# Specialty Guideline Management

**DARZALEX (daratumumab)**

## POLICY

### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. In combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy
B. 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
C. As monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor and an immunomodulatory agent or who are double-refractory to a proteasome inhibitor and an immunomodulatory agent
D. 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.

All other indications are considered experimental/investigational and are not covered benefits.

### II. CRITERIA FOR INITIAL APPROVAL

**Multiple myeloma**
Authorization of 12 months may be granted for the treatment of multiple myeloma.

### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

### IV. REFERENCES


1. Darzalex [package insert]. Horsham, PA: Janssen Biotech Inc; May 2018.
2. **The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 10, 2017.**
3. The NCCN Clinical Practice Guidelines in Oncology® Multiple Myeloma (Version 2.2018) © 2017 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed **October 10, 2017.**