 Draft Revised Policy: Do Not Implement

Pegaspargase (Oncaspar®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:
POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication(s)
Acute Lymphoblastic Leukemia (ALL):

- Oncaspar is indicated as a component of a multi-agent chemotherapeutic regimen for the first line treatment of pediatric and adult patients with ALL.
- Oncaspar is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of pediatric and adult patients with ALL and hypersensitivity to native forms of L-asparaginase.

Compendial Uses

- Extranodal natural killer/T-cell lymphoma (ENKL)
- Aggressive NK-cell leukemia (ANKL)
- Lymphoblastic lymphoma (managed in the same manner as ALL)
- Acute lymphoblastic leukemia (ALL) as a component of multi-agent chemotherapeutic regimen
- Pediatric acute lymphoblastic leukemia (ALL) as a component of a multi-agent chemotherapeutic regimen
- ~~Hepatosplenic T-cell lymphoma~~

All other indications are considered experimental/investigational and not medically necessary.

COVERAGE CRITERIA ~~FOR INITIAL APPROVAL~~

Acute Lymphoblastic Leukemia (ALL) and Lymphoblastic Lymphoma (LL)
Authorization of 12 months may be granted for the treatment of ALL or LL when the requested medication is used in conjunction with multi-agent chemotherapy

Extranodal Natural Killer/T-cell Lymphoma (ENKL) / Aggressive NK-cell Leukemia (ANKL)
Authorization of 12 months may be granted for the treatment of ENKL or ANKL when the requested medication is used in conjunction with multi-agent chemotherapy.

~~**Hepatosplenic T-cell Lymphoma**~~
~~Authorization of 12 months may be granted for the treatment of hepatosplenic T-cell lymphoma as subsequent therapy when the requested medication is used in conjunction with multi-agent chemotherapy.~~

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section ~~II~~ when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Oncaspar (Pegaspargase)	Acute Lymphoblastic Leukemia or Lymphoblastic Lymphoma	Route of Administration: Intravenous, Intramuscular <22year(s) 2500mg/m² every 2 weeks ≥22 year(s) 2000mg/m² every 2 weeks
Oncaspar (Pegaspargase)	T-Cell Lymphomas - Extranodal NK/T-Cell Lymphomas	Route of Administration: Intravenous, Intramuscular 2500mg/m² every 2 weeks

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Oncaspar [package insert]. Boston, MA: Servier Pharmaceuticals LLC; February 2024.
2. The NCCN Drugs & Biologics Compendium® ©2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 28, 2024.

EFFECTIVE DATE

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