



Louisiana

Implantable Infusion Pump for Pain and Spasticity

Policy # 00666

Original Effective Date: 12/01/2019

Current Effective Date: 10/11/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Intravenous Anesthetics for the Treatment of Chronic Pain and Psychiatric Disorders is addressed separately in medical policy 00463.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider implantable infusion pumps when used to deliver drugs for this route of access which are regulated by U.S. Food and Drug Administration and which are used for the related indication for the treatment of the following to be **eligible for coverage:****

- For the treatment of severe, chronic, intractable pain after a successful trial of opioid or nonopioid analgesics by the same route of administration as the planned treatment (e.g., intravenous, intrathecal, or epidural injection). A successful trial is defined as greater than 50% reduction in pain.
- For the treatment of severe, chronic, intractable spasticity of cerebral or spinal cord origin, in patients who are unresponsive to or who cannot tolerate oral baclofen therapy. Prior to pump implantation, the patient must have responded favorably to a trial intrathecal dose of baclofen.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers implantable infusion pumps for all other uses related to pain and spasticity to be **investigational.***

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Background/Overview

An implantable infusion pump is intended to provide long-term continuous or intermittent drug infusion. Possible routes of administration include intravenous, intra-arterial, subcutaneous, intraperitoneal, intrathecal, and epidural. The implantable infusion 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. Intrathecal and epidural catheter positions are both intraspinal; however, the intrathecal position is located in the subarachnoid space, which is passed through the epidural space and dura mater and through the theca of the spinal cord.

A drug is infused over an extended period and may be delivered at a constant or variable rate by calibrating the implantable infusion pump per physician specifications. The drug reservoir may be refilled as needed by an external needle injection through a self-sealing septum in the implantable infusion pump. Bacteriostatic water or physiological saline is often used to dilute drugs. A heparinized saline solution may also be used during an interruption of drug therapy to maintain catheter patency.

The driving mechanisms may include peristalsis, fluorocarbon propellant, osmotic pressure, piezoelectric disk benders, or the combination of osmotic pressure with an oscillating piston.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Several implantable infusion pumps have been approved by the U.S. FDA through the premarket approval process, including, but not limited to, the SynchroMed[®]‡ (Medtronic, Fridley, MN) family of pumps; the IsoMed[®]‡ infusion system (Medtronic, Minneapolis, MN); the Prometra[®]‡ programmable pump (Flowonix, Mount Olive, NJ); and Shiley Infusaid[®]‡ pumps (Norwood, MA).

Baclofen for intrathecal injection was approved for an additional indication in 1996-for use with Medtronic's implantable infusion pump in the treatment of spasticity of cerebral origin. The drug and pump were originally approved in 1992 for use in patients with severe spasticity of spinal origin. In 2012, the MedStream[™]‡ Programmable Infusion System (Codman and Shurtleff, a division of DePuy), which includes an implantable pump, was approved by the FDA through the premarket approval process for intrathecal delivery of baclofen in patients with spasticity.

Food and Drug Administration product code: LKK.

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On November 14, 2018, the FDA issued a safety communication: “Use Caution with Implanted Pumps for Intrathecal Administration of Medicines for Pain Management.” When considering a medicine for use in an implanted pump the communication recommends, in part, awareness of medicines not FDA approved for intrathecal administration or intrathecal implanted pump use (for example, hydromorphone, bupivacaine, fentanyl, clonidine). Further, the communication indicates that any mixture of two or more different kinds of medications as well as any compounded medications is not approved.

Rationale/Source

Implantable infusion pumps can provide long-term drug infusion at constant or variable rates; several devices are commercially available.

Pain

For individuals who have cancer pain who receive intravenous, intrathecal, or epidural injection of opioids with an implantable infusion pump, the evidence includes randomized controlled trials and a systematic review. The relevant outcomes are symptoms, quality of life, and treatment-related morbidity. A systematic review identified two randomized controlled trials on implantable infusion pumps for cancer pain; one did not find a difference between groups in pain scores but was likely underpowered. The other found a higher rate of pain reduction with an implantable pump compared with medical management alone; the difference between groups was marginally significant. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have severe, chronic, intractable noncancer pain who receive intravenous, intrathecal, or epidural injection of opioids with an implantable infusion pump, the evidence includes observational studies and systematic reviews. The relevant outcomes are symptoms, quality of life, and treatment-related morbidity. A 2013 systematic review of retrospective and prospective cohort studies indicated reduced pain with intrathecal opioids. A 2009 systematic review included 4 observational studies; 2 showed positive results for pain relief, 1 study had negative results, and results for the fourth were unavailable. The evidence is insufficient to determine the effects of the technology on health outcomes.

