CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Postoperative Continuous Local Delivery of Analgesia**

Effective Date **2/15/2010**
Next Review Date **2/15/2012**
Coverage Policy Number **0219**

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Hyperlink to Related Coverage Policies

Implantable Infusion Pumps

INSTRUCTIONS FOR USE

*Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines.*

Coverage Policy

CIGNA covers continuous delivery of local analgesia via ambulatory infusion pumps used according to U.S. Food and Drug Administration (FDA)–approved specifications as medically necessary for the management of postoperative pain.

CIGNA does not cover continuous intra-articular delivery of local analgesia via ambulatory infusion pumps for any indication including the management of postoperative pain because it is considered experimental, investigational or unproven.

General Background

Postoperative pain management is an integral component of a patient's overall recovery from surgery. Adequate pain management following surgery is generally achieved through the use of systemic narcotic analgesics delivered via intravenous, intramuscular or oral administration. In addition, many patients benefit from intravenous, patient-controlled anesthesia (PCA) with narcotic analgesics, a delivery mode that allows patient-specific titration that is responsive to individual needs. According to the American Society of Anesthesiologists (ASA), under-treatment of postoperative pain can result in adverse outcomes that include thromboembolic and pulmonary complications, extension of time spent in an intensive care unit and/or in a hospital, and reduced patient satisfaction (ASA, 2003).

The use of systemic narcotic analgesics carries with it several unfavorable side effects. For that reason, direct instillation of local anesthetics and/or opioids into operative sites has been proposed as a pain- management technique to decrease the need for oral or parenteral postoperative narcotics. Local anesthetics, opioids or both can be administered by an infusion pump directly into the surgical site, including perineural, soft tissue, and intra-articular locations. The perineural technique involves the percutaneous insertion of a catheter directly adjacent to the peripheral nerves supplying an affected surgical site. Local anesthetic is then infused via the catheter providing site-specific analgesia (Ilfeld and Enneking, 2005). Disposable or ambulatory pumps consist of an elastomeric membrane, which provides positive pressure for fluid delivery. These elastomeric pumps are available in various unalterable combinations of preprogrammed reservoir volumes and infusion rates. Electronic infusion pumps are programmable, allowing for various infusion rates, bolus doses and lockout periods. Anesthetic agents used for local analgesia include bupivacaine, ropivacaine and levobupivacaine. Some manufacturers provide recommended anesthetic and dosing information, but there is no consensus on optimal concentrations, dosing or administration schedules.

Potential advantages of this method of pain management are direct pain relief without the side effects of narcotics, reduction in breakthrough pain, and shorter recovery times. Anesthetic instillation via pain pump may be initiated postoperatively or started preoperatively as a preemptive pain control measure. Since these devices are ambulatory, patients may be discharged with their pain pumps in place. Potential complications associated with the use of pain pumps include surgical wound infection and leakage of medication into surrounding tissue. Recently, cases of chondrolysis (i.e., the degeneration of cartilage cells) after arthroscopic shoulder procedures involving the use of an intra-articular pain pump have been reported. Although a correlation between postarthroscopic glenohumeral chondrolysis (PAGCL) and increased duration of exposure to high concentrations of bupivacaine and lidocaine administered into the glenohumeral joint has been identified, the development of PAGCL has been said to be multifactorial (Solomon, et al., 2009). Chondrolysis has been reported to occur after both physical and surgical trauma, after meniscectomy, and with the use of irrigation fluid, thermal devices, or bioabsorbable implants (Bailie and Ellenbecker, 2009).

U.S. Food and Drug Administration (FDA)
The U.S. Food and Drug Administration (FDA) approves infusion pumps as Class II devices under the 510(k) process. 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 patient-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 (e.g., soft tissue, body cavity), perineural and percutaneous. The devices have not been FDA–approved for intra-articular use. Trade names for elastomeric pumps include ON-Q®, PainBuster™, C-bloc® and Homepump Eclipse® (all from I-Flow Corporation, Lake Forest, CA), as well as Stryker® (Stryker, Kalamazoo, MI) and Accufuser™ (McKinley Medical, Wheat Ridge, CO). I-Pump™ (Baxter International, Deerfield, IL), ambIT™ (Sorenson Medical, West Jordan, UT) and AutoMed™ (AceMedical/Algos, Salt Lake City, UT) are electronic pumps.

Literature Review
Evidence supporting the use of local infusion of anesthetics and opioids exists primarily in the form of case series and randomized controlled studies with small populations. Studies have attempted to evaluate the efficacy of local infusion following a wide range of surgical procedures, including hernia repair, abdominal and breast surgery. Much of the available evidence has involved assessing efficacy following orthopedic surgery, specifically, shoulder, knee, and foot procedures.

