

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

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|----------------|----------------|-----------------------|---------------------------|
| POLICY: | Women's Health | P&T DATE: | 12/8/2020 |
| CLASS: | Endocrine | REVIEW HISTORY | 12/19, 12/18, 5/17, 2/17, |
| LOB: | Medi-Cal | (MONTH/YEAR) | 2/16 |

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

This formulary document is intended to explain the HPSJ contraceptive pharmacy benefit. HPSJ also covers implantable, injectable, intrauterine, and transdermal birth control agents. Some of these agents may be covered under the medical benefit. Per SB-999, effective January 1st, 2017, HPSJ will cover up to 1 years supply (13 cycles) of formulary oral contraceptive agents, a 12 month supply of hormonal contraceptive patches (36 Patches) and a 12 month supply of vaginal rings (12 rings).¹ Qualified family planning professionals, pharmacists, and other providers may dispense these medications under the HPSJ pharmacy or medical benefit, where applicable. Condoms are also covered with a quantity limit of 24 per month.

Preterm birth (PTB), or birth at less than 37 gestational weeks, is the leading cause of neonatal mortality in the United States and is associated with long-term neurological disabilities such as developmental delays and cerebral palsy. Each year, preterm birth affects nearly 500,000 infants – or 1 in every 8 born in the United States.² Major risk factors for preterm birth include history of spontaneous preterm labor and a short cervix (< 25mm) in the midtrimester.

The Society of Maternal-Fetal Medicine (SMFM) and American Congress of Obstetricians and Gynecologists (ACOG) publish guidelines and practice bulletins that address the major risk factors and role of progesterone and its synthetic derivative in prevention of preterm birth. Progesterone is a steroidal hormone essential for the maintenance of pregnancy—by preventing preterm birth in women with identified risk factors and reducing risks in women with history of recurrent miscarriages.

Historically, progesterone oral capsules are administered as vaginal suppository. This route exhibits a substantially higher concentration of progesterone in the endometrial tissues and is more effective than systemic administration for prevention of preterm labor. Newer formulations include Crinone (progesterone) vaginal gel, progesterone in oil injection, and Makena (hydroxyprogesterone caproate) injection. As of today, Makena is the only drug that is FDA-approved and indicated to reduce the risk of preterm birth.

According to ACOG, The Endocrine Society, and the American Association of Clinical Endocrinologists (AACE), the most effective therapy for vasomotor symptoms is systemic hormone therapy (estrogen with or without progestin), although there is evidence supporting the use of SSRIs, SNRIs, clonidine, and gabapentin. Vaginal symptoms are also best managed with hormone therapy, but topical methods are preferred due to having fewer side effects.³⁻⁵

Oral Hormonal Contraceptive Agents: (Current as of 9/2018)

Table 1: Monophasic Birth Control Agents:

| GCN | Active Ingredients | Available Products | FDB Class | Form. Status | Average Cost per Rx |
|-------|--|--------------------|-----------|--------------|---------------------|
| 11534 | Levonorgestrel/ Ethinyl Estradiol (21/7) | Lessina | Y | F | \$7.72 |
| | | Aviane | Y | F | \$7.74 |
| | | Orsythia | Y | F | \$7.95 |
| | | Falmina | Y | F | \$7.69 |
| | | Delyla | Y | F | -- |
| | | Aubra | Y | F | \$7.69 |
| | | Sronyx | Y | F | \$7.74 |

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|-------|--|--|---|----|---------|
| | | Lutera | Y | F | \$7.80 |
| | | Larissia | Y | F | \$7.72 |
| | | Vienna | Y | F | \$7.96 |
| | | Levonorgestrel 0.1mg/ Ethinyl Estradiol 20mcg | Y | F | \$7.76 |
| 98551 | Levonorgestrel/Ethinyl Estradiol (28 active) | Amethyst | Y | F | \$42.77 |
| | | Levonorgestrel 0.09mg/ Ethinyl Estradiol 20mcg | Y | F | \$42.77 |
| 11471 | Norethindrone/Ethinyl Estradiol (21/7) | Brevicon | O | NF | -- |
| | | Necon 0.5/35 | Y | F | \$24.07 |
| | | Modicon | O | NF | -- |
| | | Nortrel 0.5/35 | Y | F | \$21.19 |
| | | Wera 0.5/35 | Y | F | \$21.71 |
| 11490 | Ethinodiol Diacetate/Ethinyl Estradiol (21/7) | Zovia 1/35E | Y | F | \$19.65 |
| | | Kelnor 1/35 | Y | F | \$20.34 |
| 11530 | Levonorgestrel/Ethinyl Estradiol (21/7) | Portia | Y | F | \$10.06 |
| | | Levora | Y | F | \$8.57 |
| | | Altavera | Y | F | \$7.58 |
| | | Chateal | Y | F | \$9.32 |
| | | Kurvelo | Y | F | \$7.21 |
| | | Marlissa | Y | F | \$9.44 |
| | | Lillow | Y | F | \$7.12 |
| | | Levonorgestrel 0.15mg/Ethinyl Estradiol 30mcg | Y | F | \$9.44 |
| 20414 | Levonorgestrel 0.15mg/Ethinyl Estradiol 0.03mg (84 active) | Quasense | Y | F | \$49.73 |
| | | Setlakin | Y | F | \$54.95 |
| 11500 | Norgestrel 0.3mg/Ethinyl Estradiol 0.03mg (21/7) | Cryselle | Y | F | \$15.43 |
| | | Low-Ogestrel | Y | F | \$15.94 |
| | | Elinest | Y | F | \$15.53 |
| 11480 | Norethindrone/ Ethinyl Estradiol (21 Pack) | Loestrin 1.5/30 | Y | F | \$19.34 |
| | | Junel 1.5/30 | Y | F | \$16.11 |
| | | Microgestin 1.5/30 | Y | F | \$18.83 |
| | | Larin 1.5/30 | Y | F | \$18.52 |
| 68101 | Norethindrone/ Ethinyl Estradiol + Iron (21/7) | Loestrin FE 1.5/30 | Y | F | \$11.63 |
| | | Junel FE 1.5/30 | Y | F | \$13.30 |
| | | Blisovi FE 1.5/30 | Y | F | \$12.90 |
| | | Microgestin FE 1.5/30 | Y | F | \$14.85 |
| | | Larin FE 1.5/30 | Y | F | \$13.28 |
| 11481 | Norethindrone/ Ethinyl Estradiol (21 Pack) | Loestrin 1/20 | Y | F | \$9.63 |
| | | Junel 1/20 | Y | F | \$9.42 |
| | | Microgestin 1/20 | O | F | \$24.36 |
| | | Larin 1/20 | Y | F | \$8.67 |
| | | Norethindrone 1mg/Ethinyl Estradiol 20mcg | Y | F | \$9.33 |
| 68102 | Norethindrone/ Ethinyl Estradiol + Iron (21/7) | Loestrin FE 1/20 | Y | F | \$11.74 |
| | | Junel FE 1/20 | Y | F | \$10.33 |
| | | Blisovi FE 1/20 | Y | F | \$11.18 |
| | | Microgestin FE 1/20 | O | F | \$28.12 |

