



DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Estrogens (Topical) – Patches Drug Quantity Management Policy – Per Days
- Climara® (estradiol transdermal system [patch] – Bayer; generic)
 - Menostar® (estradiol transdermal system [patch] – Bayer)
 - Minivelle® (estradiol transdermal system [patch] – Noven; generic, Lyllana®)
 - Vivelle-Dot® (estradiol transdermal system [patch] – Noven/Sandoz; generic, Dotti®)

REVIEW DATE: 01/29/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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

Climara (generic) and Vivelle-Dot (generic) are indicated for:^{1,4}

- Prevention of **postmenopausal osteoporosis**.
- Treatment of moderate or severe **vasomotor symptoms** associated with menopause.
- Moderate or severe **vulvar/vaginal atrophy** associated with menopause.
- **Hypoestrogenism** due to hypogonadism, castration (ovariectomy), or primary ovarian failure.

Minivelle (generic) is indicated for the treatment of:³

- Moderate to severe **vasomotor symptoms** due to menopause.
- Prevention of **postmenopausal osteoporosis**.

Menostar is the only estrogen patch product with the single indication for **prevention of postmenopausal osteoporosis.**²

Dosing and Availability

Table 1. Strength and Dosing for Estrogen Patches.¹⁻⁴

Product	Strengths Available (mg/24 hour)	Package Sizes	Dosing Frequency
Climara® (estradiol transdermal system, generic)	0.025, 0.0375, 0.05, 0.06, 0.075, 0.1	4 patches per box	Once weekly
Menostar® (estradiol transdermal system)	0.014	4 patches per box	Once weekly
Minivelle™ (estradiol transdermal system, generic, including Lyllana™)	0.025, 0.0375, 0.05, 0.075, 0.1	8 patches per box	Twice weekly
Vivelle-Dot® (estradiol transdermal system, generic, including Dotti™)	0.025, 0.0375, 0.05, 0.075, 0.1	8 patches per box	Twice weekly

Off-Label Uses

Estrogens have been used off-label in protocols for **Assisted Reproductive Technology** procedures.⁵ In these protocols, estrogens are used to prepare the endometrium, usually at higher doses than are used for labeled indications. Generally, transdermal estrogens are preferred over oral estrogens due to the bypass of the first-pass metabolism by the liver. This allows administration of estrogen at lower doses to possibly reduce the risk of adverse events.

Estrogens are also used off-label for hormone replacement in **gender-dysphoria/gender-incongruent persons and persons undergoing male-to-female gender reassignment.**⁶ Guidelines from the Endocrine Society (2017) note that transdermal estradiol patches can be used, with a new patch placed every 3 to 5 days. The guideline-recommended dose of estradiol transdermal patches ranges from 0.025 to 0.2 mg/day.

POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent the stockpiling, misuse, and/or overuse of the estrogen patch products. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. Note: Combination estrogen patches (e.g., Climara Pro® [estradiol/levonorgestrel transdermal system]) are subject to quantity limits, but are not included in this policy as they do not have override criteria. Approvals are provided for 1 year in duration, unless otherwise noted below. "One-time" approvals are provided for 30 days in duration.

Drug Quantity Limits

Product	Strengths (mg/24 hour)	Package Sizes	Retail Maximum Quantity per 28 Days*	Home Delivery Maximum Quantity per 84 Days*
Climara® (estradiol transdermal system, generic)	0.025, 0.0375, 0.05, 0.06, 0.075, 0.1	4 patches per box	4 patches	12 patches
Menostar® (estradiol transdermal system)	0.014	4 patches per box		
Minivelle® (estradiol transdermal system, generic, including Lyllana®)	0.025, 0.0375, 0.05, 0.075, 0.1	8 patches per box	8 patches	24 patches
Vivelle-Dot® (estradiol transdermal system, generic, including Dotti®)	0.025, 0.0375, 0.05, 0.075, 0.1	8 patches per box		

* The quantity limit accumulates (is combined) for weekly patches and semiweekly patches.

Estrogens (Topical) – Patches Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Climara 0.025 mg/24 hr, 0.0375 mg/24 hr, 0.05 mg/24 hr, and 0.06 mg/24 hr transdermal patches (generic)

1. If the patient is changing strengths to another once-weekly patch within the same month, approve a one-time override for 4 additional patches at retail or 12 additional patches at home delivery.
Note: At retail, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 28 days plus 4 patches. At home delivery, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 84 days plus 12 patches. ONE override may be approved ONCE every 30 days.
2. If the patient is using the patch in a protocol for Assisted Reproductive Technology procedures (e.g., *in vitro* fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer) AND infertility is a covered benefit, approve the requested quantity at retail or home delivery.

Climara 0.075 mg/24 hr transdermal patch (generic)

1. If the patient is changing strengths to another once-weekly patch within the same month, approve a one-time override for 4 additional patches at retail or 12 additional patches home delivery.
Note: At retail, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 28 days plus 4 patches. At home delivery, the approval quantity should be the number of estradiol

transdermal patches the patient has received in the past 84 days plus 12 patches. ONE override may be approved ONCE every 30 days.

2. If the patient requires two patches to be applied simultaneously, approve 8 patches per 28 days at retail or 24 patches per 84 days at home delivery.
3. If the patient is using the patch in a protocol for Assisted Reproductive Technology procedures (e.g., *in vitro* fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer) AND infertility is a covered benefit, approve the requested quantity at retail or home delivery.

Climara 0.1 mg/24 hr transdermal patch (generic)

1. If the patient is changing strengths to another once-weekly patch within the same month, approve a one-time override for 4 additional patches at retail or 12 additional patches at home delivery.

Note: At retail, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 28 days plus 4 patches. At home delivery, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 84 days plus 12 patches. ONE override may be approved ONCE every 30 days.

2. If the patient requires two patches to be applied simultaneously, approve 8 patches per 28 days at retail or 24 patches per 84 days at home delivery.
3. If the patient is using the patch in a protocol for Assisted Reproductive Technology procedures (e.g., *in vitro* fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer) AND infertility is a covered benefit, approve the requested quantity at retail or home delivery.

Menostar 0.014 mg/24 hr transdermal patch

1. If the patient is changing strengths to another once-weekly patch within the same month, approve a one-time override for 4 additional patches at retail or 12 additional patches at home delivery.

Note: At retail, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 28 days plus 4 patches. At home delivery, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 84 days plus 12 patches. ONE override may be approved ONCE every 30 days.

Minivelle 0.025 mg/24 hr, 0.0375 mg/24 hr, and 0.05 mg/24 hr transdermal patches (generic); Vivelle-Dot 0.025 mg/24 hr, 0.0375 mg/24 hr, and 0.05 mg/24 hr transdermal patches (generic)

1. If the patient is changing strengths to another twice-weekly patch within the same month, approve a one-time override for 8 additional patches at retail or 24 additional patches at home delivery.

Note: At retail, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 28 days plus 8 patches. At home delivery, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 84 days plus 24 patches. ONE override may be approved ONCE every 30 days.

2. If the patient is using the patch in a protocol for Assisted Reproductive Technology procedures (e.g., *in vitro* fertilization, gamete intrafallopian transfer,

zygote intrafallopian transfer) AND infertility is a covered benefit, approve the requested quantity at retail or home delivery.

Minivelle 0.075 mg/24 hr transdermal patch (generic), Vivelle-Dot 0.075 mg/24 hr transdermal patch (generic)

1. If the patient is changing strengths to another twice-weekly patch within the same month, approve a one-time override for 8 additional patches at retail or 24 additional patches at home delivery.

Note: At retail, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 28 days plus 8 patches. At home delivery, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 84 days plus 24 patches. ONE override may be approved ONCE every 30 days.

