GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
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

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.

POLICY
Disposable elastomeric pumps (A4305, A4306) are non-covered for HMO, PPO, Individual Marketplace, & Elite.

Disposable elastomeric pumps (A4305, A4306) do not require prior authorization for Advantage.

HMO, PPO, Individual Marketplace, Elite
Disposable elastomeric pumps (A4305, A4306) to deliver continuous local analgesics to operative sites during the post-operative period are non-covered because there is insufficient evidence in the peer-reviewed medical literature of the effectiveness of these devices.

Advantage
While there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of disposable elastomeric pumps (A4305, A4306) to deliver continuous local analgesics to operative sites during the post-operative period, The Ohio Department of Medicaid requires these devices be covered for Advantage members.

CODING/BILLING INFORMATION
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.
**CPT CODES**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>A4305</td>
<td>Disposable drug delivery system, flow rate of 50 ml or greater per hour</td>
</tr>
<tr>
<td>A4306</td>
<td>Disposable drug delivery system, flow rate of 5 ml or less per hour</td>
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**REVISION HISTORY EXPLANATION**

06/15/09: Clarification of verbiage
10/01/12: Clarification of verbiage
05/12/15: Disposable elastomeric pumps (A4305, A4306) non-covered for HMO, PPO, Individual Marketplace, Elite and covered for Advantage per ODM guidelines. Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.

**REFERENCES/RESOURCES**

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid [http://jfs.ohio.gov/](http://jfs.ohio.gov/)
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.