JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP068
		Effective Date	06/01/2022
		Review Date	04/20/2022
	Subject **Darzalex Faspro**	*Revision Date*	04/20/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Darzalex Faspro

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I. POLICY

Darzalex Faspro (daratumumab and hyaluronidase-fihj) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Darzalex Faspro may be approved for patients who meet the following:
   1. Multiple Myeloma
      a. Documentation has been submitted showing Darzalex will be used in one of the following clinical situations:
         I. Combination with lenalidomide and dexamethasone in patients identified as one of the following:
            - Not a candidate for transplant and the regimen will be used as primary therapy
            - Has received one or more previous therapies
         II. Combination with bortezomib, melphalan, and prednisone as primary therapy in patients that are not candidates for transplant.
         III. Combination with bortezomib, thalidomide, and dexamethasone as primary therapy in patients that are eligible for transplant and limited to maximum of 16 doses
         IV. Combination with bortezomib, lenalidomide and dexamethasone as primary therapy in patients that are eligible for transplant.
         V. Combination with bortezomib and dexamethasone in patients that have received at least one prior therapy
         VI. Combination with carfilzomib and dexamethasone in patients that have relapsed or progressive disease
         VII. Combination with pomalidomide and dexamethasone in patients who have received at least one prior therapy including a proteasome inhibitor (PI) and an immunomodulatory agent.
         VIII. Monotherapy in patients that have received at least three prior therapies, including a PI and an immunomodulatory agent, or patients that have double refractory to a PI and an immunomodulatory agent.
         IX. Combination with cyclophosphamide, bortezomib, and dexamethasone
   2. Light Chain Amyloidosis
      a. Documentation has been submitted showing one of the following:

I. Patient has been newly diagnosed with light chain amyloidosis and Darzalex Faspro used in combination with bortezomib, cyclophosphamide and dexamethasone
II. Patient has been diagnosed with relapsed or refractory light chain amyloidosis

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient is continuing to tolerate the regimen and there has not been disease progression while on treatment
   1. Specific caveats:
      a. Continuation of therapy of Darzalex Faspro in combination with bortezomib, thalidomide, and dexamethasone requires documentation that the patient still meets the initial criteria noted above
      b. Continuation of therapy for newly diagnosed light chain amyloidosis: Approval is limited to a maximum treatment duration of 24 months

IV. EXCLUSIONS

A. Darzalex Faspro will not be covered for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/ HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, daratumumab, 10 mg and hyaluronidase -fihj	J9144

VII. REFERENCES

1. Darzalex Faspro [prescribing information]. Horsham, PA: Janssen Biotech Inc; July 2021.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. https:// www.nccn.org. Accessed March 28, 2022.

VIII. APPROVALS

Signature on file at JHHC

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