[Example Letter of Medical Necessity: Use physician office letterhead]

Use of this document does not guarantee coverage for your patient. This document is intended to provide you with an example of the type of information that is typically required when providing a letter of medical necessity. The contents of your letter must be based on your medical judgment and align with the patient's medical records. Bracket content here is intended for guidance only; you should use appropriate patient-specific information in your customized letter to your patient's insurance provider.

[Date]
[Contact name]
[Contact title]
[Name of health insurance company]
[Address]

Re:
Letter of Medical Necessity for OLPRUVA™
(sodium phenylbutyrate) for oral suspension
Patient: [Patient name]
Group/Policy Number: [Number]
Diagnosis: [ICD code and description]

Dear [Insert contact name or department],

I am writing on behalf of my patient, [PATIENT NAME], to document medical necessity for treatment with OLPRUVA. I am a [specialty – eg, geneticist] who has been treating urea cycle disorders (UCDs) for [number] years and am confident in the medical necessity of OLPRUVA for this patient.

The patient will be treated with OLPRUVA for [DIAGNOSIS]. OLPRUVA is indicated for the chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. OLPRUVA must be used with dietary protein restriction and, in some cases, dietary supplements. OLPRUVA is not indicated for the treatment of acute hyperammonemia.[1] I have [enclosed/attached] the full Prescribing Information, which supports the use of OLPRUVA for this patient.

This letter serves to document that [PATIENT NAME] needs OLPRUVA and that OLPRUVA is medically necessary for [HIM/HER] as prescribed. On behalf of the patient, I am requesting approval for use and subsequent payment for the drug. In the event of a denial of coverage, all levels of appeal will be pursued, up to and including peer-to-peer review with like specialty and third-party review, if applicable.

Medical History and Diagnosis
[PATIENT NAME] is a[n] [AGE]-year-old [MALE/FEMALE] diagnosed with [DIAGNOSIS and SUBTYPE]. [PATIENT NAME] has been in my care since [DATE]. The attached medical records document [PATIENT NAME]'s clinical condition and the medical necessity for treatment with OLPRUVA.

Additionally, [PATIENT NAME] has tried [PREVIOUS TREATMENTS] with the following outcomes. [DESCRIBE OUTCOMES OF PREVIOUS TREATMENTS]

Based on the above facts, and my clinical judgment, I am confident that you will agree that OLPRUVA is medically necessary and the appropriate therapeutic choice for [PATIENT NAME].

Thank you for your prompt attention to this request. If you have any questions, please feel free to call me at [PHYSICIAN TELEPHONE NUMBER] to discuss.

Sincerely,
[PHYSICIAN NAME], [DEGREE INITIALS] [PROVIDER IDENTIFICATION NUMBER]

Enclosures: [Include as appropriate; OLPRUVA full Prescribing Information – available at OlpruvaHCP.com]
Prescribing Information (PI)
Clinic notes and labs

Reference: 1. OLPRUVA™ (sodium phenylbutyrate) for oral suspension. Prescribing information. Newton, MA: Acer Therapeutics Inc.

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).

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.

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.

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.

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