

#### DARZALEX FASPRO (daratumumab and hyaluronidase-fihj)

### **Pre - PA Allowance**

None

# **Prior-Approval Requirements**

Age 18 years of age and older

#### Diagnoses

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

1. Multiple myeloma (MM)

#### **AND ONE** of the following:

- a. Newly diagnosed multiple myeloma (MM) AND ONE of the following:
  - i. 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
  - ii. Patient is **eligible** for autologous stem cell transplant
    - 1. Used in combination with **ONE** of the following:
      - a. Bortezomib, lenalidomide, and dexamethasone
      - b. Bortezomib, thalidomide, and dexamethasone
- b. Used in combination with lenalidomide and dexamethasone
  - i. Patient has relapsed or refractory multiple myeloma **AND** patient has received at least one prior therapy
- c. Used in combination with bortezomib and dexamethasone
  - i. Patient has received at least one prior therapy
- d. Used in combination with pomalidomide and dexamethasone
  - i. Patient has received at least one prior therapy including lenalidomide and a proteasome inhibitor (PI)
- e. Used in combination with carfilzomib and dexamethasone
  - i. Patient has relapsed or refractory multiple myeloma **AND** patient has received one to three prior lines of therapy
- f. Used as monotherapy AND ONE of the following:
  - Patient has received at least three prior lines of therapy, including a proteasome inhibitor (PI) and immunomodulatory agent



#### DARZALEX FASPRO (daratumumab and hyaluronidase-fihj)

- ii. Patient has 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 Limits**

Duration 12 months

# Prior – Approval Renewal Requirements

Age 18 years of age and older

#### Diagnoses

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

## Prior - Approval Renewal Limits

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