Sunharbo®
(asundexian) 50 mg tablets

Access Guide

Information and resources to help appropriate patients access SUNHARBO

INDICATION

SUNHARBO® is indicated in combination with antiplatelet therapy to reduce the risk of stroke in adults with recent non-cardioembolic ischemic stroke (NIH Stroke Scale ≤ 15) or high-risk transient ischemic attack (TIA).

Please see Important Safety Information on page 11 and click here for Full Prescribing Information for SUNHARBO.

What's inside

This guide includes information and resources you can use to help your patients access SUNHARBO.

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11 **Indication and Important Safety Information**

For more information on how to help your patients access SUNHARBO, contact your Bayer representative or visit SUNHARBOhcp.com/access-and-support/patient-access.

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Not an actual patient.

Access considerations by care setting

Patient access needs may vary depending on where the prescription is initiated. The overview below outlines common care-setting scenarios and access considerations that may help support the patient's access to SUNHARBO.

	Inpatient and discharge	Skilled nursing or rehabilitation discharge	Outpatient practice
Patient Scenario	Continuing therapy as part of discharge planning after an acute event	Transitioning from a post-acute setting to home or outpatient follow-up	Support therapy initiated earlier or prescribed therapy during follow-up after a recent non-cardioembolic ischemic stroke or high-risk TIA in appropriate patients
Potential Next Step	Initiate a medical exception or prior authorization promptly and confirm coverage before discharge	Confirm medication handoff, responsible prescriber, dispensing pharmacy, and clinical documentation	Confirm current therapy, insurance and pharmacy information, and whether therapy is being initiated or continued
	FOR DISCHARGE-RELATED SCENARIOS: Ensure discharge instructions with medication requirements are integrated into the patient's care plan to avoid disruption of therapy		

Initiate a medical exception or prior authorization request when applicable (see next page)

Coverage scenarios

After reviewing the benefits verification, your patient may fall into one of three common coverage scenarios.

	Not covered	Covered	Request denied
Coverage Scenario	SUNHARBO is not covered under the patient's health insurance plan. This is a common scenario for new therapies while insurance companies review them for formulary placement.	SUNHARBO is covered but may require a PA.	A medical exception or prior authorization request for SUNHARBO was submitted to the patient's health insurance plan, but the request was denied or the plan has requested additional information.
Potential Next Step	Submit a request for a medical exception to ask the health insurance plan to cover SUNHARBO for the patient. See pages 5-7 to learn more about submitting a **medical exception**.	When applicable, submit a request for a prior authorization for SUNHARBO. Prior authorization is a common practice to establish appropriate utilization of medications. See pages 5-7 to learn more about submitting a **prior authorization**.	Submit an appeal to formally request reconsideration of a denial. See page 8 to learn more about submitting an **appeal**.

Support timely access during a high-risk period

Recurrence risk is highest in the days to weeks after stroke.[1] Address coverage requirements promptly to help avoid administrative delays in access to prescribed therapy.

Submit an electronic PA (ePA) through CoverMyMeds®* for access to payer-specific forms, real-time updates, live ePA and appeals support, and more. Log in or create your account at CoverMyMeds.com.

ePAs can be submitted up to 3x FASTER than manual PAs.[2]

*CoverMyMeds is an independent party.

References: 1. Edwards JD, Kapral MK, Fang J, Swartz RH. Long-term morbidity and mortality in patients without early complications after stroke or transient ischemic attack. *CMAJ*. 2017;189(29):E954-E961.
2. Prior authorization forms. CoverMyMeds. Accessed July 31, 2026. https://www.covermymeds.health/prior-authorization-forms

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Submitting medical exception (ME) and prior authorization (PA) requests

When to submit an ME or PA

Not covered

Before insurance plans have made the decision to add SUNHARBO to their formularies (or established coverage for SUNHARBO), they may require an ME request from the physician with additional evidence to explain, in detail, why you believe that SUNHARBO is appropriate for a patient and should be covered.

Covered

SUNHARBO is covered but may require a PA.

Two ways to submit an ME or PA

01 **Electronically** via platforms such as CoverMyMeds.health

02 **Via fax** by downloading appropriate forms from the patient's health plan's website and submitting to the patient's health plan

Bayer works with CoverMyMeds®* to provide ME and PA support for your practice to help get your patients access to SUNHARBO.

Ways this may support patient access

- Submit pharmacy-initiated ME and PA requests directly to your patient's health insurance plan
- Alerts to help monitor the status of a medical exception or prior authorization submission
- Automatically initiate appeals when needed
- Receive claim determinations
- Live support available: 1-866-452-5017 or chat at CoverMyMeds.com
- Visit **CoverMyMeds.com** to get started

Sample Letter of Medical Exception for SUNHARBO

To download a customizable sample letter of medical exception, visit SUNHARBOhcp.com/access-and-support/resources.

*CoverMyMeds is an independent party.

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Key information to include in your medical exception or prior authorization request

Consider the following criteria for SUNHARBO when preparing to submit a medical exception or prior authorization request. Including this information may help avoid a denial.

