### Coverage Summary

**Infusion Pump Therapy**

<table>
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<tr>
<th>Policy Number:</th>
<th>1-003</th>
<th>Products: UnitedHealthcare Medicare Advantage Plans</th>
<th>Original Approval Date:</th>
<th>02/18/2009</th>
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<tr>
<td>Approved by:</td>
<td>UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date:</td>
<td>01/19/2016</td>
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**Related Medicare Advantage Policy Guidelines:**
- Intravenous Immune Globulin (IVIg)
- Infusion Pumps (NCD 280.14)
- Routine Costs in Clinical Trials (310.1)

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**I. COVERAGE**

**Coverage Statement:** 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 DME, Prosthetics, Corrective Appliances/Orthotic and Medical Supplies Grid.

**Guidelines/Notes:**

1. **External infusion pumps**
   - See the [NCD for Infusion Pump (280.14)](Accessed December 15, 2015)
   - Local Coverage Determinations (LCDS) exist and compliance with these policies is required where applicable. See the [DME MAC LCDs for External Infusion Pump (L33794)](Accessed January 13, 2016)
• **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.


  Also see the Coverage Summary for Medications/Drugs (Outpatient/Part B) and the Coverage Summary for Chemotherapy, Associated Drugs and Treatments.

  a. **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).

  1) **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, see the NCD for Infusion Pump (280.14).** (Accessed December 15, 2015)

     **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; see the NCD for Routine Costs in Clinical Trials (310.1). (Accessed December 15, 2015)

     Also see the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials.

  2) **Treatment of iron poisoning** – only external pumps when used in the administration of deferoxamine for the treatment of chronic iron overload

  3) **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
4) **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.

5) **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.

6) **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.

b. **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.

2. **Implantable Infusion Pumps**

- **See the NCD for Infusion Pump (280.14).** (Accessed December 15, 2015)


- **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.*


a. **Covered Benefits** - Implantable infusion pumps may be covered for the following indications:

1) **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.

2) Anti-Spasmodic 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 beneficiaries who have proven unresponsive to less invasive medical therapy. The following criteria must be met:
   - The beneficiary 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 beneficiary must have responded favorably to a trial intrathecal dose of the antispasmodic drug.

3) 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 beneficiaries 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 beneficiary 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 beneficiary acceptance.

4) Other indications - 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.

b. Not Covered - Implantable infusion pumps are not covered for the following indications:

1) 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.

2) 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.

c. Contraindications - The implantation of an infusion pump is contraindicated in the
following patients:
1) Patients with a known allergy or hypersensitivity to the drugs being used (e.g., oral baclofen, morphine, etc.).
2) Patients who have an active infection.
3) Patients whose body size is insufficient to support the weight and bulk of the device.
4) Patients with other implanted programmable devices since crosstalk between devices may inadvertently change the prescription

II. DEFINITIONS

III. REFERENCES

See above

IV. REVISION HISTORY

01/19/2016 Annual review with the following update:
Updated reference link(s) of the applicable LCDs to reflect the new condensed LCD link(s).

01/20/2015 Annual review with the following updates:
Guideline 1 (External Infusion Pumps) and Guideline 2 (Implantable Infusion Pumps)
Updated the Part B vs Part D guideline to indicate:

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.

See the Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C Medicare Part B versus Part D Coverage Issues at
<table>
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<tr>
<th>Date</th>
<th>Update</th>
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<tr>
<td>10/21/2014</td>
<td>Removed detailed DME Face-to-Face Requirement information and replaced with a reference link to the DME, Prosthetics, Corrective Appliances/Orthotic and Medical Supplies Grid.</td>
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<tr>
<td>02/18/2014</td>
<td>Annual review; deleted reference to the UnitedHealthcare Home Infusion Coverage document.</td>
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<tr>
<td>08/20/2013</td>
<td>Added a note pertaining to the DME Face-to-Face Requirement in accordance with Section 6407 of the Affordable Care Act as defined in the 42 CFR 410.38(g).</td>
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<tr>
<td>02/19/2013</td>
<td>Annual review; no updates.</td>
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<tr>
<td>02/27/2012</td>
<td>Annual review; no updates.</td>
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<tr>
<td>01/01/2012</td>
<td>The UHC Home Infusion Part B Coverage Criteria Grid (Attachment A) was updated to include Gammagard and Gamunex under the Therapeutic Class “Immune Globulin Subcutaneous”.</td>
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<td>02/21/2011</td>
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