# stemline arc®

access | reimbursement support | connection

**access**
Support for benefits investigation and verification, information on alternate support, and co-pay support for eligible patients*

**reimbursement support**
Information regarding prior authorization, template letter of medical necessity, appeals of denied claims, and coding & billing support

**connection**
ARC Patient Advocates provide an overview of support services, confirm ELZONRIS coverage and financial assistance, and share helpful resources†

## ENROLLMENT FORM AND INSTRUCTIONS

A guide to completing the enrollment form for Stemline ARC® to help provide access, reimbursement support, and connection to resources for eligible patients throughout treatment with ELZONRIS® (tagraxofusp-erzs) Injection for Intravenous (IV) Use

For questions or more information, please call 1-833-4-STEMLINE (1-833-478-3654) from 9:00 am to 6:00 pm EST, Monday through Friday, or visit ELZONRIS.com/hcp/stemline-arc-summary. Fax completed enrollment form to 1-833-329-7836.

*In order to be eligible for the Stemline Commercial Co-Pay Program, the patient must not have government-funded health insurance (eg, Medicare, Medicaid, or any other federal or state program), must be taking ELZONRIS Injection for IV Use for an FDA-approved indication, and must confirm that they meet all of the eligibility criteria and agree to the rules set forth in the terms and conditions for the program. Patients and healthcare providers are responsible for completing and submitting enrollment forms and coverage or reimbursement documentation. Stemline Therapeutics, Inc. makes no representation or guarantee concerning coverage or reimbursement of any service or item.

†ARC Patient Advocates are available to provide resource information and answer questions about financial assistance, insurance benefits, and coverage for ELZONRIS. This supplemental support is not intended to replace discussions between patients and their healthcare providers.

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# Stemline ARC Enrollment in 4 Simple Steps

Follow these simple steps to enroll your patients in Stemline ARC, a support program to help eligible patients access and receive treatment with ELZONRIS Injection for IV Use.

Fill out the attached enrollment form, or download the form at ELZONRIS.com/hcp/stemline-arc-summary.

Together with your patient, sign and date all Stemline ARC enrollment form authorizations, certifications, and consent fields.

Work with your patient to confirm and provide all required documentation for benefits investigation, verification, or Stemline Patient Assistance Program support.

Fax completed application and required documentation to 1-833-329-7836.*

## Enrollment Reminders

Before faxing your application, please use the checklist below to ensure all of the required documentation is included:

- ☑ Obtain patient certifications and authorizations
- ☑ Be sure to include the healthcare provider's state license number
- ☑ If the patient is requesting financial assistance or Stemline Patient Assistance Program help, please include the patient's most recent W2, 1099, or other proof of income
- ☑ Attach a copy of both sides of all patient insurance cards

*Applications and required documentation may also be mailed to:

Stemline ARC
PO Box 5490
Louisville, KY 40255

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## STEP 1: PATIENT INFORMATION

| PATIENT INFORMATION *(*Required fields)* | | | |
|---|---|---|---|
| Name (First/MI/Last)* | Patient DOB (mm/dd/yyyy)* | | Sex* ○ Male ○ Female |
| Street Address* | | | City* |
| State* | ZIP Code* | Email Address | |
| Primary Phone #* ○ Home ○ Mobile ○ Work | Secondary Phone # ○ Home ○ Mobile ○ Work | | |
| Best Time to Contact ○ Morning ○ Afternoon ○ Evening | Preferred Language (if not English) | | |
| Alternate Contact Name/Relationship to Patient | Alternate Contact Phone # ○ Home ○ Mobile ○ Work | | |

Patient Authorizations

○ I give permission to Stemline ARC to communicate directly with my alternate contact on my behalf.

## STEP 2: INSURANCE INFORMATION

| INSURANCE INFORMATION: If patient is uninsured, please skip to step 3 *(*Required fields)* | | | |
|---|---|---|---|
| Primary Insurance* | Policy ID #* | | GRP ID # |
| Insurer's Phone # | Policyholder Same as Patient? ○ Yes ○ No<br>Relationship to Patient: | | |
| Policyholder Name* | Policyholder DOB (mm/dd/yyyy)* | | |
| Secondary Insurance | Policy ID #* | GRP ID # | |
| Insurer's Phone # | Policyholder Same as Patient? ○ Yes ○ No<br>Relationship to Patient: | | |
| Policyholder Name* | Policyholder DOB (mm/dd/yyyy)* | | |

Attach a copy of both sides of all patient insurance cards.

## STEP 3: PRESCRIBER INFORMATION

| PRESCRIBER INFORMATION *(*Required fields)* | | | |
|---|---|---|---|
| Prescriber Name* | State Where Licensed* | State License #* | |
| Prescriber Type | NPI #* | Tax ID #* | DEA #* |
| Facility Name | Facility Type† ○ Hospital Inpatient ○ Hospital Outpatient ○ Freestanding Clinic/Physician Office | | |
| Facility Address*‡ | City* | State* | ZIP Code* |
| Primary Contact Name | | Title/Role | |
| Primary Phone # | Primary Fax # | Primary Email | |

†The first cycle of ELZONRIS Injection for IV Use must be infused in an inpatient facility.
‡Product must be shipped to the signing prescriber's office or hospital address authorized by the prescriber and not to a third party.

