

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

-E-

Document Number: EOCCO-0585

Last Review Date: 04/04/2024

Date of Origin: 02/02/2021

Dates Reviewed: 02/2021, 09/2021, 04/2022, 04/2023, 04/2024

I. Length of Authorization ^{1,19,20,23,28}

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 or refractory/progressive 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 as maintenance therapy for multiple myeloma in combination with lenalidomide may be renewed for up to a maximum of 2 years.
- 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 † ‡ ^{1,2,17,26,1e,5e}

- 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**
 - Cyclophosphamide, bortezomib, and dexamethasone; **OR**
 - Carfilzomib, lenalidomide, 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:
 - 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 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 † ‡ Φ^{1,2,18,6e}

- 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; **AND**
 - Patient has no significant neuropathy; **OR**
 - Used as single agent therapy; **AND**
 - Used 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 or 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 ^{1,19,20,23,28}

- 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 or refractory/progressive 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.
- Use as maintenance therapy for multiple myeloma in combination with lenalidomide may be renewed for up to a maximum of 2 years.

Systemic Light Chain Amyloidosis ¹

- 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 may be renewed for a maximum of 2 years of therapy.

V. Dosage/Administration ^{1,15,19,20,23-26,28}

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:
	<u>Newly diagnosed disease in patients ineligible for ASCT in combination with bortezomib, melphalan and prednisone (D-VMP) (6-week cycle)</u> <ul style="list-style-type: none"> – 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) <i>Treat until disease progression or unacceptable toxicity.</i>

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 or refractory/progressive 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:

- Monotherapy for patients with relapsed/refractory multiple myeloma (4-week cycle)
- Combination therapy with lenalidomide and dexamethasone for newly diagnosed patients ineligible for ASCT (4-week cycle)
- 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.

	<u>Monotherapy as maintenance treatment for transplant candidates</u> ○ Every 4 weeks until disease progression or unacceptable toxicity.
	<u>In combination with lenalidomide as maintenance treatment for transplant candidates</u> ○ Every 4 or 8 weeks until disease progression or unacceptable toxicity. For a maximum of 2 years of maintenance treatment.
Systemic Light Chain Amyloidosis	<u>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):</u> – 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) <i>Treat until disease progression or unacceptable toxicity or a maximum of 2 years</i>
	<u>Single agent therapy for relapsed/refractory disease (4-week cycle):</u> – 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) <i>Treat until disease progression or unacceptable toxicity</i>
	<i>*Keep refrigerated. Darzalex Faspro should only be administered subcutaneously by a healthcare professional. Do NOT administer Darzalex Faspro intravenously.</i> <i>Note: Initiate antiviral prophylaxis to prevent herpes zoster reactivation within 1 week after starting Darzalex and continue for 3 months following the end of treatment. Refer to the PI for other pre- and post-medication therapies.</i>

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)

1. Darzalex Faspro [package insert]. Horsham, PA; Janssen Biotech, Inc; November 2022. Accessed February 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for daratumumab and hyaluronidase-fihj. National Comprehensive Cancer Network, 2024. 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 February 2024.

