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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	August 30, 2024
Subject:	Voranigo	**Page:**	1 of 4

Last Review Date: December 13, 2024

Voranigo

Description

Voranigo (vorasidenib)

Background

Voranigo (vorasidenib) is a small molecule inhibitor that targets isocitrate dehydrogenase-1 and 2 (IDH1 and IDH2) enzymes. In vitro, Voranigo inhibited the IDH1 wild type and mutant variants, including R132H and the IDH2 wild type and mutant variants. In cell-based and in vivo tumor models expressing IDH1 or IDH2 mutated proteins, Voranigo decreased production of 2-hydroxyglutarate and partially restored cellular differentiation (1).

Regulatory Status

FDA-approved indication: Voranigo is an isocitrate dehydrogenase-1 (IDH1) and isocitrate dehydrogenase-2 (IDH2) inhibitor 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 (1).

Voranigo can cause hepatic transaminase elevations, which can lead to hepatic failure, hepatic necrosis, and autoimmune hepatitis. Liver laboratory tests should be monitored prior to the start or Voranigo, every 2 weeks during the first 2 months of treatment, then monthly for the first 2 years of treatment, and as clinically indicated, with more frequent testing in patients who develop transaminase elevations (1).

Voranigo can cause fetal harm when administered to a pregnant woman. Pregnant women and females of reproductive potential should be advised of the potential risk to a fetus. Females of

reproductive potential should be advised to use effective nonhormonal contraception during treatment with Voranigo and for 3 months after the last dose, since Voranigo can render some hormonal contraceptives ineffective. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment with Voranigo and for 3 months after the last dose (1).

The safety and effectiveness of Voranigo in pediatric patients less than 12 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Voranigo may be considered **medically necessary** if the conditions indicated below are met.

Voranigo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Grade 2 astrocytoma
2. Grade 2 oligodendroglioma

AND ALL of the following:

1. Susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation
2. Patient has had at least one prior surgery, including biopsy, sub-total resection, or gross-total resection
3. Prescriber agrees to monitor for hepatotoxicity
4. Females of reproductive potential **only**: patient will be advised to use effective nonhormonal contraception during treatment with Voranigo and for 3 months after the last dose

5. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Voranigo and for 3 months after the last dose

Prior – Approval *Renewal* Requirements

Age 12 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Grade 2 astrocytoma
2. Grade 2 oligodendroglioma

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor for hepatotoxicity
3. Females of reproductive potential **only**: patient will be advised to use effective nonhormonal contraception during treatment with Voranigo and for 3 months after the last dose
4. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Voranigo and for 3 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 40 mg per day

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Voranigo is an IDH1 and IDH2 inhibitor indicated for the treatment of patients with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation following surgery including biopsy, sub-total resection, or gross total resection. Voranigo contains warnings regarding hepatotoxicity and embryo-fetal toxicity. The safety and effectiveness of Voranigo in pediatric patients less than 12 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Voranigo while maintaining optimal therapeutic outcomes.

References
1. Voranigo [package insert]. Boston, MA: Servier Pharmaceuticals LLC; August 2024.
2. NCCN Drugs & Biologics Compendium® Vorasidenib 2024. National Comprehensive Cancer Network, Inc. Accessed on October 23, 2024.

Policy History

Date	Action
August 2024	Addition to PA
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.