## **DOCUMENT REVISION HISTORY LOG**

### DO NOT DISTRIBUTE OR RELEASE

Document Revision History Log is for internal use only and not considered part of the policy

# MEMORIAL HERMANN HEALTH PLAN HOLDINGS, LLC POLICY

POLICY TITLE: MHHP MEDM-MA IGG-006 Immune Globulin

Step Therapy Criteria

PUBLICATION DATE: 06/02/2025 LAST REVIEW DATE: 06/02/2025

VERSION: 2

Version	Change Summary	Revised By
1	Legacy document; Approved by P&T Committee 5/7/2025	D. Pierce/S. Soman
2	Type o in the policy statement corrected; Related document title corrected	D. Pierce

#### DO NOT DISTRIBUTE OR RELEASE

Document Revision History Log is for internal use only and not considered part of the policy

# MEMORIAL HERMANN HEALTH SYSTEM MEMORIAL HERMANN HEALTH PLAN HOLDINGS, LLC POLICY

**POLICY TITLE:** MHHP MEDM-MA IGG-006 Immune Globulin

Step Therapy Criteria

**PUBLICATION DATE:** 06/02/2025 **LAST REVIEW DATE:** 06/02/2025

VERSION: 2

#### **POLICY PURPOSE:**

The Memorial Hermann Health Plan Immune Globulins Step Therapy Criteria policy aims to advise providers of preferred drug products and outline the exceptions to preferred drug products during the prior authorization process. Step therapy criteria is applied in conjunction with any relevant National Coverage Determinations (NCD), Local Coverage Determination (LCD), InterQual and other MHHP internal medical necessity and or Part B drug criteria.

#### **DEFINITIONS:**

None

#### SCOPE:

This policy applies to Memorial Hermann Medicare plans.

## **POLICY STATEMENT**

The step therapy program applies to immune globulin products as described in this policy. Requested Part B drug coverage must comply with step criteria in this policy. If approved, authorizations will be approved for 6 months. If a provider administers a non-preferred drug without obtaining prior authorization, the request for coverage may be denied. Preferred drugs may still require prior authorization as the review process is where medical necessity and whether any exceptions to the preferred drug is determined. This policy applies to all Medicare members who are new to treatment with a non-preferred drug. A member will not be required to change the current drug treatment. For the purposes of this policy, "current drug treatment" is defined as either a paid claim for the drug or clinical documentation confirming that the member has been using the non-preferred drug within the past 365 days. In addition, there must be

evidence of regular follow-up visits with the prescribing physician within the last 6 months. The member must also demonstrate clinical improvement as a result of the ongoing treatment. If a new plan member is currently using a particular drug, MHHP will not require the member to switch to the preferred drug upon enrollment. An existing member currently using a particular drug will not be required to change drug/products if this policy is updated. Not all indications for the non-preferred drug are listed in this policy. Indications and medications listed in this policy may change upon varying factors and should be evaluated by guidelines, the FDA and manufacturer package insert to verify appropriate use at the time of review.

#### IVIG - Immune Globulins for Intravenous administration

# Initial (New Starts) Authorization Criteria

# Preferred drug (s):

Gammaked Gamunex-C Octagam Privigen

### Non-preferred drug(s):

Alyglo Gammagard Liquid
Asceniv Gammagard S/D
Bivigam Gammaplex
Flebogamma Panzyga

Yimmugo

(Note: Any drugs not listed as preferred will be considered non-preferred until the next policy update)

# Criteria: Coverage for the non-preferred drugs (s) is provided when there is clinical documentation to support one or more of the following criteria:

1. The member has received the requested non-preferred drugs in the past 365 days and there is objective evidence of clinical benefit via imaging, lab results, or clinical assessment

OR

2. There has been an inadequate response to the preferred drug (s)

#### OR

3. There has been an adverse event related to the preferred drug(s)

#### **OR**

4. There is a contraindication to the preferred drugs

#### **AND**

5. Dosing must be in accordance with FDA approved labeling or otherwise supported by approved compendia and disease specific treatment guidelines.

#### Related documents

MHHP MEDM-MA 303 Medical Necessity Determinations

#### **REFERENCES**

- Alygo 10% [package insert]. Teaneck, NJ: CG Biopharma USA, Inc.; December 2023, FDA label website <u>Alygo Label</u>; <a href="https://www.fda.gov/files/vaccines%2C%20blood%20%26%20biologics/published/package">https://www.fda.gov/files/vaccines%2C%20blood%20%26%20biologics/published/package</a> insert - alyglo.pdf Accessed April 2025.
- 2. Asceniv [package insert]. Boca Raton, FL: ADMA Biologics; <u>Asceniv Label</u> Accessed April 2025.
- 3. Bivigam [package insert]. Boca Raton, FL: Biotest Pharmaceuticals Corporation; FDA label website <u>Bivigam Label</u>; Accessed April 2025.
- 4. Flebogamma 10% DIF [package insert]. Los Angeles, CA: Grifols Biologicals, Inc.; FDA label website Flebogamma 10% Label; Accessed April 2025.
- 5. Flebogamma 5% DIF [package insert]. Los Angeles, CA: Grifols Biologicals, Inc.; FDA label website Flebogamma `5% Label; Accessed April 2025.
- 6. Gammagard Liquid [package insert]. Westlake Village, CA: Baxter Healthcare Corporation; FDA label website <u>Gammagard Liquid Label</u>; Accessed April 2025.
- Gammagard S/D [package insert]. Westlake Village, CA: Baxter Healthcare Corporation; FDA label website Gammagard S/D Label; Accessed April 2025.
- 8. Gammagard S/D iga less than 1 mcg/ml [package insert]. Westlake Village, CA: Baxter Healthcare Corporation; Gammagard S/D Less than 1 mcg label; Accessed April 2025.
- 9. Gammaked [package insert]. Fort Lee, NJ: Kedrion Biopharma, Inc.; <u>Gammaked Label</u>; Accessed April 2025.
- 10. Gammaplex 5% [package insert]. Hertfordshire, United Kingdom: Bio Products Laboratory; <u>Gammaplex 5% Label</u>; Accessed April 2025.
- 11. Gammaplex 10% [package insert]. Elstree, United Kingdom: Bio Products Laboratory; Gammaplex 10% Label; Accessed April 2025.
- 12. Gamunex-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; FDA label website <a href="mailto:Gamunex-C Label">Gamunex-C Label</a>; Accessed April 2025.
- 13.Octagam 10% [package insert]. Hoboken, NJ: Octapharma USA, Inc.; FDA label website Octagam 10% Label; Accessed April 2025.
- 14. Octagam 5% [package insert]. Hoboken, NJ: Octapharma USA, Inc.; FDA label website Octagam 5% Label; Accessed April 2025.
- 15. Panzyga [package insert]. Hoboken, NJ: Octapharma USA.; FDA label website Pazyga Label; Accessed April 2025.

- 16. Privigen [package insert]. Kankakee, IL: CSL Behring LLC; FDA label website Privigen Label; Accessed March 2025.
- 17. Yimmugo 10% [package insert]. Dreieich, Germany: Biotest AG; FDA label website <u>Yimmugo Label</u>; Accessed April 2025.
- 18.U.S. Food & Drug Administration, (2025) Purple Book Database of Licensed Biological Products, Website: https://purplebooksearch.fda.gov/, Accessed April 2025.