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

<table>
<thead>
<tr>
<th>Applicable Lines of Business/ Products</th>
<th>This policy applies to Oxford Commercial plan membership.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefit Type</td>
<td>General Benefits Package</td>
</tr>
<tr>
<td>Referral Required</td>
<td>No</td>
</tr>
<tr>
<td>(Does not apply to non-gatekeeper products)</td>
<td>Yes¹,²</td>
</tr>
<tr>
<td>Authorization Required</td>
<td>Yes²</td>
</tr>
<tr>
<td>(Precertification always required for inpatient admission)</td>
<td></td>
</tr>
<tr>
<td>Precertification with Medical Director Review Required</td>
<td>Hospital Outpatient Facility</td>
</tr>
<tr>
<td>Applicable Site(s) of Service</td>
<td></td>
</tr>
<tr>
<td>(If site of service is not listed, Medical Director review is required)</td>
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<tr>
<td>Special Considerations</td>
<td>¹Providers must call Oxford’s Medical Management to obtain precertification for administration of immune globulin in a hospital outpatient facility.</td>
</tr>
<tr>
<td></td>
<td>²Requests for hospital outpatient facility infusion of immune globulin require review by a Medical Director or their designee.</td>
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</table>
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

Introduction
This guideline addresses the criteria for consideration of allowing hospital outpatient facility infusion service for immune globulin (IVIG and SCIG) therapy¹. This includes hospital based services with the following CMS/AMA Place of Service codes:
• 19 – Off-Campus - Outpatient Hospital, and
• 22 – On-Campus - Outpatient Hospital

Criteria and Clinical Indications for Hospital Outpatient Site of Care Selection

Criteria
When requested, hospital outpatient site of care may be approved when:
• Any of the clinical indication questions 1-8 below can be answered ‘yes’; and
• The provider has submitted the appropriate supporting documentation.

Clinical Indications
See the above criteria for the following questions.
Note: If more than one of the criteria addressed in the questions below are met, then the greatest of the applicable approval time periods will be allowed.
• Is this the patient’s initial infusion of immune globulin or re-initiation after more than 6 months off of immune globulin?
• Is the patient changing immune globulin products?
• Has the patient previously experienced a severe adverse event to immune globulin (examples might include, but are not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, and renal failure, other – provide reaction)?
• Is the patient clinically unstable?
• Is the patient continually experiencing moderate or severe adverse events not able to be mitigated by use of acetaminophen, steroids, diphenhydramine, fluids or other pre-medications on therapy?
• Has the patient had an adverse event not able to be mitigated by use of acetaminophen, steroids, diphenhydramine, fluids or other pre-medications to immune globulin therapy documented for which the physician is uncomfortable administering immune globulin in a home or ambulatory setting?
• Is the patient physically or cognitively disabled to the point where receiving treatment in at home or in a physician office would present a risk to their health?
• Does the patient have immunoglobulin A (IgA) deficiency with anti-IgA antibodies?

Supporting Information and Clinical Evidence
• Clinical use of immune globulin use is medically necessary according to the Oxford Health Plans Drug Policy titled Immune Globulin (IVIG and SCIG).
• With respect to the site of care there are several options for administering immune globulin and should be based on patient characteristics.²,³,⁴
  o Hospital inpatient physician/nurse supervised infusion
  o Hospital outpatient physician/nurse supervised infusion
  o Physician office based physician/nurse supervised infusion
  o Home based infusion with nurse supervision
Immune globulin infusion is widely used throughout the various sites of care. According to a 2008 survey by the Immune Deficiency Foundation of 1,030 patients being treated with immune globulin, two out of five (42%) IVIG users reported that they usually received their infusion at home. Of those, 7% were able to self-infuse, while the other 35% had a nurse perform the infusion. Twenty-six percent of IVIG users usually got their infusion at a hospital outpatient department (21%), or at a hospital clinic (5%). Most of the remainder said that they usually got their infusion in a doctor’s private office (9%) or an infusion suite (16%).

Home infusion as a place of service is well established and accepted by physicians. A 2010 home infusion provider survey by the National Home Infusion Association reported providing 1.24 million therapies to approximately 829,000 patients, including 129,071 infusion therapies of specialty medications, which includes immune globulin.

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 immune globulin 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.

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]


POLICY HISTORY/REVISION INFORMATION

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<th>Date</th>
<th>Action/Description</th>
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<tr>
<td>04/01/2017</td>
<td>Updated supporting information; replaced reference to &quot;MCG™ Care Guidelines, 20th edition, 2016” with &quot;MCG™ Care Guidelines, 21st edition, 2017”</td>
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<td>Archived previous policy version PHARMACY 279.5 T2</td>
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