Mass General Brigham
Health Plan

Testosterone Products
Effective 04/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☐ Prior Authorization ☐ Quantity Limit ☒ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview
Prescriptions that meet the initial step therapy requirements will adjudicate automatically at the point of sale. If the prescription does not meet the initial step therapy requirements, the prescription will deny with a message indicating that prior authorization (PA) is required. Refer to the criteria below and submit a PA request for the members who do not meet the initial step therapy requirements at the point of sale.

Initial Step-Therapy Requirements:
First-Line: Medications listed on first-line are covered without prior-authorization.
Second-Line: Second-line medications will pay if the member has filled at least two different first-line medications or a second-line medication within the past 180 days.

Coverage Guidelines
If a member does not meet the initial step therapy requirements, then approval of a second-line medication will be granted if the member has had a documented inadequate response or side effect to at least two different 1st-line testosterone products **OR** the member has documented clinical rationale to avoid therapy with all first-line agents.

FIRST-LINE	SECOND-LINE
Testosterone enanthate injection Testosterone cypionate injection Testosterone topical gel 1% *(compare to AndroGel or Testim)* Testosterone topical gel pump 1% (*compare to Vogelxo)* Testosterone topical gel 2% *(compare to Fortesta Gel)*	Androderm patch 2mg/24hr and 4mg/24hr Testosterone topical solution 30 mg/act *(compare to Axiron solution)* Testosterone topical gel 1.62% *(compare to AndroGel Pump* 1.62%) Testosterone topical 1.62% *(compare to AndroGel topical 1.62%)*

FIRST-LINE	SECOND-LINE
	Jatenzo (testosterone undecanoate) Kyzatrex (testosterone undeconoate) Tlando (testosterone undecanoate) Xyosted (testosterone enanthate) auto-injector

NOTE: Testopel is covered on the Medical Benefit only. Please refer to the Medical Specialty Drug list criteria.

References

1. Testim (testosterone) [prescribing information]. Malvern, PA: Endo Pharmaceuticals; April 2018.
2. AndroGel 1% (testosterone) [prescribing information]. North Chicago, IL: AbbVie Inc; May 2015.
3. AndroGel 1.62% (testosterone) [prescribing information]. North Chicago, IL: AbbVie Inc; May 2019
4. Axiron (testosterone) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; February 2017.
5. AndroGel 1.62% (testosterone) [prescribing information]. North Chicago, IL: AbbVie Inc; October 2016.
6. Testosterone gel [prescribing information]. Baudette, MN: Ani Pharmaceuticals, Inc; October 2016.
7. Androderm (testosterone) transdermal system [prescribing information]. Irvine, CA: Allergan USA, Inc; October 2016.
8. 38. Fortesta (testosterone) gel [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc; July 2017.
9. Bhasin S, Cunningham GR, Hayes FJ, et al. Testosterone therapy in men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2010;95(6):2536-2559.[PubMed 20525905]
10. Therapeutic activity of testosterone in metastatic breast cancer Anticancer Res. 2014 Mar;34(3):1287-90.
11. Hormone therapy for transgender patients: Journal List Transl Androl Urolv.5(6); 2016 Dec PMC518222
12. Testosterone Therapy Improves the First Year Height Velocity in Adolescent Boys with Constitutional Delay of Growth and Puberty: Int J Endocrinol Metab. 2017 Apr; 15(2): e42311.
13. Xyosted (testosterone) [prescribing information]. Ewing, NJ: Antares Pharma, Inc; September 2018.

Review History

09/18/2017: Reviewed
09/24/2018: Reviewed
01/22/2019: Removed clinical rationale from criteria. Only requirement is trials of other 1st line or 2nd line medications.
03/18/2020: Updated (added Jatenzo to 2nd line agent) (effective 6/1/20)
05/19/2021: Updated and Reviewed; Second line agents updated as generic formulations are now available for Androgel Pump 1.62% and Androgel topical 1.62%; generic testosterone 1.62% (compare to Androgel) replaced Androgel 1.62%. Effective 08/01/2021.
07/20/2022: Updated and Reviewed for July P&T; Added new formulations Tlando as a second line agent. Effective 09/01/2022
09/21/2022: Reviewed and updated for Sept P&T. Added Xyosted as a second line agent. References updated. Separated out Comm/Exch vs. MH. Effective 1/1/2023.
01/11/2023: Reviewed and Updated for Jan P&T; Added new formulation Kyzatrex to ST program as a second line agent. Effective 4/1/2023