Clinical Policy Title: Implantable infusion pumps

Clinical Policy Number: 00.02.14

Effective Date: July 1, 2016
Initial Review Date: May 18, 2016
Most Recent Review Date: April 10, 2018
Next Review Date: April 2019

Policy contains:
- Chronic pain.
- Chronic spasticity and dystonia.
- Diabetes mellitus.
- Intrathecal infusion.

Related policies:

CP# 00.02.06 Infusible pharmaceuticals for bone pain management
CP# 03.03.01 Spinal cord stimulators for chronic pain
CP# 03.03.08 Intravenous lidocaine infusion for neuropathic pain
CP# 06.02.01 Insulin infusion therapy (insulin pumps)

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas’ clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of implantable infusion pumps as durable medical equipment to be medically necessary when all of the following criteria and indications are met:

- The infused drug is medically necessary for the treatment of the member.
- The implantable infusion pump is medically necessary to administer the drug.
- U.S. Food and Drug Administration (FDA)-approved labeling for the pump specifies that the drug being administered and the purpose for which it is administered is an indicated use for the pump.
- The implantable infusion pump is administered by providers who can fully accommodate all aspects of implantable infusion pump drug delivery, including evaluation, trialing, implantation, long-term management, and troubleshooting.
Indications for use:

Implantable infusion pumps are considered medically necessary for the following conditions:

- 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 cannot be resected or, (2) the patient refuses surgical excision of the tumor.

- For administration of anti-spasmodic drugs (e.g., baclofen) intrathecally to treat chronic intractable spasticity in patients who have proven unresponsive to less invasive medical therapy. Specifically, this lack of responsiveness is indicated by at least a six-week trial in which the patient cannot be maintained on non-invasive methods of spasm control, such as oral anti-spasmodic drugs, because these methods either fail to adequately control the spasticity or produce intolerable side effects. Prior to pump implantation, the patient must have responded favorably to a trial intrathecal dose of the anti-spasmodic drug. The procedure is not indicated for children who are too small to accommodate an infusion pump (NICE, 2012).

- To administer opioid drugs (e.g., morphine) intrathecally or epidurally for treatment of severe chronic intractable pain of malignant or nonmalignant origin in patients who have a life expectancy of at least three months, and who have proven unresponsive to less invasive medical therapy, including patient history indicating they would not respond adequately to noninvasive methods of pain control, such as systemic opioids. A preliminary trial of intraspinal opioid drug administration must be undertaken with a temporary intrathecal/epidural catheter to substantiate adequately acceptable pain relief, degree of side effects (including effects on activities of daily living), and patient acceptance.

- For insulin-dependent type 1 or insulin-requiring non-insulin-dependent type 2 diabetes mellitus when glycemic control with intensive subcutaneous insulin therapy is not achieved.

Determinations may be made on coverage of other uses of implanted infusion pumps if the attending physician concludes:

- The drug is reasonable and necessary for the treatment of the individual patient.
- It is medically necessary that the drug be administered by an implanted infusion pump.
- FDA-approved labeling for the pump specifies that the drug being administered and the purpose for which it is administered is an indicated use for the pump (Centers for Medicare & Medicaid Services [CMS] National Coverage Determination [NCD], 2004).

For Medicare members only:

In addition to the above-listed indications, AmeriHealth Caritas considers the use of implantable infusion pumps as durable medical equipment to be clinically proven and, therefore, medically necessary for members who meet the following criteria and indications:

- For administration of intrahepatic floxuridine-based chemotherapy for the treatment of primary hepatocellular carcinoma.
• For intrathecal administration of morphine or ziconotide monotherapy for severe chronic intractable pain of malignant or nonmalignant origin in patients who have a life expectancy of at least three months and who have proven unresponsive to less invasive medical therapy.

Limitations:

All other uses of implantable infusion pumps are not medically necessary.

Contraindications include, but are not limited to:

• Inability or unwillingness to have the pump refilled, including inadequate social support.
• Presence of other implanted programmable devices, since crosstalk between devices may inadvertently change the prescription.
• Significant coagulopathies.
• Hemodynamic instability.
• Spinal anomalies.
• Intracranial hypertension.
• Active infection.
• Insufficient body size preventing device implantation.
• Significant psychiatric comorbidities.
• Allergy to drug being infused.

Documentation in the medical record must include medical necessity for both the drug and intrathecal or hepatic-artery-based infusion, successful trialing, and continued drug administration using the implantable infusion pump.

Replacement or upgrade of an implantable infusion pump or programmer is not medically necessary unless either:

• The existing device malfunctions and cannot be repaired.
• The individual’s condition changes in a way that makes the present device nonfunctional.

Replacement of the entire implantable infusion pump system (i.e., the catheter and programmer) is not generally required at the time of pump replacement due to the end of battery life.

Alternative covered services:

• Noninvasive, nonpharmacologic interventions (e.g., physical therapy, occupational therapy, or counseling).
• Oral medications (e.g., nonsteroidal anti-inflammatory drugs, antidepressants, anticonvulsants, serotonergic drugs, baclofen, opioids, benzodiazepines, dantrolene sodium, or imidazolines).
• Systemic chemotherapy.
• Botulinum toxin injections.
• Stimulation techniques.
• Regional anesthetic interventions.
• Surgery.

Background

Implantable infusion pumps are subcutaneously inserted devices that deliver drugs through central venous, intra-arterial, intraspinal (epidural or intrathecal), or intraperitoneal catheters. An implantable infusion pump is intended to provide long-term continuous or intermittent drug infusion directly to specific sites and can be programmed for continuous or variable rates of infusion. The pump is surgically placed in a subcutaneous pocket under the infraclavicular fossa or in the abdominal wall, and a catheter is threaded into the desired position. Implantable infusion pumps are easily removable, thus providing an important degree of therapeutic control for patients and providers.

The FDA regulates implantable infusion pumps as combination products, which comprise two or more regulated components (e.g., drugs, devices, and/or biological products), through the premarket approval process. The FDA has approved several implantable infusion pumps for use with specific drugs for targeted neuromodulation and cancer treatment. The treatments are:

• Chronic intraspinal (epidural and intrathecal) infusion of preservative-free morphine sulfate sterile solution for the treatment of chronic intractable pain.
• Chronic intrathecal infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain.
• Chronic intrathecal infusion of Lioresal® IT (baclofen injection) for the management of severe spasticity.
• Chronic intravascular infusion of floxuridine or methotrexate for the treatment of primary or metastatic cancer.

Professional guidelines exist for various uses of implantable infusion pumps. For cancer-related pain, one such guideline is a recommendation for much wider use of intrathecal infusion for pain management for terminal illness, or if standard medication management fails to adequately control pain (Deer, 2011). For chemotherapy patients, guidelines recommend hepatic artery-based infusion with or without systemic 5-FU as an option at institutions with experience in both the surgical and medical oncologic aspects of the procedure (National Comprehensive Cancer Network [NCCN], 2016a; NCCN, 2016b).

An American Society for Interventional Pain Physicians guideline for continuous intrathecal infusion to alleviate chronic spinal pain provides strong evidence for short-term relief and moderate evidence for long-term improvement (Boswell, 2007). There are concerns that guidelines for such treatment of chronic spinal pain are based on a paucity of literature (Manchikanti, 2009b). Guidelines exist on intrathecal baclofen therapy for spasticity. One recommends a screening test prior to intrathecal baclofen therapy for spasticity as a best practice (Boster, 2016). Another guideline for problematic spasticity involving muscles, including neurologic diseases, finds the treatment can be effective in
certain ambulatory patients who have failed other approaches, and is also effective in managing children (Saulino, 2016). Several European professional societies recommend intrathecal baclofen to treat spasticity in selected multiple sclerosis patients (Gold, 2013).

The Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society found insufficient evidence to support or refute the use of continuous intrathecal baclofen for the treatment of spasticity in children with cerebral palsy (Delgado, 2010). The National Institute for Health and Care Excellence recommends considering intrathecal baclofen for children and young people with spasticity or dystonia that causes difficulty with pain or muscle spasms, posture or function, or self-care or ease of care by parents or caregivers (NICE, 2012). Contraindications to intrathecal baclofen for spasticity (including known adverse reactions to the drug and other factors affecting compliance) have also been presented (Saulino, 2016).

Continuous subcutaneous insulin infusion therapy is recommended as a treatment option for adults and children 12 and older with type 1 diabetes mellitus, as long as attempts to reduce HbA1C levels with daily injections result in disabling hypoglycemia, or if HbA1C levels remain high. For children under 12 with type 1 diabetes, continuous therapy is recommended if multiple injections are considered inappropriate (NICE, 2008). Another guideline states that trials have yet to confirm an association between oral opioids and response to intrathecal therapy, or a basis for treating diabetes-related pain (Deer, 2011). The Society of Critical Care Medicine asserts that compelling evidence is lacking to recommend for or against continuous insulin infusion (AHRQ, 2012).

