

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)

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 one of the following:
- i. Patient has received at least one prior therapy*, AND used in combination 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: Cytosan (cyclophosphamide), Melphalan
Histone Deacetylase Inhibitor	Monoclonal Antibodies	BCL-2 inhibitor
Farydak (panobinostat)	Darzalex (daratumumab) Darzalex Faspro (daratumumab and hyaluronidase-fihj) Empliciti (elotuzumab) Sarclisa (isatuximab)	Vendexta (venetoclax)
Antibody-Drug Conjugate	Nuclear export inhibitor	CAR-T Cell Agent
Blenrep (belantamab mafodotin-blmf)	Xpovio (Selinexor)	Abecma (idecabtagene vicleuce)l
Peptide-Drug Conjugate	Stem Cell Transplantation	
Pepaxto (melphalan flufenamide)	High-dose chemotherapy and stem cell transplantation	

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 used as a single agent

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

Indefinite

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. Multiple Myeloma (Version.1.2022). Available at <http://www.nccn.org>.
- National Comprehensive Cancer Network. Systemic light chain amyloidosis (Version 1.2022). Available at <http://www.nccn.org>.

(7) Policy Update

Date of last review: 4Q2022

Date of next review: 4Q2023

Changes from previous policy version:

- No clinical change to policy following routine annual review.

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