


## Prior Authorization Review Panel

### CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.  
Policies submitted without this form will not be considered for review.

<b>Plan: PA Health &amp; Wellness</b>	<b>Submission Date: 05/01/2021</b>
<b>Policy Number: PA.CP.PHAR.479</b>	<b>Effective Date: 04/2021</b> <b>Revision Date: 04/2021</b>
<b>Policy Name: Decitabine/Cedazuridine (Inqovi)</b>	
<p><b>Type of Submission – <u>Check all that apply:</u></b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> <b>New Policy</b></li> <li><input type="checkbox"/> <b>Revised Policy*</b></li> <li><input type="checkbox"/> <b>Annual Review - No Revisions</b></li> <li><input type="checkbox"/> <b>Statewide PDL - <i>Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.</i></b></li> </ul>	
<p><b>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</b></p> <p><b>Please provide any changes or clarifying information for the policy below:</b></p>          	
<b>Name of Authorized Individual (Please type or print):</b>  <b>Auren Weinberg, MD</b>	<b>Signature of Authorized Individual:</b>  

## Clinical Policy: Decitabine/Cedazuridine (Inqovi)

Reference Number: PA.CP.PHAR.479

Effective Date: 04/2021

Last Review Date: 04/2021

[Revision  
Log](#)

### Description

Decitabine/cedazuridine (Inqovi<sup>®</sup>) is a combination of decitabine, a nucleoside metabolic inhibitor, and cedazuridine, a cytidine deaminase inhibitor.

### FDA Approved Indication(s)

Inqovi is indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with PA Health & Wellness<sup>®</sup> that Inqovi is **medically necessary** when the following criteria are met:

### I. Initial Approval Criteria

#### A. Myelodysplastic Syndromes (must meet all):

1. Diagnosis of MDS;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age  $\geq$  18 years;
4. Member must use decitabine (Dacogen<sup>®</sup>), unless contraindicated or clinically significant adverse effects are experienced;  
*\*Prior authorization may be required for decitabine*
5. Request meets one of the following (a or b):
  - a. Dose does not exceed 35 mg decitabine/100 mg cedazuridine (1 tablet) per day on Days 1 through 5 of each 28-day cycle;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration:** 6 months

#### B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

### II. Continued Therapy

#### A. Myelodysplastic Syndromes (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
  - a. New dose does not exceed 35 mg decitabine/100 mg cedazuridine (1 tablet) per day on Days 1 through 5 of each 28-day cycle;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration:** 12 months

**B. Other diagnoses/indications**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

**Approval duration: Duration of request or 6 months (whichever is less);** or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

CMML: chronic myelomonocytic leukemia      MDS: myelodysplastic syndrome  
 FDA: Food and Drug Administration          NCCN: National Comprehensive Cancer Network

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
decitabine (Dacogen®)	<u>MDS</u> <u>Three day regimen:</u> 15 mg/m <sup>2</sup> by IV infusion every 8 hours for 3 days. Repeat cycle every 6 weeks. <u>Five day regimen:</u> 20 mg/m <sup>2</sup> by IV infusion repeated daily for 5 days. Repeat cycle every 4 weeks.	See regimens

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

None reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
MDS	1 tablet (35 mg decitabine/100 mg cedazuridine) PO QD on Days 1 through 5 of each 28-day cycle for a minimum of 4 cycles until disease progression or unacceptable toxicity. A complete or partial response may take longer than 4 cycles.	1 tablet (35 mg decitabine/100 mg cedazuridine)/day

**VI. Product Availability**

Tablet: 35 mg decitabine/100 mg cedazuridine

**VII. References**

1. Inqovi Prescribing Information. Princeton, NJ: Otsuka Pharmaceutical Co., Ltd.; July 2020. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/212576s0001bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212576s0001bl.pdf). Accessed January 14, 2021.
2. Dacogen Prescribing Information. Rockville, MD: Otsuka America Pharmaceuticals, Inc.; June 2020. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/021790s0251bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021790s0251bl.pdf). Accessed January 14, 2021.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed January 14, 2021.
4. National Comprehensive Cancer Network Myelodysplastic Syndromes Version 2.2021. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/mds.pdf](https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf). Accessed January 14, 2021.
5. Garcia-Manero G, Griffiths EA, Steensma DP, et al. Oral cedazuridine/decitabine: a phase 2, pharmacokinetic/pharmacodynamic, randomized, crossover study in MDS and CMML [published online ahead of print, 2020 Apr 13]. *Blood*. 2020;blood.2019004143. doi:10.1182/blood.2019004143
6. Garcia-Manero G, McCloskey J, Griffiths EA, et al. Pharmacokinetic exposure equivalence and preliminary efficacy and safety from a randomized cross over Phase 3 study (ASCERTAIN study) of an oral hypomethylating agent ASTX727 (cedazuridine/decitabine) compared to IV decitabine. *Blood* 2019; 134 (Supplement\_1).

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04/2021	