Anthem

# Clinical UM Guideline

**Subject:** Continuous Local Delivery of Analgesia to Operative Sites using an Elastomeric Infusion Pump during the Post-Operative Period
**Guideline #:** CG-DME-09
**Publish Date:** 09/27/2023
**Status:** Reviewed
**Last Review Date:** 08/10/2023

## Description

This document addresses the use of the elastomeric infusion pump as a means of local delivery of analgesia to operative sites during the post-operative period. These pumps are designed to reduce post-operative pain, while limiting the systemic side effects of analgesia.

This document does not address the use of infused analgesia or anesthesia during an operative procedure.

## Clinical Indications

**Not Medically Necessary:**

Continuous local delivery of analgesia to operative sites using an elastomeric infusion pump during the post-operative period is considered **not medically necessary** as a technique of postoperative pain control.

## Coding

*The following codes for treatments and procedures applicable to this document 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 are Not Medically Necessary:**

**CPT**

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| | No separate specific procedure code for insertion of a disposable drug delivery system |

**HCPCS**

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| A4305 | Disposable drug delivery system, flow rate of 50 ml or greater per hour |
| A4306 | Disposable drug delivery system, flow rate of less than 50 ml per hour |

**ICD-10 Diagnosis**

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|---|---|
| | All diagnoses |

## Discussion/General Information

Local delivery of analgesia to operative sites is designed to reduce postoperative pain, while limiting systemic side effects of analgesia. Drug delivery can be regulated through the use of simple, disposable, elastomeric pumps filled with analgesics that are attached to a variety of catheters that provide continuous delivery of the drug to the surgical site. Catheters may contain multiple openings, so that the drug seeps into the operative wound all along its length, similar in concept to a “soaker” hose. Elastomeric infusion pumps are devices in which fluid containing various analgesic agents is held in a stretchable balloon reservoir, and pressure from the elastic walls of the balloon drives fluid delivery. These pumps are designed to deliver analgesic drugs directly to, or around, the operative site for up to five days postoperatively, after which time the catheter is removed.

Use of elastomeric pumps to deliver local analgesics has been investigated, to date, by studies that were primarily case series and other small studies of the following postoperative clinical situations:

- orthopedic procedures, such as repair of the anterior cruciate ligament;
- urology procedures, such as prostatectomy;
- plastic surgery procedures;
- obstetrical/gynecologic procedures, such as cesarean section;
- gastrointestinal surgery procedures, such as hemorrhoidectomy or gastric bypass;
- thoracic surgery procedures, such as thoracotomy;
- cardiovascular surgery procedures, such as sternotomy.

Evaluation of the medical necessity of continuous delivery of local analgesia using elastomeric pain pumps requires additional, well designed, large studies to determine and validate the role of these devices in the realm of postoperative pain management. While several randomized studies have reported reductions in narcotic requirements, most of these studies were small and failed to demonstrate statistically significant, superior clinical outcomes, in terms of reductions in need for opioid pain medications (Allen, 2009; Banerjee, 2008; Bray, 2007; Chen, 2010; Coghlan, 2009; Heller, 2008; Hoenecke, 2002; Kazmier, 2008; Nechleba, 2005; Oakley, 1998). Variances in the surgical procedures studied and the number of catheters utilized further confound the available trial results (Forastiere, 2008). Additional small studies have been insufficiently powered to demonstrate improvements from the local analgesic technique in all key outcome variables, such as time to endotracheal extubation, time to intensive care unit (ICU) discharge, etc. (Chiu, 2008; White, 2003). In addition, a placebo-related beneficial effect has been noted in studies of local infusion of analgesics to multiple surgical sites (Alford and Fadale, 2003; Baroody, 2004; Schurr, 2004). A meta-analysis was conducted by Richman which evaluated data from available randomized controlled trials to determine the efficacy of perineural catheters for reducing postoperative pain, opioid-related side effects, (e.g., nausea, vomiting, sedation) and opioid use, compared with opioid analgesia alone. The level of individual satisfaction was also assessed. Although the results showed better postoperative analgesia from use of the perineural catheters, compared to opioids ($p<0.001$) for all catheter locations and time periods ($p<0.05$), lack of consistency was noted in the analgesic regimens reviewed across the various included trials (Richman, 2006).

