Hemady™ (dexamethasone)

Policy # 00744
Original Effective Date: 04/12/2021
Current Effective Date: 04/08/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Hemady™‡ (dexamethasone) for the treatment of multiple myeloma to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Hemady (dexamethasone) will be considered when the following criteria are met:

- Patient has a diagnosis of multiple myeloma; AND
- Hemady will be used in combination with another anti-myeloma product (e.g., lenalidomide); AND
- There is clinical evidence or patient history that suggests the use of GENERIC dexamethasone 4 mg tablets will be ineffective or cause an adverse reaction to the patient. *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Hemady (dexamethasone) when there is no evidence that generic dexamethasone 4 mg tablets will be ineffective or cause an adverse reaction to the member to be **not medically necessary.****

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Hemady (dexamethasone) when patient selection criteria are not met (except those denoted above as **not medically necessary****) to be **investigational.***

Background/Overview

Hemady is a formulation of dexamethasone containing 20 mg of dexamethasone per tablet that is indicated for the treatment of adults with multiple myeloma in combination with another anti-myeloma product. The recommended dose is determined by the prescribing information of the anti-myeloma product being used but is typically 20 or 40 mg once daily on specific days. Dexamethasone is also available as generic 4 mg tablets which provide a more economical treatment option.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Hemady is indicated in combination with other anti-myeloma products for the treatment of adults with multiple myeloma.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy ensure that this medication is being used for its FDA approved indication and take into consideration whether or not the patient can tolerate the generic dexamethasone 4 mg tablet. Taking multiple generic dexamethasone 4 mg tablets offers a vastly more economical option for therapy compared to Hemady.

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References

1. Hemady [package insert]. Acrotech Biopharma LLC. East Windsor, NJ. Updated Oct 2020.

Policy History

Original Effective Date: 04/12/2021
Current Effective Date: 04/08/2024
03/04/2021 Medical Policy Committee review
03/10/2021 Medical Policy Implementation Committee approval. New policy.
03/03/2022 Medical Policy Committee review
03/09/2022 Medical Policy Implementation Committee approval. No change to coverage.
03/02/2023 Medical Policy Committee review
03/08/2023 Medical Policy Implementation Committee approval. No change to coverage.
03/07/2024 Medical Policy Committee review
03/13/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 03/2025

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

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1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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