I. POLICY/Criteria

A. Evaluation of impotence is covered as a medical service. The treatment of impotence with equipment is covered at the DME benefit level; treatment with drugs is not a covered benefit unless the group has purchased a rider for coverage. Treatment with insertion of a penile prosthesis is covered as a medical service.

B. Limits/Indications

1. These diagnostic services are covered under the base plan. Appropriate diagnostic tests for impotence include tests to:
   - Determine if the cause of impotency is organic or non-organic.
   - Measure blood pressure and blood flow in the penis.
   - Evaluate the condition of blood vessels leading to the penis.
   - Determine if the nerve supply to the penis is adequate.

2. Drug Therapy (oral, injectable, pellets).
   *Note:* Drug therapy is not a covered benefit unless the group has purchased the Sexual Dysfunction Rider. Drug therapy is *NOT* a covered benefit for Medicaid members as governed by State and Federal regulations.

3. External Penile Erectile Vacuum Devices:
   a. External male erectile vacuum devices are covered at the Durable Medical Equipment benefit level. Coverage requirements include:
      - Males at least 18 years of age with a diagnosis of organic ED.
      - An appropriate evaluation must be done to determine the necessity for the external penile vacuum pump.
      - This would include, but is not limited to, a medical, psychosocial and sexual history; physical examination; and appropriate laboratory and diagnostic evaluation. The laboratory testing should be “thorough enough to identify comorbid conditions that may predispose the patient to ED and that may contraindicate certain therapies.”
      - The effect of the patient’s other medications on ED should also be considered.
      - Patient has the manual dexterity to utilize the device.
      - Adequate penile blood supply is present.
      - Devices are most effective in partial impotence.
Contraindicated in patients with blood dyscrasias, including sickle cell disease, or those taking anticoagulants. Coverage is provided for only one external penile vacuum pump per member lifetime under the DME benefit.

4. Female erectile devices (e.g. Eros) are covered under the Medical Supply or Durable Medical Equipment (DME) benefit. Priority Health will provide coverage for Female Erectile Dysfunction Therapy if there is a documented underlying disease/condition.

Indications for use of the Eros device include:
- Greater clitoral and genital engorgement
- Increased vaginal lubrication
- Enhanced ability to achieve orgasm
- Improved overall sexual satisfaction

Female erectile devices are NOT a covered benefit for Medicaid members.

5. Penile prosthesis implantation:
   a. Covered according to Penile Implant Insertion InterQual® criteria.
   b. Coverage is provided for only one penile prosthesis implantation per member lifetime.

6. Coverage is not provided for:
   - Psychological counseling for ED
   - Exogenous testosterone replacement therapy given solely for ED
   - Extracorporeal shock wave therapy for Peyronie’s disease
   - Stem Cell Therapy for erectile dysfunction is experimental and investigational and is not a covered benefit.

II. MEDICAL NECESSITY REVIEW

☑ Required-For Medicaid members only for penile prosthesis only
☒ Not Required-For other services, therapies and devices above
☐ Not Applicable

III. APPLICATION TO PRODUCTS

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

- HMO/EPO: This policy applies to insured HMO/EPO plans.
- POS: This policy applies to insured POS plans.
IV. DESCRIPTION

Male erectile dysfunction (ED) is defined as the inability of a man to attain and maintain an erection sufficient for sexual intercourse. ED may be organic in nature, that is, caused by a detectable physiological or structural change. “Appropriate evaluation of erectile dysfunction leads to accurate advice, management and referral of patients….” A medication review is imperative during the assessment period, since as many as 25% of ED cases are caused by medications (including over-the-counter preparations).8

Likely causes of male erectile dysfunction, based on clinical presentation, are listed in Appendix A. Treatment will vary depending on the severity and cause of the dysfunction. In the case of uncomplicated ED, treatment usually consists of oral medication known as phosphodiesterase-5 inhibitors (PDE-5). PDE-5 agents are more commonly known as Viagra (sildenafil citrate), Cialis (tadalafil) and Levitra (vardenafil) and are generally considered safe and effective.

For men who do not respond to these oral medications, injectable drugs are available for treatment. Alprostadil, papaverine and phentolamine are drugs that are injected into the corpus cavernosa. These drugs require titration and are initially injected by the physician. Self-injection will ultimately occur after titration has been achieved. Two of these drugs, alprostadil and papaverine, can also be administered through a small catheter into the urethra.

