FEP Medical Policy Manual

FEP 8.01.18 Lysis of Epidural Adhesions

Effective Date: April 15, 2018  Related Policies: None

Lysis of Epidural Adhesions

Description
Lysis of epidural adhesions involves passing a catheter, either endoscopically or percutaneously, under fluoroscopic guidance into the epidural space to break up adhesions and reduce pain and inflammation. Lysis of epidural adhesions, also called the Racz procedure, has been investigated as a treatment option for epidural fibrosis with or without adhesive arachnoiditis. The Racz procedure involves the passage of a fluoroscopically guided catheter (the Racz catheter), inserted either endoscopically or percutaneously, and the use of epidural injections of hypertonic saline in conjunction with corticosteroids and analgesics.

FDA REGULATORY STATUS
Lysis of epidural adhesions is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration. The Racz catheter received FDA approval via the 510k process.

POLICY STATEMENT
Catheter-based techniques for lysis of epidural adhesions, with or without endoscopic guidance, are considered investigational. Techniques used either alone or in combination include mechanical disruption with a catheter and/or injection of hypertonic solutions with corticosteroids, analgesics, or hyaluronidase.

BENEFIT APPLICATION
Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE
Summary of Evidence
For individuals who have epidural adhesions who receive lysis, the evidence includes randomized controlled trials. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Several randomized controlled trials have reported benefits for epidural lysis of adhesions compared with placebo treatment. Many of these trials were from the same center. The interpretation of these trials is limited by differences in patients, populations, and treatment protocols. The treatment for lysis of adhesions varied in the use of mechanical disruption, the type of lytic medications used, and the number of injections given. There was also a large effect in the placebo group, raising questions whether some component of the placebo treatment may be therapeutic. Larger trials with standardized treatment protocols would help determine whether specific treatment protocols have

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beneficial effects in specific patient populations. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Society of Interventional Pain Physicians
The American Society of Interventional Pain Physicians updated its practice guidelines on the management of chronic spinal pain in 2013. The guidelines stated that “for lumbar percutaneous adhesiolysis, the evidence is fair in managing chronic low back and lower extremity pain secondary to post surgery syndrome and spinal stenosis.” Percutaneous adhesiolysis was recommended “after failure of conservative management of physical therapy, chiropractic, drug therapy, structured exercise program, and fluoroscopically directed epidural injections.” The guidelines also indicated that spinal epidural endoscopic adhesiolysis was not discussed because there is limited evidence, moreover the procedure is rarely used. The studies cited in the guidelines were evaluated for this evidence review.

American Pain Society
The American Pain Society’s 2009 clinical practice guidelines on interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain did not include a discussion or conclusion on adhesiolysis. The guidelines stated that “for other interventions or specific clinical circumstances, the panel found insufficient evidence from randomized controlled trials to reliably judge benefits or harms.”

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>June 2012</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 3 and 11 added, others reordered, policy statement unchanged.</td>
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<tr>
<td>March 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review through November 17, 2014. No references were added, policy statement was unchanged.</td>
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<tr>
<td>March 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review through November 11, 2015; no references added. Policy statement unchanged.</td>
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<tr>
<td>March 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review through September 14, 2017; no references were added. Policy statement unchanged except not medically necessary” corrected to “investigational”.</td>
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