leukemia. September 2015.

Schaich M, Parmentier S, Kramer M, et al. High-dose cytarabine consolidation with or without additional amsacrine and mitoxantrone in acute myeloid leukemia: results of the prospective randomized AML2003 trial. J Clin Oncol 2013 Jun 10;31(17):2094-102. doi: 10.1200/JCO.2012.46.4743

Thomas X, Elhamri M, Raffoux E, et al. Comparison of high-dose cytarabine and timed-sequential chemotherapy as consolidation for younger adults with AML in first remission: the ALFA-9802 study. Blood 2011 Aug 18;118(7):1754-62. doi: 10.1182/blood-2011-04-349258

November 2021 new ST-QBP regimen; added NDFP form for gemtuzumab ozogamicin

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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, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for

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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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