# C5.10 - COMBINED HORMONAL CONTRACEPTIVE PATCH (XULANE®)

## Policy

This policy outlines the use of the combined hormonal contraceptive patch. It is easy to use and works like the pill, but only needs to be changed once a week. The patch contains both estrogen, in the form of ethinyl estradiol, and progestin, in the form of norelgestromin.

## Procedure

### *Mode of Action*

The primary mechanism of action for combined hormonal contraceptive patch is inhibition of ovulation and forming thickened cervical mucus that inhibits sperm mobility.

The patch contains the same hormones as combined birth control pills, but the hormones are delivered through the skin. This is why there is likely a decrease in efficacy for patients who weigh more than 90kg (198lbs). The hormones from the patch get into the bloodstream and are processed by the body differently than hormones from birth control pills - they are not metabolized in the liver. Women are exposed to about 60% more estrogen using the patch than a typical birth control pill containing 35 micrograms of estrogen. Theoretically, increased estrogen may increase the risk of side effects, including blood clots - however, studies comparing combined hormonal contraceptive methods are lacking.

See full prescribing information. The FDA has issued this black box warning for the contraceptive patch:
***WARNING: CARDIOVASCULAR RISK ASSOCIATED WITH SMOKING, RISK OF VENOUS THROMBOEMBOLISM, AND PHARMACOKINETIC PROFILE OF ETHINYL ESTRADIOL.***

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### *Cigarette Smoking and Serious Cardiovascular Risks*

Cigarette smoking increases the risk of serious cardiovascular events from hormonal contraceptive use. This risk increases with age, particularly in individuals over 35 years of age, and with the number of cigarettes smoked. For this reason, hormonal contraceptives, including the patch, should not be used by individuals who are over 35 years of age and smoke. This is true for all combined hormonal contraceptive options.

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### *Risk of Venous Thromboembolism*

The risk of venous thromboembolism (VTE) among individuals aged 15 to 44 who used the norelgestromin and ethinyl estradiol transdermal system compared to women who used several different oral contraceptives was assessed in five U.S. epidemiologic studies using electronic healthcare claims data. The relative risk estimates ranged from 1.2 to 2.2; one of the studies found a statistically significant increased relative risk of VTE for current users of norelgestromin and ethinyl estradiol transdermal system.

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### *Pharmacokinetic (PK) Profile of Ethinyl Estradiol*

The Pharmacokinetic (PK) profile for the norelgestromin and ethinyl estradiol (EE) transdermal system is different from the PK profile for oral contraceptives in that it has a higher steady state concentration and a lower peak concentration. It is not known whether there are changes in the risk of serious adverse events based on the differences in PK profiles of

EE in individuals using norelgestromin and EE transdermal system compared with women using oral contraceptives containing 30 mcg to 35 mcg of EE. Increased estrogen exposure may increase the risk of adverse events, including VTE.

## *Effectiveness*

Theoretical effectiveness is 99% effective.

Typical use effectiveness is thought to be 91%. The patch may not be as effective in women weighing more than 198 lbs (90 kg).

## *Indications for Use*

Any individual who is a candidate for combination oral contraceptives may use the patch with the limitations identified in the black box warning. See contraindications below.

## *Contraindications for Use*

Please review guidelines for combined hormonal contraceptive pills.

## *Advantages*

- The same as for oral contraceptives.
- The patch only needs to be placed once per week.
- The patch does not interfere with intercourse.
- The client controls starting or stopping this method. Discontinuation of the method is controlled by the client.
- The patch does not require a daily regimen.

## *Side Effects*

The same side effects as oral contraceptives. Review warning label.

## *Risks*

Risks are the same as for combined oral contraceptive pills. In general, increased estrogen may increase the risk of side effects, including blood clots, however studies directly comparing the patch to oral combined hormonal contraception are lacking.

## *Precautions*

Precautions are the same as for combined oral contraceptive pills.

Hormonal birth control methods help to lower the chances of becoming pregnant. They do not protect against HIV infection (AIDS) and other STIs.

## *Drug Interactions*

See complete prescribing information. Examples include Hepatitis C drug combinations; itraconazole, voriconazole, fluconazole, grapefruit juice, or ketoconazole may increase plasma hormone concentrations; HIV/Hepatitis C Virus (HCV) Protease Inhibitors and Non-Nucleoside Reverse Transcriptase Inhibitors.

Certain anti-microbial, anti-epileptics and anti-retrovials as well as certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal and implantable contraceptives.Initiation

### *No Hormonal Contraceptive Used in the Last Month*

- Begin on or before day 5 of the menstrual cycle. Apply even if not done bleeding.
- Use back-up method until patch has been in place for 7 consecutive days.

### *Switching from Combination Oral Contraceptives*

- Apply on or before start of the new pill cycle and back-up method need not be used.
- Use back-up method for 7 consecutive days if applied after oral contraceptive restart day.

### *Switching from Progestin Only Method*

- Use a back-up method until patch has been in place for 7 days.
- Progestin only pills may apply on any day. Do not skip any days between pills and patch application.
- Apply on the same day as removal of the progestin implant.
- Apply on the same day as removal of LNG IUD.
- Apply prior to the 14th week or 98 days from last Depo-Provera injection. If applied after the 14th week or 98th day, use a back-up method until patch has been in place for 7 consecutive days.

