

Daratumumab IV (DARZALEX) and Daratumumab/hyaluronidase-fijh SubQ (DARZALEX FASPRO) Criteria for Use July 2021

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or [PBM INTRANet](#) for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive daratumumab or daratumumab/hyaluronidase.

- Known hypersensitivity to daratumumab
- Unable to be observed in clinic for an extended period following the first dose
- Absolute Neutrophil Count (ANC) < 1000/mm³
- Hemoglobin < 8 g/dL; must transfuse to hemoglobin > 8 g/dL prior to therapy initiation
- Platelet count < 50,000/mm³ (< 30,000/mm³ if myeloma involvement in bone marrow > 50%)
- Estimated creatinine clearance (CrCl) < 15 ml/min
- New York Heart Association (NYHA) Class III or IV heart failure
- Ongoing or active systemic infection including active hepatitis B or C or known HIV infection
- Patient has not been screened for Hepatitis B Virus (HBV)
- Pregnancy (e.g. known or positive pregnancy test)
- Breastfeeding

Inclusion Criteria

Treatment for one of the following indications, per FDA labeling, must apply to meet criteria.

- Multiple myeloma
- Light chain amyloidosis

Additional Inclusion Criteria

- Care is provided by a VA/VA Community Care hematology/oncology provider
- Goals of care and role of Palliative Care consult have been discussed and documented
- Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- Type and screen patients for Red Blood Cell antibodies PRIOR to starting therapy
- Provider has informed Blood Bank that patient will be starting daratumumab
- Antiviral prophylaxis to prevent herpes zoster reactivation to start within 1 week after starting daratumumab and continue for 3 months following the end of treatment
- Female patients of child-bearing potential and male patients with female partners of child-bearing potential: counseling provided on contraception (use during treatment and 3 months after) and risks vs. benefits of treatment.