SITE OF CARE REVIEW GUIDELINES FOR MEDICAL NECESSITY OF HOSPITAL OUTPATIENT FACILITY SPECIALTY MEDICATION INFUSION

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Effective Date: October 1, 2014

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INSTRUCTIONS FOR USE
This Utilization Review Guideline provides assistance interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee’s document (e.g., Certificate of Coverage or Summary Plan Description) may differ greatly. In the event of a conflict, the enrollee’s specific benefit document supersedes this Guideline. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Guideline. Other policies and guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its policies and guidelines as necessary. This 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.

UTILIZATION MANAGEMENT GUIDING PRINCIPLES

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 (such as maternity benefits), 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 enrollee’s specific plan document to determine benefit coverage.

Introduction
This guideline addresses the criteria for consideration of allowing hospital outpatient facility specialty medication infusion service and claim submission for hospital based services with CMS/AMA Place of Service code 22 therapy.
This Policy applies to these specialty medications that require healthcare provider infusion:

- eculizumab (Soliris®)

**Review Criteria for Site of Care Selection**

Hospital facility-based intravenous medication infusion is medically necessary for persons who meet any of the following criteria:

- Medically unstable based upon submitted clinical history; or
- Initial medication infusion of or re-initiation after more than 6 months following discontinuation of therapy; or
- Previous experience of a severe adverse event following infusion. Examples include but are not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure; or
- Continuing experience of adverse events that cannot be mitigated by pre-medications; or
- Physically and/or cognitively impaired and no home caregiver available.

**Additional information:** Medical necessity criteria for administration of intravenous infusion therapy at home are addressed in MCG CMT-0009 “Home Infusion Therapy.”

**Benefit Considerations**

This guideline applies to members with 2011 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 UHC Commercial and Medicaid plans. This guideline does not apply to Medicare plans.

**Supporting Information and Clinical Evidence**

**Background:**

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.¹

**Clinical Evidence:**

MCG Guideline CMT-0009 “Home Infusion Therapy” guideline addresses criteria for home infusion therapy. Clinical patient characteristics for home suitability include: clinical stability, no need for close observation or daily nurse care, and reliable venous access. Additional criteria for home environment, infusion plan and patient ability to participate in care are summarized.²

**Professional Societies:**

The American Academy of Allergy Asthma and Immunology has published guidelines for the suitability of patients to receive treatment in various care setting including clinical characteristics of patients needing a high level of care in the hospital outpatient facility which includes patient characteristics: previous serious infusion reaction such as anaphylaxis, seizure, myocardial infarction, or renal failure, immune globulin therapy naive, continual experience of moderate or serious infusion related adverse reactions, physical or cognitive impairment.³

The Hunter Syndrome European Expert Council: European recommendations for the diagnosis and multidisciplinary management of a rare disease published an article reviewing the collective experiences with agalsidase beta home infusion therapy and outlines how safe, patient-centered homecare can be organized in enzyme replacement therapy for patients with Fabry disease.
Criteria include that “Patients must have received ERT in hospital for 3-6 months; if patients have previously had IRRs, they must be under control with premedication, and they must not have had an IRR in the 2-8 weeks before homecare is approved and premedication must be given. If a patient has significant respiratory disease (%FVC, 40% or less; or evidence of serious obstructive airway disease), homecare may not be suitable.”

The Agency for Healthcare Research and Quality (AHRQ) publication on Enzyme Replacement Therapy states, “Home infusion of ERT was initially studied in patients with type I Gaucher disease. It has been reported as an option for patients with Fabry disease, MPS I, and MPS II, and MPS VI. However, patients with infantile Pompe disease may not be able to transfer to home care because of an increased risk for serious adverse events during an infusion. In general, the outcomes measured in these studies and the follow-up durations were similar to those reported by disease in the clinical studies summarized under Guiding Question 3. Safety was the main focus of most home infusion studies, as the patients had already been receiving ERT in a more controlled setting.”

Medication or Condition Specific Studies:

**Eculizumab - Paroxysmal Nocturnal Hemoglobinuria**

In a trial evaluating patients with paroxysmal nocturnal hemoglobinuria, after initial 2-5 doses of eculizumab (Soliris), 79 patients received continued infusion with every 14 days in the home setting for the duration of the study – 1-98 months, mean duration of 39 months. The survival of patients treated with eculizumab was not different from age- and sex-matched normal controls (P = .46) but was significantly better than 30 similar patients managed before eculizumab (P = .030). Three patients on eculizumab, all over 50 years old, died of causes unrelated to PNH. Twenty-one patients (27%) had a thrombosis before starting eculizumab (5.6 events per 100 patient-years) compared with 2 thromboses on eculizumab (0.8 events per 100 patient-years; P < .001). Twenty-one patients with no previous thrombosis discontinued warfarin on eculizumab with no thrombotic sequelae. Forty of 61 (66%) patients on eculizumab for more than 12 months achieved transfusion independence. The 12-month mean transfusion requirement reduced from 19.3 units before eculizumab to 5.0 units in the most recent 12 months on eculizumab (P < .001). Eculizumab dramatically alters the natural course of PNH, reducing symptoms and disease complications as well as improving survival to a similar level to that of the general population.

**Applicable Codes**

The HCPCS code listed in this policy is for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document.

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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>J1300</td>
<td>Injection, eculizumab, 10 mg</td>
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**DEFINITIONS**

**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**

2. MCG Guideline CMT-0009 “Home Infusion Therapy”.


**GUIDELINE HISTORY/REVISION INFORMATION**

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<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tbody>
<tr>
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