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| JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE | Johns Hopkins HealthCare LLC<br>**Pharmacy Public**<br>**Medical Management Drug Policies** | *Policy Number* | MMDP045 |
| | | *Effective Date* | 06/01/2022 |
| | | *Review Date* | 04/20/2022 |
| | *Subject*<br>**Darzalex** | *Revision Date* | 04/20/2022 |
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This document applies to the following Participating Organizations:

US Family Health Plan

**Keywords**: Darzalex

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## I. POLICY

A. Darzalex (daratumumab) 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 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
         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 two prior therapies including a proteasome inhibitor (PI) and an immunomodulatory agent.
         VIII. Combination with cyclophosphamide, bortezomib, and dexamethasone.
         IX. 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.
         X. 1.
   2. Systemic Light Chain Amyloidosis
      a. Documentation has been submitted showing the patient has relapsed or refractory disease.

## III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
   1. Regimen-specific limitation: When used in combination with bortezomib, thalidomide, and dexamethasone, Darzalex will be approved for a maximum of 16 doses

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. Regimen-specific limitation: Continuation of Darzalex in combination with bortezomib, thalidomide will require that patients must still meet the initial criteria

## IV. EXCLUSIONS

A. Darzalex 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 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 | J9145 |

## VII. REFERENCES

1. Darzalex [prescribing information]. Horsham, PA: Janssen Biotech Inc; January 2022.
2. The NCCN Drugs & Biologics Compendium 2022 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 4, 2022.

## VIII. APPROVALS

Signature on file at JHHC

| DATE OF REVISION | SUMMARY OF CHANGE |
|---|---|
| 04/20/2022 | Policy Creation |

Review Dates: 04/20/2022

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