Pharmacy Policy Bulletin: J-1401 Voranigo (vorasidenib) – Commercial and Healthcare Reform	
Number: J-1401	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1., 2., or 3.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1401-002	**Original Date:** 10/02/2024
Effective Date: 07/18/2025	**Review Date:** 06/25/2025

Drugs Product(s):	• Voranigo (vorasidenib)
FDA-Approved Indication(s):	• Treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase (IDH)-1 or IDH-2 mutation, as detected by an FDA-approved test, following surgery including biopsy, sub-total resection, or gross total resection.

Background:	• Voranigo targets IDH1 and IDH2 enzymes and in modeling inhibited IDH. • Gliomas are tumors that arise from glial or precursor cells within the central nervous system (CNS). Gliomas deter normal brain function and cause symptoms such as headaches, memory problems, weakness, and numbness. The World Health Organization (WHO) classification recognizes four general groups of gliomas and their grades. Diffuse gliomas, which includes astrocytoma or oligodendroglioma, with IDH mutations are the most common malignant primary brain tumors diagnosed in adults younger than 50 years of age. Astrocytomas have four grades with the higher the grade the more aggressive the tumor. Grade II astrocytoma is low-grade. Low grade indicates it has spread into surrounding brain tissue. Oligodendrogliomas have two grades – Grade II is low grade, while Grade III is malignant. These tumors are linked to mutations in the metabolic enzyme IDH, and molecular testing is required for proper diagnosis. Diffuse gliomas are not curable and without treatment can grow and infiltrate normal brain tissue. • FDA-approved companion diagnostics for Voranigo can be found at: https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools#table. • ICD-10 Code Information: ○ ICD-10: C71 “Malignant neoplasm of brain” or C71.9 “Malignant neoplasm of brain, unspecified” may apply to Voranigo; however, the prescriber must confirm that the member has a specific diagnosis of Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation.

	• Prescribing Considerations:
	  ○ Voranigo has warnings or precautions for hepatotoxicity and embryo-fetal toxicity.
	  ○ Patients must be monitored for liver function while using Voranigo.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Voranigo may be approved when all of the following criteria are met **(A., B., and C.)**:

A. The member is 12 years of age or older.

B. The member has a diagnosis of one (1) of the following criteria **(1. or 2.)**:

1. Grade 2 astrocytoma (no ICD-10 code) with a susceptible IDH1 or IDH2 mutation, as detected by an FDA- approved test.

2. Grade 2 oligodendroglioma (no ICD-10 code) with a susceptible IDH1 or IDH2 mutation, as detected by an FDA-approved test.

C. The member is requesting the drug following surgery including biopsy, sub-total resection, or gross total resection.

II. Reauthorization

When a benefit, reauthorization of Voranigo may be approved when the following criterion is met **(A.)**:

A. The prescriber attests that the member is tolerating therapy and has experienced a therapeutic response defined as one (1) of the following **(1. or 2.)**:

1. Disease improvement

2. Delayed disease progression

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

IV. Coverage of oncology drug(s) listed in this policy may be approved on a case-by-case basis per indications supported in the most current NCCN guidelines.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Voranigo [package insert]. Boston, MA: Servier Pharma LLC; April 2025.

2. American Association of Neurological Surgeons. Astrocytoma Tumors. Available at: https://www.aans.org/patients/conditions-treatments/astrocytoma-tumors/. Accessed August 12, 2024.
3. National Cancer Institute. Oligodendroglioma and Other IDH-Mutated Tumors: Diagnosis and Treatment. Available at: https://www.cancer.gov/rare-brain-spine-tumor/tumors/oligodendroglioma. Accessed August 12, 2024.
4. National Comprehensive Cancer Network. NCCN Guidelines Version 02.2025 Pediatric Central Nervous System Cancers. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_cns.pdf. Accessed May 12, 2025.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.