Clinical Policy: Pegaspargase (Oncaspar), Calaspargase pegol-mknl (Asparlas)

Reference Number: CP.PHAR.353
Effective Date: 09.05.17
Last Review Date: 11.19
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Pegaspargase (Oncaspar®) and calaspargase pegol-mknl (Asparlas™) are an asparagine specific enzyme.

FDA Approved Indication(s)

Oncaspar is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of pediatric and adult patients with:

- First-line treatment of acute lymphoblastic leukemia (ALL)
- ALL and hypersensitivity to native forms of L-asparaginase

Asparlas is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of ALL in pediatric and young adult patients age 1 month to 21 years.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Oncaspar and Asparlas are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acute Lymphoblastic Leukemia (must meet all)**:**

1. Diagnosis of ALL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Request meets one of the following (a, b, or c):*
   a. Request is for Oncaspar: dose does not exceed 2,500 IU/m^2 every 14 days (age ≤ 21 years) or 2,000 IU/m^2 every 14 days (age > 21 years);
   b. Request is for Asparlas: dose does not exceed 2,500 IU/m^2 every 21 days (age 1 month to 21 years);
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Extranodal NK/T-Cell Lymphoma (off-label) (must meet all)**:**

1. Diagnosis of NK/T-cell lymphoma, nasal type;

2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Prescribed as a component of any of the following regimens (a, b, or c):*
   a. Modified-SMILE (steroid [dexamethasone], methotrexate, ifosfamide, pegaspargase, etoposide);
   b. P-GEMOX (gemcitabine, pegaspargase, oxaliplatin);
   c. AspaMetDex (pegaspargase, methotrexate, dexamethasone);

   **Prior authorization may be required*
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).**

   ***Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Oncaspar or Asparlas for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):*
   a. Request is for Oncaspar: new dose does not exceed 2,500 IU/m^2 every 14 days (age ≤ 21 years) or 2,000 IU/m^2 every 14 days (age > 21 years);
   b. Request is for Asparlas: new dose does not exceed 2,500 IU/m^2 every 21 days (age 1 month to 21 years);
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices

Appendix A: Abbreviation Key

ALL: acute lymphoblastic leukemia
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - History of serious allergic reactions to Oncaspar or to pegylated L-asparaginase therapy
  - History of serious thrombosis with prior L-asparaginase therapy
  - History of pancreatitis with prior L-asparaginase therapy
  - History of serious hemorrhagic events with prior L-asparaginase therapy
  - Severe hepatic impairment
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Oncaspar (pegaspargase)	ALL	Age ≤ 21 years: 2,500 IU/m^2 IM or IV no more frequently than every 14 days Age > 21 years: 2,000 IU/m^2 IM or IV no more frequently than every 14 days	Age ≤ 21 years: 2,500 IU/m^2 every 14 days Age >21 years: 2,000 IU/m^2 every 14 days
Asparlas (calaspargase pegol-mknl)	ALL	Age 1 month to 21 years: 2,500 IU/m^2 IV no more frequently than every 21 days	2,500 IU/m^2 every 21 days

VI. Product Availability

Drug Name	Availability
Oncaspar (pegaspargase)	Single-dose vial: 3,750 IU/5 mL solution
Asparlas (calaspargase pegol-mknl)	Single-dose vial: 3,750 units/5 mL solution

VII. References

1. Oncaspar Prescribing Information. Boston, MA: Servier Pharmaceuticals LLC; August 2019. Available at: http://www.oncaspar.com/. Accessed November 13, 2019.
2. Asparlas Prescribing Information. Boston, MA: Servier Pharmaceuticals LLC; September 2019. Available at: http://asparlas.com/. Accessed November 13, 2019.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 13, 2019.
4. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version 2.2019. Available at www.nccn.org. Accessed July 22, 2019.
5. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version 1.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed July 22, 2019.
6. National Comprehensive Cancer Network. T-Cell Lymphomas Version 4.2018. Available at www.nccn.org. Accessed July 22, 2019.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9118	Injection, calaspargase pegol-mknl (Asparlas), 10 units
J9266	Injection, pegaspargase (Oncaspar), per single dose vial
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug
96411	Intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)

Reviews, Revisions, and Approvals	Date	Approval Date
New policy created.	09.05.17	11.17
4Q 2018 annual review: added Commercial and HIM lines of business; added age requirements; summarized NCCN and FDA-approved uses for improved clarity; added specialist involvement in care; added off-label use for Ph+ ALL following tyrosine kinase inhibitor therapy; references reviewed and updated.	07.12.18	11.18
4Q 2019 annual review: ALL age limit/drug trial removed per PI; off-label T-cell age limit added in absence of NCCN pediatric guidance; FDA/NCCN dosing limitation added; references reviewed and updated.	08.27.19	11.19
RT4: added Asparlas to policy; updated HCPCS codes.	11.13.19	

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.