



POLICIES AND PROCEDURE MANUAL

Policy: MBP 139.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Darzalex (daratumumab)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:

Darzalex (daratumumab)

II. Purpose/Objective:

To provide a policy of coverage regarding Darzalex (daratumumab)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

Darzalex (daratumumab) is an IgG1k human monoclonal antibody directed against CD38. CD38 is a cell surface glycoprotein which is highly expressed on myeloma cells, yet is expressed at low levels on normal lymphoid and myeloid cells (Lokhorst 2015). By binding to CD38, daratumumab inhibits the growth of CD38 expressing tumor cells by inducing apoptosis directly through Fc mediated cross linking as well as by immune-mediated tumor cell lysis through complement dependent cytotoxicity, antibody dependent cell mediated cytotoxicity, and antibody dependent cellular phagocytosis.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Darzalex (daratumumab) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation a diagnosis of multiple myeloma **AND**

If newly diagnosed multiple myeloma (transplant **ineligible**):

- Medical record documentation that the member is not eligible for stem-cell transplantation (e.g. coexisting conditions, age greater than 65, etc.) **AND**
- Medical record documentation that Darzalex will be given in combination with one of the following options:
 - Bortezomib (Velcade)*, melphalan (Alkeran, Evomela), AND prednisone [VMP] **OR**
 - Lenalidomide (Revlimid)* AND dexamethasone

OR

If newly diagnosed multiple myeloma (transplant **eligible**):

- Medical record documentation that the member is eligible for stem-cell transplantation **AND**
- Medical record documentation that Darzalex will be given in combination with bortezomib (Velcade)*, thalidomide (Thalomid)*, and dexamethasone (DVTd)

OR

If relapsed/refractory multiple myeloma:

- One of the following:
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three prior lines of therapy including a proteasome inhibitor [including but not limited to bortezomib (Velcade)*, carfilzomib (Kyprolis)*, or ixazomib (Ninlaro)*] and an immunomodulatory agent [including but not limited to pomalidomide (Pomalyst)*, lenalidomide (Revlimid)*, thalidomide (Thalomid)*] **OR**
 - Medical record documentation that the patient is double-refractory to a proteasome inhibitor [including but not limited to bortezomib (Velcade)*, carfilzomib (Kyprolis)*, or ixazomib (Ninlaro)*] and an immunomodulatory agent [including but not limited to pomalidomide (Pomalyst)*, lenalidomide (Revlimid)*, thalidomide (Thalomid)*] **OR**
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two prior lines of therapy including lenalidomide and a proteasome inhibitor [including but not limited to bortezomib (Velcade)*, carfilzomib (Kyprolis)*, or ixazomib (Ninlaro)*] AND Darzalex will be prescribed in combination with pomalidomide (Pomalyst)* and dexamethasone **OR**
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior therapy including a proteasome inhibitor [including but not limited to bortezomib (Velcade)*, carfilzomib (Kyprolis)*, or ixazomib (Ninlaro)*] or an immunomodulatory agent [including but not limited to pomalidomide (Pomalyst)*, lenalidomide (Revlimid)*, thalidomide (Thalomid)*] AND one of the following:
 - Medical record documentation that Darzalex will be prescribed in combination with lenalidomide (Revlimid)* and dexamethasone **OR**
 - Medical record documentation that Darzalex will be prescribed in combination with bortezomib (Velcade)* and dexamethasone **OR**
 - Medical record documentation that Darzalex will be prescribed in combination with carfilzomib (Kyprolis)* and dexamethasone

*prior authorization may be required

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Darzalex [prescribing information]. Horsham, PA: Janssen Biotech Inc; April 2025.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 1/19/2016

Revised: 1/17/17 (updated indication), 7/17/18 (updated indication), 9/17/19 (updated indication), 11/19/19 (transplant status), 10/22/20 (combo with Kyprolis), 9/21/21 (relapsed/refractory two prior lines with lenalidomide and proteasome), 9/21/22 (Medicaid PARP statement), 9/12/23 (LOB carve out, Medicaid business segment), 12/30/23 (references added), 8/29/24 (LOB table, taglines)

Reviewed: 10/28/16, 10/31/17, 5/31/19, 7/29/25

MA UM Committee approval: 12/31/23, 12/31/24, 9/10/25

DHS PARP approval: 8/6/25