Clinical Policy Title:	segesterone acetate/ethinyl estradiol
Policy Number:	RxA.344
Drug(s) Applied:	Annovera™
Original Policy Date:	03/06/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Segesterone acetate and ethinyl estradiol (Annovera™) is a combination hormonal contraceptive (CHC). Annovera™ is indicated for use by females of reproductive potential to prevent pregnancy.
Limitations of use: Not adequately evaluated in females with a body mass index of > 29 kg/m^2.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
segesterone acetate/Ethinyl estradiol (Annovera™)	Contraception	One ring inserted vaginally for 3 weeks followed by a 1 week dose-free interval. One system provides contraception for 13 28-day cycles (1 year).	1 vaginal system/year

Dosage Forms

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

Clinical Policy

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

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:
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Contraception (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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:
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CHC: Combination hormonal contraceptive
FDA: Food and Drug Administration
PO: Per Os/ orally

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name*	Dosing Regimen	Maximum Dose
ethinyl estradiol/norethindrone (e.g., Junel®, Necon®, Ortho-Novum®)	1 tablet PO once daily	1 tablet/day
ethinyl estradiol/norgesterol (e.g., Cryselle™)	1 tablet PO once daily	1 tablet/day
ethinyl estradiol/ethynodiol (e.g., Kelnor®, Zovia®)	1 tablet PO once daily	1 tablet/day
ethinyl estradiol/desogestrel (e.g., Kariva™)	1 tablet PO once daily	1 tablet/day
ethinyl estradiol/drospirenone (e.g., Yasmin®, Yaz®)	1 tablet PO once daily	1 tablet/day
ethinyl estradiol/norgestimate (e.g., Sprintec®)	1 tablet PO once daily	1 tablet/day

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.

APPENDIX D: General Information

- Not applicable

References

1. Annovera™ Prescribing Information. New York, NY: Population Council; January 2020. Available at: https://www.annovera.com/pi.pdf . Accessed January 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Line of Business Policy Applies to was updated to all lines of business. 3. Initial and Continued approval duration was updated to include Medicaid, Commercial & HIM approval duration. 4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 5. Reference was reviewed and updated.	07/19/2020	09/14/2020
Policy was reviewed: 1. Initial and Continued approval duration was updated, deleted HIM approval duration. 2. Dosage regimen updated. 3. Appendix B standard verbiage has been changed and updated. 4. Therapeutic alternatives were updated: Deleted the discontinued drugs.	01/22/2021	03/09/2021