RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	decitabine/cedazuridine
Policy Number:	RxA.645
Drug(s) Applied:	Inqovi®
Original Policy Date:	09/14/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Inqovi® is a combination of decitabine, a nucleoside metabolic inhibitor, and cedazuridine, a cytidine deaminase inhibitor. It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Inqovi® (decitabine/cedazuridine)	MDS, CMML	One (1) tablet (35 mg decitabine and 100 mg cedazuridine) orally once daily on an empty stomach 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	One (1) tablet (35 mg decitabine and 100 mg cedazuridine) days 1 through 5 of each 28-day cycle

Dosage Forms

- Tablets: 35 mg decitabine and 100 mg cedazuridine

Clinical Policy

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

I. Initial Approval Criteria

A. Myelodysplastic Syndromes and Chronic Myelomonocytic Leukemia (must meet all):

1. Diagnosis of myelodysplastic syndrome or CMML;
2. Prescribed by or in consultation with an oncologist;
3. Age 18 years of age or older;

Approval Duration

Commercial: 6 months

Medicaid: 6 months

II. Continued Therapy Approval

A. Myelodysplastic Syndromes and Chronic Myelomonocytic Leukemia (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy.
2. Member is responding positively to therapy (i.e. no evidence of unacceptable toxicity or disease progression)

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CMML: Chronic Myelomonocytic Leukemia
FDA: Food and Drug Administration
IPSS: International Prognostic Scoring System
MDS: Myelodysplastic Syndromes
NCCN: National Comprehensive Cancer Network

APPENDIX B: Therapeutic Alternatives
Certain subtypes of MDS may be treated with specific pharmacologic agents:

- Jakafi® (ruxolitinib): Approved for intermediate or high-risk myelofibrosis and polycythemia vera
- Gleevec® (imatinib): Approved for adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with PDGFR gene re-arrangements
- Inrebic® (fedratinib): Approved for adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).
- Reblozyl® (luspatercept-aamt): Approved for the treatment of anemia due to myelodysplastic syndrome in patients failing an erythropoiesis stimulating agent (ESA) and requiring 2 or more red blood cell (RBC) units over 8 weeks.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None

- Boxed Warning(s):
  - None

APPENDIX D: General Information
The National Comprehensive Cancer Network (NCCN) Myelodysplastic Syndromes Guidelines have not been updated to include Inqovi®.

References

1. Decitabine/cedazuridine. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI; 2020, March 17. Accessed with subscription at: http://www.micromedexsolutions.com. Accessed August 27, 2020.

2. Decitabine/cedazuridine. Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed August 27, 2020.
3. Inqovi® (decitabine/cedazuridine) tablets, for oral use prescribing information (per FDA). Princeton, NJ: Otsuka Pharmaceutical Co., Ltd., 2020, July. Accessed August 27, 2020.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Accessed with subscription at: http://www.nccn.org. Accessed August 27, 2020.
5. National Comprehensive Cancer Network Guidelines. Myelodysplastic Syndromes Version 2.2020. Available at: http://www.nccn.org. Accessed August 27, 2020

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	08/27/2020	09/14/2020