Regimen Monograph

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

A - Regimen Name

ARSEATRA(CONS HI) Regimen

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.

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 Combination therapy in the first-line or relapsed/refractory setting for high-risk acute promyelocytic leukemia (APL), as consolidation treatment

Supplementary Public Funding

tretinoin (ATRA)
Exceptional Access Program (tretinoin (ATRA))

arsenic trioxide
New Drug Funding Program (Arsenic Trioxide - First Line Consolidation of Acute Promyelocytic Leukemia (APL))

arsenic trioxide
New Drug Funding Program (Arsenic Trioxide - Relapsed_Refractory Consolidation of Acute Promyelocytic Leukemia (APL))

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B - Drug Regimen

Option 1#

Consolidation Cycle 1 (to start 3-4 weeks after the end of induction):

tretinoin (ATRA)	45 * mg /m²/day	PO	Days 1 to 28
(*In 2 divided doses per day)			
arsenic trioxide	0.15 mg /kg/day	IV	Days 1 to 28

Consolidation Cycle 2: (to start 3-4 weeks after Consolidation Cycle 1)

tretinoin (ATRA)	45 * mg /m²/day	PO	Days 1-7, 15-21, 29-35
(*In 2 divided doses per day)			
arsenic trioxide	0.15 mg /kg	IV	Days 1-5, 8-12, 15-19, 22-26, 29-33

#APML4 consolidation regimen (Iland et al.)

Option 2†

Consolidation:

tretinoin (ATRA)	45 * mg /m²/day	PO	Days 1 to 14 (every 28 days)
(*in 2 divided doses per day)			
arsenic trioxide	0.15 mg /kg/day	IV	5 days per week x 4 weeks (every 8 weeks)

† APL0406 consolidation regimen (Lo-Coco et al.)

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C - Cycle Frequency

Option 1 (APML4 regimen):

SINGLE COURSE (containing cycle 1 and cycle 2)

Followed by maintenance treatment, 3-4 weeks after the end of consolidation cycle 2 (refer to ATRAMERCMTRX).

Option 2 (APL0406 regimen):

Repeat tretinoin component for a total of 7 cycles (1 cycle = 2 weeks on and 2 weeks off).

Repeat arsenic trioxide component for a total of 4 cycles (1 cycle = 4 weeks on and 4 weeks off).

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate

Other Supportive Care:

Also refer to CCO Antiemetic Recommendations.

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J - Administrative Information

Approximate Patient Visit	2 hours
Pharmacy Workload (average time per visit)	19.35 minutes
Nursing Workload (average time per visit)	62.5 minutes

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K - References

Iland HJ, Bradstock K, Supple SG, et al. All-trans-retinoic acid, idarubicin, and IV arsenic trioxide as initial therapy in acute promyelocytic leukemia (APML4). Blood 2012;120(8):1570-80.

Lo-Coco F, Avvisati G, Vignetti M, et al. Retinoic Acid and Arsenic Trioxide for Acute Promyelocytic Leukemia. N Engl J Med 2013;369:111-21.

July 2021 Updated Dosing regimen and Cycle frequency sections based on arsenic trioxide NDFP funding criteria

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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.

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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.

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