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|-------|---|---|---|----|----------|
| | | Larin FE 1/20 | Y | F | \$11.66 |
| | | Tarina FE | Y | F | \$6.87 |
| | | Norethindrone 1mg/Ethinyl Estradiol 20mcg/Fe 75mg | Y | F | -- |
| 29264 | Norethindrone 1mg/Ethinyl Estradiol 10mcg (24 Pack) | Lo Loestrin Fe | N | F | \$128.46 |
| 26629 | Norethindrone 1mg/Ethinyl Estradiol 20mcg/Fe 75mg | Blisovi 24 FE | Y | NF | \$59.45 |
| 34725 | Norethindrone 1mg/Ethinyl Estradiol 20mcg (24) + Iron (Chewable) | Minastrin 24 FE | N | NF | -- |
| 26629 | Norethindrone 1mg/Ethinyl Estradiol 20mcg (24) + Iron | Larin 24 FE | Y | NF | -- |
| 11300 | Norgestimate/ Ethinyl Estradiol (21/7) | Ortho-Cyclen | O | NF | -- |
| | | Sprintec | Y | F | \$10.58 |
| | | Mononessa | Y | F | \$14.03 |
| | | Previfem | Y | F | \$13.26 |
| | | Estarlylla | Y | F | \$9.63 |
| | | Mono-linyah | Y | F | \$12.66 |
| | | Femynor | Y | F | \$11.39 |
| | | Norgestimate 0.25mg/ Ethinyl Estradiol 35mcg | Y | F | \$14.11 |
| 11474 | Norethindrone/ Ethinyl Estradiol (21/7) | Ortho Novum 1/35 | O | NF | -- |
| | | Nortrel 1/35 (28) | Y | F | \$20.80 |
| | | Nortrel 1/35 (21) | Y | F | \$15.43 |
| | | Norinyl 1/35 | O | NF | -- |
| | | Necon 1/35 | Y | F | -- |
| | | Cyclafem 1/35 | Y | F | \$20.42 |
| | | Alyacen 1/35 | Y | F | \$20.18 |
| | | Dasetta 1/35 | Y | F | \$20.82 |
| | | Pirmella 1/35 | Y | F | \$14.69 |
| 29719 | Norethindrone 0.8mg/ Ethinyl Estradiol 0.035mg (24 Pack) (Chewable) | Kaitlib Fe | Y | NF | \$87.91 |
| 11470 | Norethindrone 0.4mg/ Ethinyl Estradiol 0.035mg (21/7) | Ovcon-35 | O | NF | -- |
| | | Balziva | Y | F | \$23.56 |
| | | Zenchant | Y | F | \$24.72 |
| | | Briellyn | Y | F | \$24.70 |
| | | Philith | Y | F | \$23.68 |
| | | Gildagia | Y | F | \$23.40 |
| | | Vyfemla | Y | F | \$24.15 |
| 97167 | Norethindrone 0.4mg/ Ethinyl Estradiol 0.035mg + Iron (21/7) | Femcon Fe (Chew and Swallow) | O | NF | -- |
| | | Zeosa | Y | NF | -- |
| | | Zenchant Fe | Y | NF | -- |
| | | Wymzya Fe | O | NF | -- |
| 11501 | Norgestrel/ Ethinyl Estradiol (21/7) | Ogestrel | N | F | \$37.36 |
| 11461 | Norethindrone/ Mestranol (21/7) | Necon 1/50 | N | F | \$24.95 |
| 11491 | Ethinodiol diacetate/Ethinyl Estradiol (21/7) | Zovia 1/50E | N | F | \$21.55 |
| 26737 | | Drospirenone 3mg/ Ethinyl Estradiol 20mcg | Y | F | \$22.00 |

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|-------|---|---|---|----|----------|
| | Drospirenone 3mg/ Ethinyl Estradiol 20mcg (24 Pack) | Loryna | Y | F | \$49.77 |
| | | Nikki | Y | F | \$53.68 |
| | | Vestura | Y | F | \$24.54 |
| | | Yaz | O | F | \$139.73 |
| 13083 | Drospirenone 3mg/ Ethinyl Estradiol 30mcg (21/7) | Yasmin | O | F | -- |
| | | Ocella | O | F | -- |
| | | Syeda | Y | F | -- |
| | | Zarah | Y | F | -- |
| | | Drosperinone 3mg /Ethinyl Estradiol 30mcg | Y | F | \$32.54 |
| 29382 | Drospirenone 3mg/Ethinyl Estradiol 0.03mg + Levomefolate calcium (21/7) | Safyral | N | NF | -- |
| 68811 | Desogestrel 0.15mg/Ethinyl Estradiol 0.03mg (21/7) | Apri | Y | F | \$17.92 |
| | | Cyred | Y | F | -- |
| | | Desogen | O | NF | -- |
| | | Reclipsen | Y | F | \$18.81 |
| | | Enskyce | Y | F | \$17.16 |
| | | Emoquette | Y | F | \$18.09 |
| | | Juleber | Y | F | \$18.37 |
| | | Desogestrel 0.15mg/Ethinyl Estradiol 0.03mg | Y | F | \$18.22 |

Table 2: Biphasic Birth Control Agents:

| GCN | Active Ingredients | Available Products | FDB Class | Form. Status | Average Cost per Rx |
|-------|--|---|-----------|--------------|---------------------|
| 94868 | Desogestrel 0.15mg/ Ethinyl Estradiol (20, 10mcg) (21/2/5) | Kariva | Y | F | \$16.22 |
| | | Mircette | Y | F | -- |
| | | Bekyree | Y | F | -- |
| | | Kimidess | Y | F | -- |
| | | Azurette | Y | F | -- |
| | | Viorele | Y | F | -- |
| | | Pimtrea | Y | F | \$17.33 |
| | | Desogestrel 0.15mg/ Ethinyl Estradiol (20, 10mcg) | Y | F | \$15.41 |

FDB Class – Generic Classification Y = Generic, O = Brand, N = Single Source Brand. F = Formulary, NF = Non-Formulary

Table 3: Triphasic Birth Control Agents:

| GCN | Active Ingredients | Available Products | FDB Class | Form. Status | Average Cost per Rx |
|-------|--|--|-----------|--------------|---------------------|
| 68105 | Norethindrone/ Ethinyl Estradiol + Iron Triphasic: 0.02mg-1mg (5), 0.03mg-1mg (7), 0.035mg-1mg (9) | Estrostep Fe | O | NF | -- |
| | | Tilia Fe | O | NF | -- |
| | | Tri-Legest Fe | Y | NF | -- |
| 11301 | Norgestimate/ Ethinyl Estradiol Triphasic (7/7/7) | Ortho Tri-Cyclen | O | NF | \$49.67 |
| | | Tri-Sprintec | Y | F | \$9.04 |
| | | Tri-Previfem | Y | F | \$14.57 |
| | | Tri-Nessa | O | F | \$13.73 |
| | | Tri-Linyah | Y | F | \$13.82 |
| | | Tri-Estarylla | Y | F | \$11.71 |
| | | Norgestimate (0.18, 0.215, 0.25mg)/Ethinyl Estradiol 35mcg Triphasic | Y | F | \$13.77 |
| | Ortho Tri-Cyclen Lo | O | NF | \$152.25 | |

