

Clinical Policy: Endocrine Agents: Estrogenic Agents

Reference Number: OH.PHAR.PPA.51

Effective Date: 01/01/2020

Last Review Date:

[Revision Log](#)

Line of Business: Medicaid

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

ESTROGENS – ORAL ESTROGENS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ESTRADIOL (generic of Estrace®) ESTROPIPATE MENEST® (esterified estrogens) PREMARIN® (conjugated estrogens)	

ESTROGENS – ORAL ESTROGEN/PROGESTERONE COMB

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ETHINYL ESTRADIOL/NORETHINDRONE ACETATE (generic of FemHRT®) FEMHRT® (norethindrone/ethinylestradiol) PREMPHASE® (medroxyprogesterone/estrogens conj) PREMPRO® (medroxyprogesterone/estrogens conj)	ANGELIQ® (drospirenone/estradiol) ESTRADIOL/NORETHINDRONE ACETATE tablets (generic of Activella®) PREFEST® (estradiol/norgestimate)

ESTROGENS & ESTROGEN AGONIST/ANTAGONIST COMB

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	DUAVEE (conjugated estrogens/bazedoxifene)

ENDOCRINE AGENTS: ESTROGENS – TRANSDERMAL ESTROGENS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ALORA® patch (estradiol) ESTRADIOL patch (generic of Climara®, Vivelle-Dot®)	DIVIGEL® transdermal gel (estradiol) ELESTRIN® transdermal gel (estradiol) EVAMIST® transdermal solution (estradiol) MENOSTAR® patch (estradiol) MINIVELLE® patch (estradiol)

ESTROGENS – TRANSDERMAL ESTROGEN/ PROGESTERONE COMB

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CLIMARA PRO® (estradiol/levonorgestrel oral) COMBIPATCH® (estradiol/norethindrone)	

ESTROGENS – VAGINAL ESTROGENS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ESTRING® vaginal ring (estradiol) PREMARIN® vaginal cream (estrogens conjugated) Estradiol vaginal cream (generic of Estrace®)	ESTRACE® vaginal cream (estradiol) FEMRING® vaginal ring (estradiol) VAGIFEM® vaginal tablet (estradiol)

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Estradiol is indicated for:

- Systemic treatment of the vasomotor symptoms (hot flashes) and genitourinary symptoms of menopause (oral, transdermal, topical, vaginal ring dosages)
- Treatment of isolated vaginal and/or urogenital symptoms of menopause (vaginal cream/ring, tablet dosages)
- Osteoporosis prophylaxis in women due to menopause (either natural or surgical); (oral, transdermal dosages)
- Estrogen replacement for premenopausal women with primary ovarian failure or female hypogonadism (oral, transdermal dosages)
- Palliative treatment of advanced inoperable prostate cancer (oral dosage)
- Palliative treatment of breast cancer that is inoperable and progressive in selected men and postmenopausal women (oral dosage)

Estropipate is indicated for:

- Treatment of moderate to severe vasomotor symptoms (hot flashes) of menopause and/or related genitourinary symptoms including atrophic vaginitis, vulvar atrophy (kraurosis vulvae), whether menopause is natural or surgical (e.g., due to oophorectomy)
- Osteoporosis prophylaxis in women due to menopause (either natural or surgical)
- Treatment of premenopausal females with estrogen deficiency due to hypogonadism or primary ovarian failure

Menest is indicated for:

- Treatment of moderate to severe vasomotor symptoms (hot flashes) of menopause and/or related genitourinary symptoms including atrophic vaginitis, vulvar atrophy (kraurosis vulvae), whether menopause is natural or surgical (e.g., due to oophorectomy)
- Treatment of premenopausal females with estrogen deficiency due to hypogonadism or primary ovarian failure
- Palliative treatment of breast cancer that is inoperable and progressive in selected men and postmenopausal women
- Treatment of advancing inoperable prostate cancer

Premarin is indicated for:

- Treatment of moderate to severe vasomotor symptoms (hot flashes) of menopause and/or related genitourinary symptoms including atrophic vaginitis, vulvar atrophy (kraurosis vulvae), whether menopause is natural or surgical (e.g., due to oophorectomy); (oral dosage)
- Treatment of isolated vaginal and/or urogenital symptoms of menopause (vaginal cream)
- Osteoporosis prophylaxis in women due to menopause (either natural or surgical); (oral dosage)
- Treatment of premenopausal females with estrogen deficiency due to hypogonadism or primary ovarian failure (oral dosage)
- Palliative treatment of breast cancer that has metastasized, in appropriately selected men or women (oral dosage)

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- Palliative treatment of advanced inoperable prostate cancer (oral dosage)

Ethinyl estradiol/norethindrone acetate is indicated for:

- Treatment of moderate to severe vasomotor symptoms (hot flashes) of menopause and/or related genitourinary symptoms including atrophic vaginitis, vulvar atrophy (kraurosis vulvae) in women with an intact uterus (oral and transdermal dosages)
- Osteoporosis prophylaxis due to menopause (natural or surgical) in women with an intact uterus (oral dosage)
- Treatment of female hypogonadism or primary ovarian failure in premenopausal females with an intact uterus (transdermal dosage)

Premphase and Prempro are indicated for:

- Treatment of moderate to severe vasomotor symptoms (hot flashes) associated with menopause and/or related genitourinary symptoms including atrophic vaginitis, vulvar atrophy (kraurosis vulvae), or dyspareunia in women with an intact uterus
- Osteoporosis prophylaxis due to menopause (either natural or surgical) in women with an intact uterus

Angeliq is indicated for:

- Treatment of moderate to severe vasomotor symptoms (hot flashes) of menopause and/or related genitourinary symptoms including atrophic vaginitis, vulvar atrophy (kraurosis vulvae) in women with an intact uterus

Prefest, Duavee, and Climara Pro are indicated for:

- Treatment of moderate to severe vasomotor symptoms (hot flashes) of menopause and/or related genitourinary symptoms including atrophic vaginitis, vulvar atrophy (kraurosis vulvae) in women with an intact uterus
- Osteoporosis prophylaxis due to menopause (natural or surgical) in women with an intact uterus

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation® that Estrogenic Agents are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. Failure of at least two preferred medications, each used for ≥ 30 days, unless member meets one of the following (a, b, or c):
 - a. Allergy to medications not requiring prior approval;

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- b. Contraindications to or drug interaction with medications not requiring prior approval;
- c. History of unacceptable/toxic side effects to medications not requiring prior approval.

Approval duration: 12 months

II. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy - CP.PMN.53 or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

- Dosing varies by drug product. See FDA approved dosing and administration.

Appendix C: Contraindications/Boxed Warnings

- Refer to Clinical Pharmacology or other appropriate clinical resource.

IV. Dosage and Administration

- A. Varies by drug product. See FDA approved dosing and administration.

V. Product Availability

- A. Varies by drug product. Please refer to Clinical Pharmacology or other appropriate clinical resource for product availability.

VI. References

Refer to package inserts.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.19	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that

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has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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