



PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Voranigo Prior Authorization Policy

- Voranigo® (vorasidenib tablets – Servier Pharmaceuticals)

REVIEW DATE: 08/09/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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 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.

• **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 Indications

- 1. Gliomas.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A)** Patient is \geq 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 experimental, investigational, or unproven 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; 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

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