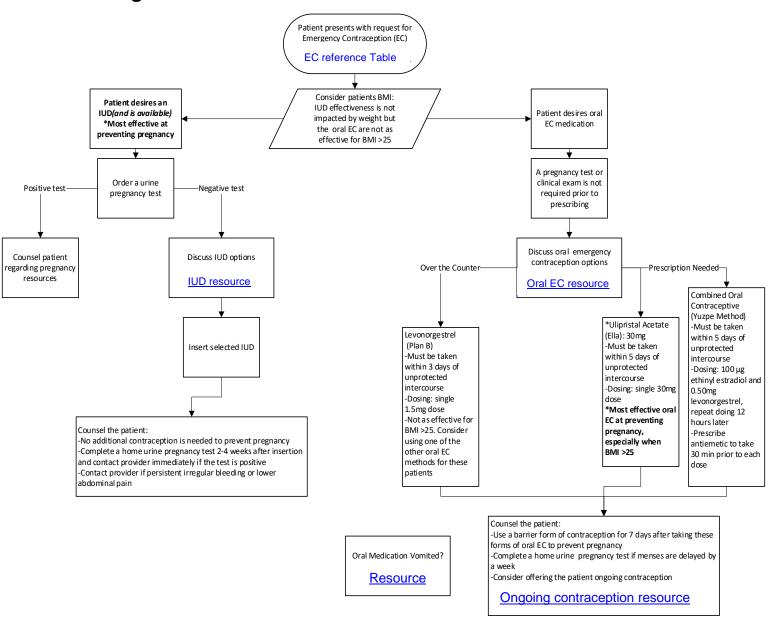


Clinical Standardization

EMERGENCY CONTRACEPTION, ADULT, EMERGENCY DEPARTMENT AND AMBULATORY, PATHWAY

Updated: August 8, 2022

Clinical Algorithm:





Clinical Pathway Summary

CLINICAL PATHWAY NAME: Emergency Contraception (EC), Emergency Room/Ambulatory Practice, Guideline

PATIENT POPULATION AND DIAGNOSIS: Any patient capable of becoming pregnant.

APPLICABLE TO: All Beaumont Health Spectrum Health sites and Lakeland

BRIEF DESCRIPTION: This guideline outlines best practice regarding recommending and prescribing emergency contraception (EC) by reviewing the evidence for the efficacy and safety of available methods of EC. Also provided is a <u>Summary Table Comparing Emergency Contraception Methods</u>

This guideline was created to increase awareness of EC among obstetricians-gynecologists, primary care providers, and emergency medicine providers. Through an increase in knowledge around EC, we will increase access to EC for patients at risk for pregnancy.

OPTIMIZED EPIC ELEMENTS (if applicable): Emergency Contraception Smartgroup and EC counseling System SmartPhrase.

IMPLEMENTATION DATE: August 9, 2022

LAST REVISED: August 8, 2022

Clinical Pathways Clinical Approach

TREATMENT AND MANAGEMENT:

A. Emergency Contraception (EC) Definition:

Emergency contraception (EC) describes contraceptive methods used to **prevent pregnancy** after unprotected intercourse, sexual assault, and contraceptive failure before a pregnancy is established. EC must be used as soon as possible after unprotected intercourse to be effective. EC is sometimes confused with medical abortion (the abortion pill RU-486). Medical abortion terminates an existing pregnancy. EC is ineffective after implantation and will not interrupt an existing pregnancy.

Numerous studies have looked at teratogenic risk of conception during daily use of oral contraceptives. These studies included the older, higher dose preparations and found no risk to an established pregnancy or harm to a developing embryo. Even though no study has been done that specifically investigated adverse effect to an existing pregnancy after exposure to EC, these studies support the conclusion that EC will not harm an existing pregnancy.

B. Emergency Contraception Options Available (listed in order of most to least effective):

I. Intrauterine device (IUD):



The IUDs are the most effective form of EC and have been shown to have a pregnancy rate of less than 1 percent, provide ongoing contraception, and are well tolerated. The IUD's effectiveness for EC is not affected by a patient's weight.

- a. Copper TCu380A IUD (ParaGard): IUDs are the most effective form of EC and must be placed by a provider. It is highly effective if placed within 5 days of unprotected intercourse and in some studies was shown to be effective up to 10 days. The effectiveness is not affected by weight and is the best option for patients with a BMI of 30 or higher. The Copper IUD has the added benefit of providing the patient with a highly effective, long-term reversible contraception for up to 10 years. The FDA does not label IUDs as EC although it is used for this purpose. IUDs can be safely used in nulliparous patients regardless of age.
- b. Levonorgestrel (LNG) 52 mg IUD (Mirena and Liletta): IUDs are the most effective form of EC and must be placed by a provider. It is highly effective if placed within 5 days of unprotected intercourse. The effectiveness is not affected by weight and is the best option for patients with a BMI of 30 or higher. The Levonorgestrel 52 mg IUD has the added benefit of providing the patient with a highly effective, long-term reversible contraception for up to 6-7 years and has been associated with a reduction in menstrual bleeding and cramping. The FDA does not label IUDs as EC although it is used for this purpose. The other IUDs with a lower dose of levonorgestrel have not been studied and should not be used for EC. IUDs can be safely used in nulliparous patients regardless of age.

