REQUEST FOR AN ALTERNATIVE CONTRACEPTIVE DRUG, DEVICE, OR PRODUCT

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 - Select those that apply (or provide comments in 'other' or additional explanation)

Based on your clinical judgement clearly identify the rationale for the request. Consider attaching if appropriate, documents that provide additional clinical information to support your request such as full prescribing information, clinical guidelines, etc.

☐ 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 provider determination that 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. In a head-to-head study of **Twirla® compared to a 35 mcg EE pill**, the steady state concentration (Css) and total estrogen exposure (AUC) were 14% and 10% lower than the 35 mcg pill. This differs from the pharmacokinetic profile of the other available transdermal option in relation to a 35 mcg pill.[1,2]

☐ Provider determination that a transdermal option with the estrogen-related side effect profile of Twirla®, as demonstrated in the clinical trial as described in the prescribing information, is the most appropriate option to facilitate patient adherence and reduce the risk of unintended pregnancy/adverse outcome.[3]

☐ Provider determination that a transdermal option is the best method to facilitate patient adherence and reduce the risk of unintended pregnancy/adverse outcome. Patient tried and failed the 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

Per the FAQ's regarding the Affordable Care Act dated May 11, 2015, please provide a waiver for this product with no deductible and no cost share.[4]

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. Archer DF, et al. Contraception 2012;85:595-601. 3.Twirla full prescribing information. https://www.twirla.com/hcp/pdf/Twirla%20FINAL%20PI%20IFU%20PPI.pdf 4. 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

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EXCERPTED FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION May 11, 2015

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 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 health care 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 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.

These FAQs provide further guidance on the scope of coverage required for contraception and the extent to which plans and issuers may utilize reasonable medical management. Specifically:

1) Plans and issuers must cover without cost sharing of at least one form of contraception in each of the methods (currently 18) that the FDA has identified for women in its current Birth Control Guide. This coverage must also include the clinical services, including patient education and counseling, needed for provision of the contraceptive method.
2) Within each method, plans and issuers may utilize reasonable medical management techniques. A plan or issuer generally may impose cost sharing (including full cost sharing) on some items and services to encourage an individual to use other specific items and services within the chosen contraceptive method. For example, a plan may discourage use of brand name pharmacy items over generic pharmacy items through the imposition of cost sharing. Similarly, a plan may use cost sharing to encourage use of one of several FDA-approved intrauterine devices (IUDs) with progestin.
3) 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 a provider (or other individual acting as a patient's authorized representative).

a. 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. (Emphasis added)
b. This exceptions process must make 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.

Because the Departments' prior guidance may reasonably have been interpreted in good faith as not requiring coverage without cost sharing of at least one form of contraception in each method identified by the FDA, the Departments will apply this clarifying guidance for plan years (or, in the individual market, policy years) beginning on or after the date that is 60 days after publication of these FAQs.

https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.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 ≥30 kg/m^2 had reduced effectiveness and may have a higher risk for 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/m^2; 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.