PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/18/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Inqovi, a combination of decitabine (a nucleoside metabolic inhibitor) and cedazuridine (a cytidine deaminase inhibitor), is indicated 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 (IPSS) groups in adults.[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. The guidelines (version 2.2025 – January 17, 2025) state that Inqovi can be considered as a substitute for intravenous decitabine. The guidelines recommend intravenous decitabine in patients with IPSS intermediate-1 and above, CMML, and MDS/myeloproliferative neoplasm overlap neoplasms.[3]

POLICY STATEMENT

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

- **Inqovi® (decitabine and cedazuridine tablets – Taiho Oncology/Otsuka)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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.

Other Uses with Supportive Evidence

3. **Myelodysplastic Syndrome With Myeloproliferative Neoplasm Overlap Syndrome**. Approve for 1 year if the patient is ≥ 18 years of age.

CONDITIONS NOT COVERED

- **Inqovi® (decitabine and cedazuridine tablets – Taiho Oncology/Otsuka)**

is(are) considered not medically necessary for ANY other use(s); 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 2.2025 – January 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 11, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Myelodysplastic Syndrome/Myeloproliferative Neoplasm Overlap Neoplasms:** Condition of approval was added to "Other Uses with Supportive Evidence."	08/30/2023
Annual Revision	**Myelodysplastic Syndrome With Myeloproliferative Neoplasm Overlap Syndrome**: The condition of approval was reworded; previously it was Myelodysplastic Syndrome/Myeloproliferative Neoplasm Overlap Neoplasms**.**	06/19/2024
Annual Revision	No criteria changes.	06/18/2025