Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First Community HealthChoices	**Submission Date**: April 27, 2021
Policy Number: CCP.1347	**Effective Date:** 12/2017 **Revision Date:** April 6, 2021
Policy Name: Ambulatory continuous peripheral nerve block for chronic pain	

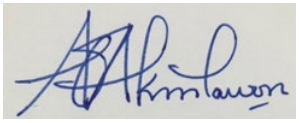
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☑ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

Please see revisions below using tracked changes

Name of Authorized Individual (Please type or print):	**Signature of Authorized Individual:**
Akintayo Akinlawon, MD	

Keystone First
Community HealthChoices

Ambulatory continuous peripheral nerve block for chronic pain

Clinical Policy ID: CCP.1347

Recent review date: 4/2021

Next review date: 8/2022

Policy contains: Chronic pain; continuous peripheral nerve block; perineural infusion.

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First Community HealthChoices when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

Continuous peripheral nerve block for the management of chronic pain in an ambulatory setting is investigational and, therefore, not medically necessary.

For any determinations of medical necessity for medications, refer to the applicable state approved pharmacy policy.

For Medicare members

Continuous peripheral nerve block is clinically proven and, therefore, medically necessary for the treatment of Medicare members with (Local Coverage Articles A56607, A57452, A57589, A57788; Local Coverage Decisions L33933, L35222, L36850, L37641, L37642):

- Chronic pain conditions or hyperhidroses that respond to nerve blocks (e.g., celiac block for pain of pancreatic cancer).
- Peripheral nerve injuries/entrapment or other extremity trauma leading to complex regional pain syndrome.

Continuous peripheral nerve block is not medically necessary for chronic pain associated with metabolic peripheral neuropathy.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Standards of care involve a range of multimodal approaches depending on pain severity and underlying condition, including, but not limited to:

- Non-pharmacologic interventions (e.g., acupuncture, physical therapy and exercise, cognitive behavioral therapy, and mindfulness meditation).
- Systemic opioid and non-opioid pharmacotherapy.
- Local anesthetic injections.
- Epidural or intrathecal regional infusions.
- Neuroablation.
- Neurostimulation.
- Surgical intervention.

Background

Chronic pain is a significant and underreported health problem, particularly among people of African American and Hispanic ethnicities, of lower income and education, with cognitive impairment, and after surgery, and in pediatric populations (Blackwell, 2014; Ilfeld, 2011; Institute of Medicine, 2011). Those with an underlying propensity or increased risk for chronic pain are also at risk for under-treatment, as chronic pain can be challenging to treat.

The goals of treatment are to decrease pain intensity and functional outcomes (National Academies of Sciences, Engineering, and Medicine, 2017). Prescription opioids are effective analgesics for chronic pain, but their long-term use is associated with an increased risk of opioid use disorder, death from opioid overdose, and other adverse outcomes (e.g., cardiovascular events or fractures). In the context of the growing opioid problem, reducing the burden of suffering from chronic pain poses a significant public health challenge. The National Academies of Sciences, Engineering, and Medicine (2017) proposed multidisciplinary and multimodal non-opioid approaches to reduce the burden of opioid misuse and abuse and manage pain more effectively.

Interventional neuromodulation therapies deliver pharmaceutical agents, electrical signals, or other forms of energy directly to the pain source, and are reversible, thereby avoiding side effects associated with more systemic or irreversible treatments. They increase the flexibility of both duration and density of local anesthetic effect depending on the chosen dose. A peripheral nerve block is neuromodulatory therapy delivered as a single injection or by continuous infusion. Single-injection peripheral nerve block offers effective pain relief for up to 24 hours but requires a dense motor block, and important sensory loss must be taken into account (Aguirre, 2012).

