Patient Access Support Kit



vorasidenib tablets

Supporting Patient Access to VORANIGO

The purpose of this resource is to provide health care providers and their practices with support to optimize authorization and appeals requests to facilitate patient access to VORANIGO. Follow the patient's health plan requirements when requesting VORANIGO; otherwise, treatment initiation may be delayed.

Use of the information in this document does not guarantee that the health plan or pharmacy benefit manager (PBM) will provide coverage and it is not intended to be a substitute for, or an influence on, your independent medical judgment. Consult with the applicable payer or PBM for plan-specific requirements. The checklists are neither medical guidance nor a suggestion that you submit a request for coverage or appeal a denial. The information provided in the checklists is general in nature and is not intended to be conclusive or exhaustive.

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INDICATION

VORANIGO (40 mg tablets) is indicated for the treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation, as detected by an FDA-approved test, following surgery including biopsy, sub-total resection, or gross total resection.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hepatotoxicity: VORANIGO can cause hepatic transaminase elevations, which can lead to hepatic failure, hepatic necrosis, and autoimmune hepatitis. Monitor liver laboratory tests (AST, ALT, GGT, total bilirubin, and alkaline phosphatase) prior to the start of 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. Reduce the dose, withhold, or permanently discontinue VORANIGO based on severity.

Please see additional Important Safety Information on <u>page 11</u> and accompanying <u>Full Prescribing Information</u>.

Letter of Medical Necessity Guide



The Letter of Medical Necessity is an opportunity for the prescribing physician to present the rationale and clinical decision-making for choosing VORANIGO®. This letter may be required to support access to VORANIGO when a health plan has coverage restrictions of any kind or when coverage has been denied for any reason. Some plans require that a Letter of Medical Necessity be submitted along with a formulary exception request, prior authorization request, or an appeal.

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Checklist for Preparing a Letter of Medical Necessity

- Key Patient Information
 - Full name, date of birth, insurance ID number and group number, case ID number
- Relevant Medical History
 - Brief medical record
 - Statement of diagnosis, including mIDH status and grade
 - Diagnosis of Grade 2 astrocytoma or oligodendroglioma with a susceptible *IDH1* or *IDH2* mutation, as detected by an FDA-approved test
 - Applicable ICD-10 code(s)



er to page 9 for the ICD-10 codes relevant to VORANIGO

- Allergies and existing comorbidities
- Patient's applicable labs or scans showing disease progression
- Pathology report(s)
- List of current medication(s)
- IDH mutation reports showing IDH mutation status

Supporting Documentation

- VORANIGO Prescribing Information
- Clinical notes/medical history that support your recommendation
- Diagnostic test results
- Scans showing progressive disease
- Pathology reports
- Peer-reviewed clinical articles
- NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)





Sample Letter of Medical Necessity



PRINT THE LETTER USING THE PRACTICE'S LETTERHEAD

DATE

ATTN: [CONTACT TITLE/MEDICAL DIRECTOR]
[CONTACT NAME (if available)]
[PAYER NAME]
[PAYER ADDRESS]
[CITY, STATE, ZIP]

Re: Letter of Medical Necessity for Voranigo® (vorasidenib tablets)

Patient: [PATIENT FIRST AND LAST NAME]

Date of Birth: [MM/DD/YYYY]

Policy ID Number: [INSURANCE ID NUMBER]
Policy Group Number: [INSURANCE GROUP NUMBER]
Case ID Number: [CASE ID NUMBER (if available)]

Dear [CONTACT NAME/MEDICAL DIRECTOR]:

My name is [PHYSICIAN'S NAME], and I am a [board-certified (if applicable) medical specialty] writing on behalf of my patient, [PATIENT FIRST AND LAST NAME], to demonstrate the medical necessity and obtain authorization for Voranigo® (vorasidenib tablets). [PATIENT FIRST AND LAST NAME] has been under my care for [# MONTHS/YEARS] for the treatment of [DISEASE OR SYMPTOMS].

PATIENT'S MEDICAL HISTORY, DIAGNOSIS, AND TREATMENT PLAN

This letter documents the medical necessity for use of Voranigo® (vorasidenib tablets) for my patient and provides information about [PATIENT FIRST AND LAST NAME]'s medical history, treatment, and pertinent results.

