## Coverage Summary

### Impotence Treatment

<table>
<thead>
<tr>
<th>Policy Number:</th>
<th>I-004</th>
<th>Products: UnitedHealthcare Medicare Advantage Plans</th>
<th>Original Approval Date:</th>
<th>07/16/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved by:</td>
<td>UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date:</td>
<td>08/21/2018</td>
<td></td>
</tr>
</tbody>
</table>

**Related Medicare Advantage Policy Guidelines:**

- Cavernous Nerves by Electrical Stimulation with Penile Plethysmography (NCD 160.26)
- Diagnosis and Treatment of Impotence (NCD 230.4)
- Testosterone Replacement Therapy

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**INDEX TO COVERAGE SUMMARY**

<table>
<thead>
<tr>
<th>I.</th>
<th>COVERAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Diagnosis and Treatment of Sexual Impotency</td>
</tr>
<tr>
<td>2.</td>
<td>Vacuum Erection Devices (VED) or Constriction Rings</td>
</tr>
<tr>
<td>3.</td>
<td>Electrical stimulation of the cavernous and associated parasympathetic nerves with penile plethysmography</td>
</tr>
<tr>
<td>4.</td>
<td>Prescription or injectable medications</td>
</tr>
<tr>
<td>5.</td>
<td>Elective or voluntary procedures</td>
</tr>
<tr>
<td>6.</td>
<td>Nerve Graft to Restore Erectile Function During Radical Prostatectomy</td>
</tr>
</tbody>
</table>

II. DEFINITIONS

III. REFERENCES

IV. REVISION HISTORY

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**Coverage Statement:** The treatment of impotency is covered when Medicare criteria are met.

**Guidelines/Notes:**

1. Diagnosis and treatment of sexual impotency may be covered. Depending on the cause of the condition, treatment may be:
a. Non-surgical treatment, including but not limited to:
   1) Medical or psychotherapeutic treatment; see Coverage Summary for Mental Health Services and Procedures.

b. Surgical treatment, including but not limited to:
   1) Implantation of penile prosthesis

Notes:
- Since causes, and therefore, appropriate treatment varies, if abuse is suspected it may be necessary to request documentation of appropriateness in individual cases. Documentation of a history or radical prostatectomy would be an indication for treatment.
- See the NCD for Diagnosis and Treatment of Impotence/Impotence (Male Erectile Dysfunction (230.4)). (Accessed August 7, 2018)

2. External Vacuum Erection Devices (VED) (L7900) or Constriction Rings (L7902) (e.g., ErecAid)

   For dates of service on or after July 1, 2015, vacuum erection devices and related accessories are statutorily non-covered based on the Achieving a Better Life Experience (ABLE) Act of 2014. See the DME MAC for LCD for Vacuum Erection Devices (L34824). (Accessed June 19, 2019)

   For additional info, see the CMS MLN Matters NumberSE1511 Discontinued Coverage of Vacuum Erection Systems (VES) Prosthetic Devices in Accordance with the Achieving a Better Life Experience Act of 2014. (Accessed August 7, 2018)

3. Electrical stimulation of the cavernous and associated parasympathetic nerves with penile plethysmography is not covered for members undergoing nerve-sparing prostatic or colorectal surgical procedures. See the NCD for Cavernous Nerves by Electrical Stimulation with Penile Plethysmography (160.26). (Accessed August 7, 2018)

4. Prescription or injectable medications for the treatment of sexual or erectile dysfunction are not covered. ED drugs will meet the definition of a Part D drug when prescribed for medically-accepted indications approved by the FDA other than sexual or erectile dysfunction (such as pulmonary hypertension). However, ED drugs will not meet the definition of a Part D drug when used off-label, even when the off label use is listed in one of the compendia found in section 1927(g)(1)(B)(i) of the Act: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications), and DRUGDEX Information System. Examples include, but are not limited to:
   a. Alprostadil urethral suppository (MUSE)
   b. Viagra
   c. Testosterone patches
   d. Caverject
   e. Papaverine
   f. Regitine

   See the Medicare Prescription Drug Benefit Manual, Chapter 6, Section 20.1 - Excluded Categories (Accessed August 7, 2018)

   Also see the Coverage Summary for Medications/Drugs (Outpatient/Part B).

5. Elective or voluntary procedures, services, supplies and medications for the enhancement of sexual performance are not covered except as covered in #1 above.
See the Medicare Benefit Policy Manual, Chapter 16, Section 20 - Services Not Reasonable and Necessary (Accessed August 7, 2018)

Also see the Medicare Prescription Drug Benefit Manual, Chapter 6, Section 20.1- Excluded Categories, (Accessed August 7, 2018)

6. Nerve Graft to Restore Erectile Function During Radical Prostatectomy
   - Medicare does not have a National Coverage Determination (NCD) nerve graft to restore erectile function during radical prostatectomy.
   - Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time.
   - For coverage guidelines, see the UnitedHealthcare Commercial Medical Policy for Nerve Graft to Restore Erectile Function During Radical Prostatectomy. (IMPORTANT NOTE: After searching the Medicare Coverage Database, if no state LCD/LCA is found, then use the above referenced policy.)
   - Committee approval date: August 21, 2018
   - Accessed August 7, 2018

