Universal Letter of Medical Necessity/Prior Authorization

Dear Health Care Provider:

Disclaimer: For your independent consideration and review, please make all changes that you believe appropriate, or disregard these suggestions in their entirety. The treating physician in his or her medical judgment is ultimately responsible for the accuracy, truthfulness, and completeness of all claims and communications submitted to third-party payers. Nothing in this document should be construed as a guarantee by Stemline Therapeutics, Inc. regarding coverage or payment by any payor at any specific level, and Stemline Therapeutics, Inc. does not advocate or promote the appropriateness of the use of any billing codes. This template is intended for determining medical necessity and meeting general prior authorization requirements, not for promotional purposes. Please see the **ELZONRIS® (tagraxofusp-erzs) Injection for Intravenous (IV) Use** FDA-approved label for information relevant to any prescribing decisions.

We have provided this **sample Letter of Medical Necessity/Prior Authorization** to help request coverage as part of a prior authorization process. This sample letter may be utilized to help justify your patient's need for treatment with ELZONRIS to his or her insurance provider. Use of this document does not guarantee health insurance coverage your patient.

To use this letter, please copy the text from the next page and paste it onto your office letterhead. Be sure to replace all bolded and bracketed text with the appropriate patient-specific information before forwarding your customized letter to your patient's insurance provider. If the provided fields do not accurately reflect your practices, please modify them to represent your circumstances.

Tips for completing the disease and medical history fields:

- Include specific diagnosis codes where appropriate
- List previous therapy, length of therapy, and outcomes (ie, specify reasons for unsuccessful results)
- Clearly state the rationale for the recommended therapy and why it is appropriate for your patient

Tips for completing the enclosed materials field:

- List and enclose documents that support your rationale for the recommended therapy:
    - Summary of patient's medical records
    - Journal articles
    - Copies of medical correspondence
    - Specific information about the recommended drug or procedure (Prescribing Information, FDA approval letter, treatment guidelines compiled by professional physician organizations)
- Be sure to include all the listed documents with the letter when you send it to your patient's insurance provider

We hope you find this **sample Letter of Medical Necessity/Prior Authorization** to be a valuable resource to your practice.

Sincerely,

Date: **[Insert date]**

RE: **[Patient name]**
[Patient insurance ID number]
[Insurance group #]
[Patient date of birth]

Dear **[health plan contact name]:**

I am writing on behalf of my patient**, [insert patient name],** to document the medical necessity for ELZONRIS® (tagraxofusp-erzs) Injection for Intravenous (IV) Use. This letter provides information about my patient's medical history, diagnosis, and a summary of my treatment rationale.

Patient Diagnosis:
My patient has been diagnosed with blastic plasmacytoid dendritic cell neoplasm (BPDCN): ICD-10 code C86.4.

Patient History
[If applicable, include a list of previous misdiagnoses]

Please also note that:

- I have been working with my patient since **[insert date]**
- I have prescribed ELZONRIS to treat this patient's BPDCN
- The claim for ELZONRIS was denied for treatment dates: **[insert treatment period in question]**

Decision to prescribe ELZONRIS
The FDA granted ELZONRIS Breakthrough Therapy Designation and subsequently approved it as the ONLY FDA-approved therapy to treat BPDCN. In April 2019, The *New England Journal of Medicine* published an article summarizing the pivotal trial results of ELZONRIS in BPDCN (Pemmaraju N, Lane AA, Sweet KL, et al. Tagraxofusp in blastic plasmacytoid dendritic-cell neoplasm. *N Engl J Med*. 2019;380(17):1628-1637).

[Based on your clinical judgment, summarize why your patient requires treatment with ELZONRIS]

I am prescribing ELZONRIS and request coverage for my patient because I have concluded that it is the most appropriate therapeutic option for this patient. Please review the clinical information I have submitted, which supports the diagnosis of BPDCN and my decision to prescribe ELZONRIS.

Please feel free to contact me if you require further information regarding this request, and I look forward to your response as soon as possible.

Sincerely,

[**Signature]**

[Name]

INDICATION

- ELZONRIS is a CD123-directed cytotoxin for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older

IMPORTANT SAFETY INFORMATION

Boxed WARNING: CAPILLARY LEAK SYNDROME

- **Capillary Leak Syndrome (CLS), which may be life-threatening or fatal, can occur in patients receiving ELZONRIS. Monitor for signs and symptoms of CLS and take actions as recommended**

WARNINGS AND PRECAUTIONS

Capillary Leak Syndrome

- ELZONRIS can cause capillary leak syndrome (CLS), which may be life-threatening or fatal if not properly managed. The overall incidence of CLS in clinical trials was 55% in patients receiving ELZONRIS, including 46% in Grades 1 or 2, 6% in Grade 3, 1% in Grade 4, and 2 fatal events. Common signs and symptoms (incidence ≥ 20%) associated with CLS that were reported during treatment with ELZONRIS include hypoalbuminemia, edema, weight gain, and hypotension
- Before initiating therapy with ELZONRIS, ensure that the patient has adequate cardiac function and serum albumin is ≥ 3.2 g/dL
- During treatment with ELZONRIS, ensure that serum albumin levels are ≥ 3.5 g/dL and have not been reduced by ≥ 0.5 g/dL from the albumin value measured prior to dosing initiation of the current cycle. Monitor serum albumin levels prior to the initiation of each dose or more often as indicated clinically thereafter. Additionally, assess patients for other signs or symptoms of CLS, including weight gain, new onset or worsening edema including pulmonary edema, hypotension, or hemodynamic instability
- Counsel patients to seek immediate medical attention should signs or symptoms of CLS occur at any time

Hypersensitivity Reactions

- ELZONRIS can cause severe hypersensitivity reactions. Grade 3 or higher events were reported in 10% of patients in clinical trials. Monitor patients for hypersensitivity reactions during treatment with ELZONRIS. Interrupt ELZONRIS infusion and provide supportive care as needed if a hypersensitivity reaction should occur. If the reaction is severe, discontinue ELZONRIS permanently

Hepatotoxicity

- Elevations in liver enzymes can occur with ELZONRIS. Grade 3 or higher elevations in liver enzymes occurred in approximately 40% of patients in clinical trials
- Monitor alanine aminotransferase (ALT) and aspartate aminotransferase (AST) prior to each infusion with ELZONRIS. Temporarily withhold ELZONRIS if the transaminases rise to greater than 5 times the upper limit of normal (ULN) and resume treatment upon normalization or when resolved

ADVERSE REACTIONS:

The most common adverse reactions in the clinical trials (incidence ≥ 30%) are capillary leak syndrome, nausea, fatigue, peripheral edema, pyrexia, and weight increase. The most common laboratory abnormalities (incidence ≥ 50%) are decreases in albumin, platelets, hemoglobin, calcium, sodium, and increases in glucose, ALT, and AST.

Please see full Prescribing Information, including Boxed WARNING.

To report SUSPECTED ADVERSE REACTIONS, contact Stemline Therapeutics, Inc. at 1-877-332-7961 or contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.