DOCUMENT REVISION HISTORY LOG

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MEMORIAL HERMANN HEALTH PLAN HOLDINGS, LLC
POLICY

POLICY TITLE: MHHP MEDM-MA BIO-007 Biosimilar First

PUBLICATION DATE: 05/26/2025
LAST REVIEW DATE: 05/26/2025
VERSION: 1

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POLICY PURPOSE:

The Memorial Hermann Health Plan Biosimilar First policy aims to ensure appropriate and safe use of FDA-approved prescription products (i.e., reference biologic products and biosimilars) when used for medically accepted indications; and encourages the use of clinically appropriate biosimilar products within specific therapeutic drug classes. The criteria are applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD).

DEFINITIONS:

Biosimilar: Refers to copies of biologic drugs. They are similar to an FDA-approved biologic, known as the reference product.

Brand Name Drug: Means the first version of a particular medication to be developed or a medication that is sold under a pharmaceutical manufacturer's own registered trade name or
trademark. The original manufacturer is granted a patent, which allows it to be the only company to make and sell the new drug for a certain number of years.

Centers for Medicare & Medicaid Services (CMS): CMS is the federal agency that provides health coverage to more than 160 million through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. CMS works in partnership with the entire health care community to improve quality, equity and outcomes in the health care system.

CMS Recognized Compendia: The Centers for Medicare and Medicaid Services (CMS) recognizes several compendia for determining if a drug or biological is medically accepted for off-label use. The CMS uses these compendia to determine if a drug or biological is medically accepted for off-label use in anti-cancer chemotherapeutic regimens.

Food and Drug Administration (FDA): An agency of the United States federal government responsible for protecting and promoting public health through the

regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter
medications, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices, cosmetics, and veterinary products. The FDA's main goal is to ensure that these products are safe and effective for their intended use, and that their labeling and marketing are truthful and not misleading.

Generic Drugs: Prescription Drugs that have been determined by the Food and Drug Administration (FDA) to be equivalent to Brand Name Drugs but are not made or sold under a registered trade name or trademark. Generic Drugs have the same active ingredients, meet the same FDA requirements for safety, purity, and potency and must be dispensed in the same dosage form (e.g., tablet, capsule, cream) as the Brand Name Drug.

Off Label Drug: The prescription and administration of a medication for a purpose, dosage, or patient population that is not approved by the regulatory agency food and drug administration (FDA).

SCOPE:

This policy applies to Memorial Hermann Medicare plans.

POLICY STATEMENT

The Biosimilar First policy governs the approval and utilization of biosimilars in reference to biologic products approved by the U.S. Food and Drug Administration (FDA) as published in the FDA Purple Book. This policy does not supersede existing CMS guidelines, internal coverage criteria (i.e. InterQual), or disease specific policies or other administrative policies.

Initial Authorization Criteria

Initial Authorization Criteria
Product: Reference Product Requests when Biosimilar Exists
Approval Length: 6 Month(s)
Guideline Type: Prior Authorization
Approval Criteria 1. Requested reference drug has been approved as safe and effective by the U.S. Food and Drug Administration (FDA) for at least ONE indication in the United States. **AND** 2. The requested reference product or drug must meet one of the following: **a.** There is no approved biosimilar product that exists for the

requested indication supported in the drug labeling (manufacturer's prescribing information),

OR

b. No interchangeable biosimilar product exists on the market for the requested product per the FDA purple book.

AND

3. The provider must submit medical records documenting the following for the reference product:
   a. Documentation member has tried and failed, or has a contraindication to, the FDA labeled alternatives for the member's diagnosis**.**

   OR

   b. Documentation member has tried and failed, or has a contraindication to, the treatment guideline recommended alternatives which are considered to be standard of care and which are of equal or greater efficacy compared to the requested agent for the member's diagnosis.

   OR

   c. The reference product is clinically required based on disease-specific guidelines, compendia, or manufacturer prescribing information.

   OR

   d. Documentation member has tried and failed or has a contraindication to the biosimilar for the requested reference product**.**

   AND

4. The reference product requested is not being requested for an off-label use.
   a. A drug is considered off-label if the diagnosis requested is not listed in the package insert of the drug or in the FDA-approved indications list in a CMS recognized compendia.