II. Oral Medications:

- a. 30 mg ulipristal acetate (UPA) oral pill (Ella): The most effective type of EC pill and is only available with a prescription. It must be taken within 5 days after unprotected intercourse. Taken as a single 30 mg UPA dose. The sooner the medication is taken, the more effective it is. Patient's whose BMI is greater than 30 should be informed that this formulation of EC is less effective than an IUD used for EC but they should not be refused or discouraged from using EC because of their weight. Hormonal contraception should not be started within 5 days of taking UPA. Patients are instructed to abstain or use a backup method for 7 days after taking EC.
- b. 1.5 mg levonorgestrel (LNG) oral pill (Plan B): This regiment is less effective than UPA in patient's whose BMI is > 25 and is available over the counter without age restriction. It must be taken within 3 days after unprotected intercourse and is taken as a single 1.5 mg LNG dose. The sooner the medication is taken, the more effective it is. Patient's whose BMI is greater than 25 should be informed that this formulation of EC is less effective than other forms of EC but they should not be refused or discouraged from using EC because of their weight. A 2022 randomized controlled study evaluated if doubling the dose to 3 mg in patients whose BMI was greater than 30 would improve ovulation suppression in these patients. The study did not show a statistically significant difference between the 1.5 mg and 3 mg LNG doses. Hormonal contraception can be initiated at the time LNG is taken. Patients are instructed to abstain or use a backup method for 7 days after taking EC.
- c. Combined oral contraceptive (COC) pills (**Yuzpe Method**): This is the least effective form of EC and can be used when the patient does not have access to the other two oral EC methods (UPA and LNG). It can cause significant nausea and vomiting due to the high dose of estrogen. This EC regiment is only available with a prescription but may be easier to obtain in regional areas. It must be **taken within 5 days** after unprotected intercourse and is taken as a split dose 12 hours apart. The dosage includes one dose of 100 µg ethinyl estradiol plus 0.50 mg of levonorgestrel, followed by the same dosing 12 hours later. The sooner the medication is taken, the more effective it is. It is recommended that an antiemetic (such as Zofran) also be prescribed due to the increased incidence of nausea and vomiting with this EC formulation. The effect of a patient's weight on the effectiveness of this EC method has not been studied. Hormonal contraception can be initiated at the time EC is taken. Patients are instructed to abstain or use a backup method for 7 days after taking EC. You can find information regarding regiments for specific birth control pills at www.not-2-late.com.



C. Mechanism of Action:

According to the American College of Obstetricians and Gynecologists (ACOG) "No single mechanism of action has been established for emergency contraception; rather, the mode of action varies according to the day of the menstrual cycle on which sexual intercourse occurs, the time in the menstrual cycle that the emergency contraceptive is administered, and the type of emergency contraceptive."

- Copper TCu380A IUD (ParaGard) and Levonorgestrel (LNG) 52 mg IUD (Mirena and Liletta): Unlike the clearly defined mechanism of action known for the oral EC methods, there is no clearly shown reason why IUDs are so effective at preventing pregnancy when used as EC. The IUD does not prevent ovulation but is effective in preventing pregnancy by inhibiting fertilization by affecting sperm viability and function of both the egg and sperm. The IUD also likely affects the endometrium and inhibits implantation after the egg is fertilized and that is why it has superior efficacy when compared to the oral EC methods. The IUD will not affect an established pregnancy and cannot be used as an abortifacient.
- II. 30 mg ulipristal acetate (UPA) oral pill **(Ella)** and 1.5 mg levonorgestrel (LNG) oral pill **(Plan B)**: It has been shown through multiple, well-designed studies that oral UPA and LNG EC regiments work by preventing ovulation and do not prevent implantation of a fertilized embryo. Levonorgestrel (Plan B) prevents ovulation by delaying the luteinizing hormone (LH) surge, thus inhibiting follicular development and release of the egg. UPA (Ella) prevents ovulation both by delaying the LH surge and delays release of the egg even after the LH surge. This may explain why Ella is more effective at preventing pregnancy than Plan B.
- III. Combined oral contraceptive (COC) pills (**Yupze method**): The combined oral contraceptive pills works by preventing ovulation and does not prevent implantation of a fertilized embryo. This EC method has more side effects including nausea and vomiting than the other oral EC methods. A prescription for an antiemetic should be prescribed at the same time help patient tolerate.

D. Efficacy in preventing pregnancy:

	Copper TCu380A IUD - commercial name Paragard	52 mg Levonorgestrel (LNG) IUD – commercial names Liletta and Mirena	Ulipristal acetate (Ella) – RECOMMENED ORAL EC	Levonorgestrel (Plan B)	Combined oral contraceptives (Yupze method)
Overall	99%	97%	82 - 89%	74 – 83%	56 – 89%
BMI 25-29.9	99%	97%	89%	75%	Has not been studied
BMI ≥ 30	99%	97%	74%	42%	Has not been studied
Timing of use related to unprotected intercourse	Highly effective at any time during the cycle	Up to 5 days	Up to 5 days	Up to 3 days but may have efficacy up to 5 days	Up to 5 days



E. Eligibility:

All emergency contraception (EC) methods can be offered or made available to any person, regardless of age. The Centers for Disease Control and Prevention's *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010* include no conditions in which the risks of oral emergency contraception use outweigh the benefits. According to ACOG "These criteria specifically note that women with previous ectopic pregnancy, cardiovascular disease, migraines, or liver disease and women who are breastfeeding may use emergency contraception. Therefore, any emergency contraceptive regimen may be made available to women with contraindications to the use of conventional oral contraceptive preparations."

F. Screening prior to and after prescribing

No clinical exam or pregnancy testing is required prior to prescribing oral EC methods. A negative urine pregnancy prior to insertion is always necessary when an IUD is used for EC. Oral emergency contraception should not be withheld or delayed waiting for a pregnancy test result.

No scheduled follow up is required after use of emergency contraception. The patient should be instructed to do a home urine pregnancy test if menses are delayed by a week or more after expected time. All patients who chose an IUD for EC should be instructed to do a home pregnancy test 2-4 weeks after insertion and to contact their provider immediately if the test is positive. A clinical evaluation and pregnancy test is indicated if the patient develops lower abdominal pain or persistent irregular bleeding. These symptoms can indicate an ectopic pregnancy and must be evaluated by a provider as soon as possible. Patients should also be counseled and referred as needed to discuss ongoing contraception and screening for sexually transmitted infections if desired.

G. Obtaining Emergency Contraception:

IUDs must be scheduled with a provider and timely access can be an issue. Ulipristal Acetate (Ella) is the most effective oral method but requires a prescription and many pharmacies do not keep this medication in stock, delaying access to the medication by 1-2 days. This is covered by insurance if the patient has contraceptive coverage. Levonorgestrel (Plan B) is available over the counter without age restriction and should be the easiest to obtain but is less effective in patient's whose BMI is > 25-30. The out-of-pocket expense can vary between \$5.59 - \$50 (can be as low as \$9 if ordered online). Many pharmacies stock Levonorgestrel (Plan B) behind the counter.

H. Initiating ongoing contraception after taking emergency contraception

Repeated doses of emergency contraception may not reduce the risk of pregnancy in subsequent acts of intercourse if used in the same cycle. Patients may even be at an increased risk of pregnancy later in the same cycle due to the delayed ovulation later in the cycle. Recommendations regarding when to initiate hormonal contraception after EC vary based on the type of EC utilized.

- I. IUD: No additional contraception is necessary.
- II. Ulipristal acetate (Ella): Delay initiating hormonal contraception at least 5 days after taking ulipristal acetate. Instruct patients to abstain or use a barrier contraceptive method for 7 days. This recommendation is based on two pharmacodynamic studies that showed that coadministration of ulipristal acetate and progestin may decrease effectiveness.
- III. Levonorgestrel (Plan B) or combined oral contraceptives: Hormonal contraception can be initiated immediately but patients should be instructed to abstain or use a barrier contraceptive method for 7 days.



I. Oral medication vomited

Vomiting is unlikely after taking the Ulipristal Acetate (Ella) and Levonorgestrel (Plan B) methods but if it does occur within 2 hours of taking Plan B or 3 hours of taking Ella, it is recommended that dosing be repeated. Nausea and vomiting are much more common with the combined oral contraceptives (Yuzpe method). If vomiting occurs within 2 hours, it is recommended that dosing be repeated. If vomiting continues with Plan B or the combined oral contraceptive methods, it is recommended that further dosing be placed high in the vagina instead of continuing to take orally.

Consider prescribing an antiemetic for anyone who has vomited and is repeating a dose.