II. DEFINITIONS

Electrical Stimulation of the Cavernous and Associated Parasympathetic Nerves (also referred to as Cavernosal Nerve Mapping): The assessment of the function of the cavernous nerves by direct application of electrical stimulation with penile plethysmography which may be performed to assess the integrity of the cavernous nerves. Through an open or laparoscopic procedure, the surgeon may want to assess the function of the cavernous nerves by stimulating the most distal end of the nerve that can be located by using an electrical nerve stimulator. The presence of a response and the degree of the response may be used to provide the surgeon with a more realistic assessment of the chance of the patient regaining potency and assist in choosing appropriate therapy. NCD for Cavernous Nerves by Electrical Stimulation with Penile Plethysmography (160.26). (Accessed August 7, 2018)

III. REFERENCES

See above.

IV. REVISION HISTORY

04/01/2019 – Updated policy introduction; added language to clarify:
   - There are instances where [the Coverage Summary] may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG)
   - In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5)
   - Retitled reference link that directs users to UnitedHealthcare Commercial policy

08/21/2018 Annual review; no updates.

02/20/2018 Re-review with the following update:
   - Guideline 4 – added a cross reference link to the Coverage Summary for Medications/Drugs (Outpatient/Part B).
08/15/2017 Annual review with the following recommended updates:

- Guideline 1.b (Surgical treatment, including but not limited to) – updated language to reflect exact verbiage from the NCD for Diagnosis and Treatment of Impotence/Impotence (Male Erectile Dysfunction (230.4).
- Definitions: Impotence – deleted; unable to find exact language in any of the CMS references.

01/17/2017 Re-review with the following recommended updates:

- Guideline 1 (Diagnosis and Treatment of Impotence) – revised the coverage language, based on NCD 230.4, to read: Diagnosis and treatment of sexual impotency may be covered.
- Guideline 1.a.1) – revised, based on NCD 230.4, to: Medical or psychotherapeutic treatment.
- Guideline 1.a.2) [External vacuum devices, pumps, or constriction rings (e.g., ErecAid)] – deleted from this section and moved as Guideline 2, to read:
  For dates of service on or after July 1, 2015, vacuum erection devices and related accessories are statutorily non-covered based on the Achieving a Better Life Experience (ABLE) Act of 2014. See the DME MAC for LCDs for Vacuum Erection Devices (L34824).
  For additional info, see the CMS MLN Matters NumberSE1511 Discontinued Coverage of Vacuum Erection Systems (VES) Prosthetic Devices in Accordance with the Achieving a Better Life Experience Act of 2014.

08/16/2016 Annual review; no updates.

09/15/2015 Annual review with the following updates:

- Guideline #1.2.a (Non-surgical treatment, including but not limited to) –
  - Removed all existing references to the DME MAC LCDs - Vacuum Erection Devices (VED): Noridian (L34736), National Government Services (L34740), CGS (L34675) and NHIC (L34732); as these LCDs will retire on 9/30/2015.
  - Removed the following language “Note: Discontinued Coverage of Vacuum Erection Devices” and “(effective July 1, 2015)”
  - Added reference and link to the new DME MAC LCDs for Vacuum Erection Devices (L34824) effective 10/1/2015.
- Guideline #3 (Prescription or injectable medications for the treatment of erectile dysfunction are not covered. Examples include, but are not limited to) – Added reference and link to the Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements Section 20.1 Excluded Categories.
- Guideline #4 (Elective or voluntary procedures, services, supplies and medications for the enhancement of sexual performance are not covered except as covered in #1 above.)
  - Added reference and link to the Medicare Benefit Policy Manual Chapter 16 - General Exclusions From Coverage Section 20 - Services Not Reasonable and Necessary
  - Added reference and link to Medicare Prescription Drug Benefit Manual
Chapter 6 – Part D Drugs and Formulary Requirements Section 20.1

Excluded Categories

06/16/2015  Guideline 1.a.2 [External vacuum devices, pumps, or constriction rings (e.g., ErecAid)]
- Added reference links to the applicable DME MAC LCDs – Vacuum Erection Devices (VED) and CMS MLN Matters Article
- Added the following language:
  Discontinued Coverage of Vacuum Erection Devices:

  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

10/21/2014  Annual review with following updates:
- Guidelines #1 (Diagnosis of sexual impotency) – Removed reference link to the retired LCDs for Erectile Dysfunction, Evaluation and Treatment
- Definitions:
  - Electrical Stimulation of the Cavernous and Associated Parasympathetic Nerves – added reference link to the NCD for Cavernous Nerves by Electrical Stimulation with Penile Plethysmography (160.26)
  - Impotence – added reference link to the NCD for Diagnosis and Treatment of Impotence/Impotence (Male Erectile Dysfunction (230.4)

10/24/2013  Annual review; no updates

03/05/2013  Policy number changed from “I-003” to “I-004”

10/31/2012  Annual review; no updates

10/13/2011  Annual review; no updates

09/07/2010  Policy updated to include guidelines for Nerve Graft to Restore Erectile Function During Radical Prostatectomy