

Infusion Pumps

DME.SU.103.A

v1.0.2026

Introduction/general information

This guideline addresses infusion pumps.

Criteria

An external infusion pump and related supplies are considered medically necessary for an individual when **both** of the following criteria are met:

- There is documentation that an individual requires an external infusion pump for **any** of the following:
 - enteral and parenteral nutrition
 - parenterally administered medications (e.g., chemotherapy, antivirals, antifungals, narcotic analgesics, epoprostenol or treprostinil, and antibiotics other than vancomycin)
- The external infusion pump and related supplies are required to safely administer the medication or nutrition at home.

An IV pole is considered medically necessary when an individual uses a medically necessary stationary infusion pump.

Supplies

When an external infusion pump is considered medically necessary, all associated supplies required for its effective use are also considered medically necessary.

Not Covered

The coverage of vancomycin as a durable medical equipment (DME) infusion pump is not covered as there is insufficient evidence to support the medical necessity of using an external infusion pump instead of a disposable elastomeric pump or the gravity drip method.

An implantable infusion pump is not covered as it does not meet the definition of DME.

Drugs are only covered as a supply to a covered DME infusion pump.

Evidence Discussion

Infusion pumps are medical devices engineered to administer fluids or medications in controlled, continuous volumes over prolonged periods. These systems regulate flow rates, ensuring accurate and consistent delivery for a wide range of therapeutic applications. Infusion pumps are classified by attributes such as operating mechanism (i.e., mechanical or electronic), pumping mechanism design, delivered drug, and safety features. Portable pumps for home use were introduced to alleviate pressure from hospitals and support ambulatory treatment.¹

A 2021 study conducted by García-Queiruga et al. evaluated the use of elastomeric infusion pumps (EIPs) for continuous intravenous antibiotic therapy in a hospital-at-home setting. Researchers analyzed 106 outpatient parenteral antibiotic therapy episodes involving 102 individuals over two years with common antibiotics including piperacillin/tazobactam, ceftazidime, and meropenem. The average treatment duration was about 13 days, and the clinical cure rate reached 84%, demonstrating effectiveness comparable to inpatient care. Respiratory infections were the most frequent indication, followed by urinary tract and skin/soft tissue infections. Overall, the findings suggest that EIPs provide a safe and effective alternative to traditional hospitalization for continuous antibiotic infusion.²

A systematic review by Diamantis et al. (2021) found that outpatient parenteral antimicrobial therapy (OPAT) using elastomeric pumps enabled continuous or prolonged infusion of time-dependent antibiotics, improving pharmacokinetic/pharmacodynamic (PK/PD) profiles and reducing resistance risk, while also enhancing individual mobility and quality of life. Clinical efficacy appeared comparable to inpatient care, lessened with observational studies reporting cure rates above 90%. However, the authors noted that OPAT generally lacks rigorous monitoring, increasing risks of therapeutic failure and adverse events, which occurred in about 11% of individuals in one study.³

Barrera et al. (2023) conducted an open-label study evaluating the safety and patient-reported outcomes of home-based ocrelizumab infusions. Ninety-nine individuals with multiple sclerosis (MS) received a 600mg ocrelizumab infusion at home over approximately 2.5 hours, following premedication and under nurse supervision. Infusion-related reactions occurred in 25.3% of individuals, all mild or moderate, with no severe ($\geq$ Grade 3) reactions reported. Adverse events were common but non-serious, affecting 66.7% of participants; the most frequent were itch, fatigue, and grogginess.

¹ Sabbagh Dit Hawasli R, Barton S, Nabhani-Gebara S. Ambulatory chemotherapy: Past, present, and future. *J Oncol Pharm Pract.* 2021;27(4):962-973. doi:10.1177/1078155220985916

² García-Queiruga M, Feal Cortizas B, Lamelo Alfonsín F, Pertega Díaz S, Martín-Herranz I. Continuous infusion of antibiotics using elastomeric pumps in the hospital at home setting. *Rev Esp Quimioter.* 2021;34(3):200-206. doi:10.37201/req/122.2020

³ Diamantis S, Dawudi Y, Cassard B, Longuet P, Lesprit P, Gauzit R. Home intravenous antibiotherapy and the proper use of elastomeric pumps: Systematic review of the literature and proposals for improved use. *Infect Dis Now.* 2021;51(1):39-49. doi:10.1016/j.medmal.2020.10.019

No medication errors or serious adverse events occurred. Patient-reported outcomes indicated significantly higher satisfaction with home infusions compared to prior infusion center experiences, including improved confidence in care, comfort, and feelings of safety. Participants also expressed a strong preference for home-based treatment. These results suggest that at-home ocrelizumab infusion using a shortened protocol is safe, feasible, and associated with enhanced individual satisfaction.⁴

