



## DRUG QUANTITY MANAGEMENT POLICY – PER RX

**POLICY:** Testosterone Products (Topical) Drug Quantity Management Policy – Per Rx

### Transdermal Patch

- Androderm® (testosterone transdermal system [2 mg/day and 4 mg/day] – Allergan)

### Transdermal Gels

- AndroGel® (testosterone 1% gel, 1.62% gel – AbbVie, generic)
- Fortesta® (testosterone 2% gel – Endo, generic)
- Testim® (testosterone 1% gel – Endo, generic)
- Vogelxo® (testosterone 1% gel – Upsher-Smith, generic)

### Transdermal Solution

- testosterone 2% solution (generic only)

### Nasal Gel

- Natesto® (testosterone nasal gel – Acerus)

**REVIEW DATE:** 07/08/2024

---

### INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

## CIGNA NATIONAL FORMULARY COVERAGE:

### OVERVIEW

The topical testosterone replacement products are all indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.<sup>1-8</sup> The labels for the FDA-approved products define those patients and/or conditions for which use of testosterone replacement products is indicated:

- **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 normal.
- **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.

## Guidelines

- **Hypogonadism:** Guidelines from the American Urological Association (2018) note that clinicians should use a total testosterone level below 300 ng/dL as a reasonable cutoff in support of the diagnosis of low testosterone.<sup>9</sup> A clinical diagnosis requires low testosterone levels (two separate levels, both conducted in the early morning) combined with signs and symptoms. The Endocrine Society guidelines on testosterone therapy in men with hypogonadism (2018) recommend diagnosing hypogonadism in men with symptoms and signs of testosterone deficiency and unequivocally and consistently low serum total testosterone and/or free testosterone concentrations (when indicated).<sup>10</sup>
- **Gender-Dysphoric/Gender-Incongruent Persons; Persons Undergoing Female-To-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization):** A clinical practice guideline published by the Endocrine Society (2017) recommends that, prior to initiation of hormonal therapy, the treating endocrinologist should confirm the diagnostic criteria of gender dysphoria/gender incongruence and the criteria for the endocrine phase of gender transition.<sup>11</sup> The clinician should also evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment. Guidelines mention that clinicians can use either parenteral or transdermal preparations to achieve appropriate testosterone values. The recommended dose of a transdermal testosterone patch cited in the guideline is 2.5 mg to 7.5 mg/day; testosterone gel is recommended at a dose of 50 to 100 mg/day.

## Dosing

### *Androderm*

The recommended starting dose is one 4 mg/day patch (not two 2 mg/day patches) applied nightly for 24 hours (to deliver 4 mg of testosterone/day).<sup>1</sup> To ensure proper dosing, approximately 2 weeks after starting therapy, the early morning serum testosterone concentration should be measured following system application in the previous evening. Serum testosterone concentrations measured in the early morning outside the range of 400 ng/dL to 930 ng/dL require increasing the daily dose up to 6 mg (as one 4 mg/day and one 2 mg/day patch) or decreasing the daily dose to 2 mg (as one 2 mg/day patch).

### *AndroGel (generic)*

The recommended starting dose of AndroGel 1% is 50 mg of testosterone (two 25 mg packets or one 50 mg packet), applied topically once daily (QD) in the morning to the shoulders and upper arms and/or abdomen area (preferably at the same time every day).<sup>3</sup> To ensure proper dosing, serum testosterone concentrations should be measured. If the serum testosterone concentration is below the normal range, the daily AndroGel 1% dose may be increased from 50 mg to 75 mg and from 75 mg to 100 mg for adult males as instructed by the physician.

The recommended starting dose of AndroGel 1.62% is 40.5 mg of testosterone (two pump actuations or a single 40.5 mg packet) applied topically QD in the morning to the shoulders and upper arms.<sup>4</sup> The dose can be adjusted between a minimum of 20.25 mg of testosterone (one pump actuation or a single 20.25 mg packet) and a maximum of 81 mg of testosterone (four pump actuations or two 40.5 mg packets). To ensure proper dosing, the dose should be titrated based on the pre-dose morning serum testosterone concentration from a single blood draw at approximately 14 days and 28 days after starting treatment or following dose adjustment. Table 1 provides the number of pumps or packets needed to achieve the desired AndroGel 1.62% dose.

**Table 1. AndroGel 1.62% Dosing.<sup>4\*</sup>**

<b>Total Dose of Testosterone</b>	<b>Total Pump Actuations</b>	<b>Total Packets</b>
20.25 mg	1 pumps	1 x 20.25 mg packet
40.5 mg	2 pumps	1 x 40.5 mg packet
60.75 mg	3 pumps	1 x 20.25 mg packet + 1 x 40.5 mg packet
81 mg	4 pumps	2 x 40.5 mg packets

\*The total number of pump actuations or packets are for each dosage form separately, not a combined dose to achieve the total dose of testosterone.

### *Fortesta (generic)*

The recommended starting dose of Fortesta is 40 mg (four pump actuations) of testosterone applied QD to the thighs in the morning.<sup>6</sup> The dose can be adjusted between a minimum of 10 mg of testosterone and a maximum of 70 mg of testosterone (Table 2). To ensure proper dosing, the dose should be titrated based on the serum testosterone concentration from a single blood draw 2 hours after applying Fortesta at approximately Day 14 and Day 35 after starting treatment or following dose adjustment.

**Table 2. Fortesta Dosing.<sup>6</sup>**

<b>Total Dose of Testosterone</b>	<b>Total Pump Actuations</b>
10 mg	1
20 mg	2
30 mg	3
40 mg	4
50 mg	5
60 mg	6
70 mg	7

### *Testim (generic)*

The recommended starting dose of Testim is 50 mg of testosterone applied QD to the shoulders and/or upper arms in the morning.<sup>2</sup> To ensure proper dosing, serum testosterone concentrations should be measured. Morning, pre-dose serum testosterone concentrations should be measured approximately 14 days after initiation of therapy to ensure proper serum testosterone concentrations are achieved. The daily Testim dose may be increased from 50 mg testosterone (1 tube) to 100 mg testosterone (2 tubes) QD. The maximum recommended dose is 100 mg QD.

### *Vogelxo (generic)*

The recommended starting dose of Vogelxo is 50 mg of testosterone (one tube, one packet, or four pump actuations) applied QD to the shoulders and/or upper arms in the morning.<sup>7</sup> To ensure proper dosing, serum testosterone concentrations should be measured. Morning, pre-dose serum testosterone concentrations should be measured approximately 14 days after initiation of therapy to ensure proper serum testosterone concentrations are achieved. The daily Vogelxo dose may be increased from 50 mg of testosterone QD to 100 mg testosterone QD (two tubes, two packets, or eight pump actuations). The maximum recommended dose is 100 mg of testosterone QD.

### *Natesto*

The recommended starting dose of Natesto is 11 mg of testosterone (two pump actuations; one actuation per nostril) administered intranasally three times daily for a total daily dose of 33 mg (6 pump actuations/day).<sup>8</sup> To ensure proper dosing, serum testosterone concentrations should be measured.

### *Testosterone 2% topical solution (generic only)*

The recommended starting dose of testosterone 2% topical solution is 60 mg of testosterone (two pump or two twist actuations) applied QD.<sup>5</sup> To ensure proper dosing, serum testosterone concentrations should be measured after initiation of therapy to ensure that the desired concentrations (300 ng/dL to 1,050 ng/dL) are achieved. The daily testosterone dose may be increased from 60 mg to 90 mg (three pump or three twist actuations) or from 90 mg to 120 mg (four pump or four twist actuations).

## **Availability**

### *Androderm*

Androderm is available as a transdermal patch that delivers 2 mg/day or 4 mg/day of testosterone.<sup>1</sup> Androderm 2 mg/day is available in a carton containing 60 patches, Androderm 4 mg/day is available in a carton containing 30 patches. Patches must be stored inside the provided pouch.

### *AndroGel (generic)*

AndroGel is available as a 1% and 1.62% gel.<sup>3,4</sup> AndroGel 1% is supplied in unit-dose aluminum foil packets in cartons of 30. Each packet of 2.5 g or 5 g gel contains 25 mg or 50 mg testosterone (25 mg/2.5 g and 50 mg/5 g), respectively.

The generic AndroGel 1% gel is also available as a metered-dose 75 g pump. Each pump actuation delivers 12.5 mg of testosterone /1.25 g of gel. AndroGel 1.62% is supplied in non-aerosol, metered-dose pumps that deliver 20.25 mg of testosterone/complete pump actuation. Each 88 g metered-dose pump is capable of dispensing 75 g of gel or 60-metered pump actuations; each pump actuation dispenses 1.25 g of gel. AndroGel 1.62% is also supplied in unit-dose aluminum foil packets in cartons of 30. Each packet of 1.25 g or 2.5 g gel contains 20.25 mg or 40.5 mg testosterone (20.25 mg/1.25 g or 40.5 mg/20.25 g), respectively.

