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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	August 14, 2020
Subject:	Inqovi	**Page:**	1 of 5

Last Review Date: December 13, 2024

Inqovi

Description

Inqovi (decitabine and cedazuridine)

Background
Inqovi is a combination of decitabine, a nucleoside metabolic inhibitor, and cedazuridine, a cytidine deaminase inhibitor. Decitabine is thought to exert its effects after phosphorylation and direct incorporation into DNA and inhibition of DNA methyltransferase, causing hypomethylation of DNA and cellular differentiation and/or apoptosis. Non-proliferating cells are relatively insensitive to decitabine. Administration of cedazuridine with decitabine increases systemic exposure of decitabine (1).

Regulatory Status
FDA-approved indications: Inqovi is indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously 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).

The recommended dosage of Inqovi is 1 tablet 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 (1).

Myelosuppression can occur in patients treated with Inqovi. Complete blood counts should be obtained prior to initiating Inqovi and before each cycle. Then next cycle should be delayed if absolute neutrophil count (ANC) is less than 1,000/µL and platelets are less than 50,000/µL in the absence of active disease. Complete blood count should be monitored until ANC is 1,000/µL or greater and platelets are 50,000/µL or greater (1).

Inqovi can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with Inqovi and for 6 months after the last dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Inqovi and for 3 months after the last dose (1).

The safety and effectiveness of Inqovi in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Inqovi may be considered **medically necessary** if the conditions indicated below are met.

Inqovi may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Myelodysplastic syndromes (MDS), including:
   a. De novo and secondary MDS
   b. Chronic myelomonocytic leukemia (CMML)

c. Intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups

AND ALL of the following:

a. Prescriber agrees to monitor absolute neutrophil count (ANC) and platelets prior to initiating Inqovi and before each cycle and delay the next cycle resuming at the same or reduced dose as clinically indicated
b. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Inqovi and for 6 months after the last dose
c. Male patients with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Inqovi and for 3 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Myelodysplastic syndromes (MDS), including:
   a. De novo and secondary MDS
   b. Chronic myelomonocytic leukemia (CMML)
   c. Intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor absolute neutrophil count (ANC) and platelets before each cycle and delay the next cycle resuming at the same or reduced dose as clinically indicated
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Inqovi and for 6 months after the last dose
d. Male patients with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Inqovi and for 3 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 15 tablets per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Inqovi is a combination of decitabine, a nucleoside metabolic inhibitor, and cedazuridine, a cytidine deaminase inhibitor. Decitabine is thought to exert its effects after phosphorylation and direct incorporation into DNA and inhibition of DNA methyltransferase, causing hypomethylation of DNA and cellular differentiation and/or apoptosis. Non-proliferating cells are relatively insensitive to decitabine. Administration of cedazuridine with decitabine increases systemic exposure of decitabine. The safety and effectiveness of Inqovi in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Inqovi while maintaining optimal therapeutic outcomes.

References

1. Inqovi [package insert]. Princeton, NJ: Taiho Oncology, Inc.; March 2022.
2. NCCN Drugs & Biologics Compendium® Decitabine and cedazuridine 2024. National Comprehensive Cancer Network, Inc. Accessed on October 1, 2024.

Policy History

Date	Action
August 2020	Addition to PA

September 2020	Annual review
December 2020	Annual review
June 2021	Annual review and reference update
June 2022	Annual review and reference update
June 2023	Annual review and reference update
September 2023	Annual review and reference update
June 2024	Annual review and reference update
September 2024	Annual review and reference update
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.