CONTRACEPTION FORMULARY EXCEPTION REQUEST

Patient's Information

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

Patient's address, city, state & zip code _____

Payer Name _____ Patient's Member ID_____

Prescriber's Information

Name _____ DATE _____ NPI/DEA # _____

Street Address _____ City, State _____ Zip Code _____

Office Contact Name _____ Office Contact Email Address _____

Office Contact Phone Number_____

Medication

Contraceptive Drug/Device/Product Name: Twirla® 120mcg/day levonorgestrel and 30mcg/day ethinyl estradiol

☐ 3 cartons (9 patches) X 4 refills ☐ 1 carton (3 patches) X 12 refills

Reason for request for exception:
After reviewing the patient's history and contraceptive needs, I believe based on my clinical judgment, that use of the contraceptive drug listed above is warranted to prevent an unintended pregnancy

If applicable, other medications/therapies tried: _____

_____

Medical Information (complete applicable items)

Diagnosis Code:

☐ Z30.016 Encounter for initial prescription of transdermal patch hormonal contraceptive device

☐ Z30.45 Encounter for surveillance of transdermal patch hormonal contraceptive device

☐ Other: _____

_____

Rationale for Request

In my clinical judgment, the requested product is the most clinicially appropriate based on the following considerations:

- ☐ Patient intolerant of or not willing to use a patch with a higher estrogen exposure[1]
- ☐ Patient has had a successful trial on the product and disrupting therapy would increase the risk of an unintended pregnancy/adverse outcome.
- ☐ Provider determination to limit the level of estrogen exposure in a transdermal option. As described in the package inserts of the different products, the pharmacokinetic profile of Twirla® differs from the pharmacokinetic profile of the other available transdermal options in relation to the estrogen delivered dose compared to a 35 mcg pill.[1,2,3,4]
- ☐ Provider determination that a transdermal option with the estrogen-related side effect profile of Twirla® is the most appropriate option to facilitate patient adherence and reduce the risk of unintended pregnancy/adverse outcome.[4]
- ☐ Provider determination that the Twirla® transdermal patch is necessary to facilitate patient adherence and reduce the risk of unintended pregnancy/adverse outcome.
- ☐ Patient tried and failed an alternative transdermal option due to intolerance, side effects or issues related to adhesion.
- ☐ Other _____

Additional Explanation for Rationale:

Request for no cost share waiver per the Affordable Care Act

☐ As the attending provider, I am recommending this product as the most medically appropriate for this patient. As required by the FAQ's regarding the Affordable Care Act dated January 10,2022, I am requesting this product be made available with no deductibe or cost sharing.[5]

I certify that the information provided in this form is accurate to the best of my knowledge.

Health Care Provider's Signature _____ Date: _____

References: 1. Xulane full prescribing information. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=f7848550-086a-43d8-8ae5-047f4b9e4382&type=display 2. Zafemy full prescribing information https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=5ee34c07-65af-42b8-a98f-e299ff90a8a1&type=display 3. Archer DF, et al. Contraception 2012;85:595-601 4.Twirla full prescribing information. https://www.twirla.cohcp/pdf/Twirla%20FINAL%20PI%20IFU%20PPI.pdf 5. FAQs about Affordable Care Act implementation (Part 51). Centers for Medicare and Medicaid Services website. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf

Page intentionally left blank

EXCERPTED FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION JANUARY 10,2022

Below are additional Frequently Asked Questions (FAQs) regarding implementation of the Affordable Care Act. These FAQs have been prepared jointly by the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs these FAQs answer questions from stakeholders to help people understand the Affordable Care Act and benefit from it, as intended.

