APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then “Tools” and “Clinical Guidelines”.

BACKGROUND

Over 50% of all surgeries are performed on an ambulatory or outpatient basis, but poor management of postoperative pain may delay discharge or lead to hospital readmission. Although oral analgesics, such as opioids, are effective, they can cause undesirable side effects such as nausea, vomiting, sedation, pruritis or insomnia. In an effort to improve pain control during the postoperative period, disposable pumps have been developed that infuse anesthesia continuously to a specific region of the body, providing local pain relief. This technique involves the infusion of anesthesia into a surgical wound or perineural tissue using a catheter connected to an elastomeric or spring-loaded disposable pump. In a typical case, the pump delivers an anesthetic, such as ropivacaine or bupivacaine, for 2 days, while the patient is at home. After the infusion is completed, the patient, or a properly instructed caregiver, removes the catheter, eliminating the need for transport of the patient to the hospital or clinic.
Postoperative disposable ambulatory regional anesthesia (PDARA) has been used to manage pain after a variety of outpatient surgical procedures, with catheter placement dependent on the site of surgery.

Clinical evidence supports the use of disposable ambulatory regional anesthesia for the management of postoperative pain for spinal fusion, inguinal hernia repair, and shoulder, knee, or foot surgery. Disposable ambulatory regional anesthesia should be used in conjunction with appropriate conventional pain management techniques, such as oral analgesics or intravenous (IV) morphine, since it has been established as an adjunct to but not a replacement for conventional postoperative pain management. Clinical evidence does not support the use of disposable ambulatory regional anesthesia for the management of postoperative pain control for procedures other than those listed above. Further studies involving larger numbers of participants are needed to conclude that disposable pumps to infuse anesthesia into a surgical wound or perineural tissue are a safe and effective method of postoperative pain management for procedures other than spinal fusion, inguinal hernia repair, and shoulder, knee, or foot surgery.

Complications associated with postoperative disposable ambulatory regional anesthesia are generally minor and easily managed. Complications may include abnormal sensations such as pain, tingling, or total sensation loss; dislodgement or accidental early removal of catheters; pump failure; and inability to establish a nerve block. Since these devices are ambulatory, patients may be discharged with their pain pumps in place. Potential complications include surgical wound infection and leakage of medication into surrounding tissue.

A number of disposable pumps used for postoperative ambulatory regional anesthesia are commercially available. These include but are not limited to the following: Accufuser™ Plus (McKinley Medical, Wheat Ridge, CO), Delivery of Anesthesia for Postoperative Pain Control by Elastomeric Infusion Pump, Eysypump, ON-Q® Soaker Post-Operative Pain Relief System and C-Bloc Continuous Peripheral Nerve Block System™ (I-Flow Corp, Lake Forest, CA), Freedom Infusion System, Hospira Gemstar® (Hospira Inc.), Homepump, Intralesional Anesthetic Pumps, Intra-Joint Disposable Pain Pump, Go Medical Ballon Infusion System P.O.P. Pain Kit, Pain Mate, Stryker PainPump® Pain Care 3000, 3200, 4200.

Professional Associations

The American Society of Regional Anesthesia and Pain Medicine (ASRA) have not developed a position statement or practice guideline for PDARA (Hayes, 2013). ASRA President Dr. Terese Horlocker wrote an editorial stating that the introduction of long-lasting anesthetics and use of portable pumps allowing local anesthetic infusion after hospital discharge has improved the efficacy and popularity of continuous peripheral blockade. Horlocker added that usage of a portable pump system to deliver regional anesthetic may allow more surgical procedures to be performed on an outpatient basis. The editorial cautions that additional experience is necessary beyond the minimum requirements established for accreditation.

The American Society of Anesthesiologists (2012) made the following recommendations for acute pain management in the perioperative setting:

**Institutional Policies and Procedures for Providing Perioperative Pain Management**

- Anesthesiologists offering perioperative analgesia services should provide, in collaboration with other healthcare professionals as appropriate, ongoing education and training to ensure that hospital personnel are knowledgeable and skilled with regard to the effective and safe use of the available treatment options within the institution.
  - Educational content should range from basic bedside pain assessment to sophisticated pain management techniques (e.g., epidural analgesia, PCA, and various regional anesthesia techniques) and non-pharmacologic techniques (e.g., relaxation, imagery, hypnotic methods).
  - For optimal pain management, ongoing education and training are essential for new personnel, to maintain skills, and whenever therapeutic approaches are modified.
- Anesthesiologists and other healthcare providers should use standardized, validated instruments to facilitate the regular evaluation and documentation of pain intensity, the effects of pain therapy, and side effects caused by the therapy.
• Anesthesiologists responsible for perioperative analgesia should be available at all times to consult with ward nurses, surgeons, or other involved physicians. They should assist in evaluating patients who are experiencing problems with any aspect of perioperative pain relief.

