SmartPA Criteria Proposal

Drug/Drug Class:	Androgenic Agents PDL Edit
First Implementation Date:	December 31, 2008
Revised Date:	July 1, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Male hypogonadism is caused by insufficient production of testosterone. It is most often characterized by low serum concentration, presenting as testosterone deficiency, infertility, or both. Causes of hypogonadism are classified as primary or secondary. Primary male hypogonadism includes conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, chemotherapy, or toxic damage from alcohol or heavy metals. These patients usually present with low testosterone levels and elevated follicle stimulating hormone, and luteinizing hormone levels. Secondary hypogonadism includes idiopathic gonadotropin or luteinizing hormone releasing hormone deficiency and pituitary hypothalamic injury from tumors, trauma, or radiation. Supplementation of endogenous testosterone can maintain secondary sex characteristics, optimize bone density, and restore fertility.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	• Androderm® Gel Patch • Testosterone Cypionate • Testosterone Enanthate • Testosterone 1.62% Pump (gen AndroGel® 1.62% Pump)	• Anadrol®-50 • AndroGel® • Android® • Aveed® • Depo®-Testosterone • Fortesta® • Jatenzo® • Methitest™ • Methyltestosterone Caps • **Natesto®** • Striant® • Testim® • Testopel® • Testosterone 1% Pump (gen AndroGel®) • Testosterone Gel (gen Fortesta®) • Testosterone Gel (gen Testim®) • Testosterone Gel Pack (gen AndroGel® Pack) • Testosterone Gel Pump (gen Axiron®) • Testred® • Vogelxo® • Xyosted™

Type of Criteria:	☐ **Increased risk of ADE**	☒ **Preferred Drug List**
	☐ **Appropriate Indications**	☐ **Clinical Edit**
Data Sources:	☐ **Only Administrative Databases**	☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Androgenic Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 3 or more preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

1. Evidence-Based Medicine and Fiscal Analysis: “Topical Androgenic Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; January 2021.
2. Evidence-Based Medicine Analysis: “Topical Androgenic Agents”, UMKC-DIC; October 2020.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2021.
4. USPDI, Micromedex; 2021.
5. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.