3. Chari A, San Miguel J, McCarthy H, et al. Subcutaneous Daratumumab Plus Standard Treatment Regimens in Patients with Multiple Myeloma across Lines of Therapy: Pleiades Study Update. *Blood* (2019) 134 (Supplement_1): 3152.
4. Mateos MV, Nahi H, Legier W, et al. Efficacy and safety of the randomized, open-label, non-inferiority, phase 3 study of subcutaneous (SC) versus intravenous (IV) daratumumab (DARA) administration in patients (pts) with relapsed or refractory multiple myeloma (RRMM): COLUMBA. *JCO* 2019 37:15_suppl, 8005-8005.
5. Lancman G, Arinsburg S, Jhang J, et al. Blood Transfusion Management for Patients Treated With Anti-CD38 Monoclonal Antibodies. *Front. Immunol.*9:2616. Doi: 10.3389/fimmu.2018.02616.
6. Chari A, Martinez-Lopez J, Mateos MV, et al. Daratumumab plus carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma. *Blood*. 2019 Aug 1;134(5):421-431. doi: 10.1182/blood.2019000722. Epub 2019 May 21.
7. Facon T, Kumar S, Plesner T, et al. Daratumumab plus Lenalidomide and Dexamethasone for Untreated Myeloma. *N Engl J Med*. 2019 May 30;380(22):2104-2115. doi: 10.1056/NEJMoa1817249.
8. Mateos MV, Dimopoulos MA, Cavo M, et al. Daratumumab plus Bortezomib, Melphalan, and Prednisone for Untreated Myeloma. *N Engl J Med*. 2018 Feb 8;378(6):518-528. doi: 10.1056/NEJMoa1714678. Epub 2017 Dec 12.
9. Moreau P, Attal M, Hulin C, et al. Bortezomib, thalidomide, and dexamethasone with or without daratumumab before and after autologous stem-cell transplantation for newly diagnosed multiple myeloma (CASSIOPEIA): a randomised, open-label, phase 3 study. *Lancet*. 2019 Jul 6;394(10192):29-38. doi: 10.1016/S0140-6736(19)31240-1. Epub 2019 Jun 3.
10. Dimopoulos MA, Oriol A, Nahi H, et al. Daratumumab, Lenalidomide, and Dexamethasone for Multiple Myeloma. *N Engl J Med*. 2016 Oct 6;375(14):1319-1331.
11. Palumbo A, Chanan-Khan A, Weisel K, et al. Daratumumab, Bortezomib, and Dexamethasone for Multiple Myeloma. *N Engl J Med*. 2016 Aug 25;375(8):754-66. doi: 10.1056/NEJMoa1606038.
12. Chari A, Suvannasankha A, Fay JW, et al. Daratumumab plus pomalidomide and dexamethasone in relapsed and/or refractory multiple myeloma. *Blood*. 2017 Aug 24;130(8):974-981. doi: 10.1182/blood-2017-05-785246. Epub 2017 Jun 21.
13. Lonial S, Weiss BM, Usmani SZ, et al. Daratumumab monotherapy in patients with treatment-refractory multiple myeloma (SIRIUS): an open-label, randomised, phase 2 trial. *Lancet*. 2016 Apr 9;387(10027):1551-1560. doi: 10.1016/S0140-6736(15)01120-4. Epub 2016 Jan 7.
14. Lokhorst HM, Plesner T, Laubach JP, et al. Targeting CD38 with Daratumumab Monotherapy in Multiple Myeloma. *N Engl J Med*. 2015 Sep 24;373(13):1207-19. doi: 10.1056/NEJMoa1506348. Epub 2015 Aug 26.
15. Kaufman GP, Schrier SL, Lafayette RA, et al. Daratumumab yields rapid and deep hematologic responses in patients with heavily pretreated AL amyloidosis. *Blood*. 2017 Aug 17;130(7):900-902. doi: 10.1182/blood-2017-01-763599. Epub 2017 Jun 14.

16. Dimopoulos M, Quach H, Mateos MV, et al. Carfilzomib, dexamethasone, and daratumumab versus carfilzomib and dexamethasone for patients with relapsed or refractory multiple myeloma (CANDOR): results from a randomised, multicentre, open-label, phase 3 study. *Lancet*. 2020 July 18;396(10245):186-197.
17. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma Version 2.2024. National Comprehensive Cancer Network, 2024. 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 February 2024.
18. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Systemic Light Chain Amyloidosis Version 2.2024. National Comprehensive Cancer Network, 2024. 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 February 2024.
19. Voorhees PM, Kaufman JL, Laubach J, et al. Daratumumab, lenalidomide, bortezomib, and dexamethasone for transplant-eligible newly diagnosed multiple myeloma: the GRIFFIN trial. *Blood*. 2020 Aug 20;136(8):936-945.
20. Yimer H, Melear J, Faber E, et al. Daratumumab, bortezomib, cyclophosphamide and dexamethasone in newly diagnosed and relapsed multiple myeloma: LYRA study. *Br J Haematol*. 2019 May;185(3):492-502.
21. Palladini G, Kastiris E, Maurer M, et al. Daratumumab plus CyBORd for patients with newly diagnosed AL amyloidosis: safety run-in results of ANDROMEDA. *Blood* 2020 Jul 2;136(1):71-80. doi: 10.1182/blood.2019004460.
22. Dimopoulos MA, Terpos E, Boccadoro M, et al; APOLLO Trial Investigators. Daratumumab plus pomalidomide and dexamethasone versus pomalidomide and dexamethasone alone in previously treated multiple myeloma (APOLLO): an open-label, randomised, phase 3 trial. *Lancet Oncol*. 2021 Jun;22(6):801-812. doi: 10.1016/S1470-2045(21)00128-5.
23. Landgren O, Hultcrantz M, Diamond B, et al. Safety and Effectiveness of Weekly Carfilzomib, Lenalidomide, Dexamethasone, and Daratumumab Combination Therapy for Patients With Newly Diagnosed Multiple Myeloma: The MANHATTAN Nonrandomized Clinical Trial. *JAMA Oncol*. 2021 Jun 1;7(6):862-868. doi: 10.1001/jamaoncol.2021.0611.
24. Gasparetto C, Lentzsch S, Schiller G, et al. Selinexor, daratumumab, and dexamethasone in patients with relapsed or refractory multiple myeloma. *eJHaem*. 2020;1-10. <https://doi.org/10.1002/jha2.122>.
25. Kastiris E, Minnema MC, Dimopoulos MA, et al. Daratumumab Monotherapy in Previously Untreated High-Risk Patients with Stage 3B Light Chain (AL) Amyloidosis: A Phase II Multicenter

