

POLICY TITLE	IMPLANTABLE INFUSION PUMPS FOR PAIN AND SPASTICITY
POLICY NUMBER	MP- 1.058

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I. POLICY

Implantable infusion pumps are considered **medically necessary** when used to deliver drugs having FDA approval for this route of access and for the related indication for the treatment of:

- Severe, chronic, intractable pain (intravenous, intrathecal, and epidural injection of opioids), following a successful temporary trial of opioid or non-opioid analgesics by the same route of administration as the planned treatment. A successful trial is defined as greater than 50% reduction in pain following implementation of treatment;
- Severe spasticity of cerebral or spinal cord origin in patients who are unresponsive to or who cannot tolerate oral baclofen therapy (intrathecal injection of baclofen).

Implantable infusion pumps are considered **investigational** for all other uses related to pain and spasticity. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

II. PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO- Refer to FEP Benefit Brochure for information on Implantable Infusion Pumps for Pain and Spasticity <https://www.fepblue.org/benefit-plans/benefit-plans-brochures-and-forms>

*Note** - The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

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III. DESCRIPTION/BACKGROUND

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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.

Regulatory Status

Several implantable infusion pumps have been approved by the U.S. Food and Drug Administration (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 August 2012, the MedStream™ Programmable Infusion System (Codman and Shurtleff, a division of DePuy), which includes an implantable pump, was approved by FDA through the premarket approval process for intrathecal delivery of baclofen in patients with spasticity.

FDA product code: LKK.

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.

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IV. RATIONALE

SUMMARY OF EVIDENCE

Pain

For individuals who have cancer pain who receive intravenous, intrathecal, or epidural injection of opioids with an implantable infusion pump, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. A systematic review identified 2 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. 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.

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. 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.

V. DEFINITIONS

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EPIDURAL is the space outside or above the dura mater of the brain and spinal cord.

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INTRAHEPATIC refers to within the liver

INTRATHECAL refers to within a sheath. For example, cerebrospinal fluid that is contained within the dura mater. It also refers to drugs administered into the cerebrospinal fluid bathing the spinal cord and brain.

INFUSION PUMP is a pump used to administer fluids into an artery, vein, epidural space or enteral tube. Infusion pumps are beneficial in overcoming arterial resistance or administering thick solutions. The pump can be programmed to set the rate of administration, depending on the patient's needs.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
62350	62351	62355	62360	62361	62362	62365	62367	62368
62369	62370	95990	95991					

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HCPCS Codes	Description
A4220	Refill kit for implantable infusion pump
A4300	Implantable access catheter, (e.g., venous, arterial, epidural subarachnoid, or peritoneal, etc.) external access
A4301	Implantable access total catheter, port/reservoir (e.g., venous, arterial, epidural, subarachnoid, peritoneal, etc.)
C1772	Infusion pump, programmable (implantable)
C1891	Infusion pump, non-programmable, permanent (implantable)
C2626	Infusion pump, non-programmable, temporary (implantable)
C8957	Intravenous infusion for therapy/diagnosis; initiation of prolonged infusion (more than 8 hours), requiring use of portable or implantable pump
E0782	Infusion pump, implantable, non-programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0783	Infusion pump system, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0785	Implantable intraspinal (epidural/intrathecal) catheter used with implantable infusion pump, replacement
E0786	Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter)
S9328	Home infusion therapy, implanted pump pain management infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

ICD-10-CM Diagnosis Codes	Description
G04.1	Tropical spastic paraplegia
G35	Multiple sclerosis
G56.40	Causalgia of unspecified upper limb
G56.41	Causalgia of right upper limb
G56.42	Causalgia of left upper limb
G56.43	Causalgia of bilateral upper limbs
G57.70	Causalgia of unspecified lower limb
G57.71	Causalgia of right lower limb
G57.72	Causalgia of left lower limb
G57.73	Causalgia of bilateral lower limbs
G80.0	Spastic quadriplegic cerebral palsy
G80.1	Spastic diplegic cerebral palsy
G80.2	Spastic hemiplegic cerebral palsy
G80.8	Other cerebral palsy
G80.9	Cerebral palsy, unspecified
G81.10	Spastic hemiplegia affecting unspecified side

