Regimen Monograph

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

A - Regimen Name

AZCTVENE Regimen

AzaCITIDine-Venetoclax

Disease Site

Hematologic
Leukemia - Acute Myeloid (AML)

Intent

Palliative

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

First-line treatment of acute myeloid leukemia (AML) in adult patients who are 75 years of age or older, or who have comorbidities that preclude the use of intensive chemotherapy.

Supplementary Public Funding

azaCITIDine
New Drug Funding Program (Azacitidine in combination with Venetoclax (Outpatient) - Previously Untreated Acute Myeloid Leukemia) (NDFP Website)

venetoclax
Exceptional Access Program (venetoclax - Venetoclax in combination with azacitidine - Previously untreated acute myeloid leukemia)

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B - Drug Regimen

azaCITIDine	75 mg /m²	Subcut	Daily; Days 1 to 7
Alternative Schedule:			
azaCITIDine	75 mg /m²	Subcut	Daily on days 1-5 and 8-9 (5-2-2 regimen)
Alternative Schedule:			
azaCITIDine	75 mg /m²	Subcut	Daily; Days 1 to 6
AND			
venetoclax*	400 mg	PO	Daily

*A 3-day ramp up is required in Cycle 1:

- venetoclax 100 mg once daily on day 1, 200 mg once daily on day 2, then 400 mg once daily from day 3 onwards

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C - Cycle Frequency

REPEAT EVERY 28 DAYS in the absence of disease progression or unacceptable toxicity, whichever comes first*

*For patients without unacceptable toxicity, it is recommended that patients be treated for a minimum of 6 cycles.

(If azacitidine is discontinued due to toxicities or intolerance, venetoclax should also be discontinued.)

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J - Administrative Information

Approximate Patient Visit	0.5 hours
Pharmacy Workload (average time per visit)	11.879 minutes
Nursing Workload (average time per visit)	27.5 minutes

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K - References

CADTH reimbursement recommendation: venetoclax in combination with azacitidine for the treatment of patients with newly diagnosed AML. August 2021.

DiNardo C, Jones B, Pullarkat V, et al. A randomized, double-blind, placebo-controlled study of venetoclax with azacitidine vs azacitidine in treatment-naïve patients with acute myeloid leukemia ineligible for intensive therapy – VIALE-A. Presented at: Virtual Edition of the 25th European Hematology Association (EHA) Annual Congress; June 2020. Abstract LB2601.

DiNardo CD, Jonas BA, Pullarkat V, et al. Azacitidine and venetoclax in previously untreated acute myeloid leukemia. N Engl J Med 2020 Aug 13;383(7):617-29.

DiNardo CD, Pratz K, Pullarkat V, et al. Venetoclax combined with decitabine or azacitidine in treatment-naive, elderly patients with acute myeloid leukemia. Blood 2019;133(1):7-17.

August 2022 Updated azacitidine (NDFP) and venetoclax funding (EAP), Rationale and uses, Drug regimen and Cycle frequency sections

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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.

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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