FEP Medical Policy Manual

FEP 7.01.81 Nerve Graft with Radical Prostatectomy

Effective Policy Date: July 1, 2023

Original Policy Date: June 2012

Related Policies:

None

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 individuals who have had resection of one or both neurovascular bundles as part of a radical prostatectomy.

POLICY GUIDELINES

None

BENEFIT APPLICATION

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

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.

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 (RCT), cohort studies, and case series. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. The RCT 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in "Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Comprehensive Cancer Network

The National Comprehensive Cancer Network guidelines on the treatment of prostate cancer (v.1.2023) states: "Replacement of resected nerves with nerve grafts has not been shown to be beneficial" for recovery of erectile function after radical prostatectomy.\(^1\)
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

# 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>
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<tbody>
<tr>
<td>June 2012</td>
<td>New policy</td>
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<tr>
<td>March 2013</td>
<td>Replace policy</td>
<td>Literature review update; No change in policy statement.</td>
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<tr>
<td>March 2014</td>
<td>Replace policy</td>
<td>Literature review updated adding reference 7. No change in policy statement.</td>
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<tr>
<td>March 2015</td>
<td>Replace policy</td>
<td>Literature review updated adding reference 7. No change in policy statement.</td>
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<tr>
<td>June 2017</td>
<td>Replace policy</td>
<td>Title changed to &quot;Nerve Graft With Radical Prostatectomy.&quot; 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, corrected to &quot;investigational, 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).&quot;</td>
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<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>
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<tr>
<td>June 2021</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 11, 2021; no references added; NCCN reference updated. Policy statement unchanged.</td>
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<tr>
<td>June 2022</td>
<td>Replace policy</td>
<td>Policy updated with literature review through February 24, 2022; no references added. NCCN reference updated. The word &quot;patients&quot; was replaced with &quot;individuals&quot; in the Policy Statement per updated Document Standards, intent unchanged.</td>
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<tr>
<td>June 2023</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 16, 2023; no references added; NCCN reference updated. Policy statement unchanged.</td>
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