MEDICAL POLICY

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

Effective Date:	7/1/2023

I. POLICY

Implantable infusion pumps are considered **medically necessary** when used to deliver drugs having the U.S. Food and Drug Administration (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 general conclusion concerning the health outcomes or benefits associated with these procedures.

The National Comprehensive Cancer Network (NCCN) is a nonprofit alliance of cancer centers throughout the United States. NCCN develops the Clinical Practice Guidelines in Oncology which are recommendations aimed to help health care professionals diagnose, treat and manage patients with cancer. Guidelines evolve continuously as new treatments and diagnostics emerge and may be used by Capital Blue Cross when determining medical necessity according to this policy.

II. PRODUCT VARIATIONS

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

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

Top

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 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.

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

TOP

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

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

TOP

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 Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. Disclaimer

TOP

Capital Blue Cross'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 Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

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:

Procedure Codes								
62350	62351	62355	62360	62361	62362	62365	62367	62368

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

Procedure Codes								
62369	62370	95990	95991	A4220	A4300	A4301	C1772	C1891
C2626	C8957	E0782	E0783	E0785	E0786	S9328		

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
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

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

ICD-10-CM Diagnosis Codes	Description
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
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

TOP

1. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.41, Implantable Infusion Pump for Pain and Spasticity. Archived April 2020*

2. *Borrini L, Bensmail D, Thiebaut JB, et al. Occurrence of adverse events in long-term intrathecal baclofen infusion: a 1-year follow-up study of 158 adults. Arch Phys Med Rehabil. Jun 2014;95(6):1032-1038. PMID 24407102*
3. *Falco FJ, Patel VB, Hayek SM, et al. Intrathecal infusion systems for long-term management of chronic non-cancer pain: an update of assessment of evidence. Pain Physician. Apr 2013;16(2 Suppl):SE185-216. PMID 23615891*
4. *FDA. FDA alerts doctors, patients about risk of complications when certain implanted pumps are used to deliver pain medications not approved for use with the devices: FDA News Release (November 14, 2018)*
5. *Ghosh D, Mainali G, Khera J, et al. Complications of intrathecal baclofen pumps in children: experience from a tertiary care center. Pediatr Neurosurg. Mar 2013;49(3):138-144. PMID 24577095*
6. *Guyatt G, Gutterman D, Baumann MH, et al. Grading strength of recommendations and quality of evidence in clinical guidelines: report from an American College of Chest Physicians task force. Chest. Jan 2006;129(1):174-181. PMID 16424429*
7. *Hamza M, Doleys D, Wells M, et al. Prospective study of 3-year follow-up of low-dose intrathecal opioids in the management of chronic nonmalignant pain. Pain Med. Oct 2012;13(10):1304-1313. PMID 22845187*
8. *Malheiro L, Gomes A, Barbosa P, et al. Infectious complications of intrathecal drug administration systems for spasticity and chronic pain: 145 patients from a tertiary care center. Neuromodulation. Jul 2015;18(5):421-427. PMID 25580571*
9. *Manchikanti L, Boswell MV, Singh V, et al. Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain. Pain Physician. Jul-Aug 2009;12(4):699-802. PMID 19644537*
10. *Margetis K, Korfias S, Boutos N, et al. Intrathecal baclofen therapy for the symptomatic treatment of hereditary spastic paraplegia. Clin Neurol Neurosurg. Aug 2014;123:142-145. PMID 24973568*
11. *Mathur SN, Chu SK, McCormick Z, et al. Long-term intrathecal baclofen: outcomes after more than 10 years of treatment. PM R. Jun 2014;6(6):506-513 e501. PMID 24355547*
12. *McIntyre A, Mays R, Mehta S, et al. Examining the effectiveness of intrathecal baclofen on spasticity in individuals with chronic spinal cord injury: a systematic review. J Spinal Cord Med. Jan 2014;37(1):11-18. PMID 24089997*
13. *Morton RE, Gray N, Vloeberghs M. Controlled study of the effects of continuous intrathecal baclofen infusion in non-ambulant children with cerebral palsy. Dev Med Child Neurol. Aug 2011;53(8):736-741. PMID 21707598*
14. *Motta F, Antonello CE, Stignani C. Intrathecal baclofen, and motor function in cerebral palsy. Dev Med Child Neurol. May 2011;53(5):443-448. PMID 21480874*
15. *Motta F, Antonello CE. Analysis of complications in 430 consecutive pediatric patients treated with intrathecal baclofen therapy: 14-year experience. J Neurosurg Pediatr. Mar 2014;13(3):301-306. PMID 24404968*
16. *Myers J, Chan V, Jarvis V, et al. Intraspinal techniques for pain management in cancer patients: a systematic review. Support Care Cancer. Feb 2010;18(2):137-149. PMID 19943068*
17. *National Comprehensive Cancer Network (NCCN). NCCN Clinical practice guidelines in oncology: adult cancer pain. Version 2.2022*

18. *National Institute for Health and Care Excellence (NICE). Spasticity in under 19s: management [CG145]. 2016 November*
19. *Patel VB, Manchikanti L, Singh V, et al. Systematic review of intrathecal infusion systems for long-term management of chronic non-cancer pain. Pain Physician. Mar-Apr 2009;12(2):345-360. PMID 19305484*
20. *Pin TW, McCartney L, Lewis J, et al. Use of intrathecal baclofen therapy in ambulant children and adolescents with spasticity and dystonia of cerebral origin: a systematic review. Dev Med Child Neurol. Oct 2011;53(10):885-895. PMID 21635230*
21. *Stokic DS, Yablon SA. Effect of concentration and mode of intrathecal baclofen administration on soleus H-reflex in patients with muscle hypertonia. Clin Neurophysiol. Nov 2012;123(11):2200-2204. PMID 22595326*
22. *Vles GF, Soudant DL, Hoving MA, et al. Long-term follow-up on continuous intrathecal baclofen therapy in non-ambulant children with intractable spastic cerebral palsy. Eur J Paediatr Neurol. Nov 2013;17(6):639-644. PMID 23871360*

X. POLICY HISTORY

TOP

MP 1.058	**4/1/20 Consensus review**. Policy statement unchanged. Background, references, rationale, and coding updated.
	6/30/2021 Consensus review. No change to policy statement. References reviewed and updated.
	10/07/2022 Consensus review. No change to policy statement. FEP language revised. NCCN language added. References updated.
	3/17/2023 Consensus review. No change to policy statement. References and coding reviewed.

TOP