POLICY NUMBER UM ONC_1340	**SUBJECT** Tibsovo™ (ivosidenib)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 2**
DATES COMMITTEE REVIEWED 08/08/18, 07/10/19, 12/11/19, 07/08/20	**APPROVAL DATE** July 8, 2020	**EFFECTIVE DATE** July 31, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 08/08/18, 07/10/19, 12/11/19, 07/08/20	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1		**NCQA STANDARDS** UM 2	**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** All	

I. PURPOSE

To define and describe the accepted indications for Tibsovo (ivosidenib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**
    a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand-name drugs.
2. **Acute Myeloid Leukemia (AML)**
    a. The member has AML with a documented IDH1 gene-mutation as detected by an FDA approved test, e.g. Abbott RealTime IDH1 Assay **AND**
    b. Tibsovo (ivosidenib) may be used as a single agent as **ANY** of the following:
        i. Induction/initial treatment,
        ii. Post-remission/consolidation therapy following response to induction/initial treatment
        iii. For relapsed/refractory AML

III. EXCLUSION CRITERIA

1. Disease progression on Tibsovo (ivosidenib)
2. Dosing exceeds single dose limit of Tibsovo (ivosidenib) 500 mg.
3. Treatment exceeds the maximum limit of 60 (250 mg) tablets/month.
4. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Tibsovo PI prescribing information. Agios Pharmaceuticals, Inc. Cambridge, MA 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.