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

Document Number: IC-0535

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I. Length of Authorization [1,9,19,20]

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 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 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 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* ***OR***
  - *Weekly Weeks 1 to 8, then every two weeks Weeks 9-16 for induction therapy, then every two weeks Weeks 1 to 8 for consolidation therapy* ***OR***
  - *Weekly Weeks 1 to 18, then every four weeks for up to 2 years for maintenance therapy;* ***OR***

- *Weekly Weeks 1 to 8, then every two weeks Weeks 9-24, and then every four weeks Weeks 25 to 32 for induction therapy, then every four weeks for up to 48 weeks for maintenance therapy*

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

- 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 or Pomalidomide or Carfilzomib or Selinexor 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/Dexamethasone Regimen
  - 180 billable units per dose
    (Weekly Weeks 1 to 9, then every three weeks Weeks 10-24, then every four weeks Week 25 onwards)
- Monotherapy 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/Thalidomide Regimen
  - 180 billable units per dose
    (Weekly Weeks 1 to 8, then every two weeks Weeks 9-16 for induction therapy, then every two weeks Weeks 1 to 8 for consolidation therapy)
- Bortezomib/Lenalidomide/Dexamethasone Regimen
  - 180 billable units per dose
    (Weekly Weeks 1 to 18, then every four weeks for up to 2 years for maintenance therapy)
- Cyclophosphamide/Bortezomib/Dexamethasone Regimen *(for systemic light chain amyloidosis)*
  - 180 billable units per dose
    (Weekly Weeks 1 to 8, then every two weeks Weeks 9-24, then every four weeks Week 25 onwards for up to 2 years)
- Cyclophosphamide/Bortezomib/Dexamethasone Regimen *(for multiple myeloma)*
  - 180 billable units per dose
    (Weekly Weeks 1 to 8, then every two weeks Weeks 9-24, and then every four weeks Weeks 25 to 32 for induction therapy, then every four weeks for up to 48 weeks for maintenance therapy)

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 [1,2,6-14,16,17,19,20]

- 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**
- 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 in combination with dexamethasone and ONE of the following:
  - Lenalidomide; **OR**
  - Bortezomib; **OR**
  - Carfilzomib; **OR**
  - Cyclophosphamide and bortezomib; **OR**
  - Selinexor; **OR**
- Used in combination with pomalidomide and dexamethasone after at least two prior therapies including an immunomodulatory agent (e.g., lenalidomide, pomalidomide, etc.) 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

Systemic Light Chain Amyloidosis † ‡ [1,2,15,18,21]

- 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) for newly diagnosed disease; **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 [1,2,6,9,19,20]

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: severe infusion reactions including anaphylactic reactions, neutropenia, thrombocytopenia, cardiac toxicity, etc.; **AND**

Multiple Myeloma

- Use for newly diagnosed disease in combination with bortezomib, thalidomide and dexamethasone after 24 weeks of induction/consolidation therapy 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).*

Systemic Light Chain Amyloidosis (newly diagnosed disease)

- Use for newly diagnosed disease 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)
	<u>Newly diagnosed disease in patients eligible for ASCT in combination with bortezomib, lenalidomide and dexamethasone:</u> Induction – **3 week cycle** – Weekly Weeks 1 to 12 (twelve doses; cycles 1 to 4) Consolidation – *(after ASCT)* – **3 week cycle** – Weekly Weeks 13 to 18 (six doses; cycles 5 and 6) Maintenance – **4 week cycle** – Every 4 or 8 weeks Weeks 1 to 102 for a maximum of 2 years of maintenance treatment
	<u>Newly diagnosed OR relapsed disease in combination with cyclophosphamide, bortezomib and dexamethasone (4-week cycle):</u> 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 Weeks 33-48 for up to 12 cycles
	<u>Treatment as one of the following:</u> 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 or pomalidomide and low-dose dexamethasone in patients with relapsed/refractory disease (4-week cycle) o Combination therapy with selinexor and dexamethasone 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.*
	<u>Combination therapy with carfilzomib and dexamethasone for relapsed/refractory disease (4-week cycle):</u> – Weekly Weeks 1 to 8 (eight doses; cycles 1 to 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/refractory disease (3-week cycle):</u> – 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.*
Systemic Light Chain Amyloidosis	<u>Newly diagnosed disease 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) *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:

- J9999 – Not otherwise classified, antineoplastic drugs *(Discontinue use effective 1/1/21)*
- J9144 - Injection, daratumumab, 10 mg and hyaluronidase-fihj; 1 billable unit=10 mg *(Effective 1/1/21)*

NDC(s):

- 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; January 2021. Accessed January 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for daratumumab and hyaluronidase-fihj. National Comprehensive Cancer Network, 2021. 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 January 2021.
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17. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma Version 4.2021. National Comprehensive Cancer Network, 2021. 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 January 2021.
18. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Systemic Light Chain Amyloidosis 1.2021. National Comprehensive Cancer

Network, 2021. 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 January 2021.
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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
E85.81	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: 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/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

Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. *We* do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:
Provide free aids and services to people with disabilities to communicate effectively with us, such as:
- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provide free language services to people whose primary language is not English, such as:
- Qualified interpreters
- Information written in other languages

If *you* need these services, contact *us* at the phone number shown on the inside cover of this *contract*, *your* id card, or aspirushealthplan.com.

If *you* believe that *we* have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity, *you* can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1.866.631.5404 (TTY: 711)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If *you* need help filing a grievance, the Nondiscrimination Grievance Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1.866.631.5404 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً . اتصل بن اعلى رقم الهاتف 1.866.631.5404(رقم هاتف الصم والبك : 711)

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_: य_द आप ि◌हंदी बोलते ह_ तो आपके ि◌लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1.866.631.5404 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

Traditional Chinese: 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請 致電 1.866.631.5404 (TTY:711).

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັ້ງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.866.631.5404 (TTY:711).