**Searches**

AmeriHealth Caritas searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- CMS.

We conducted searches on February 27, 2018. Search terms were: "infusions, parenteral," "infusion pumps, implantable," "intrathecal clonidine," "intrathecal ziconotide," and "intrathecal baclofen."

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies —
which also rank near the top of evidence hierarchies.

**Findings**

A number of systematic reviews have been conducted on continuous implantable infusion pumps. For various types of (non-cancer) pain, one such review of seven trials (none randomized) found a paucity of evidence to support use (Falco, 2013). A review of intrathecal infusion for chronic intractable pain included 15 trials (none randomized) of 12 months’ follow-up for pain, concluding the devices had positive outcomes for long-term relief (Patel, 2009).

A review found insufficient evidence to compare intrathecal infusion with other types of long-term relief for chronic spinal pain (Manchikanti, 2009a). A review of eight trials, none randomized, found intrathecal baclofen for spinal cord injury reduced spasticity, using limited strength of evidence (McIntyre, 2014). A systematic review of three studies measuring a visual analogue scale of pain intensity after use of ziconotide, a new non-opioid calcium channel blocker for chronic neuropathic pain, documented a significant pooled odds ratio of 2.77 (Brookes, 2017).

A recommendation for using intrathecal infusion for cancer-related pain for over 12 months based on a literature review is limited to moderate, based on the moderate quality of evidence (Hayek, 2011). The value of locoregional chemotherapy treatment with hepatic artery-based infusion for patients with non-resectable intrahepatic cholangiocarcinoma is unclear (NCCN, 2016c).

A meta-analysis of 20 articles (n = 657) of patients with non-resectable intrahepatic cholangiocarcinoma indicated that hepatic arterial infusion produced superior survival results compared to other treatments (Boehm, 2015). Another study of 10 randomized trials did not support continuous therapy of hepatic arterial infusion alone to treat liver metastases from colorectal cancer (Mocellin, 2009). A 2016 Cochrane review of nine trials (n = 2119) of ovarian cancer patients found survival improvements if an intraperitoneal infusion therapy was added to chemotherapy (Jaaback, 2016).

Numerous systematic reviews and meta-analyses address efficacy of continuous infusion of insulin for persons with diabetes mellitus. One Cochrane study found no difference in maternal and infant outcomes for pregnant women given continuous insulin infusion compared to daily multiple insulin injections, based on five trials with 154 patients (Farrar, 2016), which validated an earlier analysis (Mukhopadhyay, 2007). Another Cochrane study of 976 participants with type 1 diabetes in 23 reviews indicated continuous infusion had significantly reduced HbA1C levels (Misso, 2010). Continuous infusion with implantable insulin pumps (four trials and eight cohorts) was found to be effective in lowering HbA1C levels and reducing hypoglycemic events, as well as raising patient satisfaction (Spaan, 2014). A review of children younger than age 6 with type 1 diabetes diagnosed more than six months before study (n = 176) documented significant improvements in HbA1C and more than 50 percent decreases in hypoglycemia in five of seven studies (Churchill, 2009).

A review of 15 moderate-quality trials comparing continuous subcutaneous insulin infusion with
multiple daily injections for type 1 diabetes indicated slightly lower HbA1C for the continuous infusion group and no difference in hypoglycemia; adolescents and adults with type 1 diabetes had fewer minor hypoglycemia episodes (not significant), and there was no difference in the number of hypoglycemia episodes in patients with type 2 diabetes (Fatourechi, 2009). A similar review of 16 randomized controlled trials (RCTs) showed the continuous group was superior in reduced HbA1C, reduced swings in blood glucose, fewer hypoglycemic episodes, and improved quality of life (Cummins, 2010).

A Hayes review last updated in 2015 assigned a “B” rating to the efficacy of implantable, continuous insulin pumps for patients with type 1 or 2 diabetes mellitus who have not otherwise achieved glycemic control, or for type 2 patients (Hayes, 2015).