Abdominal Hysterectomy: The results of studies evaluating the safety and effectiveness of pain pumps following abdominal hysterectomy are mixed. Gupta et al. (2004) randomized 40 postoperative abdominal hysterectomy patients to receive a continuous infusion of 0.25% levobupivacaine or placebo intraperitoneally. Pain at the incision site, deep pain, and pain on coughing, and nausea were all found to be significantly less in levobupivacaine group in the early postoperative period.

A prospective randomized controlled trial (RCT) (n=52) by Leong et al. (2002) found no significant differences in visual analogue scale (VAS) pain rates or PCA morphine use for patients who received 0.5% bupivacaine

infusion into the incisional wound via an elastomeric pump for 48 hours postoperatively versus control patients. While Zohar et al. (2001) (n=36) reported significantly less rescue analgesia and antiemetics administered to patients in a bupivacaine treatment group compared to controls.

Ankle/Foot Surgery: Supportive evidence for the safety and efficacy of pain pump use for ankle and foot includes a technology assessment and a few RCTs. The Danish Centre for Health Technology Assessment (DACEHTA) published a technology assessment on the treatment of postoperative pain at home using an elastomeric pump after ambulatory foot surgery. The report summarized that the efficacy and safety for the use of both a single-shot nerve block and a block plus elastomeric pump are similarly high. Utilizing a pain pump in addition to a nerve block provides effective analgesia for a longer duration. Most side effects (e.g., nausea and vomiting, tiredness, dizziness, constipation) occur in patients who have received a nerve block to shorter duration of analgesia and the need for rescue analgesics (DACEHTA, 2008).

A prospective, double-blinded RCT (n=60) by Zaric et al. (2004) reported that pain after foot surgery was significantly less in the treatment group compared to the control group on the first and second postoperative days ($p=0.001$). There were no statistically significant differences between the groups in their need for rescue opioid medication. No adverse effects were reported. An RCT (n=20) by White et al. (2003) found a statistically significant reduction ($p<0.05$) in both pain scores and opioid analgesic use in the bupivacaine group compared to the control group for patients undergoing various foot and ankle procedures.

Breast Surgeries: The evidence evaluating the use of pain pumps for breast surgeries is in the form of randomized and non-randomized controlled trials and is supportive of the safety and effectiveness for these procedures. A nonrandomized study (n=46) by Tan and Farrow (2009) found that local anesthetic infusion delivery to the rectus sheath significantly reduced narcotic requirements and had an associated significant decrease in postoperative nausea and vomiting following transverse rectus abdominis myocutaneous (TRAM) flap surgery.

An RCT (n=48) by Sidiropoulou et al. (2008) compared continuous wound infiltration with local anesthetic to thoracic paravertebral block (PVB) after modified radical mastectomy with axillary dissection. No significant different found between the two pain control methods in terms of morphine consumption absolute pain scores.

In an RCT (n=48) of TRAM flap breast reconstruction patients, Heller et al. (2008) reported that continuous infusion patients used less mean patient-controlled anesthesia narcotic during the first two postoperative days and transitioned earlier to oral narcotics than did control patients. Patients' overall pain satisfaction scores were significantly better in the continuous infusion group than in the control group. Likewise, a cohort study by Losken et al. (2005) found the pain pump useful in reducing the intravenous narcotic requirements and length of stay in patients following TRAM flap breast reconstruction.

Baroody et al. (2004) reported that patients who underwent mastectomy with immediate breast reconstruction and received intralesional medication experienced a significant decrease in the need for supplemental pain medication. They also rated their pain levels as one-half those of the controls.

Iliac Crest Bone-Grafting: Studies evaluating the use of continuous local anesthesia infusion via pain pumps for iliac crest bone-grafting include randomized and nonrandomized trials and are generally supportive of safety and effectiveness. Narcotic consumption, demand frequency, and mean VAS scores have been reported to be significantly less in treatment groups at 24 and 48 hours postoperatively (Coulthard, et al., 2007; Singh, et al., 2005; Blumenthal, et al., 2005). A prospective, double-blind randomized study (n=60) by Morgan et al. (2006) found no significant differences between bupivacaine and placebo groups in the perception of pain or in the amount of narcotic medication used.

Knee Surgery: There is evidence in the form of RCTs (n=16–49) to support the safety and effectiveness of continuous wound instillation of anesthesia following knee surgery (Andersen, et al., 2010; Alford and Fadale, 2003; Bianconi, et al., 2003).

There is insufficient evidence to support the safety and efficacy of postoperative intra-articular infusion of anesthetics via pain pumps (Dauri, et al., 2009; Parker, et al., 2007; Dauri, et al., 2003; Hoenecke, et al., 2002).

