Daratumumab and hyaluronidase-fihj (Darzalex Faspro™)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration Outpatient Facility Administration HCPCS: **J9144** per 10 mg

Condition listed in policy (*see criteria for details*)

- Multiple myeloma
  - First-line treatment
  - Previously treated
- Systemic light chain amyloidosis

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: combination of daratumumab, a CD38-directed cytolytic antibody, and hyaluronidase, an endoglycosidase

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Darzalex Faspro™ (daratumumab and hyaluronidase-fihj) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Multiple myeloma - first-line treatment

1. First-line treatment, **AND**
2. Combination use with one of the following regimens:
   a. Used in combination with Velcade (bortezomib), cyclophosphamide, and dexamethasone, or
   b. Used in combination with Velcade (bortezomib), lenalidomide, and dexamethasone, or
   c. Used in combination with Velcade (bortezomib), melphalan, and prednisone, or
   d. used in combination with Velcade (bortezomib), thalidomide and dexamethasone, or
   e. Used in combination with Kyprolis (carfilzomib), lenalidomide, and dexamethasone, or
   f. Used in combination with Revlimid (lenalidomide) and dexamethasone

Covered Doses

Combination with Velcade (bortezomib), cyclophosphamide, and dexamethasone

Induction: 4-8 cycles (28-day cycle)
Cycle 1: Up to 1,800 mg SC on Days 1 and 2, then 16 mg/kg weekly starting Day 8 (8 doses) *9*
Cycles 3-6 (week 9-24): Up to 1,800 mg SC every 2 weeks (8 doses)
Cycles 7-8 (week 25-32): Up to 1,800 mg SC every 4 weeks (2 doses)
Maintenance for 12 cycles
Up to 1,800 mg SC every 4 weeks (12 doses)

Combination with Velcade (bortezomib), melphalan, and prednisone
Weeks 1 to 6: up to 1,800 mg SC weekly (6 doses)
Weeks 7 to 54: up to 1,800 mg SC every 3 weeks (16 doses)
Weeks 55 onward: up to 1,800 mg SC every 4 weeks until disease progression

Combination with Velcade (bortezomib), Revlimid (lenalidomide), and dexamethasone
Induction: (21-day cycle)
Cycle 1-4: Up to 1,800 mg SC on Days 1, 8, 15 (12 doses)
Consolidation: (21-day cycle)
Cycles 5-6: Up to 1,800 mg SC on Day 1 of every 3 weeks (2 doses)
Maintenance: (28-day cycle or 56-day cycle)
Up to 1,800 mg SC on Day 1 of every 4-8 weeks until disease progression

Combination with Velcade (bortezomib), thalidomide and dexamethasone
Induction:
Weeks 1 to 8: Up to 1,800 mg SC weekly (8 doses)
Weeks 9 to 16: Up to 1,800 mg SC every 2 weeks (4 doses)
Stop for high dose chemotherapy and ASCT
Consolidation:
Weeks 1 to 8: Up to 1,800 mg SC every 2 weeks (4 doses)

Combination with Kyprolis (carfilzomib), lenalidomide, and dexamethasone
8 cycles (28-day cycle)
Cycle 1 and 2 (Weeks 1 to 8): Up to 1,800 mg SC on Days 1, 8, 15, 22 (8 doses)
Cycles 3-6 (week 9-24): Up to 1,800 mg SC every 2 weeks (8 doses)
Cycles 7-8 (week 25-32): Up to 1,800 mg SC every 4 weeks (2 doses)

Combination with Revlimid (lenalidomide) and dexamethasone
Weeks 1 to 8: up to 1,800 mg SC weekly (8 doses)
Weeks 9 to 24: up to 1,800 mg SC every 2 weeks (8 doses)
Weeks 25 onward: up to 1,800 mg SC every 4 weeks thereafter

Coverage Period
Combination with carfilzomib, lenalidomide, and dexamethasone: **One year**
Combination with bortezomib, cyclophosphamide, and dexamethasone: **One year**
Combination with bortezomib, melphalan, and prednisone: **Indefinite**
Combination with bortezomib, thalidomide and dexamethasone: **One year**
Combination with bortezomib, lenalidomide and dexamethasone: **Indefinite**
Combination with lenalidomide and dexamethasone: **Indefinite**

ICD-10:
C90.00, C90.02, C90.10, C90.12, C90.20, C90.22, C90.30, C90.32, Z85.79

Multiple myeloma – previously treated

1. Patient has received prior treatment, **AND**
2. Meets one of the following:

a. Monotherapy, and one of the following:
    i. Patient has received at least 3 prior regimens that include the use of a proteasome inhibitor (PI) (e.g. Kyprolis, Velcade) and an immunomodulatory agent (e.g. Revlimid, Thalomid), or
    ii. Patient is refractory to a PI and refractory to an immunomodulatory agent

