OH MEDICAID POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
07/26/2016	07/26/2017	07/26/2016

Policy Name	Policy Number
Erectile Dysfunction	MM-0033

Policy Type		
☒ Medical	☐ Administrative	☐ Payment

Medicaid Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) apply to Medicaid health benefit plans administered by CSMG and its affiliates and are derived from literature based on and supported by applicable federal or state coverage mandates, clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medicaid Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan benefit document (i.e., Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medicaid Policy Statement and the plan benefit document, then the plan benefit document will be the controlling document used to make the determination. In the absence of any applicable controlling federal or state coverage mandate, benefits are ultimately determined by the applicable plan benefit document

A. SUBJECT

Erectile Dysfunction

B. BACKGROUND

Erectile Dysfunction (ED) is “the consistent or recurrent inability to acquire or sustain an erection of sufficient rigidity and duration for sexual intercourse”. ED is the most common sexual problem effecting males. Surveys suggest that 5-10 percent of men between the age of 20 and 30 are effected; the number increases to 35-40 percent of men in their 70’s. The NIH estimates that up to 30 million suffer from erectile dysfunction.

Like Cardiovascular (CV) disease, several risk factors have been identified. In addition to age, the best predictors of ED are diabetes mellitus, hypertension, obesity, dyslipidemia, cardiovascular disease, smoking, and the use of many specific medications (estimated to cause up to 25 per cent of cases). The overlap in risk factors between CV disease and ED is felt to be pathophysiologicially mediated through endothelial dysfunction. Not only does cardiovascular disease and its risk factors increase the risk for later ED, but, on the other hand, ED may be an early warning sign of future cardiovascular events.

In addition, surveys have suggested a strong and independent relationship between ED and other health conditions. These include systemic sclerosis (scleroderma), Peyronie's disease, prostate cancer treatments (e.g., brachytherapy, prostatectomy), as well as obstructive sleep apnea and restless leg syndrome (RLS).

Decreased libido causes that impact ED include psychological, low testosterone, partner interactions, alcoholism, and medications. Management approaches used are identifying the underlying etiology, identifying and treating cardiovascular risk factors, initiating medical therapy, and treating men with low serum testosterone levels through medication. Lifestyle change recommendations include treatment for weight loss and smoking cessation, increased physical activity, medical management, gastric bypass surgery, and treatment for sleep apnea. Surgical implantation is utilized for men who cannot use or have not responded to all other therapies. Surgical therapy options include penile prostheses and penile revascularization. Other disorders related to ED include premature ejaculation, delayed ejaculation, inability to ejaculate, anejaculation, and retrograde ejaculation.

According to the American Urological Association's (AUA) Guideline on the Management of Erectile Dysfunction, currently available therapies that should be considered for the treatment of erectile dysfunction are as follows and should be practiced in a stepwise fashion developing invasiveness and risk balanced opposed to the likelihood of efficacy:

- oral phosphodiesterase type 5 [PDE5] inhibitors
- intra-urethral alprostadil
- intracavernous vasoactive drug injections
- vacuum constriction devices
- penile prosthesis implantation.

According to the National Health Services (NHS), 2012, there are two main categories of erectile dysfunction: psychogenic and organic. Multiple causes of organic ED including disease processes, trauma, drug and alcohol use/abuse, as well as smoking exist. There are four main types of health conditions that can cause physical problems resulting in ED (National Health Services [NHS], 2012):

- vasculogenic - affecting blood flow to the penis
- neurogenic - affecting the nervous system (i.e., brain, nerves, spinal cord)
- hormonal –affecting the levels of certain hormones (e.g., testosterone)
- anatomical –affecting the physical structure of the penis

Overview of management:
Identification of the underlying etiology is an important first step. This includes ruling out the adverse effects of medication(s) (e.g. antidepressants, antihypertensive agents etc.), identifying and treating cardiovascular risk factors (e.g. smoking, obesity, hypertension, and dyslipidemia) and ruling out hypogonadism (i.e. low testosterone) as a potential cause. Three lines of therapeutic options are listed in sequence of recommendation.

