CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Darzalex Faspro (daratumumab and hyaluronidase-fihj)
BILLING CODE	J9144
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Darzalex Faspro is a combination of daratumumab, a CD38-directed cytolytic antibody, and hyaluronidase, an endoglycosidase used to increase the dispersion and absorption of co-administered drugs, indicated for the treatment of adult patients with light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone (CyBorD) in newly diagnosed patients. In 2021 it became the first drug approved for treating AL amyloidosis. Approval was based on the ANDROMEDA study in which patients treated with CyBorD plus daratumumab experienced a significantly higher rate of complete hematologic response compared to the CyBorD alone group. There is also evidence to support off label use in relapsed cases.
Amyloidosis is a group of protein misfolding disorders characterized by deposition of insoluble protein fibrils in organs and tissues and loss of normal protein function. There are multiple forms of systemic amyloidosis, with AL amyloidosis (also known as light-chain amyloidosis) as the most common type. AL amyloidosis occurs from an abnormality of plasma cells in bone marrow and is closely related to multiple myeloma.

Darzalex Faspro (daratumumab and hyaluronidase-fihj) will be considered for coverage when the following criteria are met:

Light Chain Amyloidosis

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a hematologist/oncologist; AND
3. Member meets ONE of the following:
    a. Newly diagnosed light chain amyloidosis with one or more organs affected (e.g., heart, kidney) AND medication will be used in combination with bortezomib, cyclophosphamide, and dexamethasone;
    b. Relapsed light chain amyloidosis previously treated with at least one prior therapy (note: this is an off-label use); AND
4. Member does NOT have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB.
5. **Dosage allowed/Quantity limit**:
   Newly diagnosed: 1,800 mg/30,000 units (1,800 mg daratumumab and 30,000 units hyaluronidase) administered subcutaneously (1 single dose vial), in combination with bortezomib, cyclophosphamide, and dexamethasone as follows:

Weeks	Schedule
Weeks 1 to 8	weekly (total of 8 doses)
Weeks 9 to 24[a]	every two weeks (total of 8 doses)
Week 25 onwards until disease progression or a maximum of 2 years[b]	every four weeks

[a] First dose of the every-2-week dosing schedule is given at Week 9
[b] First dose of the every-4-week dosing schedule is given at Week 25

QL: 4 vials per 28 days for weeks 1-8; 2 vials per 28 days for weeks 9-24; 1 vial per 28 days thereafter.

For relapsed disease, consult NCCN or another clinical guideline for dosing information (off-label).

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Member has not yet completed 2 years of treatment with Darzalex Faspro; AND
2. Member does not have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB; AND
3. Chart notes must show the member's disease has not progressed since starting treatment.

If all the above requirements are met, the medication will be approved for an additional 12 months, NOT TO EXCEED A TOTAL OF 2 YEARS.

Multiple Myeloma

Any request for cancer must be submitted through NantHealth/Eviti portal.

CareSource considers Darzalex Faspro (daratumumab and hyaluronidase-fihj) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/23/2022	New policy for Darzalex Faspro created.

References:

1. Darzalex Faspro [prescribing information]. Janssen Biotech, Inc.; 2022.
2. NCCN Clinical practice guidelines. Systemic Light Chain Amyloidosis: Version 1.2023. https://www.nccn.org/professionals/physician_gls/pdf/amyloidosis.pdf. Accessed September 23, 2022.
3. Kastritis E, Palladini G, Minnema MC, et al. Daratumumab-Based Treatment for Immunoglobulin Light-Chain Amyloidosis. *N Engl J Med*. 2021;385(1):46-58. doi:10.1056/NEJMoa2028631.
4. Wechalekar AD, Cibeira MT, Gibbs SD, et al. Guidelines for non-transplant chemotherapy for treatment of systemic AL amyloidosis: EHA-ISA working group [published online ahead of print, 2022 Jul 15]. *Amyloid*. 2022;1-15. doi:10.1080/13506129.2022.2093635.
5. Elsayed M, Usher S, Habib MH, et al. Current Updates on the Management of AL Amyloidosis. *J Hematol*. 2020;10(4):147-161. doi:10.14740/jh866.
6. Abdallah M, Sanchorawala V. Update on the Contemporary Treatment of Light Chain Amyloidosis Including Stem Cell Transplantation. *Am J Med*. 2022;135 Suppl 1:S30-S37. doi:10.1016/j.amjmed.2022.01.011.

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