Darzalex® (daratumumab)
(Intravenous)

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I. Length of Authorization [1,16,17,19,21,24,29,30,36]

- 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.
    - Pediatric Acute Lymphoblastic Leukemia.
  - Prior authorization validity may be renewed for up to a maximum of 2 years of therapy for the following:
    - Newly diagnosed multiple myeloma in combination with bortezomib, lenalidomide and dexamethasone as maintenance therapy *(for members eligible for ASCT)*.
    - Maintenance therapy for multiple myeloma in combination with lenalidomide or as a single agent.
    - Newly diagnosed OR repeat of initial therapy if 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:
  - ❖ Monotherapy for primary treatment of high-risk smoldering myeloma (asymptomatic).

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
- **Pediatric ALL:** 180 billable units every 7 days for 8 doses

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member 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; **AND**

Multiple Myeloma † ‡ Φ [1-11,13,14,16-19,22,23,15e-17e]

- 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**
  - Cyclophosphamide, bortezomib, and dexamethasone; **OR**
  - Carfilzomib, lenalidomide, and dexamethasone; **AND**

- Use of daratumumab in combination with carfilzomib, lenalidomide, and dexamethasone will be restricted to members with a contraindication or intolerance to one of the following regimens:
  - Bortezomib/lenalidomide/dexamethasone
  - Daratumumab/lenalidomide/bortezomib/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 for relapsed or refractory disease after prior therapy with lenalidomide and a proteasome inhibitor (bortezomib, carfilzomib, etc.), in combination with ONE of the following regimens; **AND**
  - 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**
- 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 as primary treatment for high-risk smoldering myeloma (asymptomatic) as a single agent

Systemic Light Chain Amyloidosis ‡ [2,12,15,25-27]

- 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 as a single agent

Pediatric Acute Lymphoblastic Leukemia (ALL) ‡ [2,20,21]

- Member age ≥ 1 and ≤ 30 years; **AND**
- Member has relapsed/refractory T-cell ALL; **AND**
- Used in combination with vincristine, pegaspargase/calaspargase, doxorubicin, and prednisone/dexamethasone

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Enhanced Oncology Value (EOV) Program – Redacted indications
Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity. Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

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

IV. Renewal Criteria [1]

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

- Member continues to meet the 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 or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions including anaphylactic reactions, neutropenia, thrombocytopenia, etc.

V. Dosage/Administration [1,12,16-19,21-24,27,29,30-40]

Indication	Dose
Multiple Myeloma	<u>Newly diagnosed disease in members eligible for ASCT in combination with bortezomib, 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)
	<u>Newly diagnosed disease in combination with bortezomib, lenalidomide and dexamethasone</u> ▪ 16 mg/kg body weight given as an intravenous infusion as follows: <u>For members *eligible* for ASCT:</u> ▪ 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 <u>For members *ineligible* for ASCT:</u> ▪ Induction – **3 week cycle** – Weekly Weeks 1 to 6 (six doses; cycles 1 and 2) ▪ Consolidation – **3 week cycle** – Every 3 weeks Weeks 7 to 24 (six doses; cycles 3 to 8) ▪ Maintenance – **4 week cycle**

	– Every 4 weeks Weeks 25 (cycle 9) and beyond *treat until disease progression or unacceptable toxicity*
	<u>Newly diagnosed disease in members eligible for ASCT in combination with carfilzomib, lenalidomide, and dexamethasone</u> ▪ 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)
	<u>Newly diagnosed disease in members ineligible for ASCT in combination with bortezomib, melphalan and prednisone</u> ▪ 16 mg/kg body weight given as an intravenous infusion in a 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*
	<u>Newly diagnosed OR relapsed or refractory/progressive disease in combination with cyclophosphamide, bortezomib and dexamethasone</u> Induction ▪ 8 mg/kg body weight given as an intravenous infusion on days 1 and 2 (Week 1; total 2 doses) ▪ 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 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)* ▪ 16 mg/kg body weight given as an intravenous infusion every 4 weeks for up to 12 cycles (48 weeks)
	<u>Treatment as one of the following:</u> • Monotherapy for members with relapsed/refractory multiple myeloma • Combination therapy with lenalidomide and dexamethasone for newly diagnosed members ineligible for ASCT • Combination therapy with lenalidomide, pomalidomide, or selinexor AND dexamethasone in members with relapsed or refractory/progressive disease • Combination therapy with carfilzomib, pomalidomide, and dexamethasone in members with relapsed or refractory/progressive disease • Combination therapy with venetoclax and dexamethasone for relapsed or refractory/progressive t(11;14) disease • Monotherapy as primary treatment for high-risk smoldering myeloma (asymptomatic)^ • Combination therapy with teclistamab ▪ 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 onwards (cycle 7 and beyond) *treat until disease progression or unacceptable toxicity* *^For high-risk smoldering myeloma (asymptomatic): Treat until disease progression or unacceptable toxicity for a maximum of 36 months*
	<u>Combination therapy with carfilzomib and dexamethasone for relapsed or refractory/progressive disease</u> ▪ 8 mg/kg body weight given as an intravenous infusion on days 1 and 2 (Week 1; total 2 doses) OR 16 mg/kg IV on day 1 cycle 1 (Week 1; total 1 dose) ▪ 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 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 or refractory/progressive disease</u> ▪ 16 mg/kg body weight given as an intravenous infusion in a 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>Maintenance treatment for transplant candidates</u> ▪ Combination with lenalidomide: 16 mg/kg body weight given as an intravenous infusion every 4 or 8 weeks until disease progression or unacceptable toxicity. For a maximum of 2 years of maintenance treatment. ▪ Single agent: 16 mg/kg body weight given as an intravenous infusion every 8 weeks until disease progression or unacceptable toxicity. For a maximum of 2 years of maintenance treatment.
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 Light Chain Amyloidosis	<u>Combination with bortezomib, cyclophosphamide, and dexamethasone for newly diagnosed disease OR repeat of initial therapy if relapse-free for several years</u> ▪ 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 and 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, OR stage IIIB disease with no significant neuropathy and newly diagnosed OR repeat of initial therapy if relapse-free for several years ▪ 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 and onwards (cycle 7 and beyond) *Treat 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 (STANDARD)

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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
C83.30	Diffuse large B-cell lymphoma, unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.398	Diffuse large B-cell lymphoma of other extranodal and solid organ sites
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
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
E85.81	Light chain (AL) amyloidosis

ICD-10	ICD-10 Description
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		
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