LETTER OF MEDICAL NECESSITY TEMPLATE

**GIVLAARI® (givosiran) injection for subcutaneous use  
for the treatment of acute hepatic porphyria (AHP)**

**To the HCP:** The following is a sample letter of medical necessity template that can be customized based on your patient’s medical history and demographic information using your independent clinical judgment. You are responsible for providing information that completely and accurately represents your patient’s circumstances. Please note that some payers may have specific forms that must be completed in order to request prior authorization or to document medical necessity. Use of this document does not guarantee coverage or reimbursement by any third-party payer.

|  |  |
| --- | --- |
| [Date] | RE: [Patient Name] |
| [Medical Director Name] | [Group Number] |
| [Payer Name] | [Policy Number] |
| [Payer Address Line 1] | [Claim Number] |
| [Payer City, State, ZIP] | [Diagnosis, ICD-10] |

Dear [Medical Director],

I am writing this letter of medical necessity to request that my patient, [insert patient name], receive GIVLAARI® (givosiran), a product that is approved by the United States Food and Drug Administration (FDA) for the treatment of adults with acute hepatic porphyria (AHP).1

**Product Description**

GIVLAARI® is a double-stranded small interfering RNA (siRNA), that reduces elevated levels of ALAS1 mRNA in the liver, thereby leading to substantial and sustained reductions in circulating levels of neurotoxic ALA and PBG, factors associated with attacks and other disease manifestations of AHP.1 The efficacy and safety of givosiran were evaluated in the Phase 3 ENVISION study, a global, randomized, double-blind, placebo-controlled study, and are supported by the open-label extension (OLE) period of the Phase 3 study, a Phase 1 study, and long-term data from a Phase 1/2 OLE study.2-4 These data support the use of givosiran for the treatment of adults with AHP.

**Rationale for Treatment**

***[Add additional information that is pertinent to your patient]***

Based on the clinical safety and efficacy data of GIVLAARI® (givosiran) it is my medical opinion that initiating GIVLAARI® for [patient’s name] is appropriate and medically necessary at this time. Coverage of GIVLAARI® therapy, including all administration services (described in further detail below), should be reimbursed. The remainder of the letter describes the patient’s medical history, prognosis, and rationale for treatment with GIVLAARI®.

***Summary of Patient’s Medical History***

***[Please complete based on your patient’s medical history; delete any categories that are not pertinent to your patient]***

□ Date of AHP diagnosis: [complete]

* Biochemical testing: [If applicable, provide results of your patient’s biochemical testing]
* Other evaluation(s): [If applicable, describe other means of diagnosis]

□ Family history of AHP:

* [Provide a brief description of relevant family history (e.g., impacted family members, known outcomes)]

□ Relevant Medical History:

* AHP sign(s) and symptom(s):
  + Central, peripheral, and autonomic nervous system manifestations: (if applicable) [please describe]
  + Cutaneous manifestations: (if applicable) [please describe]
* Comorbidities: (If applicable, describe relevant comorbidities) [please describe]

□ Previous/current treatments:

* [Describe previous and current treatment strategies (include treatments for acute attacks, chronic symptoms, relevant comorbidities; include the dose, start date, end date (if applicable) of each treatment, and reason for discontinuation (if applicable)]

□ Other relevant medical information:

* [Add any additional medical information that would be useful in assessing use of GIVLAARI® for the patient.]

**Dosing and Administration**1

The recommended dose of GIVLAARI® is 2.5 mg/kg administered via subcutaneous injection once monthly. Dosing is based on actual body weight. GIVLAARI® is intended for administration by a healthcare professional only. I will ensure that medical support is available to appropriately manage anaphylactic reactions when administering GIVLAARI®. My patient weighs [insert weight in kilograms]. Therefore, [he/she] should receive a dose of [insert dose] mg once monthly.

**Closing Remarks**

*[Please provide closing comments relative to this patient’s case (e.g., given the patient’s existing signs and symptoms, the potentially life threatening or debilitating nature of AHP, and the existing efficacy and safety of GIVLAARI®, it is medically necessary and appropriate to initiate GIVLAARI® therapy using the FDA-approved dosing regimen.)]*

Please contact my office at [insert phone number] if more information is needed. I look forward to receiving your timely response to this claim.

Sincerely,

[Insert physician name and provider number]

[Attachments: describe]

**References:**

1. GIVLAARI® (givosiran) [Prescribing Information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; 2019.
2. Balwani M, Sardh E, Ventura P, Aguilera-Peiro P, Rees DC. Phase 3 trial of RNAi therapeutic givosiran for acute intermittent porphyria. *N Engl J Med*. 2020; 382(24):2289-2301.
3. Ventura P, Bonkovsky HL, Gouya L, Aguilera-Peiro P, Bissel, DM. Efficacy and safety of givosiran for acute hepatic porphyria: 24-month interim analysis of the randomized phase 3 ENVISION study [published online ahead of print, October 30, 2021]. *Liver International*. 2021; doi: 10.1111/liv.15090.
4. Sardh E, Harper P, Balwani M, Stein P, Rees D, Bissell DM, et al. Phase 1 trial of an RNA interference therapy for acute intermittent porphyria. *N Engl J Med* 2019;380:549-558.