FEP 7.01.81 Nerve Graft With Radical Prostatectomy

Effective Date: July 15, 2017
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.

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 the 21 CFR Part 1271 regulations for Human Cellular and Tissue-based Products (HCT/P).

POLICY STATEMENT
Unilateral or bilateral nerve graft is considered not medically necessary in patients who have had resection of one or both neurovascular bundles as part of a radical prostatectomy.

BENEFIT APPLICATION
Services, drugs, or supplies that are not medically necessary are not covered (See General Exclusion Section of brochure).

RATIONALE
Summary of Evidence
For individuals who have radical prostatectomy with resection of neurovascular bundles who receive nerve grafting, the evidence includes 1 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 postsurgery. 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.2.2017) states: "Replacement of resected nerves with nerve grafts has not been shown to be beneficial" for
recovery of erectile function after radical prostatectomy.

**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**


**POLICY HISTORY**

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<tr>
<td>March 2013</td>
<td>Update Policy</td>
<td>Literature review update; No change in policy statement</td>
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<td>March 2014</td>
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<td>June 2017</td>
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<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>
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