2. If the patient requires two patches to be applied simultaneously, approve 16 patches per 28 days at retail or 48 patches per 84 days at home delivery.
3. If the patient is using the patch in a protocol for Assisted Reproductive Technology procedures (e.g., *in vitro* fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer) AND infertility is a covered benefit, approve the requested quantity at retail or home delivery.

Minivelle 0.1 mg/24 hr transdermal patch (generic), Vivelle-Dot 0.1 mg/24 hr transdermal patch (generic)

1. If the patient is changing strengths to another twice-weekly patch within the same month, approve a one-time override for 8 additional patches at retail or 24 additional patches at home delivery.

Note: At retail, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 28 days plus 8 patches. At home delivery, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 84 days plus 24 patches. ONE override may be approved ONCE every 30 days.

2. If the patient requires two patches to be applied simultaneously, approve 16 patches per 28 days at retail or 48 patches per 84 days at home delivery.
3. If the patient is using the patch in a protocol for Assisted Reproductive Technology procedures (e.g., *in vitro* fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer) AND infertility is a covered benefit, approve the requested quantity at retail or home delivery.
4. If the patient is a gender-dysphoric/gender-incongruent person or a person undergoing male-to-female gender reassignment, approve the requested quantity, not to exceed 32 patches per 28 days at retail or 96 patches per 84 days at home delivery.

REFERENCES

1. Climara® transdermal system [prescribing information] Whippany, NJ: Bayer; December 2023.
2. Menostar® transdermal system [prescribing information]. Whippany, NJ: Bayer; December 2023.
3. Minivelle® transdermal system [prescribing information]. Miami, FL: Noven; February 2024.
4. Vivelle-Dot® transdermal system [prescribing information]. Miami, FL/Princeton, NJ: Noven/Sandoz; February 2024.
5. Vartanyan E, Tsaturova K, Devyatova E. Thin endometrium problem in IVF programs. *Gynecol Endocrinol*. 2020; 36(sup 1):24-27.
6. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric-gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017; 102(11): 3869-3903.

History

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	04/22/2024
Early Annual Revision	<p>Alora 0.025 mg/24 hr, 0.05 mg/24 hr, 0.075 mg/24 hr, and 0.1 mg/24 hr transdermal patches were removed from the policy (obsolete).</p> <p><u>Climara 0.025 mg/24 hr, 0.0375 mg/24 hr, 0.05 mg/24 hr, 0.06 mg/24 hr, 0.075 mg/24 hr, and 0.1 mg/24 hr transdermal patches (generic) and Menostar 0.014 mg/24 hr transdermal patch:</u> <u>Criteria were updated to approve a one-time override for 4 additional patches at retail or 12 additional patches at home delivery if the patient is changing strengths to another once-weekly patch within the same month. Previously, criteria approved a one-time override for 4 additional patches at retail or home delivery.</u> Criteria Note was updated to clarify "At retail, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 28 days plus 4 patches. At home delivery, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 84 days plus 12 patches. ONE override may be approved ONCE every 30 days."</p> <p><u>Minivelle 0.025 mg/24 hr, 0.0375 mg/24 hr, 0.05 mg/24 hr, 0.075 mg/24 hr, and 0.1 mg/24 hr transdermal patches (generic); Vivelle-Dot 0.025 mg/24 hr, 0.0375 mg/24 hr, 0.05 mg/24 hr, 0.075 mg/24 hr, and 0.1 mg/24 hr transdermal patches (generic)</u> <u>Criteria were updated to approve a one-time override for 8 additional patches at retail or 24 additional patches at home delivery if the patient is changing strengths to another once-weekly patch within the same month. Previously, criteria approved a one-time override for 8 additional patches at retail or home delivery.</u> Criteria Note was updated to clarify "At retail, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 28 days plus 8 patches. At home delivery, the approval quantity should be the number of estradiol transdermal patches the patient has received in the past 84 days plus 24 patches. ONE override may be approved ONCE every 30 days."</p>	01/29/2025

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