

Clinical Pharmacy Program Guidelines for Inqovi

Program	Prior Authorization- Inqovi
Medication	Inqovi® (decitabine and cedazuridine) tablet
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	12/2020
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	1/2021

1. Background:

Inqovi is 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 groups.

The National Cancer Comprehensive Network (NCCN) notes that Inqovi could be considered as a substitution for intravenous decitabine.

2. Coverage Criteria:

<p>A. <u>Myelodysplastic Syndrome (MDS)/Chronic Myelomonocytic Leukemia (CMML)</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Inqovi will be approved based on <u>one</u> of the following:</p> <p style="padding-left: 40px;">(1) <u>Both</u> of the following:</p> <p style="padding-left: 80px;">(a) Diagnosis of myelodysplastic syndrome (MDS)</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 80px;">(b) Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)</p> <p style="text-align: center;">-OR-</p>

(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.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Inqovi** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Inqovi therapy

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 October 28, 2020.

Program	Prior Authorization– Inqovi® (decitabine and cedazuridine) tablet
Change Control	
Date	Change
12/2020	New program