ANNOVERA LETTER OF MEDICAL NECESSITY PROCESS GUIDE

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):

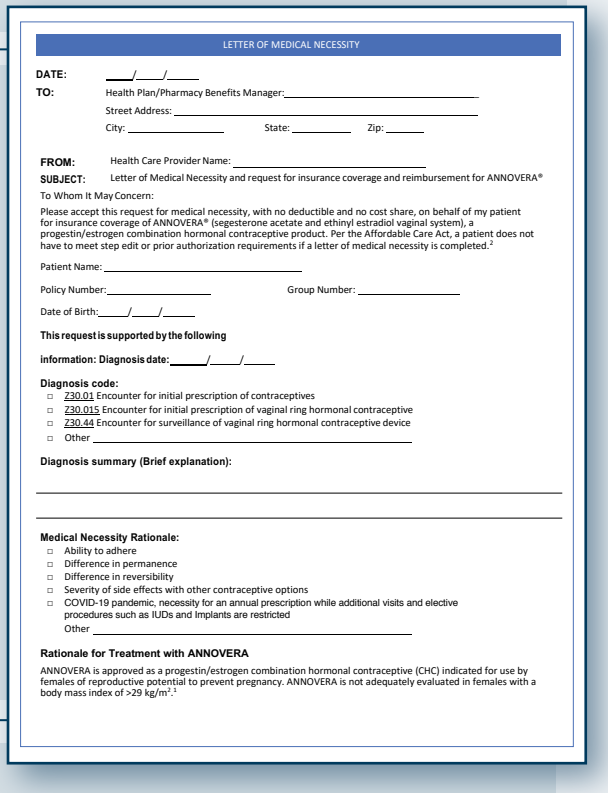
Birth Control Coverage is Mandated Under the Affordable Care Act (ACA)

- The ACA mandates that most private health plans must cover all US Food and Drug Administration (FDA)-approved classes of contraceptive methods[1]
- 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[2,3]
- 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[4]

1. Access template Letter of Medical Necessity at **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.[2]

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/m².[1]

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

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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^2.

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. Published May 11, 2015. Accessed May 18, 2020.

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