⚠ Avoid common mistakes

- ✓ Include a complete record of the patient's personal and member/beneficiary information, including the patient's pharmacy benefit member ID
- ✓ Include all relevant prescriber information, including the provider's signature
- ✓ Include a complete and accurate summary of patient's medical history
- ✓ It may help to include the SUNHARBO Prescribing Information (PI) to describe the efficacy, safety, and appropriateness (SUNHARBO PI can be accessed at SUNHARBOhcp.com)

Diagnosis details

Provide the patient's diagnosis and corresponding ICD-10-CM code(s). Multiple ICD-10-CM codes may be included as applicable to the patient. (Coding requirements vary by payer, so check the health insurance plan's website and use accurate coding to help facilitate timely claims processing.) These ICD-10-CM diagnosis codes may be relevant for SUNHARBO.

Relevant ICD-10-CM codes

ICD-10-CM Code	Description
I63.0	Cerebral infarction due to thrombosis of precerebral arteries
I63.3	Cerebral infarction due to thrombosis of cerebral arteries
I63.5	Cerebral infarction due to unspecified occlusion or stenosis of cerebral arteries
I63.9	Cerebral infarction, unspecified
G45.9	Transient cerebral ischemic attack, unspecified
Z86.73	Evaluating a history of TIA without current deficits

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

Key information to include in your submission (cont'd)

Secondary stroke risk reduction therapies

- Include medications initiated for the risk reduction of secondary stroke*:
  - Single or dual antiplatelet therapy
    - eg, aspirin, Plavix® (clopidogrel), Brilinta® (ticagrelor)[1]
- Specify if the patient has taken SUNHARBO before (including free samples or continuation of therapy)
- Include dose, treatment duration, and reason for discontinuation (if applicable) for each medication listed. It is important to provide all information to underscore the medical necessity for SUNHARBO

NOTE: Because each plan has an individual pathway for medical exceptions, the required information may vary and the list above may be incomplete per a plan's specific criteria.



Not an actual patient or doctor.

*Product names are listed as examples of each therapeutic class and do not imply a comparison of efficacy or safety. The products listed may not represent all the products for the therapeutic class.

Reference: 1. Kleindorfer DO, et al. 2021 guideline for the prevention of stroke in patients with stroke and transient ischemic attack. *Stroke*. 2021;52:e364-e467.

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Appealing coverage denials

When to submit an appeal

Request was denied

After reviewing a medical exception or prior authorization request, the patient's health plan may deny the request.

Potential reasons for denials

- Missing, incomplete, or incorrect information or missing HCP signature
- Inaccurate diagnosis (ICD-10-CM) codes (refer to p 6)
- Incomplete medical history
- Missing documentation of current therapies used or additional therapy needed

Two ways to approach the appeals process

01 **Request a peer-to-peer (P2P) review**

P2P reviews take place when the prescribing healthcare professional discusses the clinical need for SUNHARBO with another physician who works for the patient's health insurance plan, following denial of a medical exception or prior authorization request.

P2P reviews may enable SUNHARBO coverage even when medical exceptions and prior authorizations are denied

- A doctor's persuasive explanation of their medical decision in a P2P review may be more compelling than a formal written request
- To contact the health insurance plan regarding a P2P review request, follow the guidance provided on the denial notice

02 **Submit a letter of appeal**

A letter of appeal can be submitted via fax or mail to formally request reconsideration of a prior authorization denial. The letter can be tailored to address the reason(s) provided for the denial and supported with accompanying evidence as needed or as requested by the patient's health insurance plan.

Sample Letter of Appeal for SUNHARBO

To download a customizable sample letter of appeal, visit SUNHARBOhcp.com/access-and-support/resources.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

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Access and affordability resources

Everyone deserves access to the treatment they need, regardless of their financial situation or insurance status. Bayer provides a variety of options to address individual needs and navigate access to SUNHARBO.

Accessing SUNHARBO

All patients	**30-Day Free Trial Offer**
	• New patients can get SUNHARBO at no cost
	• Terms and conditions apply.* To learn more:
	  • Call 844-4SUNHARBO Option 1, or
	  • Visit SUNHARBOSavings.com
		7-Day Free Sample Program
		With the program, you can:
		• Help patients get SUNHARBO right in your office
		• Provide your patients with a 7-day supply of SUNHARBO at no cost
		Ordering a sample is simple:
		• Your sales representative will process your sample request
		• Orders will be shipped within 24-48 hours

Connecting patients to savings and affordability resources

Commercial	**$15 SUNHARBO Co-pay Savings Program** Eligible patients may pay as little as $15 per month. • Benefit limitations and terms and conditions apply* • Eligible patients will be automatically re-enrolled every January Enroll at SUNHARBOhcp.com/co-pay 	
Medicare	Medicare Part D members' annual out-of-pocket spend for prescription drugs is capped at $2400 in 2027.[1]	
	Low-Income Subsidy (LIS)/Extra Help • Many Medicare patients prescribed SUNHARBO may qualify for Extra Help • In 2027, eligible LIS patients may pay no more than **$14.40** for a covered brand-name prescription[1] • Patients can apply at ssa.gov/medicare/part-d-extra-help	**Medicare Prescription Payment Plan** • To help manage the OOP costs, patients can opt in to the Medicare Prescription Payment Plan to help manage out-of-pocket drug costs by spreading them out over the year[2] • Learn more at medicare.gov/prescription-payment-plan

*To view terms and conditions and program eligibility, visit SUNHARBOSavings.com

If your patients cannot afford their prescription medication, Bayer may be able to help.