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ICD-10-CM Diagnosis Codes	Description
G81.11	Spastic hemiplegia affecting right dominant side
G81.12	Spastic hemiplegia affecting left dominant side
G81.13	Spastic hemiplegia affecting right nondominant side
G81.14	Spastic hemiplegia affecting left nondominant side
G82.20	Paraplegia, unspecified
G82.21	Paraplegia, complete
G82.22	Paraplegia, incomplete
G82.50	Quadriplegia, unspecified
G82.51	Quadriplegia, C1-C4 complete
G82.52	Quadriplegia, C1-C4 incomplete
G82.53	Quadriplegia, C5-C7 complete
G82.54	Quadriplegia, C5-C7 incomplete
G83.0	Diplegia of upper limbs
G83.10	Monoplegia of lower limb affecting unspecified side
G83.11	Monoplegia of lower limb affecting right dominant side
G83.12	Monoplegia of lower limb affecting the left dominant side
G83.13	Monoplegia of lower limb affecting right nondominant side
G83.14	Monoplegia of lower limb affecting left nondominant side
G83.20	Monoplegia of upper limb affecting unspecified side
G83.21	Monoplegia of upper limb affecting right dominant side
G83.22	Monoplegia of upper limb affecting left dominant side
G83.23	Monoplegia of upper limb affecting right nondominant side
G83.24	Monoplegia of upper limb affecting left nondominant side
G83.30	Monoplegia, unspecified affecting unspecified side
G83.31	Monoplegia, unspecified affecting right dominant side
G83.32	Monoplegia, unspecified affecting left dominant side
G83.33	Monoplegia, unspecified affecting right nondominant side
G83.34	Monoplegia, unspecified affecting left nondominant side
G83.5	Locked-in state
G83.81	Brown-Sequard syndrome
G83.82	Anterior cord syndrome
G83.83	Posterior cord syndrome
G83.84	Todd's paralysis (postepileptic)
G83.89	Other specified paralytic syndromes
G83.9	Paralytic syndrome, unspecified
G89.0	Central pain syndrome
G89.21	Chronic pain due to trauma
G89.22	Chronic post-thoracotomy pain
G89.28	Other chronic post procedural pain
G89.29	Other chronic pain
G89.3	Neoplasm related pain (acute) (chronic)
G89.4	Chronic pain syndrome
G90.50	Complex regional pain syndrome I, unspecified

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ICD-10-CM Diagnosis Codes	Description
G90.511	Complex regional pain syndrome I of right upper limb
G90.512	Complex regional pain syndrome I of left upper limb
G90.513	Complex regional pain syndrome I of upper limb, bilateral
G90.519	Complex regional pain syndrome I of unspecified upper limb
G90.521	Complex regional pain syndrome I of right lower limb
G90.522	Complex regional pain syndrome I of left lower limb
G90.523	Complex regional pain syndrome I of lower limb, bilateral
G90.529	Complex regional pain syndrome I of unspecified lower limb
G90.59	Complex regional pain syndrome I of other specified site
G95.11	Acute infarction of spinal cord (embolic) (nonembolic)
M96.0	Pseudarthrosis after fusion or arthrodesis
M96.1	Postlaminectomy syndrome, not elsewhere classified

IX. REFERENCES

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Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.41, Implantable Infusion Pump for Pain and Spasticity. March 2020.

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	CAC 11/30/04
	CAC 11/29/05
	CAC 11/28/06
	CAC 1/29/08
	CAC 1/27/09
	CAC 3/31/09
	CAC 3/30/2010 Consensus
	CAC 4/26/11 Consensus
	CAC 11/22/11 Adopt BCBSA. Policy statements related to implantable infusion pumps for heparin delivery and antibiotics for osteomyelitis changed from medically necessary to investigational. Deleted requirement for a 6 week trial of baclofen and documentation of a favorable response prior to insertion of the pump. Chemotherapeutics for treatment of cancer now limited to liver, metastatic colorectal cancer where metastases is limited to the liver, and head/neck cancer. Other wording changes result in condensed policy statements but do not alter intent of the policy. Remains medically necessary for specific indications.
	05/16/2013 Administrative code review completed.
	6/19/14 Administrative change. Changed Medicare variation to reference LCD L33115 effective 8/1/13 and deleted reference to NCD 280.14.
	CAC 6/4/13 Minor. <ul style="list-style-type: none"> ○ Primary epithelial ovarian cancer (intraperitoneal infusion as component of chemotherapy) added as medically necessary. ○ Head/neck cancers (intra-arterial injection of chemotherapeutic agents) changed from medically necessary to investigational ○ Added gastric cancer to list of investigational uses. ○ FEP variation added to reference FEP medical policy manual ○ Added Rationale Section ○ References updated
	CAC 3/25/14 Consensus review. References updated; no changes to the policy statements. Rationale updated.
CAC 6/2/15 Consensus review. Bone and soft tissue sarcomas and skin cancers added to investigational policy statement. Policy statements otherwise unchanged. Updated rationale and references. Coding reviewed.	
11/2/15 Administrative change. LCD number changed from L33115 to L35112 due to Novitas update to ICD-10.	

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CAC 5/31/16 Consensus. No change to policy statements. References and rationale reviewed. Coding reviewed.
Administrative Update Variation reformatting 1/01/17. New diagnosis code G56.43 added effective 10/1/16
CAC 7/25/17 Minor. Medically necessary bullet points on severe, chronic, intractable pain and severe spasticity retained and unchanged; medically necessary policy statements related to intraperitoneal infusion for primary epithelial ovarian cancer, and for intrahepatic artery therapy for primary liver cancer or hepatic metastases removed. Investigational statement changed to “...investigational for all other uses related to pain and spasticity”. Title changed to “Implantable Infusion Pump for Pain and Spasticity”. Coding Reviewed.
1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
5/7/18 Consensus review. No change to policy statements. Rationale condensed. References and background updated.
3/25/19 Consensus review. No change to policy statements. References updated.
8/1/19 Coding Review. Removed coding not applicable to policy (intra-arterial and central venous), added electronic analysis and refilling codes, updated diagnosis coding.
4/1/20 Consensus review. Policy statement unchanged. Background, references, rationale and coding updated.

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