GETTING YOUR PATIENTS STARTED

A guide to helping your patients get timely and consistent access to their medication

OLPRUVA™ (sodium phenylbutyrate) for oral suspension is a nitrogen-binding agent indicated as adjunctive therapy to the standard of care, which includes dietary management, in the chronic management of adult and pediatric patients, weighing 20 kg or greater and with a body surface area (BSA) of 1.2 m^2 or greater, with urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS).

Limitation of Use

OLPRUVA is not indicated for the treatment of acute hyperammonemia, which can be a life-threatening medical emergency that requires rapidly acting interventions to reduce plasma ammonia levels.

Inside this guide, you'll find useful information about Navigator by Acer Therapeutics and the Copay Assistance Program, a prescription road map, and more to help your office understand the OLPRUVA prescription process.

Visit **OlpruvaHCP.com** for more information.

Please see Important Safety Information on pages 7-8 and full Prescribing Information.

OLPRUVA™
(sodium phenylbutyrate)
for oral suspension

Contents

Indication

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Navigator by Acer Therapeutics and CVS Specialty: Partnering for you and your patients

Navigator by Acer Therapeutics helps you and your patients throughout the prescription process

Acer Therapeutics is dedicated to helping you and your patients have a seamless start to OLPRUVA™ (sodium phenylbutyrate) for oral suspension treatment and providing support throughout therapy. To help us do that, Navigator by Acer Therapeutics has partnered with CVS Specialty.

Submit an OLPRUVA Prescription Enrollment Form, and the dedicated OLPRUVA Navigator Team at CVS Specialty will get to work helping to provide timely access to OLPRUVA with:

- Copay assistance available for eligible patients*
- A single, designated specialty pharmacy to streamline the prescription process
- Home delivery service or pickup at any of the approximately 10,000 CVS Pharmacy® locations
- Kits containing 90 doses (up to 30 days of treatment) packaged in individual, easily transported, premeasured dosing envelopes
- Support for your patients throughout their OLPRUVA experience

IMPORTANT: Inform your patients that they must answer or return calls from CVS Specialty to have their prescriptions filled.

The OLPRUVA Navigator Team is available for you and your patients, Monday-Friday, 7 AM-7 PM Central Time, at 1-833-OLPRUVA (1-833-657-7882). A pharmacist is available at that number 24/7.

*Eligibility criteria and maximum limits apply. Contact the OLPRUVA Navigator Team for details.

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You start the process, your OLPRUVA Navigator Team does the rest

You and your office

1

Complete the OLPRUVA™ (sodium phenylbutyrate) for oral suspension Prescription Enrollment Form

2

You and the patient or caregiver **sign the form**

- The patient/caregiver signature enrolls the patient for support and resources, including potential financial assistance and more

3

Fax the form to **1-855-624-2566**

OLPRUVA Navigator Team

Benefits verification
- Completes benefits verification and assists with prior authorization
- Helps with financial assistance options for eligible patients*

OLPRUVA dispensing
Multiple prescription delivery options are available to meet patient/caregiver needs:
- Home delivery
- Delivery to any of ~10,000 CVS Pharmacy® locations in the US

Reorder process
- CVS Specialty staff will proactively reach out to the patient/caregiver to schedule the next delivery/refill

Education
- CVS Specialty staff will address questions about OLPRUVA or UCDs throughout treatment

*Eligibility criteria and maximum limits apply. Contact the OLPRUVA Navigator Team for details.

NAVIGATOR by acertherapeutics

CVS specialty®

OLPRUVA patients and their caregivers shouldn't have to feel alone. The OLPRUVA Navigator Team will serve as their dedicated point of contact to help throughout treatment.

OLPRUVA™ (sodium phenylbutyrate) for oral suspension

Please see Important Safety Information on pages 7-8 and full Prescribing Information.

Help your patients get access to OLPRUVA

Tips to remember when prescribing OLPRUVA™ (sodium phenylbutyrate) for oral suspension

Here are some best practices to follow to help ensure the OLPRUVA access process goes as smoothly as possible.

Fill out the Prescription Enrollment Form completely and accurately.

- Review the form to ensure that all necessary information is entered and correct
- Make sure you and the patient or caregiver sign and date the form
- See the OLPRUVA Prescription Enrollment Form How-To Guide (provided in the Access Toolkit) for more information about completing the form
- Fax copies of front and back of all insurance cards with the form

Verify that your fax was sent successfully when submitting the form.