## STEP 4: PREFERRED DISTRIBUTION

| SPECIALTY DISTRIBUTOR | | |
|---|---|---|
| ○ ASD | ○ Cardinal | ○ McKesson |

## STEP 5: PRESCRIPTION INFORMATION

| | |
|---|---|
| Primary Diagnosis Code (ICD-10) | |
| Primary Diagnosis Description | |
| MEDICATION AND CODING INFORMATION§ | |
| BILLING DESCRIPTION | HCPCS CODE |
| ELZONRIS Injection, tagraxofusp-erzs, 10 mcg | J9269 |
| DOSAGE AND ADMINISTRATION | |
| Administer ELZONRIS at 12 mcg/kg intravenously over 15 minutes once daily on days 1-5 of a 21-day cycle. | |
| Patient Weight: (lb/kg) | Specify the Number of Vials Requested: |
| NOTE: Each single-use vial contains 1,000 mcg/mL. An 83-kg (183-lb) patient would receive 1 entire vial per day. | |

§It is the physician's responsibility to ensure accurate coding and billing.

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Please see accompanying Full Prescribing Information, including Boxed WARNING.

## STEP 6: HEALTHCARE PROFESSIONAL POLICY AND CONSENT

Stemline Therapeutics, Inc., and its contractors and agents (Stemline ARC®), will use the information you provide to administer and improve Stemline ARC® (the "Program").
By signing below, you represent, covenant, and certify as follows: (i) My patient has provided all required written authorization(s) as required by HIPAA 164.508 and other federal or state laws to release to Stemline Therapeutics, Inc. and the Program all patient information needed for this application, including without limitation financial and personally identifiable information in order to (1) conduct coverage support services, and (2) determine eligibility and enroll patient for financial assistance; (ii) all of the information provided in this application is complete and accurate; (iii) ELZONRIS was prescribed based on my medical judgment (or the medical judgment of another healthcare professional in my office) of medical necessity and that I will supervise the patient's medical treatment; (iv) I understand and have explained to my patient that Stemline Therapeutics, Inc. may modify or terminate the Program at any time without notice and that completion of this application does not guarantee enrollment in any particular part of the Program; (v) I have discussed with the patient and the patient has agreed and acknowledged that any medications supplied by Stemline Therapeutics, Inc. under the Program are for use by the named patient only and shall not be sold, traded, bartered, transferred, returned for credit, submitted to any third-party payer (private or government) for reimbursement, or counted toward the patient's Medicare Part D out-of-pocket costs; (vi) I have not received nor will I seek or accept payment from my patient for any
co-insurance amount paid for by the Program; (vii) I understand that I am under no obligation to prescribe any Stemline Therapeutics, Inc. drug, and I have not received and will not receive any benefit from Stemline Therapeutics, Inc. for prescribing a Stemline Therapeutics, Inc. drug; and (viii) if I become aware of any errors in the information provided, I will promptly notify Stemline Therapeutics, Inc. of those errors.

Prescriber's Signature (No stamps please): _____ Date: _____

## PATIENT AUTHORIZATION AND CONSENT TERMS

Patient authorization is required for enrollment into the Stemline ARC patient support services. Please read and sign the Patient Authorization terms below:

By signing this Authorization, I authorize each of my physicians, pharmacists (including any specialty distributor or specialty pharmacy that receives my prescription for ELZONRIS) and other healthcare providers (together, "Healthcare Providers") and each of my health insurers (together, "Insurers") to disclose my Protected Health Information, including but not limited to medical records, information related to my medical condition and treatment, my health insurance coverage, my name, address, telephone number, insurance plan and/or group numbers (together, "PHI"), to Stemline Therapeutics, Inc., its affiliated companies, vendors, agents, collaboration partners, and representatives (together, "Stemline Therapeutics, Inc."), including providers of alternate sources of funding for prescription drug costs, and other service providers supporting access programs for Healthcare Providers and patients to provide me with support related to Stemline products. Such support may include (1) establishing my eligibility for the Stemline ARC program (the "Program") and enrolling me in the Program if I am eligible; (2) communicating with my Healthcare Providers and Insurers regarding my coverage and medical care related to my ELZONRIS prescription and treatment; (3) providing support and materials pursuant to the Program; (4) administering, evaluating, and improving the Program; (5) reporting safety information, including in communications with the U.S. Food and Drug Administration and other government authorities; and (6) contacting me regarding this enrollment form or my use or potential use of ELZONRIS and providing me with related patient support communications, including messages left for me that disclose that I take or may take ELZONRIS.

*(Continued on next page.)*

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from 9:00 am to 6:00 pm EST, Monday through Friday, or visit ELZONRIS.com/hcp/stemline-arc-summary.
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I understand that, in cases when an Authorized Personal Representative must sign this Authorization in place of the patient, Stemline Therapeutics, Inc. may use the patient's PHI to contact the Authorized Personal Representative for the purpose of verifying the information in the enrollment form and/or coordinating the provision of benefits that may be available to the patient under the programs, and to disclose PHI to the Authorized Personal Representative solely for the aforementioned purposes.

