

STEP THERAPY POLICY

- POLICY:** Estrogen – Transdermal Step Therapy Policy
- Climara® (estradiol patches – Bayer, generics)
 - Divigel® (estradiol gel 0.1% – Vertical, generics)
 - Elestrin™ (estradiol gel 0.06% – Meda)
 - EstroGel® (estradiol gel 0.06% – Ascend, generic)
 - Evamist™ (estradiol transdermal spray – Padagis)
 - Minivelle® (estradiol patches – Noven, generics)
 - Vivelle-Dot® (estradiol patches – Novartis, generics)

REVIEW DATE: 06/12/2024

OVERVIEW

All of the transdermal estrogen products are indicated for the treatment of **moderate to severe vasomotor symptoms associated with menopause**.^{1-7,12} EstroGel (estradiol gel 0.06%, generic) and the estradiol patches, Climara and Vivelle-Dot (and generics), are also indicated for the treatment of moderate to **severe symptoms of vulvar and vaginal atrophy associated with menopause**.^{1,5,7} Climara, Minivelle, and Vivelle-Dot (and generics) are all additionally indicated for the **prevention of postmenopausal osteoporosis**.⁵⁻⁷ Climara and Vivelle-Dot (and generics) have an additional indication for the treatment of **hypoestrogenism due to hypogonadism, castration, or primary ovarian failure**.^{5,7}

Guidelines

Hormone therapy is the most effective treatment for vasomotor symptoms associated with menopause and genitourinary symptoms of menopause.⁸ Systemic estrogen therapy can be used when vasomotor symptoms are present.⁹ Hormone therapy should be individualized, taking into account the indication(s) or evidence-based treatment goals and considering the woman's age and/or time since menopause in relation to initiation or continuation, the woman's personal health risks and preferences, and the balance of potential benefits and risk of hormonal versus non-hormonal therapies. Multiple guidelines, including from the American Academy of Clinical Endocrinologists (2017) and the American College of Obstetricians and Gynecologists (reaffirmed 2019), note that transdermal use of estrogen as compared with oral estrogen products may be less likely to produce thrombotic risk; although neither guidelines recommend a specific transdermal agent.^{10,11}

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy

Step 1: estradiol patches (generic)

Step 2: Elestrin, EstroGel, Evamist, Divigel, estradiol 0.1% gel, estradiol 0.06% gel

06/12/2024

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CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. If the patient has tried brand Climara patches, brand Minivelle patches, or brand Vivelle-Dot patches, approve a Step 2 Product.
3. No other exceptions are recommended.

REFERENCES

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2. Elestrin[™] gel [prescribing information]. Canonsburg, PA: Meda; December 2023.
3. Divigel[®] gel [prescribing information]. Alpharetta, GA: Vertical; May 2023.
4. Evamist[™] transdermal spray [prescribing information]. Allegan, MI: Padagis; December 2023.
5. Climara[®] patches [prescribing information]. Whippany, NJ: Bayer; December 2023.
6. Minivelle[®] patches [prescribing information]. Miami, FL: Noven; February 2024.
7. Vivelle-Dot[®] patches [prescribing information]. East Hanover, NJ: Novartis; October 2021.
8. North American Menopause Society. The 2022 hormone therapy position statement of the North American Menopause Society. *Menopause*. 2022;29:767-794.
9. North American Menopause Society (NAMS). NAMS Position Statement. The 2020 genitourinary syndrome of menopause position statement of The North American Menopause Society. Available at: <http://www.menopause.org/publications/professional-publications/position-statements-other-reports>. Accessed on May 31, 2024.
10. AACE Reproductive Endocrinology Scientific Committee. American Association of Clinical Endocrinologists and American College of Endocrinology position statement on menopause 2017 update. *Endocr Pract*. 2017;23(7):869-880.
11. The American College of Obstetricians and Gynecologists. Postmenopausal estrogen therapy: route of administration and risk of venous thromboembolism. Committee on Gynecologic Practice. Committee Opinion Number 556. April 2013 (reaffirmed 2019).
12. Estradiol gel 0.1% [prescribing information]. Florham Park, NJ: Xiromed; February 2024.
13. Estradiol gel 0.06% [prescribing information]. Bridgewater, NJ: Solaris; April 2024.