• Anesthesiologists providing perioperative analgesia services should do so within the framework of an Acute Pain Service. They should participate in developing standardized institutional policies and procedures.

Preoperative Evaluation of the Patient
• A directed pain history, a directed physical examination, and a pain control plan should be included in the anesthetic preoperative evaluation.

Preoperative Preparation of the Patient
• Patient preparation for perioperative pain management should include appropriate adjustments or continuation of medications to avert an abstinence syndrome, treatment of preexistent pain, or preoperative initiation of therapy for postoperative pain management.

• Anesthesiologists offering perioperative analgesia services should provide, in collaboration with others as appropriate, patient and family education regarding their important roles in achieving comfort, reporting pain, and in proper use of the recommended analgesic methods.
  o Common misconceptions that overestimate the risk of adverse effects and addiction should be dispelled.
  o Patient education for optimal use of PCA and other sophisticated methods, such as patient-controlled epidural analgesia, might include discussion of these analgesic methods at the time of the preanesthetic evaluation, brochures and videotapes to educate patients about therapeutic options, and discussion at the bedside during postoperative visits.
  o Such education may also include instruction in behavioral modalities for control of pain and anxiety.

Perioperative Techniques for Pain Management
• Anesthesiologists who manage perioperative pain should use therapeutic options such as epidural or intrathecal opioids, systemic opioid PCA, and regional techniques after thoughtfully considering the risks and benefits for the individual patient.
  o These modalities should be used in preference to intramuscular opioids ordered “as needed.”

• The therapy selected should reflect the individual anesthesiologist’s expertise, as well as the capacity for safe application of the modality in each practice setting.
  o This capacity includes the ability to recognize and treat adverse effects that emerge after initiation of therapy.

• Special caution should be taken when continuous infusion modalities are used because drug accumulation may contribute to adverse events.

Multimodal Techniques for Pain Management
• Whenever possible, anesthesiologists should use multimodal pain management therapy. Unless contraindicated, patients should receive an around-the-clock regimen of NSAIDs, COXIBs, or acetaminophen. Regional blockade with local anesthetics should be considered.

• Dosing regimens should be administered to optimize efficacy while minimizing the risk of adverse events.

• The choice of medication, dose, route, and duration of therapy should be individualized.
Patient Subpopulations

- Pediatric patients
  - Aggressive and proactive pain management is necessary to overcome the historic under-treatment of pain in children.
  - Perioperative care for children undergoing painful procedures or surgery requires developmentally appropriate pain assessment and therapy.
  - Analgesic therapy should depend upon age, weight, and comorbidity, and unless contraindicated should involve a multimodal approach.
  - Behavioral techniques, especially important in addressing the emotional component of pain, should be applied whenever feasible.
  - Sedative, analgesic, and local anesthetics are all important components of appropriate analgesic regimens for painful procedures.
  - Because many analgesic medications are synergistic with sedating agents, it is imperative that appropriate monitoring be used during the procedure and recovery.

- Geriatric patients
  - Pain assessment and therapy should be integrated into the perioperative care of geriatric patients.
  - Pain assessment tools appropriate to a patient’s cognitive abilities should be used. Extensive and proactive evaluation and questioning may be necessary to overcome barriers that hinder communication regarding unrelied pain.
  - Anesthesiologists should recognize that geriatric patients may respond differently than younger patients to pain and analgesic medications, often because of comorbidity.
  - Vigilant dose titration is necessary to ensure adequate treatment while avoiding adverse effects such as somnolence in this vulnerable group, who are often taking other medications (including alternative and complementary agents).

- Other subpopulations
  - Anesthesiologists should recognize that patients who are critically ill, cognitively impaired, or have communication difficulties may require additional interventions to ensure optimal perioperative pain management.
  - Anesthesiologists should consider a therapeutic trial of an analgesic in patients with increased blood pressure and heart rate or agitated behavior when causes other than pain have been excluded.

Continuous Peripheral Nerve Blocks (CPNB)

Out of necessity, multiple continuous peripheral nerve blocks (CPNB) were administered in Operation Iraqi Freedom in 2003. Real-time imaging (portable ultrasound) and peripheral nerve stimulation have revolutionized the practice of CPNB anesthesia by providing objective evidence of needle proximity to targeted nerves. In the majority of peripheral nerve blocks, stimulation of nerves at a current of 0.5 mA or less suggests accurate needle placement for injection of local anesthetic. Differential blockade to achieve pain and temperature block while minimizing motor block can be achieved by using levorotatory enantiomers of local anesthetics and delivering specific concentrations to the nerve. A variety of anesthesia textbooks publish maximum recommended dosages for local anesthetics in an attempt to prevent high dose injections leading to toxicity. Because local anesthetic toxicity is related more to intravascular injection than to total dose, some physicians have suggested maximum dose recommendations are irrelevant. It is reasonable to assume that intravascular injections will occur, and practitioners of regional anesthesia should select techniques designed to minimize their occurrence. (CMS, 2011).

LCD 34289 (CMS, 2016) addresses the use of these blocks in the definition and treatment of pain and conditions primarily treated with nerve blockade, such as complex regional pain syndrome and certain hyperhidroses. Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Pain is chronic when it has been present, continuously or intermittently, despite therapy for three months or more. CPNB involves the percutaneous insertion of a catheter directly adjacent to a peripheral nerve. The catheter is then...
infused with local anesthetic resulting in potent, site-specific analgesia that lasts well beyond the normal duration of a single injection nerve block. Longer-lasting or permanent blockade may be induced with the injection of neurolytic agents and/or application of thermal (not pulsed) radiofrequency.

Prior to blockade, all patients with pain complaints require an evaluation that includes an assessment of the source of the pain and treatment of any underlying pathology. Evaluation must be documented in the patient’s records. In addition, those patients who do not respond to injections or otherwise continue with persistent or poorly responsive pain should be referred for a multi-disciplinary comprehensive evaluation.

POSITION STATEMENT

Applicable To:
- Medicaid
- Medicare

Postoperative Disposable Ambulatory Regional Anesthesia (PDARA)

PDARA delivered via ambulatory infusion pump is considered medically necessary for the management of postoperative pain related to the following surgical procedures:
- Spinal fusion; OR,
- Inguinal hernia repair; OR,
- Shoulder surgery; OR,
- Knee surgery; OR,
- Foot surgery

Postoperative Disposable Ambulatory Regional Anesthesia (PDARA) is considered experimental and investigational and NOT a covered benefit for the management of postoperative pain related to the following surgical procedures:
- Hip surgery; OR,
- Open-heart surgery; OR,
- Cesarean surgery; OR,
- Abdominal hysterectomy; OR,
- Any other procedure not listed as medically necessary above

Continuous Peripheral Nerve Blocks (CPNB)

CPNB is considered medical necessary when the following criteria are met:
1. Therapeutic - to treat painful conditions or hyperhidrosis that respond to nerve blocks; AND / OR,
2. Prognostic - to predict the outcome of long-lasting interventions (e.g., neurolysis, rhizotomy).

Limitations of CPNB include:
- CPNB is a physician (or other qualified practitioner) service.
- There is no coverage of CPNB services and supplies ‘incident to’ the professional services of a physician (or other qualified practitioner) in private practice.
- CPNB should be performed with real-time ultrasound imaging and/or peripheral nerve stimulation to help prevent undesirable side effects such as muscle weakness.
- In general, different types of nerve blocks should not be performed at the same setting as other blocks in the same body region.
- Reimbursement for the control or management of pain in the immediate postoperative period is bundled into the payment for the procedure, surgical or anesthetic - regardless of the method by which the care provider, including the anesthesiologist, decides to manage pain. When not used as the primary mode of anesthesia, the medically reasonable and necessary placement of CPNB may be reimbursable. For example:
o A continuous femoral nerve block placed to provide post-operative analgesia for an anterior cruciate ligament repair or a total knee replacement could be reported separately from the surgical anesthesia.

o For shoulder surgery performed under continuous interscalene brachial plexus block along with a general anesthetic as the primary anesthesia, the block would be separately reportable as long as it will be used for post-op pain control.

o A continuous brachial plexus block might also provide both the anesthesia and the postoperative pain control for an open reduction of a wrist fracture. Only the anesthesia code would be reported.

**CODING**

**Postoperative Disposable Ambulatory Regional Anesthesia (PDARA)**

CPT® Codes – No applicable codes.

