FEP 7.01.81 Nerve Graft With Radical Prostatectomy

Nerve Graft With Radical Prostatectomy

Description

Nerve grafting at the time of radical prostatectomy, most commonly using the sural nerve, has been proposed to reduce the risk of postoperative erectile dysfunction.

OBJECTIVE

The objective of this evidence review is to evaluate whether nerve grafting in conjunction with radical prostatectomy reduces erectile dysfunction.

POLICY STATEMENT

Unilateral or bilateral nerve graft is considered investigational in patients who have had resection of one or both neurovascular bundles as part of a radical prostatectomy.

BENEFIT APPLICATION

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

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
Nerve grafting with radical prostatectomy is a specialized procedure that may require out-of-network referral. In some cases, the nerve-harvesting procedure may be performed by a plastic surgeon or a neurosurgeon; in other cases, a urologist may perform both the nerve-harvesting, graft, and radical prostatectomy.

Specific contractual exclusions regarding treatment of impotence may apply.

**FDA REGULATORY STATUS**

A nerve graft with radical prostatectomy is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA).

Several nerve cuff products have been cleared for marketing by FDA through the 510(k) process. FDA product code: JXI. An example of a human tissue nerve graft product, the Avance nerve graft (AxoGen), is regulated by FDA under 21 CFR, Part 1271 regulations for Human Cellular and Tissue-based Products (HCT/P).

**RATIONALE**

**Summary of Evidence**

For individuals who have radical prostatectomy with resection of neurovascular bundles who receive nerve grafting, the evidence includes a randomized controlled trial, cohort studies, and case series. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. The randomized controlled trial did not find that unilateral nerve grafting was associated with a statistically significant improvement in potency rates at 2 years post-surgery. Cohort studies also did not result in better outcomes with nerve grafting. The evidence is insufficient to determine the effects of the technology on health outcomes.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**

The National Comprehensive Cancer Network guidelines on the treatment of prostate cancer (v.2.2018) states: “Replacement of resected nerves with nerve grafts has not been shown to be beneficial” for recovery of erectile function after radical prostatectomy. 7

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**REFERENCES**


The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.


**POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2012</td>
<td>New policy</td>
<td></td>
</tr>
<tr>
<td>March 2013</td>
<td>Replace policy</td>
<td>Literature review update; No change in policy statement.</td>
</tr>
<tr>
<td>March 2014</td>
<td>Replace policy</td>
<td>Literature review updated adding reference 7. No change in policy statement.</td>
</tr>
<tr>
<td>March 2015</td>
<td>Replace policy</td>
<td>Literature review updated adding reference 7. No change in policy statement.</td>
</tr>
<tr>
<td>June 2017</td>
<td>Replace policy</td>
<td>Title changed to “Nerve Graft With Radical Prostatectomy.” Policy updated with literature review through March 31, 2017; references 2 and 6 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>June 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through February 5, 2018; no references added; reference 7 updated. Policy statement unchanged except &quot;not medically necessary&quot; corrected to &quot;investigational&quot; since a nerve graft with radical prostatectomy is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA).</td>
</tr>
<tr>
<td>June 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through February 5, 2019; no references added. Policy statement unchanged.</td>
</tr>
</tbody>
</table>

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.