

Oscar Clinical Guideline: Site-of-Service (Site-of-Care) (Infusion Therapy & Physician-Administered Drugs) (CG046, Ver. 10)

Site of Service (Site of Care) (Infusion Therapy & Physician-Administered Drugs)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

The Plan members may be eligible for medication infusions or injections to treat acute and chronic conditions. These infusions/injections can be delivered in several different settings, including inpatient hospitals, outpatient hospitals, infusion centers, and the home or office. The site of care for the medication delivery depends on a number of factors, such as the results of previous infusions, the medication(s) being used, and the member's other medical conditions. This guideline provides guidance for selecting the appropriate site of care for infusion or injection, but it does not determine the clinical coverage of the selected medications.

NOTE: The Plan may require the use of preferred medications as a first-line treatment. For a comprehensive list of preferred and non-preferred drugs, please refer to the Plan Clinical Guideline - Commercial Preferred Physician-Administered Specialty Drugs (CG052).

Definitions

“Inpatient hospital” is a traditional hospital setting where patients with acute medication conditions are typically managed. An inpatient hospital may have several care settings within, including intensive care units.

“Outpatient hospital facility” is similar to an inpatient medical center and may be the same physical location, but the service is provided in an outpatient setting, meaning that the patient is not admitted to the hospital for care. In these cases, the patient will usually leave the same day as they arrive. This care setting may be used for certain procedures, same day surgeries, or infusions of certain medications or chemotherapy agents.

“Non-hospital outpatient facility” (e.g., infusion center) is an outpatient setting that is not hospital-based. Non-hospital based outpatient facilities can be freestanding infusion centers, dialysis locations, or even physician offices. Infusions or injections of medications, simple procedures, and standard office visits may be conducted in this care setting.

“Home” refers to using the non-healthcare location that the patient resides as the site of care. Medical support staff including physicians, nurses, and other skilled healthcare workers may visit the patient at their home to deliver infusions, injections, and other specialized care. Patients may also be instructed on how to perform their own injections/infusions in the home care setting.

State Law Conflicts

For any provision of this policy that directly conflicts with or is prohibited by state law, the provisions of the state law will apply instead of the provisions of this policy. This means that in instances where state regulations diverge from or directly oppose the Site-of-Service (Site-of-Care) (Infusion Therapy & Physician-Administered Drugs) (CG046) Medical Necessity Criteria for Authorization or requirements, the policy's criteria will not apply.

Clinical Indications

Medical Necessity Criteria for Authorization

The Plan considers the **infusion or injection of medications in the outpatient hospital facility setting** medically necessary for members meeting **ANY** one of the following criteria:

1. Member is receiving the first infusion/injection of the requested medication; **or**

2. Member is resuming therapy after a period of 6 months or longer since the previous infusion/injection since the previous infusion/injection; **or**
3. Member experienced a severe and/or life-threatening adverse event attributed to a previous infusion/injection that cannot be safely managed through pre-medication or other preventive care in an alternative setting (i.e., the home, office, or non-hospital outpatient setting); **or**
4. Member is considered a poor candidate for other care settings due to **ANY** of the following:
 - a. comorbid conditions that may create an unsafe setting for home or office infusion (e.g., dementia, active drug abuse); **or**
 - b. documented comorbidities that increase the risk of serious adverse events; **or**
 - c. poor or unreliable vascular access; **or**
 - d. medical instability; **or**
 - e. need for continued close observation or daily nursing care; **or**
 - f. The member's overall medical condition or the specific medication(s) being infused require specialized monitoring that may not be available or appropriate for alternative settings such as:
 - i. Pediatric members (up to 18 years of age) who may require special monitoring; **or**
 - ii. Members actively receiving a chemotherapy regimen at the hospital which might be disrupted when moved to an alternative site.

If the above prior authorization criteria are met, administration of the requested product by infusion or injection in the outpatient hospital facility setting will be authorized for an initial period of up to 6-months.

*When the above criteria for outpatient hospital facility infusion/injection are NOT met, the member should be directed to an alternative site of care within access standards for medication delivery, such as the home or a non-hospital outpatient facility. Coverage is not authorized for administration of medications in an outpatient hospital facility infusion center if the above medical necessity criteria are not met. **Please note the following:***

- *Infusions for medications in-scope for this policy will not be covered when administered in a hospital outpatient infusion center if the above criteria for outpatient hospital facility infusion/injection are not met.*
- *Home infusion services are separate from the Home Health Care coverage/benefit and do not have the same limitations or requirements.*
 - *Home infusions provided by preferred home infusion providers or in a professional office setting will not count toward the Plan's limit for Home Health Care services.*

- Members receiving home infusion services are not required to meet the home-bound status criteria applicable to Home Health Care services (e.g., [Home Care - Skilled Nursing Care \(RN, LVN/LPN\) \(CG020\)](#)). Home Health Care coverage/benefit specifically covers part-time or intermittent care provided by a Home Health Agency, while home infusions can be delivered by medical support staff, including physicians, nurses, and other skilled healthcare workers.

