Clinical UM Guideline

Subject:	Implantable Infusion Pumps		
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Description

This document addresses the use of implantable infusion pumps, intended to provide long-term, continuous, or intermittent drug infusion. The document does not address implantable reservoirs or implantable infusion systems without a pump.

Clinical Indications

Medically Necessary:

Implantable infusion pumps are considered **medically necessary** when used to deliver drugs for the treatment of:

A. Primary liver cancer (intrahepatic artery injection of chemotherapeutic agents); **or**
B. Metastatic colorectal cancer where metastases are limited to the liver (intrahepatic artery injection of chemotherapeutic agents); **or**
C. Severe, refractory spasticity of cerebral or spinal cord origin in individuals who are unresponsive to or cannot tolerate oral baclofen (Lioresal®) therapy (intrathecal injection of baclofen); **or**
D. Pulmonary arterial hypertension for individuals that have previously been receiving the drug treprostinil (Remodulin®) via an external infusion pump; **or**
E. Severe, chronic, intractable pain when a successful trial of opioid or nonopioid analgesics by the same route of administration as the planned treatment (for example, intravenous, intrathecal, or epidural injection).

Note: A successful trial is defined as greater than 50% reduction in pain.

Note: *When an implantable/intrathecal infusion pump is determined to be medically necessary, the supplies necessary for the proper use of the pump are considered medically necessary.*

Replacement of an implantable/intrathecal infusion pump (which may also involve upgrading to the most current technology) is considered **medically necessary** when the device is not functioning or when a built-in system in the pump provides notification of an impending failure.

Not Medically Necessary:

Replacement or upgrades of an implantable/intrathecal infusion pump is considered **not medically necessary** when requested for convenience or to upgrade to newer technology when the current components remain functional.

Implantable infusion pumps are considered **not medically necessary** for the infusion of heparins for thromboembolic disease or antibiotics for osteomyelitis.

All other uses of implantable infusion pumps, including fully implantable insulin pumps, are considered **not medically necessary.**

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:
For the procedure codes listed below for all other diagnoses not specified as not medically necessary

CPT	
36260	Insertion of implantable intra-arterial infusion pump (eg, for chemotherapy of liver)
36261	Revision of implanted intra-arterial infusion pump [when specified as replacement]
36563	Insertion of tunneled centrally inserted central venous access device with subcutaneous pump
36583	Replacement, complete, of a tunneled centrally inserted central venous access device, with subcutaneous pump, through same venous access
61215	Insertion of subcutaneous reservoir, pump or continuous infusion system for connection to ventricular catheter [when specified as an implantable pump]
62350	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
62351	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; with laminectomy
62360	Implantation or replacement of device for intrathecal or epidural drug infusion; subcutaneous reservoir [when used with an implantable pump]
62361	Implantation or replacement of device for intrathecal or epidural drug infusion; non-programmable pump
62362	Implantation or replacement of device for intrathecal or epidural drug infusion; programmable pump, including preparation of pump, with or without programming

HCPCS	
C1772	Infusion pump, programmable (implantable)
C1891	Infusion pump, nonprogrammable, permanent (implantable)
C2626	Infusion pump, nonprogrammable, temporary (implantable)
E0782	Infusion pump, implantable, non-programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0783	Infusion pump, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0786	Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter)
ICD-10 Procedure	
0JH60VZ- 0JH63VZ	Insertion of infusion pump into chest subcutaneous tissue and fascia [by approach; includes codes 0JH60VZ, 0JH63VZ]
0JH70VZ-0JH73VZ	Insertion of infusion pump into back subcutaneous tissue and fascia [by approach; includes codes 0JH70VZ, 0JH73VZ]
0JH80VZ-0JH83VZ	Insertion of infusion pump into abdomen subcutaneous tissue and fascia [by approach; includes codes 0JH80VZ, 0JH83VZ]
0JHT0VZ-0JHT3VZ	Insertion of infusion pump into trunk subcutaneous tissue and fascia [by approach; includes codes 0JHT0VZ, 0JHT3VZ]
ICD-10 Diagnosis	
	All other diagnoses not listed below as not medically necessary

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met, for the following diagnoses, or for situations designated in the Clinical Indications section as not medically necessary.

ICD-10 Diagnosis	
E08.00-E08.9	Diabetes mellitus due to underlying conditions
E09.00-E09.9	Drug or chemical induced diabetes mellitus
E10.10-E10.9	Type 1 diabetes mellitus
E11.00-E11.9	Type 2 diabetes mellitus
E13.00-E13.9	Other specified diabetes mellitus
H05.021-H05.029	Osteomyelitis of orbit
I74.0-I74.9	Arterial embolism and thrombosis
M27.2	Inflammatory conditions of jaws (osteomyelitis)
M46.20-M46.28	Osteomyelitis of vertebra
M86.00-M86.69	Osteomyelitis

M86.8X0-M86.8X9	Other osteomyelitis
M86.9	Osteomyelitis, unspecified
O24.011-O24.93	Diabetes mellitus in pregnancy, childbirth, and the puerperium

Discussion/General Information

Implantable Infusion Pumps

Implantable infusion pump use for the delivery of intrathecal (intraspinal) opiates is based on the existence of opioid (narcotic) receptors on the spinal cord to achieve "selective spinal analgesia" (pain relief). Pumps provide for the long-term delivery of opioid (narcotic) medication in the management of malignant (cancer) pain and nonmalignant (non-cancer) pain. Examples of appropriate nonmalignant pain syndromes which may be treated with implantable pumps include "failed back surgery," chronic arachnoiditis, visceral pain syndromes, post herpetic neuralgia, phantom limb pain, spinal cord injuries, peripheral neuropathies and reflex sympathetic dystrophy. A successful temporary trial of spinal opiates is required both to evaluate analgesic responsiveness and to increase the long-term success of the procedure. Individuals must be closely monitored as conversion from high dose oral or systemic opioids to spinally administered opioids will sometimes result in withdrawal symptoms.

The National Comprehensive Cancer Network (NCCN) 2024 Adult Cancer Pain Guidelines V.2.2024 recommend regional infusions of opioids, local anesthetics, clonidine, and ziconotide via implanted intrathecal pumps to minimize the distribution of drugs to receptors in the brain. This also lowers serum opioid levels, which may avoid the adverse effects of systemic administration. The guidelines states:

> The intrathecal route of opioid administration should be considered in patients with intolerable sedation, confusion, constipation, and/or inadequate pain management with systemic opioid administration. This approach is a valuable tool to improve analgesia for patients who have pain from a variety of anatomical locations (for example, head and neck, upper and lower extremities, trunk). However, due to the risk of catheter migration and infection risk, consider limiting the duration of use to several days.

Treatment with this therapy should remain a last resort, used only after all other appropriate therapies have failed. A permanently implantable drug-infusion system is not usually appropriate when life expectancy is 3 months or less; for such individuals, external drug infusion systems can appropriately provide spinal analgesia and comparable pain relief.

The implantable infusion pump (IIP) is a drug delivery system that provides continuous infusion of an agent at a constant and precise rate. The purpose of an IIP is to deliver therapeutic levels of a drug directly to a target organ or compartment. It is frequently used to deliver chemotherapy directly to the hepatic artery or superior vena cava.

An IIP 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. A drug is infused over an extended period of time. The drug reservoir

may be refilled as needed by an external needle injection through a self-sealing septum in the IIP. Bacteriostatic water or physiological saline is often used to dilute therapeutic drugs. A heparinized saline solution may also be used during an interruption of drug therapy to maintain catheter patency.

There is a range of totally implanted catheters with implanted reservoirs and manual pumps as well as totally implanted catheters with implanted infusion pumps. Implantable infusion pumps are available in either programmable or non-programmable models, depending on the type of medication delivery required. Programmable pumps are for flexible medication delivery as dose titration and regulation will vary due to the dynamic nature of the individual. Programmable designs facilitate flexible dosing options and precise dose titration over time.

An example of a flexible medication delivery pump is the SynchroMed® electronic pump, manufactured by Medtronic Inc. (Minneapolis, MN, USA). This pump contains a collapsible reservoir that can be filled with 10 to 18 ml of liquid medication and a peristaltic pump that pushes the medication through a bacteriostatic filter and catheter into the spinal canal. The SynchroMed II Infusion system is indicated to deliver prescribed medication for the treatment of chronic pain, severe chronic pain and severe spasticity, respectively. The infusion system has a battery life of 5-7 years with a maximum shut-down design to ensure that the pump provides proper administration of intrathecal therapy. The pump has a built in elective replacement indicator (ERI), this alarm sounds when the pump is nearing the end of service (EOS). The pump will no longer operate 90 days after the alarm has sounded, a pump replacement is recommended to avoid interruption in service and risk of withdrawal of baclofen. The U. S. Food and Drug Administration (FDA) issued a Class I recall in September 2011 due to the potential for reduction of battery performance in the SynchroMed II pump. Codman & Shurtleff, Inc. (Raynham, MA), manufacturer of Medstream™ Programmable Infusion System received FDA premarket supplement for the implantable infusion pump and catheter system for use with baclofen in the treatment of severe spasticity.

Programmable Infusion Pumps

Medtronic Inc. (Minneapolis, MN) and United Therapeutics Corp. (Research Triangle Park, NC) received FDA approval for the Implantable System for Remodulin®. The system is comprised of the SynchroMed II Pump programmable implantable drug delivery system and a newly developed intravascular catheter to deliver Remodulin intravenously for adults with pulmonary arterial hypertension (Class I, II, and III) who were receiving Remodulin via continuous intravenous infusion with an external infusion pump. The FDA approval was based on data reported from the DellVery for Pulmonary Arterial Hypertension (PAH) clinical study (NCT01321073), a prospective, single-arm, nonrandomized, open-label multicenter study, by Waxman and colleagues (2017). The trial enrolled 64 adults with PAH (World Health Organization group 1); 4 exited the study prior to device implantation, and the remaining 60 participants had successful implant procedures. The study showed the implantable intravascular delivery system was an effective option for delivery of treprostinil (Remodulin), with a low rate of catheter-related complications, and a high rate of participant satisfaction. Clinically significant implant procedure-related complications included one pneumothorax, two infections unrelated to catheter placement, and one episode of atrial

fibrillation. Three catheter dislocations in 2 participants occurred early in the trial; catheters were removed and replaced via surgical procedure. In conclusion:

> Procedural success was demonstrated: 100% of the attempted implant procedures were successfully completed. PAH therapy, anticoagulation, and other comorbidities were safely managed during the surgical procedure and postoperatively. The implant procedure was successfully performed with a low complication rate by clinicians with diverse range of specialty training.

Non-programmable Infusion Pumps

Non-programmable pumps are for fixed rate medication delivery when the dosage is expected to be stable. Possible routes of administration include intravenous, intrahepatic, intra-arterial, subcutaneous, intraperitoneal, intrathecal, epidural, and intraventricular.

The role of opioid therapy in treatment of pain is well established in the medical literature. Individuals who have proven unresponsive to less invasive medical therapy and who require large doses of opioids may be candidates for an implantable delivery system that permits intrathecal administration. This system delivers the opioid directly to the receptors in the spinal cord, allowing smaller doses to be used and thereby minimizing side effects. A preliminary trial of an intraspinal opioid drug is administered using a temporary intrathecal/epidural catheter (continuous infusion or bolus injection) to substantiate adequate pain relief and acceptable degree of side effects. This position is supported by multiple case control studies.

In 2017, the North American Spine Society (NASS) published coverage policy recommendations addressing the use of spinal intrathecal drug delivery systems (IDDS) for the treatment of pain and spasticity caused by spinal pathology. The use of IDDS to treat pain and spasticity is established in the literature. IDDS are typically considered when other therapies have failed. The NASS clinical indications include the following recommendations:

Nonmalignant Pain:

1. Severe chronic pain caused by verifiable spinal pathology with clinical manifestations known to be associated with the underlying condition.
2. Patient has failed or could not tolerate other treatment methods including but not limited to nonopioid medications, physical therapy and appropriate interventional (nonsurgical) treatments.
3. Patient has demonstrated compliance with previous attempts to treat their condition.
4. Demonstrable improvement of pain and function with systemic opiates and development of intolerable side effects, tolerance, or hyperalgesia.
5. Psychosocial evaluation to rule out active drug and alcohol disorders and psychiatric conditions.
6. Patient is not a candidate for other surgical interventions.

7. Patient agrees to a 50% reduction in systemic opiates prior to undergoing an IT opiate trial. While undergoing the IT trial there is ≥50% decrease in pain with a concomitant increase in function.
8. Patients who have had a successful trial agree to continue to taper their systemic opioids.
9. Candidates have undergone a trial of IT treatment with at least 50% improvement in symptoms.

Spasticity:

IDDS are indicated for the treatment of severe spasticity when either of the following conditions are met:
1. Patients with severe spasticity who either fail to respond to oral baclofen or develop intolerable side-effects to the medication.
2. Patient has a baseline average Ashworth score of at least 3 and a Spasm Frequency score of at least 2 and demonstrates at least a 2-point reduction in the Ashworth or Spasm Frequency score for 4 hours following an intrathecal trial bolus of baclofen.

Implantable pumps for delivery of medication to the intrathecal space have been developed as an alternative to chronic systemic administration for the treatment of spasticity of cerebral or spinal origin. These pumps have been demonstrated in numerous randomized controlled trials to reduce adverse effects such as tolerance, dependency, and neurotoxicity.

The use of continuous chemotherapy infusion treatment has been studied for individuals with primary hepatic cancer and metastatic colorectal cancer to the liver. This method of chemotherapy infusion has been found to improve medical outcomes in select individuals where continuous chemotherapy is believed to be appropriate. The evidence supporting this conclusion includes multiple randomized controlled trials. Prospective randomized trials of individuals with unresectable liver disease have shown that compared to conventional systemic therapy, hepatic artery infusion is associated with an increased tumor response rate.

In 2023, Ho and colleagues completed a meta-analysis to examine if adjuvant hepatic artery infusion of chemotherapy improved outcomes for individuals with hepatocellular carcinoma (HCC) following liver resection. The primary outcomes measured were overall survival and disease-free survival. The analysis included 11 studies (2 randomized controlled trials and 9 retrospective studies) which included 1290 individuals; 513 individuals were treated with liver resection and adjuvant hepatic artery infusion chemotherapy (HAIC), and 777 individuals were treated with liver resection only. The results demonstrated that adjuvant HAIC improved overall survival rate ($p<0.01$) and disease-free survival ($p<0.01$) respectively. A sub-analysis showed that individuals with portal vein invasion or microvascular invasion benefit from adjuvant HAIC in overall survival ($p<0.01$ and $p=0.0373$, respectively), and disease-free survival ($p<0.01$ and $p=0.0125$, respectively). Adjuvant HAIC with the oxaliplatin-based approach improved overall survival ($p=0.02$ and $p<0.01$, respectively). The authors concluded that postoperative adjuvant HAIC in individuals with hepatocellular carcinoma with portal vein invasion or microvascular invasion is clinically beneficial, however, it is not clear whether HAIC may improve the survival outcome in all individuals with hepatocellular carcinoma after liver resection.

Cao and colleagues (2024) published a meta-analysis that investigated better first-line treatments for unresectable hepatocellular carcinoma. The study was based on data from 13 phase III RCTs that evaluated the safety and efficacy of triple therapy compared to a retrospective single-center study with 442 participants that received angiogenesis inhibitors plus programmed cell death of protein 1 [PD-1], and its ligand PD-L1 blockades (also known as AIPB) treatment only. A total of 176 HCC individuals included in the analysis received triple therapy, defined as HAIC combined with inhibitors, from January 2018 to April 2023. The median age in both groups was 55.0 years, and all the participants were evaluated as having an ECOG ranging from 0-1 and received an average 5.08 rounds of HAIC in the triple therapy group. The results demonstrated that both HAIC alone and with AIPB were effective treatments (HAIC p=0.95; and HAIC + AIPB, p=0.04). However, the triple therapy group (n=88) had a longer median overall survival, 31.6 months, compared to the AIPB group (n=88), 14.6 months (p< 0.001), as well as higher incidence of adverse events 94.3% compared to 75.4%, respectively (p< 0.001). The authors concluded that triple therapy is more effective for unresectable hepatocellular carcinoma than AIPB alone.

Several studies have evaluated interventions that combine radiotherapy and concomitant intra-arterial cisplatin, otherwise known as RADPLAT for treatment of head and neck cancer. Ackerstaff and colleagues (2009) reported results from a randomized multicenter study that examined 17 quality-of-life scale assessments after treatment with radiotherapy with intravenous or intra-arterial cisplatin. A total of 207 participants with advanced head and neck cancer were included in the study. Quality-of-life symptoms reported between both groups were similar; the only statistically significant difference reported between groups was the nausea/vomiting scale at 7 weeks, at which time the rate of symptoms was higher in the intravenous compared to the intra-arterial population. Current evidence has not demonstrated a clear advantage of intra-arterial chemotherapy delivery via an intra-arterial catheter compared to intravenous chemotherapy in combination with radiotherapy for individuals with advanced head and neck cancer (Rasch, 2010). Clinical trials are underway to explore the use of intra-arterial chemotherapy in locally advanced squamous cell carcinoma.