Another study reported on a continuous wound infusion of ropivacaine in conjunction with best practice postoperative analgesia after midline laparotomy for abdominal colorectal surgery. The investigators performed a randomized, participant and outcome assessor-blinded, placebo-controlled trial on subjects presenting for major abdominal colorectal surgery. Subjects were allocated to receive ropivacaine 0.54 percent or normal saline via a dual catheter continuous infusion device into their midline laparotomy wound for 72 hours postoperatively. A total of 310 trial participants were included in this study. The investigators found that the continuous wound infusion of ropivacaine after abdominal colorectal surgery conveyed minimal benefit, compared with saline wound infusion with no statistically significant difference for: pain at rest, morphine usage, length of stay, mobility, nausea, or return of bowel function. There was a small, statistically significant difference in mean pain on movement on day 1 for the ropivacaine group (adjusted mean difference -0.6 [range, -1.08 to -0.13]). The investigators reported that, although this trend continued on days 2 and 3, the differences between groups were no longer statistically significant. The investigators concluded that delivery of ropivacaine to midline laparotomy wounds did not demonstrate any significant clinical advantage over current best practice (Polglase, 2007).

A single-institution, prospective, randomized, double-blinded study of 96 post-appendectomy subjects sought to evaluate the analgesic efficacy and safety of ropivacaine (0.2%), when administered continuously via elastomeric pump. Study subjects were randomly assigned into two groups: 500 mg of ropivacaine in 48 hours (10 mL of 0.2% ropivacaine 20 mg, starter dose plus 5 mL/h continuous wound infusion via elastomeric pump device; n=48) in the experimental group and 250 mL of normal saline, as placebo, in the control group. Postoperative pain was measured either with a simple verbal scale or with a visual analog scale; also parenteral analgesic consumption and global satisfaction scores were measured. A reduction in postoperative pain was observed in the ropivacaine group. The perceived degree of pain was assessed with a simple verbal scale measurement of severe and unbearable, with findings which were significantly lower in the ropivacaine group than in the normal saline group from time 0 to 24 hours at rest and from time 0 to 36 hours on coughing. Significantly lower pain intensity (visual analog scale) was found in the ropivacaine group both at rest and on coughing, beginning at 3 hours and continuing to 36 hours postoperatively ($p<0.05$), and the mean number of rescue analgesic doses was significantly lower in the ropivacaine group ($p<0.001$). There were no statistically significant differences in the frequency of adverse events between the two groups. The authors concluded that wound instillation with ropivacaine 0.2% is a useful, practical, and safe method for management of postoperative pain after appendectomy (Ansaloni, 2007).

A study completed by Goldsby and colleagues (2021) evaluated the effectiveness of continuous infusion of local anesthetics (CILA) in kidney donors after laparoscopic nephrectomy. A retrospective analysis was conducted on 176 sample subjects: 88 in the standard of care (SOC) post-operative analgesia group and 88 in the CILA group. The primary outcome was the total mean oral morphine equivalents administered after surgery. In the CILA group, the total oral morphine equivalents were higher than in the SOC group: 194.8 versus 133.5 mg (P=0.003). The total of postoperative administration of acetaminophen was also higher in the CILA group than in the SOC group at 48 hours: 2464.1 versus 1932.1mg (P=0.043). The total length of stay following surgery was longer in the CILA group than in the SOC group. The time to ambulation and return of bowel functions was not significantly different between the two groups. The authors concluded that CILA did not reduce the use of opioids as compared with SOC and does not improve patient outcomes in individuals who have undergone laparoscopic donor nephrectomy.

Several elastomeric pumps and associated catheters have received clearance through the U.S. Food and Drug Administration (FDA) 510(k) approval process as Class II devices. FDA-approved devices include, but are not limited to, the ON-Q®, PainBuster™, C-bloc® and Homepump Eclipse® (all from I-Flow Corporation, Lake Forest, CA), as well as the Stryker® (Stryker, Kalamazoo, MI) and Accufuser™ (McKinley Medical, Wheat Ridge, CO). FDA labeling indicates that these devices are generally intended for continuous and/or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. The devices are, “Intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to surgical wound sites or close proximity to nerves when compared with narcotic-only pain management” (FDA, 2004). Several versions include individual-controlled bolus dosing features, which allow for the delivery of fixed bolus dose volumes of medication at fixed time intervals. Approved routes of administration are intraoperative, (for example, soft tissue, body cavity), perineural and percutaneous. The devices have not been cleared by the FDA for intra-articular use (FDA, 2009).

On November 13, 2009 the FDA issued a safety alert regarding 35 reports of chondrolysis (necrosis and destruction of cartilage) in individuals given continuous intra-articular infusions of local anesthetics with elastomeric infusion devices to control post-surgical pain. However, this FDA Alert has been archived on the FDA website and not updated with any further information.