Covered HCPCS®* Codes

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-CM Diagnosis Codes *Requires a primary & secondary diagnosis to meet medical necessity

Primary diagnosis:

G89.18  Other Acute Postprocedural pain

Secondary diagnoses:

Status Post Spinal Fusion for:

C41.2  Malignant neoplasm of vertebral column

C70.1  Malignant neoplasm of spinal meninges

C79.31 Secondary malignant neoplasm of brain

C79.49 Secondary malignant neoplasm of other parts of nervous system

C79.51 Secondary malignant neoplasm of bone

D32.1  Benign neoplasm of spinal meninges

D33.4  Benign neoplasm of spinal cord

D42.1  Neoplasm of uncertain behavior of spinal meninges

D34.4 D43.4  Neoplasm of uncertain behavior of spinal cord

D48.0  Neoplasm of uncertain behavior of bone and articular cartilage

M40.205  Unspecified kyphosis, thoracolumbar region

M40.209  Unspecified kyphosis, site unspecified

M40.50  Lordosis, unspecified, site unspecified

M40.55  Lordosis, unspecified, thoracolumbar region

M40.56  Lordosis, unspecified, lumbar region

M41.05  Infantile idiopathic scoliosis, thoracolumbar region

M41.06  Infantile idiopathic scoliosis, lumbar region

M41.115 Juvenile idiopathic scoliosis, thoracolumbar region

M41.125 Adolescent idiopathic scoliosis, thoracolumbar region

M41.25  Other idiopathic scoliosis, thoracolumbar region

M41.35  Thoracogenic scoliosis, thoracolumbar region

M41.85  Other forms of scoliosis, thoracolumbar region

M43.00  Spondylolysis, site unspecified

M43.05  Spondylolysis, thoracolumbar region

M43.06  Spondylolysis of lumbar region

M43.10  Spondylolisthesis, site unspecified

M43.15  Spondylolisthesis, thoracolumbar region

M43.16  Spondylolisthesis of lumbar region

M48.05  Spinal stenosis, thoracolumbar region.
POSTOPERATIVE DISPOSABLE AMBULATORY REGIONAL ANESTHESIA (PDARA)

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M48.06 Spinal stenosis, lumbar region
M48.07 Spinal stenosis, lumbosacral region
M51.25 Other intervertebral disc displacement, thoracolumbar region
M51.26 Other intervertebral disc displacement, lumbar region
M84.48XS Pathological fracture, other site; sequela
M84.58XS Pathological fracture in neoplastic disease, vertebrae; sequela
M84.68XS Pathological fracture in other disease, other site; sequela
Q76.2 Congenital spondylolisthesis
S12.000K Unsp displaced fracture first cervical vertebra, subsequent encounter for fracture with nonunion
S12.001K Unsp nondisplaced fracture first cervical vertebra, subsequent encounter for fracture with nonunion
S12.100K Unsp displaced fracture second cervical vertebra, subsequent encounter for fracture with nonunion
S12.101K Unsp nondisplaced fracture second cervical vertebra, subsequent encounter for fracture with nonunion
S12.200K Unsp displaced fracture third cervical vertebra, subsequent encounter for fracture with nonunion
S12.201K Unsp nondisplaced fracture third cervical vertebra, subsequent encounter for fracture with nonunion
S12.300K Unsp displaced fracture fourth cervical vertebra, subsequent encounter for fracture with nonunion
S12.301K Unsp nondisplaced fracture fourth cervical vertebra, subsequent encounter for fracture with nonunion
S12.400K Unsp displaced fracture fifth cervical vertebra, subsequent encounter for fracture with nonunion
S12.401K Unsp nondisplaced fracture fifth cervical vertebra, subsequent encounter for fracture with nonunion
S12.500K Unsp displaced fracture sixth cervical vertebra, subsequent encounter for fracture with nonunion
S12.501K Unsp nondisplaced fracture sixth cervical vertebra, subsequent encounter for fracture with nonunion
S12.600K Unsp displaced fracture seventh cervical vertebra, subsequent encounter for fracture with nonunion
S12.601K Unsp nondisplaced fracture seventh cervical vertebra, subsequent encounter for fracture with nonunion
S22.019K Unsp fracture of first thoracic vertebra, subsequent encounter for fracture with nonunion
S22.029K Unsp fracture of second thoracic vertebra, subsequent encounter for fracture with nonunion
S22.039K Unsp fracture of third thoracic vertebra, subsequent encounter for fracture with nonunion
S22.049K Unsp fracture of fourth thoracic vertebra, subsequent encounter for fracture with nonunion
S22.059K Unsp fracture of T5-T6 vertebra, subsequent encounter for fracture with nonunion
S22.069K Unsp fracture of T7-T8 vertebra, subsequent encounter for fracture with nonunion
S22.079K Unsp fracture of T9-T10 vertebra, subsequent encounter for fracture with nonunion
S22.089K Unsp fracture of T11-T12 vertebra, subsequent encounter for fracture with nonunion
S22.099K Unsp fracture of unspecified lumbar vertebra
S32.029K Unsp fracture of first lumbar vertebra, subsequent encounter for fracture with nonunion
S32.039K Unsp fracture of second lumbar vertebra, subsequent encounter for fracture with nonunion
S32.049K Unsp fracture of third lumbar vertebra, subsequent encounter for fracture with nonunion
S32.059K Unsp fracture of fourth lumbar vertebra, subsequent encounter for fracture with nonunion
S32.069K Unsp fracture of fifth lumbar vertebra, subsequent encounter for fracture with nonunion