OR

b. Combination therapy, AND all of the following:
    i. Patient has received at least one prior therapy*, AND
    ii. Used with one of the following regimens:
        1. Velcade (bortezomib) and dexamethasone, or
        2. Velcade (bortezomib), cyclophosphamide and dexamethasone, or
        3. Kyprolis (carfilzomib) and dexamethasone, or
        4. Revlimid (lenalidomide) and dexamethasone, or
        5. Pomalyst (pomalidomide) and dexamethasone, or
        6. Xpovio (selinexor) and dexamethasone

*** Therapy Classes**

IMiDs (Immunomodulatory Drugs)	Proteasome Inhibitors	Chemotherapy
Revlimid (lenalidomide) Pomalyst (pomalidomide) Thalomid (thalidomide)	Velcade (bortezomib) Kyprolis (carfilzomib) Ninlaro (ixazomib)	Doxil (doxorubicin HCl liposome injection) Alkylator chemotherapy: Cytoxan (cyclophosphamide), Melphalan
BCMA-directed CD3 T-cell engager	**Monoclonal Antibodies**	**BCL-2 inhibitor**
Tecvayli (teclistamab-cqyv)	Darzalex (daratumumab) Darzalex Faspro (daratumumab and hyaluronidase-fihj) Empliciti (elotuzumab) Sarclisa (isatuximab)	Venclexta (venetoclax)
Stem Cell Transplantation	**Nuclear export inhibitor**	**CAR-T Cell Agent**
High–dose chemotherapy and stem cell transplantation	Xpovio (Selinexor)	Abecma (idecabtagene vicleucel) Carvykti (ciltacabtagene autoleucel)

Covered Doses

Monotherapy, OR
Combination with Revlimid (lenalidomide) and dexamethasone, OR
Combination with Pomalyst (pomalidomide) and dexamethasone, OR
Combination with Kyprolis (carfilzomib) and dexamethasone
Combination with Xpovio (selinexor) and dexamethasone
Weeks 1 to 8: up to 1,800 mg SC weekly (8 doses)
Weeks 9 to 24: up to 1,800 mg SC every 2 weeks (8 doses)
Weeks 25 onward: up to 1,800 mg SC every 4 weeks until disease progression

Combination with Velcade (bortezomib) and dexamethasone
Weeks 1 to 9: up to 1,800 mg SC weekly (9 doses)
Weeks 10 to 24: up to 1,800 mg SC every 3 weeks (5 doses)
Week 25 onward: up to 1,800 mg SC every 4 weeks until disease progression

Coverage Period
Indefinite

ICD-10:

C90.00, C90.02, C90.10, C90.12, C90.20, C90.22, C90.30, C90.32, Z85.79

Systemic light chain amyloidosis

1. Meets one of the following:
    a. First-line (primary) therapy, and used in combination with bortezomib, cyclophosphamide, and dexamethasone, **OR**
    b. Relapsed or refractory disease, and either of the following:
        i. Being used as a single agent, or
        ii. Being used in combination with bortezomib, cyclophosphamide, and dexamethasone as repeat initial therapy

Covered Doses
Monotherapy OR
Combination with Velcade (bortezomib), cyclophosphamide, and dexamethasone
Weeks 1 to 8: up to 1,800 mg daratumumab and 30,000 units hyaluronidase SC weekly (8 doses)
Weeks 9 to 24: up to 1,800 mg daratumumab and 30,000 units hyaluronidase SC every 2 weeks (8 doses)
Weeks 25 onward: up to 1,800 mg daratumumab and 30,000 units hyaluronidase SC every 4 weeks thereafter

Coverage Period
Monotherapy: Indefinite
Combination with Velcade (bortezomib), cyclophosphamide, and dexamethasone: 2 years

ICD-10:
E85.81, E85.89, E85.9

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for Darzalex Faspro™ (daratumumab and hyaluronidase-fihj) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)
Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information
How supplied:
- 1,800 mg daratumumab and 30,000 units hyaluronidase per 15 mL (120 mg and 2,000 units/mL) solution in a single-dose vial

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- Darzalex Faspro® (daratumumab and hyaluronidase-fihj) [Prescribing information]. Horsham, PA: Janssen Biotech, Inc. 11/2022.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

- National Comprehensive Cancer Network Drugs and Biologics Compendium. Darzalex Faspro (2023). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Multiple Myeloma (Version 1.2022). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Systemic light chain amyloidosis (Version 2.2023). Available at http://www.nccn.org.

(7) Policy Update

Date of last review: 2Q2023
Date of next review: 2Q2024
Changes from previous policy version:

- Section (2): Systemic light chain amyloidosis - Expanded coverage of combination regimen to include repeat initial therapy

  Rationale: NCCN category 2A support

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee