Regimen Monograph

A - Regimen Name

AZCTGILTVENE Regimen

Azacitidine-Gilteritinib-Venetoclax

Intent

Curative
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

Treatment of:

- newly diagnosed FLT3-mutated AML who were unfit for intensive chemotherapy*, or

* Refer to NDFP and EAP for azacitidine and venetoclax funding criteria.

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) (EAP Website)

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B - Drug Regimen

Cycle 1:

azaCITIDine[1]	75 mg /m²	Subcut	Days 1 to 7

[1]Alternative dosing schedule is azacitidine 75 mg/m^2 Subcut given on days 1 to 5, then 8 and 9, or Days 1 to 6.

venetoclax[2]	400 mg	PO	Days 1 to 28

[2] Requires ramp-up to 400 mg daily

gilteritinib[3]	80 mg	PO	Days 1 to 28

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

[3] Dose of 80 mg in phase II clinical trial; 80 or 120 mg in phase I.

Cycle 2 and onward:

azaCITIDine	75 mg /m²	Subcut	Days 1 to 5
venetoclax	400 mg	PO	Days 1 to 7
gilteritinib	80 mg	PO	Days 1 to 28

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

In the clinical trial, two doses of prophylactic intrathecal cytarabine were recommended on cycle 1, day 21 and again during cycle 2.

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

For up to 24 cycles unless disease progression or unacceptable toxicity occurs

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J - Administrative Information

Venetoclax and gilteritinib: Outpatient prescription for home administration

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

Short NJ, Daver N, Dinardo CD, et al. Azacitidine, Venetoclax, and Gilteritinib in Newly Diagnosed and Relapsed or Refractory *FLT3*-Mutated AML. J Clin Oncol 2024 Jan 26:JCO2301911. doi: 10.1200/JCO.23.01911.

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M - Disclaimer

Regimen Abstracts

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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.

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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