[Provide a brief medical record, including diagnosis, allergies, existing comorbidities, and International Classification of Diseases (ICD) code(s). Discuss the rationale for using the product versus other treatments. Include a summary of your recommendation and your professional opinion of your patient's likely prognosis or disease progression without treatment with the product].

SUMMARY

I believe Voranigo® (vorasidenib tablets) is appropriate and medically necessary for this patient based on the information noted above and the supplemental documentation provided. If you have any further questions about this matter, please contact me at [PHYSICIAN PHONE NUMBER] or email me at [PHYSICIAN EMAIL].

Thank you for your time and consideration.

Sincerely,

[PHYSICIAN NAME AND CREDENTIALS]

Enclosures: (suggested)

• Bullet and list all attachments that are being provided [List enclosures such as: Prescribing information, clinical notes/medical records, diagnostic test results, relevant peer-reviewed clinical articles, clinical practice guidelines, scans showing progressive disease, pathology reports.]



Formulary Exception Request Guide



A formulary exception is a request to have VORANIGO® covered by a health plan when it is not included on a plan's formulary or is subject to an NDC block.

Best Practices for Submitting a Formulary Exception Request

- Some plans may have specific formulary exception criteria and/or may provide a form on its website that can be used to apply for an exception
- If required, complete and submit the formulary exception request form to the health plan. The form can be submitted along with the Letter of Medical Necessity
- If a form is not available, a Letter of Formulary Exception will be required; this is a written request asking that the restriction placed on VORANIGO be released

✓ Checklist for Preparing a Letter of Formulary Exception

- Key Patient Information
 - Full name, date of birth, insurance ID number and group number, case ID number
- Clinical Rationale
 - Patient-specific rationale for prescribing a product that is not on formulary and why the formulary agents are not appropriate, if applicable
 - Statement of diagnosis, including mIDH status and grade
 - Diagnosis of Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation, as detected by an FDA-approved test
 - Applicable ICD-10 code(s)



Refer to page 9 for the ICD-10 codes relevant to VORANIGO

- Patient's applicable labs or scans showing disease progression
- Pathology report(s)
- List of current medication(s)
- IDH mutation reports showing IDH mutation status

Supporting Documentation

- VORANIGO Prescribing Information
- Clinical notes/medical history that support your recommendation
- Diagnostic test results
- Scans showing progressive disease
- Pathology reports
- Letter of Medical Necessity (if applicable)
- Peer-reviewed clinical articles
- NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)







Sample Letter of Formulary Exception



PRINT THE LETTER USING THE PRACTICE'S LETTERHEAD

DATE

ATTN: [CONTACT TITLE/MEDICAL DIRECTOR]
[CONTACT NAME (if available)]
[PAYER NAME]
[PAYER ADDRESS]
[CITY, STATE, ZIP]

Re: Letter of Formulary Exception for Voranigo® (vorasidenib tablets)

Patient: [PATIENT FIRST AND LAST NAME]

Date of Birth: [MM/DD/YYYY]

Policy ID Number: [INSURANCE ID NUMBER]
Policy Group Number: [INSURANCE GROUP NUMBER]
Case ID Number: [CASE ID NUMBER (if available)]

Dear [CONTACT NAME/MEDICAL DIRECTOR]:

My name is [PHYSICIAN'S NAME], and I am a [board-certified (if applicable) medical specialty] writing on behalf of my patient, [PATIENT FIRST AND LAST NAME], to request an exception to your formulary for Voranigo® (vorasidenib tablets). [PATIENT FIRST AND LAST NAME] has been under my care for [# MONTHS/ YEARS] for the treatment of [DISEASE OR SYMPTOMS].

PATIENT'S MEDICAL HISTORY, DIAGNOSIS, AND TREATMENT PLAN

This letter documents the medical necessity for use of Voranigo® (vorasidenib tablets) for my patient and provides information about [PATIENT FIRST AND LAST NAME]'s medical history, treatment, and pertinent results.

[Provide relevant medical history (including surgical history) and diagnosis (including applicable ICD-10 code(s)). Discuss the rationale for using the product versus other treatments. Include a summary of your recommendation and your professional opinion of your patient's likely prognosis or disease progression without treatment with the product].

SUMMARY

I believe Voranigo® (vorasidenib tablets) is appropriate and medically necessary for this patient based on the information noted above and the supplemental documentation provided. If you have any further questions about this matter, please contact me at [PHYSICIAN PHONE NUMBER] or email me at [PHYSICIAN EMAIL].

