

Darzalex™ (daratumumab)

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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]:

- Darzalex 100 mg single-dose vial for injection: 3 vials per dose
 - Weekly Weeks 1 to 6, then every three weeks Weeks 7-54, then every four weeks Week 55 onwards **OR**
 - Weekly Weeks 1 to 8, then every two weeks Weeks 9-24, then every four weeks Week 25 onwards **OR**
 - Weekly Weeks 1 to 9, then every three weeks Weeks 10-24, then every four weeks Week 25 onwards)
- Darzalex 400mg single dose vial for injection: 4 vials per dose
 - (Weekly Weeks 1 to 6, then every three weeks Weeks 7-54, then every four weeks Week 55 onwards **OR**
 - Weekly Weeks 1 to 8, then every two weeks Weeks 9-24, then every four weeks Week 25 onwards **OR**
 - Weekly Weeks 1 to 9, then every three weeks Weeks 10-24, then every four weeks Week 25 onwards)

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

- Bortezomib/Melphalan/Prednisone Regimen
 - 180 billable units per dose
(Weekly Weeks 1 to 6, then every three weeks Weeks 7-54, then every four weeks Week 55 onwards)
- Lenalidomide/Pomalidomide Regimen
 - 180 billable units per dose
(Weekly Weeks 1 to 8, then every two weeks Weeks 9-24, then every four weeks Week 25 onwards)
- Bortezomib Regimen
 - 180 billable units per dose

III. Initial Approval Criteria

Coverage is provided in the following conditions:

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

Multiple myeloma †

- Used in combination with bortezomib, melphalan and prednisone for patients with newly diagnosed and are ineligible for autologous stem cell transplant; **OR**
- Used as subsequent therapy in combination with dexamethasone and either lenalidomide or bortezomib; **OR**
- Used in combination with pomalidomide and dexamethasone after at least two prior therapies including an immunomodulatory agent (e.g., lenalidomide) and a proteasome inhibitor; **OR**
- Used as a single agent therapy; **AND**
 - Patient must have received at least three previous lines of therapy including a proteasome inhibitor (e.g., bortezomib, carfilzomib, etc.) and an immunomodulatory agent (e.g., lenalidomide, pomalidomide, etc.); **OR**
 - Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

† FDA Approved 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**
- Stabilization of disease and/or absence of progression of disease; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infusion reactions, neutropenia, thrombocytopenia, etc.

V. Dosage/Administration

Indication	Dose
Newly diagnosed Multiple myeloma in combination with bortezomib, melphalan and prednisone	16 mg/kg body weight given as an IV infusion: <ul style="list-style-type: none">– Weekly Weeks 1 to 6– Every three weeks Weeks 7 to 54– Every four weeks Week 55 onwards
Multiple myeloma monotherapy and in combination with lenalidomide or pomalidomide and dexamethasone	16 mg/kg body weight given as an IV infusion: <ul style="list-style-type: none">– Weekly Weeks 1 to 8– Every two weeks Weeks 9 to 24– Every four weeks Week 25 onwards
Multiple myeloma in combination with bortezomib and dexamethasone	16 mg/kg body weight given as an IV infusion: <ul style="list-style-type: none">– Weekly Weeks 1 to 9– Every three weeks Weeks 10 to 24

	- Every four weeks	Week 25 onwards
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VI. Billing Code/Availability Information

Jcode:

- J9145 - Injection, daratumumab, 10 mg; 1 billable unit = 10 mg.

NDC(s):

- Darzalex 100 mg/5 mL single-dose vial: 57894-0502-xx
- Darzalex 400 mg/20 mL single-dose vial: 57894-0502-xx

VII. References

1. Darzalex [package insert]. Horsham, PA; Janssen Biotech, Inc; May 2018. Accessed May 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for daratumumab. 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 May 2018.

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