



If a conflict arises between a Clinical Payment and Coding Policy (“CPCP”) and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. “Plan documents” include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. BCBSNM may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSNM has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act (“HIPAA”) approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing (“UB”) Editor, American Medical Association (“AMA”), Current Procedural Terminology (“CPT®”), CPT® Assistant, Healthcare Common Procedure Coding System (“HCPCS”), ICD-10 CM and PCS, National Drug Codes (“NDC”), Diagnosis Related Group (“DRG”) guidelines, Centers for Medicare and Medicaid Services (“CMS”) National Correct Coding Initiative (“NCCI”) Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

Testosterone Testing

Policy Number: CPCPLAB009

Version 1.0

Enterprise Medical Policy Committee Approval Date: 1/25/2022

Plan Effective Date: May 1, 2022

Description

BCBSNM has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

Reimbursement Information:

1. Testing for serum total testosterone (See **Note 1**) **may be reimbursable** in symptomatic males being evaluated for androgen deficiency.
2. Repeat testing for serum total testosterone (See **Note 1**) **may be reimbursable** in males with low initial serum testosterone results. Sample collection should occur in early morning, after fasting, and at least one week after the initial test.

3. For males with hypogonadism, gynecomastia, and/or other forms of testicular hypofunction, measurement of serum free testosterone, sex hormone-binding globulin (SHBG), and/or albumin **may be reimbursable** if total testosterone is confirmed as borderline or low.
4. Testing for serum total testosterone (See **Note 1**) **may be reimbursable** in symptomatic males being evaluated for conditions associated with androgen excess.
5. Measurement of serum free testosterone using a medically accepted algorithm based on total serum testosterone, SBHG, and/or albumin or bioavailable testosterone **may be reimbursable** in individuals suspected of having a disorder that is accompanied by increased or decreased SHBG levels (See **Notes 2 and 3**).
6. Testing for serum total testosterone measurements (See **Note 1**) **may be reimbursable** in monitoring treatment response in men taking enzyme inhibitors for prostate cancer.
7. Testing for serum total testosterone (See **Note 1**) **may be reimbursable** in men receiving testosterone replacement therapy every 3-6 months for the first year after initiation of therapy, and annually thereafter.
8. Testing for serum total testosterone (See **Note 1**) **may be reimbursable** in gender-dysphoric/gender-incongruent persons at baseline, during the treatment and for the therapy monitoring.
9. For males with gynecomastia, serum estradiol testing **may be reimbursable ONCE** in a lifetime prior to initiating testosterone therapy.
10. Testing for serum testosterone (See **Note 1**) **may be reimbursable** in symptomatic females being evaluated for conditions associated with androgen excess (e.g., polycystic ovary syndrome and functional hypothalamic amenorrhea). The technology used for testing should be sensitive enough to detect the low concentrations normally found in females.
11. Testing for serum free testosterone and/or bioavailable testosterone as primary testing (i.e., in the absence of prior serum TOTAL testosterone testing) **is not reimbursable**.
12. Testing for serum total testosterone, free testosterone, and/or bioavailable testosterone **is not reimbursable** in asymptomatic individuals or in individuals with non-specific symptoms.
13. Testing for serum testosterone **is not reimbursable** for the identification of androgen deficiency in women.
14. Salivary testing for testosterone **is not reimbursable**.
15. Measurement of serum dihydrotestosterone in individuals **is not reimbursable** except in diagnosing 5-alpha reductase deficiency in individuals with ambiguous genitalia, hypospadias, or microphallus.

NOTE 1: Due to considerable variability in serum total testosterone testing, the Centers for Disease Control and Prevention (CDC) developed a standardization program for total testosterone assays (Hormone Standardization [HoSt]/Testosterone). An assay certified by the CDC's HoSt/Testosterone program is standardized to within $\pm 6.4\%$ of the CDC total testosterone reference standard. It is **STRONGLY RECOMMENDED** that serum total testosterone testing be performed on an assay that has been certified by the CDC HoSt/Testosterone program (Bhasin et al., 2018). A list of CDC-certified assays is available on the HoSt website (CDC, 2021).