Díaz-Manera et al. (2024) reported on the feasibility and safety of administering enzyme replacement therapy (ERT) at home for individuals with Pompe disease. Across three clinical trials (NEO-EXT, COMET, and Mini-COMET), 17 participants received a total of 419 home infusions under healthcare professional supervision. Adverse event rates during home infusions were comparable to those in clinic settings (0.028 vs. 0.039 participants with events per infusion), and infusion-associated reactions were rare (0.003 vs. 0.006 per infusion). No medication errors were reported. Most adverse events were unrelated, non-serious, and resolved without complications. Immunogenicity analysis showed that anti-drug antibody status did not correlate with infusion reactions. The study concluded that home infusion of ERT was feasible and safe for appropriately selected individuals, offering potential benefits such as improved quality of life, reduced treatment burden, and enhanced adherence. Real-world evaluations and post-authorization safety studies are necessary to confirm these findings.⁵

Current literature does not demonstrate superior clinical outcomes for vancomycin administration using external infusion pumps compared to disposable elastomeric pumps or gravity drip methods. While continuous infusion may improve pharmacokinetic control and potentially reduce nephrotoxicity, these benefits can be achieved with elastomeric devices without requiring an electronic pump. No randomized trials or systematic reviews confirm that external pumps provide additional safety or efficacy for vancomycin beyond simpler, lower-cost alternatives. Therefore, in the absence of documented need for prolonged infusion or precise rate control to prevent toxicity, the use of an external infusion pump for vancomycin is considered not medically necessary.^{6,7}

The most commonly reported adverse events that occur with infusion pumps were due to defects in the software, user interface, and mechanical or electrical functioning.¹

⁴ Barrera B, Simpson H, Engebretson E, et al. Safety and patient experience with at-home infusion of ocrelizumab for multiple sclerosis. *Ann Clin Transl Neurol*. 2023;10(4):579-588. doi:10.1002/acn3.51745

⁵ Díaz-Manera J, Hughes D, Erdem-Özdamar S, et al. Home infusion experience in patients with Pompe disease receiving avalglucosidase alfa during three clinical trials. *Mol Genet Metab*. 2024;143(4):108608. doi:10.1016/j.ymgme.2024.108608

⁶ Wysocki M, Delatour F, Faurisson F, et al. Continuous versus intermittent infusion of vancomycin in severe Staphylococcal infections: prospective multicenter randomized study. *Antimicrob Agents Chemother*. 2001;45(9):2460-2467. doi:10.1128/AAC.45.9.2460-2467.2001

⁷ Waite MF, Kuhn TC, Brown DL. The pharmacokinetic/pharmacodynamic rationale for administering vancomycin via continuous infusion. *J Clin Pharm Ther*. 2015;40(3):259-265. doi:10.1111/jcpt.12270

Codes

HCPCS code descriptions

HCPCS Code	Description
A4220	Refill kit for implantable infusion pump
A4221	Supplies for maintenance of non-insulin drug infusion catheter, per week (list drugs separately)
A4222	Infusion supplies for external drug infusion pump, per cassette or bag (list drugs separately)
A4223	Infusion supplies not used with external infusion pump, per cassette or bag (list drugs separately)
A4602	Replacement battery for external infusion pump owned by patient, lithium, 1.5 volt, each
E0459	Chest wrap
E0776	IV pole
E0779	Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater
E0780	Ambulatory infusion pump, mechanical, reusable, for infusion less than 8 hours
E0781	Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient
E0791	Parenteral infusion pump, stationary, single or multi-channel
K0455	Infusion pump used for uninterrupted parenteral administration of medication, (e.g., epoprostenol or treprostinol)
K0552	Supplies for external non-insulin drug infusion pump, syringe type cartridge, sterile, each
K0601	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each
K0602	Replacement battery for external infusion pump owned by patient, silver oxide, 3 volt, each

HCP Code	Description
K0603	Replacement battery for external infusion pump owned by patient, alkaline, 1.5 volt, each
K0604	Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each
K0605	Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each

References

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3. LCD - External Infusion Pumps (L33794). www.cms.gov. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33794>
4. Sabbagh Dit Hawasli R, Barton S, Nabhani-Gebara S. Ambulatory chemotherapy: Past, present, and future. J Oncol Pharm Pract. 2021;27(4):962-973. doi:10.1177/1078155220985916
5. Hobbs JG, Ryan MK, Ritchie B, et al. Protocol for a randomised crossover trial to evaluate patient and nurse satisfaction with electronic and elastomeric portable infusion pumps for the continuous administration of antibiotic therapy in the home: the Comparing Home Infusion Devices (CHID) studyBMJ Open 2017;7:e016763. doi: 10.1136/bmjopen-2017-016763