Ensure the patient or caregiver understands that they must answer/return the phone calls from CVS Specialty to have their OLPRUVA prescription filled.

Provide all additional information requested by CVS Specialty.

- CVS Specialty may contact your office for clarifications, verifications, additional materials for prior authorizations, denial appeals, etc

Remember that you and your patients can reach the OLPRUVA Navigator Team Monday-Friday, 7 AM-7 PM Central Time, or a pharmacist 24/7 at **1-833-OLPRUVA** (1-833-657-7882).

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Copay Assistance Program

Copay assistance available for eligible patients*

Navigator by Acer Therapeutics is committed to helping your patients get access to OLPRUVA. Commercially insured patients with a valid OLPRUVA prescription may be eligible for copay assistance through the OLPRUVA Copay Assistance Program.*

- Patients are not eligible for this assistance if they are uninsured or if the prescription is eligible to be reimbursed, in whole or in part, by any state or federal healthcare programs, including but not limited to Medicare or Medicaid, Medigap, VA, DOD, or TRICARE
- A maximum benefit limit may also apply; patients should confirm their out-of-pocket cost with the OLPRUVA Navigator Team at CVS Specialty
- Copay assistance may also be available through independent foundations

Once you complete the Prescription Enrollment Form, the OLPRUVA Navigator Team will offer eligible patients access to the Copay Assistance Program.

*Eligibility criteria and maximum limits apply. Contact the OLPRUVA Navigator Team for details.

OLPRUVA™
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Indication and Important Safety Information for OLPRUVA

OLPRUVA [ol proo vah] (sodium phenylbutyrate) for oral suspension

Indication

OLPRUVA is a nitrogen-binding agent indicated as adjunctive therapy to the standard of care, which includes dietary management, in the chronic management of adult and pediatric patients, weighing 20 kg or greater and with a body surface area (BSA) of 1.2 m^2 or greater, with urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS).

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Important Safety Information

Warnings and Precautions

Neurotoxicity of Phenylacetate: Increased exposure to phenylacetate, the major metabolite of OLPRUVA, may be associated with neurotoxicity in patients with UCDs. If neurotoxicity symptoms of vomiting, nausea, headache, somnolence, or confusion are present in the absence of high ammonia levels or other intercurrent illnesses, consider reducing the dose of OLPRUVA.

Hypokalemia: Renal excretion of phenylacetylglutamine may induce urinary loss of potassium. Monitor serum potassium during therapy and initiate appropriate treatment when necessary.

Conditions Associated with Edema: OLPRUVA contains 124 mg of sodium per gram of sodium phenylbutyrate, and the Mix-Aid contains 5 mg of sodium per packet. Calculate the total amount of sodium based on the patient's body surface area. If a patient develops new-onset edema or worsening edema while on treatment, discontinue administration of sodium phenylbutyrate and initiate appropriate therapy.

Drug Interactions

Valproic acid, haloperidol, or corticosteroids may increase plasma ammonia levels. Monitor ammonia levels closely. Probenecid may inhibit renal excretion of metabolites of OLPRUVA including phenylacetate and phenylacetylglutamine; monitor for potential neurotoxicity.

Important Safety Information continued on page 8.

Important Safety Information (continued)

Use in Specific Populations
No studies with OLPRUVA have been conducted in subjects with renal or hepatic impairment. Monitor ammonia levels and in patients with hepatic impairment, it is recommended to start at the lowest dose that controls ammonia levels. Dose selection for elderly patients should be cautious, usually starting at the low end of the dosing range.

OLPRUVA should be used with caution in patients who are pregnant or planning to become pregnant. Report pregnancies to Acer Therapeutics Inc. at 1-833-657-7882. There are no data on the presence of OLPRUVA in human milk, the effects on the breastfed infant, nor the effects on milk production. This should be considered when assessing the mother's need for OLPRUVA.

Adverse Reactions
Most common adverse reactions (incidence ≥ 3%) are amenorrhea or menstrual dysfunction (irregular menstrual cycles), decreased appetite, body odor and bad taste or taste aversion.

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

This information is not comprehensive.

For additional information, please see full Prescribing Information for OLPRUVA at OlpruvaHCP.com.

Committed to providing you and your patients support that starts when you submit the prescription and continues throughout OLPRUVA™ (sodium phenylbutyrate) for oral suspension treatment.

acertherapeutics

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NAVIGATOR
by acertherapeutics