

Infusion Pump Therapy

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[Instructions for Use](#)

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Related Medicare Advantage Policy Guidelines
• Infusion Pumps (NCD 280.14)
• Intravenous Immune Globulin (IVIG)
• Routine Costs in Clinical Trials (310.1)

Coverage Guidelines

Infusion pump therapy is covered when Medicare coverage criteria are met.

DME Face to Face Requirement: Effective July 1, 2013, Section 6407 of the Affordable Care Act (ACA) established a face-to-face encounter requirement for certain items of DME (including implantable infusion pumps; implantable programmable infusion pump, replacement and external ambulatory infusion pump). For DME Face to Face Requirement information, refer to the Coverage Summary titled [Durable Medical Equipment \(DME\), Prosthetics, Corrective Appliances/Orthotics \(Non-Foot Orthotics\) and Medical Supplies Grid](#).

COVID-19 Public Health Emergency Waivers and Flexibilities: In response to the COVID-19 Public Health Emergency, the Centers for Medicare and Medicaid (CMS) has updated some guidance for certain home infusion pumps.

For a comprehensive list of coronavirus waivers and flexibilities, refer to <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>. (Accessed January 7, 2021)

External Infusion Pumps

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable.

Refer to the

- [NCD for Infusion Pump \(280.14\)](#).
- DME MAC [LCD for External Infusion Pumps \(L33794\)](#)

(Accessed August 23, 2021)

Part B vs Part D Guideline

In general, the supplier would bill Part B if the drug was administered using an infusion pump and bill the Part D plan for infusion using other methods (e.g., IV push). While professional services and supplies related to the administration of the infused drug are not payable under Part D, some coverage may be available under Part A or B home health benefits, under Medicaid, or from secondary commercial health benefits.

As a rule, drugs infused using an implantable pump would be covered under Part B. Drugs infused in the home using an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare DME MAC.

In the case of a member in a hospital, or a SNF bed, (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out or (3) whose stay is non-covered - infusible DME supply drugs are not covered under Part B because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the member's "home" for this purpose. In this case, coverage for the drugs would be available under Part D.

Refer to the [Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C – Medicare Part B versus Part D Coverage Issues](#) (Accessed January 7, 2021)

Also refer to the Coverage Summaries titled [Medications/Drugs \(Outpatient/Part B\)](#) and [Chemotherapy, and Associated Drugs and Treatments](#).

Covered Benefits

External infusion pumps are covered for the following indications.

Note: Payment may also be made for drugs necessary for the effective use of a covered external infusion pump as long as the drug being used with the pump is itself reasonable and necessary for the patient's treatment.

Treatment of Diabetes Mellitus

Treatment of diabetes mellitus – Continuous subcutaneous insulin infusion (CSII) and related drugs/supplies are covered as medically reasonable and necessary in the home setting for the treatment of diabetic patients.

For coverage criteria, refer to the [NCD for Infusion Pump \(280.14\)](#). (Accessed January 7, 2021)

Note: CMS will continue to allow coverage of all other uses of CSII in accordance with the Category B investigational device exemption (IDE) clinical trials regulation (42 CFR 405.201) or as a routine cost under the clinical trials policy; refer to the [NCD for Routine Costs in Clinical Trials \(310.1\)](#). (Accessed January 7, 2021)

Also refer to the Coverage Summary titled [Experimental Procedures and Items, Investigational Devices and Clinical Trials](#).

For coverage guideline for specific diabetes equipment and supplies, refer to the Coverage Summary titled [Diabetes Management, Equipment and Supplies](#).

Treatment of Iron Poisoning

Only external pumps when used in the administration of deferoxamine for the treatment of chronic iron overload.

Chemotherapy

When used in the treatment of primary hepatocellular carcinoma or colorectal cancer when the disease is not resectable or the patient refuses surgery to remove the tumor.

Treatment of Intractable Cancer Pain

Morphine infusion via an external infusion pump is recommended when used in the treatment of intractable pain caused by cancer in either an inpatient or outpatient setting including hospice.

Treatment of Thromboembolic Disease

When used in the administration of heparin for the treatment of thromboembolic disease and/or pulmonary embolism, only external pumps when used in an institutional setting.

Other Uses

Other uses of external infusion pumps maybe covered when criteria are met. The administration of other drugs using an external infusion pump is limited to certain situations.

