Reference number(s)
4002-A

SPECIALTY GUIDELINE MANAGEMENT

INQOVI (decitabine and cedazuridine)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Inqovi is indicated for 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.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Myelodysplastic syndromes (MDS)/Chronic myelomonocytic leukemia (CMML)
Authorization of 12 months may be granted for the treatment of myelodysplastic syndromes (MDS), including chronic myelomonocytic leukemia (CMML).

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Inqovi [package insert]. Japan: Otsuka Pharmaceutical Co, Ltd; July 2020.