Generic Name: Vorasidenib

Therapeutic Class or Brand Name: Voranigo

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/24/2025

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

I. Documentation of one of the following diagnoses AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication

A. Astrocytoma or oligodendroglioma

1. Documentation of WHO grade 2 astrocytoma or oligodendroglioma.
2. Documentation of IDH1 or IDH2 mutation using an FDA-approved test.
3. Documentation of residual or recurrent tumor after biopsy or resection.
4. Documentation that there are no uncontrolled, disease-related symptoms (ex: uncontrolled seizures, brain-stem involvement, clinically relevant functional or neurocognitive deficits) caused by the tumor, or use of glucocorticoids for signs or symptoms of glioma.
5. Documentation that treatment with radiation and chemotherapy is not preferred.
6. Documentation of Karnofsky performance-status score ≥60.
7. Voranigo will be used as a single agent.

II. Minimum age requirement: 12 years old or older.

III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Quantity limits:
  - 40 mg tablets (adult and pediatric patients 12 years old and older ≥40 kg): 30 tablets per 30 days
  - 10 mg tablets (pediatric patients 12 years old and older < 40kg): 60 tablets per 30 days

Approval Length

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

Appendix

N/A

References

1. Voranigo. Prescribing Information. Servier Pharmaceuticals LLC. August 2024. Accessed December 20, 2024. www.accessdata.fda.gov/drugsatfda_docs/label/2024/218784s000lbl.pdf
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. DOI: 10.1056/NEJMMoa2304194
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. Version 3.2024. Updated September 30, 2024. www.nccn.org/professionals/physician_gls/pdf/cns.pdf Accessed December 20, 2024.