SUNHARBO® (asundexian)

Medical Exception and Prior Authorization Checklist

While SUNHARBO coverage is being established, some plans may require a medical exception (ME) or prior authorization (PA) to confirm why treatment is appropriate. Therefore, timely submission is important—especially if a patient has started treatment with a sample. The following is intended to provide you with information you may find useful in completing a PA or ME and may facilitate your patient's access to SUNHARBO. 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).

☐ **Patient's personal and member/beneficiary information, prescriber information, and prescriber's signature**

☐ **Prescription information and appropriate diagnosis code**

- Prescribed dose, quantity, and frequency of SUNHARBO (asundexian)
- See relevant ICD-10-CM diagnosis codes:

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

☐ **Patient's treatment history, including secondary stroke risk reduction therapies**

- Medications initiated to reduce the risk of secondary stroke*:
  - Single or dual antiplatelet therapy[1]
    - eg, aspirin, Plavix® (clopidogrel), Brilinta® (ticagrelor)
- Dose, treatment duration, and reason for discontinuation (if applicable) for each medication listed
- Whether the patient has taken SUNHARBO before (including samples or continuation of therapy)

☐ **Additional supporting documentation**

- Consider including one or more of the following:
  - Patient chart notes (ie, hospital admission, discharge instructions, etc)
  - SUNHARBO Prescribing Information (to describe the efficacy, safety, and appropriateness of SUNHARBO)
  - Letter of medical exception (download a sample letter at **SUNHARBOhcp.com/access-and-support/resources**)

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

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.

Submit an ME/PA request at CoverMyMeds.com

- Live chat support and demos are available through the CoverMyMeds®† portal
- 1-866-452-5017 (Monday through Friday 8 AM to 11 PM and Saturday 8 AM to 6 PM EST)

NOTE: Because each insurance plan has an individual pathway for the ME or PA processes, the required information may vary.

*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.

†CoverMyMeds® is an independent party.

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).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS and WARNINGS & 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).

Please see additional Important Safety Information on the next page and click here for full Prescribing Information for SUNHARBO.

Sunharbo® (asundexian) 50 mg tablets

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS (continued)

Bleeding (continued)

- 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.

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.

For more information on how to help your appropriate patients access SUNHARBO, contact your Bayer representative or visit SUNHARBOhcp.com/request-a-rep

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