Medical Policy:

Imdelltra (Tarlatamab-dlle), intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.425	August 22, 2024	September 9, 2024

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Imdelltra, a bispecific delta-like ligand 3 (DLL3)-directed CD3 T-cell engager, is indicated for the treatment of extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy in adults. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Length of Authorization

Coverage duration is for 1 year

Dosing Limits [Medical Benefit]

Approve the following dosing regimens (1 **and** 2):

1. Step-up dosing (A, B, and C):
   A. Dose 1: Approve 1 mg given by intravenous infusion on Day 1; **AND**
   B. Dose 2: Approve 10 mg given by intravenous infusion 7 days after Dose 1; **AND**
   C. Dose 3: Approve 10 mg given by intravenous infusion 14 days after Dose 1.
2. Approve 10 mg given by intravenous infusion no more frequently than once every 2 weeks.

Guideline

1. **Small Cell Lung Cancer.** Approve if the patient meets ALL of the following (A, B, C, and D):
   A. Patient is ≥ 18 years of age; **AND**
   B. Patient has relapsed or refractory extensive stage disease; **AND**
   C. Patient has previously received platinum-based chemotherapy; **AND**
      Note: Examples of platinum medications include cisplatin and carboplatin.
   D. Imdelltra is prescribed by or in consultation with an oncologist.

Applicable Procedure Codes

Code	Description
J9026	Injection, tarlatamab-dlle, 1 mg

Applicable NDCs

Code	Description
55513-0059-01	Imdelltra 1mg single dose vial
55516-0069-01	Imdelltra 10mg single dose vial Inner Pack
55513-0077-01	Imdelltra 10mg single dose vial
55516-0103-01	Imdelltra 1mg single dose vial Inner Pack

ICD-10 Diagnoses

Code	Description
C33	Malignant Neoplasm Of Trachea
C34.00	Malignant Neoplasm Of Unspecified Main Bronchus
C34.01	Malignant Neoplasm Of Right Main Bronchus
C34.02	Malignant Neoplasm Of Left Main Bronchus
C34.10	Malignant Neoplasm Of Upper Lobe, Unspecified Bronchus Or Lung
C34.11	Malignant Neoplasm Of Upper Lobe, Right Bronchus Or Lung
C34.12	Malignant Neoplasm Of Upper Lobe, Left Bronchus Or Lung
C34.2	Malignant Neoplasm Of Middle Lobe, Bronchus Or Lung
C34.30	Malignant Neoplasm Of Lower Lobe, Unspecified Bronchus Or Lung
C34.31	Malignant Neoplasm Of Lower Lobe, Right Bronchus Or Lung
C34.32	Malignant Neoplasm Of Lower Lobe, Left Bronchus Or Lung
C34.80	Malignant Neoplasm Of Overlapping Sites Of Unspecified Bronchus And Lung
C34.81	Malignant Neoplasm Of Overlapping Sites Of Right Bronchus And Lung

C34.82	Malignant Neoplasm Of Overlapping Sites Of Left Bronchus And Lung
C34.90	Malignant Neoplasm Of Unspecified Part Of Unspecified Bronchus Or Lung
C34.91	Malignant Neoplasm Of Unspecified Part Of Right Bronchus Or Lung
C34.92	Malignant Neoplasm Of Unspecified Part Of Left Bronchus Or Lung

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	9/9/2024	New Policy

References

1. Imdelltra™ intravenous infusion [prescribing information]. Thousand Oaks, CA: Amgen; May 2024.