Thank you for your time and consideration.

Sincerely,

[PHYSICIAN NAME AND CREDENTIALS]

Enclosures: (suggested)

• Bullet and list all attachments that are being provided [List enclosures such as: Prescribing information, clinical notes/medical records, diagnostic test results, relevant peer-reviewed clinical articles, clinical practice guidelines, scans showing progressive disease, pathology reports.]



Prior Authorization Request Guide



A prior authorization is a payer management tool that requires the prescribing physician to justify the clinical need and therapeutic rationale for VORANIGO® before the health plan will reimburse the claim or process the prescription.

Best Practices for Submitting a Prior Authorization Request

- Check the health plan's prior authorization requirements before sending a prescription to the pharmacy
- If a prior authorization is required, please note that some plans have specific forms that must be utilized to document a prior authorization request
- Check plan-specific criteria and be sure to provide all required information and include documentation and a Letter of Medical Necessity if requested

Checklist for Preparing a Prior Authorization Request

- Key Patient Information
 - Full name, date of birth, insurance ID number and group number, case ID number
- Potential Prior Authorization Criteria
 - Statement of diagnosis, including mIDH status and grade
 - Diagnosis of Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation, as detected by an FDA-approved test
 - Applicable ICD-10 code(s)
 - 1

Refer to page 9 for the ICD-10 codes relevant to VORANIGO

- Patient surgeries including biopsy, sub-total resection, or gross total resection (including dates if available) relevant to the diagnosis
- Patient age and weight
- Patient's applicable labs or scans showing disease progression
- Pathology report(s)
- List of current medication(s)
- *IDH* mutation reports showing *IDH* mutation status

Supporting Documentation (if applicable)

- VORANIGO Prescribing Information
- Clinical notes/medical history that support your recommendation
- Diagnostic test results
- Scans showing progressive disease
- Pathology reports
- Letter of Medical Necessity (if applicable)
- Peer-reviewed clinical articles
- NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)





Letter of Appeal Guide



When a patient's initial claim or request for coverage has been denied, an appeal can be submitted to the plan requesting that the decision be reconsidered. Refer to the plan's coverage denial letter and follow plan requirements when requesting an appeal of a coverage denial.



Best Practices for Submitting an Appeal

- Refer to the plan's coverage denial letter for:
 - Plan-specific appeal process
 - Case identification number
 - Reason(s) for denial
 - Deadline to submit an appeal
 - Timeline for review
 - Number of appeals permitted
 - Appeal form required by the health plan or PBM (if applicable)

☑ Checklist for Preparing a Coverage Denial Letter of Appeal

- Key Patient Information
 - Full name, date of birth, insurance ID number and group number, and case ID number
 - Copy of the patient's health plan and prescription card (front and back)
- Clinically Relevant and Patient-specific Information that Supports Overturning the Denial
 - Patient's applicable labs or scans showing disease progression
 - Applicable ICD-10 code(s)



Refer to page 9 for the ICD-10 codes relevant to VORANIGO

- Pathology report(s)
- List of current medication(s)
- IDH mutation reports showing IDH mutation status
- Supporting Documentation
 - VORANIGO® Prescribing Information
 - Clinical notes/medical history that support your recommendation
 - Diagnostic test results
 - Scans showing progressive disease
 - Pathology reports
 - Prior Authorization Denial Letter from plan
 - Letter of Medical Necessity (if applicable)
 - Peer-reviewed clinical articles
 - NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)





Sample Coverage Denial Letter of Appeal



PRINT THE LETTER USING THE PRACTICE'S LETTERHEAD

DATE

ATTN: [CONTACT TITLE/MEDICAL DIRECTOR]
[CONTACT NAME (if available)]
[PAYER NAME]
[PAYER ADDRESS]
[CITY, STATE, ZIP]

Re: Appeal for Denial of Voranigo® (vorasidenib tablets)

Patient: [PATIENT FIRST AND LAST NAME]

Date of Birth: [MM/DD/YYYY]

Policy ID Number: [INSURANCE ID NUMBER]

Policy Group Number: [INSURANCE GROUP NUMBER]

Case ID Number: [CASE ID NUMBER]

Dear [CONTACT NAME/MEDICAL DIRECTOR]:

My name is [PHYSICIAN'S NAME], and I am a [board-certified (if applicable) medical specialty] writing on behalf of my patient, [PATIENT FIRST AND LAST NAME], to request that you reconsider your denial of coverage dated [INSERT DATE] for Voranigo® (vorasidenib tablets). The denial reason was stated as [INSERT SPECIFIC DENIAL REASON(S)]. I respectfully request a redetermination of the denial of coverage for Voranigo® (vorasidenib tablets).

