

CLINICAL GUIDELINES FOR MEDICAL NECESSITY

MEDICAL ONCOLOGY

Daratumumab and hyaluronidase-fihj (Darzalex Faspro[®])

Version: 1.0

EFFECTIVE DATE: 1/1/2024



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Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at <http://www.cms.gov> for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Daratumumab and hyaluronidase-fihj (Darzalex Faspro): Discussion

Daratumumab and hyaluronidase-fihj is a CD38-targeted monoclonal antibody in a subcutaneous formulation. The monoclonal antibody attaches itself to the CD38 protein expressed on the surface of hematopoietic cells, including plasma cells in multiple myeloma and light chain amyloidosis (AL), as well as other cell types. Daratumumab bound to CD38 inhibits the growth of CD38-expressing tumor cells by inducing cell death. The hyaluronidase helps daratumumab to be injected into the skin and absorbed into the body. ^{1,2,3}

Daratumumab and hyaluronidase-fihj is a combination of daratumumab, a CD38-directed cytolytic antibody, and hyaluronidase, approved by the FDA and indicated for the treatment of adult patients with:

Multiple Myeloma

1. In combination with bortezomib, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant; OR
2. In combination with lenalidomide and dexamethasone in newly diagnosed patients 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; OR
3. In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant; OR
4. In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy; OR
5. In combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor; OR
6. In combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy; OR
7. As a monotherapy, in patients 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. ²

Systemic Light Chain Amyloidosis

1. In combination with bortezomib, cyclophosphamide, and dexamethasone in newly diagnosed patients. This indication is approved under accelerated approval based on response rate. ²

The National Comprehensive Cancer Network (NCCN) endorses daratumumab and hyaluronidase-fihj in the following cancer types: multiple myeloma and systemic light-chain amyloidosis. ^{5,6}

Daratumumab and hyaluronidase-fihj: Definitions

- **CD38 protein** –A glycoprotein that plays a role in cell adhesion, migration, and signal transduction. ⁴
- **Food and Drug Administration (FDA)** – The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- **National Comprehensive Cancer Network (NCCN)** - An alliance of thirty-two leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.

Daratumumab and hyaluronidase-fihj: Policy

Daratumumab and hyaluronidase-fihj will be considered for coverage when the following criteria are met:

Multiple Myeloma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Used as a single agent or in combination with other systemic therapies where intravenous daratumumab is recommended. ⁵

Systemic Light Chain Amyloidosis

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. As a single agent for treatment for relapsed/refractory disease; OR

- Treatment for a newly diagnosed disease or for relapsed/refractory disease as a repeat of initial therapy if relapse-free for several years in combination with bortezomib, cyclophosphamide, and dexamethasone.⁶

Note: Coverage of daratumumab and hyaluronidase-fihj will be provided for an FDA-approved indication or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1, 2A, or 2B recommendation or when all criteria are met.

Authorization Period and Renewal Criteria

- Initial Authorization Period: 12 months
- Renewal Criteria: No evidence of disease progression or unacceptable toxicity
- Renewal Authorization Period: 12 months

Daratumumab and hyaluronidase-fihj: References

- Darzalex Faspro Resource Information. <https://www.darzalexhcp.com/multiple-myeloma-resources>. Accessed June 15, 2023.
- DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj): Package Insert. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761036s044lbl.pdf. Accessed June 15, 2023.
- What is DARZALEX FASPRO®? <https://www.darzalex.com/faspro/what-is-darzalex-faspro>. Accessed on June 15, 2023.
- Advances in Immunology. Unraveling the mysteries of plasma cells. <https://www.sciencedirect.com/topics/neuroscience/cd38>. Accessed on June 6, 2023.
- National Comprehensive Cancer Network Guidelines. Multiple Myeloma (Version 3.2023). https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf Accessed June 15, 2023.
- National Comprehensive Cancer Network Guidelines. Systemic Light Chain Amyloidosis (Version 2.2023). https://www.nccn.org/professionals/physician_gls/pdf/amyloidosis.pdf. Accessed June 15, 2023.

Daratumumab and hyaluronidase-fihj: Coding (CPT®, ICD 10 and HCPCS) *

*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment. CPT codes are available through the AMA.

CODE	DESCRIPTION
C90.0	Multiple Myeloma
E85.81	Systemic Light Chain Amyloidosis

J9145	Daratumumab and hyaluronidase-fihj (Faspro®)
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Daratumumab and hyaluronidase-fihj: Revision and Review History

No.	Description	Date(s)
1	Original Effective Date:	1/1/2024
2	Policy Review Dates:	6/20/2023
3	Policy Revision Dates:	
4	Department Owner:	Medical Affairs
5	NH Advisory Committee Approval Dates:	9/13/2023
6	Revision Changes:	