*Fortesta (generic)*

Fortesta is available as a gel supplied in a 60 g canister with a metered dose pump that delivers 10 mg of testosterone per complete pump actuation.<sup>6</sup> The metered dose pump is capable of dispensing 120 metered pump actuations. One pump actuation dispenses 0.5 g of gel.

*Testim (generic)*

Testim is available as a gel in a unit-dose tube in cartons of 30 tubes.<sup>2</sup> Each tube contains 50 mg of testosterone in 5 g of gel.

*Vogelxo (generic)*

Vogelxo is a gel supplied in unit-dose tubes or unit-dose packets each in cartons of 30.<sup>7</sup> Each tube or packet contains 50 mg testosterone/5 g of gel. Vogelxo is also supplied in a metered-dose pump that delivers 12.5 mg of testosterone/complete pump actuation. Each 88 g metered-dose pump is capable of dispensing 75 g of gel or 60-metered pump actuations. Each pump actuation delivers 12.5 mg of testosterone in 1.25 g of gel (four actuations = 50 mg testosterone). The metered-dose pump is supplied in cartons of two.

**Table 3. Vogelxo (generic) Availability.<sup>7</sup>**

<b>Strength</b>	<b>Package Size</b>
50 mg testosterone	30 tubes (5 g gel/tube)
50 mg testosterone	1 tube (5 g gel/tube)
50 mg testosterone	30 packets (5 g gel/packet)
50 mg testosterone	1 packet (5 g gel/packet)
12.5 mg of testosterone per pump actuation	2 x 75 g pumps (each pump dispenses 60 metered actuation [1.25 g of gel each])

*Natesto*

Natesto is a nasal gel available as a metered dose pump containing 11 grams of gel dispensed as 60 metered pump actuations.<sup>8</sup> One pump actuation delivers 5.5 mg of testosterone in 0.122 g of gel (one bottle contains a 10-day supply at a dose of 33 mg testosterone/day).

*Testosterone 2% solution (generic only)*

Testosterone 2% solution (generic only) is available as a topical solution that delivers 30 mg of testosterone in 1.5 mL of solution (one pump or twist actuation).<sup>6</sup> The topical solution is available as a metered-dose pump containing 110 mL of

solution and is capable of dispensing 90 mL of solution in 60 metered pump or twist actuations.

## POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse use of the topical testosterone products. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted below.

### Drug Quantity Limits\*

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Androderm® (testosterone transdermal system)	2 mg/day patch (box of 60 patches)	30 patches	90 patches
	4 mg/day patch (box of 30 patches)	30 patches	90 patches
AndroGel® 1% (testosterone 1% gel, generic)	2.5 gram gel packet (25 mg testosterone per packet)	75 grams (30 packets)	225 grams (90 packets)
	5 gram gel packet (50 mg testosterone per packet)	300 grams (60 packets)	900 grams (180 packets)
Testosterone 1% gel pump (generic to obsolete AndroGel pump)	Gel pump (60 metered pump actuations/75 grams of gel) [12.5 mg testosterone/1.25 gram pump actuation]	300 grams	900 grams
AndroGel® 1.62% (testosterone 1.62% gel, generic)	1.25 gram gel packet (20.25 mg testosterone)	30 packets	90 packets
	2.5 gram gel packet (40.5 mg testosterone)	60 packets	180 packets
	Gel pump (60 metered pump actuations/75 grams of gel) [20.25 mg testosterone/1.25 grams pump actuation]	150 grams	450 grams
Fortesta® (testosterone 2% gel, generic)	120 metered pump actuations/60 g [10 mg testosterone/0.5 gram pump actuation]	120 grams	360 grams
Testim® (testosterone 1% gel, generic)	50 mg testosterone/5 gram gel tube	60 tubes	180 tubes
Vogelxo® (testosterone 1% gel, generic)	50 mg testosterone/5 gram gel tube	60 tubes	180 tubes
	50 mg testosterone/5 gram gel packet	60 packets	180 packets
	Gel pump (60-metered pump actuations/75 grams of gel)	300 grams	900 grams

	[12.5 mg testosterone/1.25 gram pump actuation]		
--	---	--	--

**Drug Quantity Limits (continued)\***

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Natesto® (testosterone nasal gel)	Metered dose pump (60-metered pump actuations/7.32 gram bottle) [5.5 mg testosterone/1.22 gram pump actuation]	21.96 grams (3 bottles)	65.88 grams (9 bottles)
Testosterone 2% solution (generic to obsolete Axiron)	Metered dose pump (60 metered pumps or twist actuations/90 mL solution) [30 mg testosterone/1.5 mL solution]	180 mL (2 bottles)	540 mL (6 bottles)

\* These limits allow for a sufficient quantity for each of the products for a 30-day supply at retail or a 90-day supply at home delivery at maximum recommended doses (rounded up to the nearest package size, if needed). Overrides for additional quantities of AndroGel, Fortesta and Androderm are provided below.

