Disclaimer:

Please note that Baptist Health Plan updates Coverage Guidelines throughout the year. A printed version may not be most up to date version available. The health plan reserves the right to review and update this policy as needed. Refer to the website to ascertain that you are utilizing the most current available version. Clinical guideline policies are not intended to serve as treatment guidelines or treatment recommendation. Treating providers must use their own clinical judgment in rendering care to their patient population.

For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern. In addition, coverage for Medicare Advantage members may differ. This is a result of applicable coverage statements by the Center for Medicare and Medicaid Services (CMS). The National Coverage Determinations, Local Coverage Determinations, and Local Medical Review Policies may be found at the CMS website, http://www.cms.gov. Please note that for all plans, the member’s health plan benefits that are in effect on the rendered date of service must be used in coverage determinations.

DEFINITION

Postoperative Disposable Ambulatory Regional Anesthesia (PDARA) also referred to as intraleisional and intraarticular infusion pumps, deliver narcotics and/or anesthetics directly into operative sites following surgery. They were developed to provide pain relief without the side effects of systemic analgesics such as nausea, vomiting, and/or sedation following surgery.

PDARA pain relief devices are generally used to deliver a narcotic or non-narcotic local anesthetic directly to a surgical or nerve site for two to five days following surgery. There are intraleisional and intraarticular pain relief systems that can be used for both continuous and on-demand pain relief delivered directly to the wound site.

COVERAGE CRITERIA

Postoperative Disposable Ambulatory Regional Anesthesia (PDARA) may be medically...
necessary as an adjunct to conventional postoperative pain management in the following instances:

- Inguinal hernia repair
- Cesarean delivery
- Joint surgery only on the shoulder, knee, or foot. ¹

Postoperative Disposable Ambulatory Regional Anesthesia (PDARA) is not medically necessary or is considered experimental/investigational even as an adjunct to conventional pain management in the following instances:

- Abdominal hysterectomy
- Appendectomy
- Axillary lymph node dissection
- Cardiac surgery
- Gastric banding or bypass
- Gynecologic surgery via laparotomy
- Hip surgery
- Mastectomy
- Nephrectomy
- Prostatectomy
- Spinal fusion
- Any surgical procedure other than those listed previously²

**MEDICAL BACKGROUND**

Postoperative disposable ambulatory regional anesthesia (PDARA), more commonly referred to as a pain pump, was developed with the goal of providing pain relief following surgery without the side-effects usually associated with systemic pain relief. When applying PDARA directly to the surgical site in addition to conventional pain control, patients experienced reduced pain, and in some cases required less of the conventionally delivered pain relieving drugs. However, PDARA is not yet recommended for every surgical procedure because pain control was not significantly improved when used following abdominal hysterectomy, prostatectomy, and gynecologic surgery via laparotomy.³

Intra-articular injections and use of pain pumps in joints have been linked to glenohumeral chondrolysis (deteriorated shoulder cartilage). An investigative review of the effects of local anesthetics on articular cartilage has been undertaken because recent studies demonstrated local anesthetic chondrotoxicity in both human and animal subjects. Further research is needed to better determine the long-term effects and risks, if any, from single intra-articular injections of local anesthetics.⁴

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A retrospective cohort study of 308 patients found “no difference in postoperative morbidity, rates of rehospitalization, in-patient mortality or hospitalization costs in geriatric patients undergoing regional or general anesthesia for repair of hip fracture”. Of the 308 patients 73 received regional anesthesia and 235 received general anesthesia. There was no added cost for the regional anesthesia and since the authors consider regional anesthesia to be opioid sparing it became the more desirable method of pain relief for hip replacement surgery.\(^5\)

The American Association of Orthopaedic Surgeons has an interview with Constance R. Chu, M.D. on their web site. Dr. Chu has been studying the effects of local anesthetics on articular chondrocytes for several years. She states that “it’s pretty well accepted that the loss of chondrocytes is a factor in cartilage loss, cartilage degeneration, and eventual osteoarthritis.” It is not clear yet how much local anesthetic is safe to use. Using intra-articular injections of local anesthetics is safe when needed but orthopaedic surgeons need to be aware of the potentially toxic effect of anesthetics and steroids on cartilage. Dr. Chu recommends reducing the amount used to the least amount possible.\(^6\)

A small but more recent (2011), randomized double-blind, placebo controlled study of 46 patients (actually only 39 patients after seven were dropped for adverse events or non-compliance) showed no advantage in using the ON-Q pain pump. It did not reduce pain or the need for additional narcotic or nausea medication. This study is mentioned only to demonstrate the need for further studies with larger numbers of patients.\(^7\)

Maureen Leahy, the assistant managing editor of AAOS Now, reported on a recent article in the Journal of Bone and Joint Surgery by Dr. Frank R. Noyes. In that article Dr. Noyes stated that continuous intra-articular infusion of bupivacaine following surgery resulted in rapid chondrolysis in both the shoulder and the knee. However, this was a very small study of only 21 patients. In other studies that included control groups the incidence of pain pump-induced chondrolysis varied from 42% to 63%. Dr. Noyes added, “The incidence of pain pump-induced knee chondrolysis will probably never be known because clinicians now understand the potential risks of these devices.”\(^8\)

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**REGULATORY INFORMATION**

Kentucky – No legislative mandates were found for PDARA.

Indiana – No legislative mandates were found for PDARA.

Tennessee – No legislative mandates were found for PDARA.

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**COVERAGE DETAIL**

For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.

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<tr>
<th>CPT® Codes</th>
<th>Description</th>
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<td>Medically necessary when criteria are met</td>
</tr>
<tr>
<td>A4306</td>
<td>Disposable drug delivery system, flow rate of less than 50 ml per hour</td>
<td>Medically necessary when criteria are met</td>
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<tr>
<td>E0781</td>
<td>Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient [for intralesional or intraarticular infusion of narcotic analgesics or anesthesia]</td>
<td>Medically necessary when criteria are met</td>
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<td>715.00 - 719.96</td>
<td>Osteoarthrosis and allied disorders, other and unspecified arthropathies, internal derangement of knee, other derangement of joint, and other and unspecified disorders of joint</td>
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<td>726.0 - 727.9</td>
<td>Peripheral enthesopathies and allied syndromes and other disorders of synovium, tendon, and bursa</td>
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<td>729.0 - 729.9</td>
<td>Other disorders of soft tissues</td>
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<td>836.0</td>
<td>Tear of medial cartilage or meniscus of knee, current</td>
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<td>Tear of lateral cartilage or meniscus of knee, current</td>
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<td>Other tear of cartilage or meniscus of knee, current</td>
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<td>844.0 - 844.9</td>
<td>Sprains and strains of knee and leg</td>
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REFERENCES


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