Status Post Hernia Repair for:
K40.00 - K40.91 Inguinal hernia

Status Post Shoulder Surgery for:
M24.111 - M24.119 Other articular cartilage disorders, shoulder
M24.211 - M24.219 Disorder of ligament, shoulder
M24.311 - M24.319 Pathological dislocation of shoulder, not elsewhere classified
M24.411 - M24.419 Recurrent dislocation, shoulder
M66.811 - M66.819 Spontaneous rupture of other tendons, shoulder
M75.00 - M75.02 Adhesive capsulitis of shoulder
M75.100 - M75.122 Rotator cuff tear or rupture, not specified as traumatic
M75.30 - M75.32 Calcific tendinitis of shoulder
S41.001S - S41.029S Open wound of shoulder, sequela
S43.001S - S43.006S Unspecified subluxation and dislocation of shoulder joint; sequela
S43.401S - S43.92S Sprain of shoulder joint, sequela
S44.8X1S - S44.8X9S Injury of other nerves at shoulder and upper arm level, sequela
S46.921S - S46.929S  Laceration of unsp muscle, fascia and tendon at shoulder and upper arm level, sequela
S49.80XS – S49.82XS  Other specified injuries of shoulder and upper arm, sequela

Status Post Knee Surgery for:
M01.X61 - M01.X69  Direct infection of knee in infectious and parasitic diseases classified elsewhere
M12.261 - M12.269  Villonodular Synovitis (pigmented), knee
M179  Osteoarthritis of knee, unspecified
M22.40 - M22.42  Chondromalacia patellae
M23.200 - M23.269  Derangement of meniscus due to old tear or injury
M23.40 - M23.42  Loose body in knee
M24.461 - M24.469  Recurrent dislocation, knee
S81.001S - S81.009S  Unspecified open wound of knee
S82.001S - S82.09XS  Fracture of patella
S83.001S - S83.09XS  Unspecified subluxation and dislocation of patella, sequela
S83.101S - S83.103S  Unspecified subluxation and dislocation of knee
S86.921S - S86.929S  Laceration of unspecified muscle and tendon at lower leg level
S89.80XS - S89.82XS  Other specified injuries of lower leg, sequela
Z96.651 - Z96.659  Presence of artificial knee joint

Status Post Foot Surgery for:
G57.50 - G57.52  Tarsal tunnel syndrome
M12.271 - M12.279  Villonodular Synovitis (pigmented), ankle and foot
M12.571 - M12.579  Traumatic arthropathy, ankle and foot
M19.90 - M19.93  Osteoarthritis, unspecified site
M21.961 - M21.969  Unspecified acquired deformity of lower leg
M24.071 - M24.076  Loose body in ankle and toe joints
M24.171 - M24.176  Other articular cartilage disorders, ankle and foot
M24.871 - M24.876  Other specific joint derangements of ankle and foot, not elsewhere classified
M65.871 - M25.879  Other specified joint disorders, ankle and foot
Q66.80 - Q66.89  Other congenital deformities of feet
S91.301S - S91.309S  Unspecified open wound of foot
S92.001S - S92.919S  Fracture of foot and toe, except ankle

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>9/15/2016, 6/5/2015</td>
<td>Approved by MPC. No changes.</td>
</tr>
<tr>
<td>7/11/2014</td>
<td>Approved by MPC.</td>
</tr>
<tr>
<td>5/2/2013, 5/3/2015</td>
<td>Inclusion of items re: continuous peripheral nerve blocks (CPNB).</td>
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<tr>
<td>12/1/2011</td>
<td>Approved by MPC.</td>
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<tr>
<td>7/18/2011</td>
<td>New template design approved by MPC.</td>
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