Empliciti® (elotuzumab)

(Intravenous)

Document Number: IC-0268

Last Review Date: 07/20/2022
Date of Origin: 02/23/2016
Dates Reviewed: 02/2016, 01/2017, 05/2017, 08/2017, 11/2017, 02/2018, 05/2018, 09/2018, 12/2018, 03/2019, 06/2019, 09/2019, 12/2019,03/2020, 6/2020, 09/2020, 03/2021, 03/2022, 07/2022
Customization Date: 07/20/2022
Effective Date: 01/01/2023

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Empliciti 300 mg single-dose vial: 16 vials per 28 days for 2 cycles; subsequent cycles are 8 vials per 28 days
- Empliciti 400 mg single-dose vial: 12 vials per 28 days for 2 cycles; subsequent cycles are 6 vials per 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

Multiple Myeloma – Given in combination with Lenalidomide/Dexamethasone:

- 1200 billable units weekly for the first two 28-day cycles (8 doses), then every two weeks thereafter beginning day 1 of cycle 3

Multiple Myeloma – Given in combination with Pomalidomide/Dexamethasone:

- 1200 billable units weekly for the first two 28-day cycles (8 doses), then 2300 billable units every four weeks thereafter beginning day 1 of cycle 3

Multiple Myeloma – Given in combination with Bortezomib/Dexamethasone:

- 1200 billable units weekly for the first two 21-day cycles (6 doses), then every 10 days for the next six 21-day cycles (cycles 3 to 8 [12 doses]), then every 2 weeks per 28-day cycle thereafter beginning day 1 of cycle 9

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Multiple Myeloma † Φ [1-5]

- Used in combination with lenalidomide and dexamethasone for the treatment of relapsed or progressive disease; **OR**
- Used in combination with pomalidomide and dexamethasone after failure of at least two prior therapies, including lenalidomide and a proteasome inhibitor (i.e., bortezomib, carfilzomib, etc.); **OR**
- Used in combination with bortezomib and dexamethasone for the treatment of relapsed or progressive disease ‡

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1,2]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions, infections, second primary malignancies, hepatotoxicity, etc.

V. Dosage/Administration [1,3]

Indication	Dose
Multiple myeloma in combination with lenalidomide and dexamethasone	10 mg/kg intravenously every week (Days 1, 8, 15, & 22) for the first two 28-day cycles (8 doses); then every 2 weeks thereafter (Days 1 & 15) beginning with cycle 3. Continue treatment until disease progression or unacceptable toxicity.
Multiple myeloma in combination with pomalidomide and dexamethasone	10 mg/kg intravenously every week (Days 1, 8, 15, & 22) for the first two 28-day cycles (8 doses); then 20 mg/kg every 4 weeks thereafter (Day 1) beginning with cycle 3. Continue treatment until disease progression or unacceptable toxicity.
Multiple myeloma in	10 mg/kg intravenously every week (Days 1, 8 & 15) for the first two 21-day cycles (6 doses); then on Days 1 & 11 for the next six 21-day cycles (cycles 3 to 8

combination with bortezomib and dexamethasone	[12 doses]); then every 2 weeks per 28-day cycle thereafter (Days 1 & 15) beginning with cycle 9. Continue treatment until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

- J9176 – Injection, elotuzumab, 1 mg; 1 billing unit = 1 mg

NDC(s):

- Empliciti 300 mg single-dose vial: 00003-2291-xx
- Empliciti 400 mg single-dose vial: 00003-4522-xx

VII. References

1. Empliciti [package insert]. Princeton, NJ; Bristol-Myers Squibb Company; October 2019. Accessed January 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for elotuzumab. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2022.
3. Jakubowiak A, Offidani M, Pégourie B, et al. Randomized phase 2 study: elotuzumab plus bortezomib/dexamethasone vs bortezomib/dexamethasone for relapsed/refractory MM. Blood. 2016 Jun 9;127(23):2833-40.
4. Lonial S, Dimopoulos M, Palumbo A, et al. Elotuzumab Therapy for Relapsed or Refractory Multiple Myeloma. N Engl J Med. 2015 Aug 13;373(7):621-31. doi: 10.1056/NEJMoa1505654. Epub 2015 Jun 2.
5. Dimopoulos MA, Dytfeld D, Grosicki S, et al. Elotuzumab plus Pomalidomide and Dexamethasone for Multiple Myeloma. N Engl J Med. 2018 Nov 8;379(19):1811-1822. doi: 10.1056/NEJMoa1805762.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma, in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse

ICD-10	ICD-10 Description
C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC