



Medicare Part C Medical Coverage Policy

Penile Implants

Origination: July 16, 1990

Review Date: May 15, 2019

Next Review: May, 2021

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services.******

DESCRIPTION OF PROCEDURE OR SERVICE

Impotence is the failure of a body part for which the diagnosis and frequently the treatment requires medical expertise. Depending on the cause of the condition, treatment may be surgical; e.g., implantation of a penile prosthesis, or non surgical; e.g., medical or psychotherapeutic treatment

POLICY STATEMENT

Coverage will be provided for penile implants when it is determined to be medically necessary, as outlined in the below guidelines and medical criteria.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (E.O.C.) for benefit determination. Coverage will be approved according to the E.O.C. limitations if the criteria are met.

Coverage decisions for members will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations(NCD);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (E.O.C.), the E.O.C. always governs the determination of benefits.

INDICATIONS FOR COVERAGE

Preauthorization by the Plan is required.

Penile implants are covered when all of the following criteria are met:

1. The history and physical exam of the member are consistent with sexual dysfunction.
 - The member has a medical (organic) condition that directly contributes to sexual dysfunction;

AND

- Medical therapies have been tried and failed, such as testosterone replacement therapy using topical creams, patches or IM injections, or PDE5 inhibitors (which may be covered under Part D formulary if member has elected Part D coverage).

Replacement of a penile implant is covered:

1. If the device malfunctions, breaks, or becomes infected;
2. If medical necessity criteria continue to be met; *and*
3. If replacement is not part of the manufacturer warranty.

WHEN COVERAGE WILL NOT BE APPROVED

When the above medical criteria and guidelines are not met.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable codes: 54400, 54401, 54405, 54408, 54410, 54411, 54416, 54417

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SPECIAL NOTES

For dates of service on or after July 1, 2015, vacuum erection devices (VES), HCPCS codes L7900 and L7902 are statutorily non-covered based on the Achieving a Better Life Experience (ABLE) Act of 2014.

References:

1. Medicare National Coverage Determination for Diagnosis and Treatment of Impotence (ID #230.4); Effective date: Longstanding determination- effective date not posted: Accessed on 05/15/19 via Internet site www.cms.gov/mcd/viewnccd
2. CMS MLN Matters SE1511, Discontinued Coverage of Vacuum Erection Systems (VES) Prosthetic Devices in Accordance with the Achieving a Better Life Experience Act of 2014. Accessed online on 05/15/19.
3. United Healthcare Medicare Advantage Plans: Impotence Treatment Coverage Summary, Original Approval Date 07/15/2008; Last Review Date: 06/16/2015. Accessed online at www.unitedhealthcareonline.com on 05/15/19.

Policy Implementation/Update Information:

Revision Date: September 29, 1999; October 8, 2003; August 24, 2005

Policy renamed: Impotence, 11/3/2003. Previous policy name: Impotence / Penile Implants

November 2008: Name changed from Impotence to Penile Implants for clarification; Clarified language to state "The member has failed a trial use of a vacuum erection system and/or medications" to when coverage will be approved; Moved to organic causes for impotence to the Special Notes section instead of the criteria section; Added guidelines for replacement of the penile implant

Revision Date: August 2012: No criteria changes

Revision Date: July 15, 2015: Annual Review, updated Description of Procedure or Services with current NCD language, reformatted Indications For Coverage, item #1 to keep pertinent therapies as tried and failed; removed "appropriate diagnostic test" language as no CMS guidance referencing this criteria; added the following under When Coverage Will Not Be Approved: For dates of service on or after July 1, 2015, vacuum erection devices (HCPCS codes L7900 and L7902) are statutorily non-covered based on the Achieving a Better Life Experience (ABLE) Act of 2014; Removed Special Notes for Causes and Treatments of Organic Impotence for Men, as this language is not noted in CMS or referenced guidelines; Updated Reference section.

Revision Date: July 12, 2017: Annual Review; No CMS Updates. Minor Revisions Only.

Revision Date: May 15, 2019: Annual Review; No CMS Updates. Minor Revisions Only.

Approval Dates:

Medical Coverage Policy Committee:

May 15, 2019

Policy Owner: Carolyn Wisecarver, RN, BSN
Medical Policy Coordinator