Inqovi® (decitabine and cedazuridine)
(Oral)

Document Number: IH-0554

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Inqovi (35 mg decitabine and 100 mg cedazuridine) tablets: 5 tablets per 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- MDS: 5 tablets (35 mg decitabine and 100 mg cedazuridine per tablet) per 28 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient has a contraindication to injectable decitabine; **AND**

- Patient is at least 18 years of age; **AND**

Universal Criteria [1]

- Therapy will not be substituted for intravenous decitabine within the same cycle; **AND**
- Used as single agent therapy; **AND**

Myelodysplastic syndrome (MDS) † Φ [1-5]

- Patient has a confirmed diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS; **AND**
- Patient should have received no more than one previous cycle of decitabine or one previous cycle of azacitidine; **AND**
- Patient has one of the following French-American-British (FAB) sub-types with an International Prognostic Scoring System (IPSS) group risk classification of Intermediate-1, Intermediate-2, or High-risk:
  - Refractory anemia

- Refractory anemia with ringed sideroblasts
- Refractory anemia with excess blasts
- Chronic myelomonocytic leukemia (CMML)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,5,6]

Coverage can be renewed based on the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe myelosuppression, serious infectious complications, etc.; **AND**
- Adequate documentation of disease stability and/or improvement as indicated by one of the following: decrease in bone marrow blasts percentage, increase in platelets, increase in hemoglobin or decrease in transfusions (if transfusion dependent), increase in WBC/ANC over pretreatment values, or reduction in abnormal cytogenetic metaphases

V. Dosage/Administration [1]

Indication	Dose
MDS	The recommended dosage of Inqovi is 1 tablet (containing 35 mg decitabine and 100 mg cedazuridine) orally once daily 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.

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 – Prescription drug, oral, chemotherapeutic, not otherwise specified
- C9399 – Unclassified drugs or biologicals *(Hospital Outpatient Use ONLY)*

NDC:

- Inqovi (35 mg decitabine and 100 mg cedazuridine) tablets: 64842-0727-xx

VII. References

1. Inqovi [package insert]. Princeton, NJ; Taiho Oncology, Inc.; July 2020. Accessed July 2021.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) for decitabine and cedazuridine. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL

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3. Swerdlow SH, Campo E, Harris NL, et al., editors. WHO Classification of Tumours of Hematopoietic and Lymphoid Tissues. Lyon, France: IARC; 2008.
4. Savona MR, Odenike O, Amrein PC, et al. An oral fixed-dose combination of decitabine and cedazuridine in myelodysplastic syndromes: a multicentre, open-label, dose-escalation, phase 1 study. Lancet Haematol. 2019 Apr;6(4):e194-e203. doi: 10.1016/S2352-3026(19)30030-4.
5. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myelodysplastic Syndromes Version 3.2021. National Comprehensive Cancer Network, 2021. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2021.
6. Cheson BD, Greeberg PL, Bennet JM, et al. Clinical Application and Proposal for Modification of the International Working Group (IWG) Response Criteria in Myelodysplasia. Blood. 2006 Jul 15;108(2):419-25. doi: 10.1182/blood-2005-10-4149.
7. 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 [abstract no. 846]. Blood. 2019;134(Suppl 1):846

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C93.10	Chronic myelomonocytic leukemia not having achieved remission
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.22	Refractory anemia with excess of blasts 2
D46.4	Refractory anemia, unspecified
D46.9	Myelodysplastic syndrome, unspecified
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality

ICD-10	ICD-10 Description
D46.Z	Other myelodysplastic syndromes

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC