CONTRACEPTIVE 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 judgement, the product requested is the most clinically 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. The pharmacokinetic profile of Twirla® differs from the pharmacokinetic profile of the other available transdermal options in relation to the estrogen delivered dose compared with 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.[3]

☐ Provider determination that the Twirla® transdermal patch is necessary to facilitate patient adherence and appropriate use 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 per the FAQ's regarding the Affordable Care Act dated July 28, 2022. I request this product be made available to the patient with no deductible and no cost share.[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/drugInfo.cfm?setid=f7848550-086a-43d8-8ae5-047f4b9e4382
2.Zafemy full prescribing information https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5ee34c07-65af-42b8-a98f-e299ff90a8a1
3.Twirla full prescribing information. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bcaf8db0-1750-425d-b008-255b5e7a9cc6 4. Archer DF, et al. Contraception 2012;85:595-601. 5. FAQs about Affordable Care Act implementation (Part 54).Centers for Medicare and Medicaid Services website. https://www.cms.gov/files/document/faqs-part-54.pdf

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FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 54

July 28, 2022
Set out below are Frequently Asked Questions (FAQs) regarding implementation of the Affordable Care Act. These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs#Affordable_Care_Act), these FAQs answer questions from stakeholders to help people understand the law and promote compliance.

On January 10, 2022, the Departments issued an FAQ that summarized previously issued FAQs related to coverage of contraceptive services and provided examples of practices reported to the Departments that denied contraceptive coverage to participants, beneficiaries, and enrollees. The FAQ also reminded plans and issuers that are subject to the contraceptive coverage requirements of their responsibility to fully comply with the requirements of PHS Act section 2713 and the Departments' regulations and guidance. This includes the requirement that if an individual's attending provider determines that a particular service or FDA-approved, cleared, or granted contraceptive product is medically appropriate for a specific individual, a plan or issuer must cover that service or product for that individual without cost sharing, whether or not the service or product is specifically identified in the current FDA Birth Control Guide.

The Departments are issuing the following FAQs in response to reports that individuals continue to experience difficulty accessing contraceptive coverage without cost sharing; to clarify application of the contraceptive coverage requirements to fertility awareness-based methods and to emergency contraceptives; and to address federal preemption of state law. The Departments are committed to ensuring consumers have access to the contraceptive benefits, without cost sharing, that they are entitled to under the law, and will take enforcement action as warranted. Violations may be subject to an excise tax under section 4980D of the Internal Revenue Code (Code) or a civil money penalty under section 2723 of the PHS Act, as applicable.

Q2: Are plans and issuers required to cover, without the imposition of any cost sharing, contraceptive products and services that are not included in a category of contraception described in the HRSA-Supported Guidelines?

Yes. The 2019 HRSA-Supported Guidelines include a recommendation 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 as part of contraceptive care. The range of identified categories of contraception in the currently applicable 2019 HRSA-Supported Guidelines include: (1) sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives (combined pill), (8) oral contraceptives (progestin only), (9) oral contraceptives (extended or continuous use), (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms; (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, (17) emergency contraception (levonorgestrel), and (18) emergency contraception (ulipristal acetate); and additional methods as identified by the FDA. Plans and issuers must cover without cost sharing at least one form of contraception in each of the categories above.

In addition, as clarified in FAQs Part 51, the Departments interpret 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130 as applied to the HRSA-Supported Guidelines to require plans and issuers to cover without cost sharing any contraceptive services and FDA-approved, cleared, or granted contraceptive products that an individual and their attending provider have determined to be medically appropriate for the individual, whether or not those services or products are specifically identified in the categories listed in the HRSA-Supported Guidelines, including contraceptive products more recently approved, cleared, or granted by FDA. This coverage must also include the clinical services, including patient education and counseling, needed for provision of the contraceptive product or service

Q8: How can a plan or issuer determine whether a medical management technique is reasonable for purposes of the requirements under PHS Act section 2713?

Whether a medical management technique is reasonable depends on all the relevant facts and circumstances. With respect to contraception, plans and issuers may utilize reasonable medical management techniques only *within* a specified category of contraception and only to the extent the HRSA-Supported Guidelines do not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service that is a contraceptive service or FDA-approved, cleared, or

granted product. With respect to the HRSA-Supported Guidelines as they pertain to contraception, plans and issuers must cover, without cost sharing, at least one form of contraception in each category that is described in the HRSA-Supported Guidelines (or, with respect to contraceptive categories not described in the HRSA-Supported Guidelines, at least one form of contraception in a group of substantially similar services or products).

If a plan or issuer utilizes medical management techniques within a specified category of contraception (or, with respect to contraceptive categories not described in the HRSA-Supported Guidelines, a group of substantially similar services or products), the use of those techniques will not be considered reasonable unless the plan or issuer has an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or their provider (or other individual acting as the individual's authorized representative)and covers a service or FDA-approved, cleared, or granted product determined to be medically necessary with respect to an individual, as determined by the individual's attending provider.

The Departments have continued to receive complaints and reports that participants, beneficiaries, and enrollees are being denied contraceptive coverage, in some cases due to the application of medical management techniques that are not reasonable based on all the relevant facts and circumstances.

Examples of unreasonable medical management techniques (which are the subject of a number of complaints regarding plans and issuers, as well as their pharmacy benefits managers or other service providers) may include situations like the following:

- Denying coverage for all or particular brand name contraceptives, even after the individual's attending provider determines and communicates to the plan or issuer that a particular service or FDA-approved, cleared, or granted contraceptive product is medically necessary with respect to that individual;
- Requiring individuals to fail first using numerous other services or FDA-approved, cleared, or granted contraceptive products *within the same category* of contraception before the plan or issuer will approve coverage for the service or FDA-approved, cleared, or granted contraceptive product that is medically necessary for the individual, as determined by the individual's attending health care provider;
- Requiring individuals to fail first using other services or FDA-approved, cleared, or granted contraceptive products *in other contraceptive categories* before the plan or issuer will approve coverage for a service or FDA-approved, cleared, or granted contraceptive product in a particular contraceptive category; and
- Imposing an age limit on contraceptive coverage instead of providing these benefits to all individuals with reproductive capacity.

The Departments expect plans and issuers to remove impermissible barriers and ensure that participants, beneficiaries, and enrollees have access to the contraceptive coverage they need, as required under the law.

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 who have or develop 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; 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, breast cancer, 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.