

## Pre - PA Allowance

None

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## Prior-Approval Requirements

**Age** 18 years of age or older

### Diagnoses

Patient must have **ONE** of the following:

1. Relapsed or refractory acute myeloid leukemia (AML)
2. Newly-diagnosed acute myeloid leukemia (AML)
  - a. Patient is 75 years of age or older **OR** patient has comorbidities that preclude the use of intensive induction chemotherapy
  - b. Used in combination with azacitidine **OR** as monotherapy
3. Relapsed or refractory myelodysplastic syndromes (MDS)
4. Locally advanced or metastatic cholangiocarcinoma
  - a. Previously treated with at least one prior regimen

**AND ALL** of the following:

1. Susceptible isocitrate dehydrogenase-1 (IDH1) mutation detected by an FDA-approved test
2. Prescriber agrees to monitor for signs and symptoms of differentiation syndrome
3. Prescriber agrees to monitor electrocardiograms (ECGs) for QTc prolongation
4. Prescriber agrees to monitor for signs and symptoms of Guillain-Barre syndrome

## Prior - Approval Limits

**Quantity** 180 tablets per 90 days

**Duration** 12 months

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## **Prior – Approval *Renewal* Requirements**

**Age** 18 years of age or older

### **Diagnoses**

Patient must have **ONE** of the following:

1. Relapsed or refractory acute myeloid leukemia (AML)
2. Acute myeloid leukemia (AML)
  - a. Patient is 75 years of age or older **OR** patient has comorbidities that preclude the use of intensive induction chemotherapy
  - b. Used in combination with azacitidine **OR** as monotherapy
3. Relapsed or refractory myelodysplastic syndromes (MDS)
4. Locally advanced or metastatic cholangiocarcinoma

**AND ALL** of the following:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor for signs and symptoms of differentiation syndrome
3. Prescriber agrees to monitor ECGs for QTc prolongation
4. Prescriber agrees to monitor for signs and symptoms of Guillain-Barre syndrome

## **Prior - Approval *Renewal* Limits**

Same as above