PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 08/06/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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, as detected by an FDA-approved test, 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 1.2025 – June 3, 2025) recommend Voranigo as a "Preferred" regimen for adjuvant treatment after surgery/biopsy (treatment with radiotherapy and chemotherapy is not preferred) for WHO Grade 2, IDH1 or IDH2 mutation-positive gliomas (Karnofsky performance status ≥ 60) [category 1].[4] This is for oligodendroglioma and astrocytoma. For KPS < 60, Voranigo is listed as "Useful in Certain Circumstances" (for astrocytoma) or under "Other Recommended" (oligodendroglioma) regimen (category 2A; category 2B for WHO grade 3) for IDH1 or IDH2 mutations. It is also listed as a "Preferred" regimen (category 2A) for recurrent or progressive disease after radiation and chemotherapy (WHO Grade 2; KPS ≥ 60). For WHO Grade 3 recurrent or progressive oligodendroglioma with IDH mutation, KPS ≥ 60, Voranigo is category 2A recommended therapy listed under "Preferred" regimens. Voranigo is a category 2B recommended therapy for recurrent or progressive IDH-mutant astrocytoma, WHO grade 3 or 4, KPS ≥ 60.

POLICY STATEMENT

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

- **Voranigo® (vorasidenib tablets - Servier Pharmaceuticals)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

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 COVERED

- **Voranigo® (vorasidenib tablets - Servier Pharmaceuticals)**

is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Voranigo® tablets [prescribing information]. Boston, MA: Servier Pharmaceuticals; April 2025.
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 4, 2025.
4. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 1.2025 – June 3, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 4, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/09/2024
Update	1/23/2025: Updated guidelines in the overview section. No criteria changes.	--
Annual Revision	**Gliomas:** Added qualifier "≥" in front of Grade 2 oligodendroglioma and astrocytoma.	08/06/2025