Louisiana Fee-for-Service Medicaid
Androgenic Agents

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization for androgenic agents (excluding oxandrolone).

	Generic Name (Brand Example)
	Methyltestosterone Capsules (Android®)
	Testosterone Buccal System (Striant®)
	Testosterone Cypionate
	Testosterone Enanthate
¥ *	Testosterone Gel (Generic; Fortesta®, Testim®, Vogelxo®)
¥	Testosterone Nasal Gel (Natesto®)
	Testosterone Pellets (Testopel®)
¥ *	Testosterone Topical Solution (Generic; Axiron®)
¥ *	Testosterone Transdermal Gel (Androgel® Packet, Androgel® Pump)
¥	Testosterone Transdermal Patch (Androderm®)
* †	Testosterone Undecanoate (Aveed®)

¥ Topical agents are also part of the preferred / non-preferred drug list.

*** These medications have Black Box Warnings and/or may be subject to Risk Evaluation and Mitigation Strategy (REMS) under FDA safety regulations; refer to individual prescribing information for details.**

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Requests will be considered for approval if all applicable criteria are met:

1. Requests must include patient-specific documentation of FDA-approved indications **AND** for hypogonadism in adult males; an associated medical condition must be included with requests. Indications and medical conditions are limited to specific agents as summarized in Tables 1-3.
    a. 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.
    b. 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.

c. Delayed puberty in males: to induce pubertal changes in hypogonadal males
d. In women as secondary treatment with advancing inoperable metastatic (skeletal) breast cancer who are 1 to 5 years postmenopausal. This treatment has also been used in premenopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor; **AND**

2. All initial requests must include baseline hematocrit levels. Hematocrit levels should be reevaluated at 3 to 6 months and then annually, if therapy continues for that duration; **AND**

   Approval Criteria: Less than or equal to 54%

3. Initial requests for use in hypogonadism must also include laboratory results (with date and time drawn) for 2 serum testosterone levels drawn between 8:00 AM and 10:00 AM obtained on different days; **AND**

   *Approval Criteria: Less than 300 ng/dL on both days **OR** below the lower limit of normal on both days for the individual reporting laboratory (must provide documentation of normal limits for individual reporting laboratory)*

4. For requests for use in <u>delayed puberty in males</u>, by submitting the request, the prescriber is attesting to the fact that x-rays of hand and wrist will be performed prior to initiation of requested agent and every 6 months during treatment.; **AND**

5. For requests for use in breast cancer, by submitting this request, the prescriber is attesting to the fact that the following will be monitored every 6 months:
   a. Hypercalcemia
   b. Liver function tests
   c. Hematocrit level; **AND**

6. All requests must conform to age limitations as defined in the prescribing information for each agent; **AND**

7. For a non-preferred agent, the following conditions apply:
   a. There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
   b. The recipient has had treatment failure with at least one preferred product; **OR**
   c. The recipient has had an intolerable side effect to at least one preferred product; **OR**
   d. The recipient has documented contraindication(s) to the preferred products that are appropriate for the condition being treated; **OR**
   e. There is no preferred product appropriate to use for the condition being treated; **AND**

8. By submitting the authorization request, the prescriber attests to the following:

a. The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
b. All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
c. The recipient has no inappropriate concomitant drug therapies or disease states.

Authorization renewal based upon the following criteria (ALL conditions must be met):

- Recipient continues to meet initial approval criteria; **AND**
- Recipient is tolerating and is adherent to current treatment; **AND**
- Recipient's most current hematocrit level (within the past 3 - 6 months or the past 12 months depending on duration of treatment) is provided on the request and continues to be less than 54%; **AND**
- Recipient has had a positive response to treatment as indicated by improvement in signs, symptoms, and lab results compared to baseline.

Table 1. FDA Indications and Associated Medical Conditions for Oral Testosterone Agent	
FDA Indication	**Methyltestosterone**
Primary Hypogonadism (congenital or acquired) a) cryptorchidism	Yes
b) bilateral torsion	Yes
c) orchitis	Yes
d) vanishing testis syndrome	Yes
e) orchiectomy	Yes
f) Klinefelter's Syndrome	No
g) chemotherapy	No
h) toxic damage from alcohol or heavy metals	No
Hypogonadotropic Hypogonadism (congenital or acquired) a) gonadotropin or LHRH deficiency	Yes
b) pituitary-hypothalamic injury from trauma, tumors, or radiation	Yes
Delayed Puberty in Males	Yes
Inoperable Female Metastatic (Skeletal) Breast Cancer	Yes

Duration of Authorization Approval for All Agents
Initial Approval: 6 months
Reauthorization Approval: 6 months

