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5.22.001

Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Corticosteroids	**Original Policy Date:**	October 9, 2020
Subject:	Hemady	**Page:**	1 of 3

Last Review Date: December 8, 2023

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 anti-myeloma 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

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** if the conditions indicated below are met.

Hemady may be considered **investigational** 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
    b. 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
    b. 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

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

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
March 2023	Annual review. Changed policy number to 5.22.001
December 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.