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

Document Number: IC-0535

Last Review Date: 05/05/2026
Date of Origin: 06/02/2020
Dates Reviewed: 06/2020, 09/2020, 01/2021, 02/2021, 08/2021, 03/2022, 03/2023, 03/2024, 09/2024, 05/2025, 12/2025, 03/2026, 05/2026

I. Length of Authorization [1,19,20,23,28]

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter, unless otherwise specified.
  - Prior authorization validity may NOT be renewed for the following:
    - ❖ Newly diagnosed multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone.
    - ❖ Newly diagnosed multiple myeloma when used as part of the **Induction and Consolidation Therapy Regimen** in combination with bortezomib, lenalidomide and dexamethasone.
  - Prior authorization validity may be renewed for up to a maximum of 2 years of therapy for the following:
    - ❖ Newly diagnosed multiple myeloma when used as part of the **Induction, Consolidation, and Maintenance Therapy Regimen** in combination with bortezomib, lenalidomide and dexamethasone.
    - ❖ Maintenance therapy for multiple myeloma in combination with lenalidomide.
    - ❖ 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.
  - Prior authorization validity may be renewed for up to a maximum of 32 weeks of therapy for the following:
    - ❖ Newly diagnosed multiple myeloma in combination with carfilzomib, lenalidomide, and dexamethasone.
  - Prior authorization validity may be renewed for up to a maximum of 80 weeks of therapy for the following:
    - ❖ Newly diagnosed OR relapsed or refractory/progressive multiple myeloma in combination with cyclophosphamide, bortezomib and dexamethasone *(32 weeks of induction therapy and 48 weeks of maintenance therapy)*.
  - Prior authorization validity may be renewed for up to a maximum of 36 months of therapy for the following:
    - ❖ High-risk smoldering multiple myeloma as monotherapy.

II. Dosing Limits

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

- Multiple Myeloma
  - 180 billable units every 7 days for 12 doses, every 14 days for 8 doses, every 21 days for 16 doses, then every 28 days
- Systemic Light Chain Amyloidosis
  - 180 billable units every 7 days for 8 doses, every 14 days for 8 doses, then every 28 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Universal Criteria [1]

- Therapy will not be used in combination with other anti-CD38 therapies; **AND**

Multiple Myeloma*† ‡ [1,2,17,37]

- Used in the treatment of newly diagnosed disease in members 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**
  - Bortezomib, lenalidomide, and dexamethasone; **OR**
- Used in the treatment of newly diagnosed disease in members 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; **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**

- Carfilzomib and pomalidomide; **OR**
- Cyclophosphamide and bortezomib; **OR**
- Selinexor; **OR**
- Venetoclax *(for members with t(11:14) ONLY);* **OR**

- Used after prior therapy with lenalidomide and a proteasome inhibitor (bortezomib, carfilzomib, etc.), in combination with ONE of the following regimens:
  - Pomalidomide and dexamethasone; **OR**
  - Teclistamab; **OR**
- Used as single agent therapy; **AND**
  - Member 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**
  - Member is double refractory to a proteasome inhibitor and an immunomodulatory agent; **OR**
  - Member has high-risk smoldering myeloma; **OR**
- Used as maintenance therapy for symptomatic disease in transplant candidates; **AND**
  - Used as a single agent 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 members; **OR**
- Used for the management of POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome; **AND**
  - Used in combination with lenalidomide and dexamethasone

***The regimens listed for treatment of Multiple Myeloma may also be used for the treatment of Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein, Skin changes (POEMS), Monoclonal Immunoglobulin Deposition Disease (MIDD), and plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)*

Systemic Light Chain Amyloidosis † ‡ Φ [1,2,18]

- Member does not have NYHA Class IIIB or Class IV, or Mayo Stage IIIB cardiac disease, unless otherwise specified; **AND**
  - Used for newly diagnosed disease OR as a repeat of initial therapy if relapse-free for several years; **AND**
    - Used in combination with bortezomib, cyclophosphamide, and dexamethasone (D-VCd); **OR**
    - Used as a single agent; **AND**
      - Member has stage IIIb disease with no significant neuropathy; **OR**

- Used for relapsed or refractory disease; **AND**
  - Used in combination with lenalidomide and dexamethasone; **OR**
  - Used in combination with venetoclax for t(11;14); **OR**
  - Used as a single agent

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

IV. Renewal Criteria [1,2]

Prior authorization validity may be renewed based upon the following criteria:

- Member 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**
- Duration of authorization has not been exceeded (*refer to Section I*); **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.

V. Dosage/Administration [1,15,19,20,23-26,28-31,33,34,36,38]

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 members **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 members **ineligible** for ASCT in combination with bortezomib, lenalidomide and dexamethasone (VRd) (3-week cycle) – Weekly Weeks 1 to 6 (six doses; cycles 1 and 2) – Every three weeks Weeks 7 to 24 (six doses; cycles 3 to 8) – Every four weeks Week 25 onwards (cycle 9 and beyond) *Treat until disease progression or unacceptable toxicity.*
	Newly diagnosed disease in members **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 members **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 members **eligible** for ASCT in combination with bortezomib, lenalidomide and dexamethasone: **Induction, Consolidation, and Maintenance Therapy Regimen:** 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 **-OR-** **Induction and Consolidation Therapy Regimen ONLY:** Induction – **4 week cycle** – 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 – **4 week cycle** – Every two weeks Weeks 1 to 8 (four doses; cycles 5 and 6)
	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 (4-week cycles): o Monotherapy for members with relapsed/refractory multiple myeloma o Combination therapy with lenalidomide and dexamethasone for newly diagnosed members **ineligible** for ASCT o Combination therapy with lenalidomide, pomalidomide, selinexor, or carfilzomib AND dexamethasone in members with relapsed or refractory/progressive disease o Combination therapy with carfilzomib, pomalidomide, and dexamethasone in members with relapsed or refractory/progressive disease o Combination therapy with venetoclax and dexamethasone for relapsed or refractory/progressive t(11;14) disease o Combination therapy with lenalidomide and dexamethasone for the management of POEMS

