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RE: Reconsideration Request: LCD – External Infusion Pumps (L33794) for BLINCYTO® (blinatumomab) (J9039)[1]

Dear Medical Directors:

Amgen, Inc. (Amgen) is writing to request a reconsideration of Local Coverage Determination L33794 (LCD) to update the coverage of BLINCYTO® (blinatumomab) consistent with the recent approval by the United States Food and Drug Administration (FDA). As set out below the FDA-approved labeling for BLINCYTO® (blinatumomab) was expanded to include CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (ALL) in the consolidation phase of multiphase chemotherapy and as a result, LCD L33794 is no longer current with the approved intended uses. Amgen requests LCD L33794 be updated to include additional information. This letter reviews the changes to the approved labeling below and proposes updates to LCD L33794.

I. Background

On June 14, 2024, the United States Food and Drug Administration (FDA) granted additional approval for BLINCYTO® (blinatumomab) for the treatment of CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (ALL) in the consolidation phase of multiphase chemotherapy in adult and pediatric patients one month and older.[2]

1 Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): External Infusion Pumps (L33794). Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33794. Accessed June 14, 2024.

2 BLINCYTO® (blinatumomab) prescribing information, Amgen.

The approval was based on evidence from a randomized controlled study in adults (Study E1910 [NCT02003222]) and evidence from two randomized, controlled studies in pediatric patients (Study 20120215 [NCT02393859], and Study AALL1331 [NCT02101853]).[3] The Dosage and Administration section of the U.S. Prescribing Information provides the recommended dosing schedule of BLINCYTO® for this indication and the Clinical Studies section reviews the evidence for up to 4 cycles in the consolidation phase of multiphase chemotherapy.

II. Request Changes to LCD L33794

The current coverage language for BLINCYTO® (blinatumomab) is contained in subsection J of LCD L33794, and limits coverage to the specific FDA approved indications. The DME MACs have previously updated the coverage of BLINCYTO® in the LCD following FDA approvals. With the recent additions to the approved labeling for BLINCYTO®, the LCD does not reflect the current label, and we request the document be revised accordingly. For this reason, we are recommending the following revisions:

A. The deletion of language in the current LCD L33794

"Blinatumomab (J9039) is only covered for (1) Up to nine (9) cycles for adult and pediatric beneficiaries with relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL); or (2) Up to four (4) cycles for adult and pediatric beneficiaries with B-cell precursor ALL in first or second remission with minimal residual disease (MRD) greater than or equal to 0.1%."

And replacement with modified language

"Blinatumomab (J9039) is only covered for (1) Up to nine (9) cycles for adult and pediatric beneficiaries <u>one month and older</u> *with relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL); or (2) Up to four (4) cycles for adult and pediatric beneficiaries* <u>one month and older</u> *with B-cell precursor ALL in first or second remission with minimal residual disease (MRD) greater than or equal to 0.1%;* <u>or (3) Up to four (4) cycles for adult and pediatric beneficiaries one month and older with CD19-positive Philadelphia chromosome-negative B-cell precursor ALL in the consolidation phase of multiphase chemotherapy."</u>

III. Requested Confirmation

Thank you for your review and consideration of the updated FDA label for BLINCYTO®. Please confirm that the current LCD L33794 will be updated with the newly approved BLINCYTO® indication for adult and pediatric patients one month and older with CD19-positive Philadelphia chromosome-negative B-cell precursor ALL in the consolidation phase of multiphase chemotherapy and beneficiaries will be covered as of the FDA supplemental BLA approval date of June 14, 2024.

3 BLINCYTO® (blinatumomab) prescribing information, Amgen.

For more information on Dosage and Administration as well as BOXED WARNINGS, please refer to the BLINCYTO® Prescribing Information.

Sincerely,

Kelly Velasco
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Attachments

A. BLINCYTO® (blinatumomab) prescribing information, Amgen.
B. Locatelli F, et al. Effect of Blinatumomab vs Chemotherapy on Event-Free Survival Among Children with High-risk First-Relapse B-Cell Acute Lymphoblastic Leukemia: A Randomized Clinical Trial. JAMA 2021; 325(9):842-845.
C. Brown PA, Ji L, Xu X, et al. Effect of post reinduction therapy consolidation with blinatumomab vs chemotherapy on disease-free survival in children, adolescents, and young adults with first relapse of b-cell acute lymphoblastic leukemia: a randomized clinical trial. JAMA. 2021;325(9):833-842.
D. Hogan LE, et al. Children's Oncology Group AALL1331: Phase III Trial of Blinatumomab in Children, Adolescents, and Young Adults with Low-Risk B-Cell ALL in First Relapse. J Clin Oncol 2023; 41(25):4118-4129.
E. Local Coverage Determination (LCD):[1]
External Infusion Pumps (L33794); Coverage Indications, Limitations, and/or Medical Necessity (Section V), Criteria set 2, J.
F. LCD Reconsideration Request Form