Therapeutic options:

1. Medical therapy is the initial line of therapy using Phosphodiesterase-5 inhibitors to include Cialis, Levitra, Staxyn, Stendra, and Viagra. While there are some variation in terms of time of onset and duration of action between these agents they are considered first-line therapy because of their efficacy, ease of use, and generally favorable side effect profile. Related therapies may include psychotherapy, either alone or in combination with medication in men with ED caused by depression or anxiety.
2. Second line therapies include vacuum devices, penile self-injectable drugs such as Caverject, Edex, and Prostin VR, and intra-urethral agents such as alprostadil.
3. Surgical treatments including penile prosthesis and revascularization procedures should be reserved for men with no response to first and second line therapies. Due to the low success rates and long-term complications avoidance of penile arterial revascularization is suggested.

C. DEFINITIONS

N/A

D. POLICY

Medications for the treatment of erectile dysfunction are not a covered benefit through Ohio Medicaid: OAC 5160-9-03.

I. Drugs/Injectables
   A. Oral Drugs: Cialis (tadalafil), Levitra (vardenafil), Staxyn (vardenafil hydrochloride), Stendra (avanafil), and Viagra (sildenafil citrate)
      1. **Cialis (tadalafil)** is a phosphodiesterase 5 (PDE5) inhibitor and is a treatment option when the following criteria are met:
         1.1 Erectile Dysfunction (ED)
         1.2 Signs/symptoms of benign prostatic hyperplasia (BPH)
         1.3 ED and signs/symptoms of BPH
      2. **Levitra (vardenafil)**, **Staxyn (vardenafil hydrochloride)**, **Stendra (avanafil)**, and **Viagra (sildenafil citrate)** are phosphodiesterase 5 (PDE5) inhibitors and are a treatment option when the following criteria are met:
         2.1 Erectile Dysfunction (ED)

      Note: Cialis is a covered benefit for the treatment of Benign Prostatic Hyperplasia (BPH).

   B. Injectables: Caverject (alprostadil), Edex (alprostadil), and Prostin VR (alprostadil)
      1. **Caverject (alprostadil), Edex (alprostadil)**, and **Prostin VR (alprostadil)** are a naturally occurring form of prostaglandin E1 (PGE1) and are a treatment option when the following criteria are met:
         1.1 Erectile Dysfunction (ED)
            a. Injections into the corpus cavernosa to cause an erection.
            b. Medicated Urethral System for Erection (MUSE) method of treatment involving inserting a pellet of alprostadil through a small catheter into the urethra.

      Note: Transdermal medications for the treatment of non-hypogonadal impotence and topical creams or gels containing vasodilators, such as verapamil cream are not a covered benefit through Ohio Medicaid.

II. External Devices/Pumps
   A. Vacuum Constriction Devices (VCD)
      1. **Vacuum Constriction Devices (VCD)** are considered medically necessary with **OR** without first line ED therapy when the criteria are met for the following indications:
         1.1 First line ED therapy has been documented as ineffective or contraindicated

      Note: External penile pumps or VCD are considered experimental and investigational for other indications including for the prevention of erectile dysfunction following prostatectomy as effectiveness for these indications are not established.

III. Surgery/Internal Implants
   A. Internal Penile Prosthetic Implants
      1. **Internal Penile Prosthetic Implant** is considered medically necessary when all of the following criteria are met:

1.1 First and second line ED therapy has been documented ineffective for intracavernosal injection, intra-urethral medications, a vacuum constriction device and oral medications
1.2 Absence of active alcohol or substance abuse
1.3 Absence of drug-induced impotence related to **ALL** of the following:
   a. Anabolic steroid use
   b. Anticholinergics
   c. Antidepressants
   d. Antipsychotics or central nervous system depressants

   AND
1.4 Neurogenic impotence due to **1 (one)** of the following:
   a. Diabetes
   b. Fractured pelvis
   c. Major surgery of the pelvis or retroperitoneum, radical prostatectomy, or colorectal surgery
   d. Multiple Sclerosis
   e. Spina Bifida
   f. Spinal cord injury/disease
   g. Syringomyleia

   OR
1.5 Vasculogenic impotence due to **1 (one)** of the following:
   a. Hypertension
   b. Intrapenile arterial disease
   c. Penile contusion
   d. Penile fracture
   e. Peyronie's disease
   f. Smoking
   g. Status post cavernosal infection

   OR
1.6 Impotence due to radiation therapy to the pelvis or retroperitoneum

Note: Implantable penile prostheses are considered experimental and investigational for other indications because their effectiveness for indications other than those listed above has not been established.

