

External Vacuum Erection Devices

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. *Please refer to individual product lines certificates of coverage for possible exclusions of benefit.*

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not meeting coverage guidelines.

Penile implants and vacuum erection devices require precertification. Requires physician face-to-face

National Coverage Determination Policy	None
Local Coverage Determination Policy	J-B
Effective Date	The Health Plan Policy effective date: 10/31/13
Revisions/Review Date	01/19, 10/18, 06/04/2018, 04/01/17, 04/01/16, 07/01/15, 03/01/15, 01/01/15
The Health Plan	Plans will follow Coverage Determination posted on the CGS website unless otherwise indicated in sections of this policy, contractual agreements, or benefit plan documents.

DESCRIPTION

A penile implant is a surgically placed prosthetic device, which allows the patient to obtain an erection without external system. Two methods are available:

1. Insertion of the penile prosthesis; non-inflatable (semi-rigid) code 54400; inflatable (self-contained) CPT code 54401.
2. Insertion of inflatable (multi-component) penile prosthesis, including placement of pump, cylinders, and/or reservoir. CPT code 54005.

This policy focuses on the external vacuum erection devices (VED):

A vacuum constriction system works by placing a cylinder with an attached pump over the penis and activating the pump. The pump then creates a vacuum, which draws blood into the penis, creating an erection. A constriction ring is then placed to maintain an erection by keeping the blood in the penis.

COVERAGE GUIDELINES

For those plans that cover the vacuum erection device (L7900) and its related accessory, tension ring (L7902), there must be documentation presented that the member has been diagnosed with erectile dysfunction secondary to organic impotence, and is medically unable to take prescription drugs or any other form of medical management. There is no diagnosis of hypogonadism or hyperprolactinemia, and has history of normal erectile function.

This device falls under the ACA face-to-face rule. A physician face-to-face discussing the issue of impotence must have been done within the last six months of ordering the device

Must be considered a permanent condition. A condition is considered permanent if the medical record, including the judgment of the attending physician, indicates that the impairment will be of long and indefinite duration, typically greater than three months in duration.

NONCOVERAGE STATEMENT

As of 7/1/15 Medicare no longer covers external vacuum erection devices coded L7900 and L7902.

External vacuum device is a West Virginia Medicaid exclusion.

External penile pumps are considered experimental and investigational for other indications including for the prevention of erectile dysfunction following prostatectomy because their effectiveness for these indications has not been established.

Vacuum erection devices are noncovered in temporary situations, those situations where the need is three months or less.

Vacuum erection devices not found on the PDAC (Pricing, Data Analysis, and Coding contractor) website will be denied as not covered and must be coded A9270.

REPAIR, REPLACEMENT AND REASONABLE USEFUL LIFETIME

For those plans that allow VED and accessories replacement is 1 every 3 years.

CODING INFORMATION

CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS

EY	NO PHYSICIAN OR OTHER LICENSED HEALTH CARE PROVIDER ORDER FOR THIS ITEM OR SERVICE
GA	WAIVER OF LIABILITY STATEMENT ISSUED AS REQUIRED BY PAYOR POLICY, INDIVIDUAL CAS
GZ	ITEM OR SERVICE EXPECTED TO BE DENIED AS NOT REASONABLE AND NECESSARY
KX	REQUIREMENTS SPECIFIED IN THE MEDICAL POLICY HAVE BEEN MET

HCPCS CODES

L7900	MALE VACUUM ERECTION SYSTEM
L7902	TENSION RING FOR VACUUM ERECTION DEVICE, ANY TYPE, REPLACEMENT ONLY

ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY IF COVERED

N52.9	IMPOTENCE OF ORGANIC ORIGIN
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Diagnosis that supports medical necessity indicated above.

DOCUMENTATION REQUIREMENTS

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports.

This documentation must be available with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:
 - a. Member's name
 - b. Date
 - c. Description of item. The medical record must contain the information that supports the request for each item, and must be submitted with the precertification, if the item requires precertification, or with the claim, if no precertification was required
 - d. Order must include diagnosis code
 - e. Physician signature with date. Date stamps are not appropriate
 - f. Quantity of items required and duration. A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used

The supplier is to contact The Health Plan in this instance to update referral

2. There must be documentation in the supplier's records to support the medical necessity of that item. Examples of the information required: history and nature of condition, duration, clinical course (worsening or improving), prognosis, nature and extent of functional limitations, other therapeutic interventions, treatment of co morbid condition, and results, past experience with related items, etc. This information must be available upon request usually with precertification per The Health Plan policy.

NOTE: Often claims for these devices do not have diagnostic information that relates to organic impotence. It is important to assure that specifically treatable conditions are identified before ordering a vacuum erection device. Documentation of this evaluation must be submitted with

precertification. In addition to the ICD-10 diagnosis code for organic impotence (N52.9), it is recommended that providers also include a secondary diagnosis to identify the cause of the impotence.

3. Proof of delivery to be kept on file by the provider of the item.
4. Include manufacturer and model number of device to ensure billing guidelines are met.

Note: If templates or forms are submitted, (i.e., a Medicare Certificate of Medical Necessity, and/or a provider created form), and all of the required information is not included, The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, and home health records.

Note: Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

VACUUM ERECTION DEVICE PROVIDED TO MEMBER WHILE IN A PART A COVERED STAY

Reimbursement for a VED provided to a member while the member is covered under a Part A facility is based on specific contract information with the individual facility, and whether or not the device is intended for use while the member is in the facility and if the device is covered by the member's Plan. Rarely would there be a need for this device while in a skilled nursing unit.

BILLING GUIDELINES

L7900 is a purchase. Useful lifetime not clearly indicated.

L7902 is not separately billable at the time of initial issue of L7900.

Replacement of tension ring (L7902) is allowed one every 12 months.

Devices coded and billed L7900 and L7902, must meet these coding guidelines as follows:

1. Have an approved manually operated quick release mechanism
2. Must not include features that provide for extended continuous use
3. Draw a vacuum of less than 17" of mercury
4. Must include a vacuum limiter
5. An electronically powered device must have adequate isolation between the power source and the user. Must conform to the IEC 60601-1, Medical Electrical Equipment Part 1: General requirements for Safety (General) standards
6. Be made of rubber, silicone or similar soft pliable material. Must conform to the International Standard Organization Standard (ISO)-10993

KX, GA, and GZ MODIFIERS

Suppliers may submit a claim with a KX modifier only if all the criteria for that item are met.

If the coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

ADVANCED BENEFICIARY NOTICE

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

NOTE: Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

PRICING, DATA ANALYSIS, AND CODING (PDAC)

The Health Plan has implemented use of Medicare's PDAC contractor for review of authorizations. Suppliers should contact the PDAC contractor for guidance on the correct coding of these items. dmepdac.com/

MEDICARE DEFINITIONS AND DESCRIPTION

Prosthetic devices and related supplies are covered when the device is required to replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.

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INTERNET LINKS AND SOURCES

Noridian Healthcare Solutions. Website. Durable Medical Equipment. News and Publications. Vacuum Erection Devices. Documentation

Requirements noridianmedicare.com/dme/news/docs/2009/12_dec/l7900.html

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West Virginia Medicaid Internet Provider Manual. Chapter 506C. Non-Covered Services, DMEPOS Supplies. Last accessed 10/26/18. Retrieved from: <https://dhhr.wv.gov/bms/Pages/default.aspx>

Face-to-Face Examination and Prescription Requirements Prior to the Delivery of Certain DME Items Specified in the Affordable Care Act DME MAC Joint Publication. Posted February 20, 2014. Last accessed 10/26/18. Retrieved from:

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