Clover

Clover Health Nerve Graft After Prostatectomy Reimbursement Policy

Policy # RP-020

Policy Title	Nerve Graft After Prostatectomy
Policy Department	Payment Strategy and Operations
Effective Date	1/1/2022
Revision Date(s)	1/1/2022
Next Review Date	

Disclaimer:

Clover Health applies CMS criteria and guidelines, National Coverage Determinations (NCD), Local Coverage Determinations (LCD), Clover Policies, and MCG for determining medical necessity. Clover Policies are intended to provide a standard guideline but are not used to preempt providers' judgment in rendering services. Providers are expected to provide care based on best practices and use their medical judgment for appropriate care.

Description:

This policy describes the coding requirements for nerve grafting, which is performed to replace cavernous nerves that have been resected during radical prostatectomy for prostate cancer. This procedure is considered to be experimental and investigational in nature. Nerve Graft after Prostatectomy is a procedure performed after a radical retropubic prostatectomy in which a bilateral nerve graft (sural nerve) is used to replace the resected cavernous nerves. At present, there is insufficient clinical evidence to demonstrate the value of sural nerve graft in managing patients with Erectile Dysfunction (ED), and there are at present no comparative studies between this approach and conventional medical management.

Definitions:

- **Nerve Graft**
  - A piece of nerve whose extraneural supports tissues will align and guide the outgrowth of axons from the proximal stump of a discontinuous nerve towards its target.

- **US Food and Drug Administration (FDA)**
  - The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ESRD), cosmetics, animal foods & feed and veterinary products.

Policy:

Erectile dysfunction (ED) is a common problem after radical prostatectomy (RP). In particular, spontaneous erections are absent in patients who have bilateral resection of the neurovascular bundles as part of the RP procedure for treatment of localized prostate cancer. A technique called nerve-sparing surgery has been developed to prevent damage to these nerves; however, this technique is not possible in some patients.
Nerve grafting to replace resected cavernous nerves during radical retropubic prostatectomy (RRP) has been proposed as a technique to increase the likelihood of restoring spontaneous erectile function (EF).

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

Based on the review of many studies, Clover Health considers a nerve graft after prostatectomy to be experimental and investigational in nature and is non-covered.

Note: According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an objective, evidence-based process, based on authoritative evidence. (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5). .

Claim Codes (if applicable)	
64911	Nerve repair; with autogenous vein graft (includes harvest of vein graft), each nerve
64912	Nerve repair; with nerve allograft, each nerve, first strand (cable)
64913	Nerve repair; with nerve allograft, each additional strand (List separately in addition to code for primary procedure)

References
Davis JW, Chang DW, Chevray P, et al. Randomized phase II trial evaluation of erectile function after attempted unilateral cavernous nerve-sparing retropubic radical prostatectomy with versus without unilateral sural nerve grafting for clinically localized prostate cancer. Eur Urol. 2009;55(5):1135-1143
Fujioka M, Tasaki I, Kitamura R, et al. Cavernous nerve graft reconstruction using an autologous nerve guide to restore potency. BJU Int. 2007;100(5):1107-1109
Kendirci M, Hellstrom WJ. Current concepts in the management of erectile dysfunction in men with prostate cancer. Clin Prostate Cancer. 2004;3(2):87-92