I believe that Voranigo® (vorasidenib tablets) is the most appropriate treatment. [PATIENT FIRST AND LAST NAME] has been under my care for [# months/years] for the treatment of [DISEASE, SYMPTOMS, MUTATION STATE]. In support of my recommendation for Voranigo® (vorasidenib tablets) treatment, an overview of the patient's relevant clinical history is provided highlighting the following areas:

- · Patient's medical history
- · Diagnosis
- · Treatment plan
- · Letter of Medical Necessity

[Include the patient's story in a compelling manner. Provide a brief medical record, including diagnosis, allergies, existing comorbidities, physician notes, patient's labs, scans, and International Classification of Diseases (ICD) code(s). Include peer-reviewed literature. Discuss the rationale for using the product versus other treatments. Indicate previous therapies as part of the patient's treatment plan. Include a summary of your recommendation and your professional opinion of your patient's likely prognosis or disease progression without treatment with the product].

I believe Voranigo® (vorasidenib tablets) is appropriate and medically necessary for this patient. If you have any further questions about this request, please contact me at [PHYSICIAN PHONE NUMBER] or email me at [PHYSICIAN EMAIL].

Thank you for your time and consideration.

Sincerely

[PHYSICIAN NAME AND CREDENTIALS]

Enclosures: (suggested)

 Bullet and list all attachments that are being provided [List enclosures such as: Letter of Medical Necessity, prescribing information, clinical notes/medical records, diagnostic test results, relevant peer-reviewed clinical articles, clinical practice notes, scans showing progressive disease, pathology reports.]



Codes Applicable to VORANIGO®



International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes¹

Code	Description
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles
C71.1	Malignant neoplasm of frontal lobe
C71.2	Malignant neoplasm of temporal lobe
C71.3	Malignant neoplasm of parietal lobe
C71.4	Malignant neoplasm of occipital lobe
C71.5	Malignant neoplasm of cerebral ventricle
C71.6	Malignant neoplasm of cerebellum
C71.7	Malignant neoplasm of brain stem
C71.8	Malignant neoplasm of overlapping sites of brain
C71.9	Malignant neoplasm of brain, unspecified

Healthcare Common Procedure Coding System (HCPCS) Code²

Code	Description
J8999	Prescription drug, oral, chemotherapeutic, NOS
C9399	Unclassified drugs or biologicals

National Drug Code (NDC)3

Dosage Strength	NDC
40 mg	72694-728-40 72694- <mark>0</mark> 728-40
10 mg	72694-879-10 72694- <mark>0</mark> 879-10

The red zero converts the 10-digit NDC to the 11-digit NDC. Some payers may require each NDC to be listed on the claim. Payer requirements regarding the use of NDCs may vary. Electronic data exchange generally requires use of the 11-digit NDC.

Current Procedural Terminology (CPT®) Codes⁴

CPT codes 81120 and 81121, *IDH1* and *IDH2*, are considered medically necessary for the ICD-10-CM codes C71.0-C71.9

Code	Description
81120	IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (eg, glioma), common variants (eg, R132H, R132C)
81121	<i>IDH2</i> (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants (eg, R140W, R172M)

NAD, nicotinamide adenine dinucleotide; NOS, not otherwise specified.



NCCN Guidelines Recommendation



Vorasidenib (VORANIGO®) is recommended for the treatment of Grade 2 astrocytoma and oligodendroglioma⁵:

In the adjuvant setting

- An NCCN Category 1,* Preferred[†] treatment option in patients with residual/measurable disease with a KPS ≥60 after surgery/biopsy⁵
- An NCCN Category 2A,[‡] Preferred[†] treatment option in patients without residual/measurable disease with a KPS ≥60 after surgery/biopsy⁵

In the recurrent/progressive setting

An NCCN Category 2A,[‡] Preferred[†] treatment option in patients with a KPS ≥60⁵

To access the latest NCCN Guidelines for Central Nervous System Cancers, visit NCCN.org.

If an IDH inhibitor is being considered for a patient with newly diagnosed or recurrent or progressive oligodendroglioma or astrocytoma, the NCCN Panel strongly recommends multidisciplinary discussion or referral to a brain tumor center for consultation.

