Regimen Monograph

A - Regimen Name

CEDADECI Regimen

Cedazuridine/decitabine

Disease Site

Hematologic
- Chronic myelomonocytic leukemia (CMML)
- Myelodysplastic Syndrome (MDS)

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.

Rationale and Uses

For the treatment of myelodysplastic syndromes (MDS), in patients who have IPSS intermediate-1, intermediate-2, and/or high-risk MDS*, adequate organ function, and have not had disease progression while on a hypomethylating agent

*Patient may have previously treated or untreated, de novo or secondary MDS, including all French-American-British (FAB) subtypes (Refractory anemia (RA), refractory anemia with ringed sideroblasts (RARS), refractory anemia with excess blasts (RAEB), and chronic myelomonocytic leukemia (CMML)).

(Refer to EAP funding criteria)

Supplementary Public Funding	**decitabine / cedazuridine** Exceptional Access Program (decitabine / cedazuridine - For the treatment of adult patients with myelodysplastic syndromes (MDS), according to clinical criteria) (EAP Website)

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B - Drug Regimen

Note: Decitabine/cedazuridine is not interchangeable with other decitabine products. Do not substitute.

decitabine / cedazuridine	35 / 100 mg	PO	Days 1 to 5

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

Until disease progression or unacceptable toxicity

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D - Premedication and Supportive Measures

Antiemetic Regimen: Low – No routine prophylaxis; PRN recommended

- 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.

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated.

Dosage with toxicity

Do not modify the recommended dose for the first 2 cycles.

Hematologic Toxicity

Dosage Reduction for Myelosuppression:

Dose Level	Decitabine / Cedazuridine Dose
0	1 tablet once daily on days 1 through 5
-1	1 tablet once daily on days 1 through 4
-2	1 tablet once daily on days 1 through 3
-3	1 tablet once daily on days 1, 3, and 5

Dose modifications in the absence of active disease:

Toxicity	Decitabine / Cedazuridine Dose
ANC < 1 x 10^9/L and/or Platelets < 50 x 10^9/L	Hold, and: • If hematologic recovery* occurs within 2 weeks of the last treatment cycle, resume at same dose. • If hematological recovery* does not occur within 2 weeks of the last treatment cycle: ◦ Delay treatment for up to 2 additional weeks. Resume at 1 dose level ↓. ◦ Consider further dose level ↓ if myelosuppression persists after a dose reduction. ◦ Maintain or ↑ dose in subsequent cycles as clinically indicated.

*ANC ≥ 1 x 10^9/L and Platelets ≥ 50 x 10^9/L

Non-hematologic Toxicity

Toxicity	Decitabine / Cedazuridine Dose
Serum creatinine ≥ 176.8 µmol /L	Delay treatment until resolved; manage patient appropriately. Resume at same dose level or at 1 dose level ↓ (e.g., administer fewer days per cycle).
Bilirubin ≥ 2 x ULN	
ALT or AST ≥ 2 x ULN	
Active or uncontrolled infection	
Severe hypersensitivity	Discontinue; manage patient appropriately.

Hepatic Impairment

Hepatic Impairment	Decitabine / Cedazuridine Starting Dose
Mild (bilirubin > 1 to ≤ 1.5 × ULN)	No dosage adjustment necessary.
Moderate (bilirubin > 1.5 to 3 x ULN)	No data available.
Severe (bilirubin > 3 × ULN)	

Renal Impairment

Creatinine Clearance (mL / min)	Decitabine / Cedazuridine Starting Dose
≥ 60	No dosage adjustment necessary.
≥ 30 to 59	No dosage adjustment necessary; monitor for increased incidence of adverse reactions.
15 to 29	Use with caution; No data available.
< 15 (ESRD)	

Dosage in the Elderly

No adjustment required. Overall, no differences in efficacy and safety were observed between patients ≥ 65 years and younger patients.

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F - Adverse Effects

Refer to decitabine / cedazuridine drug monograph(s) for additional details of adverse effects.

Very common (≥ 50%)	Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• Myelosuppression ± infection, bleeding • Fatigue	• Constipation • Musculoskeletal pain • Mucositis • Nausea, vomiting • Cough, dyspnea • Diarrhea • Dizziness • Rash • Edema • Headache	• Anorexia, weight loss • ↑ serum transaminase • Abdominal pain • Creatinine increased • Neuropathy • Fall • Insomnia • Arrhythmia • Hypotension	• Tumor lysis syndrome • Acute febrile neutrophilic dermatosis • Differentiation syndrome • Anaphylaxis • Enterocolitis • Interstitial lung disease

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G - Interactions

Refer to decitabine / cedazuridine drug monograph(s) for additional details.

- Avoid co-administration with drugs metabolized by cytidine deaminase (CDA).
- Avoid gastric acid reducing agents within 4 hours of decitabine / cedazuridine administration.

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H - Drug Administration and Special Precautions

Refer to decitabine / cedazuridine drug monograph(s) for additional details.

Administration

- Administer at approximately the same time each day for 5 days in each cycle.
- Tablets should be swallowed whole with water; do not cut, crush, or chew.
- Decitabine / cedazuridine should be taken on an empty stomach; do not consume food 2 hours before and 2 hours after each dose.
- Missed dose:
  - If the missed dose is within 12 hours of the time it is usually taken, administer the missed dose as soon as possible and then resume the normal daily dosing schedule.
  - If dose is missed by more than 12 hours of the time it is usually taken, the patient should wait and take the missed dose the following day at the usual time and extend the dosing period by 1 day for every missed dose to complete 5 daily doses for each cycle.
- If a dose is vomited, do not administer an additional dose, continue with the next scheduled dose.
- Store tablets in original packaging at room temperature (15 to 30°C).

Contraindications

- Patients who have a hypersensitivity to this drug or any of its components

Other Warnings/Precautions

- Caution with driving or using machinery as fatigue or dizziness may occur with treatment due to anemia.
- Contains lactose; carefully consider use in patients with hereditary galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption.

Pregnancy/Lactation

- This regimen is not recommended for use in pregnancy. Adequate contraception should be used by patients and their partners while on treatment and after the last treatment dose. Recommended methods and duration of contraception may differ depending on the treatment. Refer to the drug monograph(s) for more information.
- Breastfeeding is not recommended during this treatment and after the last treatment dose. Refer to the drug monograph(s) for recommendations after the last treatment dose (if available).
- Fertility Effects: Probable

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I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Refer to the hepatitis B virus screening and management guideline for monitoring during and after treatment.

Recommended Clinical Monitoring

- CBC; Baseline, prior to each cycle, and as clinically indicated
- Liver function tests; Baseline and as clinically indicated
- Renal function tests; Baseline and as clinically indicated
- Clinical toxicity assessment for infection, bleeding, fatigue, rash, hypersensitivity, tumour lysis syndrome, differentiation syndrome, GI and respiratory effects; At each visit
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

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J - Administrative Information

Outpatient prescription for home administration

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K - References

CADTH reimbursement final recommendation: Decitabine and cedazuridine (MDS), September 2021.

Garcia-Manero, Guillermo. Oral cedazuridine/decitabine for MDS and CMML: a phase 2 pharmacokinetic/pharmacodynamic randomized crossover study. Blood. 2020; 136(6): 674-683.

Inqovi (decitabine/cedazuridine) product monograph. Oakville, Ontario: Taiho Pharma Canada Inc., July 2020.

February 2025 Updated Pregnancy and Lactation section

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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.

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