Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Administrative Information | References | Other Notes | Disclaimer

A - Regimen Name

AMSAATRACYTA Regimen

Amsacrine-Cytarabine-Tretinoin (ATRA)

Disease Site	Hematologic - Leukemia - Acute Promyelocytic (APL)
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.
Rationale and Uses	Consolidation treatment for APL

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B - Drug Regimen

amsacrine	125 mg /m²	IV	Days 1 to 3
cytarabine	1500 mg /m²	IV	q12h Days 1, 3, 5
tretinoin (ATRA)	45 * mg /m²/day	PO	Days 1 to 28

(This drug is not currently publicly funded for this regimen and intent)

(*In 2 divided doses per day)

(Outpatient prescription in multiples of 10 mg capsules)

Alternative schedule:

amsacrine	100 mg /m²	IV	Days 1 to 5
cytarabine	100 mg /m²/day	IV continuous infusion	Days 1 to 7
tretinoin (ATRA)	45 * mg /m²/day	PO	Days 1 to 28

(This drug is not currently publicly funded for this regimen and intent)

(*In 2 divided doses per day)

(Outpatient prescription in multiples of 10 mg capsules)

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

(Also refer to local protocols which may be modified according to age and/or white blood cell count at presentation)

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate (D1, 3, 5)
Low (D2)
No routine prophylaxis for tretinoin

Other Supportive Care:

Also refer to CCO Antiemetic Recommendations.

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J - Administrative Information

Approximate Patient Visit	5 hours; AMSA days: 1.5 hours; Cytarabine days: 4 hours
Pharmacy Workload (average time per visit)	26.702 minutes
Nursing Workload (average time per visit)	82.5 minutes

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K - References

Cunningham I, Gee TS, Reich LM, et al. Acute Promyelocytic Leukemia: Treatment Results During A Decade at Memorial Hospital. Blood 1989;73(5):1116-22.

Fenaux P, Chevret S, Guerci A, et al. Long-term follow-up confirms the benefit of all-trans retinoic acid in acute promyelocytic leukemia. European APL group. Leukemia 2000;14(8):1371-7.

Fenaux P, Chastang C, Chevret S, et al. A randomized comparison of all transretinoic acid (ATRA) followed by chemotherapy and ATRA plus chemotherapy and the role of maintenance therapy in newly diagnosed acute promyelocytic leukemia. The European APL Group. Blood 1999;94(4):1192-200.

Fenaux P, Tertian G, Castaigne S, et al. A randomized trial of amsacrine and rubidazone in 39 patients with acute promyelocytic leukemia. J Clin Oncol 1991;9:1556-61.

May 2019 Updated emetic risk category

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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 the use of this information, and for any claims, actions, demands or suits that arise from such use.

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.

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.

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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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