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.

Effective Date: 08/08/2024

Imdelltra™ (tarlatamab-dlle)

HCPCS: J3590

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. FDA approved indication
   b. FDA approved age
   c. Prescribed by or in consultation with an oncologist
   d. Treatment of extensive-stage small cell lung cancer with disease progression on or after platinum-based chemotherapy
      i. Being used as second line therapy for patients whose chemotherapy treatment free interval (CTFI) is less than 6 months
      OR
      ii. Patient has documented intolerance or contraindication to platinum based therapy
      OR
      iii. Being used as third line or later therapy
   e. Patient must meet all of the following:
      i. ECOG performance status 0 - 2
      ii. Platelet count greater than 100,000/µL
      iii. Serum alanine aminotransferase/aspartate aminotransferase less than 5 times the upper limit of normal
      iv. Creatinine clearance greater than 30 mL/min
      v. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable
      vi. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy
      vii. No untreated or symptomatic brain metastases and leptomeningeal disease
      viii. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 12 months
      ix. No thromboembolic events within 12 months
      x. No pulmonary disease requiring oxygen dependence
   f. Have not received prior treatment with any bispecific delta-like ligand 3 (DLL3)-directed T-cell engager therapy
   g. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list.

B. Quantity Limitations, Authorization Period and Renewal Criteria
    a. Quantity Limits: Align with FDA recommended dosing
    b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time up to the maximum FDA approved duration of treatment
    c. Renewal Criteria: Treatment may be continued until disease progression or until unacceptable toxicity occurs

***Note: Coverage and approval duration 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.

Background Information:

- Imdelltra is a bispecific delta-like ligand 3 (DLL3)-directed CD3 T-cell engager indicated for the treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.

- Safety and efficacy were evaluated in the DeLLphi-301, a phase II, open-label, multicenter, multi-cohort study of 99 patients with relapsed/refractory SCLC with disease progression after receiving previous treatment with platinum-based chemotherapy and at least one other line of prior therapy. Patients had to have a ECOG score of 0 – 2, a platelet count greater than 100,000/µL, liver enzymes less than 5 times the upper limit of normal, and a creatinine clearance greater than 30 mL/min. They could not have HIV infection or hepatitis B or C virus infection unless the viral load was undetectable or any uncontrolled infection. Brain metastases and leptomeningeal disease must have been treated and unsymptomatic. Patients could not have myocardial infarction, cardiac angioplasty or stenting, unstable angina, New York Heart Association Class II or greater congestive heart failure events, or a thromboembolic events within the 12 months prior to Imdelltra administration. Subjects had not received prior bispecific DLL3-directed CD3 T cell engager. The primary endpoints were overall response rate (ORR) and duration of response (DOR). The ORR was 40% (95% CI: 31, 51) and median DOR was 9.7 months (range 2.7, 20.7+).

- Due to the risk of cytokine release syndrome and neurological toxicities, the step-up doses of Indelltra require patients to be monitored in an appropriate healthcare setting 22 – 24 hours post-infusion. Patients must also remain within 1 hour of an appropriate healthcare setting for a total of 48 hours from start of infusion and need to be accompanied by a caregiver.

- Imdeltlra has not been studied when given following prior treatment with Imdelltra or following any other DLL3)-directed CD3 T-cell engager therapy.

References:

1. Imdelltra [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; May 2024.
2. Ahn MJ, Cho BC, Felip E, et al. Tarlatamab for patients with previously treated small-cell lung cancer. NEJM. 2023 Oct 20; 389: 2063 – 75.
3. National Comprehensive Cancer Network. Small cell lung cancer (Version 2.2024). 2023 Nov 21. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. Accessed on May 17, 2024.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.0</td><td>Effective Date: 08/08/2024</td><td>New policy
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (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>No</td></tr><tr><td>BCNA</td><td>No</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.*