Erectile Dysfunction AHS - G2132

Description of Procedure or Service

Erectile dysfunction (ED), 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 (Cunningham & Khera, 2018).

For guidance on hormonal testing in males, please refer to AHS-G2013 Hormonal Testing in Males.

Related Policies

Hormonal Testing in Males AHS – G2013

***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 to be medically necessary because the medical criteria and guidelines shown 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

The following lab tests are considered medically necessary 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
When testing for erectile dysfunction is not covered

The following tests for the diagnosis of erectile dysfunction are considered INVESTIGATIONAL 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 and a common reason for consultation of family physicians and specialists (Brotons et al., 2004; Cunningham & Khera, 2018). However, men younger than 40 also seek medical help for new-onset ED; one study reports one in four patients younger than 40 years, with almost 50% of the young men complaining of severe ED (Capogrosso 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, and a problem with any of these components (endocrine, cardiovascular, neurological, and so on) can result in ED. For example, low intracavernosal nitric oxide synthase, which is necessary for nitric oxide to maximize blood flow to the penis, is often found in low levels in diabetic patients or patients with low testosterone. Any disruption of blood flow or nitric oxide synthesis may prevent intracavernosal blood pressure from rising enough to maintain acceptable rigidity for an erection (Cunningham & Khera, 2018).

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).

Clinical Utility and Validity

The evaluation of male sexual dysfunction may 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 include fasting glucose or glycated hemoglobin (A1C) to examine for diabetes or level of glucose control, complete blood count (CBC), 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, 2018; Hatzimouratidis et al., 2010; Qaseem et al., 2009).

Proprietary tests exist for the assessment of risk factors for ED. For example, Walk-In Lab offers an ED panel consisting of several biomarkers (TSH, CBC, luteinizing hormone [LH], and so on) (Walk-In, 2017). Genova offers a similar panel, which evaluates hormones, including testosterone, estradiol, PSA, and DHEA (GENOVA, 2019). Finally, GX Sciences offers a genetic “Men’s Health Panel” that evaluates 15 gene variants proposed to play a significant role in “Testosterone conversion and breakdown, estrogen formation, risk of metabolic weakness, and
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risk of hypertension”. Besides low sex drive and testicular atrophy, GX Sciences states that their genetic test can also be used to address “carbohydrate cravings”, “slow recovery”, and male pattern baldness (GXSciences, 2019).

Lane-Cordova et al performed a study assessing cardiovascular health with ED. 1136 men were divided into 3 categories of cardiovascular health (CVH, low, medium, high) and were assessed for ED. 58% of men with low CVH were found to have ED (233/387), 41% with moderate CVH (277/670), and 33% (26/79) with CVH. ED was also found to have a prevalence ratio of 0.75 with moderate CVH and 0.68 with high CVH (Lane-Cordova, Kershaw, Liu, Herrington, & Lloyd-Jones, 2017).

Brooke et al conducted a study examining testosterone levels’ association with ED in patients with type 2 diabetes. 355 diabetic patients were evaluated, and on average, patients with ED were found to have 9.1% lower SF-36 health questionnaire score, which correlated with total, bioavailable, and free testosterone (Brooke et al., 2014).

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

American College of Physicians (ACP)
The ACP 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 (Qaseem et al., 2009).

European Association of Urology (EAU)
In 2016, EAU published revised guidelines for the diagnosis and treatment of patients suffering from erectile dysfunction. 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) (Hatzimouratidis, 2016).

American Urological Association (AUA)
The AUA recommends measuring morning serum total testosterone in men with ED. The AUA also states that “with the possible exception of serum testosterone, glucose/hemoglobin A1c, and in some cases serum lipids, no routine serum study is likely to alter ED management”, but list “serum BUN/Cr, fasting lipids, fasting glucose or hemoglobin A1c, morning testosterone, thyroid function studies (i.e. thyroid-stimulating hormone, free T4) and PSA” as potentially appropriate tests for men with ED (Burnett et al., 2018).

American Association of Clinical Endocrinologists (AACE)
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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.”

British Society for Sexual Medicine (BSSM, 2017)
The BSSM recommends the following lab testing for ED: “fasting glucose and/or glycated hemoglobin, lipid profile, and fasting testosterone level in all cases”. Serum PSA may also be considered if “clinically indicated”. The BSSM also notes that if serum testosterone is borderline or low, the test should be repeated together with serum LH and prolactin (Hackett et al., 2018).

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, 82947, 83036, 83550, 84066, 84153, 84402-84403, 84410, 84439, 84443, 84520, 84540, 85025, 85027

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)


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