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|-------|---|--|---|----|---------|
| 18126 | Norgestimate/ Ethinyl Estradiol Triphasic (7/7/7) | Trinessa Lo (obsolete 10/11/18) | O | F | \$20.81 |
| | | Tri-Lo-Marzia | Y | F | \$13.92 |
| | | Tri-Lo-Estarylla | Y | F | \$13.73 |
| | | Tri-Lo-Sprintec | Y | F | \$13.93 |
| | | Norgestimate (0.18, 0.215, 0.25mg) / Ethinyl Estradiol 25mcg Triphasic | Y | F | \$13.83 |
| 11478 | Norethindrone/ Ethinyl Estradiol Triphasic: 0.5mg/1mg/0.5mg-35mcg (7/9/5) | Tri-Norinyl | O | NF | -- |
| | | Aranelle | Y | F | \$25.50 |
| | | Leena | O | F | -- |
| 13094 | Desogestrel/ Ethinyl Estradiol Triphasic: 0.025mg-0.1mg, 0.025mg-0.125mg, 0.025mg-0.15mg (7/7/7) | Cyclessa | O | NF | -- |
| | | Velivet | Y | F | \$28.92 |
| | | Caziant | Y | F | \$27.71 |
| 11477 | Norethindrone/ Ethinyl Estradiol Triphasic: 0.035mg-0.5mg, 0.035mg-0.75mg, 0.035mg-1mg | Ortho Novum 7/7/7 | O | NF | -- |
| | | Nortrel 7/7/7 | Y | F | \$21.75 |
| | | Necon 7/7/7 | O | F | -- |
| | | Cyclafem 7/7/7 | Y | F | \$20.92 |
| | | Alyacen 7/7/7 | Y | F | \$19.51 |
| | | Dasetta 7/7/7 | Y | F | \$21.27 |
| | | Pirmella 777 | Y | F | \$15.72 |
| 11531 | Levonorgestrel/ Ethinyl Estradiol Triphasic: 0.03mg-0.05mg, 0.04mg-0.075mg, 0.03mg-0.125mg (6/5/10) | Enpresse | Y | F | \$18.08 |
| | | Trivora | Y | F | \$18.55 |
| | | Levonest | Y | F | \$18.40 |
| | | Myzilra | Y | F | \$18.03 |
| | | Levonorgestrel/Ethinyl Estradiol Triphasic | Y | F | \$18.20 |

Table 4: Quadriphasic Oral Contraception:

| GCN | Active Ingredients | Available Products | FDB Class | Form. Status | Avg. Cost per Rx |
|-----|---|--------------------|-----------|--------------|------------------|
| -- | Dienogest (2mg, 3mg)/ Estradiol Valerate (3mg, 2mg, 2mg, 1mg) Quadriphasic (2/5/17) | Natazia | N | NF | -- |

Table 5: Progestin Only Pills:

| Active Ingredients | Available Products | FDB Class | Form. Status | Average Cost per Rx |
|-----------------------------|----------------------|-----------|--------------|---------------------|
| Norethindrone (GCN = 11520) | Camila | Y | F | \$17.89 |
| | Ortho Micronor | O | NF | -- |
| | Nor-QD | O | NF | -- |
| | Nora-BE | Y | F | \$14.04 |
| | Errin | Y | F | \$12.83 |
| | Heather | Y | F | \$13.61 |
| | Jencycla | Y | F | \$7.31 |
| | Jolivette | Y | F | \$13.92 |
| | Deblitane | Y | F | \$13.46 |
| | Sharobel | Y | F | \$13.56 |
| | Lyza | Y | F | -- |
| | Norlyroc | Y | F | -- |
| | Norlyda | Y | F | \$14.00 |
| | Norethindrone 0.35mg | Y | F | \$13.38 |

FDB Class – Generic Classification Y = Generic, O = Brand, N = Single Source Brand. F = Formulary,

Table 6: Barrier Contraceptives:

| Active Ingredients | Available Products | FDB Class | Form. Status | Average Cost per Rx |
|--------------------|-------------------------|-----------|--------------|---------------------|
| Condoms, latex | Condoms lubricated | O | QL | \$5.46 |
| | Condoms, non-lubricated | O | QL | \$16.57 |
| Condoms, female | FC2 female condom | O | QL | \$351.12 |

QL = Quantity Limit (Male Condoms are limited to 24 per month, Female Condoms are limited to 6 per month)

Table 7: Emergency Contraception:

| Active Ingredients | Available Products | FDB Class | Form. Status | Average Cost per Rx |
|---|----------------------|-----------|--------------|---------------------|
| Levonorgestrel 1.5mg (GCN = 23549) | Aftera | O | NF | -- |
| | Econtra EZ | Y | F | \$11.50 |
| | Fallback SOLO | Y | F | \$24.66 |
| | My Way | O | F | \$30.37 |
| | Next Choice One Dose | O | F | \$31.84 |
| | Opcicon One-Step | Y | F | \$20.27 |
| | Plan B One-Step | O | NF | -- |
| | Take Action | O | NF | -- |
| | Levonorgestrel 1.5mg | Y | F | \$24.64 |
| Ulipristal acetate 30 mg (GCN = 27585) | Ella | N | F | \$36.19 |

Table 8: Alternative Hormonal Contraceptive Agents:

| Therapeutic Class | Drug Name | Form Status | Notes | Cost/Rx |
|-------------------|---|-------------|------------------------------------|----------|
| Intravaginal | Ethinyl Estradiol/Etonogestrel (Nuvaring) | F | Provides 1 month of contraception | \$154.10 |
| Intrauterine | Levonorgestrel 52mg (20mcg/day) (Mirena) | MB | Provides 5 years of contraception | \$927.15 |
| | Levonorgestrel 52mg (18.6mcg/day) (Liletta) | MB | Provides 3 years of contraception | -- |
| | Levonorgestrel 13.5mg (14mcg/day) (Skyla) | MB | Provides 3 years of contraception | -- |
| | Copper IUD (Paragard) | MB | Provides 3 years of contraception | -- |
| Injectable | Medroxyprogesterone Acetate vial (DepoProvera) | F, MB | Provides 3 months of contraception | \$66.20 |
| | Medroxyprogesterone Acetate syringe (DepoProvera) | F, MB | Provides 3 months of contraception | \$71.62 |
| Implantable | Etonogestrel 68mg Implant (Nexplanon) | MB | Provides 3 years of contraception | -- |
| Transdermal | Ethinyl Estradiol/ Norelgestromin (Xulane) | F, PA | Provides 1 month of contraception | \$127.19 |

FDB Class = Generic Classification Y = Generic, O = Brand, N = Single Source Brand. MB = Available through the Medical Benefit. PA = Prior Authorization required. F = Formulary. NF = Non-Formulary.

Table 9: Agents for Menopause:

| Therapeutic Class | GCN | Drug Name | FDB Class | Form. Status | Cost/Rx |
|-------------------|-------|--|-----------|--------------|----------|
| Estrogen Agents | 69123 | Estradiol 0.05mg-Norethindrone 0.14mg patch (Combipatch) | N | NF | \$177.84 |
| | 15567 | Norethindrone 0.5mg-Ethinyl Estradiol 2.5 mcg tablet | Y | F | \$79.65 |
| | 92296 | Norethindrone 1mg-Ethinyl Estradiol 5mcg tablet | Y | F | \$49.66 |
| | | Jinteli 1mg-5mcg tablet | Y | F | \$53.68 |
| | 19739 | Estrogen, conjugated 0.45mg-Medroxyprogesterone 1.5mg (Prempro) | N | F | \$185.07 |
| | 20769 | Estrogen, conjugated 0.3mg-Medroxyprogesterone 1.5mg (Prempro) | N | F | \$186.25 |
| | 55731 | Estrogen, conjugated 0.625mg-Medroxyprogesterone 2.5mg (Prempro) | N | F | \$171.74 |

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|-------|---|---|----|----------|
| 55730 | Estrogen, conjugated 0.625mg-Medroxyprogesterone 5mg (Prempro) | N | F | \$186.60 |
| 55733 | Estrogen, conjugated 0.625mg-Medroxyprogesterone 5mg (Premphase) | N | F | \$187.62 |
| 10943 | Estrogen, conjugated 0.3mg tablet (Premarin) | N | F | \$155.62 |
| 19975 | Estrogen, conjugated 0.45mg tablet (Premarin) | N | F | \$162.48 |
| 10942 | Estrogen, conjugated 0.625mg tablet (Premarin) | N | F | \$157.38 |
| 10944 | Estrogen, conjugated 0.9mg tablet (Premarin) | N | F | \$158.35 |
| 10945 | Estrogen, conjugated 1.25mg tablet (Premarin) | N | F | \$168.62 |
| 28410 | Estrogen, conjugated 0.625mg/gram vaginal cream (Premarin) | N | F | \$360.21 |
| 11051 | Estrogens (esterified) 0.625mg tablet (Menest) | N | F | \$67.81 |
| 10772 | Estradiol 0.5mg tablet | Y | F | \$3.55 |
| 10770 | Estradiol 1mg tablet | Y | F | \$4.18 |
| 10771 | Estradiol 2mg tablet | Y | F | \$9.11 |
| 28842 | Estradiol 0.025mg patch | Y | F | \$47.08 |
| | Alora 0.025mg patch | O | F | \$105.22 |
| 28848 | Estradiol TDS 0.025mg/day patch | Y | F | \$67.71 |
| 20069 | Estradiol TDS 0.0375mg/day patch | Y | F | \$63.29 |
| 28846 | Estradiol 0.0375mg patch | Y | F | \$70.03 |
| | Minivelle 0.0375mg patch | O | F | \$163.85 |
| 28840 | Estradiol 0.05mg patch | Y | F | \$55.29 |
| | Minivelle 0.05mg patch | O | F | \$170.22 |
| 28845 | Estradiol TDS 0.05mg/day | Y | F | \$58.55 |
| 20068 | Estradiol 0.06mg/day patch | Y | F | \$56.59 |
| 28843 | Estradiol 0.075mg patch | Y | F | \$71.79 |
| | Minivelle 0.075mg patch | O | F | \$153.17 |
| 28853 | Estradiol TDS 0.075mg/day patch | Y | F | \$73.06 |
| 28841 | Estradiol 0.1mg patch | Y | F | \$70.80 |
| | Alora 0.1mg patch | O | F | \$118.94 |
| | Minivelle 0.1mg patch | O | F | \$159.91 |
| | Vivelle-Dot 0.1mg patch | O | F | \$125.98 |
| 67170 | Estradiol 0.01% cream | Y | F | \$234.79 |
| | Estrace 0.01% cream | O | F | \$307.24 |
| 28844 | Estradiol TDS 0.1mg/day | Y | F | \$66.82 |
| 98723 | Estradiol 1.53mg/spray (Evamist) | N | NF | \$121.08 |
| 28107 | Estradiol 10 mcg vaginal insert | Y | F | \$119.20 |
| | Yvafem 10 mcg vaginal insert | Y | F | \$131.97 |
| 22606 | Estradiol 1.25 gram/actuation (0.06%) transdermal gel pump (EstroGel) | N | NF | \$116.77 |
| 10660 | Estradiol cypionate 5mg/ml IM vial | N | NF | \$103.69 |
| 10692 | Delestrogen 10mg/ml vial | N | NF | \$135.39 |
| 10690 | Estradiol valerate 20mg/ml IM vial | Y | F | \$53.17 |
| | Delestrogen 20mg/ml IM vial | O | NF | \$191.03 |

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|--|-------|--|---|----|----------|
| | 20849 | Estradiol 0.045mg-Levonorgestrel 0.015mg/24 hour (Climara Pro Patch) | N | F | \$200.18 |
| Selective Serotonin Reuptake Inhibitor | 34876 | Paroxetine mesylate 7.5mg capsule (Brisdelle) | Y | NF | -- |
| Selective Estrogen Receptor Modulator (SERM) | 34336 | Ospemifene 60mg tablet (Osphena) | N | NF | -- |

Table 10: Agents for Abnormal Uterine Bleeding:

| Therapeutic Class | GCN | Drug Name | FDB Class | Form. Status | Cost/Rx |
|-----------------------|-------|----------------------------------|-----------|--------------|---------|
| Progestational Agents | 11261 | Medroxyprogesterone 2.5mg tablet | Y | F | \$3.84 |
| | 11262 | Medroxyprogesterone 5mg tablet | Y | F | \$3.46 |
| | 11260 | Medroxyprogesterone 10mg tablet | Y | F | \$3.68 |
| | 11280 | Norethindrone 5mg tablet | Y | F | \$63.98 |
| | 28578 | Tranexamic Acid 650mg tablet | Y | F | -- |

