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.

Plan: PA Health & Wellness	**Submission Date: 05/01/2022**
Policy Number: PA.CP.PHAR.479	**Effective Date: 04/2021** **Revision Date: 04/2022**
Policy Name: Decitabine/Cedazuridine (Inqovi)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

2Q 2022 annual review: for decitabine redirection added by-passing of redirection for state regulations; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Decitabine/Cedazuridine (Inqovi)

Reference Number: PA.CP.PHAR.479
Effective Date: 04/2021
Last Review Date: 04/2022

Revision Log

Description
Decitabine/cedazuridine (Inqovi®) 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® 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 ≥ 18 years;
4. Member must use decitabine (Dacogen®), unless one of the following (a or b):
   a. Decitabine (Dacogen) is contraindicated or clinically significant adverse effects are experienced;
   b. Request is for treatment associated with cancer for stage 4 advanced, metastatic cancer;

   **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
FDA: Food and Drug Administration
MDS: myelodysplastic syndrome
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®)	MDS Three day regimen: 15 mg/m^2 by IV infusion every 8 hours for 3 days. Repeat cycle every 6 weeks. Five day regimen: 20 mg/m^2 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/2020/212576s000lbl.pdf. Accessed February 14, 2022.
2. Dacogen Prescribing Information. Rockville, MD: Otsuka America Pharmaceuticals, Inc.; June 2020. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021790s025lbl.pdf. Accessed February 14, 2022.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 14, 2022.
4. National Comprehensive Cancer Network Myelodysplastic Syndromes Version 3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed February 14, 2022.
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	
2Q 2022 annual review: for decitabine redirection added by-passing of redirection for state regulations; references reviewed and updated.	04/2022	