# Safe Use of Dolutegravir (DTG) by Women and Girls of Child-bearing Potential: A Decision-making Tool

## Assess life stage and fertility intentions of client*

### Actively trying to get pregnant

**EFV-based regimen is preferred**

Explain the risks of using DTG at conception and early in pregnancy; facilitate informed choice of ART.

If woman wants to use DTG, support informed decision.

### Currently pregnant in 1st trimester ‡

**EFV-based regimen is preferred**

Explain the risks of using DTG early in pregnancy; facilitate informed choice of ART.

If woman wants to use DTG, support informed decision.

### Currently pregnant in 2nd-3rd trimester

**DTG-based regimen is preferred**

Counsel about safe pregnancy.

Help woman decide on postpartum contraceptive method.

### Postpartum (breastfeeding or not), wants to avoid pregnancy

### Adolescent or young woman wants to delay pregnancy

### Wants to space pregnancies

### Perimenopausal (≥ 40 years old), wants to limit childbearing

## Assess for current use of contraception

### YES

**DTG-based regimen is preferred**

Support consistent use of reliable contraception.

### NO

## Screen for pregnancy using checklist and/or test

### Early pregnancy ruled out with reasonable certainty

Counsel about and help woman choose a reliable FP option. Support consistent use.

**DTG-based regimen is preferred**

If woman does not want to use contraception, explain the risks of using DTG at conception and early in pregnancy; facilitate and support informed choice of ART. Once counseled, the woman still can choose to use DTG without concurrent use of a contraceptive method.

### Early pregnancy cannot be ruled out with reasonable certainty

**EFV-based regimen is preferred**

Explain the risks of using DTG early in pregnancy; facilitate informed choice of ART.

If woman wants to use DTG, support informed decision.

* Ask clients about changes in fertility desires every time they come for regular follow-up (about once every 3 months); track their FP method use; and refer for any FP methods not available on site.

‡ The concern over birth defects with DTG use applies to the first 8 weeks of pregnancy only; however, because it is not always possible to accurately establish the date of conception, avoiding use during the entire first trimester is recommended.

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***See next page for counseling guidance and messages to share with women and girls at various life stages. ►***

ADVANCING PARTNERS & COMMUNITIES

# Provider Guidance and Key Counseling Messages Based on Client's Various Life Stages

All individuals, regardless of their HIV status, have the right to choose the number, timing, and spacing of their children; and make an informed choice about the use of FP methods.

Providers can offer informed choice counseling, confirm medical eligibility and provide FP methods, or refer.

## General messages for all women about dolutegravir (DTG)

- DTG is a new ARV drug with many advantages including fewer side effects, lower risk of HIV drug resistance, more rapid viral suppression, and fewer drug interactions (e.g., unlike EFV, it does not interact with hormonal contraceptives).
- It is also easier to take when given as TLD—a combination pill (one pill containing three ARVs).
- There are concerns regarding DTG safety when women and adolescent girls use DTG at conception and during the first 8 weeks of pregnancy. Exposure to DTG during this time may be associated with neural tube defect among infants. For this reason, women at risk of pregnancy who use DTG should be counseled about these concerns, offered a choice of reliable contraceptive options, and advised on consistent use.

## General messages for all women about FP

- Almost any FP method can be used safely and effectively by women with HIV.
- Injectables, pills, condoms, and fertility awareness methods can be very effective when used consistently and correctly.
- IUDs and implants are highly effective, don't depend on a woman's ability to use them correctly, and provide several years of protection. IUD insertion should be delayed in women with AIDS until they are clinically well on ART.
- Permanent contraception (sterilization) is an option for women who have completed their childbearing.
- Only condoms (male or female) prevent STI/HIV transmission between partners; the best protection from both pregnancy and STIs/HIV can be achieved when a condom is used with another contraceptive method (dual method use).
- Emergency contraceptive pills can prevent pregnancy when taken within 5 days after unprotected sex (e.g. when method was used incorrectly or not used, including in cases of rape).

## For all women who want to avoid pregnancy but are not using contraception:

- Offer informed choice counseling about effective contraceptive methods.
- For women who want to use contraception:
  - help her to choose a method that suits her life stage, individual needs, and fertility intentions
  - encourage correct and consistent use
  - provide DTG-based regimen
- For women who do not want to use contraception:
  - counsel about risk associated with DTG
  - allow informed choice of ART regimen (DTG- or EFV-based regimen)

## Additional considerations for clients in these *life stages* who wish to avoid pregnancy:

### *Adolescent or young woman*

- Age or parity alone do not restrict contraceptive method options.
- Emphasize dual method use—especially if multiple partners or frequent new partners.

### *Postpartum woman*

Breastfeeding

- The lactational amenorrhea method (LAM) can offer protection from pregnancy if less than six months postpartum AND fully or nearly fully breastfeeding AND menses have not resumed.
- Choose contraceptive method before LAM effectiveness ends or consider using EFV-based regimen to avoid exposure to DTG should unintended pregnancy occur.

Not breastfeeding

- Counsel about the risk of pregnancy after 4 weeks postpartum and healthy spacing (waiting for 2 years before trying to conceive again).
- Help to choose effective contraception.