NOTE 2: Conditions associated with decreased SHBG concentrations according to the 2018 Endocrine Society Guidelines (Bhasin et al., 2018):

- Obesity
- Diabetes mellitus
- Use of glucocorticoids, progestins, and androgenic steroids
- Nephrotic syndrome
- Hypothyroidism
- Acromegaly
- Polymorphisms in the SHBG gene

NOTE 3: Conditions associated with increased SHBG concentrations according to the 2018 Endocrine Society Guidelines (Bhasin et al., 2018):

- Aging
- HIV disease
- Cirrhosis and hepatitis
- Hyperthyroidism
- Use of some anticonvulsants
- Use of estrogen
- Polymorphisms in the SHBG gene

Procedure Codes

Codes
82040, 82642, 82670, 82681, 84270, 84402, 84403, 84410

References:

A. Salonia (Chair), C. B., J. Carvalho, G. Corona, T.H. Jones, A. Kadioglu, I. Martinez-Salamanca, S. Minhas (Vice-Chair), E.C. Serefoğlu, P. Verze. (2021). European Association of Urology: Sexual and Reproductive Health. <https://uroweb.org/guideline/sexual-and-reproductive-health/>

AAP. (2017, 10/02/2017). Avoid ordering LH and FSH and either estradiol or testosterone for children with pubic hair and/or body odor but no other signs of puberty. ABIM Foundation. Retrieved 10/19/2018 from <http://www.choosingwisely.org/clinician-lists/aap-soen-testing-children-pubic-hair-no-other-signs-puberty/>

ACOG. (2018a). ACOG Committee Opinion No. 728: Müllerian Agenesis: Diagnosis, Management, And Treatment. *Obstet Gynecol*, 131(1), e35-e42. <https://doi.org/10.1097/aog.0000000000002458>

ACOG. (2018b). ACOG Practice Bulletin No. 194: Polycystic Ovary Syndrome. *Obstet Gynecol*, 131(6), e157-e171. <https://doi.org/10.1097/aog.0000000000002656>

ACOG. (2019a). ACOG Committee Opinion No. 773 Summary: The Use of Antimüllerian Hormone in Women Not Seeking Fertility Care. *Obstet Gynecol*, 133(4), 840-841. <https://doi.org/10.1097/aog.0000000000003163>

ACOG. (2019b). Screening and Management of the Hyperandrogenic Adolescent: ACOG Committee Opinion, Number 789. *Obstet Gynecol*, 134(4), e106-e114. <https://doi.org/10.1097/aog.0000000000003475>

Andersson, C. R., Bergquist, J., Theodorsson, E., & Strom, J. O. (2017). Comparisons between commercial salivary testosterone enzyme-linked immunosorbent assay kits. *Scand J Clin Lab Invest*, 77(8), 582-586. <https://doi.org/10.1080/00365513.2017.1339231>

Bhasin, S., Brito, J. P., Cunningham, G. R., Hayes, F. J., Hodis, H. N., Matsumoto, A. M., Snyder, P. J., Swerdloff, R. S., Wu, F. C., & Yialamas, M. A. (2018). Testosterone Therapy in Men With Hypogonadism: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*, 103(5), 1715-1744. <https://doi.org/10.1210/jc.2018-00229>

Burger, H. G. (2002). Androgen production in women. *Fertil Steril*, 77 Suppl 4, S3-5. [https://doi.org/10.1016/s0015-0282\(02\)02985-0](https://doi.org/10.1016/s0015-0282(02)02985-0)

Carnegie, C. (2004). Diagnosis of hypogonadism: clinical assessments and laboratory tests. *Rev Urol*, 6 Suppl 6(Suppl 6), S3-8.

