

Clinical Policy: Segesterone acetate/Ethinyl estradiol (Annovera)

Reference Number: CP.PMN.190

Effective Date: 10.02.18

Last Review Date: 02.19

Line of Business: Commercial, TBD HIM*, Medicaid

[Revision Log](#)

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

***For Health Insurance Marketplace members**, this policy applies only when the referenced drug is on the health plan approved formulary. Request for non-formulary drugs must be reviewed using the policy: HIM.PA.103.

Description

Segesterone acetate and ethinyl estradiol (Annovera[™]) is a combination hormonal contraceptive (CHC).

FDA Approved Indication(s)

Annovera is indicated for use by females of reproductive potential to prevent pregnancy.

Limitation(s) of use: Not adequately evaluated in females with a body mass index of > 29 kg/m².

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Annovera is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Contraception (must meet all):

1. Prescribed for prevention of pregnancy;
2. Failure of two formulary contraceptive alternatives, unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed 1 vaginal system per year.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Contraception (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 vaginal system per year.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. 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 policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CHC: combined hormonal contraceptive

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name*	Dosing Regimen	Dose Limit/ Maximum Dose
ethinyl estradiol/norethindrone (e.g., Junel [®] , Necon [®] , Ortho-Novum [®])	1 tablet PO QD	1 tablet/day
ethinyl estradiol/levonorgestrel (e.g., Alesse [®])	1 tablet PO QD	1 tablet/day
ethinyl estradiol/norgestrel (e.g., Cryselle [™] , Ogestrel [®])	1 tablet PO QD	1 tablet/day
ethinyl estradiol/ethynodiol (e.g., Kelnor [®] , Zovia [®])	1 tablet PO QD	1 tablet/day

Drug Name*	Dosing Regimen	Dose Limit/ Maximum Dose
ethinyl estradiol/desogestrel (e.g., Kariva [™])	1 tablet PO QD	1 tablet/day
ethinyl estradiol/drospirenone (e.g., Yasmin [®] , Yaz [®])	1 tablet PO QD	1 tablet/day
ethinyl estradiol/norgestimate (e.g., Ortho Cyclen [®] , Sprintec [®])	1 tablet PO QD	1 tablet/day

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

*Active ingredients are listed first. Please note that multiple brand names are available for each active ingredient. This is not a complete list of all brand names.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - A high risk of arterial or venous thrombotic diseases
 - Current or history of breast cancer or other estrogen-or progestin-sensitive cancer
 - Liver tumors, acute hepatitis, or severe (decompensated) cirrhosis
 - Undiagnosed abnormal uterine bleeding
 - Hypersensitivity to any of the components of Annovera
 - Use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir
- Boxed warning(s): Females over 35 years old who smoke should not use Annovera
 Cigarette smoking increases the risk of serious cardiovascular events from CHC use.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Contraception	One ring inserted vaginally for 3 weeks followed by a 1 week vaginal system-free interval. One system provides contraception for 13 cycles (1 year).	1 vaginal system/year

VI. Product Availability

Vaginal ring: 0.15 mg/day of segesterone acetate and 0.013 mg/day of ethinyl estradiol

VII. References

1. Annovera Prescribing Information. New York, NY: Population Council; August 2018.
 Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209627s000lbl.pdf.
 Accessed August 21, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2019 Policy created	10.02.18	02.19

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 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.

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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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