BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
1310 G Street, N.W.
Washington, D.C. 20005
202.942.1000
Fax 202.942.1125

5.21.147

Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Antineoplastic Agents	**Original Policy Date:**	May 29, 2020
Subject:	Darzalex Faspro	**Page:**	1 of 5

Last Review Date: March 12, 2021

Darzalex Faspro

Description

Darzalex Faspro (daratumumab and hyaluronidase-fihj)

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 multiple myeloma and other cell types and tissues. 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 indication: Darzalex Faspro is indicated for the treatment of adult patients with: (1)

1. Multiple myeloma
    a. In combination with bortezomib, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
    b. 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
    c. In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
    d. In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy

e. 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).

Related Policies
Darzalex, Sarclisa

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Darzalex Faspro may be considered **medically necessary** in patients 18 years of age or older for the treatment of multiple myeloma or light chain (AL) amyloidosis and if the conditions indicated below are met.

Darzalex Faspro is considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have **ONE** of the following:

1. Multiple myeloma (MM)
   a. Newly diagnosed multiple myeloma (MM) **AND ONE** of the following:
      a. Patient is eligible for autologous stem cell transplant
         1. Used in combination with bortezomib, thalidomide, and dexamethasone
      ii. Patient is ineligible for autologous stem cell transplant
         1. Used in combination with **ONE** of the following:
            a. Bortezomib, melphalan, and prednisone
            b. Lenalidomide and dexamethasone
   b. Patient has received at least one prior therapy and will used in combination with **ONE** of the following:
      i. Lenalidomide and dexamethasone
      ii. Bortezomib and dexamethasone
   c. Patient has received at least three prior lines of therapy, including the following:
      i. Proteasome inhibitor (PI)
      ii. Immunomodulatory agent
   d. Patients must have had a double-refractory failure to a proteasome inhibitor (PI) and an immunomodulatory agent

2. Newly diagnosed light chain (AL) amyloidosis
   a. Used in combination with bortezomib, cyclophosphamide, and dexamethasone
   b. Patient does **NOT** have NYHA Class IIIB or Class IV cardiac disease
   c. Patient does **NOT** have Mayo Stage IIIB light chain (AL) amyloidosis

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have **ONE** of the following:

1. Multiple myeloma (MM)
   a. **NO** disease progression or unacceptable toxicity
2. Light chain (AL) amyloidosis

a. **NO** disease progression or unacceptable toxicity
b. Treatment with Darzalex Faspro has not exceeded 2 years
c. Patient does **NOT** have NYHA Class IIIB or Class IV cardiac disease
d. Patient does **NOT** have Mayo Stage IIIB light chain (AL) amyloidosis

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Duration 12 months (**ONE** renewal **ONLY** for light chain amyloidosis)

Rationale

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, including multiple myeloma and other cell types and tissues. 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.; February 2021.

Policy History

Date	Action
May 2020	Addition to PA

September 2020	Annual review
February 2021	Addition of indication: newly diagnosed MM patients who are eligible for autologous stem cell transplant, in combination with bortezomib, thalidomide, and dexamethasone. Addition of indication: light chain (AL) amyloidosis
March 2021	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.