Reference number(s)
1210-A

Initial Prior Authorization Testosterone Products

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
Androderm	testosterone	transdermal patch
Androgel	testosterone	topical gel
Azmiro	testosterone cypionate	injection
Delatestryl	testosterone enanthate	injection
Depo-Testosterone	testosterone cypionate	injection
Fortesta	testosterone	topical gel
Jatenzo	testosterone undecanoate	oral
Kyzatrex	testosterone undecanoate	oral
Natesto	testosterone	nasal gel
Testim	testosterone	topical gel
Testopel	testosterone propionate	implant pellets
testosterone (all brands)	testosterone	topical solution
Tlando	testosterone undecanoate	oral
Undecatrex	testosterone undecanoate	oral
Vogelxo	testosterone	topical gel
Xyosted	testosterone enanthate	all

Indications

FDA-approved Indications

Androderm, AndroGel, Fortesta, Natesto, Testim, testosterone topical gel, testosterone topical solution, Vogelxo

Topical and nasal testosterone products are indicated for 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's 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.
- 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 topical and nasal testosterone products in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.
- Safety and efficacy of topical and nasal testosterone products in males less than 18 years old have not been established.
- Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure.

Azmiro

Azmiro is indicated for testosterone replacement therapy in males in 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; or orchiectomy, Klinefelter's syndrome, or toxic damage from alcohol or heavy metals, 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.
- 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 Azmiro in men with "age- related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.
- Safety and efficacy of Azmiro in pediatric patients below the age of 12 years have not been established.

Depo-Testosterone

Depo-Testosterone Injection is indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired)-testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchiectomy.
- Hypogonadotropic hypogonadism (congenital or acquired)-gonadotropic or LHRH deficiency or pituitary- hypothalamic injury from tumors, trauma or radiation.

Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

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.
- 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.

Testopel

MALES

Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome; or orchiectomy.
- Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropic LHRH deficiency, or pituitary - hypothalamic injury from tumors, trauma or radiation.

If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Safety and efficacy of Testopel (testosterone pellets) in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

- Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An x-ray of the hand and wrist to determine bone age should be taken every 6 months to assess the effect of treatment on epiphyseal centers.

Testosterone Enanthate Injection

Males

Testosterone Enanthate Injection (generic Delatestryl), USP is indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

Primary hypogonadism (congenital or acquired) - Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy.

Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. (Appropriate adrenal cortical and thyroid hormone replacement therapy are still necessary, however, and are actually of primary importance).

If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Safety and efficacy of Testosterone Enanthate Injection (generic Delatestryl), USP in men with age-related hypogonadism have not been established.

Delayed puberty - Testosterone Enanthate Injection (generic Delatestryl), USP may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

Females

Metastatic mammary cancer - Testosterone Enanthate Injection (generic Delatestryl), USP may be used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are one to five years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other

methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or anti-estrogen therapy. This treatment has also been used in pre-menopausal women with breast cancer who have benefited from oophorectomy and are considered to a have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

Xyosted

Xyosted (testosterone enanthate) injection is an androgen 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 cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's 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.
- 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 low or normal range.

Limitations of Use:

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

Compendial Uses

Gender dysphoria[18,20,22-24] (also known as transgender and gender diverse (TGD) persons)

Coverage Criteria

Breast Cancer (Hormone-Responsive Tumor)

Authorization may be granted when the requested drug is being prescribed for a premenopausal patient with breast cancer who has benefited from oophorectomy AND is considered to have a hormone-responsive tumor 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).
- The request is for intramuscular testosterone enanthate injection (generic Delatestryl).

Delayed Puberty

Authorization may be granted when the requested drug is being prescribed for delayed puberty 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).
- The request is for intramuscular testosterone enanthate injection (generic Delatestryl) OR testosterone propionate implant pellet (Testopel).

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).
- 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 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.

Inoperable Metastatic Breast Cancer

Authorization may be granted when the requested drug is being prescribed for inoperable metastatic breast cancer in a patient who is 1 to 5 years postmenopausal AND had an incomplete response to other therapy for metastatic breast cancer 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).
- The request is for intramuscular testosterone enanthate injection (generic Delatestryl).

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).
- 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

Breast Cancer (Hormone-Responsive Tumor), Delayed Puberty, Gender Dysphoria, Inoperable Metastatic Breast Cancer

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).
- 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)

- 1210-A: DOA: 36 months

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Document History

Written by: UM Development (CF/JH)

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Revised: 11/2015, 02/2017; (KC) 02/2018, 10/2018 (added Xyosted), 02/2019 (no clinical changes), 04/2019 (added Jatenzo), 06/2019 (updated gender dysphoria question), 02/2020, 02/2021 (added age-related hypogonadism question); (VLS) 02/2022 (removed Striant), 04/2022 (added Tlando, Aetna alignment TGC coverage criteria update), 07/2022 (added Kytrexa); (MRS) 02/2023 (added Tanner stage 2 criteria for GD if under 18), 02/2024 (no clinical changes); (NSS) 11/2024 (added Azmiro); (MRS) 02/2025 (off cycle-added Undecatrex)

Reviewed: Medical Affairs: (DNC) 10/2014, 05/2015; (LCB) 11/2015; (SD) 02/2017; (AN) 02/2018; (ME) 10/2018; (GAD) 05/2019; (ME) 07/2019; (CHART) 02/27/20, 02/25/21, 02/24/2022, 04/14/2022, 04/21/2022, 04/28/2022, 08/11/2022, 10/13/2022, 03/02/2023, 02/29/2024, 12/05/2024, 02/20/2025

External Review: 06/2016, 06/2017, 06/2018, 12/2018, 06/2019, 06/2020, 06/2021, (FYI) 06/2022, 06/2022, (FYI) 10/2022, 10/2022, 06/2023, 12/2024 (FYI), 04/2025 (FYI)

CRITERIA FOR APPROVAL

Reference number(s)
1210-A

1	Is the requested drug being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism)? [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 go to 14.]	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
14	Is this request for testosterone propionate implant pellets (Testopel)? [If Yes, then go to 18. If No, then go to 15.]	Yes	No
15	Is this request for intramuscular testosterone enanthate injection (generic Delatestryl)? [If Yes, then go to 16. If No, then no further questions.]	Yes	No
16	Is the requested drug being prescribed for inoperable metastatic breast cancer in a patient who is 1 to 5 years postmenopausal and had an incomplete response to other therapy for metastatic breast cancer? [If Yes, then no further questions. If No, then go to 17.]	Yes	No
17	Is the requested drug being prescribed for a pre-menopausal patient with breast cancer who has benefited from oophorectomy and is considered to have a hormone-responsive tumor? [If Yes, then no further questions. If No, then go to 18.]	Yes	No
18	Is the requested drug being prescribed for delayed puberty? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Deny	Go to 2	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.

			[Short Description: Exclusion, age-related hypogonadism]
2.	Go to 3	Go to 6	
3.	Go to 4	Go to 5	
4.	Approve, 36 Months	Deny	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. [Short Description: Continuation, lab/test]
5.	Approve, 36 Months	Deny	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) 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. [Short Description: Lab/test]
6.	Go to 7	Go to 14	
7.	Go to 8	Deny	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. [Short Description: Exclusion, comorbidities]
8.	Go to 9	Deny	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 meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Other, education]
9.	Go to 10	Go to 12	
10.	Go to 11	Deny	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. [Short Description: Prescriber specialty]
11.	Go to 12	Deny	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.

			[Short Description: Exclusion, puberty]
12.	Go to 13	Approve, 36 Months	
13.	Approve, 36 Months	Deny	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 documents for your review. [Short Description: Other, fertility preservation]
14.	Go to 18	Go to 15	
15.	Go to 16	Deny	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. [Short Description: Diagnosis, not generic Delatestryl and Testopel]
16.	Approve, 36 Months	Go to 17	
17.	Approve, 36 Months	Go to 18	

18.	Approve, 36 Months	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are: A) Primary hypogonadism, B) Hypogonadotropic hypogonadism, C) Breast cancer in specific situations, D) Delayed puberty, and E) 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. [Short Description: Diagnosis, generic Delatestryl and Testopel]