**Testosterone Products (Topical) Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

**CRITERIA**

Androderm 2 mg/day transdermal patch

No overrides recommended.

Androderm 4 mg/day transdermal patch

1. If the request is for Gender-Dysphoric/Gender-Incongruent Persons/Female-to-Male (FTM) Gender Reassignment, approve 60 patches per dispensing at retail or 180 patches per dispensing at home delivery.

AndroGel 1%, 2.5 g gel packet (generic)

1. If the dose is being titrated, approve a one-time override for the requested quantity, not to exceed 225 grams (90 packets) at retail or 675 grams (270 packets) at home delivery.  
Note: If the dose is being titrated to > 75 mg/day, the patient should use the 5 g gel packets.
2. If the maintenance dose is 75 mg/day, approve 225 grams (90 packets) per dispensing at retail or 675 grams (270 packets) per dispensing at home delivery.  
Note: If the maintenance dose is > 75 mg/day, the patient should use the 5 g gel packets.

AndroGel 1%, 5 g gel packet (generic)

No overrides recommended.

Testosterone gel 1% gel pump (AndroGel, generic only)

No overrides recommended.

AndroGel 1.62%, 1.25 g packet (generic)

1. If the dose is being titrated, approve a one-time override for the requested quantity, not to exceed 90 packets at retail or 270 packets at home delivery.  
Note: If the dose is being titrated to > 60.75 mg/day, the patient should use the 2.5 g gel packets.
2. If the maintenance dose is 60.75 mg/day, approve 90 packets per dispensing at retail or 270 packets per dispensing at home delivery.  
Note: If the maintenance dose is > 60.75 mg/day, the patient should use the 2.5 g gel packets.

AndroGel 1.62%, 2.5 g gel packets (generic)

No overrides recommended.

AndroGel 1.62%, gel pump (generic)

1. If the request is for Gender-Dysphoric/Gender-Incongruent Persons/Female-to-Male (FTM) Gender Reassignment, approve 225 grams per dispensing at retail or 675 grams per dispensing at home delivery.

Fortesta 2%, gel pump (generic)

1. If the request is for Gender-Dysphoric/Gender-Incongruent Persons/Female-to-Male (FTM) Gender Reassignment, approve 180 grams per dispensing at retail or 540 grams per dispensing at home delivery.

Testim 1% gel, 5 g tube (generic)

No overrides recommended.

Vogelxo 1% gel, 5 g tube, 5 g packet, and gel pump (generic)

No overrides recommended.

Natesto nasal gel pump

No overrides recommended.

Testosterone 2% topical solution metered-dose pump (generic to obsolete Axiron)

No overrides recommended.

## REFERENCES

1. Androderm® transdermal [prescribing information]. Madison, NJ: Allergan; May 2020.
2. Testim® gel [prescribing information]. Malvern, PA: Endo; August 2021.
3. AndroGel® 1% gel [prescribing information]. North Chicago, IL: AbbVie; May 2019.
4. AndroGel® 1.62% gel [prescribing information]. North Chicago, IL: AbbVie; May 2019.
5. Testosterone solution [prescribing information]. Parsippany, NJ: Actavis; February 2019.



6. Fortesta® gel [prescribing information]. Malvern, PA: Endo; June 2020.
7. Vogelxo® gel [prescribing information]. Maple Grove, MN: Upsher-Smith; April 2020.
8. Natesto® nasal gel [prescribing information]. Mississauga, ON Canada: Acerus; October 2016.
9. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and Management of Testosterone Deficiency. American Urological Association. 2018. Available at: [http://www.auanet.org/guidelines/testosterone-deficiency-\(2018\)](http://www.auanet.org/guidelines/testosterone-deficiency-(2018)). Accessed on May 30, 2024.
10. 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.
11. Hembree WC, Cohen-Kettenis P, 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.

## HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. <b>Striant:</b> Removed from policy (obsolete for more than 3 years). No criteria changes.	06/08/2023
Annual Revision	No criteria changes.	07/08/2024

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2024 The Cigna Group.