TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Estradiol Topical Products

Effective: February 14, 2017

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

This Pharmacy Medical Necessity Guidelines applies to the following:	Fax Numbers:
Tufts Health Plan Commercial Plans	
☐ Tufts Health Plan Commercial Plans – large group plans	
☐ Tufts Health Plan Commercial Plans – small group and individual plans	
Tufts Health Public Plans	RXUM: 617-673-0988
☐ Tufts Health Direct – Health Connector	
☒ Tufts Health Together – A MassHealth Plan	
☐ Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan	
Tufts Health Freedom Plan products	
☐ Tufts Health Freedom Plan - large group plans	
☐ Tufts Health Freedom Plan - small group plans	

OVERVIEW

FDA-APPROVED INDICATION

The estradiol-containing topical products, Divigel®, Elestrin®, Estrasorb™, EstroGel®, and Evamist®, are indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause.

EstroGel is also indicated for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy associated with menopause.

COVERAGE GUIDELINES

The plan may authorize coverage of transdermal estradiol products for Members when **all** of the following criteria for a particular regimen are met and limitations do not apply:

1. The request is for a female patient with the diagnosis of menopause or conditions associated with menopause or peri-menopause
2. The Member tried and failed therapy with an estradiol transdermal patch, or the provider indicates clinical inappropriateness of treatment with an estradiol transdermal patch

LIMITATIONS

None

CODES

None

REFERENCES

1. Divigel (estradiol gel) [prescribing information]. Sayrevlle, NJ: Vertical Pharmaceuticals, LLC; May 2014.
2. Elestrin (estradiol gel) [prescribing information]. Philadelphia, PA: Azur Pharma; July 2010.
3. Estrasorb (estradiol topical emulsion) [prescribing information]. Scottsdale, AZ: Medicis; December 2011.
4. EstroGel (estradiol gel) [prescribing information]. Herndon, VA: Ascend Therapeutics; January 2008
5. Evamist (estradiol transdermal spray) [prescribing information]. Chesterfield, MO: Ther-Rx Corporation; March 2014.
6. North American Menopause Society. The 2012 hormone therapy position statement of The North American Menopause Society. Menopause. 2012;19(3):257-271
7. Lexi-Drugs Online: Estradiol (Topical) [cited May 7, 2013]. Available from: http://online.lexi.com/crlsql/servlet/crlonline
8. Minivelle Prescribing Information. Noven Pharmaceuticals, Inc. October, 2012.

APPROVAL HISTORY

June 13, 2013: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 12, 2014: No changes
- August 11, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.

- February 14, 2017: Effective 2/14/17, retired Medical Necessity Guideline
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink^{SM} Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.