Effective Date **1/15/2024**
Next Review Date **1/15/2025**
Coverage Policy Number **IP0590**

Estrogen - Transdermal

Table of Contents

Related Coverage Resources

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.

Overview

This policy supports medical necessity review for formulary exceptions to the following non-covered transdermal estrogen products:

- **Climara®** (estradiol patch)
- **Climara Pro®** (estradiol/levonorgestrel patch)
- **Divigel®** (estradiol gel 0.1%)
- **Elestrin™** (estradiol gel 0.06%)
- **Minivelle®** (estradiol patch)
- **Vivelle-Dot®** (estradiol patch)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

Non-Covered Product	Criteria
Climara (estradiol patch)	**Climara patch** is considered medically necessary when there is documentation of a trial of **estradiol transdermal patch** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.
Climara Pro (estradiol/levonorgestrel patch)	**Climara Pro patch** is considered medically necessary when there is documentation of failure, contraindication, or intolerance to CombiPatch® (estradiol/norethindrone acetate) transdermal patch.
Divigel (estradiol gel 0.1%)	**Divigel gel** is considered medically necessary when there is documentation of failure, contraindication, or intolerance to EstroGel® (estradiol gel 0.06%).
Elestrin (estradiol gel 0.06%)	**Elestrin gel** is considered medically necessary when there is documentation of failure, contraindication, or intolerance to EstroGel® (estradiol gel 0.06%).
Minivelle (estradiol patch)	**Minivelle patch** is considered medically necessary when there is documentation of a trial of **estradiol transdermal patch** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.
Vivelle-Dot (estradiol patch)	**Vivelle-Dot patch** is considered medically necessary when there is documentation of a trial of **estradiol transdermal patch** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of transdermal estrogen products is considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months

Reauthorization approval duration: up to 12 months

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.
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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.