LETTER OF MEDICAL NECESSITY FROM:

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:

I, Dr. _____, have created and prepared this request of medical necessity acting on behalf of my patient _____. Through the doctor-patient relationship, I am acting as my patient's authorized representative in submitting this request for medical necessity.

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:

- ☐ COVID-19 pandemic, necessity for an annual prescription while additional visits and elective procedures such as IUDs and Implants are restricted
- ☐ Difference in permanence
- ☐ Difference in reversibility
- ☐ Fit, physical characteristics, or use issues with other rings
- ☐ Ability to adhere
- ☐ Severity of side effects with other contraceptive options
- ☐ Seeks to continue current treatment
- ☐ 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^2.[1]

Per the Health Resources and Services Administration (HRSA) guidelines, women should have access to the full range of FDA-approved contraceptive methods including, but not limited to, barrier methods, hormonal methods, and implanted devices, as well as patient education and counseling, as prescribed by a healthcare provider.[2] Based on the Affordable Care Act Implementation (Part XXVI)[2]:

- If utilizing reasonable medical management techniques within a specified method of contraception, plans and issuers must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or provider
- **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. The plan or issuer must defer to the determination of the attending provider**
- **Medical necessity may include considerations such as the severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service, as determined by the attending provider**

ANNOVERA is the first and only contraceptive that provides an entire year of protection against unintended pregnancy that is patient controlled, reversible, and does not require a medical procedure or repeat HCP visits. **ONE ANNOVERA VAGINAL SYSTEM PROVIDES 364 MEDICATION DAYS SUPPLY* TO THE PATIENT**. It lasts for 13 cycles, remaining in place for 21 days and removed for 7 days each cycle.[1] Unlike NuvaRing® (etonogestrel/ethinyl estradiol vaginal ring) and oral contraceptives, ANNOVERA only requires one visit to the pharmacy each year. Unlike intrauterine devices (IUDs) and implants, ANNOVERA does not require a medical procedure and can be reversed at any time.[1]

In summary, ANNOVERA is necessary for this patient to prevent pregnancy for up to 1 year. I appreciate your timely approval of this request for insurance coverage for ANNOVERA. If you have any further questions regarding this matter, or need additional information, please do not hesitate to contact my office.

Sincerely,

Signed name: _____,_____

Printed name: _____,_____

NPI Number: _____

Phone Number: _____

Fax Number: _____

*Calculated quantity of medication to be dispensed per day divided by the number of doses per day—ie, how many days the supply of dispensed medication will last.[3]

References: 1. ANNOVERA [package insert]. Boca Raton, FL: TherapeuticsMD; 2020. **2.** FAQs about Affordable Care Act implementation (Part XXVI). 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 September 27, 2019. **3.** Pharmacy auditing and dispensing job aid: billing other dosage forms. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/pharmacyselfaudit-jobaid-billing-other.pdf. Published December 2015. Accessed September 27, 2019.

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 (segesterone acetate and ethinyl estradiol vaginal system) 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.

IMPORTANT SAFETY INFORMATION

- 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.

IMPORTANT SAFETY INFORMATION (cont.)

INDICATION

ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system) 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 that this information is not comprehensive. Please see the Full Prescribing Information, including BOXED WARNING, at ANNOVERA.com/pi.pdf.

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