

Empliciti™ (elotuzumab) (Intravenous)

Document Number: IC-0268

Last Review Date: 12/04/2018

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

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

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

B. Max Units (per dose and over time) [Medical Benefit]:

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 D1 of cycle 3

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 D1 of cycle 3

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is 18 years or older; **AND**

Multiple myeloma †

- Patient has a diagnosis of relapsed or progressive disease; **AND**
 - Used in combination with lenalidomide and dexamethasone after failure of one to three prior therapies; **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 ‡

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria 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

Indication	Dose
In combination with lenalidomide and dexamethasone	<p>10 mg/kg intravenously every week (D1, D8, D15, & D22) for the first two 28-day cycles (8 doses); then every 2 weeks thereafter (D1 & D15) beginning with cycle 3</p> <ul style="list-style-type: none"> • Lenalidomide 25 mg orally daily Days 1-21 • Oral dexamethasone 28 mg given weekly when elotuzumab is also given & 40 mg on weeks elotuzumab is not given • Intravenous dexamethasone 8 mg given weekly when elotuzumab is given
In combination with pomalidomide and dexamethasone	<p>10 mg/kg intravenously every week (D1, D8, D15, & D22) for the first two 28-day cycles (8 doses); then 20 mg/kg every 4 weeks thereafter (D1) beginning with cycle 3</p> <ul style="list-style-type: none"> • <u>Patients < 75 years old:</u> <ul style="list-style-type: none"> ○ Pomalidomide 4 mg orally daily Days 1-21 ○ Oral dexamethasone 28 mg given weekly when elotuzumab is also given & 40 mg on weeks elotuzumab is not given) ○ Intravenous dexamethasone 8 mg given weekly when elotuzumab is given • <u>Patients ≥ 75 years old:</u> <ul style="list-style-type: none"> ○ Pomalidomide 4 mg orally daily Days 1-21 ○ Oral dexamethasone 8 mg given weekly when elotuzumab is also given & 20 mg on weeks elotuzumab is not given ○ Intravenous dexamethasone 8 mg given weekly when elotuzumab is given
Multiple myeloma in combination with bortezomib	<p>10 mg/kg intravenously weekly for cycles 1 and 2, on days 1 and 11 for cycles 3 to 8, and then on days 1 and 15 thereafter</p> <ul style="list-style-type: none"> • Bortezomib (1.3 mg/m² IV or subcutaneously) administered on days 1, 4, 8, and 11 for cycles 1 to 8 and then on days 1, 8, and 15 thereafter • Dexamethasone 20 mg administered orally on non-elotuzumab dosing days, and as 8 mg orally plus 8 mg IV on elotuzumab dosing days

VI. Billing Code/Availability Information

Jcode:

- 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; November 2018. Accessed November 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for elotuzumab. National Comprehensive Cancer Network, 2018. 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 November 2018.
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.

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
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) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage>

[database/search/advanced-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): 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