2. **Internal Penile Prosthetic Implant Removal** is considered medically necessary when **ALL** of the following are met:
   2.1 Infection
   2.2 Mechanical failure
   2.3 Urinary obstruction
   2.4 Intractable pain

B. Vascular Reconstructive Surgery
1. **Vascular Reconstructive Surgery** is considered medically necessary for men less than 55 years of age when all of the following are met:
   1.1 Preoperative pelvic and penile arteriogram determining location and severity of vascular obstruction
   1.2 Performed at a specialty center
   1.3 Nonsmoking, otherwise healthy men without evidence of generalized vascular disease, diabetes, or hypertension, who have recently acquired erectile dysfunction secondary to a focal arterial occlusion
   1.4 No history of veno-occlusive disease with ED

Note: Penile vascular reconstructive surgery is considered experimental and investigational for any other indication not listed above because its effectiveness has not been established.

C. Nerve Graft related to Radical Prostatectomy
   1. Nerve Grafting related to Radical Prostatectomy is **NOT** considered medically necessary due to negative study findings, lack of controlled studies evaluating unilateral or bilateral nerve grafting, and lack of evidence-based clinical practice guidelines.

NOTE: CareSource considers the following treatments experimental and investigational for erectile dysfunction as their effectiveness has not been established:
- **A.** Acupuncture
- **B.** Extracorporeal shock wave therapy (ESWT)
- **C.** Percutaneous electrostimulation of the perineum
- **D.** Statins
- **E.** Stem cell therapy (including adipose-derived stem cells)

CONDITIONS OF COVERAGE
HCPCS
CPT

Step Therapy
Under some plans, including plans that use an open or closed formulary, some of the medications in this policy may be subject to step-therapy. Refer to the CareSource formulary tool or PDL for further guidance.

AUTHORIZATION PERIOD

E. RELATED POLICIES/RULES

F. REVIEW/REVISION HISTORY

Date Issued: 07/26/2016
Date Reviewed: 07/26/2016
Date Revised:

G. REFERENCES

1. Cunningham, Glenn, and Allen Seftel. Treatment of Male Sexual Dysfunction. UpToDate, 2015.
2. Cialis (tadalafil) [prescribing information]. Indianapolis, IN; Lilly USA, LLC: Revised September 2015.
3. Levitra (vardenafil) [prescribing information]. Research Triangle Park, NC; GlaxoSmithKline: Revised April 2011.
4. Staxyn (vardenafil hydrocholoride) [prescribing information]. Research Triangle Park, NC; GlaxoSmithKline: Revised September 2015.
5. Stendra (avanafil) [prescribing information]. Mountain View, CA; Vivus, Inc.: Issued September 2014.
6. Caverject (alprostadil) [prescribing information]. New York, NY; Pfizer, Inc.: Revised September 2006.

7. Edex (alprostadil) [prescribing information]. Lake Forest, IL; Actient Pharmaceuticals, LLC: Revised January 2011.
8. Prostin VR (alprostadil) [prescribing information]. New York, NY. Pfizer, Inc.: Revised April 2013.
9. Bella, A., Lee, J., Carrier, S., Benard, F., & Brock, G. (2015). 2015 CUA Practice guidelines for erectile dysfunction. Canadian Urological Association, 9(23), 1-2. http://dx.doi.org/10.5489/cuaj.2699
10. Cunningham, G. (2015). Treatment of male sexual dysfunction. UpToDate (2015).
11. Lazarou, S. (2015). Surgical treatment of erectile dysfunction. UpToDate (2015).
12. Erectile Dysfunction: American Urological Association. (n.d.). Retrieved June 01, 2016, from https://www.auanet.org/education/guidelines/erectile-dysfunction.cfm
13. Erectile dysfunction (impotence) – Causes (n.d.). Retrieved June 01, 2016, from http://www.nhs.uk/Conditions/Erectile-dysfunction/Pages/Causes.aspx

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.