PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Inqovi Prior Authorization Policy
- Inqovi® (decitabine and cedazuridine tablets – Taiho Oncology/Otsuka)

REVIEW DATE: 08/10/2022

OVERVIEW

Inqovi, a combination of decitabine (a nucleoside metabolic inhibitor) and cedazuridine (a cytidine deaminase inhibitor), is indicated in adults for the treatment of **myelodysplastic syndrome** (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.[1]

Decitabine is available as a parenteral product (Dacogen® [decitabine intravenous infusion]; generic) and possesses the same FDA-approved indication as Inqovi.[2] The oral bioavailability of decitabine is limited due to rapid degradation by cytidine deaminase in the gut and liver.[1] As a cytidine deaminase inhibitor, cedazuridine increases decitabine concentrations to therapeutic levels. Oral decitabine has systemic exposure equivalent to the intravenous form with similar clinical response rates in the population in which Inqovi is approved.[1,2] The recommended dose of Inqovi is one tablet taken orally once daily on Days 1 through 5 of each 28-day cycle for a minimum of four cycles until disease progression or unacceptable toxicity. A complete or partial response may take longer than four cycles. In the two pivotal trials, the median treatment duration was up to 8 months. Do not substitute Inqovi for the intravenous decitabine product within a cycle.

Guidelines

Inqovi is discussed in guidelines from the National Comprehensive Cancer Network (NCCN) for MDS. These guidelines (version 3.2022 – January 13, 2022) state that Inqovi can be considered as a substitute for intravenous decitabine. The guidelines recommend intravenous decitabine in various clinical scenarios (e.g., treatment of lower-risk disease or higher-risk disease) and CMML (as a single agent or with Jakafi® [ruxolitinib tablets]).[3]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Inqovi. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Inqovi is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Chronic Myelomonocytic Leukemia.** Approve for 1 year if the patient is ≥ 18 years of age.

2. **Myelodysplastic Syndrome.** Approve for 1 year if the patient is ≥ 18 years of age.
   Note: Examples of myelodysplastic syndromes include: refractory anemia, refractory anemia with ringed sideroblasts, and refractory anemia with excess blasts.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Inqovi is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Inqovi® tablets [prescribing information]. Princeton, NJ and Japan: Taiho Oncology and Otsuka; March 2022.
2. Dacogen® intravenous infusion [prescribing information]. Rockville, MD and Dublin, CA: Otsuka and Astex; June 2020.
3. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 3.2022 – January 13, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed August 8, 2022.