Shoulder Surgery: Evidence examining the safety and effectiveness of pain pumps for use following shoulder surgery has yielded mixed results. The site of infiltration varied between studies. A case series (n=583) by Busfield, et al. (2008) examined safety issues associated with the use of pain pump catheters into the subacromial space and found no cases of infection, internal catheter breakage, pump failure, or hospital admission for pain control at one-month follow-up.

A prospective, randomized study (n=50) by Jarvela and Jarvela (2008) found that the use of a pain pump in the subacromial space after arthroscopic subacromial decompression did not have any long-term effects on the patients' recovery, return to work, or final result at the minimum two-year follow-up.

An RCT (n=56) by Webb et al. (2007) evaluated the efficacy of a one-time interscalene block compared with a subacromial continuous infusion of 0.5% bupivacaine via a pain pump for postoperative pain relief in a prospective RCT. No statistically significant differences were identified between the two groups with regard to VAS pain scores or rescue medication intake. No complications were reported in either group.

Other RCTs (n=20-60) have reported pain scores to be significantly decreased for patients receiving continuous ropivacaine ($p<0.5$) compared with interscalene nerve block (Ilfeld, et al., 2003), and placebo ($p<0.5$) (Savoie, et al., 2000), as well as decreased narcotic consumption compared to placebo (Klein, et al., 2000).

Although not robust, there is some evidence n the form of small RCTs and one large case series to support the safety and efficacy of local anesthesia via pain pump delivered to the operative site in patients undergoing shoulder surgery. There is insufficient evidence to support the safety and effectiveness of continuous intra-articular anesthetic infiltration following shoulder surgery (McNickle, et al., 2009; Busfield, et al., 2009; Bailie, et al., 2009).

Miscellaneous Procedures: A Cochrane systematic review of 20 studies (n=1150) by Bamigboye and Hofmeyr (2009) assessed the effects of local anesthetic agent wound infiltration/irrIgation and/or abdominal nerve blocks on post-caesarean section pain and the mother's well being and interaction with her baby. It was concluded that in general, local analgesia infiltration and abdominal nerve blocks as adjuncts to regional analgesia and general anesthesia are of benefit in women having a caesarean section by reducing opioid consumption. These pain control methods can be recommended as part of the multimodal approach to pain relief (Bamigboye and Hofmeyr, 2009).

Study results for the use of pain pumps following thoracotomy have varied. Allen et al. (2009) conducted a randomized, double-blinded, controlled trial (n=124) of infusion of bupivacaine versus placebo through intercostal and subcutaneous catheters after thoracotomy. It was found that the infusion of local anesthetic into the subcutaneous area and around the rib fracture site in addition to epidural analgesia did not reduce the amount of narcotic usage after a thoracotomy, nor did it affect visual analog pain scores. While a retrospective comparative analysis of thoracotomy patients (n=110) by Wheatley et al. (2005) found narcotic use and pain scores to be significantly reduced for those who were treated with 0.25% bupivacaine through the ON-Q elastomeric infusion pump compared to those who received continuous epidural infusion at all intervals ($p<0.001$). There were no wound-healing complications or infections associated with the use of the pump.

A randomized, double-blinded, placebo-controlled trial (n=168) by Forastiere et al. (2008) effectiveness of continuous wound infusion of ropivacaine for postoperative pain relief after open nephrectomy. All patients received a standard postoperative pain management protocol, including patient-controlled analgesic morphine and ketorolac. VAS pain scores, morphine consumption, time to bowel recovery and mean length of hospitalization were all found to be significantly reduced ($p<0.001$) in continuous wound infusion patients compared with control patients.

Ansaloni et al. (2007) conducted a prospective, double-blinded RCT (n=96) to evaluate the analgesic efficacy and safety of ropivacaine 0.2% administered continuously via elastomeric pump after appendectomy. A significantly lower VAS pain score was also found in the ropivacaine group both at rest and on coughing, continuing to 36 hours postoperatively ($p<0.05$). The mean number of rescue analgesic doses was significantly lower in the ropivacaine group ($p<0.001$). There were no statistically significant differences between the two groups in the frequency of surgical wound infections or length of hospital stay (Ansaloni, et al., 2007).

