INSTRUCTIONS FOR USE
This protocol 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 (COC) or Evidence of Coverage (EOC)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this protocol. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Protocol. Other Protocols, Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Protocols, Policies and Guidelines as necessary. This protocol is provided for informational purposes. It does not constitute medical advice. This policy does not govern Medicare Group Retiree members.

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.

COMMERCIAL, MEDICARE & MEDICAID GUIDING PRINCIPLES

Introduction
This guideline addresses the criteria for consideration of allowing hospital outpatient facility specialty medication infusion services. This includes claim submission for hospital based services with the following CMS/AMA Place of Service codes:
- 22 On Campus-Outpatient Hospital, and
- 19 Off Campus-Outpatient Hospital

Alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion or home infusion services are well accepted places of service for medication infusion therapy. If a patient does not meet criteria to for outpatient hospital facility infusion, alternative sites of care may be used.

This Policy applies to these specialty medications that require healthcare provider administration:
Abatacept (Orencia®)
Eculizumab (Soliris®)
Golimumab (Simponi® Aria™)
Infliximab (Remicade® lyophilized concentrate for intravenous use)
Infliximab-dyyb (Inflectra™)
Tocilizumab (Actemra® injection for intravenous use)
Vedolizumab (Entyvio®)

Review Criteria for Site of Care Selection
Outpatient 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™ Care Guidelines, 20th edition, 2016, Home Infusion Therapy, CMT: CMT-0009(SR).

Home Infusion Therapy CMT-0009
Background
- Elements for successful home infusion include:
  - Patient and environmental characteristics
  - Clinical indications
  - Role of physician, pharmacist, and registered nurse
  - Criteria for equipment selection
  - Common infusions
  - Patient, family, and caregiver education

Home Infusion Tool
- Assess patient, support system, and home environment prior to initiating home infusion therapy.
  - Patient may be a candidate for home infusion if
    - Patient is medically stable and no longer requires close observation and daily nursing care.
    - Home environment is safe and adequate to support care for home infusion and is confirmed prior to hospital discharge
      - Safe area for staff to make home visits
      - Home supports the following needs, as appropriate to infusion:
        - Refrigeration (with storage available in separate compartment, such as vegetable crisper, away from all food products, and in separate plastic bag)
• Good hygiene tools available
  ▪ Antimicrobial hand sanitizer
  ▪ Running water, soap, and drying towels
• Electricity (if not available, battery-operated pumps or backup generator are possible alternatives. When no electricity is available, gravity drips or IV push methods may be considered.)
• Cleanliness
  ▪ Apply reasonable standard.
  ▪ Neat and clean work area available with separate storage area for equipment and supplies and receptacle for used needles, sharp objects, or soiled dressings.
  ▪ Infusion equipment can be kept away from children.
• Access to telephone for nursing or emergency assistance if problems occur with infusion pump or IV line
• Emergency services and support available
• Transportation for emergencies or medical follow-up available
• Health status of others living in home
  ▪ Cancer
  ▪ Immunocompromised
  ▪ Infectious disease
  ▪ Other
• Safety issues
  ▪ Neighborhood environment safe
  ▪ Presence of pets and pests that may affect sanitary medication delivery
  ▪ Bathroom accessible
  ▪ IV pole and pump can be maneuvered to locations patient needs to go (e.g., bathroom, kitchen)
  ▪ Stairs needed to be used during infusion
  ▪ Area rugs present
  ▪ Safe place for sharps disposal out of reach of small children
• Patient or caregiver demonstrates
  – Ability to understand all aspects of therapy
  – Willingness to participate in therapy
  – Ability to perform procedure
    ○ Physical attributes present
      ▪ Good visual acuity
      ▪ Good auditory acuity
      ▪ Good manual dexterity
      ▪ Sufficient strength
    ○ Aseptic technique, including effective hand-washing
    ○ Checking medication labels for accuracy and instructions on administration
    ○ Recognizing side effects related to medication (e.g., new onset of rash, diarrhea, fever, nausea)
    ○ Ability to perform dressing changes
    ○ Type of IV catheter to be used, including:
      ▪ Potential complications and when to seek medical intervention
- Specific instructions about catheter care
- Appropriate flushing instructions
- Emotional stability (ideally without current alcohol or drug problem or other psychosocial factor (e.g., major depression) that would affect ability to carry out required tasks of therapy)
  - If patient has alcohol or drug problem, carefully and clearly educate them on risks of using their line for recreational drugs, and clearly document this education.[C]
  - Consider using patient contract.

