MEDICATION POLICY:

Androgens (all dosage forms)

Generic Name: Click or tap here to enter generic name.

Therapeutic Class or Brand Name: Androgens (all dosage forms)

Applicable Drugs (if Therapeutic Class): Policy also applies to any Androgen products not listed.

GPI Code: 23100020, 23100030

Preferred: Methyltestosterone Capsule (generic), Testosterone Cypionate Injection (generic), Testosterone Enanthate Injection (generic), Testosterone Transdermal Gel (generic), Testosterone Transdermal Solution (generic).

Non-preferred: Androderm® (testosterone transdermal system), AndroGel® (testosterone gel), Depo®-Testosterone (testosterone cypionate injection), Fortesta® (testosterone gel), Methitest™ (methyltestosterone tablet), Natesto™ (testosterone nasal gel), Striant® (testosterone buccal), Testim® (testosterone gel), Testopel® (testosterone pellet), Testosterone Transdermal Gel (brand), and Vogelxo™ (testosterone gel).

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 8/6/2018

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I and II are met):

I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis:

A. Hypogonadism (for all products) and criteria 1 through 4 are met:

1. Males only.
2. Patient must have symptoms of testosterone deficiency.
3. Documentation of two morning testosterone levels below the individual lab's normal range.
4. Minimum age requirement: 18 years old.

B. Delayed Puberty (for Methitest™, Methyltestosterone, Testopel® only) and criteria 1 and 2 are met:

1. Males only.
2. Prescribing physician must indicate that patient's bone development has been checked and will be checked at least every 6 months.

C. Advancing inoperable metastatic (skeletal) mammary cancer (for Methitest™, Methyltestosterone only) and criteria 1 through 4 are met:

1. Females only.
2. Patient is 1 to 5 years postmenopausal.
3. Patient has had an incomplete response to other therapies for metastatic mammary cancer.
4. Prescribing physician is an oncologist.

II. Non-preferred products require a documented trial and failure of, intolerance to, or contraindication to a preferred product (refer to plan document for the list of preferred products).

EXCLUSION CRITERIA

- Men with carcinomas of the breast or with known or suspected carcinomas of the prostate.
- Women who are or may become pregnant.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Hypogonadism:
  - Androderm®:
    - 2 mg/day: 30 patches per 30 days.
    - 4 mg/day: 30 patches per 30 days.
  - AndroGel®/Testosterone Transdermal Gel 1%: 60 packets or 4 pump bottles per 30 days.
  - AndroGel® 1.62%: 60 packets or 2 pump bottles per 30 days.
  - Fortesta®/Testosterone Transdermal Gel 2%: 2 pump canisters per 30 days.
  - Methitest™: 150 tablets per 30 days.
  - Natesto™: 3 pump bottles per 30 days.
  - Striant®: 60 buccal systems per 30 days.
  - Testim®/Testosterone Transdermal Gel 1%: 60 tubes per 30 days.
  - Testopel®: 6 pellets per 90 days.
  - Vogelxo™/Testosterone Transdermal Gel 1%: 60 tubes or packets or 4 pump bottles per 30 days.
- Delayed Puberty:
  - Methitest™: 150 tablets per 30 days.
  - Testopel®: 6 pellets per 90 days.

- Advancing Inoperable Metastatic Mammary Cancer:
    - Methitest™: 600 tablets per 30 days.

APPROVAL LENGTH

- **Authorization:**
    - Hypogonadism: 6 months.
    - Delayed Puberty: 6 months
    - Advancing inoperable metastatic (skeletal) mammary cancer: 12 months.
- **Re-Authorization:**
    - Hypogonadism: 12 months. An updated letter of medical necessity or progress notes showing the medication is effective. Letter or notes must also be accompanied by one documented testosterone level in order to verify drug absorption. If the testosterone level exceeds the individual lab's normal range, then there must also be documentation included that the dose is being decreased.
    - Delayed Puberty: 6 months. An updated letter of medical necessity or progress notes showing the medication is effective. Letter or notes must also be accompanied by evidence that patient's bone development is being checked at least every 6 months.
    - Advancing inoperable metastatic (skeletal) mammary cancer: 12 months. An updated letter of medical necessity or progress notes showing the medication is effective.

APPENDIX

N/A

REFERENCES

1. https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Androgens.pdf.
2. http://blue.regence.com/trgmedpol/drugs/dru297.pdf.
3. http://www.bcbsnc.com/assets/services/public/pdfs/formulary/androgen_criteria.pdf.
4. http://web.southcarolinablues.com/UserFiles/scblues/Documents/Medicare%20D/PA%20Criteria.pdf.
5. NPS.
6. Medi-Span.
7. http://www.rxabbvie.com/pdf/androgel_PI.pdf.
8. http://www.rxabbvie.com/pdf/androgel1_62_PI.pdf.
9. http://pi.actavis.com/data_stream.asp?product_group=1200&p=pi&language=E.

10. http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=a9758bea-b15b-42e5-938c-03e3f042b290.
11. http://www.endo.com/File%20Library/Products/Prescribing%20Information/FORTESTA_prescribing_information.html.
12. http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=77bb4ef4-c10e-4acc-8225-651d003f4561.
13. http://www.endo.com/File%20Library/Products/Prescribing%20Information/Striant_prescribing_information.html.
14. http://www.endo.com/File%20Library/Products/Prescribing%20Information/Testim_prescribing_information.html.
15. http://www.endo.com/File%20Library/Products/Prescribing%20Information/Testopel_prescribing_information.html.
16. http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=09db5a9d-9662-4bfb-824c-9c9aaad488dc.
17. http://www.upsher-smith.com/wp-content/uploads/Vogelxo-MI.pdf.
18. http://www.natesto.com/pdf/Natesto_Prescribing_Information_Consumers.pdf.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
8/6/2018	1. Removed All references within document to the following products due to product discontinuation: Axiron® Android® Testred®
11/9/2017	1. **Changed** "All Methyltestosterone and Testosterone products including but not limited to the following: Androderm® (testosterone transdermal system), AndroGel® (testosterone gel), Android® (methyltestosterone tablet), Axiron® (testosterone topical solution), Fortesta® (testosterone gel), Methitest™ (methyltestosterone tablet), Natesto™ (testosterone nasal gel), Striant® (testosterone buccal), Testim® (testosterone gel), Testopel® (testosterone pellet), Testred® (methyltestosterone capsule), and Vogelxo™ (testosterone gel)" **to** "Preferred: Methyltestosterone Capsule (generic), Testosterone Cypionate Injection (generic), Testosterone Enanthate Injection (generic), Testosterone Transdermal Gel (generic), Testosterone Transdermal Solution (generic); Non-Preferred: Androderm® (testosterone transdermal system), AndroGel® (testosterone gel), Android® (methyltestosterone tablet), Axiron® (testosterone topical solution), Depo®-Testosterone (testosterone cypionate injection), Fortesta® (testosterone gel), Methitest™ (methyltestosterone tablet), Natesto™ (testosterone nasal gel), Striant® (testosterone buccal), Testim® (testosterone gel), Testopel® (testosterone pellet), Testosterone Transdermal Gel (brand), Testred® (methyltestosterone capsule), and Vogelxo™ (testosterone gel); Policy also applies to any Androgen products not listed" **under Applicable Drugs**.

	2. **Changed** "I. B. Delayed Puberty (for Android®, Methitest™, Testopel®, Testred® only) and criteria 1 and 2 are met…" **to** "I. B. Delayed Puberty (for Android®, Methitest™, Methyltestosterone, Testopel®, Testred® only) and criteria 1 and 2 are met…" **under Prior Authorization Criteria**. 3. **Changed** "I. C. Advancing inoperable metastatic (skeletal) mammary cancer (for Android®, Methitest™, Testred® only) and criteria 1 through 4 are met…" **to** "I. C. Advancing inoperable metastatic (skeletal) mammary cancer (for Android®, Methitest™, Methyltestosterone, Testred® only) and criteria 1 through 4 are met…" **under Prior Authorization Criteria**. 4. **Added** "II. Non-preferred products require a documented trial and failure of, intolerance to, or contraindication to a preferred product (refer to plan document for the list of preferred products)" **under Prior Authorization Criteria**. 5. **Changed** "Hypogonadism: AndroGel® 1%...Android®...Axiron®...Fortesta®...Testim®...Testred®...Vogelxo™...Delayed Puberty: Android®...Testred®...Advancing Inoperable Metastatic Mammary Cancer: Android®...Testred®" **to** "Hypogonadism: AndroGel®/Testosterone Transdermal Gel...Android®/Methyltestosterone...Axiron®/Testosterone Transdermal Solution...Fortesta®/Testosterone Transdermal Gel 2%...Testim®/Testosterone Transdermal Gel 1%...Testred®/Methyltestosterone...Vogelxo™/Testosterone Transdermal Gel 1%...Delayed Puberty: Android®/Methyltestosterone...Testred®/Methyltestosterone...Advancing Inoperable Metastatic Mammary Cancer: Android®/Methyltestosterone...Testred®/Methyltestosterone" **under Quantity/Days Supply Restrictions**. 6. **Updated** "http://www.bcbsnc.com/assets/services/public/pdfs/formulary/androgens_um_criteria_new.pdf" **to** "http://www.bcbsnc.com/assets/services/public/pdfs/formulary/androgen_criteria.pdf" **and** "http://endo.com/File%20Library/Products/Prescribing%20Information/Natesto_prescribing_information.html" **to** "http://www.natesto.com/pdf/Natesto_Prescribing_Information_Consumers.pdf"**under References**.
5/28/2016	1. **Changed** "Preferred Brand: AndroGel® (testosterone gel); Non-Preferred: Androderm® (testosterone transdermal system), Android® (methyltestosterone tablet), Axiron® (testosterone topical solution), Fortesta® (testosterone gel), Methitest™ (methyltestosterone tablet), Natesto™ (testosterone nasal gel), Striant® (testosterone buccal), Testim® (testosterone gel), Testopel® (testosterone pellet), Testred® (methyltestosterone capsule), and Vogelxo™ (testosterone gel)" **to** "All Methyltestosterone and Testosterone products including but not limited to the following: Androderm® (testosterone transdermal system), AndroGel® (testosterone gel), Android® (methyltestosterone tablet), Axiron® (testosterone topical solution), Fortesta® (testosterone gel), Methitest™ (methyltestosterone tablet), Natesto™ (testosterone nasal gel), Striant® (testosterone buccal), Testim® (testosterone gel), Testopel® (testosterone pellet), Testred® (methyltestosterone capsule), and Vogelxo™ (testosterone gel)" **under Applicable Drugs**. 2. **Changed** "A3. Patient must have two morning testosterone levels below the individual lab's reference range (different laboratories use different assays and thus may have different ranges which are considered low, optimal, or high)" **to** "A3. Documentation of two morning testosterone levels below the individual lab's normal range" **under Prior Authorization Criteria**.

	3. **Removed** "II. Non-preferred products require a documented trial and failure of, intolerance to, or contraindication to a preferred product" **under Prior Authorization Criteria**. 4. **Changed** "Androderm®: 60 patches per 30 days" **to** "Androderm®: 2 mg/day: 30 patches per 30 days; 4 mg/day: 30 patches per 30 days" **under Quantity/Days Supply Restrictions**. 5. **Changed** "**Authorization:** 6 months; **Re-Authorization:** 6 months at a time. An updated letter of medical necessity or progress notes showing the medication is effective. For Hypogonadism diagnosis, letter or notes must also be accompanied by two morning testosterone levels in order to verify drug absorption; For Delayed Puberty diagnosis, letter or notes must also be accompanied by evidence that patient's bone development is being checked at least every 6 months" **to** "**Authorization:** Hypogonadism: 6 months; Delayed Puberty: 6 months; Advancing inoperable metastatic (skeletal) mammary cancer: 12 months; **Re-Authorization:** Hypogonadism: 12 months. An updated letter of medical necessity or progress notes showing the medication is effective. Letter or notes must also be accompanied by one documented testosterone level in order to verify drug absorption. If the testosterone level exceeds the individual lab's normal range, then there must also be documentation included that the dose is being decreased; Delayed Puberty: 6 months. An updated letter of medical necessity or progress notes showing the medication is effective. Letter or notes must also be accompanied by evidence that patient's bone development is being checked at least every 6 months; Advancing inoperable metastatic (skeletal) mammary cancer: 12 months. An updated letter of medical necessity or progress notes showing the medication is effective" **under Approval Length**.
7/24/2015	1. Changed GPI Code from "2310002000, 2310003000" to "23100020, 23100030".
3/16/2015	1. **Changed** "Preferred, no prior authorization required: testosterone cypionate and testosterone enanthate; Preferred, prior authorization required: AndroGel® (testosterone gel)…" **to** "Preferred Brand: AndroGel® (testosterone gel)…" **under Applicable Drugs**. 2. **Added** "Natesto™ (testosterone nasal gel)" **and** "Vogelxo™ (testosterone gel)" **to Non-Preferred list under Applicable Drugs**. 3. **Removed** "2310001000"**,** "2310003010"**, and** "2310003020" **from GPI Code**. 4. Removed "Androxy® (fluoxymesterone tablet)" from Non-Preferred list, and removed information for Androxy® under Prior Authorization Criteria and Quantity/Days Supply Restrictions. 5. **Changed** "AndroGel®: 300 grams per 30 days" **to** "AndroGel® 1%: 60 packets or 4 pump bottles per 30 days; AndroGel® 1.62%: 60 packets or 2 pump bottles per 30 days"**,** "Striant®: 60 tablets per 30 days" **to** "Striant®: 60 buccal systems per 30 days"**, and** "Testim®: 300 grams per 30 days" **to** "Testim®: 60 tubes per 30 days" **under Quantity/Days Supply Restrictions**. 6. **Added** "Natesto™: 3 pump bottles per 30 days" **and** "Vogelxo™: 60 tubes or packets or 4 pump bottles per 30 days" **under Quantity/Days Supply Restrictions**. 7. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Androgens.pdf" **to** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Androgens.pdf"**,** "http://www.auxilium.com/PDFs/58816-10_Striant_full_PI_4pager.pdf" **to** "http://www.endo.com/File%20Library/Products/Prescribing%20Information/Striant_prescribing_information.html"**,** "https://www.testim.com/hcp/_assets/pdf/Testim_PI_Medication_Guide.pdf" **to** "http://www.endo.com/File%20Library/Products/Prescribing%20Information/Testim_prescribing_information.html"**, and** "http://www.testopel.com/site/assets/files/1026/testopel-prescribing-information.pdf" **to**