CDC. (2012). Total Testosterone. Centers for Disease Control and Prevention. Retrieved 10/23/2018 from https://www.cdc.gov/nchs/data/nhanes/nhanes_11_12/tst_g_met.pdf

CDC. (2021, 07/01/2021). HoSt/VDSCP: Certified Participants. Centers for Disease Control and Prevention. Retrieved 09/28/2021 from https://www.cdc.gov/labstandards/hs_certified_participants.html

Corona, G., Goulis, D. G., Huhtaniemi, I., Zitzmann, M., Toppari, J., Forti, G., Vanderschueren, D., & Wu, F. C. (2020). European Academy of Andrology (EAA) guidelines on investigation, treatment and monitoring of functional hypogonadism in males. *Andrology*, 8(5), 970-987. <https://doi.org/10.1111/andr.12770>

Corona, G., Rastrelli, G., Di Pasquale, G., Sforza, A., Mannucci, E., & Maggi, M. (2018). Endogenous Testosterone Levels and Cardiovascular Risk: Meta-Analysis of Observational Studies. *J Sex Med*, 15(9), 1260-1271. <https://doi.org/10.1016/j.jsxm.2018.06.012>

Gill-Sharma, M. K. (2018). Testosterone Retention Mechanism in Sertoli Cells: A Biochemical Perspective. *Open Biochem J*, 12, 103-112. <https://doi.org/10.2174/1874091x01812010103>

Goldman, A. L., Bhasin, S., Wu, F. C. W., Krishna, M., Matsumoto, A. M., & Jasuja, R. (2017). A Reappraisal of Testosterone's Binding in Circulation: Physiological and Clinical Implications. *Endocr Rev*, 38(4), 302-324. <https://doi.org/10.1210/er.2017-00025>

Gordon, C. M., Ackerman, K. E., Berga, S. L., Kaplan, J. R., Mastorakos, G., Misra, M., Murad, M. H., Santoro, N. F., & Warren, M. P. (2017). Functional Hypothalamic Amenorrhea: An Endocrine

Society Clinical Practice Guideline. *J Clin Endocrinol Metab*, 102(5), 1413-1439.
<https://doi.org/10.1210/jc.2017-00131>

Hammond, G. L., & Bocchinfuso, W. P. (1995). Sex hormone-binding globulin/androgen-binding protein: steroid-binding and dimerization domains. *J Steroid Biochem Mol Biol*, 53(1-6), 543-552.

Hassanabad, M. F., & Fatehi, M. (2018). Androgen Therapy in Male Patients Suffering from Type 2 Diabetes: A Review of Benefits and Risks. *Curr Diabetes Rev*.
<https://doi.org/10.2174/1573399814666180731125724>

Heidenreich, A., Bastian, P. J., Bellmunt, J., Bolla, M., Joniau, S., van der Kwast, T., Mason, M., Matveev, V., Wiegel, T., Zattoni, F., & Mottet, N. (2014). EAU guidelines on prostate cancer. Part II: Treatment of advanced, relapsing, and castration-resistant prostate cancer. *Eur Urol*, 65(2), 467-479. <https://doi.org/10.1016/j.eururo.2013.11.002>

Hembree, W. C., Cohen-Kettenis, P. T., Gooren, L., Hannema, S. E., Meyer, W. J., Murad, M. H., Rosenthal, S. M., Safer, J. D., Tangpricha, V., & T'Sjoen, G. G. (2017). Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*, 102(11), 3869-3903. <https://doi.org/10.1210/jc.2017-01658>

Hembree, W. C., Cohen-Kettenis, P. T., Gooren, L., Hannema, S. E., Meyer, W. J., Murad, M. H., Rosenthal, S. M., Safer, J. D., Tangpricha, V., & T'Sjoen, G. G. (2018a). CORRIGENDUM FOR "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline". *J Clin Endocrinol Metab*, 103(7), 2758-2759.
<https://doi.org/10.1210/jc.2018-01268>

Hembree, W. C., Cohen-Kettenis, P. T., Gooren, L., Hannema, S. E., Meyer, W. J., Murad, M. H., Rosenthal, S. M., Safer, J. D., Tangpricha, V., & T'Sjoen, G. G. (2018b). CORRIGENDUM FOR "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline". *J Clin Endocrinol Metab*, 103(2), 699.
<https://doi.org/10.1210/jc.2017-02548>

Kanakis, G. A., Nordkap, L., Bang, A. K., Calogero, A. E., Bartfai, G., Corona, G., Forti, G., Toppari, J., Goulis, D. G., & Jorgensen, N. (2019). EAA clinical practice guidelines-gynecomastia evaluation and management. *Andrology*, 7(6), 778-793. <https://doi.org/10.1111/andr.12636>

