MEDICAL MUTUAL®

Drug Policy

Policy:	**Estrogen-Progestin Combination (patches) Preferred Step Therapy**	**Annual Review Date: 10/19/2023**
Impacted Drugs:	**Climara Pro**	**Last Revised Date: 10/19/2023**

OVERVIEW

CombiPatch and Climara Pro are transdermal hormone replacement therapy (HRT) products that combine an estrogen and a progestin. Of these two combination estrogen-progestin patch products, only Climara Pro is indicated for the prevention of postmenopausal osteoporosis. The 2017 hormone therapy position statement by the North American Menopause Society states that hormone therapy is recommended as first-line therapy for bothersome vasomotor symptom; it may be considered as a primary therapy for prevention of bone loss and fracture in postmenopausal women at elevated risk of osteoporosis or factures; and is recommended until at least the median age of menopause in women with hypoestrogenism caused by hypogonadism, primary ovarian insufficiency, or premature surgical menopause.

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 non-preferred product at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 12 months in duration.

Preferred product: CombiPatch

Non-preferred product: Climara Pro

PREFERRED STEP THERAPY CRITERIA (FOR APPLICABLE REVIEWS)

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

2. Exceptions can be made for Climara Pro if it is being used for the prevention of postmenopausal osteoporosis.

Approval Duration: 365 days (1 year)

Step Therapy Exception Criteria

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 products. If so, please list specific diagnosis and/or specific patient characteristics [documentation required]; **OR**

B. The patient has a contraindication to all preferred products. If so, please list the specific contraindications to each preferred product [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred product 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 product for 90 days within a 130-day look-back period; 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 product for 90 days AND that the patient has been receiving the requested non-preferred product 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 product); OR
    3. There are no generic alternatives to the requested non-preferred product [NOTE: ESI reviewer to list generic alternatives for requested non-preferred medication and confirm accuracy of physician response]

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other products, 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

1. CombiPatch® [prescribing information]. Miami, FL: Noven Therapeutics, LLC; December 5, 2022.
2. Climara Pro® [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; March 2023.
3. The NAMS 2017 Hormone Therapy Position Statement Advisory Panel. The 2017 hormone therapy position statement of The North American Menopause Society. *Menopause.* 2017;24(7):728-753.
4. Jewelewicz R. New developments in topical estrogen therapy. *Fertil Steril.* 1997;67:1-12.
5. Field CS, Ory SJ, Wahner HW, et al. Preventive effects of transdermal 17 beta-estradiol on osteoporotic changes after surgical menopause: a two-year placebo-controlled trial. *Am J Obstet Gynecol.* 1993;168(1 Pt 1):114-121.

6. Hirvonen E, Cacciatore B, Wahlstrom T, Rita H, Wilen-Rosenqvist G. Effects of transdermal oestrogen therapy in postmenopausal women: a comparative study of an oestradiol gel and an oestradiol delivering patch. *Br J Obstet Gynaecol.* 1997;104 Suppl 16:26-31.
7. Estradiol/levonorgestrel. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 25 September 2023. Accessed 13 October 2023.
8. Estradiol/norethindrone acetate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 25 September 2023. Accessed 13 October 2023.