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Severe Spasticity

For individuals who have severe spasticity of cerebral or spinal cord origin, unresponsive to or intolerant of oral therapy, who receive intrathecal baclofen with an implantable infusion pump, the evidence includes observational studies, a nonrandomized comparative study, and systematic reviews. The relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Uncontrolled studies and systematic reviews of these studies have reported improvements in spasticity for patients treated using implantable infusion pumps. A nonrandomized comparative study comparing patients using implantable infusion pumps for baclofen delivery with patients on a wait list found significantly greater reductions in spasticity in the group with pump implantation on some outcomes, but not others. Randomized controlled trials are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

Because of the strong rationale for use, suggestive evidence, and support from clinical guidelines, infusion pumps may be considered medically necessary for cancer pain, chronic, intractable noncancer pain, and severe spasticity.

Supplemental Information

Practice Guidelines and Position Statements

Cancer Pain

Current National Comprehensive Cancer Network guidelines (v.1.2019) for the treatment of adult cancer pain recommend placement of epidural or intrathecal infusion pumps to deliver analgesic or anesthetic drugs.

Noncancer Pain

The American Society of Interventional Pain Physicians' (2009) evidence-based guidelines on interventions for managing chronic spinal pain indicated that there is strong evidence to support the use of implantable intrathecal drug administration systems with proper patient selection criteria.

Polyanalgesic consensus conference (PACC- Recommendations for Trialing of Intrathecal Drug Delivery Infusion Therapy, published in February 2017 *Neuromodulation*) notes in part that:

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“Intrathecal drug infusion is an appropriate and necessary tool in the algorithm to treat refractory cancer and non-cancer pain. Off-label drug monotherapy or combination therapy is not recommended until FDA approved drugs are tried and failed, or contraindicated.

The on-label drugs can be used during the trial period. If the results are not acceptable due to lack of efficacy or side effects, an admixture of bupivacaine (off-label), or the primary use of fentanyl (off-label) is supported by our consensus.”

Spasticity

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2016) updated its guidance on the management of spasticity in children and young people with nonprogressive brain disorders. Intrathecal baclofen was recommended for “children and young people with spasticity if ... spasticity or dystonia are causing difficulties with ... pain or muscle spasms; posture or function; or self-care (or ease of care by parents or carers).” Additional recommendations included:

- Consider the potential adverse effects of reducing spasticity “because spasticity sometimes supports function (for example, by compensating for muscle weakness).”
- A trial of intrathecal baclofen to assess the efficacy and adverse events before deciding to implant the intrathecal pump.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Medicare provides coverage for implantable infusion pumps for the following indications:

“...intra-arterial infusion of 5-FUdR [5-fluorouracil deoxyribose] for the treatment of liver cancer for patients with primary hepatocellular carcinoma or Duke's Class D colorectal cancer, in whom metastases are limited to the liver and where the disease is unresectable or the patient refuses surgical excision of the tumor.”

Administration of “anti-spasmodic drugs intrathecally (e.g., baclofen) to treat chronic intractable spasticity in patients who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

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As indicated by at least a 6-week trial, the patient cannot be maintained on non-invasive methods of spasm control, such as oral anti-spasmodic drugs, either because these methods fail to control adequately the spasticity or produce intolerable side effects. And prior to pump implantation, the patient must have responded favorably to a trial intrathecal dose of the anti-spasmodic drug.”

Administration of “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 3 months, and who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

The patient's history must indicate that he/she 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 an exaggerated reaction to pain); and a preliminary trial of intraspinal opioid drug administration must be undertaken with a temporary intrathecal/epidural catheter to substantiate adequately acceptable pain relief and degree of side effects (including effects on the activities of daily living) and patient acceptance.”

Other uses of implanted infusion pumps included:

- “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; and
- The Food and Drug Administration-approved labeling for the pump must specify that the drug being administered and the purpose for which it is administered is an indicated use for the pump.”

Ongoing and Unpublished Clinical Trials

A search of [ClinicalTrials.gov](https://clinicaltrials.gov) in December 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

References

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Policy History

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09/05/2019 Medical Policy Committee review

09/11/2019 Medical Policy Implementation Committee approval. New policy.

09/03/2020 Medical Policy Committee review

09/09/2020 Medical Policy Implementation Committee approval. No change to coverage.

09/02/2021 Medical Policy Committee review

09/08/2021 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 09/2022

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	62350, 62351, 62360, 62361, 62362, 62365
HCPCS	C1772, C1891, C2626, E0782, E0783, E0786
ICD-10 Diagnosis	G56.40-G56.43, G57.70-G57.73, G80.0-G80.9, G81.10-G81.14, G82.20-G82.22, G83.0-G83.9, G89.21-G89.29, G89.3, G89.4, G90.50-G90.59, M96.1

***Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;

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- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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