

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Oncaspar Prior Authorization Policy

- Oncaspar® (pegaspargase injection for intramuscular or intravenous use – Servier)

REVIEW DATE: 06/02/2021

OVERVIEW

Oncaspar a conjugate of *Escherichia coli*-derived L-asparaginase and monomethoxypolyethylene glycol (mPEG), is indicated as a component of a multi-agent chemotherapy regimen for **acute lymphoblastic leukemia (ALL)**, for first-line treatment of pediatric and adult patients, and treatment of pediatric and adult ALL patients with hypersensitivity to native forms of L-asparaginase.¹

Guidelines

Oncaspar is addressed in National Comprehensive Cancer Network (NCCN) guidelines:

- **ALL:** The NCCN guidelines for **ALL** (version 1.2021 – April 6, 2021) and for **Pediatric ALL** (version 2.2021 – October 22, 2020) recommend pegaspargase as a component of a multi-agent chemotherapeutic regimen for induction/consolidation therapy for ALL, for induction therapy in Philadelphia chromosome-negative ALL in patients ≥ 65 years of age, for relapsed/refractory Philadelphia chromosome-negative ALL, and relapsed/refractory Philadelphia chromosome-positive ALL.^{2,3,5}
- **T-cell lymphomas:** The NCCN guidelines (version 1.2021 – October 5, 2020) recommend pegaspargase as a component of therapy for extranodal NK/T-cell lymphoma, nasal type and as an alternative induction regimen if no response or progressive disease after primary treatment for hepatosplenic T-cell lymphoma.^{3,4}

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Oncaspar. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Oncaspar as well as the monitoring required for adverse events and long-term efficacy, approval requires Oncaspar to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Oncaspar is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Acute Lymphoblastic Leukemia.** Approve for 1 year if Oncaspar is prescribed by or consultation with an oncologist.

Other Uses with Supportive Evidence

2. **Extranodal NK/T-cell Lymphoma, Nasal Type.** Approve for 1 year if Oncaspar is prescribed by or in consultation with an oncologist.
3. **Hepatosplenic T-cell Lymphoma.** Approve for 1 year if the patient meets the following criteria (A and B):
 - A) Patient had no response or progressive disease after primary treatment; AND
 - B) Oncaspar is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Oncaspar is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Oncaspar® injection for intramuscular and intravenous use [prescribing information]. Boston, MA: Servier Pharmaceuticals; June 2020.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (Version 1.2021 – April 6, 2021). © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed May 11, 2021.
3. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on May 11, 2021. Search term: pegaspargase.
4. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (Version 1.2021 – October 5, 2020). © 2020 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed May 11, 2021.
5. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (Version 2.2021 – October 22, 2020). © 2020 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed May 11, 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Extranodal NK/T-cell Lymphoma, Nasal Type: Removed “Oncaspar is used for one of the following (i, ii, or iii)” criteria. Added criteria for Hepatosplenic Gamma-Delta T-cell Lymphoma.	06/03/2020
Annual Revision	Hepatosplenic T-cell Lymphoma: The qualifier of “Gamma-Delta: was removed from the condition of approval.	06/02/2021

Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. We do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:

Provide free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provide free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact us at the phone number shown on the inside cover of this contract, your id card, or aspirushealthplan.com.

If you believe that we have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity, you can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1.866.631.5404 (TTY: 711)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Nondiscrimination Grievance Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلی رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_ : य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

Traditional Chinese: 注意: 如果您使用繁體中文, 您可以免費獲得語言援助服務。請致電 1.866.631.5404 (TTY: 711)。

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

Lao: ໄປດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY: 711).