

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 pediatric acute lymphoblastic leukemia may not be renewed.

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

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- Weekly Week 1 to 8, then every two weeks Weeks 9-24, then every four weeks Week 25 onwards

III. Initial Approval Criteria¹

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}

- 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
 - $\circ~$ Bortezomib, melphalan, and prednisone; \mathbf{OR}
 - \circ $\;$ Cyclophosphamide, bortezomib, and dexamethasone; \mathbf{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:
 - o Bortezomib, lenalidomide, and dexamethasone; OR
 - Bortezomib, thalidomide, and dexamethasone (VTd); OR
 - Carfilzomib, lenalidomide, and dexamethasone; OR
 - o 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:
 - \circ $\;$ Lenalidomide and dexame thasone for non-transplant candidates; \mathbf{OR}
 - o 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**
 - \circ Cyclophosphamide and bortezomib; \mathbf{OR}
 - Selinexor; **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; 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

- Used as single agent therapy; **AND**
- Used for the treatment of relapsed/refractory disease

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.

Pediatric Acute Lymphoblastic Leukemia

• May not be renewed

V. Dosage/Administration ^{1,12,16-19, 21}

Indication	Dose				
Multiple Myeloma	 <u>Newly diagnosed disease in patients eligible for ASCT in combination with bortezomib,</u> <u>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) 				
	 Newly diagnosed disease in patients eligible for ASCT in combination with bortezomib, lenalidomide and dexamethasone 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) 				
	 Every 5 weeks weeks 15 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 disease in patients eligible for ASCT in combination with carfilzomib. 				
	lenalidomide, and dexamethasone • 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)				
	 Newly diagnosed disease in patients ineligible for ASCT in combination with bortezomib, melphalan and prednisone 16 mg/kg body weight given as an intravenous infusion in a 6 week cycle: 				

DARZALEX[®] (daratumumab) Prior Auth Criteria



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– Weekly	Weeks 1 to 6 (six doses; cycle 1)	
– Every three we	•	
– Every four wee	Week 55 onwards (cycle 10 and beyond)	
Treat until disease prog	ression or unacceptable toxicity	
Newly diagnosed OR	relapsed disease in combination with cyclophosphamide, bortezomib	
and dexamethasone		
Induction		
 8 mg/kg body weigl doses) 	nt given as an intravenous infusion on days 1 and 2 (Week 1; total 2	
 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 wee 	ks Weeks 9 to 24 (eight doses; cycles 3 to 6)	
 Every four week 	Week 25 to 32 (two doses; cycles 7 and 8)	
Maintenance <i>(after A</i>		
	ght given as an intravenous infusion every 4 weeks for up to 12 cycle	
(48 weeks)		
Treatment as one of t	he following:	
• Monotherapy	for patients with relapsed/refractory multiple myeloma	
Combination	therapy with lenalidomide and low-dose dexamethasone for newly diagnosed	
patients ineli	gible for ASCT	
	therapy with lenalidomide, pomalidomide, or selinexor AND low-dose	
	ne in patients with relapsed or refractory/progressive disease	
	t given as an intravenous infusion in a 4 week cycle:	
– Weekly	Weeks 1 to 8 (eight doses; cycles 1 and 2)	
- Every two wee		
- Every four wee	eks Week 25 onwards (cycle 7 and beyond) ression or unacceptable toxicity	
	with carfilzomib and dexamethasone for relapsed or	
refractory/progressive		
 8 mg/kg body weigi doses) 	nt given as an intravenous infusion on days 1 and 2 (Week 1; total 2	
	kg body weight given as an intravenous infusion in a 4 week cycle:	
WeeklyEvery two wee	Weeks 2 to 8 (seven doses; cycles 1 and 2) ks Weeks 9 to 24 (eight doses; cycles 3 to 6)	
 Every two wee Every four wee 		
·		
Treat until disease progression or unacceptable toxicity Combination therapy with bortezomib and dexamethasone for relapsed or refractory/progressive disease		
– Weekly	Weeks 1 to 9 (nine doses; cycles 1 to 3)	
 Weekly Every three we 		
 Every four week 	-	
Treat until disease progression or unacceptable toxicity		
Monotherapy as maintenance treatment for transplant candidates		

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	 16 mg/kg body weight given as an intravenous infusion every 4 weeks until disease progression or unacceptable toxicity 			
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	•	16 mg/kg body weight given as an intravenous infusion:		
Light Chain		– Weekly	Weeks 1 to 8 (eight doses)	
Amyloidosis		 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

HCPCS Code:

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

NDC(s):

- 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

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- 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 August 2023.
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- 6. 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.
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- 14. 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 August 2023.
- 15. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Systemic Light Chain Amyloidosis 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 August 2023.



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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	

Appendix 1 – Covered Diagnosis Codes





ICD-10	ICD-10 Description	
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: <u>https://www.cms.gov/medicare-coverage-database/search.aspx</u>. Additional indications may be covered at the discretion of the health plan.

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	КҮ, ОН	CGS Administrators, LLC			

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A



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Nondiscrimination & Language Access Policy



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Aspirus Health Plan, Inc.:

Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.

- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If you need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If you believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Nondiscrimination Grievance Coordinator Aspirus Health Plan, Inc. PO Box 1890 Southampton, PA 18966-9998 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. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1-800-332-6501 (TTY: 711). (711: (تق هاتف الصم والبك) 1-800-332-6501 تنبيه : إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً التصل بن اعلى رقم الهاتف ال-800-332-6501 (TTY: 711). French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711). German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_11-800-332-6501 (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 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711). Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame all-800-332-6501 (TTY: 711). Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (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 1-800-332-6501 (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 1-800-332-6501 (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 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).