Regimen Monograph

 Regimen Name
 Drug Regimen
 Cycle Frequency
 Premedication and Supportive Measures
 Dose Modifications
 Adverse

 Effects
 Interactions
 Drug Administration and Special Precautions
 Recommended Clinical Monitoring
 Administrative

 Information
 References
 Other Notes
 Disclaimer

A - Regimen Name

FLAG+IDA+VENE Regimen

Fludarabine-Cytarabine-Filgrastim-Idarubicin-Venetoclax

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 acute amyloid leukemia (AML)

Days 1 to 2

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B -	Drug	Req	imen

After completion of induction, start consolidation as follows:

IDArubicin* 8 mg /m² IV

 * Dose for newly diagnosed patients. Use 6 mg/m 2 IV on Days 1-2 for patients with relpased/refractory AML.

fludarabine 30 mg/m² IV Days 1 to 3

4 hours after starting Fludarabine, give:

<u>cytarabine</u> 1500 mg /m² IV Days 1 to 3

venetoclax 400 mg PO Days 1 to 7

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

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

For up to 2 cycles

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate

No routine prophylaxis for venetoclax (oral)

Febrile Neutropenia

Risk:

Other Supportive Care:

Also refer to CCO Antiemetic Recommendations.

High

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

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J - Administrative Information

Approximate Patient Visit 3 to 4 hours

Pharmacy Workload (average time per visit) 21.0718 minutes

Nursing Workload (average time per visit) 51.667 minutes

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K - References

DiNardo CD, Lachowiez CA, Takahashi K, et al. Venetoclax combined with FLAG-IDA induction and consolidation in newly diagnosed acute myeloid leukemia. Am J Hematol 2022 Aug;97(8):1035-43.

DiNardo CD, Lachowiez CA, Takahashi K, et al. Venetoclax combined with FLAG-IDA induction and consolidation in newly diagnosed and relapsed or refractory acute myeloid leukemia. J Clin Oncol.

2021 Sep 1;39(25):2768-78.

July 2024 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.

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Regimen Monographs

Refer to the <u>New Drug Funding Program</u> or <u>Ontario Public Drug Programs</u> 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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