VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Voranigo Prior Authorization Policy
- Voranigo® (vorasidenib tablets – Servier Pharmaceuticals)

REVIEW DATE: 08/09/2024

OVERVIEW

Voranigo, an isocitrate dehydrogenase-1 (IDH1) and IDH2 inhibitor, is indicated for the treatment of Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation following surgery including biopsy, sub-total resection, or gross total resection, in adult and pediatric patients ≥ 12 years of age.[1]

Disease Overview

Gliomas are the most common malignant primary brain tumor in adults. These are tumors that arise from glial or precursor cells within the central nervous system (CNS).[2,3] The World Health Organization (WHO) classifies gliomas into distinct tumor subtypes and tumor grades based on histologic and molecular features. The adult-type diffuse gliomas are one of the four general groups of gliomas. Nearly all Grade 2 diffuse gliomas in adults have mutations in the genes encoding the IDH1 or IDH2 metabolic enzymes. Grade 2 diffuse gliomas are further sub-divided into three categories: astrocytoma, IDH-mutant (CNS WHO grades 2-4); oligodendroglioma, IDH-mutant and 1p19q-codeleted (CNS WHO grades 2-3); and glioblastoma, IDH-wildtype (CNS WHO grade 4).

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for Central Nervous System Cancers (version 2.2024 – July 25, 2024) have addressed the use of Voranigo, prior to its FDA approval.[4] In a footnote, the guidelines note that the FDA approval process is ongoing for Voranigo; however, eligible patients with newly diagnosed WHO grade 2, IDH1 or IDH2 mutation-positive gliomas can obtain Voranigo through an expanded access program. This footnote is referenced under WHO grade 2 IDH-mutant astrocytoma with poor performance status and as a "Preferred" systemic therapy option for adjuvant treatment after surgery/biopsy for IDH-mutant oligodendroglioma (treatment with radiotherapy and chemotherapy is not preferred) and IDH-mutant astrocytoma (if residual disease is present) [all category 2A recommendations].

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Voranigo. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Voranigo is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Gliomas.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 12 years of age; AND
   - **B)** Patient has a susceptible isocitrate dehydrogenase-1 (IDH1) or IDH2 mutation-positive disease; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has Grade 2 oligodendroglioma; OR
     - **ii.** Patient has Grade 2 astrocytoma; AND
   - **D)** Patient has had prior surgery, including biopsy, sub-total resection, or gross total resection.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Voranigo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Voranigo® tablets [prescribing information]. Boston, MA: Servier Pharmaceuticals; August 2024.
2. Mellinghoff IK, van den Bent MJ, Blumenthal DT, et al. Vorasidenib in IDH1- or IDH2-mutant low-grade glioma. *N Engl J Med.* 2023;389:589-601.
3. Servier Pharmaceuticals [press release]. Servier's Voranigo (vorasidenib) tablets receives FDA approval as first targeted therapy for Grade 2 IDH-mutant glioma. Available at: https://servier.us/blog/serviers-voranigo-vorasidenib-tablets-receives-fda-approval-as-first-targeted-therapy-for-grade-2-idh-mutant-glioma/?utm_campaign=vora_ann_webbanner_popup. Accessed on August 7, 2024.
4. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 2.2024 – July 25, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 7, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/09/2024