INSTRUCTIONS FOR USE

This Utilization Review Guideline provides assistance in interpreting UnitedHealthcare benefit plans. 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 Utilization Review Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Utilization Review Guideline. 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 Utilization Review Guideline. Other Policies and Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Utilization Review 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. 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.

BENEFIT CONSIDERATIONS

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

**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 guideline, it is important to refer to the member specific benefit plan document to determine benefit coverage.

This guideline applies to members who have medical necessity language in their Certificate of Coverage (COC) or Summary Plan Document with benefits available for health care services if medically necessary and have been approved for the requested medication clinical use.

This guideline applies to UnitedHealthcare Commercial plans. This guideline does not apply to Medicare or Medicaid plans.
COVERAGE RATIONALE

Clinical use of Immune Globulin is proven and/or medically necessary, in accordance with the UnitedHealthcare Medical Benefit Drug Policy titled Immune Globulin (IVIG and SCIG).

This guideline addresses the criteria for consideration of allowing hospital outpatient facility infusion services 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 Globulin 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 office 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 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.

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 guideline 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 and Guidelines may apply.

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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**


**GUIDELINE HISTORY/REVISION INFORMATION**

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| 04/01/2018| • Updated coverage rationale; added reference link to the Medical Benefit Drug Policy titled Immune Globulin (IVIG and SCIG) for proven and/or medically necessary clinical uses of immune globulin (relocated from the Clinical Evidence section of the policy)  
  • Updated supporting information to reflect the most current references  
    o Replaced reference to "MCG™ Care Guidelines, 21st edition, 2017" with "MCG™ Care Guidelines, 22nd edition, 2018"  
  • Archived previous policy version URG-10.02 |