Clinical Policy: Pegaspargase (Oncaspar)

Reference Number: CP.PHAR.353
Effective Date: 09.05.17
Last Review Date: 11.17
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description
Pegaspargase (Oncaspar®) is an asparagine specific enzyme.

FDA Approved Indication(s)
Oncaspar is indicated as:
- A component of a multi-agent chemotherapeutic regimen as a first line treatment for acute lymphoblastic Leukemia (ALL)
- A component of a multi-agent chemotherapeutic regimen for the treatment of patients with ALL and hypersensitivity to native forms of L-asparaginase.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

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

I. Initial Approval Criteria

A. Acute Lymphoblastic Leukemia (must meet all):
1. Diagnosis of ALL;
2. Member meets a or b:
   a. FDA approved use (i or ii):
      i. As a component of a multi-agent chemotherapeutic regimen for first line treatment;
      ii. Member has hypersensitivity to L- asparaginase;
   b. Off-label NCCN recommended use (i or ii):
      i. As a component of a multi-agent chemotherapeutic regimen for relapse or refractory disease;
      ii. As a central nervous system directed therapy;
3. Request meets one of the following:
   a. Dose does not exceed 2500 IU/m2 every 14 days;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Extranodal NK/T-Cell Lymphoma, nasal type (off-label):

1. Diagnosis of NK/T-cell lymphoma, nasal type
2. Prescribed to be used as a component of any of the following regimens (a, b, or c):
   a. SMILE (regimen containing dexamethasone, methotrexate, ifosfamide, pegaspargase, and etoposide);
   b. GELOX (regimen containing gemcitabine, pegaspargase, and oxaliplatin);
   c. AspaMetDex (regimen containing pegaspargase, methotrexate, and dexamethasone) ;
3. Request meets one of the following:
   a. Dose does not exceed 2500 IU/m2 every 14 days;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

Other diagnoses/indications

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 2500 IU/m2 every 14 days
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

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 CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – CP.PHAR.57 or evidence of coverage documents.

IV. Appendices

Appendix A: Abbreviation Key

FDA: Food and Drug Administration

NCCN: National Comprehensive Cancer Network
ALL: Acute lymphoblastic leukemia

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ALL	2500 IU/m2 every 14 days	2500 IU/m2 every 14 days

VI. Product Availability

Single-use vial: 3,750 International Units of L-asparaginase per 5 mL solution

VII. References

1. Oncaspar® prescribing information. Cambridge, MA: Baxalta US Inc.; June 2017. Available at http://www.shirecontent.com/PI/PDFs/ONCASPAR_USA_ENG.pdf. Accessed August 24, 2017.
2. Acute lymphoblastic leukemia (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed August 24, 2017.
3. T-Cell Lymphomas (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed August 29, 2017.

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
J9299	Injection, pegaspargase (Oncaspar®)
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

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.