Oral testosterone can reduce ED in some men with low levels of natural testosterone, but it is often ineffective. Studies indicate that although testosterone deficiency may affect the libido, it does not necessarily affect the ability to have erections. Yohimbine hydrochloride and its derivatives Aphrodyne, Testomar, Vigorex, Yocon, and Dayto-Himbin are not FDA approved for this purpose. Other oral drugs, such as dopamine, serotonin agonists, and trazodone, have not been proven to be effective. The results of
scientific studies to substantiate these claims have been inconsistent. Despite the fact that herbal remedies are popular worldwide in the treatment of ED, the mechanisms of action, effectiveness, and safety of these agents is questionable. Even the product potency and quality within a given brand may be inconsistent. One study even found deliberate contamination of some herbal products with therapeutic levels of PDE-5 inhibitors.\(^2\) For men who cannot or do not wish to use drug therapy, an external vacuum device may be an appropriate treatment option. With proper instruction 75% of men can achieve a functional erection.

For more severe disease, usually associated with advanced diabetes, surgical or radiation treatment for prostate or bladder cancer or Peyronie’s disease, drug treatment or treatment with an external vacuum device may be ineffective. Implantation of a penile prosthesis is a therapeutic alternative. There are three basic kinds of penile implants: semi-rigid (malleable) implant, two-piece inflatable implant, and three-piece inflatable implant.

Female erectile dysfunction (ED) can be caused by diabetes, pelvic trauma, hypertension, vascular disease, menopause, or may be idiopathic.

Female erectile devices (e.g. Eros clitoral stimulation device) are used to obtain greater clitoral engorgement and enhance the ability to achieve an orgasm.

V. CODING INFORMATION

ICD-10 Codes that may apply:

<table>
<thead>
<tr>
<th>Code Range</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E10.40 – E10.43</td>
<td>Type 1 diabetes mellitus with neurological complications</td>
</tr>
<tr>
<td>E10.49</td>
<td>Type 1 diabetes mellitus with other diabetic neurological complication</td>
</tr>
<tr>
<td>E10.59</td>
<td>Type 1 diabetes mellitus with other circulatory complications</td>
</tr>
<tr>
<td>E10.69</td>
<td>Type 1 diabetes mellitus with other specified complication</td>
</tr>
<tr>
<td>E11.40 – E11.43</td>
<td>Type 2 diabetes mellitus with neurological complications</td>
</tr>
<tr>
<td>E11.49</td>
<td>Type 2 diabetes mellitus with other diabetic neurological complication</td>
</tr>
<tr>
<td>E13.40 – E13.43</td>
<td>Other specified diabetes mellitus with neurological complications</td>
</tr>
<tr>
<td>E13.49</td>
<td>Other specified diabetes mellitus with other diabetic neurological complication</td>
</tr>
<tr>
<td>I73.9</td>
<td>Peripheral vascular disease, unspecified</td>
</tr>
<tr>
<td>N50.1</td>
<td>Vascular disorders of male genital organs</td>
</tr>
<tr>
<td>N52.01 – N52.9</td>
<td>Male erectile dysfunction</td>
</tr>
<tr>
<td>N94.89</td>
<td>Other specified conditions associated with female genital organs and menstrual cycle</td>
</tr>
<tr>
<td>N94.9</td>
<td>Unspecified condition associated with female genital organs and menstrual cycle</td>
</tr>
<tr>
<td>N95.8</td>
<td>Other specified menopausal and perimenopausal disorders</td>
</tr>
<tr>
<td>N95.9</td>
<td>Unspecified menopausal and perimenopausal disorders</td>
</tr>
<tr>
<td>Q52.6</td>
<td>Congenital malformation of clitoris</td>
</tr>
<tr>
<td>Q52.8</td>
<td>Other specified congenital malformations of female genitalia</td>
</tr>
</tbody>
</table>
Q52.9 Congenital malformation of female genitalia, unspecified
R10.2 Pelvic and perineal pain
R39.9 Unspecified symptoms and signs involving the genitourinary system

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S38.001A – S38.03xS</td>
<td>Crushing injury of external genital organs</td>
</tr>
<tr>
<td>S39.840A – S39.848S</td>
<td>Other specified injuries of external genitals</td>
</tr>
<tr>
<td>S39.94xA – S39.94xS</td>
<td>Unspecified injury of external genitals</td>
</tr>
</tbody>
</table>