Bayer US **Patient Assistance Foundation**

The Bayer US **Patient Assistance Foundation** is a charitable organization that helps eligible patients get Bayer prescription medicine at no cost.

1-866-2BUSPAF (228-7723), Monday-Friday from 9 am to 6 pm EST

www.patientassistance.bayer.us

For more affordability resources, visit SUNHARBOhcp.com/access-and-support/resources

References: 1. Centers for Medicare & Medicaid Services. Announcement of Calendar Year (CY) 2027 (MA) Capitation Rates and Part C and Part D Payment Policies. Published April 6, 2026. Accessed July 31, 2026. https://www.cms.gov/files/document/2027-announcement.pdf **2.** Centers for Medicare & Medicaid Services. Fact Sheet: What's the Medicare Prescription Payment Plan? Published September 2025. Accessed May 15, 2026. https://www.medicare.gov/publications/12211-whats-the-medicare-prescription-payment-plan.pdf

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Resources to support access to SUNHARBO for your patients



- **Sample Letter of Appeal**
  Appeal a denied claim for SUNHARBO on behalf of your patient



- **Sample Medical Exception Letter**
  Request coverage when SUNHARBO is not covered by a patient's health insurance plan



- **Sample Tiering Exception Letter**
  Request that SUNHARBO be covered at a lower cost-sharing tier under a patient's health insurance plan

Questions?

Contact your Bayer representative for help with issues accessing SUNHARBO

Visit SUNHARBOhcp.com/access-and-support/patient-access to learn more about available support services

To download any of the access resources highlighted in this guide, visit SUNHARBOhcp.com/access-and-support/resources



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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

None.

ADVERSE REACTIONS

Bleeding

- The rate of International Society on Thrombosis and Haemostasis (ISTH) major bleeding was similar between SUNHARBO and placebo groups (1.6 vs. 1.5 per 100 patient-years).
- The rate of ISTH major bleeding events within 90 days of treatment initiation was 4.5 vs. 3.1 per 100 patient-years in the SUNHARBO and placebo groups, respectively.
- In patients planned to receive DAPT, the rate of ISTH major bleeding events was 1.9 vs. 1.5 per 100 patient-years in the SUNHARBO and placebo groups, respectively.
- Among patients older than 75 years, the rate of ISTH major bleeding was 2.6 vs. 1.7 per 100 patient-years in the SUNHARBO and placebo groups, respectively.
- In the high-risk TIA subgroup, the rate of ISTH major bleeding was 2.9 vs. 1.0 per 100 patient-years in the SUNHARBO and placebo groups, respectively.
- The rate of gastrointestinal (GI) bleeding was higher in the SUNHARBO compared to placebo group (2.7 vs. 2.1 per 100 patient-years). The majority of GI bleeding events in the SUNHARBO group (74%) were clinically relevant non-major or minor bleeding, and the most frequent bleeding site was of rectal origin.

Diarrhea

- The most frequently reported (> 3%) adverse reaction in SUNHARBO-treated patients was diarrhea.

Hepatic Enzyme Increased

- SUNHARBO is associated with elevated hepatic enzymes. Substantial cholestatic liver injury or serious liver injury with jaundice were each reported in less than 0.02% of SUNHARBO-treated patients.

DRUG INTERACTIONS

- *P-glycoprotein (P-gp) substrates* - Concomitant use of SUNHARBO increased the exposure to digoxin. For digoxin and sensitive P-gp substrates where minimal concentration changes may increase the risk of adverse reactions, follow the recommendation in their approved product labeling.
- *Combined P-gp and strong CYP3A4 inducers* - Avoid concomitant use with combined P-gp and strong CYP3A4 inducers, which decreases SUNHARBO exposure and may lead to loss of efficacy.

USE IN SPECIFIC POPULATIONS

Pregnancy

- There are risks to the mother associated with untreated non-cardioembolic ischemic stroke or TIA and risk of bleeding in the mother and fetus or neonate associated with use of anticoagulants during pregnancy.

Lactation

- Breastfeeding is not recommended during treatment with SUNHARBO and for 5 days after the last dose due to the potential for serious adverse reactions in nursing infants, including bleeding.

Hepatic Impairment

- Patients with moderate to severe hepatic impairment (Child-Pugh B and C) may have intrinsic coagulation abnormalities and use of SUNHARBO in these patients is not recommended.

For additional important risk and use information, please see the full Prescribing Information.

You are encouraged to report side effects or quality complaints of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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