Table 2. FDA Indications and Associated Medical Conditions for Injectable Testosterone Agents				
FDA Indication	***SQ Implant***	***Injection***		
	Testosterone (Pellet)	**Testosterone Cypionate**	**Testosterone Enanthate**	**Testosterone Undecanoate**
Primary Hypogonadism (congenital or acquired) a) cryptorchidism	Yes	Yes	Yes	Yes
b) bilateral torsion	Yes	Yes	Yes	Yes
c) orchitis	Yes	Yes	Yes	Yes
d) vanishing testis syndrome	Yes	Yes	Yes	Yes
e) orchiectomy	Yes	Yes	Yes	Yes
f) Klinefelter's Syndrome	No	No	No	Yes
g) chemotherapy	No	No	No	Yes
h) toxic damage from alcohol or heavy metals	No	No	No	Yes
Hypogonadotropic Hypogonadism (congenital or acquired) a) gonadotropin or LHRH deficiency	Yes	Yes	Yes	Yes
b) pituitary-hypothalamic injury from trauma, tumors, or radiation	Yes	Yes	Yes	Yes
Delayed Puberty in Males	Yes	No	Yes	No
Inoperable Female Metastatic (Skeletal) Breast Cancer	No	No	Yes	No

Table 3. FDA Indications and Associated Medical Conditions for Topical, Transdermal, Buccal, and Nasal Testosterone Agents					
FDA Indication	***Topical Gel***	***Topical Solution***	***Transdermal Patch***	***Buccal***	***Nasal Gel***
	Androgel®, Fortesta®, Testim®, Vogelxo®	**Axiron®**	**Androderm®**	**Striant®**	**Natesto®**
Primary Hypogonadism (congenital or acquired)	Yes	Yes	Yes	Yes	Yes
Hypogonadotropic Hypogonadism (congenital or acquired)	Yes	Yes	Yes	Yes	Yes
Delayed Puberty in Males	No	No	No	No	No
Inoperable Female Metastatic Breast Cancer	No	No	No	No	No

Additional edits may apply at Point-of-Sale (POS). Override options may be available. For more information, refer to the Louisiana Department of Health Pharmacy Benefits Management Services Manual at www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf

References

Androderm (testosterone) transdermal system [package insert]. Parsippany, NJ: Watson Pharma Inc; June 2018. Retrieved from https://www.allergan.com/assets/pdf/androderm_pi

AndroGel 1.62% (testosterone gel) [package insert]. North Chicago, IL: AbbVie Inc; Oct 2016. Retrieved from http://www.rxabbvie.com/pdf/androgel1_62_PI.pdf

Android® (methyltestosterone) [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2015. Retrieved at https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/083976s032lbl.pdf

Aveed (testosterone undecanoate injection) [package insert]. Malvern, PA: Endo Pharmaceuticals Solutions; January 2018. Retrieved from http://www.endo.com/File%20Library/Products/Prescribing%20Information/AVEED_prescribing_information.html

Axiron (testosterone) [package insert]. Indianapolis, IN: Eli Lilly and Company; July 2017. Retrieved from http://uspl.lilly.com/axiron/axiron.html

Bhasin, S., et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018 May:103(5):1715-1744. Retrieved from https://academic.oup.com/jcem/article/103/5/1715/4939465

Fortesta (testosterone) gel [package insert]. Malvern, PA: Endo Pharmaceuticals Inc; July 2017.Retrieved from http://www.endo.com/File%20Library/Products/Prescribing%20Information/FORTESTA_prescribing_information.html

Natesto (testosterone) nasal gel [package insert]. Englewood, CO: Aytu BioScience, Inc; December 2017. Retrieved from https://www.natesto.com/pdf/Natesto_Prescribing_Information_Professionals.pdf

Striant (testosterone buccal system) [package insert]. Malvern, PA: Actient Pharmaceuticals LLC; May 2015. Retrieved from https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021543s012lbl.pdf

Testim (testosterone) [package insert]. Malvern, PA: Endo Pharmaceuticals; April 2018. Retrieved from http://www.endo.com/File%20Library/Products/Prescribing%20Information/Testim_prescribing_information.html

Testopel (testosterone) pellets [package insert]. Malvern, PA: Auxilium Pharmaceuticals Inc; August 2018. Retrieved from http://www.endo.com/File%20Library/Products/Prescribing%20Information/Testopel_prescribing_information.html

Testosterone cypionate [package insert]. Lake Forest, IL: Hospira, a Pfizer Company; November 2017 Retrieved from http://labeling.pfizer.com/ShowLabeling.aspx?id=4015

Testosterone enanthate [package insert]. Eatontown, NJ: West-Ward Pharmaceutical; December 2016 Retrieved from https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/009165s034lbl.pdf

Vogelxo (testosterone) [package insert]. Maple Grove, MN: Upsher-Smith Laboratories Inc; May 2015. Retrieved from https://www.upsher-smith.com/wp-content/uploads/Vogelxo-MI.pdf