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

The currently applicable HRSA Women's Preventive Services Guidelines (HRSA Guidelines), as updated on December 17, 2019, include a guideline that adolescent and adult women have access to the full range of female-controlled FDA-approved contraceptive methods, effective family planning practices and sterilization procedures to prevent unintended pregnancy and improve birth outcomes. The currently applicable HRSA Guidelines state that contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management and evaluation as well as changes to, and removal or discontinuation of, the contraceptive method), and that instruction in fertility awareness-based methods, including the lactation amenorrhea method, should be provided for women desiring an alternative method. 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 health care 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 health care 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 one form of contraception in each method that is identified by the FDA in its Birth Control Guide. 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 exception process that is not unduly burdensome on the individual (or provider or other individual acting as a patient's authorized representative) to ensure coverage without cost sharing of any service or FDA-approved item within the specified method of contraception. An additional FAQ 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 FAQ makes clear that a plan or issuer must defer to the determination of the attending provider. The FAQs stated that 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 FAQs also clarified that the exception process must provide for making a determination of 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. On April 20, 2016, the Departments issued an FAQ stating that if a plan or issuer utilizes reasonable medical management techniques within a specified method of contraception, the plan or issuer may develop and utilize a standard exception form and instructions as part of its steps to ensure that it provides an easily accessible, transparent, and sufficiently expedient exception process that is not unduly burdensome on the individual or a provider (or other individual acting as a patient's authorized representative). The FAQ suggested that the Medicare Part D Coverage Determination Request Form may serve as a model for plans and issuers when developing a standard exception form. The Departments are issuing the following FAQ in response to complaints and public reports of potential violations of the contraceptive coverage requirement. This FAQ makes clear that all FDA-approved cleared,or granted contraceptive products that are determined by an individual's medical provider to be medically appropriate for such individual must be covered without-cost sharing, whether or not specifically identified in the current FDA Birth Control Guide.

* * *

Plans and issuers subject to these requirements are reminded of their responsibility to fully comply with the requirements under PHS Act section 2713 and the HRSA Guidelines, as interpreted in the Departments' implementing regulations and guidance, including the requirement that, if an individual and their attending provider determine that a particular service or FDA-approved, cleared, or granted contraceptive product is medically appropriate for the individual (whether or not the item or service is identified in the current FDA Birth Control Guide), the plan or issuer must cover that service or product without cost sharing.

https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf

IMPORTANT SAFETY INFORMATION

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS and CONTRAINDICATED IN WOMEN WITH A BMI ≥30 kg/m^2

Cigarette Smoking and Serious Cardiovascular Events

Cigarette smoking increases the risk of serious cardiovascular events from combined hormonal contraceptive (CHC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, CHCs, including TWIRLA, are contraindicated in women who are over 35 years of age and smoke.

Contraindicated in Women with a BMI ≥30 kg/m^2

TWIRLA is contraindicated in women with a BMI ≥30 kg/m^2. Compared to women with a lower BMI, women with a BMI BMI ≥30 kg/m2 had reduced effectiveness and may have a higher risk of venous thromboembolic events (VTEs).

CONTRADICTIONS

TWIRLA is contraindicated and should not be used in women with a high risk of arterial or venous thrombotic disease, including women with a BMI ≥30 kg/m2; headaches with focal neurological symptoms, migraine with aura, women over 35 years of age with any migraine headache; liver tumors, acute viral hepatitis, or severe (decompensated) cirrhosis, or liver disease; undiagnosed abnormal uterine bleeding; pregnancy; current or history of breast cancer or other estrogen- or progestin-sensitive cancer; hypersensitivity to any components of TWIRLA; and use of hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir with or without dasabuvir.

WARNINGS AND PRECAUTIONS

- **Thromboembolic Disorders and Other Vascular Conditions –** Women are at increased risk for a VTE when using TWIRLA.
  - Stop TWIRLA if an arterial or VTE occurs.
  - Stop TWIRLA if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions. Evaluate for retinal vein thrombosis immediately.
  - Discontinue TWIRLA during prolonged immobilization and, if feasible, stop TWIRLA at least 4 weeks before and through 2 weeks after major surgery.
  - Start TWIRLA no earlier than 4 weeks after delivery in women who are not breast-feeding.
  - Before starting TWIRLA, evaluate any past medical history or family history of thromboembolism or thromboembolic disorders and consider whether history suggests inherited or acquired hypercoagulopathy.

