Policy: 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, which 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). 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 and is not a current part of the overall evaluation. 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. 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.

Procedure:
1. Evaluation of impotence is covered as a medical service.
   1. 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 co-morbid 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.
   2. The treatment of impotence with equipment is covered at the DME benefit level; treatment and testing with drugs is not a covered benefit unless permitted by State or Federal contract. Treatment with insertion of a penile prosthesis is covered as a medical service.
2. Limits/Indications *See special instructions

Special Instructions:
Medicare/All:
Limits/Indications: Program payment may be made for diagnosis and treatment of sexual impotence. Since causes and, therefore, appropriate treatment vary, if abuse is suspected it may be necessary to request documentation of appropriateness in individual cases. If treatment is furnished to patients (other than hospital inpatients) in connection with a mental condition, apply the psychiatric service limitation described in the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3.

Medicaid/All:
Limits/Indications:
1. Other than treatments and tests which are limited by contract or benefit, appropriate and medically necessary diagnostic tests are covered to determine if the cause of impotency is organic or non-organic for impotence.
   a. Nocturnal penile tumescence testing (NPT) or other similar test to evaluate for the presence of physiologic erections will be required prior to consideration of approval.
2. Drug Therapy (oral, injectable, pellets) 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:
      1. Males at least 18 years of age with a diagnosis of organic ED.
2. An appropriate evaluation must be done to determine the necessity for the external penile vacuum pump.
3. Patient has the manual dexterity to utilize the device.
4. Adequate penile blood supply is present.
5. Devices are most effective in partial impotence.
6. 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. Meridian Health Plan will provide coverage for Female Erectile Dysfunction Therapy if there is a documented underlying disease/condition.

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

5. Penile prosthesis implantation:
   a. An appropriate evaluation must be done to determine the necessity for penile prosthesis implantation. 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 co-morbid 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.
   b. Implantable penile prostheses are covered benefits for males at least 18 years of age with a diagnosis of organic ED and after other medical therapy has failed or is contraindicated. With surgery the normal function of the corpus cavernosa is gone.
   c. Prior Plan approval by the Medical Director is required.
   d. Coverage is provided for only one penile prosthesis implantation per member lifetime.

6. Coverage is not provided for:
   a. Psychological counseling for ED
   b. Exogenous testosterone replacement therapy or PDE-5 inhibitor medications given with the intent of treating ED
   c. Extracorporeal shock wave therapy for Peyronie’s disease

**Michigan/Medicaid:** Medical Necessity Review: Required for Michigan Medicaid members requesting penile prosthesis. Coverage is determined by the Michigan Medicaid Provider Manual and the Michigan Medicaid Fee Schedule at: [http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--00.html)

### CPT/HCPCS Codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>54400, 54401, 54405, 54406, 54408, 54410, 54411, 54415, 54416, 54417, 51792, 54230, 54231, 54235, 54240, 54250, 74445, 93980, 93981, L7900, C1813, C2622, J2440, J2760, J0275, E1399</td>
<td></td>
</tr>
</tbody>
</table>

Approved by: ____________________________________________  Date: 10/20/2015

Corporate Chief Operating Officer

Reviewed and approved by Policy and Procedure Committee:  Date: 07/29/2015

Reviewed and approved by Medical Policy Operations Committee:  Date: 07/31/2015
References:
4. Feldman, J., and M. Striepe, Women’s Sexual Health, Clinics In Family Practice, Vol. 6 No. 4, December 2004
7. Sadovsky, R., and S. Althof, Men’s Sexual Issues, Sexual Health, Clinics In Family Practice, Vol., No. 4, 863-915, December 2004