Darzalex Faspro® (daratumumab and hyaluronidase-fihj)
(Subcutaneous)

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I. Length of Authorization [1,19,20,23]

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 a maximum of 32 weeks.
- Use for newly diagnosed OR repeat of initial therapy for relapsed/refractory (after being relapse-free for several years) systemic light chain amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone may be renewed for up to a maximum of 2 years.

II. Dosing Limits

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

- Darzalex Faspro 1,800 mg/30,000 unit single-dose vial for injection: 1 vial 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 Weeks 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; **AND**

Universal Criteria [1]

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

Multiple Myeloma † Φ [1,2,17,1e]

- 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; **AND**
    - Use of daratumumab in combination with lenalidomide and dexamethasone will be restricted to patients with a contraindication or intolerance to bortezomib/lenalidomide/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; **AND**
    - Patient must use bortezomib/lenalidomide/dexamethasone (without daratumumab); **OR**
  - Bortezomib, thalidomide, and dexamethasone (VTd); **OR**
  - Cyclophosphamide, bortezomib, and dexamethasone; **OR**
  - Carfilzomib, lenalidomide, and dexamethasone; **AND**
    - Use of daratumumab in combination with carfilzomib, lenalidomide, and dexamethasone will be restricted to patients with a contraindication or intolerance to one of the following:
      - Bortezomib/lenalidomide/dexamethasone
      - Bortezomib/cyclophosphamide/dexamethasone
      - Bortezomib/doxorubicin/dexamethasone
      - Bortezomib/thalidomide/dexamethasone
      - Daratumumab/bortezomib/thalidomide/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:
  - Selinexor; **AND**
    - Used after 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**
  - Lenalidomide; **OR**
  - Bortezomib; **OR**
  - Carfilzomib; **OR**
  - Cyclophosphamide and bortezomib; **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 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; **OR**
- Used as maintenance therapy for symptomatic disease in transplant candidates; **AND**
  - Used as single agent therapy; **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 † ‡ Φ [1,2,18]

- Patient must NOT have NYHA Class IIIB or Class IV, or Mayo Stage IIIB cardiac disease; **AND**
  - Used in combination with bortezomib, cyclophosphamide and dexamethasone (D-VCd); **AND**
    - Used for newly diagnosed disease; **OR**

- Used as a repeat of initial therapy for relapsed/refractory disease if the patient has been relapse-free for several years; **OR**
  - Used as single agent therapy for the treatment of relapsed/refractory disease

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

IV. Renewal Criteria [1,2]

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 and decrease in size of tumor of tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity and other administration reactions (e.g., systemic administration-related reactions, local injection-site reactions, etc.), neutropenia, thrombocytopenia, cardiac toxicity, etc.; **AND**

Multiple Myeloma [1,19,20,23]

- 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 a maximum of 32 weeks.

Systemic Light Chain Amyloidosis (newly diagnosed disease) [1,18]

- Use for newly diagnosed disease OR repeat of initial therapy for relapsed/refractory disease (after being relapse-free for several years) in combination with bortezomib, cyclophosphamide and dexamethasone (D-VCd) may be renewed for a maximum of 2 years of therapy.

V. Dosage/Administration [1,6,8,15]

Indication	Dose
Multiple Myeloma	Administer 1,800 mg/30,000 units (1,800 mg daratumumab and 30,000 units hyaluronidase) as a 15 mL injection subcutaneously into the abdomen. Treatment as one of the following:

	Newly diagnosed disease in patients ineligible for ASCT in combination with bortezomib, melphalan and prednisone (D-VMP) (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.*
	Newly diagnosed disease in patients eligible for ASCT in combination with bortezomib, thalidomide and dexamethasone (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)
	Newly diagnosed disease in patients eligible for ASCT in combination with carfilzomib, lenalidomide, and dexamethasone (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 Weeks 25 to 32 (two doses; cycles 7 and 8)
	Newly diagnosed disease in patients eligible for ASCT in combination with bortezomib, lenalidomide and dexamethasone: 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
	Newly diagnosed OR relapsed disease in combination with cyclophosphamide, bortezomib and dexamethasone (4-week cycle): Induction – – 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) Maintenance *(after ASCT)* – – Every 4 weeks for up to 12 cycles (48 weeks)
	Treatment as one of the following: o Monotherapy for patients with relapsed/refractory multiple myeloma (4-week cycle) o Combination therapy with lenalidomide and low-dose dexamethasone for newly diagnosed patients ineligible for ASCT (4-week cycle) o Combination therapy with lenalidomide, pomalidomide, selinexor, or carfilzomib AND dexamethasone in patients with relapsed or refractory/progressive disease (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.*
	Combination therapy with bortezomib and dexamethasone for relapsed or refractory/progressive disease (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.*
	Monotherapy as maintenance treatment for transplant candidates ○ Every 4 weeks until disease progression or unacceptable toxicity.
Systemic Light Chain Amyloidosis	Newly diagnosed disease OR repeat of initial therapy for relapsed/refractory disease (after being relapse-free for several years) in combination therapy with bortezomib, cyclophosphamide and dexamethasone (D-VCd) (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 or a maximum of 2 years*
	Single agent therapy for relapsed/refractory disease (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*
**Keep refrigerated. Darzalex Faspro should only be administered subcutaneously by a healthcare professional. Do NOT administer Darzalex Faspro intravenously.*	
Note: Initiate antiviral prophylaxis to prevent herpes zoster reactivation within 1 week after starting Darzalex and continue for 3 months following treatment. Refer to the PI for other pre- and post-medication therapies.	

VI. Billing Code/Availability Information

HCPCS Code:

- J9144 – Injection, daratumumab, 10 mg and hyaluronidase-fihj; 1 billable unit=10 mg

NDC:

- Darzalex Faspro 1,800 mg of daratumumab and 30,000 units of hyaluronidase per 15 mL single-dose vial: 57894-0503-xx

VII. References (STANDARD)

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2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for daratumumab and hyaluronidase-fihj. 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 March 2023.

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17. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma Version 3.2023. 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 March 2023.
18. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Systemic Light Chain Amyloidosis Version 2.2023. 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 March 2023.
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VIII. References (ENHANCED)

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2e. Kastritis E, Palladini G, Minnema MC, et al. Subcutaneous daratumumab plus cyclophosphamide, bortezomib, and dexamethasone (CyborD) in patients with newly diagnosed light chain (AL) amyloidosis: primary results from the phase 3 Andromeda study. Abstract LB2604. Presented as part of EHA25 Virtual, June 14, 2020.

3e. Sanchorawala V, Sarosiek S, Schulman A, et al. Safety, tolerability, and response rates of daratumumab in relapsed AL amyloidosis: results of a phase 2 study. Blood. 2020 Apr 30;135(18):1541-1547. doi: 10.1182/blood.2019004436.

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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
E85.3	Secondary systemic amyloidosis
E85.4	Organ-limited amyloidosis
E85.81	Light chain (AL) amyloidosis
E85.89	Other amyloidosis
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