Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 230.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Darzalex Faspro (daratumumab/hyaluronidase)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Darzalex Faspro (daratumumab/hyaluronidase)

II. Purpose/Objective:
To provide a policy of coverage regarding Darzalex Faspro (daratumumab/hyaluronidase)

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

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 Faspro (daratumumab/hyaluronidase) is an Anti-CD38 monoclonal antibody combination therapy. Daratumumab is an IgG1κ human monoclonal antibody directed against CD38. CD38 is a cell surface glycoprotein which is highly expressed on myeloma cells. 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. Hyaluronidase increases permeability of the subcutaneous tissue by depolymerizing hyaluronan. At the recommended dose, hyaluronidase acts locally and the effects are reversible; permeability of subcutaneous tissue is restored within 24 to 48 hours.

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

Darzalex Faspro (daratumumab/hyaluronidase) 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 Faspro will be given in combination with one of the following options:
  - Bortezomib (Velcade)*, melphalan (Alkeran, Evomela), AND prednisone [VMP] **OR**
  - Lenalidomide (Revlimid)* AND dexamethasone

  AND
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

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 Faspro will be given in combination with bortezomib (Velcade)*, thalidomide (Thalomid)*, and dexamethasone (DVTd) **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

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 one prior line of therapy including lenalidomide (Revlimid) and a proteasome inhibitor [including but not limited to bortezomib (Velcade)*, carfilzomib (Kyprolis)*, or ixazomib (Ninlaro)*] AND Darzalex Faspro 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 Faspro will be prescribed in combination with lenalidomide (Revlimid)* and dexamethasone **OR**
  - Medical record documentation that Darzalex Faspro will be prescribed in combination with bortezomib (Velcade)* and dexamethasone **OR**
  - Medical record documentation that Darzalex Faspro will be prescribed in combination with carfilzomib (Kyprolis)* and dexamethasone

AND

- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

OR

If light-chain (AL) amyloidosis:

- Prescription written by or in consultation with and hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of light-chain (AL) amyloidosis **AND**
- Medical Record documentation that the patient does NOT have New York Heart Association (NYHA) Class IIIB (defined by marked limitation of physical activity, comfortable at rest, less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain, symptomatic with recent history of dyspnea at rest) or Class IV heart failure, or mayo cardiac stage IIIB **AND**
- Medical record documentation that Darzalex Faspro will be used in combination with bortezomib (Velcade)*, cyclophosphamide and dexamethasone **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Note: Mayo Cardiac Stage IIIB defined as NT-proBNP > 8500 ng/L

*Prior authorization may be required

AUTHORIZATION DURATION (all diagnoses except light-chain (AL) amyloidosis): Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Continued disease improvement or lack of disease progression **AND**
- An FDA approved dose and dosing interval

The medication will no longer be covered if patient experiences toxicity or worsening of disease or a non-FDA approved dose or dosing interval.

For requests exceeding United States Food and Drug Administration (FDA) labeling, National Comprehensive Cancer Network® (NCCN), or indication specific peer-reviewed literature, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

AUTHORIZATION DURATION (for light-chain (AL) amyloidosis): Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Continued disease improvement or lack of disease progression **AND**
- An FDA approved dose and dosing interval.

The medication will no longer be covered if patient experiences toxicity, worsening of disease, or a non-FDA approved dose or dosing interval.

Authorization of Darzalex Faspro for light-chain (AL) amyloidosis should not exceed the FDA-approved treatment duration of 2 years (24 months). For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

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 Faspro [prescribing information]. Horsham, PA: Janssen Biotech Inc; July 2024.

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

Devised: 4/29/21

Revised: 9/21/21 (relapsed/refractory one prior line with lenalidomide addition, with carfilzomib deletion), 1/18/22 (relapsed/refractory with carfilzomib now indicated), 2/15/22 (Per DHS NYHA Class IIIb definition), 2/7/23 (LOB carve out, Medicaid PARP statement, Medicaid business segment), 12/28/23 (references added), 1/16/25 (LOB table, taglines), 3/27/25 (dosing criteria, auth duration)

Reviewed: 1/18/24

MA UM Committee approval: 12/31/23, 12/31/24, 4/29/25

DHS PARP approval: 4/23/25