

## IMMUNE GLOBULIN – SITE OF CARE

**Guideline Number:** MMG145.K

**Effective Date:** May 1, 2019

[Instructions for Use](#) ⓘ

<b>Table of Contents</b>	<b>Page</b>
<a href="#">COVERAGE RATIONALE</a> .....	1
<a href="#">DEFINITIONS</a> .....	2
<a href="#">CLINICAL EVIDENCE</a> .....	2
<a href="#">REFERENCES</a> .....	2
<a href="#">GUIDELINE HISTORY/REVISION INFORMATION</a> .....	2
<a href="#">INSTRUCTIONS FOR USE</a> .....	3

### Related Medical Management Guideline

- [Skilled Care and Custodial Care Services](#)

### COVERAGE RATIONALE

This guideline addresses the criteria for consideration of allowing hospital outpatient facility infusion service for intravenous [Immune Globulin](#) (IVIG) and subcutaneous Immune Globulin (SCIG) therapy. This includes hospital based services with the following CMS/AMA Place of Service (POS) codes:

- 19 (Off Campus-Outpatient hospital); and
- 22 (On Campus-Outpatient Hospital)

Alternative [Sites of Care](#), such as non-hospital outpatient infusion, physician office, ambulatory infusion suites, or home infusion services are well accepted POS for medication infusion therapy. If a member does not meet criteria for outpatient hospital facility infusion, alternative Sites of Care may be used.

**Clinical use of Immune Globulin is proven and medically necessary, in certain circumstances.**

**Outpatient hospital facility-based Immune Globulin infusion is medically necessary for members who meet at least ONE of the following criteria (submission of medical records is required):**

- Documentation that the member is medically unstable for administration of Immune Globulin at the alternative Sites of Care as determined by any of the following:
  - The member's complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the office or home infusion setting; **or**
  - The member's documented history of a significant comorbidity (e.g., cardiopulmonary disorder) or fluid overload status that precludes treatment at an alternative Site of Care; **or**
  - Outpatient treatment in the home or office setting presents a health risk due to a clinically significant physical or cognitive impairment; **or**
  - Difficulty establishing and maintaining patent vascular access; **or**
  - To initiate, re-initiate, or change Immune Globulin products for a short duration (e.g., 4 weeks);
- or**
- Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that have not been responsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the member when administration is in the home or office setting
- or**
- Initial infusion, change of Immune Globulin product, or re-initiation of therapy after more than 6 months
- or**
- Member has immunoglobulin A (IgA) deficiency with anti-IgA antibodies
- or**
- Homecare or infusion provider has deemed that the member, home caregiver, or home environment is not suitable for home infusion therapy (if the prescriber cannot infuse in the office setting).

**Ongoing outpatient hospital facility-based infusion duration of therapy will be no more than 6 months to allow for reassessment of the member's ability to receive therapy at an alternative Site of Care.**

**Note:** If more than one of the above criteria are met, then the greatest of the applicable approval time periods will be allowed.

## DEFINITIONS

**Immune Globulin:** Immune Globulins are components of the immune system. There are several types of Immune Globulin produced by the body (e.g., IgA, IgD, IgE, IgG, IgM). This policy addresses therapeutic use Immune Globulin G (IgG) an antibody produced by the B lymphocytes. References to Immune Globulin within this guideline refer to IgG. IgG products have been referred to in multiple ways, some of which are: Immune Globulin (IG), immunoglobulin, gamma globulin, and also by its route of administration – intravenous immune globulin (IVIG), Immune Globulin intravenous (IGIV), Subcutaneous Immune Globulin (SCIG), Immune Globulin subcutaneous (IGSC).

**Site of Care:** Choice for physical location of infusion administration. Sites of care include hospital inpatient, hospital outpatient, community office, ambulatory infusion suite, or home-based setting.

## CLINICAL EVIDENCE

Immune globulin infusion is administered in various sites of care. The Immune Deficiency Foundation surveyed 1,030 patients on where they were treated with immune globulin. Twenty-six percent usually received infusions at a hospital outpatient department (21%) or at a hospital clinic (5%). Other sites reported included a doctor's private office (9%) or an infusion suite (16%). The most common site was in the home (42%), most commonly administered by a nursing professional (2008).

Infusion in the home (POS 12) is well established and accepted by physicians. A survey of home infusion providers by the National Home Infusion Association reported 1.24 million therapies had been provided to approximately 829,000 patients, including 129,071 infusion therapies of specialty medications including immune globulin (2010).

### **Professional Societies**

#### **American Academy of Allergy Asthma and Immunology (AAAAI)**

AAAAI treatment guidelines provide several site of care options for administering immune globulin, with the appropriate option being based on the patient's clinical condition (2011):

- Hospital inpatient physician/nurse supervised infusion
- Hospital outpatient physician/nurse supervised infusion
- Physician office based physician/nurse supervised infusion
- Home based infusion with nurse supervision
- Home based infusion without nurse supervision

## REFERENCES

American Academy of Allergy Asthma and Immunology (AAAAI). Guidelines for the site of care for administration of IGIV therapy; December 2011. Accessed March 20, 2019.

American Academy of Allergy Asthma and Immunology (AAAAI); Eight Guiding Principles for Effective Use of IGIV for Patients with Primary Immunodeficiency; December 2011. Accessed March 20, 2019.

Centers for Medicare & Medicaid Services: Place of Service Code Set. [http://www.cms.gov/Medicare/Coding/place-of-service-codes/Place\\_of\\_Service\\_Code\\_Set.html](http://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html). Accessed March 19, 2019

Chowdary P, Nair D, Davies N, et al.; Anaphylactic reaction with prothrombin complex concentrate in a patient with IgA deficiency and anti-IgA antibodies; Blood Coagul Fibrinolysis; 2010; 21 (8): 764.

Phase I: 2010 NHIA Provider Survey Comprehensive Aggregate Analysis Report; National Home Infusion Association; 2011.

Treatment Experiences and Preferences Among Patients with Primary Immunodeficiency Disease; National Survey of Patients: 2008; Immune Deficiency Foundation; May 6, 2009. Accessed March 20, 2019.

## GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
05/01/2019	<ul style="list-style-type: none"><li>• Changed policy title; previously titled <i>Immune Globulin Site of Care Review Guidelines for Medical Necessity of Hospital Outpatient Facility Infusion</i></li><li>• Simplified coverage rationale (no change to guidelines)</li><li>• Archived previous policy version MMG145.J</li></ul>

## INSTRUCTIONS FOR USE

This Medical Management Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Management Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare West Medical Management Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Member benefit coverage and limitations may vary based on the member's benefit plan Health Plan coverage provided by or through UnitedHealthcare of California, UnitedHealthcare Benefits Plan of California, UnitedHealthcare of Oklahoma, Inc., UnitedHealthcare of Oregon, Inc., UnitedHealthcare Benefits of Texas, Inc., or UnitedHealthcare of Washington, Inc.