	"http://www.endo.com/File%20Library/Products/Prescribing%20Information/Testopel_prescribing_information.html" **under References**. 8. **Removed** "http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=f60c5520-b336-44a2-95d5-f274939fa595", "http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=a0af5e80-8d01-4aa9-9f33-926735fdd38a", **and** "http://www.upsher-smith.com/wp-content/uploads/ANDROXY_PI.pdf" **under References**. 9. **Added** "http://www.rxabbvie.com/pdf/androgel1_62_PI.pdf", "http://www.upsher-smith.com/wp-content/uploads/Vogelxo-MI.pdf", **and** "http://endo.com/File%20Library/Products/Prescribing%20Information/Natesto_prescribing_information.html" **under References**.
11/21/2013	1. Adapted policy to new format. 2. **Added** Fortesta® (testosterone gel) and Striant® (testosterone buccal) **to "**Non-preferred, prior authorization required" product list. 3. **Changed GPI codes from** "2310003000, 2310003010, 2310003020, 2130001030, 23100010000, 23100020000" **to** "2310001000, 2310002000, 2310003000, 2310003010, 2310003020". 4. Changed Prior Authorization Criteria from: "Documented diagnosis of 253.4 or 257.2; Males only; Must have symptoms of testosterone deficiency; Must have two morning testosterone levels below the individual lab's reference range (different laboratories use different assays and thus may have different ranges which are considered low, optimal, or high); Minimum age requirement: 19 years old; Non-preferred products require a documented trial and failure of or contraindication to a preferred product (tesosterone cypionate, testosterone enanthate, and Androgel®); Minimum age requirement: 19 years old" **to**: "I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis: A. Hypogonadism (for all products) and criteria 1 through 4 are met: 1. Males only, 2. Patient must have symptoms of testosterone deficiency, 3. Patient must have two morning testosterone levels below the individual lab's reference range (different laboratories use different assays and thus may have different ranges which are considered low, optimal, or high), 4. Minimum age requirement: 18 years old; B. Delayed Puberty (for Android®, Androxy®, Methitest™, Testopel®, Testred® only) and criterion 1 is met: 1. Males only; C. Advancing inoperable metastatic (skeletal) mammary cancer (for Android®, Androxy®, Methitest™, Testred® only) and criteria 1 through 4 are met: 1. Females only, 2. Patient is 1 to 5 years postmenopausal, 3. Patient has had an incomplete response to other therapies for metastatic mammary cancer, 4. Prescribing physician is an oncologist. II. Non-preferred products require a documented trial and failure of, intolerance to, or contraindication to a preferred product (testosterone cypionate, testosterone enanthate, AndroGel®)". 5. **Added** "Men with carcinomas of the breast or with known or suspected carcinomas of the prostate; Women who are or may become pregnant" **to Exclusion Criteria**. 6. Changed Quantity/Days Supply Restrictions from: "Androderm®: 30 patches per 30 days, Androgel®: 300 grams per 30 days, Android®: 90 tablets per 30 days, Androxy®: 120 tablets per 30 days, Axiron®: 90 grams per 30 days, Methitest®: 150 tablets per 30 days, Testim®: 150 grams per 30 days, Testopel®: 1 per 90 days, Testred®: 150 capsules per 30 days" **to:** "Hypogonadism: Androderm®: 60 patches per 30 days, AndroGel®: 300 grams per 30 days, Android®: 150 capsules per 30 days, Androxy®: 60 tablets per 30 days, Axiron®: 2 pump

	botttles per 30 days, Fortesta®: 2 pump cansiters per 30 days, Methitest™: 150 tablets per 30 days, Striant® : 60 tablets per 30 days, Testim®: 300 grams per 30 days, Testopel®: 6 pellets per 90 days, Testred®: 150 capsules per 30 days; Delayed Puberty: Android®: 150 capsules per 30 days, Androxy®: 60 tablets per 30 days. Methitest™: 150 tablets per 30 days, Testopel®: 6 pellets per 90 days, Testred®: 150 capusles per 30 days; Advancing inoperable metastatic mammary cancer: Android®: 600 capsules per 30 days, Androxy®: 120 tablets per 30 days, Methitest™: 600 tablets per 30 days, Testred®: 600 capsules per 30 days". 7. Changed Re-Authorization from: "6 months at a time. Must be accompanied by two morning testosterone levels in order to verify drug absorption" **to:** "6 months at a time. An updated letter of medical necessity or progress notes showing the medication is effective. Hypogonadism requests must also be accompanied by two morning testosterone levels in order to verify drug absorption". 8. **Updated references** to include specific website address for Utah Medicaid policy used, Regence policy, BCBSNC policy, Carolina Blues policy, and website addresses for package inserts.