	syndrome ○ Monotherapy for high-risk smoldering myeloma^ ○ Combination therapy with teclistamab – 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.* *^For high-risk smoldering myeloma: Treat until disease progression or unacceptable toxicity for a maximum of 36 months*
	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.*
	In combination with lenalidomide as maintenance treatment for transplant candidates ○ Every 4 or 8 weeks until disease progression or unacceptable toxicity. For a maximum of 2 years of maintenance treatment.
Systemic Light Chain Amyloidosis	Combination with bortezomib, cyclophosphamide, and dexamethasone for newly diagnosed disease OR repeat of initial therapy if relapse-free for several years (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*
	Treatment as one of the following (4-week cycles): ○ Single agent therapy for relapsed/refractory disease, OR stage IIIb disease with no significant neuropathy and newly diagnosed OR repeat of initial therapy if relapse-free for several years ○ Combination with lenalidomide and dexamethasone for relapsed/refractory disease ○ Combination with venetoclax for relapsed or refractory/progressive t(11;14) disease – 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 Faspro and continue for 3 months following the end of 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

1. Darzalex Faspro [package insert]. Horsham, PA; Janssen Biotech, Inc.; February 2026. Accessed April 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for daratumumab and hyaluronidase-fihj. National Comprehensive Cancer Network, 2026. 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 April 2026.
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/S010-6736(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. Dimopoulous 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 5.2026. National Comprehensive Cancer Network, 2026. 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 April 2026.
18. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Systemic Light Chain Amyloidosis Version 2.2026. National Comprehensive Cancer Network, 2026. 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 April 2026.
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, Kastritis 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. Kastritis 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.
29. Sonneveld P, Dimopoulos MA, Boccadoro M, et al; PERSEUS Trial Investigators. Daratumumab, Bortezomib, Lenalidomide, and Dexamethasone for Multiple Myeloma. N Engl J Med. 2024 Jan 25;390(4):301-313. doi: 10.1056/NEJMoa2312054. Epub 2023 Dec 12. PMID: 38084760.
30. Dispenzieri, A. POEMS Syndrome: 2019 Update on diagnosis, risk-stratifications, and management. Am J Hematol. 2019;94:812-827.
31. Kawano Y, Hata H, Takashio S, et al. Daratumumab, lenalidomide and dexamethasone in newly diagnosed systemic light chain amyloidosis patients associated with multiple myeloma. Br J Haematol. 2022;198:e38-e41.
32. Chakraborty, R, Rosenbaum C, Kaur G, et al. First report of outcomes in patients with stage IIIb AL amyloidosis treated with Dara-VCD frontline therapy. Br J Haematol. 2023;201:913-916.
33. Derman BA, Zonder J, Reece D, et al. Phase 1/2 study of carfilzomib, pomalidomide, and dexamethasone with and without daratumumab in relapsed multiple myeloma. Blood Adv. 2023 Oct 10;7(19):5703-5712.
34. Dimopoulos MA, Voorhees PM, Schjesvold F, et al. Daratumumab or Active Monitoring for High-Risk Smoldering Multiple Myeloma. N Engl J Med. 2025;392(18):1777-1788. doi:10.1056/NEJMoa2409029.
35. Usmani SZ, Facon T, Hungria V, et al. Daratumumab plus bortezomib, lenalidomide and dexamethasone for transplant-ineligible or transplant-deferred newly diagnosed multiple myeloma: the randomized phase 3 CEPHEUS trial. Nat Med. 2025 Apr;31(4):1195-1202. doi: 10.1038/s41591-024-03485-7. Epub 2025 Feb 5. Erratum in: Nat Med. 2025 Apr;31(4):1366. doi: 10.1038/s41591-025-03581-2.
36. Lebel E, Kastritis E, Palladini G, et al. Venetoclax in relapse/refractory AL amyloidosis-a multicenter international retrospective real-world study. Cancers (Basel) 2023;15:1710. https://pubmed.ncbi.nlm.nih.gov/36980596/
37. Costa LJ, Bahlis NJ, Perrot A, et al. MajesTEC-3 Trial Investigators. Teclistamab plus Daratumumab in Relapsed or Refractory Multiple Myeloma. N Engl J Med. 2025 Dec 9. doi: 10.1056/NEJMoa2514663. Epub ahead of print. PMID: 41363801. https://www.nejm.org/doi/full/10.1056/NEJMoa2514663#ap2

38. Meletios-Athanasios D, Voorhees PM, Schjesvold F, *et al.* Phase 3 Randomized Study of Daratumumab Monotherapy Versus Active Monitoring in Patients with High-Risk Smoldering Multiple Myeloma: Primary Results of the Aquila Study. *Blood* 2024; 144 (Supplement 1): 773. https://doi.org/10.1182/blood-2024-201057.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in 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
D47.9	Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
E31.9	Polyglandular dysfunction, unspecified
E85.3	Secondary systemic amyloidosis
E85.4	Organ-limited amyloidosis
E85.81	Light chain (AL) amyloidosis
E85.89	Other amyloidosis
E85.9	Amyloidosis, unspecified

ICD-10	ICD-10 Description
G62.9	Polyneuropathy, unspecified
G90.9	Disorder of the autonomic nervous system, unspecified
L98.9	Disorder of the skin and subcutaneous tissue, 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		
Jurisdictio	**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