### *Use*

1. Initiate the patch:
    a. Begin the patch within the first 24 hours of menses and no back-up is needed. If the patch is started after the first 24 hours of the menses, a back-up is required for 7 days.
2. Apply one patch weekly for 3 weeks to the upper outer arm, upper torso, lower abdomen or buttocks (any hairless part of the body, avoiding the breasts). Recommend changing patch location each time it is changed. Then the patient observed a patch-free interval of 1 week.
3. Reinforce importance of not going longer than 7 days without a patch which would increase the risk for pregnancy
4. If the patch becomes partially detached for 24 hours or less, reattach it or reapply a new patch. The patch change day will remain the same.
5. If the patch has been detached for more than 24 hours, apply a new patch and that day is now the patch change day. A back-up method should be used for 7 days.
6. If it has been more than 48 hours since a patch detached and unprotected intercourse occurred in the last 72 hours, consider offering EC.
7. Advise client to observe for skin irritation at the patch removal site. Encourage rotation of site application.
8. Call the clinical or report to the ER if any of the following warning signs should occur:

**A** Abdominal Pain (severe)
**C** Chest Pain (shortness of breath)
**H** Headaches (severe)

**E** Eye Problems (blurred or loss of vision)

**S** Severe Leg Pain (calf or thigh)

9. Discuss return of normal menses and fertility after discontinuation of method.

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### *Fertility Return*

Return to fertility after discontinuation reestablishes quickly. Immediate use of an alternative contraceptive is recommended after removal if the client is not seeking pregnancy. Encourage prenatal vitamin initiation at time of removal if not switching to a different highly or moderately effective contraceptive method.

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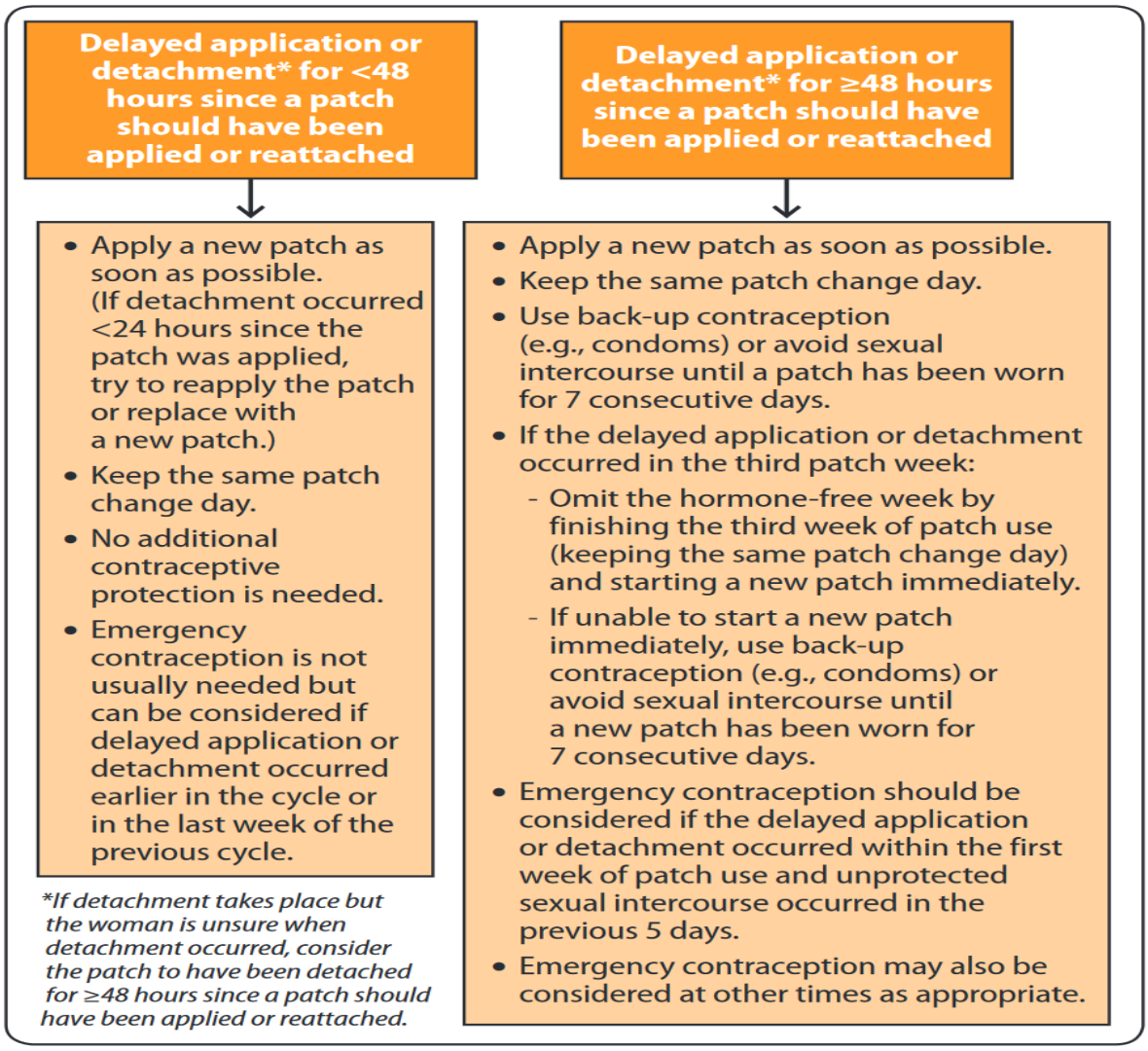
### *Hormone Contraception and HIV*

The CDC has affirmed the safe use of hormone contraception in women who are HIV positive.

# Recommended Actions After Delayed Application or Detachment With Combined Hormonal Patch



| Date Revised | September 2023 |
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| References | Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html) |
| Additional Resources | Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf) |