**CPT/HCPCS Codes:**

**Diagnostic**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>51792</td>
<td>Stimulus evoked response (eg, measurement of bulbocavernosus reflex latency time)</td>
</tr>
<tr>
<td>54230</td>
<td>Injection procedure for corpora cavernosography</td>
</tr>
<tr>
<td>54231</td>
<td>Dynamic cavernoscopy, including intracavernosal injection of vasoactive drugs (e.g., papaverine, phentolamine)</td>
</tr>
<tr>
<td>54235</td>
<td>Injection of corpora cavernosa with pharmacologic agent(s) (e.g., papaverine, phentolamine)</td>
</tr>
<tr>
<td>J2440</td>
<td>Injection, papaverine HCl, up to 60 mg</td>
</tr>
<tr>
<td>J2760</td>
<td>Injection, phentolamine mesylate, up to 5 mg</td>
</tr>
<tr>
<td>J0270</td>
<td>Injection, alprostadil, 1.25 mcg (code may be used for Medicare when drug administered under direct supervision of a physician, not for use when drug is self-administered)</td>
</tr>
<tr>
<td>J0275</td>
<td>Alprostadil urethral suppository (code may be used for Medicare when drug administered under direct supervision of a physician, not for use when drug is self-administered)</td>
</tr>
<tr>
<td>54240</td>
<td>Penile plethysmography</td>
</tr>
<tr>
<td>54250</td>
<td>Nocturnal penile tumescence and/or rigidity test (Not Covered for Medicaid)</td>
</tr>
<tr>
<td>74445</td>
<td>Corpora cavernosography, radiological supervision and interpretation</td>
</tr>
<tr>
<td>93980</td>
<td>Duplex scan of arterial inflow and venous outflow of penile vessels; complete study</td>
</tr>
<tr>
<td>93981</td>
<td>Duplex scan of arterial inflow and venous outflow of penile vessels; follow-up or limited study</td>
</tr>
</tbody>
</table>

**Surgical Treatments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>54400</td>
<td>Insertion of penile prosthesis; non-inflatable (semi-rigid)</td>
</tr>
<tr>
<td>54401</td>
<td>Insertion of penile prosthesis; inflatable (self-contained)</td>
</tr>
<tr>
<td>54405</td>
<td>Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir</td>
</tr>
<tr>
<td>54410</td>
<td>Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session</td>
</tr>
<tr>
<td>54411</td>
<td>Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue</td>
</tr>
<tr>
<td>54416</td>
<td>Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session</td>
</tr>
</tbody>
</table>
54417  Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue

(No authorization required):
54406  Removal of all components of a multi-component, inflatable penile prosthesis without replacement of prosthesis
54408  Repair of component(s) of a multi-component, inflatable penile prosthesis
54415  Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis

Devices
C1813  Prosthesis, penile, inflatable (Not separately payable for Medicaid)
C2622  Prosthesis, penile, non-inflatable (Not separately payable for Medicaid)
L7900  Male vacuum erection system (Not covered for Medicaid or Medicare)
E1399  Durable medical equipment, miscellaneous (for Eros device) (Explanatory notes must accompany claims billed with unlisted codes.)

ICD-10 Codes that are not covered for Behavioral Health or medical services:
F52.0 – F52.9  Sexual dysfunction not due to a substance or known physiological condition
R37  Sexual dysfunction, unspecified

VI. REFERENCES

7. Michigan Department of Community Health, Medical Services Administration, MSA 06-02, Termination of Sexual or Erectile Dysfunction Drug Coverage, Issued December 29, 2005.

VII. APPENDIX A

Likely Causes of Male Erectile Dysfunction Based on Clinical Presentation (This is not an all-inclusive list)²:

Psychological Causes
- Young age with abrupt onset associated with specific emotional event
- Dysfunction in certain settings while normal function in others
- Persistence of nocturnal erections
- Previous history of erectile dysfunction with spontaneous improvement
- Excessive life stressors—work, relationships
- Mental status findings suggestive of depression, psychosis or anxiety disorder

Organic Causes
- Vasculogenic—arterial
  - Persistent interest in sex
  - Older age with gradual onset
  - Impaired function in all settings
  - Presence of chronic disease (particularly diabetes, hypertension)
  - Use of prescription/over-the-counter medications associated with erectile dysfunction
  - Smoking
  - Elevated blood pressure, evidence of peripheral vascular disease (bruits, deceased pulses, skin and hair changes consistent with arterial insufficiency)
- Vasculogenic—venous
  - Inability to maintain erection once established
  - Prior history of priapism
  - Local anomalies of the penis

Neurogenic Causes
- History of spinal cord/pelvic trauma or surgery
- Presence of chronic disease (diabetes, alcoholism)
- Presence of neurologic condition (multiple sclerosis, stroke)
• Abnormal neurologic examination of genitals/perineum

Hormonal Causes
• Loss of interest in sexual activity
• Small atrophic testis
• Low testosterone, elevated prolactin