Liu et al. (2006) performed a meta-analysis of prospective RCTs to examine the efficacy of continuous wound catheters in multiple surgical procedures. The 44 RCTs (n=2141) evaluated for the quantitative portion of this systematic review were small in sample size and primarily used bupivacaine and ropivacaine for the local anesthetic. A qualitative analysis of 51 RCTs (n=2407) was also performed. Wound catheters were placed in a variety of locations, including subcutaneous, suprafascial, subfascial and intra-articular. Surgery subgroups were comprised of cardiothoracic, general, gynecologic-urologic, and orthopedic procedures. Both quantitative and qualitative systematic review of RCTs found that continuous wound catheters are associated with several benefits, including improved analgesia, reduced opioid use and side effects, increased patient satisfaction, and reduced hospital stay. Incidences of technical failure (1%) or local anesthetic toxicity (0%) from wound catheters were low. Wound infection rates were similar between catheter with local anesthetic (0.7%) and catheter with placebo or no-catheter control groups (1.2%). It was concluded that continuous wound catheters consistently demonstrated analgesic efficacy in terms of reduced pain scores or opioid use for all surgical subgroups, despite factors such as heterogeneity in type of surgical procedure, location of wound catheter, mode of delivery or dose of local anesthetic. According to the authors, additional large homogenous RCTs would be valuable to provide better quantitative data and confirm the findings in this review (Liu, et al., 2006).

In another meta-analysis of 19 RCTs (n=603), Richman et al. (2006) evaluated data from RCTs 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 patient satisfaction was also assessed. Studies that compared either upper- or lower-extremity continuous peripheral nerve block to conventional opioid analgesia met all inclusion criteria. Perineural analgesia was found to provide better postoperative analgesia compared to opioids ($p<0.001$). Perineural catheters provided improved analgesia compared to opioids for all catheter locations and time periods ($p<0.05$). Total opioid consumption over 48 hours was significantly less with the use of perineural analgesia ($p<0.001$). There were no major complications reported; however, 12 of the 19 studies reported at least one minor complication. It was noted that several of the trials were of poor quality. Also, there was no consistency in analgesic regimen for either the opioid or perineural catheter group (Richman, et al., 2006).

A Hayes report evaluated the evidence on postoperative disposable ambulatory regional anesthesia (PDARA). The report examined 13 small RCTs, 11 of which utilized a placebo control. PDARA was used as an adjunct to standard pain management strategies involving regularly scheduled and supplemental analgesics such as intravenous morphine. This combined therapy was compared to standard pain management alone. The trials assessed pain control after a wide range of surgical procedures, including abdominal hysterectomy, cesarean section, inguinal hernia repair, spinal fusion, cardiothoracic surgery and shoulder, hip, knee, foot, or ankle surgery. A VAS or a comparable verbal rating scale was used to evaluate pain control. Supplemental analgesic use, time to recovery of certain normal functions, and length of hospital stay were also assessed in some trials. In the RCTs that involved a placebo control, PDARA was found to provide statistically significant improvements in patient outcomes, such as reduced pain and, in some cases, reduced supplemental analgesic use. The report found sufficient evidence to support the use of this pain management technique during the early postoperative period following spinal fusion, inguinal hernia repair, and shoulder, knee, or foot surgery. It was noted that PDARA must be used as an adjunct pain control strategy, as it has not been evaluated as a replacement for postoperative pain management (Hayes, 2004).

Professional Societies/Organizations
The American Society of Anesthesiologists (ASA) updated their practice guidelines for acute pain management in the perioperative setting in 2003. The following terms are used by the ASA to describe the strength of the evidence reviewed:

- Supportive: Meta-analyses of a sufficient number of adequately designed studies indicate a statistically significant relationship ($p<0.01$) between a clinical intervention and a clinical outcome.
- Suggestive: Information from case reports and descriptive studies permits inference of a relationship between an intervention and an outcome. This type of qualitative information does not permit a statistical assessment of significance.
- Equivocal: Qualitative data are not adequate to permit inference of a relationship between an intervention and an outcome; and (1) there is insufficient quantitative information; or (2) aggregated comparative studies have found no significant differences among groups or conditions.

According to the ASA, the evidence was found to be supportive of postincisional infiltration with local anesthetics for postoperative analgesia. The ASA found evidence in the literature to be equivocal regarding the analgesic benefits of preincisional infiltration and suggestive that intra-articular analgesia with opioids, local anesthetics or combinations of the two provides analgesic benefit (ASA, 2003).

Summary
While not robust, there is some evidence in the published, peer-reviewed scientific to suggest that postoperative continuous delivery of local analgesia by an ambulatory infusion pump is a safe and effective option as an adjunct to conventional pain control measures. Direct infusion of local anesthetics into operative sites, including perineural, subcutaneous and percutaneous wound instillation, has been proven to improve analgesia and decrease supplemental opioid use and side effects, with a low incidence of related complications. Additional well-designed, large-population, randomized, double-blind, placebo-controlled clinical trials will further define the role of this technique in postoperative pain management.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

HCPCS Codes	Description
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-9-CM Diagnosis Codes	Description
	Multiple/Varied codes

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	2/15/2008	0219	Postoperative Continuous Local Delivery of Analgesia
Great-West Healthcare	11/30/2007	05.323.02	Pumps, Intraarticular and Intralesional, for Management of Postoperative Pain