Voranigo® (vorasidenib)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Voranigo is indicated for the treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation, following surgery including biopsy, sub-total resection, or gross total resection.

Compendial Uses

1. Recurrent or progressive IDH1 or IDH2 mutated WHO grade 2 astrocytoma or oligodendroglioma
2. Adjuvant treatment of IDH1 or IDH2 mutated WHO grade 2 astrocytoma or oligodendroglioma
3. IDH1 or IDH2 mutated high-grade glioma
    A. H3-mutated high-grade glioma
    B. High-grade astrocytoma with piloid features (HGAP)
    C. Pleomorphic xanthoastrocytoma (PXA) WHO grade 3

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review: medical record documentation of isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation.

Criteria for Initial Approval

Central Nervous System Cancers

Authorization of 12 months may be granted for the treatment of members 12 years of age and older with central nervous system (CNS) cancers with a susceptible IDH1 or IDH2 mutation, when either of the following is met:

1. Adjuvant treatment of WHO grade 2 astrocytoma or WHO grade 2 oligodendroglioma when used as a single agent.
2. The member has progressive or recurrent disease and the requested medication will be used as a single agent for the treatment of the following types of CNS cancers:
    a. H3-mutated high-grade glioma
    b. High-grade astrocytoma with piloid features (HGAP)
    c. WHO grade 3 Pleomorphic xanthoastrocytoma (PXA)
    d. WHO grade 2 or 3 oligodendroglioma and Karnofsky Performance Status (KPS) greater than or equal to 60
    e. WHO grade 2 astrocytoma and KPS greater than or equal to 60

Continuation of Therapy

Central Nervous System Cancers

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed under the criteria for initial approval section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Other

Voranigo (vorasidenib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Voranigo (vorasidenib) 10 mg oral tablet	60 capsules per 30 days	Adults: 40 mg orally once daily Pediatric patients ≥ 12 years old, weight based: • ≥ 40 kg: 40 mg orally once daily • < 40 kg: 20 mg orally once daily **Dose reduction for adverse events:** Adults and pediatric patients ≥ 40 kg: • First reduction: 20 mg orally once daily • Second reduction: 10 mg orally once daily Pediatric patients ≥ 12 years old and < 40 kg: • 10 mg orally once daily *Continue treatment with Voranigo until disease progression or unacceptable toxicity.*
Voranigo (vorasidenib) 40 mg oral tablet	30 capsules per 30 days	

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

1. Voranigo [package insert]. Boston, MA: Servier Pharmaceuticals LLC.; April 2025.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed August 13, 2025.

POLICY HISTORY

Policy #: 05.05.57

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