- Infusion planning completed:
  - Reimbursement established
    - Medicare or Medicaid patients evaluated for homebound status(6)
    - Insurance prior authorization obtained (if needed) from insurance carrier
    - Private payment arrangements made
    - Other
  - Type of infusion ordered and coordinated with pharmacy:
    - Analgesic
    - Antibiotic
    - Antiemetic
    - Antifungal
    - Antineoplastic
    - Antivirals
    - Biological agent
    - Clotting factor replacement
    - Diuretic
    - Growth hormone
    - Hydration solution
    - Inotropics (i.e., for end-stage heart failure)
    - Intravenous immunoglobulin (IVIG)
    - Enzyme replacement
    - Methylprednisolone
    - Parenteral nutrition
    - Tocolytic therapy
    - Other
  - Infusion regimen ordered
    - Continuous
    - Once a day
    - Twice a day (BID or every 12 hours)
    - Three times a day (TID or every 8 hours)
    - Four times a day (QID or every 6 hours)
    - Every week
    - Every other week
    - Monthly
    - As needed
    - Other
  - Reliable vascular access identified or arranged
- Midline catheter
- Nontunneled central venous catheter
- Implanted port
- Peripheral IV
- PICC line
- Tunneled catheter
- Other

  - Delivery system identified and equipment coordinated. See Medication Delivery Systems.
    - IV catheters
    - IV push syringes
    - Dressing supplies
    - Catheter flush supplies
    - Minibag and tubing (gravity system)
    - Disposable elastomeric device (eg, balloon)
    - Electronic infusion pump and tubing
      - Controlled-rate infusion device
      - Ambulatory infusion pump
      - Syringe pumps
      - Patient-controlled analgesia pumps (PCA)
    - Other

  - Infusion support coordinated
    - Home care (eg, nurse) coordinated
    - Pharmacist visit coordinated
    - Patient or caregiver able to perform (and demonstration confirmed)
    - Other

  - Patient and caregiver education complete with return demonstration.
    - Purpose of infusion
    - Medication information
      - Administration procedure
      - Regimen
      - Inspection
      - Side effects
    - Catheter use and care
    - Equipment use and care
    - Equipment disposal
    - Complications, including when, how, and to whom to report. See Potential Complications.
    - Follow-up physician appointment confirmed

  - Ongoing infusion support arranged, as needed
    - Access site dressing changes
    - Huber needle changes
    - Complication assessment and intervention
    - Laboratory evaluation (eg, therapeutic drug levels)
    - Equipment delivery coordination
Peripheral IV site rotation
Other

End of MCG***

Benefit Considerations
This guideline applies to Commercial, Medicare, and Medicaid 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.

Clinical Evidence
MCG™ Care Guidelines, 20th edition, 2016, Home Infusion Therapy, CMT: CMT-0009(SR) 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.

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 naïve, continual experience of moderate or serious infusion related adverse reactions, physical or cognitive impairment.

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
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. 7

Infliximab has been shown to be safely infused in the community setting. A chart review of 3161 patients who received a combined 20,976 infusions in community clinics was conducted to evaluate safety across all types of patients. Infliximab infusions are safe in the community setting.

Severe ADRs were rare. A total of 524 (2.5% of all infusions) acute ADRs in 353 patients (11.2%) were recorded. Most reactions (ie, ADRs) were mild (n=263 [50.2%, 1.3% of all infusions]) or moderate (n=233 [44.5%, 1.1% of all infusions]). Twenty-eight reactions (5.3%, 0.1% of all infusions) were severe. Emergency medical services were called to transport patients to hospital for seven of the severe reactions, of which none required admission. As per pre-established medical directives adrenaline was administered three times. The authors concluded that infliximab infusions are safe in the community setting. Severe ADRs were rare. None required active physician intervention; nurses were able to treat all reactions by following standardized medical directives. Ten children were enrolled in the home infusion program if they were compliant with hospital-based infliximab infusions and other medications, had no adverse events during hospital-based infliximab infusions, were in remission and had access to experienced pediatric homecare nursing. The children received 59 home infusions with a dose range of 7.5 to 10 mg/kg/dose. Home infusions ranged from 2 to 5 hours. Since infusions could be performed any day of the week, school absenteeism was decreased. The average patient satisfaction rating for home infusions was 9 on a scale from 1 to 10 (10 = most satisfied). Three patients experienced difficulty with IV access requiring multiple attempts, but all were able to receive their infusions. One infusion was stopped because of arm pain above the IV site. This patient had his next infusion in the hospital before returning to the home infusion program. No severe adverse events (palpitations, blood pressure instability, hyperemia, respiratory symptoms) occurred during home infusions. In the carefully selected patients, infliximab infusions administered at home were safe and are cost-effective. Patients and families preferred home infusions, since time missed from school and work was reduced.

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


MCG™ Care Guidelines, 20th edition, 2016, Home Infusion Therapy, CMT: CMT-0009(SR)

American Academy of Allergy Asthma and Immunology. Guidelines for the Site of Care for Administration of IGIV Therapy. December 2011.


GUIDELINE HISTORY / REVISION INFORMATION

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The foregoing Health Plan of Nevada/Sierra Health & Life Healthcare Operations protocol has been adopted from an existing UnitedHealthcare coverage determination guideline that was researched, developed and approved by the UnitedHealthcare Coverage Determination Committee.