Arterial Events – CHCs increase the risk of cardiovascular events and cerebrovascular events, such as myocardial infarction and stroke, particularly among older women (>35 years of age), smokers, and women with hypertension, dyslipidemia, diabetes, or obesity.

- **Liver Disease –** Discontinue TWIRLA if jaundice develops.

- **Risk of Liver Enzyme Elevations with Concomitant Hepatitis C Treatment –** Discontinue TWIRLA prior to starting therapy with the hepatitis C combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. TWIRLA can be restarted approximately 2 weeks following completion of treatment with that combination drug regimen.

- **Hypertension –** Monitor blood pressure at routine visits and stop TWIRLA if blood pressure rises significantly. An increase in blood pressure has been reported in women using CHCs, and this increase is more likely in older women with extended duration of use.

- **Gallbladder Disease –** Studies suggest CHCs increase the risk of developing gallbladder disease and may also worsen existing gallbladder disease.

- **Adverse Carbohydrate and Lipid Metabolic Effects –**
  - TWIRLA may decrease glucose tolerance. Carefully monitor prediabetic and diabetic women who are using TWIRLA.
  - Consider alternative contraception for women with uncontrolled dyslipidemia. TWIRLA may cause adverse lipid changes. Women with hypertriglyceridemia, or a family history thereof, may have an increase in serum triglyceride concentrations when using TWIRLA, which may increase the risk of pancreatitis.

- **Headache –** If a woman using TWIRLA develops new headaches that are recurrent, persistent, or severe, evaluate the cause and discontinue TWIRLA as indicated. Consider discontinuation of TWIRLA if there is any increased frequency or severity of migraines during CHC use (which may be prodromal of a cerebrovascular event).

- **Bleeding Irregularities and Amenorrhea –** Women using TWIRLA may experience unscheduled bleeding, especially during the first 3 months of use, or experience absence of scheduled bleeding. If bleeding persists or occurs after previously regular cycles on TWIRLA, or if scheduled bleeding does not occur, evaluate for causes such as pregnancy or, in the case of unscheduled bleeding, malignancy.

- **Other Warnings and Precautions –** Other warnings and precautions include depression, cervical cancer, increased serum concentrations of binding globulins, hereditary angioedema, and chloasma.

ADVERSE REACTIONS
The following serious adverse reactions occurred in <1% of women who received TWIRLA: cholelithiasis, cholecystitis, major depression, suicidal ideation, appendicitis, ectopic pregnancy, pneumonia, and gastroenteritis. A total of 4 VTEs in TWIRLA-treated patients were identified in the phase 3 clinical trial. The most common adverse reactions (≥2%) in clinical trials for TWIRLA are application site disorders, nausea, headache, dysmenorrhea, and increased weight.

Patients should be counseled that TWIRLA does not protect against HIV infection (AIDS) and other sexually transmitted infections (STIs).

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

INDICATION AND USAGE
TWIRLA is indicated as a method of contraception for use in women of reproductive potential with a BMI

<30 kg/m^2 for whom a combined hormonal contraceptive is appropriate.

Limitations of Use:

Consider the reduced effectiveness of TWIRLA in women with a BMI ≥25 to <30 kg/m^2 before prescribing TWIRLA. TWIRLA is contraindicated in women with a BMI ≥30 kg/m^2.
This is not a comprehensive list of safety information related to TWIRLA. Please see full Prescribing Information, including BOXED WARNING.

To report **SUSPECTED ADVERSE REACTIONS**, call 1-855-389-4752 or report via the FDA MedWatch Program at www.fda.gov/medwatch or 1-800-FDA-1088.