Khashchenko, E., Uvarova, E., Vysokikh, M., Ivanets, T., Krechetova, L., Tarasova, N., Sukhanova, I., Mamedova, F., Borovikov, P., Balashov, I., & Sukhikh, G. (2020). The Relevant Hormonal Levels and Diagnostic Features of Polycystic Ovary Syndrome in Adolescents. *J Clin Med*, 9(6).
<https://doi.org/10.3390/jcm9061831>

Kinter, K. J., & Anekar, A. A. (2020). *Biochemistry, Dihydrotestosterone*. StatPearls Publishing, Treasure Island (FL). <http://europepmc.org/abstract/MED/32491566>
<http://europepmc.org/books/NBK557634>
<https://www.ncbi.nlm.nih.gov/books/NBK557634>

Legro, R. S., Arslanian, S. A., Ehrmann, D. A., Hoeger, K. M., Murad, M. H., Pasquali, R., & Welt, C. K. (2013). Diagnosis and treatment of polycystic ovary syndrome: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*, 98(12), 4565-4592. <https://doi.org/10.1210/jc.2013-2350>

Longcope, C. (1986). Adrenal and gonadal androgen secretion in normal females. *Clin Endocrinol Metab*, 15(2), 213-228. [https://doi.org/10.1016/s0300-595x\(86\)80021-4](https://doi.org/10.1016/s0300-595x(86)80021-4)

Lynch, K. L. (2016). CLSI C62-A: A New Standard for Clinical Mass Spectrometry. *Clin Chem*, 62(1), 24-29. <https://doi.org/10.1373/clinchem.2015.238626>

Mathur, R., & Braunstein, G. D. (2010). Androgen deficiency and therapy in women. *Curr Opin Endocrinol Diabetes Obes*, 17(4), 342-349. <https://doi.org/10.1097/MED.0b013e32833ab083>

Meldrum, D. R., Gambone, J. C., Morris, M. A., Esposito, K., Giugliano, D., & Ignarro, L. J. (2012). Lifestyle and metabolic approaches to maximizing erectile and vascular health. *Int J Impot Res*, 24(2), 61-68. <https://doi.org/10.1038/ijir.2011.51>

Mezzullo, M., Fazzini, A., Gambineri, A., Di Dalmazi, G., Mazza, R., Pelusi, C., Vicennati, V., Pasquali, R., Pagotto, U., & Fanelli, F. (2017). Parallel diurnal fluctuation of testosterone, androstenedione, dehydroepiandrosterone and 17OHprogesterone as assessed in serum and saliva: validation of a novel liquid chromatography-tandem mass spectrometry method for salivary steroid profiling. *Clin Chem Lab Med*, 55(9), 1315-1323. <https://doi.org/10.1515/cclm-2016-0805>

Mohammed, M., Al-Habori, M., Abdullateef, A., & Saif-Ali, R. (2018). Impact of Metabolic Syndrome Factors on Testosterone and SHBG in Type 2 Diabetes Mellitus and Metabolic Syndrome. *J Diabetes Res*, 2018, 4926789. <https://doi.org/10.1155/2018/4926789>

Molina-Vega, M., Munoz-Garach, A., Damas-Fuentes, M., Fernandez-Garcia, J. C., & Tinahones, F. J. (2018). Secondary male hypogonadism: A prevalent but overlooked comorbidity of obesity. *Asian J Androl*. https://doi.org/10.4103/aja.aja_44_18

Morales, A., Bebb, R. A., Manjoo, P., Assimakopoulos, P., Axler, J., Collier, C., Elliott, S., Goldenberg, L., Gottesman, I., Grober, E. D., Guyatt, G. H., Holmes, D. T., & Lee, J. C. (2015). Diagnosis and management of testosterone deficiency syndrome in men: clinical practice guideline. *Cmaj*, 187(18), 1369-1377. <https://doi.org/10.1503/cmaj.150033>

Mulhall, J. P., Trost, L. W., Brannigan, R. E., Kurtz, E. G., Redmon, J. B., Chiles, K. A., Lightner, D. J., Miner, M. M., Murad, M. H., Nelson, C. J., Platz, E. A., Ramanathan, L. V., & Lewis, R. W. (2018, 2018). Evaluation and Management of Testosterone Deficiency. American Urological Association. Retrieved 10/22/2018 from [https://www.auanet.org/guidelines/testosterone-deficiency-\(2018\)](https://www.auanet.org/guidelines/testosterone-deficiency-(2018))

Nassar, G. N., & Leslie, S. W. (2018). Physiology, Testosterone. In StatPearls. StatPearls Publishing
StatPearls Publishing LLC.