   Note: If requested for off-label, it must be reviewed with off-label policy and the provider needs to submit documentation for safe and appropriate usage.

   AND

5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review AND the requested drug is not contraindicated by the FDA for the requested indication.

   AND

6. Prescriber attests to baseline and regular ongoing safety monitoring per FDA label for the requested drug.

AND

7. This is being Prescribed by an appropriate specialist for the indication requested.

AND

8. The requested dosage does not exceed age-appropriate quantity limits or other safety limits.

Additional Notes:
Initial authorization: up to 6 months; duration of therapy needs to be supported by the
manufacturer's prescribing information or compendia.
Age Restrictions: Not to exceed limits in compendia or articles provided
Site of Care: Infusions must occur in an outpatient infusion center unless medically necessary (e.g., high risk of infusion reactions requiring inpatient monitoring). Please refer to this policy for additional information.

Reauthorization Criteria

Reauthorization Criteria
Product: Reference Product Requests when Biosimilar Exists
Approval Length: Through the end of Plan Year
Guideline Type: Prior Authorization

Approval Criteria

1. The request is not for continuation of therapy of medications for reference product for new Memorial Hermann Health Plan members: Initial criteria must be met.

AND

2. One of the following for the reference product:
   a. Adherence to therapy at least 75% of the time as verified by the prescriber or member medication fill (or claim) history.

   OR

   b. Adherence less than 75% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation.

AND

3. Prescriber attests to or the clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity.

AND

4. Documentation of a positive clinical response to therapy (e.g., improvement in laboratory parameters or disease state response or other clinical evidence of positive benefit) with submitted medical records (such as office chart notes, lab results or other clinical information).

AND

5. Prescriber attests to ongoing safety monitoring per FDA label for the requested drug.

AND

6. The requested dose does not exceed quantity limits or other safety limits.

Additional Notes:
Reauthorization: Up to end of the plan year (12 months maximum). Duration of therapy needs to be supported by the manufacturer's prescribing information or compendia.
Age Restrictions: Not to exceed limits in compendia or articles provided
Site of Care: Infusions must occur in an outpatient infusion center unless medically necessary
(e.g., high risk of infusion reactions requiring inpatient monitoring). Please refer to this policy for additional information.

Quantity Limit Criteria

Quantity Limit Criteria
Product: Reference Product Requests when Biosimilar Exists
Approval Length: Through the end of Plan Year
Guideline Type: Quantity Limit
Approval Criteria

1. One of the following:
   a. Quantity limit override requests must involve an FDA-approved indication

   OR

   b. Quantity limit override requests involving off-label indications must meet off-label guideline requirements (initial criteria for new starts or reauthorization criteria for continuation of therapy)

AND

2. One of the following:
   a. The higher dose or quantity is supported in the drug labeling (dosage and administration section of the manufacturer's prescribing information);

   OR

   b. The higher dose or quantity is supported by one of the Medicare approved compendia:
      i. The American Hospital Formulary Service Drug Information (AHFS-DI),
      ii. Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium
      iii. DRUGDEX System by Micromedex,
      iv. National Comprehensive Cancer Network (NCCN) Compendium,

v. Elsevier Gold Standard's Clinical Pharmacology
Additional Notes: Higher dosing may be accepted if the provider supplies medical references or literature that is peer-reviewed showing support for the safety and efficacy of the drug at the requested dose.
Site of Care: Infusions must occur in an outpatient infusion center unless medically necessary (e.g., high risk of infusion reactions requiring inpatient monitoring). Please refer to this policy for additional information.

Note: Refer to the FDA's Purple Book for the most updated list of licensed biological products and their biosimilars. This can be accessed via: https://purplebooksearch.fda.gov/

REFERENCES

Centers for Medicare & Medicaid Services. Baltimore, MD. Available at: https://www.cms.gov/

DrugDex® System (database online). Greenwood Village, CO: Thomson Micromedex. Available at: http://www.micromedexsolutions.com.

Facts and Comparisons® (database online). St. Louis, MO: Wolters Kluwer Health, Inc. Available at: http://www.factsandcomparisons.com.

National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium™ (database online). Available at: http://www.nccn.org.

U.S. Food and Drug Administration (FDA). Off-label and investigational use of marketed drugs, biologics, and medical devices. Available at: http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm.