

**ATTACHMENT A**  
**MTF Formulary Management for Emergency**  
**Contraceptives** Defense Health Agency Pharmacy Operations  
 Division

**Bottom Line**

- **Plan B One Step (levonorgestrel 1.5 mg) NDC # 51285-146-19 is the designated emergency contraceptive on the Basic Core Formulary.**
- **Levonorgestrel 0.75 mg and 1.5 mg (Plan B, Plan B One Step, and generics) and ulipristal acetate (Ella) emergency contraceptives remain on the Uniform Formulary.**
- **Quantity limits apply for the emergency contraceptives: one fill per prescription with no refills**

**Uniform Formulary Decision:** The Director, DHA, approved the recommendations from the May 2016 DoD P&T Committee meeting on July 28, 2016.

Uniform Formulary (UF) Agents		Nonformulary (NF) Agents
Basic Core Formulary (BCF) MTFs <u>must</u> have on formulary	Not on BCF MTFs <u>may</u> have on formulary	MTFs <u>must not</u> have on formulary
<ul style="list-style-type: none"> <li>▪ levonorgestrel 1.5 mg (Plan B One Step) NDC# 51285-146-19 formulation labeled for clinic use</li> </ul>	<ul style="list-style-type: none"> <li>▪ levonorgestrel 1.5 mg (Plan B One Step, generics)</li> <li>▪ levonorgestrel 0.75 mg (Plan B, generics)</li> <li>▪ ulipristal acetate 30 mg (Ella)</li> </ul>	Not applicable

**Background**

- The emergency contraceptives reviewed for formulary placement included levonorgestrel 1.5 mg (Plan B One Step, generics), levonorgestrel 0.75 mg (Plan B, generics), and ulipristal acetate 30 mg (Ella).
- Levonorgestrel 1.5 mg (Plan B One Step) is available over-the-counter (OTC) with no age restrictions. There are at least 10 AB-rated generic formulations of Plan B One Step that are now available. The levonorgestrel 1.5 mg single-dose regimen has largely replaced use of the 0.75 mg two-tablet regimen (Plan B).
  - As of April 30, 2016, all Plan B One Step generic formulations are also available without age restrictions.
- Ulipristal acetate (Ella) is a proprietary product with no generic equivalents on the market. Ella requires a prescription.

**Clinical Summary**

- Both levonorgestrel and ulipristal acetate emergency contraceptives are effective in preventing unintended pregnancies by delaying or inhibiting ovulation.
- Levonorgestrel is effective when taken within 72 hours of unprotected intercourse; however, its efficacy declines over time. Ulipristal acetate is effective when taken up to 120 hours after unprotected intercourse.
- Women taking ulipristal acetate within 120 hours after unprotected intercourse have a lower risk of becoming pregnant compared to those taking levonorgestrel for emergency contraception.
- In terms of relative effectiveness, ulipristal acetate is more effective compared to levonorgestrel in preventing unintended pregnancies, based on findings from one meta-analysis and pooled data from two randomized, multicenter studies. Ulipristal acetate prevented 67% of expected pregnancies versus 52% with levonorgestrel. (Glasier AF, et al. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. *Lancet*. 2010;375:555–562.)
- The World Health Organization guidelines state that emergency contraceptives may be less effective in women with body mass indexes (BMIs)  $\geq 30$  kg/m<sup>2</sup> compared to women with BMIs  $< 25$  kg/m<sup>2</sup>. However, the benefits of emergency contraception in this population outweigh the risks of pregnancy.

## Safety

- The most commonly reported adverse events occurring with an incidence  $\geq 10\%$  with either levonorgestrel or ulipristal acetate are headache, nausea, and abdominal pain. Both products have a similar safety profile, comparable drug-drug interactions, and contraindications for use.
- In 2014, a 3½ year post-marketing study collected pharmacovigilance data from 1.4 million women across 23 countries to study long-term safety effects in women exposed to ulipristal acetate. The study found ulipristal acetate was safe for use as an emergency contraceptive without unexpected or serious adverse events.

## Overall Conclusion

- Both levonorgestrel and ulipristal acetate (Ella) are required on the UF to ensure adequate clinical coverage of emergency contraception when taken within 72 hours and 120 hours after unprotected intercourse, respectively.

## References

- DoD P&T Committee minutes: <http://www.health.mil/PandT>
- Current/future drug classes under review by the DoD P&T Committee <http://www.health.mil/About-MHS/Other-MHS-Organizations/DoD-PT-Committee>
- TRICARE Formulary Search Tool: <http://www.health.mil/formulary>
- Prior Authorization/Medical Necessity forms: See Formulary Search Tool above.
- Formulary Management Documents (including this one) available at: <http://www.health.mil/DoDPTResources>
- Point of contact for additional information: [dha.jbsa.pharmacy.list.poduf@mail.mil](mailto:dha.jbsa.pharmacy.list.poduf@mail.mil)

Emergency Contraceptives Price Comparison at MTF	
Drug	MTF Cost/Day (May 2016)
<b>Basic Formulary</b>	
<i>LABELED FOR CLINIC USE</i> <ul style="list-style-type: none"> <li>▪ levonorgestrel 1.5 mg (Plan B One Step) NDC# 51285-146-19</li> </ul>	<b>\$ Most Cost-Effective</b>
<b>Uniform Formulary</b>	
<i>LABELED FOR OTC USE</i> <ul style="list-style-type: none"> <li>▪ levonorgestrel 1.5 mg (Plan B One Step, generics); includes NDC# 51285-162-88</li> <li>▪ levonorgestrel 0.75 mg (Plan B, generics)</li> </ul> <i>AVAILABLE BY PRESCRIPTION ONLY</i> <ul style="list-style-type: none"> <li>▪ ulipristal acetate (Ella)</li> </ul>	<b>\$\$ - \$\$\$ Less Cost-Effective</b>
<b>Legend:</b> <b>\$</b> = "Most Cost-Effective" represents Rx's with the <u>lowest cost</u> and best clinical efficacy <b>\$\$</b> = "Less Cost-Effective" represents <u>higher cost</u> Rx's with similar clinical efficacy <b>\$\$\$</b> = "Less Cost-Effective" represents <u>next higher cost</u> Rx's with similar clinical efficacy <b>\$\$\$\$</b> = "Least Cost-Effective" represents Rx's with the <u>highest cost</u> with similar clinical efficacy	