UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 1343-2
Program	Prior Authorization/Notification
Medications	Inqovi® (decitabine and cedazuridine) tablet
P&T Approval Date	12/2020, 2/2022
Effective Date	5/1/2022; Oxford only: 5/1/2022

1. Background:

Inqovi is acombination of decitabine, a nucleoside metabolic inhibitor, and cedazuridine, a cytidine deaminase inhibitor, indicated for the 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 (IPSS) groups.

The National Cancer Comprehensive Network (NCCN) notes that Inqovi could be considered as a substitution for intravenous decitabine in patients with IPSS intermediate-1 and above.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria:

A. Patients less than 19 years of age

1. **Inqovi** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. Myelodysplastic Syndrome (MDS)/Chronic Myelomonocytic Leukemia (CMML)

1. **Initial Authorization**

   a. **Inqovi** will be approved based on **one** of the following:

(1) **Both** of the following:

(a) Diagnosis of myelodysplastic syndrome (MDS)

-AND-

(b) Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)

-OR-

(2) Diagnosis of chronic myelomonocytic leukemia (CMML)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Inqovi** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Inqovi therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Inqovi [package insert]. Princeton, NJ: Taiho Oncology, Inc.; July 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed January 5, 2022.

Program	Prior Authorization/Notification – Inqovi® (decitabine and cedazuridine)
Change Control	
12/2020	New program.
2/2022	Annual review. Updated background and references with no changes to the clinical criteria.