On May 8, 2012 the FDA announced a Class I recall of the I-Flow ON-Q pump with ONDEMAND bolus button which was voluntarily recalled by the manufacturer, I-Flow Corporation (Lake Forest, CA), due to a flaw in the bolus button locking mechanism. The recall stated, “While no injuries or adverse events have been reported, use of a pump with this condition may result in over medication of the patient and may potentially result in serious patient injury.” According to the FDA, “Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death” (FDA, 2012). The manufacturer claims to be working to resolve this flaw in the pump mechanism, and on May 8, 2012 the manufacturer issued a “Voluntary Recall Notice” to its customers regarding the I-Flow ON-Q pump device with instructions for product return and customer credit. Additional Class II recalls had been issued by the FDA in 2007 for the I-Flow ON-Q with ONDEMAND feature and for the I-Flow ON-Q PainBuster with ONDEMAND feature for the same bolus button malfunction related to misassembly. According to the FDA, “Class II recalls are situations where use of, or exposure to, a volatile product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote” (FDA, 2009).

Adverse Event Reports have also been issued by the FDA for the I-Flow PainBuster infusion pump system related to chondrolysis of the shoulder (FDA, 2009), as well as for other pump systems, including the Stryker pump (FDA, 2008) and the Accufuser pain pump (FDA, 2011), related to leakages. Additional information, related to chondrolysis associated with intra-articular infusions of local anesthetics using an elastomeric pump following arthroscopic and other surgical procedures, is contained in the FDA labeling for ropivacaine hydrochloride (HCL) injection, USP (Aurobindo Pharma Limited IDA, Pashamylaram, India) and other formulations, such as Carbocaine™ (mepivacaine HCLinjection USP) and bupivacaine HCL injection USP. It is noted that these medications are not approved for intra-articular infusions. There is no effective treatment for chondrolysis. According to the FDA label, adverse event reports have been submitted regarding the incidence of chondrolysis, which has primarily involved the shoulder joint, in pediatric and adult cases following intra-articular infusions of local anesthetics with and without epinephrine for periods of 48 to 72 hours and have required additional diagnostic and therapeutic procedures (including arthroscopy and joint replacement).

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**Peer Reviewed Publications:**


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**Government Agency, Medical Society, and Other Authoritative Publications:**

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## Index



**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 | 08/10/2023 | Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References section. |
| Reviewed | 08/11/2022 | MPTAC review. Updated Discussion/General Information and References sections. |
| Reviewed | 08/12/2021 | MPTAC review. Updated References section. |
| Reviewed | 08/13/2020 | MPTAC review. Updated References section. Reformatted Coding section. |
| Reviewed | 08/22/2019 | MPTAC review. References were updated. |
| Reviewed | 09/13/2018 | MPTAC review. The Discussion, References and Index sections were updated. |
| Reviewed | 11/02/2017 | MPTAC review. The document header wording was updated from “Current Effective Date” to “Publish Date.” References were updated. |
| Reviewed | 11/03/2016 | MPTAC review. References were updated. |
| Reviewed | 11/05/2015 | MPTAC review. References were updated. Removed ICD-9 codes from Coding section. |
| Reviewed | 11/13/2014 | MPTAC review. The Discussion section and References were updated. |
| Reviewed | 11/14/2013 | MPTAC review. The Discussion section and References were updated. |
| Reviewed | 11/08/2012 | MPTAC review. References were updated. |
| Reviewed | 11/17/2011 | MPTAC review. References were updated. |

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| Revised | 11/18/2010 | MPTAC review. The title and Clinical Indications statement have been revised to clarify that this document addresses delivery of analgesia during the post-op period. No other change to stance. The Discussion section and References were updated. |
| Reviewed | 11/19/2009 | MPTAC review. References were updated. |
| Reviewed | 11/20/2008 | MPTAC review. Discussion section and References were updated. |
| Revised | 11/29/2007 | MPTAC review. The clinical UM guideline stance has not changed (considered not medically necessary). However, the statement has been revised to remove reference to “surgeries typically requiring oral or parenteral narcotics for pain relief.” References were updated. |
| Reviewed | 12/07/2006 | MPTAC annual review. References updated. |
| Revised | 12/01/2005 | MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization. |

| Pre-Merger Organizations | Last Review Date | Document Number | Title |
|---|---|---|---|
| Anthem West | 08/15/2003 | UMR.015 | Intralesional and Intra-articular Pain Management |
| Anthem Southeast | 03/08/2005 | 1191 | Pain Management Systems (Pain Buster, On-Q System, Stryker Pain Pump) |
| WellPoint Health Networks, Inc. | 09/23/2004 | 5.01.05 | Continuous Local Delivery of Analgesia to Operative Sites Using an Elastomeric Infusion Pump |

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