Regimen Monograph

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

A - Regimen Name

AZCTIVOS Regimen

Azacitidine-Ivosidenib

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

Treatment of patients with newly diagnosed AML with an IDH1 R132 mutation who are not eligible for intensive induction chemotherapy.

IDH1 R132 mutation should be confirmed using an appropriate diagnostic test prior to starting ivosidenib.

Refer to NDFP form for details.

Supplementary Public Funding

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

ivosidenib
Exceptional Access Program (Ivosidenib in combination with Azacitidine (Outpatient) - Previously Untreated Acute Myeloid Leukemia) (EAP Website)

Additional Information

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B - Drug Regimen

Azacitidine for injection is **not interchangeable** with, and should not be substituted with or for, azacitidine tablets. Verify drug name, dose, and administration route. The different dosage forms are not bioequivalent.

ivosidenib	500 mg	PO	Once Daily
azaCITIDine*	75 mg /m²	Subcut	Daily; Days 1-6 OR Days 1-7

*Alternative Schedule for Azacitidine: 75 mg/m^2 Subcut Daily, on Days 1-5, and 8-9 (5-2-2 regimen).

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

Until disease progression or unacceptable toxicity, for a minimum of 6 cycles

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate (azacitidine)
Low – No routine prophylaxis; PRN recommended (ivosidenib)

- Also refer to CCO Antiemetic Recommendations.

Screen for hepatitis B virus in all cancer patients starting systemic treatment. Refer to the hepatitis B virus screening and management guideline.

Other Supportive Care:

- Consider appropriate prophylaxis and close monitoring for patients at risk of tumour lysis syndrome (i.e. high tumour burden).
- Consider the use of supportive measures such as prophylactic antibiotics, transfusion and/or growth factors, according to local practice.
- QTc should be <450 msec prior to starting ivosidenib. In the presence of an abnormal QTc 480-500 msec, treatment should only be initiated in exceptional cases if the benefits outweigh the risks.

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J - Administrative Information

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

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K - References

Azacitidine drug monograph, Ontario Health (Cancer Care Ontario).

CDA reimbursement recommendation: ivosidenib. Canadian Journal of Health Technologies 2024:4(10).

Ivosidenib drug monograph, Ontario Health (Cancer Care Ontario).

Montesinos P, Recher C, Vives S, et al. Ivosidenib and azacitidine in IDH1-mutated acute myeloid leukemia. N Engl J Med 2022;386:1519-31. DOI: 10.1056/NEJMoa2117344

September 2025 new ST-QBP regimen

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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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