I understand that pharmacies that ship my medication may be paid to share this information with Stemline ARC to help provide the requested treatment for me. Once my PHI has been disclosed to Stemline ARC, I understand that federal privacy laws no longer protect the information. However, Stemline Therapeutics, Inc. agrees to protect my PHI by using and disclosing it only for the purposes described in this Authorization, or as permitted by law.

I understand that I may refuse to sign this Authorization. My choice about whether to sign will not change the way my Healthcare Providers or Insurers treat me. I understand that I do not have to agree to receive these services and communications and that I can still receive my prescribed medication without signing this Authorization. If I refuse to sign the Authorization, or revoke my Authorization later, I understand that this means I will not be able to participate or receive assistance from Stemline ARC.

This Authorization will last until 3 years from the date this form is signed, unless a shorter period is required by law. I understand that I may cancel this Authorization at any time by mailing a request to Stemline ARC, PO BOX 5490 Louisville, KY 40255; or by calling 1-833-4-STEMLINE (1-833-478-3654).

I understand that revoking this Authorization will end further uses and disclosure of my PHI by the parties identified above except to the extent those uses and disclosures have already been made in reliance upon this Authorization, as permitted by applicable law. I am entitled to receive a copy of this Authorization.

Specifically, I authorize Stemline Therapeutics, Inc. to use and disclose my Protected Health Information in order to:

a. Enroll me in, and contact me about, Stemline ARC support for which I am eligible, including online support, financial assistance information, commercial co-pay assistance, Nurse Advocate assistance, and compliance and persistency support.

b. Verify my coverage for ELZONRIS Injection for IV Use with my Insurers.

c. Coordinate prescription fulfillment.

☐ By checking this box, I agree to receive marketing information, offers, and educational materials related to my treatment experience with ELZONRIS Injection for IV Use.

☐ By checking this box, I choose to opt out of receiving calls and materials from Stemline ARC Nurse Advocates.

Patient or Legal Representative Signature: _____ Date: _____

Patient or Legal Representative Printed Name: _____

For questions or more information, please call 1-833-4-STEMLINE (1-833-478-3654) from 9:00 am to 6:00 pm EST, Monday through Friday, or visit ELZONRIS.com/hcp/stemline-arc-summary. Fax completed enrollment form to 1-833-329-7836.

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**INDICATION**

- ELZONRIS is a CD123-directed cytotoxin indicated 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**

- Capillary leak syndrome (CLS), including life-threatening and fatal cases, has been reported among patients treated with ELZONRIS. In patients receiving ELZONRIS in clinical trials, the overall incidence of CLS was 53% (65/122), including Grade 1 or 2 in 43% (52/122) of patients, Grade 3 in 7% (8/122) of patients, Grade 4 in 1% (1/122) of patients, and four fatalities (3%). The median time to onset was 4 days (range - 1 to 46 days), and all but 5 patients experienced an event in Cycle 1.
- Before initiating therapy with ELZONRIS, ensure that the patient has adequate cardiac function and serum albumin is greater than or equal to 3.2 g/dL. During treatment with ELZONRIS, monitor serum albumin levels prior to the initiation of each dose of ELZONRIS and as indicated clinically thereafter, and assess patients for other signs or symptoms of CLS, including weight gain, new onset or worsening edema, including pulmonary edema, hypotension or hemodynamic instability.

**Hypersensitivity Reactions**

- ELZONRIS can cause severe hypersensitivity reactions. In patients receiving ELZONRIS in clinical trials, hypersensitivity reactions were reported in 43% (53/122) of patients treated with ELZONRIS and were Grade ≥ 3 in 7% (9/122). Manifestations of hypersensitivity reported in ≥ 5% of patients include rash, pruritus, and stomatitis. Monitor patients for hypersensitivity reactions during treatment with ELZONRIS. Interrupt ELZONRIS infusion and provide supportive care as needed if a hypersensitivity reaction should occur.

**Hepatotoxicity**

- Treatment with ELZONRIS was associated with elevations in liver enzymes. In patients receiving ELZONRIS in clinical trials, elevations in ALT occurred in 79% (96/122) and elevations in AST occurred in 76% (93/122). Grade 3 ALT elevations were reported in 26% (32/122) of patients. Grade 3 AST elevations were reported in 30% (36/122) and Grade 4 AST elevations were reported in 3% (4/122) of patients. Elevated liver enzymes occurred in the majority of patients in Cycle 1 and were reversible following dose interruption.
- Monitor alanine aminotransferase (ALT) and aspartate aminotransferase (AST) prior to each infusion with ELZONRIS. Withhold ELZONRIS temporarily if the transaminases rise to greater than 5 times the upper limit of normal and resume treatment upon normalization or when resolved.

**ADVERSE REACTIONS:**

Most common adverse reactions (incidence ≥ 30%) are capillary leak syndrome, nausea, fatigue, pyrexia, peripheral edema, and weight increase. Most common laboratory abnormalities (incidence ≥ 50%) are decreases in albumin, platelets, hemoglobin, calcium, and 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.

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