

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1457-3
Program	Prior Authorization/Notification
Medication	Voranigo® (vorasidenib)
P&T Approval Date	10/2024, 12/2024, 12/2025
Effective Date	3/1/2026

1. Background:

Voranigo (vorasidenib) 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.

The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium also recommends the use of Voranigo for the treatment of recurrent or progressive WHO grade 3 oligodendroglioma with a susceptible IDH1 or IDH2 mutation as well as recurrent or progressive WHO grade 2, 3 or 4 astrocytoma with a susceptible IDH1 or IDH2 mutation.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria^a:

<p>A. <u>Patients less than 19 years of age</u></p> <p>1. Voranigo will be approved based on the following criterion:</p> <p style="padding-left: 40px;">a. Patient is less than 19 years of age</p> <p style="text-align: center;">Authorization will be issued for 12 months.</p> <p>B. <u>Astrocytoma</u></p> <p>1. <u>Initial Authorization</u></p> <p style="padding-left: 40px;">a. Voranigo will be approved based on <u>all</u> of the following criteria:</p> <p style="padding-left: 80px;">(1) Diagnosis of astrocytoma</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 80px;">(2) Presence of IDH1 or IDH2 mutation</p>

-AND-

- (3) Disease is WHO Grade 2, 3, or 4

-AND-

- (4) History of prior surgery, including biopsy, sub-total resection, or gross total resection

Authorization will be issued for 12 months.

2. Reauthorization

- a. Voranigo will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Voranigo therapy

Authorization will be issued for 12 months.

C. Oligodendroglioma

1. Initial Authorization

- a. Voranigo will be approved based on **all** of the following criteria:

- (1) Diagnosis of oligodendroglioma

-AND-

- (2) Presence of IDH1 or IDH2 mutation with 1p19q codeletion

-AND-

- (3) Disease is WHO Grade 2 or 3

-AND-

- (4) History of prior surgery, including biopsy, sub-total resection, or gross total resection

Authorization will be issued for 12 months.

2. Reauthorization

- a. Voranigo will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Voranigo therapy

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Voranigo [package insert]. Boston, MA: Servier Pharmaceuticals LLC; April 2025.

Program	Prior Authorization/Notification – Voranigo (vorasidenib)
Change Control	
10/2024	New program
12/2024	Removed Grade 2 disease requirement per NCCN Compendium. Updated background and references.
12/2025	Annual review. Separated criteria for astrocytoma and oligodendroglioma into two sections. Added WHO grade requirements for both astrocytoma and oligodendroglioma. Added 1p19q codeletion as requirement for oligodendroglioma. Updated background and reference.