DETERMINATION OF MEDICAL NECESSITY UNDER ACA FAQs (PART XXVI) MAY 11, 2015

To Whom it May Concern:

I,_____ am submitting this determination of medical necessity on behalf of my patient _____. Through the provider-patient relationship, I am acting as the patient's authorized representative in this determination of medical necessity.

Per the FAQs on Affordable Care Act implementation dated May 11, 2015, you as the plan or issuer **MUST** defer to my determination of medical necessity as the attending provider and cover this contraceptive without cost sharing.[1] A patient does not have to meet medical management techniques upon a determination of medical necessity.[1]

Patient's Name: _____ Date of Birth: _____ /_____ /_____

Policy Number: _____ Group Number: _____

Prescriber's Name: _____ DATE: _____ NPI/DEA#: _____

Address: _____ City, State: _____ Zip: _____

Office Contact Name: _____ Office Contact Phone #: _____ Email: _____

Medication: Contraceptive Drug Name: ANNOVERA® (segesterone acetate and ethinyl estradiol vaginal system)

If applicable, other medications/therapies tried: _____

This determination is supported by the following Information: **Diagnosis Date:** _____ /_____ /_____

Diagnosis Code:[2]

☐ Z30.44 Encounter for surveillance of vaginal ring hormonal contraceptive device

☐ Z30.09 Encounter for other general counseling and advice on contraception

☐ Z30.9 Encounter for Contraceptive management, unspecified

☐ Other _____

Diagnosis Summary and Reason for Determination of Medical Necessity:

After reviewing the patient's history and contraceptive needs, I believe based on my clinical judgement that the use of the contraceptive drug listed above is warranted to prevent unintended pregnancy.

If applicable, additional diagnosis information: _____

Medical Necessity Determination Criteria:

☐ Provider determination that non-androgenic segesterone acetate which demonstrates no androgenic, estrogenic, or glucocorticoid activity and is not available in any other contraceptive product, is the most appropriate method to reduce the risk of unintended pregnancy/adverse side effect outcome for this individual patient.[3,4*]

☐ Provider determination that this individual patient is intolerant or not willing to use a vaginal ring with a higher estrogen exposure. ANNOVERA has ~13 mcg daily of estrogen.[3]

☐ Provider determination that 1 full year of contraceptive protection through ANNOVERA is the most appropriate method for this individual patient's ability to adhere to contraceptive therapy and reduce the risk of unintended pregnancy/adverse side effect outcome.[3]

☐ Provider determination that this individual patient is intolerant or not willing to employ a permanent surgical procedure for an IUD/Implant and needs a long-lasting contraception option as the most appropriate method for this patient's ability to adhere to contraceptive therapy.

☐ Provider determination that frequent dosing with available oral and patch forms of contraception impact this individual patient's ability to adhere and would increase the risk of an unintended pregnancy/adverse side effect outcome.

☐ This individual patient is currently on ANNOVERA and provider determination that disrupting therapy would increase the risk of an unintended pregnancy/adverse side effect outcome.

☐ Other _____

I certify that the information provided in this form is accurate to the best of my knowledge. I appreciate your expedited approval based on my medical determination for no cost share insurance coverage of ANNOVERA as required by Federal law. If you need additional information, please contact my office.

Sincerely,

Signed name: _____ Date: _____

*Based on pharmacological studies in animals and in vitro studies. The clinical significance of these data is not known.

IMPORTANT SAFETY INFORMATION FOR ANNOVERA (SEGESTERONE ACETATE AND ETHINYL ESTRADIOL VAGINAL SYSTEM)

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.

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 (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 click here for the Full Prescribing Information, including BOXED WARNING.

References: 1. 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 March 4, 2021. 2. https://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z30-Z39/Z30- Accessed March 4, 2021. 3. ANNOVERA [package insert]. Boca Raton, FL: TherapeuticsMD; 2022. 4. Kumar N, Koide SS, Tsong YY, Sundaram K. Nestorone: A progestin with a unique pharmacological profile. *Steroids*, 2000;65:629-36.

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