Darzalex® (daratumumab)
(Intravenous)

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I. Length of Authorization [1,16,17,19]

Coverage will be provided for 6 months and may be renewed (unless otherwise specified).

- Use for newly diagnosed multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone may not be renewed.
- Use for newly diagnosed multiple myeloma in combination with bortezomib, lenalidomide and dexamethasone may be renewed for up to a maximum of 2 years of maintenance therapy.
- Use for newly diagnosed or relapsed multiple myeloma in combination with cyclophosphamide, bortezomib and dexamethasone may be renewed for up to a maximum of 80 weeks *(32 weeks of induction therapy and 48 weeks of maintenance therapy)*.
- Use for newly diagnosed multiple myeloma in combination with carfilzomib, lenalidomide, and dexamethasone may be renewed for up to a maximum of 32 weeks.
- Use for maintenance of multiple myeloma in combination with lenalidomide may be renewed for up to a maximum of 2 years of maintenance therapy.
- Use for pediatric acute lymphoblastic leukemia may not be renewed.

Coverage and policy application may be contingent on federal or state laws or regulations. In the event of a conflict between this policy and applicable federal or state laws or regulations, state law should apply.

II. Dosing Limits

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

- Darzalex 100 mg single-dose vial for injection: Up to 3 vials per dose
  - *Weekly Weeks 1 to 8, then every two weeks Weeks 9-24, then every four weeks Week 25 onwards* ***OR***

- Darzalex 400 mg single-dose vial for injection: Up to 4 vials per dose
  - *Weekly Weeks 1 to 8, then every two weeks Weeks 9-24, then every four weeks Week 25 onwards*

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

- Up to 180 billable units per dose
  - *Weekly Week 1 to 8, then every two weeks Weeks 9-24, then every four weeks Week 25 onwards*

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); **AND**

Universal Criteria

- Therapy will not be used in combination with other anti-CD38 therapies (i.e., daratumumab and hyaluronidase-fihj, isatuximab, etc.); **AND**

Multiple Myeloma † Φ [1-11,13,14,16-19,22,23]

- Used in the treatment of newly diagnosed disease in patients who are ineligible for autologous stem cell transplant (ASCT) in combination with ONE of the following regimens:
  - Lenalidomide and dexamethasone; **OR**
  - Bortezomib, melphalan, and prednisone; **OR**
  - Cyclophosphamide, bortezomib, and dexamethasone; **OR**
- Used in the treatment of newly diagnosed disease in patients who are eligible for autologous stem cell transplant (ASCT) in combination with ONE of the following regimens:
  - Bortezomib, lenalidomide, and dexamethasone; **OR**
  - Bortezomib, thalidomide, and dexamethasone (VTd); **OR**
  - Carfilzomib, lenalidomide, and dexamethasone (ixazomib may be substituted for carfilzomib); **OR**
  - Cyclophosphamide, bortezomib, and dexamethasone; **OR**
- Used for disease relapse after 6 months following primary induction therapy with the same regimen in combination with ONE of the following regimens:
  - Lenalidomide and dexamethasone for non-transplant candidates; **OR**
  - Cyclophosphamide, bortezomib, and dexamethasone; **OR**
- Used as subsequent therapy for relapsed or refractory/progressive disease in combination with dexamethasone and ONE of the following:
  - Lenalidomide; **OR**
  - Bortezomib; **OR**
  - Carfilzomib; **OR**
  - Cyclophosphamide and bortezomib; **OR**

- Selinexor; **OR**
- Venetoclax *(for patients with t(11:14) ONLY);* **OR**

- Used in combination with pomalidomide and dexamethasone after prior therapy with lenalidomide and a proteasome inhibitor (bortezomib, carfilzomib, etc.); **OR**
- Used as single agent therapy; **AND**
  - Patient received at least three prior 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; **OR**
- Used as maintenance therapy for symptomatic disease in transplant candidates; **AND**
  - Used as single agent therapy or in combination with lenalidomide; **AND**
    - Used after response to primary myeloma therapy; **OR**
    - Used for response or stable disease following an autologous hematopoietic cell transplant (HCT); **OR**
    - Used for response or stable disease following a tandem autologous or allogeneic HCT for high risk***** patients

*******High-risk as defined by the Revised International Staging System for Multiple Myeloma is the presence of del(17p) and/or translocation t(4;14) and/or translocation t(14;16). This is not an all-inclusive list. Refer to the NCCN Multiple Myeloma Guidelines for additional risk factors.*

Systemic Light Chain Amyloidosis ‡ [2,12,15,25-27]