A continuous peripheral nerve block comprises an indwelling catheter, a long-acting local anesthetic, and an infusion pump (Aguirre, 2012). Guided by nerve stimulation, ultrasound, paresthesia induction, fluoroscopic imaging, or simple tactile perceptions, the catheter is inserted percutaneously in the proximity of the target nerve to deliver local anesthetic, most commonly bupivacaine and ropivacaine (Aguirre, 2012; Ilfeld, 2017). Multiple small portable infusion pumps are available, each with benefits and limitations. It is most often used for post-surgical pain control in the hospital setting, but lightweight, portable pumps allow for ambulatory infusion as well. A continuous peripheral nerve block offers adjustments of volume or concentration of local anesthetic, which reduces the need for a large initial bolus, lowers the risk of systemic toxicity, falls, and positioning injury, and potentially improves patient outcome (Aguirre, 2012).

Findings

We identified three narrative reviews (Aguirre, 2012; Ilfeld, 2011, 2017) and seven evidence-based guidelines (Blumenfeld, 2013; Horlocker, 2010; Manchikanti, 2013; Martelletti, 2013; National Comprehensive Cancer Network, 2017; Neal, 2015; Paice, 2016). The overwhelming majority of studies of continuous peripheral nerve block involve perioperative analgesia in adults, which is the only application validated with randomized controlled trials. Low-quality, retrospective studies have described experience with continuous peripheral nerve block in hundreds of pediatric post-surgical patients (Ilfeld, 2011).

Ambulatory continuous peripheral nerve block for perioperative pain control is at least as effective as sham, single-injection peripheral nerve blocks, and neuraxial routes of analgesia for controlling pain, decreasing opioid consumption and opioid-related side effects, decreasing nausea, and providing greater patient satisfaction (Bingham, 2012). Prolonged benefits of regional anesthesia after catheter removal were reported in a minority of patients. Evidence of long-term outcomes such as decreased chronic pain and improved health-related quality of life are lacking (Aguirre, 2012; Bingham, 2012).

The evidence of ambulatory continuous peripheral nerve block for chronic pain indications is anecdotal, consisting of case reports and small case series describing continuous peripheral nerve block in adult and pediatric populations for complex regional pain syndrome, intractable phantom limb pain, terminal cancer pain, trigeminal neuralgia, postsurgical chronic (> three months) pain syndromes, ischemia-induced pain, and ulcer-derived pain (Ilfeld, 2011, 2017). The evidence suggests continuous peripheral nerve block is feasible and may offer effective analgesia for certain chronic pain types that would respond to a peripheral nerve block, but the relative safety or efficacy to other treatment options, optimal delivery, or patient selection criteria cannot be determined.

The experience with ambulatory continuous peripheral nerve block in the perioperative pain settings offers some insight into its potential use for chronic pain. Regardless of technique or block location, major complications of peripheral nerve block, though rare, include vascular puncture and bleeding, nerve damage, infection, and local anesthetic systemic toxicity; minor complications involve catheter dislodgement, obstruction, and fluid leakage at the catheter site (Aguirre, 2012). Ambulatory support systems that are evidence-based and incorporate rapid diagnosis and early treatment algorithms can positively influence patient outcomes (Neal, 2015).

The complexity associated with an indwelling catheter and pump assembly raises the likelihood of technique failure. Successful home use of continuous peripheral nerve block depends on appropriate patient selection, adequate ambulatory care support to detect and address adverse events promptly, and education on pump management and catheter removal (Aguirre, 2012). While age alone is not an absolute exclusion criterion, patients for whom continuous peripheral nerve block may not be appropriate include those with (Ilfeld, 2011):

- Known renal and hepatic insufficiency to avoid possible local anesthetic toxicity.
- Heart disease, lung disease, or obesity who may not be able to compensate for mild hypoxia or hypercarbia (interscalene and cervical paravertebral infusions).
- Altered mental status or psychosocial issues that prevent understanding of, or cooperation with, protocol and care requirements.
- Inability to be contacted after discharge or to access a medical facility in case of emergency.

