REQUEST FOR FORMULARY EXCEPTION OR PRIOR AUTHORIZATION FOR CONTRACEPTIVE DRUG

Instructions for Healthcare Professionals:

Prescribers may complete this form and send it to their patient's insurer to request coverage of NEXTSTELLIS® (drospirenone and estetrol tablets) when it is not on the insurer's prescription drug formulary or if the plan requires prior authorization.[1] Insurers must cover a non-formulary contraceptive product without cost-sharing upon the recommendation of the patient's healthcare provider.[2]

Please consider the following when completing the form:

- It is important to clearly identify the rationale for the request based on your clinical judgment.
  - While the primary reason for prescribing NEXTSTELLIS may be to prevent unintended pregnancy, it will assist payers if your request includes a detailed description of why the patient should have access to NEXTSTELLIS. For example:
    - Failed trial(s) of other contraceptive(s)
    - Contraindication to formulary or preferred agent
    - Currently being treated with NEXTSTELLIS
    - Another specified reason
- Consider attaching, if appropriate, documents that provide additional clinical information to support the request, such as:
  - Full prescribing information
  - Patient chart notes
  - Clinical guidelines
  - A front and back copy of the patient's prescription drug card
- Carefully review the form for completeness and accuracy before sending to the payer. Payers are likely to return incomplete forms to request additional documentation, which can delay their review of your request.
- A special word about expedited requests:
  - You can ask the payer to expedite its decision if you believe that waiting the amount of time for a standard decision would increase the risk of unintended pregnancy and/or harmful adverse events or if your patient is currently being treated with NEXTSTELLIS.

See Important Safety Information on pages 4–5 and full prescribing information for NEXTSTELLIS at www.NEXTSTELLIS.com.

References: 1. NEXTSTELLIS prescribing information. Mayne Pharma; April 2021. 2. Centers for Medicare & Medicaid Services. FAQs about Affordable Care Act implementation (Part 31). Accessed June 7, 2021. https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf

REQUEST FOR FORMULARY EXCEPTION OR PRIOR AUTHORIZATION FOR CONTRACEPTIVE DRUG

Patient Information

Patient's Name: Date of Birth: / /

Street Address:

City, State: Zip Code: Patient Phone Number:

Insurance Information

Name of Subscriber (if different than patient):

Patient Relationship to Subscriber: Subscriber Date of Birth: / /

Medical Insurance Plan Information **Plan Type (check one):** ◉ Commercial ○ Exchange ○ Medicaid ○ Medicare ○ Other

Payer Name: Member ID: Group Number:

Prescription Drug Plan Information Pharmacy Benefit Manager:

Prescription Drug Plan Name: Member ID: Group Number:

Prescriber Information

Prescriber's Name: Title: NPI #:

Clinic Name: Specialty:

Clinic Address:

City, State: Zip Code: Office Contact Name:

Office Contact Email Address: Office Contact Phone Number: Secure Fax Number:

Medication

Contraceptive Name: NEXTSTELLIS® (drospirenone and estetrol tablets) 3 mg / 14.2 mg[1]

☐ 3 blister cards (24 active tablets each) x 4 refills ☐ 1 blister card (24 active tablets each) x 12 refills

Medical Information (check applicable items)

ICD-10-CM Diagnosis Code(s):

☐ Z30.011 Encounter for initial prescription of contraceptive pills

☐ Z30.41 Encounter for surveillance of contraceptive pills

☐ Z30.8 Encounter for other contraceptive management

☐ Other:

Rationale for Request

1. Is the patient currently treated with the requested medication? ☐ Yes ☐ No
   If yes, when was treatment with the medication started?

2. Please list all reasons for selecting NEXTSTELLIS over alternatives (e.g., contraindications, allergies, history of adverse drug reactions to alternatives, other reason, etc).

3. Please list all medications the patient is **currently taking for treatment of this diagnosis** (include drug name, dosage, frequency, dates of course of therapy).

4. Please list all medications the patient has **previously tried and failed for treatment of this diagnosis** (include drug name, dosage, frequency, dates of course of therapy).

5. **For expedited requests:** As the patient's healthcare provider, I am requesting that you expedite your determination on this request within 24 hours because (check one):

   ◉ The patient is undergoing a current course of treatment with NEXTSTELLIS ○ Waiting for a standard decision would increase the risk of unintended pregnancy and/or harmful adverse events

Request for No Cost-Share Waiver per the Affordable Care Act:

Per the Frequently Asked Questions (FAQs) regarding the Affordable Care Act dated April 20, 2016, please provide a waiver for this product so there is no associated drug deductible, copayment, or co-insurance.[2]

I Certify That the Information Provided in This Form Is Accurate to the Best of My Knowledge.

Healthcare Provider's Signature Date

References: 1. NEXTSTELLIS prescribing information. Mayne Pharma; April 2021. 2. Centers for Medicare & Medicaid Services. FAQs about Affordable Care Act implementation (Part 31). Accessed June 7, 2021. https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf

Excerpts From Affordable Care Act Implementation FAQs: April 20, 2016[2]

Below are excerpts from FAQs regarding implementation of the market reform provisions of the Affordable Care Act. These FAQs were prepared jointly by the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at www.cms.gov/cciio/resources/fact-sheets-and-faqs/index.html), these FAQs answer questions from stakeholders to help people understand the laws and benefits from them, as intended.