### *Perimenopausal woman after age 40*

- Age alone does not restrict contraceptive method options.
- May be interested in a long-acting/permanent method; however, if she chooses a short-acting method, encourage correct and consistent use until she stops having periods for one year.

## Women who want to avoid pregnancy and are currently using contraception:

- Can safely use DTG-based regimen.
- Evaluate satisfaction with current method; depending on fertility intentions, discuss availability of long-acting methods (e.g., implant, IUD).
- If using client-dependent method, support correct and consistent use (e.g., use condoms every time you have sex, take a pill every day, come for re-injection on time).

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## Women who are actively trying to get pregnant:

- Counsel about safe conception and pregnancy; family planning can be used to delay conception until viral load is undetectable.
- EFV-based regimen recommended to avoid DTG exposure at conception and during first 8 weeks of pregnancy. Counsel about risks associated with DTG and facilitate informed choice of ARV regimen. Support woman's informed decision.

## Women currently pregnant — 1st trimester:

- DTG-based regimen not recommended until later in pregnancy. Counsel about risks; support informed choice of ARV regimen.

## Women currently pregnant — 2nd-3rd trimester:

- Can safely use DTG-based regimen.
- Decide on postpartum contraceptive method. LAM can be an effective option during the first 6 months postpartum for fully breastfeeding women who have not resumed their menses.

# Excluding Pregnancy Prior to Initiation of DTG and Desired Contraceptive Method

*Match the client's menstrual status with the options below and follow the instructions.*

## Client with amenorrhea (postpartum or other type)

**Use pregnancy checklist.**

Pregnancy ruled out: provide DTG and FP method.

Pregnancy not ruled out: use a pregnancy test.

Pregnancy test is negative[1] (or test is not immediately available): pregnancy cannot be ruled out until the test is repeated in 3-4 weeks. **EFV-based regimen is preferred.** Counsel about DTG risks and facilitate informed choice of ART regimen. If client still wants to use DTG-based regimen, support informed decision.

Provide implant, DMPA, or COCs (but not IUD) as desired; or abstain/use condoms for 3-4 weeks, then repeat the pregnancy test.

If second pregnancy test is negative:[2] switch to (or continue with) DTG and use any effective FP method, including IUD.

## Client between two regular menses (monthly bleeding)

**Use pregnancy checklist.**

Pregnancy ruled out: provide DTG and FP method.

*Do not use a pregnancy test—in most cases, tests are not effective until a woman misses her menses.**

Pregnancy not ruled out: **EFV-based regimen is preferred.** Counsel about DTG risks and facilitate informed choice of ART regimen. If client still wants to use DTG-based regimen, support informed decision.

Provide implant, DMPA, or COCs (but not IUD) as desired. At onset of next menses, switch to (or continue with) DTG; provide IUD if desired.

Return for a pregnancy test if next menses are delayed (see instructions below*).

[1] First pregnancy test is positive: estimate gestational age by ultrasound or pelvic exam. If more than 8 weeks, DTG use is preferred.

[2] First pregnancy test is negative, second is positive: gestational age is at least 5 weeks. DTG use will be preferred in 3-4 weeks. If planning to continue pregnancy, discontinue FP method.

* **If the client presents with a late/missed menses, use a pregnancy test to rule out pregnancy.**
If using a highly sensitive pregnancy test (for example, 25 mIU/ml) and it is negative, provide DTG-based regimen and her desired FP method.

If using a test with lower sensitivity (for example, 50 mIU/ml) and it is negative during the time of her missed period, wait until at least 10 days after expected date of menses to repeat the test. Advise the woman to use condoms or abstain in the meantime. Until pregnancy can be ruled out, EFV-based regimen is preferred. Counsel about the risks of using DTG early in pregnancy and facilitate/support informed choice. If the test is still negative after 10 days, switch to (or continue with) DTG-based regimen and provide her desired FP method.

*If test sensitivity is not specified, assume lower sensitivity.*

# PREGNANCY CHECKLIST

## How to be Reasonably Sure a Client is Not Pregnant: Client History

Ask the client questions 1–6. As soon as the client answers **YES** to ***any question,*** stop, and follow the instructions.

| | | |
|---|---|---|
| NO | 1. Did your last menstrual period start within the past 7 days?* | YES |
| NO | 2. Have you abstained from sexual intercourse since your last menstrual period, delivery, abortion or miscarriage? | YES |
| NO | 3. Have you been using a reliable contraceptive method consistently and correctly since your last menstrual period, delivery, abortion or miscarriage? | YES |
| NO | 4. Have you had a baby in the last 4 weeks? | YES |
| NO | 5. Did you have a baby less than 6 months ago, are you fully or nearly-fully breastfeeding, and have you had no menstrual period since then? | YES |
| NO | 6. Have you had a miscarriage or abortion in the past 7 days?* | YES |

**** If the client is planning to use a copper IUD, the 7-day window is expanded to 12 days.***

If the client answered **NO** to ***all of the questions,*** pregnancy cannot be ruled out using the checklist.

Rule out pregnancy by other means.

If the client answered **YES** to ***at least one of the questions,*** you can be reasonably sure she is not pregnant.



*In cases where pregnancy cannot be ruled out, offer emergency contraception if the woman had unprotected sex within the last 5 days. Counsel all women to come back any time they have a reason to suspect pregnancy (for example, missed period).*