The use of implantable pumps for infusion of antithrombotic medications for thromboembolic disease, or for the infusion of antibiotics for osteomyelitis, has not been demonstrated to provide any additional improvement in net health outcomes above standard care with bolus or subcutaneous drug administrations. This therapy does not prevent the occurrence of complications or morbidity, nor does it significantly relieve pain over other less invasive treatment methods. The risks involved in the implantation and maintenance of implantable infusion pumps for these conditions is not outweighed by any potential benefits. The evidence supporting this conclusion includes multiple case series studies.

Fully Implantable Insulin Pumps

The Medtronic MiniMed® 2017, an implantable insulin pump was the most recent device to be evaluated in a clinical trial. At the time of this writing, no implantable insulin pumps have received FDA approval for marketing.

Fully implantable insulin pumps are designed to deliver insulin via intraperitoneal or intravenous routes in a programmed and controlled manner to diabetics. However, these pumps have been associated with a high incidence

of device malfunction related to catheter obstruction, among other malfunctions. Newer devices are under development that are expected to drastically reduce the problem of catheter obstruction. With additional refinements underway, implantable insulin pumps may eventually prove beneficial in the treatment of insulin dependent diabetics. To show benefit, however, additional long-term randomized prospective studies are needed.

Intrathecal Drug Delivery System (IDDS)

The intrathecal (IT) catheter is inserted through a needle into the intraspinal space, usually at the lumbar or thoracic level. The other end of the catheter is connected to the pump and then filled with medication. The choice of IT pump depends on the indications for intraspinal therapy, the need for bolus versus continuous infusion, the available support services, cost to the individual, and the individual's general medical condition, ambulatory status and life expectancy.

External programming is used to set the dosage, rate and timing via telemetry to the pump. The pump needs to be refilled every 4 to 8 weeks by percutaneous injection, depending on flow rate, and trained medical, nursing or technical staff must perform the refilling process.

Definitions

Bacteriostatic: An agent that inhibits the growth or multiplication of bacteria.

Bolus: A large dose of a drug given intravenously for the purpose of rapidly achieving the needed therapeutic concentration in the bloodstream.

Hepatic colorectal metastases: Colorectal cancer that has spread from its site of origin to the liver.

Infraclavicular fossa: A triangular depression bounded by the clavicle and the adjacent borders of the deltoid and pectoralis major muscles.

Intra-arterial therapies (IAT): A group of cancer treatments that deliver concentrated doses of cancer-killing medicine directly to the affected area; they may be used to occlude arterial blood supply to a tumor, to deliver a high local concentration of chemotherapy, and/or to deliver tumor-selective radiation.

Intrathecal space: The space between the spinal cord and the surrounding membrane (dura mater), which is filled with cerebrospinal fluid. Osteomyelitis: Inflammation of the bone due to infection.

Parenteral: Is a route of administration by injection as in subcutaneous, intramuscular, or intravenous.

Primary liver cancer: A cancer that originates within liver cells, as opposed to having spread from other organs.

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Hepatic Arterial Infusion
Implantable Infusion Pumps
Intrathecal Baclofen for Spasticity
Intrathecal Drug Delivery System
Venous Access Device, Implantable

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	08/08/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion, References, and Websites sections.
Revised	08/10/2023	MPTAC review. Revised malignant pain criteria related to life expectancy. Revised non-malignant pain criteria related to duration of treatment in the Clinical Indications Section. Updated Discussion, Definitions, References, and Websites sections. Updated Coding section, added E0786.
Reviewed	08/11/2022	MPTAC review. Updated Discussion, References and Websites sections.
Reviewed	08/12/2021	MPTAC review. Updated Discussion, References, Websites and Index sections.
Reviewed	08/13/2020	MPTAC review. Updated Discussion, References and Websites sections. Reformatted Coding section.
Revised	08/22/2019	MPTAC review. Clarification to MN clinical indications criteria for implantable infusion pumps for pulmonary arterial hypertension by adding generic name of medication. Updated Discussion, References and Websites sections.
Revised	09/13/2018	MPTAC review. Updated MN indication for implantable infusion pumps when used to deliver drugs to include treatment of pulmonary arterial hypertension when criteria met. Updated description with cross-reference to CG-DRUG-82. Updated Discussion, References and Websites sections.
New	05/03/2018	MPTAC review.
New	05/02/2018	Hematology/Oncology Subcommittee review. Initial document development. Moved content of SURG.00068 Implantable Infusion Pumps to new clinical utilization management guideline document with the same name.