Coverage of Food and Drug Administration (FDA)-Approved Contraceptives

The Health Resources and Services Administration (HRSA) Guidelines include a recommendation for all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity as prescribed by a healthcare provider. On February 20, 2013, the Departments issued an FAQ stating that the HRSA Guidelines ensure women's 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. The FAQ further clarified that plans and issuers may use reasonable medical management techniques to control costs and promote efficient delivery of care, such as covering a generic drug without cost-sharing and imposing cost-sharing for equivalent branded drugs. However, in these instances, the FAQ stated that a plan or issuer must accommodate any individual for whom a particular drug (generic or brand name) would be medically inappropriate, as determined by the individual's healthcare provider, by having a mechanism for waiving the otherwise applicable cost-sharing for the brand or non-preferred brand version.

On May 11, 2015, the Departments issued an FAQ clarifying that plans and issuers must cover without cost sharing at least 1 form of contraception in each of the methods (currently 18) identified for women by the FDA. The FAQ further clarified that to the extent plans and issuers use 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 (or other individual acting as a patient's authorized representative, including a provider) to ensure coverage without cost-sharing of any service or FDA-approved item within the specified method of contraception. **The FAQ also stated that 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 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.** The FAQ also clarified that the exceptions process must provide for making a determination on the claim according to a timeframe and in a manner that takes into account the nature of the claim (e.g., pre-service or post-service) and the medical exigencies involved for a claim involving urgent care.

Additionally, health insurance issuers in the individual and small group markets that are required to provide essential health benefits (EHBs) must have an exceptions process that meets the standards in 45 CFR 156.122(c).

References: 1. NEXTSTELLIS prescribing information. Mayne Pharma; April 2021. 2. Centers for Medicare & Medicaid Services. FAQs about Affordable Care Act implementation (Part 31). Accessed June 7, 2021. https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf

IMPORTANT SAFETY INFORMATION

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use NEXTSTELLIS safely and effectively. See full prescribing information for NEXTSTELLIS at www.NEXTSTELLIS.com.

NEXTSTELLIS® (drospirenone and estetrol tablets), for oral use
Initial U.S. Approval: 2021

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 NEXTSTELLIS.**
- **Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use.**

INDICATIONS AND USAGE

NEXTSTELLIS is a combination of drospirenone, a progestin, and estetrol, an estrogen, indicated for use by females of reproductive potential to prevent pregnancy.

Limitations of Use

NEXTSTELLIS may be less effective in females with a BMI ≥30 kg/m^2. In females with BMI ≥30 kg/m^2, decreasing effectiveness may be associated with increasing BMI.

DOSAGE AND ADMINISTRATION

- Take one tablet by mouth at the same time every day.
- Take tablets in the order directed on the blister pack.

DOSAGE FORMS AND STRENGTHS

NEXTSTELLIS consists of 28 tablets in the following order:

- 24 pink active tablets each containing drospirenone 3 mg and estetrol 14.2 mg
- 4 white inert tablets

CONTRAINDICATIONS

- A high risk of arterial or venous thrombotic diseases
- Current or history of a hormonally-sensitive malignancy (e.g., breast cancer)
- Hepatic adenoma, hepatocellular carcinoma, acute hepatitis or decompensated cirrhosis
- Co-administration with hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir
- Abnormal uterine bleeding that has an undiagnosed etiology
- Renal impairment
- Adrenal insufficiency

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS

- Thromboembolic Disorders and Other Vascular Problems: Stop NEXTSTELLIS if a thrombotic or thromboembolic event occurs. Start no earlier than 4 weeks after delivery. Consider all cardiovascular risk factors before initiating in any female, particularly in the presence of multiple risk factors.
- Hyperkalemia: Check serum potassium concentration during the first NEXTSTELLIS treatment cycle in females on long-term treatment with medications that may increase serum potassium concentration.
- Hypertension: Monitor blood pressure periodically and stop use if blood pressure rises significantly.
- Migraine: Discontinue if new, recurrent, persistent, or severe migraines occur.
- Hormonally-Sensitive Malignancy: Discontinue NEXTSTELLIS if a hormonally-sensitive malignancy is diagnosed.
- Liver Disease: Withhold or permanently discontinue for persistent or significant elevation of liver enzymes.
- Glucose Tolerance and Hypertriglyceridemia: Monitor glucose in females with prediabetes or diabetes. Consider an alternate contraceptive method for females with hypertriglyceridemia.
- Gallbladder Disease and Cholestasis: Consider discontinuing NEXTSTELLIS in females with symptomatic gallbladder or cholestatic disease.
- Bleeding Irregularities and Amenorrhea: May cause irregular bleeding or amenorrhea. Evaluate for other causes if symptoms persist.

ADVERSE REACTIONS

- Most common adverse reactions (≥2%): bleeding irregularities, mood disturbance, headache, breast symptoms, dysmenorrhea, acne, weight increased, and libido decreased.

DRUG INTERACTIONS

- CYP3A Inducers: May lead to contraceptive failure and/or increase breakthrough bleeding. Avoid concomitant use. If concomitant use is unavoidable, use an alternative or back-up contraceptive method during co-administration and up to 28 days after discontinuation of the CYP3A inducer.
- See Full Prescribing Information for additional clinically significant drug interactions.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Discontinue if pregnancy occurs.
- Lactation: Advise postpartum females that NEXTSTELLIS can decrease milk production.

To report SUSPECTED ADVERSE REACTIONS, contact Mayne Pharma at 1-844-825-8500 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.