

## Nationwide, a Significant Majority of Commercial Lives Have Unrestricted Access to ANNOVERA

An ANNOVERA Letter of Medical Necessity may be required when:

- Your patient's health plan does not cover or restricts coverage for ANNOVERA
- Your patient is required to pay a deductible or high copay/coinsurance for ANNOVERA

## When a Letter of Medical Necessity is Required to Ensure Coverage for ANNOVERA® (segesterone acetate and ethinyl estradiol vaginal system):

### Birth Control Coverage is Mandated Under the Affordable Care Act (ACA)

- The ACA mandates that most private health plans must cover all US Food and Drug Administration (FDA)-approved classes of contraceptive methods<sup>1</sup>
- Plans are required to cover, without cost-sharing, at least one form of contraception in each method of contraception identified by the FDA Birth Control Guide.<sup>2,3</sup>
- If an individual's attending provider recommends a particular service or FDA-approved item based on a determination of medical necessity with respect to that individual, the plan or issuer must cover that service or item without cost sharing<sup>4</sup>

### 1. Access template Letter of Medical Necessity at [ANNOVERAHCP.com/savings-support](https://ANNOVERAHCP.com/savings-support)

### 2. Template is provided in editable PDF format

- Payer name/address
- Patient name/health plan policy/group #
- Diagnosis code/brief summary of diagnosis
- Medical necessity rationale
- Prescriber name, NPI#, contact information

LETTER OF MEDICAL NECESSITY

DATE: \_\_\_\_/\_\_\_\_/\_\_\_\_

TO: Health Plan/Pharmacy Benefits Manager: \_\_\_\_\_  
Street Address: \_\_\_\_\_  
City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

FROM: Health Care Provider Name: \_\_\_\_\_

SUBJECT: Letter of Medical Necessity and request for insurance coverage and reimbursement for ANNOVERA®

To Whom it May Concern:

Please accept this request for medical necessity, with no deductible and no cost share, on behalf of my patient for insurance coverage of ANNOVERA® (segesterone acetate and ethinyl estradiol vaginal system), a progestin/estrogen combination hormonal contraceptive product. Per the Affordable Care Act, a patient does not have to meet step edit or prior authorization requirements if a letter of medical necessity is completed.<sup>2</sup>

Patient Name: \_\_\_\_\_

Policy Number: \_\_\_\_\_ Group Number: \_\_\_\_\_

Date of Birth: \_\_\_\_/\_\_\_\_/\_\_\_\_

This request is supported by the following information:

Diagnosis date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Diagnosis code:

- Z30.01 Encounter for initial prescription of contraceptives
- Z30.015 Encounter for initial prescription of vaginal ring hormonal contraceptive
- Z30.44 Encounter for surveillance of vaginal ring hormonal contraceptive device
- Other \_\_\_\_\_

Diagnosis summary (Brief explanation): \_\_\_\_\_

Medical Necessity Rationale:

- Ability to adhere
- Difference in permanence
- Difference in reversibility
- Severity of side effects with other contraceptive options
- COVID-19 pandemic, necessity for an annual prescription while additional visits and elective procedures such as IUDs and Implants are restricted
- Other \_\_\_\_\_

Rationale for Treatment with ANNOVERA

ANNOVERA is approved as a progestin/estrogen combination hormonal contraceptive (CHC) indicated for use by females of reproductive potential to prevent pregnancy. ANNOVERA is not adequately evaluated in females with a body mass index of >29 kg/m<sup>2</sup>.<sup>1</sup>

### 3. Email/Fax/Upload ANNOVERA Letter of Medical Necessity to Health Plan

Please see Important Safety Information, including **BOXED WARNING**, on the next page and Full Prescribing Information at [ANNOVERA.com/pi.pdf](https://ANNOVERA.com/pi.pdf)

## IMPORTANT SAFETY INFORMATION

### **WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS** See full prescribing information for complete boxed warning.

