Pharmacy Policy Bulletin: J-1006 Hemady (dexamethasone) – Commercial and Healthcare Reform	
Number: J-1006	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.)** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1006-006	**Original Date:** 11/06/2019
Effective Date: 10/28/2024	**Review Date:** 10/02/2024

Drugs Product(s):	• Hemady (dexamethasone)
FDA-Approved Indication(s):	• Treatment of adults with multiple myeloma in combination with other anti-myeloma agents

Background:	• Dexamethasone is a corticosteroid with anti-inflammatory effects and low mineralocorticoid activity. Dexamethasone induces apoptosis of multiple myeloma cells, however the precise mechanism of action in multiple myeloma is unknown.
	• Multiple myeloma is a cancer of plasma cell overgrowth which can lead to anemia, thrombocytopenia, and leukopenia. Additional complications of multiple myeloma may include fatigue, bruising, increased bleeding, bone fractures, hypercalcemia, increased infections, and kidney damage.
	• The National Comprehensive Cancer Network (NCCN) includes dexamethasone in multiple myeloma regimens.
	• Hemady is indicated for use in multiple myeloma in combination with other anti-myeloma agents. Examples of other commonly used anti-myeloma agents include bortezomib, lenalidomide, cyclophosphamide, carfilzomib, ixazomib, daratumumab, elotuzumab, doxorubicin, and pomalidomide.
	• Prior authorization is utilized to ensure appropriate use per the FDA-labeled indications. Step therapy contains criteria for prior utilization of products that are equally efficacious but less costly.
	• Prescribing Considerations:
	  ○ Hemady is contraindicated in patients with a hypersensitivity to dexamethasone and patients with systemic fungal infections.
	  ○ Hemady readily crosses the placenta and can cause adverse developmental outcomes. Hemady should only be used during pregnancy if the potential benefits to the mother justify the potential risks to the fetus.

	○ Contraception should be used in men and women of reproductive potential during treatment with Hemady and for at least one month following the last dose. ○ Advise women not to breastfeed during treatment and for 2 weeks after the last dose.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Hemady may be approved when all of the following criteria are met **(A. through D.)**:

A. The member is 18 years of age or older.
B. The member has a diagnosis of multiple myeloma (ICD-10 C90).
C. The member is using Hemady in combination with other anti-myeloma agents.
D. The member has experienced therapeutic failure or intolerance to generic dexamethasone.

II. Reauthorization

When a benefit, reauthorization of Hemady may be approved when the following criterion is met **(A.)**:

A. The prescriber attests that the member is tolerating therapy and has experienced a therapeutic response defined as one (1) of the following **(1. or 2.)**:
  1. Disease improvement
  2. Delayed disease progression

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

IV. Coverage of oncology medications listed in this policy may be approved on a case-by-case basis per indications supported in the most current NCCN guidelines.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Hemady [package insert]. Jerusalem, Israel: Dexcel Pharma Technologies Ltd; June 2024.
2. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; 2017. Accessed August 20, 2020.
3. American Cancer Society. Multiple Myeloma. Available at: https://www.cancer.org/cancer/multiple-myeloma/about.html. Accessed August 20, 2020.

4. NCCN Guidelines Version 1.2025 Multiple Myeloma. National Comprehensive Cancer Network. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed September 17, 2024.