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DARZALEX (daratumumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Darzalex (daratumumab) is a CD38 monoclonal antibody indicated for the treatment of multiple myeloma (MM) as monotherapy in patients who have received at least three prior lines of therapy. Additionally, Darzalex can be used in combination with various other oncology medications for the treatment of multiple myeloma in newly diagnosed patients, as well as in patients that have failed prior lines of therapy. Multiple myeloma is a cancer that forms in a type of white blood cell called plasma cells. CD38 is a transmembrane protein found on the surface of hematopoietic cells (cells that give rise to all other blood cells), including multiple myeloma and other cell types. Darzalex binds to the CD38 receptors and inhibits the growth of tumor cells by inducing cell death (1-2).

Regulatory Status

FDA-approved indications: Darzalex is a human CD38-directed monoclonal antibody indicated for the treatment of adult patients with multiple myeloma: (1)

1. In combination with lenalidomide and dexamethasone in newly diagnosed patients with multiple myeloma who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
2. In combination with bortezomib, melphalan, and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant
3. In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
4. In combination with bortezomib and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy
5. In combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
6. In combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor
7. As monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent



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Safety and effectiveness of Darzalex have not been established in pediatric patients (1).

Summary

Darzalex (daratumumab) is a monoclonal antibody indicated for the treatment of patients with multiple myeloma as monotherapy, who have received at least three prior lines of therapy. Additionally, this can be used in combination with various other oncology medications for the treatment of multiple myeloma in newly diagnosed patients, as well as in patients that have failed prior lines of therapy. Safety and effectiveness of Darzalex have not been established in pediatric patients (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Darzalex while maintaining optimal therapeutic outcomes.

References

1. Darzalex [package insert]. Horsham, PA: Janssen Biotech, Inc.; June 2024.
2. NCCN Drugs & Biologics Compendium® Daratumumab 2025. National Comprehensive Cancer Network, Inc. Accessed on January 24, 2025.