- Females over 35 years old who smoke should not use ANNOVERA.
- Cigarette smoking increases the risk of serious cardiovascular events from combination hormonal contraceptive use.

## CONTRAINDICATIONS

ANNOVERA is contraindicated and should not be used in women with 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; and use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir.

## WARNINGS AND PRECAUTIONS

- Stop ANNOVERA if a thrombotic or thromboembolic event occurs, and at least 4 weeks before and through 2 weeks after major surgery. Start ANNOVERA no earlier than 4 weeks after delivery, in females who are not breastfeeding. Consider cardiovascular risk factors before initiating in all females, particularly those over 35 years.
- Discontinue if jaundice occurs.
- Stop ANNOVERA prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir. ANNOVERA can be restarted 2 weeks following completion of this regimen.
- Do not prescribe ANNOVERA for females with uncontrolled hypertension or hypertension with vascular disease. Monitor blood pressure and stop use if blood pressure rises significantly in females with well-controlled hypertension.
- Monitor glucose in pre-diabetic or diabetic females taking ANNOVERA. Consider an alternate contraceptive method for females with uncontrolled dyslipidemias.
- Patients using ANNOVERA who have a significant change in headaches or irregular bleeding or amenorrhea should be evaluated. ANNOVERA should be discontinued if indicated.
- Other warnings include: gallbladder disease; depression; cervical cancer; increased serum concentrations of binding globulins; hereditary angioedema; chloasma (females who tend to develop chloasma should avoid exposure to the sun or UV radiation while using ANNOVERA); toxic shock syndrome (TSS) (if a patient exhibits symptoms of TSS, remove ANNOVERA, and initiate appropriate medical treatment); vaginal use (ANNOVERA may not be suitable for females with conditions that make the vagina more susceptible to vaginal irritation or ulceration).

## ADVERSE REACTIONS

The most common adverse reactions reported in at least 5% of women who received ANNOVERA were: headache/migraine, nausea/vomiting, vulvovaginal mycotic infection/candidiasis, lower/upper abdominal pain, dysmenorrhea, vaginal discharge, urinary tract infection, breast pain/tenderness/discomfort, bleeding irregularities including metrorrhagia, diarrhea, and genital pruritus.

## DRUG INTERACTIONS

Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of ANNOVERA or increase breakthrough bleeding. Counsel patients to use a back-up or alternative method of contraception when enzyme inducers are used with ANNOVERA.

## INDICATION

ANNOVERA is a progestin/estrogen combination hormonal contraceptive indicated for use by females of reproductive potential to prevent pregnancy.

Limitations of Use: ANNOVERA has not been adequately studied in females with a body mass index >29 kg/m<sup>2</sup>.

**Please note this information is not comprehensive. See accompanying Full Prescribing Information, including BOXED WARNING, or visit ANNOVERA.com/pi.pdf**

**References:** 1. Data point: The Affordable Care Act is improving access to preventive services for millions of Americans. ASPE.HHS.gov website. <https://aspe.hhs.gov/pdf-report/affordable-care-act-improving-access-preventive-services-millions-americans>. Published May 14, 2015. Accessed May 18, 2020. 2. Women's preventive services guidelines. HRSA website. <https://www.hrsa.gov/womens-guidelines/index.html>. Updated September 2018. Accessed May 18, 2020. 3. Health benefits & coverage: birth control benefits. Healthcare.gov website. <https://www.healthcare.gov/coverage/birth-control-benefits/>. Accessed May 18, 2020. 4. FAQs about Affordable Care Act implementation. Centers for Medicare and Medicaid Services website. [https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca\\_implementation\\_faqs26.pdf](https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf). Published May 11, 2015. Accessed May 18, 2020.

ANNOVERA is a registered trademark licensed to TherapeuticsMD, Inc.  
© 2020 TherapeuticsMD, Inc. All rights reserved.

**TherapeuticsMD**<sup>®</sup>  
*For Her. For Life.*