Evidence-based guidelines provide little direction on the optimal use of continuous peripheral nerve block in chronic non-malignant pain care. Where peripheral nerve block is mentioned as a treatment option, guidelines recommend single-injection peripheral nerve block as an alternative when more conservative treatment has failed, with no specific mention of continuous delivery systems except when recommending neuraxial techniques (Blumenfeld, 2013; Horlocker, 2010; Manchikanti, 2013; Martelletti, 2013; Neal, 2015). The American Society of

Regional Anesthesia and Pain (2017) does not mention continuous infusion of peripheral nerve block in their list of treatment options for chronic pain.

For malignant pain, the American Society of Clinical Oncology (Paice, 2016) recommends peripheral nerve blocks as an interventional therapy option based on a Cochrane review (Arcidiacono, 2011) demonstrating improved pain and lower opioid consumption at four weeks in adults receiving a single-injection celiac plexus block for pancreatic cancer pain. Neither the review nor the guideline specifically mentioned continuous infusion except with neuraxial techniques.

The National Comprehensive Cancer Network (2017) recommends continuous peripheral nerve block as one of several regional infusion options in adults. Interventional approaches using regional infusions are generally not appropriate in the presence of ongoing infection, coagulopathy, very short life expectancy, distorted anatomy, patient unwillingness, medications that increase risk of bleeding, or unavailable technical expertise. Catheter displacement and infection generally limit use beyond a few days or weeks. The main patient selection criteria are:

- Pain that is likely to be relieved with a nerve block (e.g., pancreas/upper abdomen with celiac plexus block or lower abdomen with superior hypogastric plexus block, or peripheral/plexus nerve).
- Inability to achieve adequate analgesia or functional activities of daily living with other pharmacologic therapy.
- Presence of intolerable side effects from other interventions (e.g., opioid titration program).

In 2018, we updated the National Comprehensive Cancer Network guideline on adult cancer pain (2018) and added one guideline from the American Society of Anesthesiologists and American Society of Regional Anesthesia and Pain Medicine (2010) that does not mention continuous peripheral nerve blocks for chronic pain management. No policy changes are warranted. The policy ID was changed from CP# 10.02.06 to CCP.1347.

In 2019, we updated the National Comprehensive Cancer Network guideline on adult cancer pain (2019), with no policy changes warranted. We identified no other newly published, relevant literature to add to the policy.

In 2020, we updated Medicare Local Coverage Articles and Local Coverage Decisions and added no new published information to the policy, which resulted in no material changes to the policy.

In 2021, we updated the references, including the National Comprehensive Cancer Network 2020 guideline on adult cancer pain, and added the results of a blinded, multisite trial of participants with phantom limb pain randomized to receive a six-day ambulatory perineural local anesthetic infusion with ropivacaine (n = 71) or normal saline placebo (n = 73) (Ilfeld, 2020). The primary outcome was the average phantom pain severity measured with a Numeric Rating Scale (0 to 10) at four weeks followed by an optional crossover treatment for up to an additional 12 weeks.

Baseline pretreatment pain severity scores were similar in both groups (median = 5.0, interquartile range 4.0, 7.0). Compared to the placebo group, those receiving the local anesthetic infusion substantially decreased phantom limb pain four weeks after the initiation of treatment (reported as mean phantom pain intensity (standard deviation):3.0 (2.9) in patients given the active treatment versus 4.5 (2.6) in the placebo group, *P* = .003). The main study limitation was that self-selection of optimal crossover treatment introduced significant selection bias for data collected subsequent to the primary and secondary end points. The authors recommended additional research to investigate the optimal perineural infusion parameters and define the precise duration of analgesic benefits. These results warrant no policy changes.

References

On January 12, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Nerve block/methods (MeSH),” “Chronic pain (MeSH),” and free text terms “continuous peripheral nerve block” and “perineural infusion. We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Center for Medicare & Medicaid Services. L37641 Continuous peripheral nerve blocks. https://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx.

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Policy updates

10/2017: initial review date and clinical policy effective date: 12/2017

10/2018: Policy references updated. Policy ID changed from CP# 10.02.06 to CCP.1347.

4/2019: Policy references updated.

4/2020: Policy references updated.

4/2021: Policy references updated.