MEDICAL MUTUAL®

Drug Policy

Policy:	**Estrogen Transdermal (Non-Patch)** **Preferred Step Therapy Policy** • Estradiol gel 0.1% – generics • Estradiol gel 0.06% – generic • Evamist™ (estradiol transdermal spray – Perrigo Pharmaceuticals)	**Annual Review Date: 07/18/2024** **Last Revised Date: 07/18/2024**

OVERVIEW

All of the transdermal (non-patch) estrogen products are indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause. In addition, EstroGel is also indicated for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy (VVA) associated with menopause. When EstroGel is prescribed solely for the treatment of moderate to severe symptoms of VVA, a topical vaginal product should be considered. There are no direct head-to-head comparative trials available with these agents.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients with a history of one preferred product within the 130-day look-back period are excluded from this preferred step therapy.

Preferred Products: estrogen patches (generic)
Non-preferred products: estradiol 0.1% gel, estradiol 0.06% gel, Evamist

RECOMMENDED AUTHORIZATION CRITERIA

1. If the patient has tried a preferred product, then authorization for a non-preferred product may be given.

2. If the patient has tried brand Climara patches, brand Minivelle patches, or brand Vivelle-Dot patches, approve a non-preferred product.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year (365 days)
B) *Extended Approval:* 1 year (365 days)

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

- EstroGel® [prescribing information]. Herndon, VA: Ascend Therapeutics, Inc.; August 2014.
- Elestrin™ [prescribing information]. San Antonio, TX: DPT Laboratories; June 2012.
- Divigel® [prescribing information]. Sayreville, NJ: Upsher Smith Laboratories; May 2014.

- Evamist™ [prescribing information]. San Antonio, TX; DPT Laboratories; March 2014.
- AACE Menopause Guidelines Revision Task Force. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of menopause. *Endocr Pract.* 2011;17:949-954.
- De Villiers TJ, Gass MLS, Haines CJ, et al. Global consensus statement on menopausal hormone therapy. *Climacteric.* 2013;16:203-204.
- North American Menopause Society. The 2012 hormone therapy position statement of the North American Menopause Society. *Menopause.* 2012;19:257-271.
- North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause.* 2013;20(9):888-902