BlueCross BlueShield
Federal Employee Program

DARZALEX FASPRO
(daratumumab and hyaluronidase-fihj)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Darzalex Faspro is a combination of daratumumab, a CD38-directed cytolytic antibody, and hyaluronidase, an endoglycosidase. CD38 is a transmembrane glycoprotein expressed on the surface of hematopoietic cells, including clonal plasma cells in multiple myeloma and light chain (AL) amyloidosis, as well as other cell types. Daratumumab binds to CD38 and inhibits the growth of CD38 expressing tumor cells by inducing apoptosis. Hyaluronidase increases the permeability of the subcutaneous tissue by depolymerizing hyaluronan (1).

Regulatory Status

FDA-approved indications: Darzalex Faspro is indicated for the treatment of adult patients with: (1)

1. Multiple myeloma
    a. In combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant
    b. In combination with bortezomib, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
    c. In combination with lenalidomide and dexamethasone in newly diagnosed patients with multiple myeloma who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
    d. In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
    e. In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
    f. In combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor
    g. In combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy

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h. As monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent

2. Light chain (AL) amyloidosis
   a. In combination with bortezomib, cyclophosphamide, and dexamethasone in newly diagnosed patients
   b. Limitations of Use: Darzalex Faspro is not indicated and is not recommended for the treatment of patients with light chain (AL) amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB outside of controlled clinical trials.

Patients being treated for light chain (AL) amyloidosis should be treated with Darzalex Faspro until disease progression, unacceptable toxicity or a maximum of 2 years (1).

The safety and effectiveness of Darzalex Faspro in pediatric patients less than 18 years of age have not been established (1).

Summary

Darzalex Faspro is a combination of daratumumab, a CD38-directed cytolytic antibody, and hyaluronidase, an endoglycosidase. CD38 is a transmembrane glycoprotein expressed on the surface of hematopoietic cells. Daratumumab binds to CD38 and inhibits the growth of CD38 expressing tumor cells by inducing apoptosis. Hyaluronidase increases the permeability of the subcutaneous tissue by depolymerizing hyaluronan. The safety and effectiveness of Darzalex Faspro in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Darzalex Faspro while maintaining optimal therapeutic outcomes.

References

1. Darzalex Faspro [package insert]. Horsham, PA: Janssen Biotech, Inc.; July 2024.
2. NCCN Drugs & Biologics Compendium® Daratumumab and hyaluronidase-fihj 2025. National Comprehensive Cancer Network, Inc. Accessed on January 24, 2025.