



## STEP THERAPY POLICY

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

**REVIEW DATE:** 07/05/2023

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### **INSTRUCTIONS FOR USE**

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

## **CIGNA NATIONAL FORMULARY COVERAGE:**

### **OVERVIEW**

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

### **Guidelines**

Hormone therapy is the most effective treatment for vasomotor symptoms associated with menopause and genitourinary symptoms of menopause.<sup>8</sup> Systemic estrogen therapy can be used when vasomotor symptoms are present.<sup>9</sup> 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.<sup>10,11</sup>

## **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.

**Estrogen – Transdermal product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.**

**Step 1:** estradiol patches (generic)

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

## **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.

## **REFERENCES**

1. EstroGel® gel [prescribing information]. Herndon, VA: Ascend; December 2021.
2. Elestrin™ gel [prescribing information]. Somerset, NJ: Meda; October 2020.
3. Divigel® gel [prescribing information]. Bridgewater, NJ: Vertical; April 2022.
4. Evamist™ transdermal spray [prescribing information]. Minneapolis, MN: Perrigo; August 2021.
5. Climara® patches [prescribing information]. Whippany, NJ: Bayer; September 2021.
6. Minivelle® patches [prescribing information]. Miami, FL: Noven; October 2021.
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 June 19, 2023.
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; August 2022.

## HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	06/15/2022
Selected Revision	<b>Estradiol 0.1% gel:</b> Added estradiol 0.1% gel (generic Divigel) as a Step 2 product.	11/2/2022
Annual Revision	No criteria changes	7/5/2023

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