Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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Darzalex (daratumumab)

DRUG.00082

Override	Approval Duration
Prior Authorization	1 year

Medication
Darzalex (daratumumab)

APPROVAL CRITERIA

Requests for Darzalex (daratumumab) **may be approved** for the treatment of individuals with multiple myeloma, including plasma-cell leukemia, when treatment meets the following criteria I., II., III., or IV., and V.

I. Darzalex (daratumumab) is being used in combination with melphalan, prednisone and a proteasome inhibitor (PI) (for example, bortezomib) for newly diagnosed multiple myeloma for those who are ineligible for stem cell transplantation; **OR**
II. Darzalex is being used as a single agent for individuals with relapsed or refractory disease following therapy with at least two prior lines of therapy including a PI (for example, bortezomib, carfilzomib, or ixazomib) and an immunomodulatory agent (for example, thalidomide, lenalidomide, or pomalidomide); **OR**
III. Darzalex is being used as combination therapy for individuals with relapsed or refractory disease following therapy with at least one prior line of therapy including a PI or an immunomodulatory agent when used with one of the following:
    A. Bortezomib and dexamethasone; **OR**
    B. Lenalidomide and dexamethasone;

    OR
IV. Darzalex is being used in combination with pomalidomide and dexamethasone for individuals with relapsed or refractory disease following therapy with at least two prior lines of therapy including a PI and lenalidomide; **AND**
V. Individual has not received treatment with Darzalex or another anti-CD38 agent.

Darzalex (daratumumab) **may not be approved** when the above criteria are not met, and for all other conditions, including but not limited to **any** of the following:

I. Presence of human immunodeficiency virus (HIV) infection or hepatitis B virus infection; **OR**
II. The reason for treatment is other than for a diagnosis of multiple myeloma, including plasma-cell leukemia.

Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

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