NCCN. (2021a). Neuroendocrine and Adrenal Tumors Version 3, 2021. https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf

NCCN. (2021b). Prostate Cancer, Version 1, 2022. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf

Rochira, V., Antonio, L., & Vanderschueren, D. (2018). EAA clinical guideline on management of

bone health in the andrological outpatient clinic. *Andrology*, 6(2), 272-285.
<https://doi.org/10.1111/andr.12470>

Sachdev, S., Cucchiara, A. J., & Snyder, P. J. (2020). Prostate Specific Antigen Concentrations in Response to Testosterone Treatment of Severely Hypogonadal Men. *Journal of the Endocrine Society*. <https://doi.org/10.1210/jendso/bvaa141>

Sartorius, G., Ly, L. P., Sikaris, K., McLachlan, R., & Handelsman, D. J. (2009). Predictive accuracy and sources of variability in calculated free testosterone estimates. *Ann Clin Biochem*, 46(Pt 2), 137-143. <https://doi.org/10.1258/acb.2008.008171>

Schulster, M., Bernie, A. M., & Ramasamy, R. (2016). The role of estradiol in male reproductive function. *Asian J Androl*, 18(3), 435-440. <https://doi.org/10.4103/1008-682x.173932>

Shukla, A., Sharda, B., Bhardwaj, S., Kailash, U., Kalani, R., Satyanarayana, L., & Shrivastava, A. (2018). Association Between Serum Testosterone and Serum PSA Among Men With and Without Partial Androgen Deficiency. *Indian Journal of Clinical Biochemistry*, 1-5.
<https://link.springer.com/article/10.1007/s12291-018-0785-3>

Skinner, R., Mulder, R. L., Kremer, L. C., Hudson, M. M., Constine, L. S., Bardi, E., Boekhout, A., Borgmann-Staudt, A., Brown, M. C., Cohn, R., Dirksen, U., Giwercman, A., Ishiguro, H., Jahnukainen, K., Kenney, L. B., Loonen, J. J., Meacham, L., Neggers, S., Nussey, S., Petersen, C., Shnorhavorian, M., van den Heuvel-Eibrink, M. M., van Santen, H. M., Wallace, W. H., & Green, D. M. (2017). Recommendations for gonadotoxicity surveillance in male childhood, adolescent, and young adult cancer survivors: a report from the International Late Effects of Childhood Cancer Guideline Harmonization Group in collaboration with the PanCareSurFup Consortium. *Lancet Oncol*, 18(2), e75-e90. [https://doi.org/10.1016/s1470-2045\(17\)30026-8](https://doi.org/10.1016/s1470-2045(17)30026-8)

Snyder, P. J. (2020). Clinical features and diagnosis of male hypogonadism. Wolters Kluwer. <https://www.uptodate.com/contents/clinical-features-and-diagnosis-of-male-hypogonadism>
Stanworth, R. D., & Jones, T. H. (2008). Testosterone for the aging male; current evidence and recommended practice. *Clin Interv Aging*, 3(1), 25-44.

Star-Weinstock, M., & Dey, S. (2019). Development of a CDC-certified total testosterone assay for adult and pediatric samples using LC-MS/MS. *Clinical Mass Spectrometry*, 13, 27-35.
<https://www.sciencedirect.com/science/article/pii/S2376999819300017>

Sun, G., Xue, J., Li, L., Li, X., Cui, Y., Qiao, B., Wei, D., & Li, H. (2020). Quantitative determination of human serum testosterone via isotope dilution ultra-performance liquid chromatography tandem mass spectrometry. *Mol Med Rep*, 22(2), 1576-1582.
<https://doi.org/10.3892/mmr.2020.11235>