Newly diagnosed patients with oligodendroglioma/astrocytoma (WHO Grade 2 or 3) who did not have residual disease were excluded from participation in the INDIGO study. Therefore, the Panel recommends discussing the possible risks and benefits of starting treatment right away with an IDH inhibitor with these patients. For recurrent/progressive disease there are multiple reasonable options, but there is no uniformly recommended option at this time.

*Category 1: Based upon high-level evidence (≥1 randomized Phase 3 trials or high-quality, robust meta-analyses), there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.⁵

†Preferred intervention: Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.⁵

[‡]Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.⁵ KPS, Karnofsky Performance Scale; WHO, World Health Organization.

Support for Your Patients

VORANIGO Financial & Personal Support Program

1) \$0 Copay Program*

The \$0 Copay Program lowers the out-of-pocket cost of VORANIGO for eligible patients with commercial insurance to as little as \$0 per prescription if the copay exceeds that amount



2) Bridge Program

The Bridge Program is designed to provide a one-time, 1-month supply of VORANIGO to eligible patients who experience a short-term lapse in coverage. If eligible, this program gives the patient access to VORANIGO while their insurance issues are being resolved

3) QuickStart Program

The QuickStart Program is intended for patients who experience an insurance coverage delay lasting five or more business days. If eligible, the patient will receive one 30-day supply as prescribed by their health care provider

4) Patient Assistance Program (PAP)†

The PAP is dedicated to assisting uninsured and underinsured patients by offering medication to those who meet the eligibility criteria. The benefits of the PAP are reassessed at the beginning of each calendar year

*This program is available to eligible patients who meet the following criteria: U.S./Puerto Rico resident, commercially insured and paying a portion of their cost, and don't have government insurance.

†Terms and conditions apply.







Call **1-800-813-5905** (Monday through Friday, 8 AM to 8 PM ET)

Register your patients online for the Commercial Copay Program at ServierONE-copay.com

Please see additional Important Safety Information on <u>page 11</u> and accompanying <u>Full Prescribing Information</u>.



Important Safety Information



INDICATION

VORANIGO (40 mg tablets) is indicated for the treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation, as detected by an FDA-approved test, following surgery including biopsy, sub-total resection, or gross total resection.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hepatotoxicity: VORANIGO can cause hepatic transaminase elevations, which can lead to hepatic failure, hepatic necrosis, and autoimmune hepatitis. Monitor liver laboratory tests (AST, ALT, GGT, total bilirubin, and alkaline phosphatase) prior to the start of 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. Reduce the dose, withhold, or permanently discontinue VORANIGO based on severity.

Embryo-Fetal Toxicity: Based on findings from animal studies, VORANIGO can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential 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. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with VORANIGO and for 3 months after the last dose.

ADVERSE REACTIONS

The most common (≥15%) adverse reactions included fatigue, headache, COVID-19, musculoskeletal pain, diarrhea, nausea, and seizure. Grade 3 or 4 (≥2%) laboratory abnormalities were ALT increased, AST increased, and neutrophils decreased.

DRUG INTERACTIONS

Avoid concomitant use of VORANIGO with strong and moderate CYP1A2 inhibitors. Avoid concomitant use with moderate CYP1A2 inducers and smoking tobacco. Avoid concomitant use with CYP3A substrates, where a minimal concentration change can reduce efficacy. If concomitant use of hormonal contraception cannot be avoided, use nonhormonal contraception methods.

LACTATION

Advise women not to breastfeed during VORANIGO treatment and for 2 months after the last dose.

IMPAIRED FERTILITY

VORANIGO may impair fertility of females and males of reproductive potential.

Please see accompanying Full Prescribing Information.

Please visit VoranigoHCP.com for more information about VORANIGO.

References: 1. Centers for Medicare & Medicaid Services. 2024 ICD-10-CM. Updated April 1, 2024. Accessed July 3, 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm 2. Centers for Medicare & Medicaid Services. HCPCS quarterly update. August 19, 2024. Accessed August 26, 2024. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update 3. Voranigo. Package insert. Servier Pharmaceuticals LLC; 2025. 4. Centers for Medicare & Medicaid Services. Billing and coding: molecular pathology procedures. Accessed August 26, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=56199 5. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines*) for Central Nervous System Cancers V.1.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed June 9, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.



