Drug Infusion Site of Care Policy

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Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will NOT provide coverage for hospital outpatient infusion sites unless a clinical medical necessity or cost of care exception applies.

This policy applies to the following infusions administered by health care professionals (list subject to change):
- Immune Globulin (IVIG and SCIG)
- Prolia, Xgeva (denosumab)
- Remicade (infliximab)
- Inflectra (infliximab-dyyb)
- Tysabri (natalizumab)

When Policy Topic is covered

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. Alternative sites of care are considered medically necessary.

The first dose of the medications subject to this policy may be given at the physician’s facility of choice. This includes hospital outpatient facilities, non-hospital outpatient facilities and home care.

All subsequent doses will be subject to the BlueKC Drug Infusion Site of Care Policy, which requires the use of non-hospital outpatient facilities or home infusion when clinically appropriate.

When Policy Topic is not covered

Clinical rationale and documentation must be provided for review of Medical Necessity exceptions.

BlueKC considers hospital outpatient facility medication infusion medically necessary for members that have been documented as meeting one of more of the six criteria below:
- Member is medically unstable for infusions at alternate sites of care as noted by any of the following:
  - Documented clinical history of cardiopulmonary conditions that may cause an increases risk of severe adverse reactions
  - An inability to safely tolerate intravenous volume loads, including from unstable renal function
  - Unstable vascular access
  - Physical or cognitive impairments such that home infusion would present an unnecessary health risk and no home caregiver is available
- Member is initiating therapy
- Member is reinitiating therapy after not being on therapy for at least 6 months
Member has a previously documented severe or potentially life-threatening adverse event during or following infusion of the prescribed drug, and the adverse event cannot be managed through pre-medication in the home or office setting. Examples include but are not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure.

In addition to the above considerations, for IVIG:

- Member is changing to a different immune globulin product
- Member has immunoglobulin A (IgA) deficiency with anti-IgA antibodies

If the member does not meet any of the above criteria, a cost of care exception may apply if the proposed hospital outpatient facility is deemed no most costly than an alternative site of care.

**Considerations**

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

This policy addresses the site of care for the infusion of the medication. The following policies are to be referenced for medical necessity of the drug:

**Immune Globulin Therapy  8.01.05**

- J1459 Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g liquid), 500 mg
- J1556 Injection, immune globulin (Bivigam), 500 mg
- J1557 Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500mg
- J1559 Injection, immune globulin (Hizentra), 100 mg
- J1460 Injection, gamma globulin, intramuscular, 1 cc
- J1561 Injection, immune globulin, (Gamunex-C/Gammaked), non-lyophilized (e.g. liquid), 500 mg
- J1566 Injection, immune globulin, intravenous, lyophilized (e.g powder), not otherwise specified, 500 mg (Only Carimune NF, Panglobulin NF and Gammagard S/D should be billed using this code)
- J1568 Injection, immune globulin, (Octagam), intravenous, non-lyophilized (e.g liquid), 500 mg
- J1569 Injection, immune globulin, (Gammagard liquid), non-lyophilized, (e.g. liquid), 500 mg
- J1571 Injection, hepatitis B immune globulin (Hepagam B), intramuscular, 0.5 mL (see J1573 for IV use)
- J1572 Injection, immune globulin, (Flebogamma/Flebogamma DIF), intravenous, non-lyophilized (e.g. liquid), 500 mg
- J1573 Injection, hepatitis B immune globulin (Hepagam B), intravenous, 0.5 mL (see J1571 for IM use)
- J1579 Injection, immune globulin, intravenous, non-lyophilized (e.g. liquid), not otherwise specified, 500 mg

**Prolia; Xgeva (denosumab)  5.02.533**

- J0897 Prolia 60 MG/ML SOLN J0897 Injection, denosumab, 1 mg

**Remicade (infliximab)  5.01.15**

- J1745 Remicade 100 MG SOLR J1745 Injection, infliximab, excludes biosimilar, 10 mg

**Inflectra (infliximab-dyyb)  5.01.15**

- Q5102 Injection, infliximab, biosimilar, 10 mg

**Tysabri (natalizumab)  5.02.504**
J2323 Injection, natalizumab, 1 mg

**Description of Procedure or Service**

This policy addresses the criteria for consideration of allowing hospital outpatient facility medication infusion services.

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 for outpatient hospital facility infusion, alternative sites of care may be used.

**Rationale**

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

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.2

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.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.”4

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.”5

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. 6

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.7 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.7,8

References:


**Billing Coding/Physician Documentation Information**
Infusion services; drugs are all medical benefit

**Additional Policy Key Words**
Policy 5.02.538

**Policy Implementation/Update Information**
03.2017  New policy titled Drug Infusion Site of Care

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