Clinical Policy Title:	ivosidenib
Policy Number:	RxA.508
Drug(s) Applied:	Tibsovo®
Original Policy Date:	03/06/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Acute Myeloid Leukemia (AML) (must meet all)**:**

1. Diagnosis of AML;
2. Member meets one of the following (a, b, or c):
   a. Disease is newly diagnosed, prescribed in combination with azacitidine, or prescribed as monotherapy, and one of the following (i or ii):
      i. Age ≥ 75 years;
      ii. Medical justification supports inability to use intensive induction chemotherapy;*
   b. Disease is relapsed or refractory;
   c. Age ≥ 60 years and one of the following (i or ii);
      i. Member is not a candidate for intensive induction therapy;
      ii. Used for post-induction therapy with previous lower-intensity therapy ;*

   *Prior authorization may be required.
3. Presence of an IDH1 mutation.

Approval duration

All Lines of Business (except Medicare): 6 months

B. Biliary Tract Cancers (Intrahepatic and Extrahepatic Cholangiocarcinoma) (must meet all)**:**

1. Diagnosis of locally advanced and metastatic cholangiocarcinoma;
2. Presence of an IDH1 mutation;
3. Disease has progressed on or after treatment with at least 1 but not more than 2 prior regimens, including at least one gemcitabine- or 5-FU-containing regimen;
4. Tibsovo® will be used as a single agent for subsequent treatment.

Approval duration

All Lines of Business (except Medicare): 6 months

C. Bone Cancers (Chondrosarcoma and Osteosarcoma) (off- label) (must meet all)**:**

1. Diagnosis of chondrosarcoma or osteosarcoma;
2. Presence of an IDH1 mutation;
3. Request meets one of the following (a or b):
   a. Patient has conventional chondrosarcoma of grades 1-3;
   b. Patient has differentiated chondrosarcoma;
4. Disease has progressed on or after systemic treatment recommended by NCCN.

Approval duration
All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All indication in section I (must meet all)**:**

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration
All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network Guidelines. Acute Myeloid Leukemia Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed August 28, 2024.
2. National Comprehensive Cancer Network Guidelines. Hepatobiliary Cancer Version 2.2024. Available at: Accessed August 28, 2024.
3. National Comprehensive Cancer Network Guidelines. Bone Cancer Version 2.2024. Available at: Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title updated 2. Line of business policy applies to was updated to All lines of business 3. Age criteria for Initial approval criteria was updated to ≥ 75 years from > 60 years. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Added criteria for off-label use cholangiocarcinoma. 6. Reference reviewed and updated.	11/06/2020	12/07/2020
Policy was reviewed: 1. Initial Approval Criteria I.B Biliary Tract Cancers (Intrahepatic and Extrahepatic Cholangiocarcinoma) was changed from off label indication to FDA approved indication. 2. Initial Approval Criteria I.B.5 was updated from "Disease has progressed on or after systemic treatment recommended by NCCN" to "Disease has progressed on or after treatment with at least 1 but not more than 2	09/22/2021	12/07/2021

prior regimens, including at least one gemcitabine- or 5-FU-containing regimen". 3. Initial Approval Criteria I.C was updated to include off-label indication, "Bone Cancers (Chondrosarcoma and Osteosarcoma)." 4. Continued Therapy Approval II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 5. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.4.a: Updated diagnostic criteria from Disease is newly diagnosed to Disease is newly diagnosed, prescribed in combination with azacitidine or as monotherapy. 2. Initial Approval Criteria, I.A.4.b: "Disease has relapsed after or is in remission following Tibsovo® therapy" was replaced with Disease is relapsed or refractory. 3. Initial Approval Criteria, I.A.4.c: " Disease has relapsed after or is refractory to induction therapy was replaced with Age ≥ 60 years and one of the following (i or ii); i. Member is not a candidate for intensive induction therapy; ii. Used for post-induction therapy with previous lower-intensity therapy. 4. Initial Approval Criteria, I.B.1: Updated diagnostic criteria from Diagnosis of unresectable and metastatic cholangiocarcinoma to Diagnosis of locally advanced and metastatic cholangiocarcinoma. 5. Initial Approval Criteria, I.B.2: Updated prescriber criteria from Prescribed by or in consultation with an oncologist or gastroenterologist to Prescribed by or in consultation with an oncologist, a hepatologist or a gastroenterologist.	08/04/2022	10/19/2022

6. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	8/28/2024	9/13/2024