Erectile Dysfunction AHS - G2132

Description of Procedure or Service

Erectile dysfunction, or impotence, is defined as the inability to achieve or maintain an erection of sufficient rigidity to enable penetration and completion of the sexual act (Ayta et al 1999), (McKinlay, 2000).

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

BCBSNC will provide coverage for testing for erectile dysfunction when it is determined the medical criteria or reimbursement guidelines below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When testing for erectile dysfunction is covered

Reimbursement is allowed for the following lab tests in the diagnosis of erectile dysfunction:

- Blood glucose (Fasting / HbA1c)
- Complete blood count
- Creatinine and Blood Urea Nitrogen
- Hepatic panel
- Lipid profile
- Prostate specific antigen
- Serum testosterone (Total/ Free or Bioavailable)
- Thyroid function studies
- Urinalysis

Reimbursement is allowed for tests for evaluation of pituitary dysfunction (e.g., measurement of luteinizing hormone, follicle-stimulating hormone, and prolactin levels) if serum testosterone level is below normal.

When testing for erectile dysfunction is not covered
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Reimbursement is not allowed for the following tests for the diagnosis of erectile dysfunction because their effectiveness has not been established:

- Angiotensin-converting enzyme insertion/deletion polymorphism testing
- Endothelial nitric oxide synthase polymorphism (4 VNTR, G894T, and T786C) testing for estimating risk of erectile dysfunction
- Iron binding capacity
- Prostatic acid phosphatase

**Policy Guidelines**

It has been projected that approximately 150 million men in the world suffer from erectile dysfunction (ED) making it one of the most frequent chronic health problems in men over 40 years of age (Feldman, Goldstein, Hatzichristou, Krane, & McKinlay, 1994) and a common reason for consultation of family physicians and specialists (Brotons et al., 2004). However, men younger than 40 also seek medical help for new-onset ED, with one study reporting one in four patients younger than 40 years, with almost 50% of the young men complaining of severe ED (Capogrosso et al., 2013) (Capogrosso P, et al, 2013). ED may be an indicator for other underlying disease such as diabetes, hypertension, or atherosclerosis and thus merits investigation (Brotons et al., 2004; Yoshimura, Kato, Chencellor, Nelson, & Glorioso, 2010).

The development of an erection is a complex process that involves the brain, hormones, emotions, nerves, muscles and blood vessels, a problem with one or more can result in erectile dysfunction. Stress, mental health concerns, alcohol, smoking and medications can cause or worsen erectile dysfunction (Cunningham & Khera, 2017; Goldstein, 2000).

Other causes of erectile dysfunction may be penile trauma, spinal cord injuries, abnormalities of the penis (e.g., penile fibrosis and Peyronie’s disease), veno-occlusive dysfunction or as a result of a radical pelvic surgery (e.g., radical prostatectomy or cystectomy). (Shindel, Brant, Bochinski, Bella, & Lue, 2014). Regardless of the cause, ED has a negative impact on the quality of life of both the patient and partner (Althof, 2002).

The evaluation of male sexual dysfunction should include sexual history and physical examination which have been reported to have a 95 percent sensitivity but only a 50 percent specificity in determining the cause of ED (Davis-Joseph, Tiefer, & Melman, 1995). Additional diagnostic tests recommended include fasting glucose or glycated hemoglobin (A1C) to examine for diabetes or level of glucose control, complete blood count, comprehensive metabolic profile to assess liver and kidney function, thyroid-stimulating hormone (TSH) to rule out thyroid disease, lipid profile to assess cardiac risk factors, and serum total testosterone to assess gonadal function (Cunningham & Khera, 2017; Hatzimouratidis et al., 2010; Qaseem et al., 2009).

Applicable Federal Regulations

FDA prescribing information for drugs that treat erectile dysfunction contraindicate their use in patients with severe renal impairment, hepatic impairment or if sexual activity is inadvisable due to cardiovascular status or any other reason.

FDA approved methods for fasting glucose or glycated hemoglobin (A1C), complete blood count, comprehensive metabolic profile to assess liver and kidney function, thyroid-stimulating hormone (TSH) to rule out thyroid disease, lipid profile to assess cardiac risk factors, and serum total testosterone are available in most CLIA certified laboratories.

**Guidelines and Recommendations**

Cunningham and Khera (2017) stated that laboratory tests for men with sexual dysfunction should include fasting glucose or glycated hemoglobin (A1C), complete blood count, comprehensive metabolic profile, thyroid-stimulating hormone (TSH), lipid profile, and serum
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total testosterone to assess gonadal function. If serum testosterone is low, serum prolactin should be measured.

**Practice Guidelines and Position Statements**

**American College of Physicians (ACP)**
Qaseem et al (2009) concluded that the evidence for the utility of hormonal blood tests in identifying and affecting therapeutic outcomes for treatable causes of ED is inconclusive. The ACP makes no recommendations either for or against routine use of hormonal blood tests or hormonal treatment in the management of patients with ED. Clinicians should make decisions to measure hormone levels on a case-by-case basis, in accordance with the patient’s clinical presentation.

**European Association of Urology (EAU)**
In 2016, EAU published revised guidelines for the diagnosis and treatment of patients suffering from erectile dysfunction (Hatzimouratidis et al, 2016). It recommended that laboratory testing must be ordered based on the patient’s complaints and risk factors. It recommended that “patients may need a fasting blood glucose or Hba1C and lipid profile if not recently assessed. Hormonal tests include an early morning total testosterone. If indicated, bioavailable or calculated-free testosterone may be needed to corroborate total testosterone measurements.” It further recommended that additional laboratory testing may be considered in some patients (for example, prostate-specific antigen, prolactin and luteinizing hormone).

**American Urological Association (AUA)**
The AUA recommends that the initial evaluation for patients complaining of ED should include “laboratory tests thorough enough to identify comorbid conditions that may predispose the patient to ED and that may contraindicate certain therapies” (Montague et al, 2005). The AUA further recommended PSA measurement when considering the use of testosterone in the management of ED as well as testosterone level measurement in select patients.

**American Association of Clinical Endocrinologists (AACE)**
The AACE guidelines (Guay et al., 2003) state that “chemistry testing should evaluate for anemia, increased plasma glucose levels, or impaired renal function. Thyroid testing should be done if clinically indicated. Other hormone screening should include serum testosterone and prolactin levels”. The AACE concluded that free or bioavailable testosterone assays were preferred over measurement of the total testosterone level. AACE further recommended that “if the testosterone level is low, or even borderline, a serum LH level should be obtained to distinguish primary from secondary hypogonadism.”

**American Society of Clinical Oncology (ASCO)**
The ASCO published guidelines (Carter et al., 2018) which state that “Clinicians should check testosterone levels, even if the patient has a cancer that is not typically associated with hormone changes in men reporting decreased sexual functioning and satisfaction.”

**Billing/Coding/Physician Documentation Information**

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes:* 80061, 80076, 81002-81005, 81400, 81479, 82565, 82570, 82575, 82947, 83001 – 83002, 83036, 83550, 84066, 84146, 84152 – 84154, 84402-84403, 84410, 84520, 84540, 84439, 84443, 84479, 84480, 84481, 84482, 85025, 85027

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BCBSNC 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.

Scientific Background and Reference Sources


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**Policy Implementation/Update Information**

1/1/19 New policy developed. BCBSNC will provide coverage for testing for erectile dysfunction when it is determined to be medically necessary because the medical criteria and guidelines are met. Medical Director review 1/1/2019. Policy noticed 1/1/2019 for effective date 4/1/2019. (sk)

10/1/19 Policy statement revised to read: BCBSNC will provide coverage for testing for erectile dysfunction when it is determined the medical criteria or reimbursement guidelines shown below are met. Wording changed in the When Covered section. “Medically Necessary” changed to “Reimbursement is allowed…” Wording revised in the Not Covered section. “Investigational” changed to read “Reimbursement is not allowed…” Deleted coding grid. Policy noticed 10/1/2019 for effective date 12/2/2019. (an)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.