Teede, H. J., Misso, M. L., Costello, M. F., Dokras, A., Laven, J., Moran, L., Piltonen, T., & Norman, R. J. (2018). Recommendations from the international evidence-based guideline for the assessment and management of polycystic ovary syndrome. *Hum Reprod*, 33(9), 1602-1618.
<https://doi.org/10.1093/humrep/dey256>

Travison, T. G., Vesper, H. W., Orwoll, E., Wu, F., Kaufman, J. M., Wang, Y., Lapauw, B., Fiers, T., Matsumoto, A. M., & Bhasin, S. (2017). Harmonized Reference Ranges for Circulating Testosterone Levels in Men of Four Cohort Studies in the United States and Europe. *J Clin Endocrinol Metab*, 102(4), 1161-1173. <https://doi.org/10.1210/jc.2016-2935>

van der Veen, A., van Faassen, M., de Jong, W. H. A., van Beek, A. P., Dijck-Brouwer, D. A. J., & Kema, I. P. (2019). Development and validation of a LC-MS/MS method for the establishment of reference intervals and biological variation for five plasma steroid hormones. *Clin Biochem*, 68, 15-23. <https://doi.org/10.1016/j.clinbiochem.2019.03.013>

Vermeulen, A., Verdonck, L., & Kaufman, J. M. (1999). A critical evaluation of simple methods for the estimation of free testosterone in serum. *J Clin Endocrinol Metab*, 84(10), 3666-3672. <https://doi.org/10.1210/jcem.84.10.6079>

Vesper, H., Botelho, J., & Wang, Y. (2014). Challenges and improvements in testosterone and estradiol testing [Invited Review]. *Asian Journal of Andrology*, 16(2), 178-184. <https://doi.org/10.4103/1008-682x.122338>

Viana, A., Jr., Daflon, A. C., Couto, A., Neves, D., de Araujo-Melo, M. H., & Capasso, R. (2017). Nocturnal Hypoxemia is Associated With Low Testosterone Levels in Overweight Males and Older Men With Normal Weight. *J Clin Sleep Med*, 13(12), 1395-1401. <https://doi.org/10.5664/jcsm.6832>

Wang, A., Arver, S., Flanagan, J., Gyberg, V., Nasman, P., Ritsinger, V., & Mellbin, L. G. (2018). Dynamics of testosterone levels in patients with newly detected glucose abnormalities and acute myocardial infarction. *Diab Vasc Dis Res*, 1479164118802543. <https://doi.org/10.1177/1479164118802543>

Welker, K. M., Lassetter, B., Brandes, C. M., Prasad, S., Koop, D. R., & Mehta, P. H. (2016). A comparison of salivary testosterone measurement using immunoassays and tandem mass spectrometry. *Psychoneuroendocrinology*, 71, 180-188. <https://doi.org/10.1016/j.psyneuen.2016.05.022>

Yun, Y.-M., Botelho, J. C., Chandler, D. W., Katayev, A., Roberts, W. L., Stanczyk, F. Z., Vesper, H. W., Nakamoto, J. M., Garibaldi, L., Clarke, N. J., & Fitzgerald, R. L. (2012). Performance Criteria for Testosterone Measurements Based on Biological Variation in Adult Males: Recommendations from the Partnership for the Accurate Testing of Hormones. *Clin Chem*, 58(12), 1703-1710. <https://doi.org/10.1373/clinchem.2012.186569>

Zakharov, M. N., Bhasin, S., Travison, T. G., Xue, R., Ulloor, J., Vasan, R. S., Carter, E., Wu, F., & Jasuja, R. (2015). A multi-step, dynamic allosteric model of testosterone's binding to sex hormone binding globulin. *Mol Cell Endocrinol*, 399, 190-200. <https://doi.org/10.1016/j.mce.2014.09.001>

Zitzmann, M., Nieschlag, E., Traish, A., & Kliesch, S. (2019). Testosterone Treatment in Men with Classical vs. Functional Hypogonadism: A 9-Year Registry. *Journal of the Endocrine Society*, 3. https://academic.oup.com/jes/article/3/Supplement_1/SUN-222/5484291

Policy Update History:

5/1/2022	New policy
----------	------------