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Section: Prescription Drugs Effective Date: July 1, 2022

Subsection: Corticosteroids Original Policy Date: October 9, 2020

Subject: Hemady Page: 1 of 3

Last Review Date: June 16, 2022

# Hemady

### **Description**

## Hemady (dexamethasone) tablets

### **Background**

Hemady (dexamethasone) is a corticosteroid with anti-inflammatory effects and low mineralocorticoid activity. Dexamethasone induces apoptosis in multiple myeloma cells (1).

### **Regulatory Status**

FDA-approved indication: Hemady is a corticosteroid indicated in combination with other antimyeloma products for the treatment of adults with multiple myeloma (1).

The recommended dosage of Hemady is 20 mg or 40 mg, orally, once daily, on specific days depending on the treatment regimen. Refer to the Prescribing Information of other anti-myeloma products used in combination with Hemady for specific Hemady dosing (1).

Hemady can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with Hemady and for at least 1 month after the last dose (1).

The safety and effectiveness of Hemady in pediatric patients have not been established (1).

### **Related policies**

## **Policy**

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This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Hemady may be considered **medically necessary** in patients 18 years of age or older with multiple myeloma and if the conditions indicated below are met.

Hemady may be considered **investigational** in patients less than 18 years of age and for all other indications.

## **Prior-Approval Requirements**

**Age** 18 years of age and older

### **Diagnosis**

Patient must have the following:

- 1. Multiple myeloma (MM)
  - a. Used in combination with another anti-myeloma therapy
  - b. Patient has **ONE** of the following:
    - i. An intolerance to a different dexamethasone tablet
    - ii. Treatment failure after a trial of a different dexamethasone tablet
  - Female patients of reproductive potential only: patient will be advised to use effective contraception during treatment with Hemady and for 1 month after the final dose

## Prior – Approval Renewal Requirements

Age 18 years of age and older

#### **Diagnosis**

Patient must have the following:

- 1. Multiple myeloma (MM)
  - a. Used in combination with another anti-myeloma therapy
  - Female patients of reproductive potential only: patient will be advised to use effective contraception during treatment with Hemady and for 1 month after the last dose

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## **Policy Guidelines**

### Pre - PA Allowance

None

## **Prior - Approval Limits**

**Duration** 12 months

## Prior – Approval Renewal Limits

Same as above

### Rationale

### **Summary**

Hemady (dexamethasone) is a corticosteroid with anti-inflammatory effects and low mineralocorticoid activity. Dexamethasone induces apoptosis in multiple myeloma cells. The safety and effectiveness of Hemady in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Hemady while maintaining optimal therapeutic outcomes.

#### References

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**Keywords** 

1. Hemady [package insert]. East Windsor, NJ: Acrotech Biopharma LLC; June 2021.

Policy History	
Date	Action
October 2020	Addition to PA
December 2020	Annual review
June 2022	Annual review and reference update

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.