Blue Cross Blue Shield Blue Care Network of Michigan

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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

RETIRED

Effective Date: 02/04/2021

Asparlas™ (calaspargase pegol-mknl)

FDA approval: 12/20/2018
HCPCS: J9118
Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. Prescribed by or in consultation with a hematologist or oncologist
   b. FDA approved age
   c. Diagnosis of acute lymphoblastic leukemia (ALL)
   d. Used as a component of a multi-agent chemotherapy regimen per category 1 or 2A NCCN guideline recommendations or FDA indication
   e. Trial and failure of the preferred products as specified in the BCBSM/BCN utilization management medical drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limit: FDA approved dosing
   b. Initial and Renewal Authorization Period: 6 months

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

A. **FDA approved indication/Diagnosis**
   a. For use as a component of a multi-agent chemotherapy regimen for the treatment of acute lymphoblastic leukemia (ALL) in pediatric and young adult patients age 1 month to 21 years

**Please refer to most recent prescribing information.*

B. **Background Information**
   a. Acute leukemia is the most common form of cancer in children, comprising approximately 30% of all childhood malignancies and 75% of all childhood leukemias
   b. Approximately 2,500 to 3,500 new cases of ALL are diagnosed in children each year in the United States with an incidence of approximately 3.4 cases per 100,000
   c. Treatment of children with ALL involves a multidrug regimen divided into induction, consolidation, and maintenance with most treatment protocols taking 2 – 3 years to complete
   d. Approximately 75 – 80% of children with ALL participate in clinical trials
   e. NCCN guidelines recommend clinical trials or induction therapy with chemotherapy, daily corticosteroids, and asparaginase
   f. Different blocks of chemotherapy have varying intensity depending on the group of patients at risk, with increasingly intensive regimens corresponding to more aggressive disease categories
   g. Reinduction chemotherapy after first relapse is can be successful at inducing complete remission and is often the same drug induction regimen used at initial diagnosis

C. **Efficacy**

**Please refer to most recent prescribing information.*

D. **Medication Safety Considerations**

Black Box Warning: No

**Please refer to most recent prescribing information.*

E. **Dosing and administration**
   a. Dosing: 2500 units/m^2 intravenously no more frequently than every 21 days

**Please refer to most recent prescribing information.*

F. **How supplied**
   a. 3,750 units/5 mL single-dose vial

References:

1. Asparlas [package insert]. Boston, MA: Servier Pharmaceuticals LLC; December 2018.
2. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia. Version 1.2018. Available from: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed January 2, 2019.
3. Cooper SL, Brown PA. Treatment of pediatric acute lymphoblastic leukemia. Pediatr Clin North Am. 2014; 62(1): 61-73.
4. Silverman LB, Blonquist TM, Hunt SK, et al. (2016). Randomized study of pegasparagase (SS-PEG) and calaspargase pegol (SC-PEG) in pediatric patients with newly diagnosed acute lymphoblastic leukemia or lymphoblastic lymphoma: results of DFCI ALL consortium protocol 11-001. Blood. 2016; 128(22): 175.
5. Asparlas (calaspargase pegol-mknl). IPD Analytics. December 2018.
6. Clinicaltrials.gov. Calaspargase pegol or pegaspargase and combination chemotherapy in treating younger patients with newly diagnosed high-risk acute lymphoblastic leukemia. (NCT00671034) Available at: https://clinicaltrials.gov/ct2/show/NCT00671034. Accessed on January 2, 2019.
7. Clinicaltrials.gov. SC-PEG asparaginase vs. oncaspar in pediatric acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma. (NCT01574274) Available at: https://clinicaltrials.gov/ct2/show/NCT01574274?term=01574274&rank=1. Accessed on January 2, 2019.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.3</td><td>Effective Date
02/04/2021</td><td>Policy to be retired and drug to be added to the Medical Oncology Drug Class Policy</td></tr>
<tr><td>1.2</td><td>Effective Date:
03/16/2020</td><td>PA added to MAPPO and BCNA
<table><tr><th>Line of Business</th><th>PA Required (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.1</td><td>Effective Date:
02/06/2020</td><td>Annual Review</td></tr>
<tr><td>1.0</td><td>Effective Date:
02/14/2019</td><td>New Policy
<table><tr><th>Line of Business</th><th>PA Required (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>TBD</td></tr><tr><td>BCNA</td><td>TBD</td></tr></table></td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*