Not Covered

External infusion pumps are not covered for the administration of Vancomycin. There is insufficient evidence to support the necessity of using an external infusion pump, instead of a disposable elastomeric pump or the gravity drip method, to administer vancomycin in a safe and appropriate manner.

Implantable Infusion Pumps

Refer to the [NCD for Infusion Pump \(280.14\)](#). (Accessed January 7, 2021)

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>. (Accessed August 23, 2021)

Part B vs Part D Guideline

In general, the supplier would bill Part B if the drug was administered using an infusion pump and bill the Part D plan for infusion using other methods (e.g., IV push). While professional services and supplies related to the administration of the infused drug are not payable under Part D, some coverage may be available under Part A or B home health benefits, under Medicaid, or from secondary commercial health benefits.

As a rule, drugs infused using an implantable pump would be covered under Part B. Drugs infused in the home using an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare DME MAC.

In the case of a member in a hospital, or a SNF bed, (1) who does not have Part A coverage (2) whose Part A coverage for the stay has run out or (3) whose stay is non-covered - infusible DME supply drugs are not covered under Part B because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the member's "home" for this purpose. In this case, coverage for the drugs would be available under Part D.

Refer to the [Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C – Medicare Part B versus Part D Coverage Issues](#). (Accessed January 7, 2021)

Covered Benefits

Implantable infusion pumps may be covered for the following indications:

Chemotherapy for Liver Cancer

The implantable infusion pump is covered for intra-arterial infusion of 5-FUdR for the treatment of liver cancer for patients with primary hepatocellular carcinoma or Duke's Class D colorectal cancer, in whom the metastases are limited to the liver, and where: (1) the disease is unresectable, or (2) the patient refuses surgical excision of the tumor.

Anti-Spasmotic Drugs for Severe Spasticity

An implantable infusion pump is payable when used to administer antispasmodic drugs intrathecally (e.g., baclofen) to treat chronic intractable spasticity in member's who have proven unresponsive to less invasive medical therapy. The following criteria must be met:

- The member cannot be maintained on medical non-invasive methods of spasm control, such as oral antispasmodic drugs. This must be supported by at least a six-week trial and these methods either fail to control adequately the spasticity or produce intolerable side effects.
- Prior to pump implantation, the member must have responded favorably to a trial intrathecal dose of the antispasmodic drug.

Opioid Drugs for Chronic Intractable Pain

An implantable infusion pump is coverable when used to administer opioid drugs (e.g. morphine) intrathecally or epidurally for treatment of severe chronic intractable pain of malignant or non-malignant origin in members who have a life expectancy of at

least three (3) months and who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

- The history must indicate that the member would not respond adequately to noninvasive methods of pain control, such as systemic opioids (including attempts to eliminate physical and behavioral abnormalities that may cause and exaggerated reaction to pain).
- A preliminary trial of intraspinal opioid drug administration with a temporary and intrathecal/epidural catheter to substantiate adequately acceptable pain relief, degree of side effects (including effects on the activities of daily living), and member acceptance.

Other Indicators

Determinations may be made on coverage of other uses of implanted pumps based on support that:

- The drug is reasonable and necessary;
- It is medically necessary for the drug to be administered by an implanted infusion pump;
- And the FDA-approved labeling for the pump specifies the drug administered and the purpose of administration as an indicated use for the pump.

Not Covered

Implantable infusion pumps are not covered for the following indications:

- Thromboembolic Disease: According to the Public Health Service, there is insufficient published clinical data to support the safety and effectiveness of the heparin implantable pump.
- Diabetes: An implanted infusion pump for the infusion of insulin to treat diabetes is not covered. The data does not demonstrate that the pump provides effective administration of insulin.

Contraindications

The implantation of an infusion pump is contraindicated in the following patients:

- Patients with a known allergy or hypersensitivity to the drugs being used (e.g., oral baclofen, morphine, etc.).
- Patients who have an active infection.
- Patients whose body size is insufficient to support the weight and bulk of the device.
- Patients with other implanted programmable devices since crosstalk between devices may inadvertently change the prescription.

Policy History/Revision Information

Date	Summary of Changes
05/01/2021	Template Update <ul style="list-style-type: none">• Reformatted policy; transferred content to new template
01/19/2021	<ul style="list-style-type: none">• Routine review; no change to coverage guidelines

Instructions for Use

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The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

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