

Initial Prior Authorization

Testosterone – Oral Testosterone Undecanoate

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Jatenzo	testosterone undecanoate	oral
Kyzatrex	testosterone undecanoate	oral
Tlando	testosterone undecanoate	oral
Undecatrex	testosterone undecanoate	oral

Indications

FDA-approved Indications

Jatenzo, Kyzatrex, Tlando, Undecatrex

Testosterone undecanoate is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle- stimulating hormone (FSH), luteinizing hormone (LH)) above the normal range.

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- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

Limitations of Use:

- Safety and efficacy of testosterone undecanoate in males less than 18 years old have not been established.

Compendial Uses

Jatenzo, Kyzatrex, Tlando, Undecatrex

Gender dysphoria^{7,9-11} (also known as transgender and gender diverse (TGD) persons)

Coverage Criteria

Gender Dysphoria

Authorization may be granted when the requested drug is being prescribed for gender dysphoria in a patient who is able to make an informed decision to engage in hormone therapy when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- The patient’s comorbid conditions are reasonably controlled.
- The patient has been educated on ANY contraindications AND side effects to therapy.
- Before the start of therapy, the patient has been informed of fertility preservation options.
- If the patient is less than 18 years of age, then ALL of the following criteria are met:
 - The requested drug is being prescribed by, or in consultation with, a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist), that has collaborated care with a mental health provider.
 - The patient has reached, or has previously reached, Tanner stage 2 of puberty or greater.

Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

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- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- Before the start of testosterone therapy, the patient has at least TWO confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values.

Continuation of Therapy

Gender Dysphoria

All patients (including new patients) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- Before the patient started testosterone therapy, the patient had a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values.

Duration of Approval (DOA)

- 3060-A: DOA: 12 months

References

1. Jatenzo [package insert]. Fort Collins, CO: Tolmar, Inc.; August 2023.
2. Kyzatrex [package insert]. Raleigh, NC: Marius Pharmaceuticals LLC; September 2022.
3. Tlando [package insert]. Ewing, NJ: Verity Pharmaceuticals, Inc.; February 2024.
4. Undecatrex [package insert]. San Antonio, TX: Trifluent Pharma, LLC; September 2022.
5. Testopel (testosterone pellets) [package insert]. Malvern, PA: Endo USA; March 2024.

6. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed February 4, 2025.
7. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/04/2025).
8. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018;103(5):1715-1744.
9. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022;23(S1):S1-S258.
10. 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(11):3869-3903.
11. Health Care for Transgender and Gender Diverse Individuals. ACOG Committee Opinion No. 823. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2021;137:e75-88.

Document History

Written by: UM Development (KC)

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Revised: (KC) 06/2019 (updated gender dysphoria question), 02/2020, 02/2021 (added age-related hypogonadism question); (VLS) 02/2022 (no clinical changes), 04/2022 (added Tlando, Aetna alignment TGC coverage criteria update), 07/2022 (added Kyzatrex); (SS) 02/2023 (added Tanner stage 2 criteria for GD if under 18); (MRS) 02/2024 (no clinical changes), 02/2025 (off cycle-added Undecatrex, updated title); (DMH) 02/2025 (no clinical changes)

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CRITERIA FOR APPROVAL

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| 1 | Is the requested drug being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism)? [Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]
[If Yes, then no further questions. If No, then go to 2.] | Yes | No |
| 2 | Is the requested drug being prescribed for primary or hypogonadotropic hypogonadism?
[If Yes, then go to 3. If No, then go to 6.] | Yes | No |

3	Is this request for continuation of therapy? [If Yes, then go to 4. If No, then go to 5.]	Yes	No
4	Before the patient started testosterone therapy, did the patient have a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values? [No further questions]	Yes	No
5	Does the patient have at least TWO confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values, before the start of testosterone therapy? [No further questions]	Yes	No
6	Is the requested drug being prescribed for gender dysphoria in a patient who is able to make an informed decision to engage in hormone therapy? [If Yes, then go to 7. If No, then no further questions.]	Yes	No
7	Are the patient's comorbid conditions reasonably controlled? [If Yes, then go to 8. If No, then no further questions.]	Yes	No
8	Has the patient been educated on ANY contraindications AND side effects to therapy? [If Yes, then go to 9. If No, then no further questions.]	Yes	No
9	Is the patient less than 18 years of age? [If Yes, then go to 10. If No, then go to 12.]	Yes	No
10	Is the requested drug being prescribed by, or in consultation with, a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist), that has collaborated care with a mental health provider? [If Yes, then go to 11. If No, then no further questions.]	Yes	No
11	Has the patient reached, or previously reached, Tanner stage 2 of puberty or greater? [If Yes, then go to 12. If No, then no further questions.]	Yes	No
12	Is the patient new to testosterone therapy? [If Yes, then go to 13. If No, then no further questions.]	Yes	No

13	Has the patient been informed of fertility preservation options? [No further questions]	Yes	No
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Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Deny	Go to 2	<p>We have denied your request because your plan does not cover this drug for age-related hypogonadism, also referred to as late-onset hypogonadism. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Exclusion, age-related hypogonadism]</p>
2.	Go to 3	Go to 6	
3.	Go to 4	Go to 5	
4.	Approve, 12 Months	Deny	<p>Your plan only covers this drug when you had a morning testosterone test before you started testosterone treatment and your test results were in a certain range (low). We denied your request because: A) You did not have a morning testosterone test before you started treatment, or B) Your results were not in the approvable range. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Continuation, lab/test]</p>
5.	Approve, 12 Months	Deny	<p>Your plan only covers this drug when you have had two morning testosterone tests before starting treatment and your test results are in a certain range (low). We denied your request because: A)</p>

			<p>You did not have two morning testosterone tests before starting treatment, or B) Your results were not in the approvable range. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Lab/test]</p>
6.	Go to 7	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered uses are primary hypogonadism, hypogonadotropic hypogonadism, and certain other health conditions for which you can make an informed decision about using this drug. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>
7.	Go to 8	Deny	<p>We have denied your request because your plan does not cover this drug unless your other health conditions are under control. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Exclusion, comorbidities]</p>
8.	Go to 9	Deny	<p>Your plan only covers this drug for your health condition when you have been told about reasons you cannot take this drug and side effects of this drug. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to</p>

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			<p>meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Other, education]</p>
9.	Go to 10	Go to 12	
10.	Go to 11	Deny	<p>Your plan only covers this drug when your doctor has expertise in treating your health condition or is working with a doctor who has that knowledge. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Prescriber specialty]</p>
11.	Go to 12	Deny	<p>We have denied your request because your plan does not cover this drug for your health condition unless you have reached a certain stage of puberty. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Exclusion, puberty]</p>
12.	Go to 13	Approve, 12 Months	
13.	Approve, 12 Months	Deny	<p>Your plan only covers this drug for your health condition when you have been told about fertility preservation options. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan</p>

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			documents for your review. [Short Description: Other, fertility preservation]
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