Applicable Billing Codes (HCPCS/CPT Codes)

Infusion/Injection Medications	
CPT/HCPCS Codes subject to review for Site of Service:	
Code	Description
J0129	Injection, abatacept, 10 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)
J0202	Injection, alemtuzumab, 1 mg
J0490	Injection, belimumab, 10 mg
J0585	Injection, onabotulinumtoxinA, 1 unit
J0881	Injection, darbepoetin alfa, 1 mcg (non-ESRD use)
J0897	Injection, denosumab, 1 mg
J1568	Injection, immune globulin, (Octagam), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), nonlyophilized, (e.g., liquid), 500 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J1786	Injection, imiglucerase, 10 units
J2323	Injection, natalizumab, 1 mg
J2350	Injection, ocrelizumab, 1 mg

J3380	Injection, vedolizumab, 1 mg
J9217	Leuprolide acetate (for depot suspension), 7.5 mg
J9311	Injection, rituximab 10 mg and hyaluronidase
J9312	Injection, rituximab, 10 mg
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5109	Injection, infliximab-qbtx, biosimilar, (ixifi), 10 mg
Q5115	Injection, rituximab-abbs, biosimilar, (truxima), 10 mg
Q5119	Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (avsola), 10 mg
Q5123	Injection, rituximab-arxx, biosimilar, (riabni), 10 mg

<i>Infusion Therapy</i>	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour
96361	Intravenous infusion, hydration; each additional hour (List separately in addition to code for primary procedure)
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or

	drug); concurrent infusion (List separately in addition to code for primary procedure)
96369	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump set-up and establishment of subcutaneous infusion site(s)
96370	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
96371	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); additional pump set-up with establishment of new subcutaneous infusion site(s) (List separately in addition to code for primary procedure)
96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96373	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intraarterial
96374	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
96375	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)
96376	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure)
96377	Application of on-body injector (includes cannula insertion) for timed subcutaneous injection
96379	Unlisted therapeutic, prophylactic or diagnostic intravenous or intra-arterial injection or infusion
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal antineoplastic
96405	Chemotherapy administration; intralesional, up to and including 7 lesions
96406	Chemotherapy administration; intralesional, more than 7 lesions
96409	Chemotherapy administration; intravenous, push technique, single or initial

	substance/drug
96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)
96420	Chemotherapy administration, intra-arterial; push technique
96422	Chemotherapy administration, intra-arterial; infusion technique, up to 1 hour
96423	Chemotherapy administration, intra-arterial; infusion technique, each additional hour (List separately in addition to code for primary procedure)
96425	Chemotherapy administration, intra-arterial; infusion technique, initiation of prolonged infusion (more than 8 hours), requiring the use of a portable or implantable pump
96440	Chemotherapy administration into pleural cavity, requiring and including thoracentesis
96446	Chemotherapy administration into the peritoneal cavity via indwelling port or catheter
96450	Chemotherapy administration, into CNS (e.g., intrathecal), requiring and including spinal puncture
96521	Refilling and maintenance of portable pump
96522	Refilling and maintenance of implantable pump or reservoir for drug delivery, systemic (e.g., intravenous, intra-arterial)
96523	Irrigation of implanted venous access device for drug delivery systems
96542	Chemotherapy injection, subarachnoid or intraventricular via subcutaneous reservoir, single or multiple agents

96549	Unlisted chemotherapy procedure
G0498	Chemotherapy administration, intravenous infusion technique; initiation of infusion in the office/clinic setting using office/clinic pump/supplies, with continuation of the infusion in the community setting (e.g., home, domiciliary, rest home or assisted living) using a portable pump provided by the office/clinic, includes follow up office/clinic visit at the conclusion of the infusion
S9347	Home infusion therapy, uninterrupted, long-term, controlled rate intravenous or subcutaneous infusion therapy (e.g., epoprostenol); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9359	Home infusion therapy, antitumor necrosis factor intravenous therapy; (e.g., Infliximab); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9497	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 3 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9500	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 24 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9501	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 12 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9502	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 8 hours, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9503	Home infusion therapy, antibiotic, antiviral, or antifungal; once every 6 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9504	Home infusion therapy, antibiotic, antiviral, or antifungal; once every 4 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

S9537	Home therapy; hematopoietic hormone injection therapy (e.g., erythropoietin, G-CSF, GM-CSF); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9542	Home injectable therapy, not otherwise classified, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9558	Home injectable therapy; growth hormone, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9559	Home injectable therapy, interferon, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9560	Home injectable therapy; hormonal therapy (e.g.; leuprolide, goserelin), including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9562	Home injectable therapy, palivizumab, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9810	Home therapy; professional pharmacy services for provision of infusion, specialty drug administration, and/or disease state management, not otherwise classified, per hour (do not use this code with any per diem code)

Appendix

Evidence

Current evidence supports the use of alternative sites of care such as home infusion or non-hospital outpatient facilities for many medications requiring infusion/injection compared to hospital outpatient infusion centers. Several studies have suggested alternative sites of care, such as home infusion or non-hospital outpatient facilities, may provide favorable outcomes compared to hospital outpatient infusion centers for certain medications:

- A study by Wasserman et al. found the rate of infection-related events was double in hospital outpatient settings compared to home infusion for IV immunoglobulin therapy. The decreased infection rate is attributed to less exposure to pathogens in healthcare settings.
- A study by Souayah et al. analyzed over 4000 infusions across 420 patients and found 99% of infusions resulted in no or only mild adverse reactions, with no serious adverse events reported. This demonstrates the safety of infusions in non-hospital settings.

- A systematic review by Polinski et al. identified 13 studies comparing home infusion to hospital outpatient infusions. The analysis found no difference in adverse events between settings. Furthermore, home infusion patients reported better quality of life, less disruption, and lower costs compared to hospital outpatient infusions.
- Additional studies have shown similar outcomes between alternative sites of care versus hospital outpatient infusion for various medication classes.

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