A recent review of multiple sclerosis patients given intrathecal baclofen and intrathecal phenol showed a positive effect on severe spasticity, although evidence is limited (Otero-Romero, 2016). A systematic review of 16 studies, most low level, of intrathecal baclofen therapy in ambulant adults with spasticity of cerebral origin noted some improvement, but methodological limits and common adverse events led authors to conclude that use of this therapy is not supported (Pin, 2011). A 2015 Cochrane review found some short-term evidence that intrathecal baclofen effectively reduces spasticity in children with cerebral palsy (Hasnat, 2015), as did a Hayes review (Hayes, 2009).

A review of 430 children who underwent intrathecal baclofen therapy and were tracked for an average of 8.6 years showed 25 percent had at least one complication, and five percent had multiple complications. A total of 9.3 percent experienced an infection, a rate significantly lower (p < .001) in patients whose pump was placed subfascially versus subcutaneously. A higher infection rate was observed after pump replacement compared with the first pump implantation (10.6 percent versus 6.0 percent) (Motta, 2014).

There is a growing body of information on the pharmacokinetics and pharmacodynamics of infusion therapy. One review summarized the current information on intrathecal baclofen therapy, which is helpful to clinicians for drug concentration, infusion regimens, localization of catheter tip, and management of tolerance (Heetla, 2014).

**Policy updates:**

A total of one guideline/other and two peer reviewed references were added to, and four guidelines/other removed from, this policy in February 2018.

A total of nine guidelines/other and 15 peer reviewed references were added to this policy, in 2017.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brookes (2017)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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</table>
| Ziconotide monotherapy for chronic neuropathic pain | - Systematic review and meta-analysis of three RCTs.  
- Overall quality: moderate with a moderate risk of bias.  
- Frequent serious adverse events that resulted in two studies revising the protocol.  
- Pooled odds ratio (ziconotide versus placebo) 2.77.  
- Results suggest ziconotide is beneficial for pain reduction for chronic neuropathic pain. |
| Boehm (2015) Comparative effectiveness of hepatic artery-based therapies (HATs) for unresectable intrahepatic cholangiocarcinoma (ICC) | **Key points:**  
- Meta-analysis of 20 studies (n = 657 patients) of hepatic arterial infusion, transcatheter arterial chemoembolization, drug-eluting bead transcatheter arterial chemoembolization and yttrium (90) radioembolization.  
- Median overall survival (months): hepatic arterial infusion (22.8); yttrium (90) radioembolization (13.9); transcatheter arterial chemoembolization (12.4); and drug-eluting bead transcatheter arterial chemoembolization (12.3).  
- Complete and partial response to therapy (rate): hepatic arterial infusion (56.9 percent); yttrium (90) radioembolization (27.4 percent); and transcatheter arterial chemoembolization (17.3 percent).  
- Grade III/IV toxicity (events per patient): hepatic arterial infusion (0.35); transcatheter arterial chemoembolization (0.26); and drug-eluting bead transcatheter arterial chemoembolization (0.32).  
- For patients with unresectable ICC treated with hepatic artery-based therapy, hepatic arterial infusion offered the best outcomes in tumor response and survival, but may be limited by toxicity. |
| Falco (2013) Long-term management of chronic non-cancer pain using IT opioids | **Key points:**  
- Systematic review of seven non-randomized studies (n = 767).  
- Quality assessment: low to moderate.  
| Hayek (2011) IT infusions used in long-term management (> six months) of chronic pain | **Key points:**  
- Systematic review of 20 studies: 15 observational studies for non-cancer pain and five studies (four observational, one RCT) for cancer pain. Eleven studies assessed intrathecal morphine alone or in combination with other analgesics; four studies assessed other analgesics, including ziconotide.  
- Overall quality: moderate (high for the one RCT).  
- Intrathecal therapy is moderately effective and safe in controlling refractory painful conditions that have failed multiple other treatment modalities, both in cancer-related and non-cancer-related conditions.  
- Complications: granuloma formation, catheter kinking, fracture/leakage and migration, cerebrospinal fluid leak, seroma, hygroma, infection, pump erosion through the skin, and medication side effects. |
| Jaaback (2011) Cochrane review IP chemotherapy for the | **Key points:**  
- Systematic review and meta-analysis of nine RCTs (n = 2,119 women) comparing intraperitoneal versus intravenous administration.  
- Overall quality: high (for six RCTs). |
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<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| initial management of primary epithelial ovarian cancer | - Overall survival (hazard ratio): 0.81 (eight RCTs, 2,026 women); disease-free interval (HR): 0.78 (five RCTs, 1,311 women).  
- Intraperitoneal route was associated with greater serious toxicity (gastrointestinal effects, pain, fever, and infection) but less ototoxicity than intravenous route.  
- Clinical trials needed to address optimal dose, timing, and mechanism of administration. |
| Mocellin (2009) Cochrane review | **Key points:**  
- Systematic review and meta-analysis of 10 RCTs (n = 1,277 patients).  
- Overall quality: moderate to high.  
- Tumor response rate: 42.9 percent and 18.4 percent for hepatic arterial infusion and systemic chemotherapy, respectively (RR = 2.26; P < 0.0001).  
- Mean weighted median overall survival times: 15.9 and 12.4 months for hepatic arterial infusion and systemic chemotherapy, respectively; meta-risk of death was not statistically different between groups (HR = 0.90; P = 0.24).  
- Evidence does not support the clinical or investigational use of flouxuridine-based hepatic arterial infusion alone for the treatment of patients with unresectable colorectal cancer liver metastases; superior tumor response rate of hepatic arterial infusion regimen does not translate into a survival advantage over systemic chemotherapy. |

