

IMMUNE GLOBULIN SITE OF CARE REVIEW GUIDELINES FOR MEDICAL NECESSITY OF HOSPITAL OUTPATIENT FACILITY INFUSION

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Related Policies

- [Immune Globulin \(IVIG and SCIG\)](#)
- [Skilled Care and Custodial Care Services](#)

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care 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.

CONDITIONS OF COVERAGE

Applicable Lines of Business/ Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General Benefits Package
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes ^{1,2}
Precertification with Medical Director Review Required	Yes ²
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	Hospital Outpatient Facility

Special Considerations

¹Providers must call Oxford's Medical Management to obtain precertification for administration of Immune Globulin in a hospital outpatient facility.

²Requests for hospital outpatient facility infusion of Immune Globulin require review by a Medical Director or their designee.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

This guideline applies to Oxford Commercial Plan membership.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Clinical use of Immune Globulin is proven and/or medically necessary, in accordance with the Oxford policy titled [Immune Globulin \(IVIG and SCIG\)](#).

This guideline addresses the criteria for consideration of allowing hospital outpatient facility infusion service for Immune Globulin (IVIG and SCIG) therapy. In accordance with CMS, this includes hospital based services with either of the following Place of Service (POS) codes:

- 19 (Off-Campus - Outpatient Hospital)
- 22 (On-Campus - Outpatient Hospital)

Criteria and Clinical Indications for Hospital Outpatient Site of Care Selection

Criteria

Hospital outpatient Site of Care may be approved when:

- The patient's condition meets **any** of the Clinical Indications below, and
- The provider has submitted the appropriate supporting documentation

Clinical Indications

- Initial infusion of Immune Globulin, or re-initiation of therapy after more than 6 months off of Immune Globulin
- Change of Immune gGobulin products
- History of severe adverse events to Immune Globulin (including but not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure)
- Patient is clinically unstable
- Episodes of moderate to severe adverse events that have not been responsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other therapy pre-medications, thereby increasing risk to the patient when administration is in the home or office setting
- Patient has immunoglobulin A (IgA) deficiency with anti-IgA antibodies
- Outpatient treatment in the home or ambulatory setting presents a health risk due to a clinically significant physical or cognitive impairment

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 iImmune 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.

APPLICABLE CODES

The following list of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

Place of Service Code	Description
19	Off Campus-Outpatient Hospital
22	On Campus-Outpatient Hospital

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

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [*URG-10.03*]

American Academy of Allergy Asthma and Immunology (AAAAI). Eight Guiding Principles for Effective Use of IVIG for Patients with Primary Immunodeficiency. December 2011. Accessed January 23, 2018.

American Academy of Allergy Asthma and Immunology (AAAAI). Guidelines for the site of care for administration of IVIG therapy. December 2011. Accessed January 23, 2018.

Centers for Medicare & Medicaid Services (CMS): Place of Service Code Set. Accessed January 23, 2018.

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.

MCG™ Care Guidelines, 22nd edition, 2018. Home Infusion Therapy: CMT: CMT-0009 (SR).

Phase I: 2010 NHIA Provider Survey Comprehensive Aggregate Analysis Report. National Home Infusion Association. 2011. Accessed January 23, 2018.

Treatment Experiences and Preferences Among Patients with Primary Immunodeficiency Disease. National Survey of Patients: 2008. Immune Deficiency Foundation. May 6, 2009. Accessed January 23, 2018.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
04/01/2018	<ul style="list-style-type: none">• Updated coverage rationale; added reference link to the policy titled <i>Immune Globulin (IVIG and SCIG)</i> for proven and/or medically necessary clinical uses of immune globulin (relocated from the <i>Clinical Evidence</i> section of the policy)• Updated supporting information to reflect the most current references<ul style="list-style-type: none">○ Replaced reference to "MCG™ Care Guidelines, 21st edition, 2017" with "MCG™ Care Guidelines, 22nd edition, 2018"• Archived previous policy version PHARMACY 279.7 T2