Study By European Myeloma Network (EMN). *Blood* 2019; 134 (Supplement_1): 1868. doi: <https://doi.org/10.1182/blood-2019-126524>.

26. Bahlis NJ, Baz R, Harrison SJ, et al. Phase I Study of Venetoclax Plus Daratumumab and Dexamethasone, With or Without Bortezomib, in Patients With Relapsed or Refractory Multiple Myeloma With and Without t(11;14). *J Clin Oncol*. 2021 Nov 10;39(32):3602-3612. doi: 10.1200/JCO.21.00443. Epub 2021 Aug 13. PMID: 34388020; PMCID: PMC8577687.
27. Moreau P, Hulin C, Perrot A, et al. Maintenance with daratumumab or observation following treatment with bortezomib, thalidomide, and dexamethasone with or without daratumumab and autologous stem-cell transplant in patients with newly diagnosed multiple myeloma (CASSIOPEIA): an open-label, randomised, phase 3 trial. *Lancet Oncol* 2021;22:1378-1390.
28. Laubach JP, Kaufman JL, Sborov DW, et al. Daratumumab (DARA) Plus Lenalidomide, Bortezomib, and Dexamethasone (RVd) in Patients (Pts) with Transplant-Eligible Newly Diagnosed Multiple Myeloma (NDMM): Updated Analysis of Griffin after 24 Months of Maintenance. *Blood* 2021; 138 (Supplement 1): 79. doi: <https://doi.org/10.1182/blood-2021-149024>.

VIII. References (ENHANCED)

- 1e. Durie BG, Hoering A, Abidi MH, et al. Bortezomib with lenalidomide and dexamethasone versus lenalidomide and dexamethasone alone in patients with newly diagnosed myeloma without intent for immediate autologous stem-cell transplant (SWOG S0777): a randomised, open-label, phase 3 trial. *Lancet*. 2017;389(10068):519–527. doi:10.1016/S0140-6736(16)31594-X.
- 2e. Kastiris 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. Santhorawala 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.
- 4e. Roussel M, Merlini G, Chevret S, et al. A prospective phase 2 trial of daratumumab in patients with previously treated systemic light-chain amyloidosis. *Blood*. 2020 Apr 30;135(18):1531-1540. doi: 10.1182/blood.2019004369.
- 5e. Facon T, Venner, CP, Bahlis, NJ, et al. Ixazomib Plus Lenalidomide Dexamethasone (IRd) vs. Placebo for Newly Diagnosed Multiple Myeloma (NDMM) Patients Not Eligible for Autologous Stem Cell Transplant: The Double-Blind, Placebo-Controlled, Phase 3 TOURMALINE-MM2 Trial [Abstract]. Abstract MM-347 presented at Society of Hematology Oncology (SOHO) Eighth Annual Meeting 2020.
- 6e. Kastiris E, Minnema MC, Dimopoulos MA, et al. Daratumumab Monotherapy in Previously Untreated High-Risk Patients with Stage 3B Light Chain (AL) Amyloidosis: A Phase II Multicenter

Study By European Myeloma Network (EMN). Blood 2019; 134 (Supplement_1): 1868. doi: <https://doi.org/10.1182/blood-2019-126524>.

7e. Sonneveld P, Dimopoulos MA, Boccadoro M, et al. Daratumumab, Bortezomib, Lenalidomide, and Dexamethasone for Multiple Myeloma. N Engl J Med. 2024 Jan 25;390(4):301-313.

8e. Prime Therapeutics Management. Darzalex Faspro Clinical Literature Review Analysis. Last updated February 2024. Accessed February 2024.

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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied 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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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