Pathway Information

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CLINICAL PRACTICE COUNCIL (CPC): Spectrum Women's Health Clinical Practice Council (CPC); Beaumont Women's Health Clinic Care Programs (CCP); BHSH Clinical Excellence Council (CEC)

CPC APPROVAL DATE: WH CPC: July 19, 2022; CCP July 29, 2022; CEC August 9, 2022

OTHER TEAM(S) IMPACTED: Emergency Room providers, Nursing, Pharmacy

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Appendix 1. Summary Table Comparing Emergency Contraception Methods

Emergency Contraception Reference Table

	Copper TCu380A IUD - commercial name Paragard	52 mg Levonorgestrel (LNG) IUD – commercial names Liletta, and Mirena	Ulipristal Acetate (UPA) – commercial name Ella RECOMMENDED ORAL EC METHOD	Levonorgestrel (LNG) – commercial name Plan B	Combined oral contraceptive (COC) pills – Yuzpe method
Formulation	N/A	52 mg levonorgestrel IUD	30 mg tablet – one time dose	1.5 mg tablet – one time dose	Combination of COC (100 µg ethinyl estradiol plus 0.50 mg of levonorgestrel) Repeat same dosing 12 hours later Prescribe antiemetic with this method
Efficacy pregnancy prevention	99%	97%	82-89 % overall ■ BMI 25-29, 89% ■ BMI ≥ 30, 74%	74-83 % overall • BMI 25-29, 75% • BMI ≥ 30, 42%	56-89%
Decreased efficacy with BMI > 25?	Not affected by BMI	Not affected by BMI	More effective than LNG (Plan B) when BMI > 25	Less effective that IUD and UPA (Ella) when BMI > 25	Has not been studied
Timing after unprotected intercourse	Highly effective at any time during the cycle with negative pregnancy test	Up to 5 days	Up to 5 days	Up to 3 days but may have efficacy up to 5 days	Up to 5 days
Mechanism of Action	Primarily works by delaying ovulation and preventing fertilization but if fertilization does occur, may also inhibit implantation	Primarily works by delaying ovulation and preventing fertilization but if fertilization does occur, may also inhibit implantation	Delays ovulation and does not interfere with fertilization or implantation	Delays ovulation and does not interfere with fertilization or implantation	Delays ovulation and does not interfere with fertilization or implantation
Drug Interactions	NA	NA	Concurrent use of CYP3A4 inducers may reduce the efficacy of oral EC. A reasonable alternative is to double the dose.	Concurrent use of CYP3A4 inducers may reduce the efficacy of oral EC. A reasonable alternative is to double the dose.	No data but likely concurrent use of CYP3A4 inducers may reduce absorption and decrease efficacy.
Cost - Insurance	Usually covered 100% with no copay or deductible if patient has contraceptive coverage.	Usually covered 100% with no copay or deductible if patient has contraceptive coverage.	Usually covered 100% with no copay or deductible if patient has contraceptive coverage.	Available over the counter so will only be covered if patient has coverage for OTC medications (Medicaid)	Usually covered 100% with no copay or deductible if patient has contraceptive coverage.
Cost - Cash	\$2,135.62	Liletta: \$2188.81 Mirena: \$2717.54	\$42.71-\$46.97	\$5.59-\$49.99	



Availability	Must be inserted by a provider in the office or ED	Must be inserted by a provider in the office or ED	Requires a prescription	Available over the counter with no age restriction *If not available in pharmacy aisle, the product may be available behind the counter. Ask the pharmacist.	Requires a prescription
Pregnancy test required before use	Yes	Yes	No	No	No
Follow up after use	Home urine pregnancy test 2-4 weeks after insertion Counsel patient on increased risk of ectopic pregnancy with failure (<1% risk) and to call with bleeding lasting longer than 2 weeks or severe abdominal pain	Home urine pregnancy test 2-4 weeks after insertion Counsel patient on increased risk of ectopic pregnancy with failure (<1% risk) and to call with bleeding lasting longer than 2 weeks or severe abdominal pain	Home pregnancy test if menses more than a week late Inform patient to use barrier method for remainder of cycle. Inform patient of increased risk of pregnancy if unprotected intercourse in same cycle after taking EC.	Home pregnancy test if menses more than a week late Inform patient to use barrier method for remainder of cycle. Inform patient of increased risk of pregnancy if unprotected intercourse in same cycle after taking EC.	Home pregnancy test if menses more than a week late Inform patient to use barrier method for remainder of cycle. Inform patient of increased risk of pregnancy if unprotected intercourse in same cycle after taking EC. 56-89% depending on the type used and the patient's weight.
Timing of starting ongoing hormonal contraception	N/A Provides birth control efficacy for up to 10 years	NA Provides birth control efficacy up to 7 years	Delay started hormonal birth control for at least 5 days after use (OCPs, Depo, Nexplanon, etc) Instruct patient to use barrier method for 7 days after initiating hormonal contraception	Available to start hormonal birth control method immediately (OCPs, Depo, Nexplanon, etc) Instruct patient to use barrier method for 7 days after initiating hormonal contraception	Available to start hormonal birth control method immediately (OCPs, Depo, Nexplanon, etc) Instruct patient to use barrier method for 7 days after initiating hormonal contraception