UnitedHealthcare

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2018-19
Program	Prior Authorization/Medical Necessity – Testosterone
Medication	Androgel®*, Jatenzo®*, Natesto®*, Kyzatrex™, Testim®, testosterone gel (generic Fortesta) ®*, testosterone topical solution (generic Axiron®)*, testosterone transdermal gel (generic Testim)*, Tlando™*, Undecatrex™*, Vogelxo®*, Xyosted®*
P&T Approval Date	2/2014, 4/2014, 5/2014, 7/2014, 10/2014, 10/2015, 5/2016, 6/2017, 6/2018, 2/2019, 6/2019, 7/2020, 8/2021, 9/2022, 1/2023, 2/2024, 2/2025, 11/2025
Effective Date	2/1/2026

1. Background:

Testosterone products are approved by the Food and Drug Administration (FDA) for testosterone replacement therapy in males with primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired). Primary hypogonadism originates from a deficiency or disorder in the testicles. Secondary hypogonadism indicates a problem in the hypothalamus or the pituitary gland. Testosterone use has been strongly linked to improvements in muscle mass, bone density, and libido.

The purpose of this program is to provide coverage for androgens and anabolic steroid therapy for the treatment of conditions for which they have shown to be effective and are within the scope of the plan's pharmacy benefit. Coverage for the enhancement of athletic performance or body building will not be provided.

2. Coverage Criteria[a]:

A. Initial Authorization for Hypogonadism

1. **Topical testosterone** (gel, solution), **testosterone transdermal systems** (patches), and **oral testosterone** (capsules) will be approved based on **one** of the following:

   a. **Both** of the following:

      1) Patient has a history of **one** of the following:

         i. Bilateral orchiectomy
         ii. Panhypopituitarism
         iii. A genetic disorder known to cause hypogonadism (eg, congenital anorchia, Klinefelter's syndrome)

-AND-

      2) Patient was male at birth

-OR-

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b. **All** of the following:

1) **One** of the following:

   a) Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab, taken at separate times (This may require treatment to be temporarily held. Document lab value and date for both levels)

   -OR-

   b) **Both** of the following:

      i. Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)
      ii. One pre-treatment calculated free or bioavailable testosterone level less than 50 pg/mL (<5 ng/dL or < 0.17 nmol/L) or less than the reference range for the lab (This may require treatment to be temporarily held. Document lab value and date)

-AND-

2) Patient is **not** taking any of the following:

   a) One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen
   b) Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

-AND-

3) Patient was male at birth

-AND-

4) Diagnosis of hypogonadism

-AND-

5) **One** of the following:

   a) Significant reduction in weight (less than 90% ideal body weight) (e.g., AIDS wasting syndrome)
   b) Osteopenia
   c) Osteoporosis
   d) Decreased bone density
   e) Decreased libido

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f) Organic cause of testosterone deficiency (eg, injury, tumor, infection, or genetic defects)

Authorization will be issued for 12 months.

2. **Xyosted*** will be approved based on **one** of the following:

a. **All** of the following:

1) Patient has a history of **one** of the following:

a) Bilateral orchiectomy
b) Panhypopituitarism
c) A genetic disorder known to cause hypogonadism (eg, congenital anorchia, Klinefelter's syndrome)

-AND-

2) Patient was male at birth

-AND-

3) History of failure, contraindication, or intolerance to **both** of the following:

a) testosterone cypionate injection (generic Depo-Testosterone)
b) testosterone enanthate injection

-AND-

4) History of failure, contraindication, or intolerance to **both** of the following:

a) testosterone 1.62% gel (generic Androgel 1.62%)
b) Testim

-OR-

b. **All** of the following:

1) **One** of the following:

a) Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab, taken at separate times (This may require treatment to be temporarily held. Document lab value and date for both levels)

-OR-

b) **Both** of the following:

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1. Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)
2. One pre-treatment calculated free or bioavailable testosterone level less than 50 pg/mL (<5 ng/dL or < 0.17 nmol/L) or less than the reference range for the lab (This may require treatment to be temporarily held. Document lab value and date)

-AND-

2) Patient is **not** taking any of the following:

   a) One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen
   b) Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

-AND-

3) Patient was male at birth

-AND-

4) Diagnosis of hypogonadism

-AND-

5) **One** of the following:

   a) Significant reduction in weight (less than 90% ideal body weight) (e.g., AIDS wasting syndrome)
   b) Osteopenia
   c) Osteoporosis
   d) Decreased bone density
   e) Decreased libido
   f) Organic cause of testosterone deficiency (eg, injury, tumor, infection, or genetic defects)

-AND-

6) History of failure, contraindication, or intolerance to **both** of the following:

   a) testosterone cypionate injection (generic Depo-Testosterone)
   b) testosterone enanthate injection

-AND-

7) History of failure, contraindication, or intolerance to **both** of the following:

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a) testosterone 1.62% gel (generic Androgel 1.62%)
b) Testim

Authorization will be issued for 12 months.

B. Initial Authorization for Gender Dysphoria+

1. **Topical testosterone** (gel, solution), **testosterone transdermal systems** (patches), and **oral testosterone** (capsules) will be approved based on **all** of the following:

   a. Using hormones to change physical characteristics to align with gender expression

   -AND-

   b. The covered person must be diagnosed with gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)

   -AND-

   c. Patient is **not** taking any of the following:

      1) One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen
      2) Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

Authorization will be issued for 12 months.

2. **Xyosted*** (testosterone enanthate) will be approved based on **all** of the following:

   a. Using hormones to change physical characteristics to align with gender expression

   -AND-

   b. The covered person must be diagnosed with gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)

   -AND-

   c. Patient is **not** taking any of the following:

      1) One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen

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2) Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

-AND-

d. History of failure, contraindication, or intolerance to **both** of the following:

1) testosterone cypionate injection (generic Depo-Testosterone)
2) testosterone enanthate injection

Authorization will be issued for 12 months.

C. Reauthorization for both Non-Gender Dysphoria (includes hypogonadism) and Gender Dysphoria

1. Reauthorization will be approved based on **one** of the following:

a. Patient has a history of **one** of the following:

1) Bilateral orchiectomy
2) Panhypopituitarism
3) A genetic disorder known to cause hypogonadism (eg, congenital anorchia, Klinefelter's syndrome)

-OR-

b. Reauthorization will be approved based on **both** of the following:

1) **One** of the following:

a) Follow-up total serum testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document value and date)

-OR-

b) Follow-up total serum testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

-OR-

c) **Both** of the following:

i. Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

-AND-

ii. **One** of the following:

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(a) Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document lab value and date)

-OR-

(b) Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

-AND-

2) Patient is **not** taking any of the following:

a) One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen
b) Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- * May be excluded from coverage
- + Coverage for patient population may be dependent upon benefit design

4. References:

1. The World Professional Association for Transgender Health (WPATH), Standards of Care for the Health of Transgender and Gender Diverse People, 8th Version. Sept 15, 2022. Androgel [package insert]. Bridgewater, NJ: Ascend Therapeutics U.S., LLC; July 2025.
2. Testosterone gel, metered [package insert]. Parsippany, NJ: Actavis Pahrma, Inc.; June 2020.
3. Testim [package insert]. Malvern, PA: Endo Pharmaceuticals Inc; July 2025.
4. Natesto [package insert]. Mississauga, ON: Acerus Pharmaceuticals Corporation; July 2025.
5. Vogelxo [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; April 2020.
6. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 2017; 102:3869.

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7. Shalender Bhasin, Juan P Brito, Glenn R Cunningham, Frances J Hayes, Howard N Hodis, Alvin M Matsumoto, Peter J Snyder, Ronald S Swerdloff, Frederick C Wu, Maria A Yialamas, Testosterone Therapy in Men With Hypogonadism: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 103, Issue 5, May 2018, Pages 1715–1744, https://doi.org/10.1210/jc.2018-00229
8. Mulhall JP, Trost LW, Brannigan RE et al: Evaluation and management of testosterone deficiency: AUA guideline. J Urol 2018; 200: 423Xyosted [package insert]. Ewing, NJ: Antares Pharma, Inc; July 2025.
9. Jatenzo [package insert]. Fort Collins, CO: Tolmar, Inc; September 2025..
10. Tlando [package insert]. Ewing, NJ: Antares Pharma, Inc; March 2022.
11. Kyzatrex [package insert]. Raleigh, NC: Marius Pharmaceuticals LLC; August 2025.
12. Undecatrex [package insert]. San Antonia, TX: Trifluent Pharma LLC; September 2022.

Program	Prior Authorization/Medical Necessity - Testosterone
Change Control	
Date	Change
2/2014	Create Prior Authorization Criteria
4/2014	Revised Reauthorization Criteria; formatting corrections, references updated.
5/2014	Revised the initial authorization criteria to include subsections for the male population and the female to male transsexual population, updated to include language from the gender identity disorder/ gender dysphoria treatment medical coverage determination guideline, references updated
7/2014	Added Natesto and Vogelxo to criteria. Changed coverage criteria from specific product names to topical testosterone products.
10/2014	Modified criteria for total testosterone to consider reference range of the laboratory. Added criteria for when Free Testosterone level may be utilized. Added criteria for conditions that do not require testosterone levels. Extended initial authorization period for patients already on therapy.
12/2014	Testosterone free level units corrected.
10/2015	Clarified initial authorization periods. Clarified that levels for reauthorization should be within the past 6 months for patients new to testosterone and within the past 12 months for continuing users. Updated references.
5/2016	Removed age requirement from female to male transsexual coverage requirements. Updated gender identity disorder to gender dysphoria.
6/2017	Updated criteria for Gender Dysphoria. Updated reauthorization criteria to clarify that new to therapy refers to use of less than one year and continuing therapy refers to use of one year or longer.
6/2018	Updated required testosterone level to less than 300 ng/dL based on 2018 American Urological Society treatment guidelines.
2/2019	Program name change from Topical Androgens to Testosterone. Xyosted added to program.
6/2019	Jatenzo added to program.
7/2020	Updated initial authorization to 6 months for both new and existing users. Added state mandate language. Updated references.

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8/2021	Annual review. Updated references. Removed Striant as it is no longer on the market.
9/2022	Tlando added to program. Removed brand Axiron from program since it is no longer available. Updated to note generic Testim is typically excluded. Updated references.
1/2023	Kyzatrex added to program. Increased initial authorization to 12 months and changed reauthorization to require a lab value within the past 12 months.
2/2024	Annual review. Updated references.
2/2025	Added Undecatrex to program. Updated references.
11/2025	Added requirement male at birth to orchiectomy, panhypopituitarism and genetic disorders requirement section. Added step through topical products for Xyosted. Removed Androderm and brand Fortesta as they are off the market.

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