- Used as single agent therapy; **AND**
  - Used for the treatment of relapsed/refractory disease; **OR**
  - Used for newly diagnosed disease; **AND**
    - Patient has significant neuropathy; **OR**
    - Patient has stage IIIb if no significant neuropathy

Pediatric Acute Lymphoblastic Leukemia (ALL) ‡ [2, 20-21]

- Patient age ≥ 1 and ≤ 30 years; **AND**
- Patient has relapsed/refractory T-cell ALL; **AND**
- Used in combination with vincristine, pegaspargase/calaspargase, doxorubicin, and prednisone/dexamethasone

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,2,16,17,19]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other 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 including anaphylactic reactions, neutropenia, thrombocytopenia, etc.; **AND**

Multiple Myeloma

- Use for newly diagnosed disease in combination with bortezomib, thalidomide, and dexamethasone may not be renewed.
- Use for newly diagnosed disease in combination with bortezomib, lenalidomide and dexamethasone may be renewed for up to a maximum of 2 years of maintenance therapy.
- Use for newly diagnosed or relapsed disease in combination with cyclophosphamide, bortezomib and dexamethasone may be renewed for up to a maximum of 80 weeks *(32 weeks of induction therapy and 48 weeks of maintenance therapy)*.
- Use for newly diagnosed disease in combination with carfilzomib, lenalidomide, and dexamethasone may be renewed for up to a maximum of 32 weeks.
- Use for maintenance of multiple myeloma in combination with lenalidomide may be renewed for up to a maximum of 2 years of maintenance therapy.

Pediatric Acute Lymphoblastic Leukemia

- May not be renewed

V. Dosage/Administration [1,12,16-19, 21,23,27]

Indication	Dose
Multiple Myeloma	<u>Newly diagnosed disease in patients eligible for ASCT in combination with bortezomib, thalidomide and dexamethasone</u> ▪ 16 mg/kg body weight given as an intravenous infusion in a 4 week cycle: ▪ Induction – – Weekly Weeks 1 to 8 (eight doses; cycles 1 and 2) – Every two weeks Weeks 9 to 16 (four doses; cycles 3 and 4) *Stop for high dose chemotherapy and ASCT* ▪ Consolidation – – Every two weeks Weeks 1 to 8 (four doses; cycles 5 and 6)
	<u>Newly diagnosed disease in patients eligible for ASCT in combination with bortezomib, lenalidomide and dexamethasone</u> ▪ 16 mg/kg body weight given as an intravenous infusion as follows: ▪ Induction – **3 week cycle** – Weekly Weeks 1 to 12 (twelve doses; cycles 1 to 4)

	▪ Consolidation – *(after ASCT)* – **3 week cycle** – Every 3 weeks Weeks 13 to 18 (two doses; cycles 5 and 6) ▪ Maintenance – **4 week cycle** – Every 4 or 8 weeks Weeks 1 to 104 for a maximum of 2 years of maintenance treatment
	<u>Newly diagnosed disease in patients eligible for ASCT in combination with carfilzomib, lenalidomide, and dexamethasone</u> ▪ 16 mg/kg body weight given as an intravenous infusion in a 4 week cycle: – Weekly Weeks 1 to 8 (eight doses; cycles 1 and 2) – Every two weeks Weeks 9 to 24 (eight doses; cycles 3 to 6) – Every four weeks Week 25 to 32 (two doses; cycles 7 and 8)
	<u>Newly diagnosed disease in patients ineligible for ASCT in combination with bortezomib, melphalan and prednisone</u> ▪ 16 mg/kg body weight given as an intravenous infusion in a 6 week cycle: – Weekly Weeks 1 to 6 (six doses; cycle 1) – Every three weeks Weeks 7 to 54 (16 doses; cycles 2 to 9) – Every four weeks Week 55 onwards (cycle 10 and beyond) *Treat until disease progression or unacceptable toxicity*
	<u>Newly diagnosed OR relapsed disease in combination with cyclophosphamide, bortezomib and dexamethasone</u> Induction ▪ 8 mg/kg body weight given as an intravenous infusion on days 1 and 2 (Week 1; total 2 doses) ▪ Followed by 16 mg/kg body weight given as an intravenous infusion in a 4 week cycle: – Weekly Weeks 2 to 8 (seven doses; cycles 1 and 2) – Every two weeks Weeks 9 to 24 (eight doses; cycles 3 to 6) – Every four weeks Week 25 to 32 (two doses; cycles 7 and 8) Maintenance *(after ASCT)* ▪ 16 mg/kg body weight given as an intravenous infusion every 4 weeks for up to 12 cycles (48 weeks)
	<u>Treatment as one of the following:</u> • Monotherapy for patients with relapsed/refractory multiple myeloma • Combination therapy with lenalidomide and low-dose dexamethasone for newly diagnosed patients ineligible for ASCT • Combination therapy with lenalidomide, pomalidomide, or selinexor AND low-dose dexamethasone in patients with relapsed or refractory/progressive disease ▪ 16 mg/kg body weight given as an intravenous infusion in a 4 week cycle: – Weekly Weeks 1 to 8 (eight doses; cycles 1 and 2) – Every two weeks Weeks 9 to 24 (eight doses; cycles 3 to 6) – Every four weeks Week 25 onwards (cycle 7 and beyond) *Treat until disease progression or unacceptable toxicity*
	<u>Combination therapy with carfilzomib and dexamethasone for relapsed or refractory/progressive disease</u> ▪ 8 mg/kg body weight given as an intravenous infusion on days 1 and 2 (Week 1; total 2 doses) ▪ Followed by 16 mg/kg body weight given as an intravenous infusion in a 4 week cycle:

	– Weekly Weeks 2 to 8 (seven doses; cycles 1 and 2) – Every two weeks Weeks 9 to 24 (eight doses; cycles 3 to 6) – Every four weeks Week 25 onwards (cycle 7 and beyond) *Treat until disease progression or unacceptable toxicity*
	<u>Combination therapy with bortezomib and dexamethasone for relapsed or refractory/progressive disease</u> ▪ 16 mg/kg body weight given as an intravenous infusion in a 3 week cycle: – Weekly Weeks 1 to 9 (nine doses; cycles 1 to 3) – Every three weeks Weeks 10 to 24 (five doses; cycles 4 to 8) – Every four weeks Week 25 onwards (cycle 9 and beyond) *Treat until disease progression or unacceptable toxicity*
	<u>Combination therapy with venetoclax and dexamethasone for relapsed or refractory/progressive t(11;14) disease</u> ▪ 16 mg/kg body weight given as an intravenous infusion in a 4 week cycle: – Weekly Weeks 1 to 8 (eight doses; cycles 1 and 2) – Every two weeks Weeks 9 to 24 (eight doses; cycles 3 to 6) – Every four weeks Week 25 onwards (cycle 7 and beyond)
	<u>Monotherapy as maintenance treatment for transplant candidates</u> ▪ 16 mg/kg body weight given as an intravenous infusion every 4 weeks until disease progression or unacceptable toxicity
	<u>In combination with lenalidomide as maintenance treatment for transplant candidates</u> ▪ 16 mg/kg body weight given as an intravenous infusion every 4 or 8 weeks until disease progression or unacceptable toxicity. For a maximum of 2 years of maintenance treatment.
Pediatric ALL	▪ 16 mg/kg body weight given as an intravenous infusion in a 4 week cycle: – Weekly Weeks 1 to 8 (eight doses; cycles 1 and 2)
Systemic Light Chain Amyloidosis	▪ 16 mg/kg body weight given as an intravenous infusion: – Weekly Weeks 1 to 8 (eight doses) – Every two weeks Weeks 9 to 24 (eight doses) – Every four weeks Week 25 onwards until disease progression or unacceptable toxicity
**To facilitate administration, the first prescribed 16 mg/kg dose at Week 1 may be split over two consecutive days (i.e., 8 mg/kg on Day 1 and Day 2 respectively).*	
Note: Initiate antiviral prophylaxis to prevent herpes zoster reactivation within 1 week after starting Darzalex and continue for 3 months following treatment.	

VI. Billing Code/Availability Information

<u>HCPCS Code</u>:

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

<u>NDC(s)</u>:

- Darzalex 100 mg/5 mL single-dose vial: 57894-0502-xx
- Darzalex 100 mg/5mL single-dose vial: 57894-0505-xx
- Darzalex 400 mg/20 mL single-dose vial: 57894-0502-xx
- Darzalex 400 mg/20 mL single-dose vial: 57894-0505-xx

VII. References

1. Darzalex [package insert]. Horsham, PA; Janssen Biotech, Inc; January 2023. Accessed November 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for daratumumab. National Comprehensive Cancer Network, 2023. 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 2023.
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14. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma Version 2.2024. National Comprehensive Cancer Network, 2023. 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 Guidelines, go online to NCCN.org. Accessed November 2023.
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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
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.02	Acute lymphoblastic leukemia, in relapse
E85.3	Secondary systemic amyloidosis
E85.4	Organ-limited amyloidosis
E85.81	Light chain (AL) amyloidosis
E85.89	Other amyloidosis

ICD-10	ICD-10 Description
E85.9	Amyloidosis, unspecified
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