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**CMS NCDs:**


**Local Coverage Determinations (LCDs):**
Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>36260</td>
<td>Insertion of implantable intra-arterial infusion pump (e.g., for chemotherapy of liver)</td>
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<tr>
<td>36261</td>
<td>Revision of implanted intra-arterial infusion pump</td>
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<tr>
<td>36563</td>
<td>Insertion of tunneled centrally inserted central venous access device with subcutaneous pump</td>
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<tr>
<td>36583</td>
<td>Replacement, complete, of a tunneled centrally inserted central venous access device, with subcutaneous pump, through same venous access</td>
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<tr>
<td>61215</td>
<td>Insertion of subcutaneous reservoir, pump or continuous infusion system for connection to ventricular catheter</td>
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<td>62350</td>
<td>Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; without laminectomy</td>
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<td>62360</td>
<td>Implantation or replacement of device for intrathecal or epidural drug infusion; subcutaneous reservoir</td>
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<td>62361</td>
<td>Implantation or replacement of device for intrathecal or epidural drug infusion; nonprogrammable pump</td>
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<tr>
<td>62362</td>
<td>Implantation or replacement of device for intrathecal or epidural drug infusion;</td>
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<td>CPT Codes</td>
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<tr>
<td>14</td>
<td>programmable pump, including preparation of pump, with or without programming</td>
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<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
<th>Comments</th>
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<tr>
<td>C18.0 - C21.8</td>
<td>Malignant neoplasm of colon, rectosigmoid junction, rectum, anus and anal canal</td>
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<tr>
<td>C22.0</td>
<td>Liver cell carcinoma</td>
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<tr>
<td>C78.7</td>
<td>Secondary malignant neoplasm of liver and intrahepatic bile duct</td>
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<tr>
<td>G25.82</td>
<td>Stiff-hyphenman syndrome</td>
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<tr>
<td>G35</td>
<td>Multiple sclerosis</td>
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<td>G80.0 - G80.9</td>
<td>Cerebral palsy</td>
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<td>Spastic hemiplegia</td>
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<td>Chronic pain syndrome</td>
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<td>M62.40 - M62.49</td>
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<td>M62.830 - M62.838</td>
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<td>S12.000+ - S12.001+</td>
<td>Fracture of vertebral column with spinal cord injury</td>
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<td>S14.151+</td>
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<td>S14.157+</td>
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<tr>
<td>S14.101+</td>
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<td>Injury of nerves and spinal cord at neck level</td>
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<td>S14.139+</td>
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<td>S14.151+</td>
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<td>S14.159+</td>
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<td>C1772</td>
<td>Infusion pump, programmable (implantable)</td>
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<tr>
<td>C1891</td>
<td>Infusion pump, nonprogrammable, permanent (implantable)</td>
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<tr>
<td>C2626</td>
<td>Infusion pump, nonprogrammable, temporary (implantable)</td>
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<tr>
<td>E0782</td>
<td>Infusion pump, implantable, nonprogrammable (includes all components, e.g., pump, catheter, connectors, etc.)</td>
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<tr>
<td>E0783</td>
<td>Infusion pump system, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.)</td>
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