Table 11: Preterm Birth Prevention Agents (Current as of 09/2018):

| Therapeutic Class | Generic Name (Brand Name) | Strength & Dosage form | Formulary Limits | Avg. Cost per 30 days* | Notes/Restriction Language |
|-------------------|---|--|------------------|--------------------------|--|
| Progesterone | Progesterone (First- Progesterone Vgs) | 100mg suppository 200mg suppository | NF | \$320.36 | Non-formulary. Formulary alternative = Progesterone capsules. |
| | Micronized Progesterone Gel (Crinone) | 4% vaginal gel 8% vaginal gel | NF | -- | |
| | Micronized Progesterone (Prometrium) | 100mg capsules 200mg capsules | PA; QL | \$27.51 \$49.54 | Limit 2 capsules per day. Reserved for pregnancy with history of pre-term birth, short cervix, or history of 2 consecutive miscarriages, or for the prevention of endometrial hyperplasia in postmenopausal women receiving conjugated estrogen. |
| | Progesterone in Oil | 50mg/ml intramuscular oil | PA | -- | Reserved for women with ≥2 consecutive miscarriages |
| Progestin | Hydroxyprogesterone caproate (Makena) | 1250mg/5mL vial 250mg/ml vial | PA; QL | \$4,043.19 \$2,736.95 | Limit 5 mL per 35 days. Reserved for women with a singleton pregnancy with history of spontaneous preterm birth (less than 37 weeks). |
| | | 275mg/1.1 ml autoinjector | NF | \$3,235.74 | |

PA = Prior Authorization; QL = Quantity Limit; AL = Age Limit; NF = Non-formulary

Clinical Justification:

| Table 12: Female Hormones | | | | |
|----------------------------------|-------------------|------------------|------------------------|--|
| Progestins | | | | Estrogens |
| Testosterone Derived | | | Spironolactone Derived | -- |
| First Generation | Second Generation | Third Generation | Fourth Generation | First Generation |
| Norethindrone | Levonorgestrel | Desogestrel | Drospirenone | Ethinyl Estradiol |
| Ethinodiol Diacetate | Norgestrel | Dienogest | | Mestranol (Ethinyl-Estradiol-Methyl-Ether) |
| | | Norgestimate | | |

Progestins:

Progestins are chemical derivatives of testosterone (with the exception of Drospirenone, which is derived from spironolactone). Each of these agents has varying affinities to estrogen, androgen, and progesterone receptors. These properties result in various side effects seen with each of these progestins. These agents are grouped into “generations” by their chemical structure. First generation tend to have the widest effect on all three receptor types (estrogenic, androgenic, and progestational). Second generation progestins have little to no effect on the estrogen receptor, but have large activity towards the progestational and androgen receptors. Third generation progestins, like second generation progestins, have little to no activity towards estrogenic receptors, but tend to have less activity on progestational and androgenic receptors.

Estrogens:

Mestranol is a prodrug of Ethinyl Estradiol with no contraceptive action. This prodrug is converted by the liver at approximately 75% efficiency. This drug exposure is variable from person to person. Fifty micrograms of Mestranol is approximately equivalent to 35 micrograms of Ethinyl Estradiol. Necon 1/50 and Norinyl 1/50 are equivalent to Nortrel 1/35 and Cyclofem 1/35. Both formulations of Ethinyl Estradiol are on HPSJs formulary and are priced similarly. In an effort to provide enhanced access to oral contraception, both formulations of Ethinyl Estradiol are on the HPSJ formulary.

Monophasic vs. Multiphasic Formulations:

According to the World Health Organization and several Cochrane reviews, there is no evidence that multiphasic birth control agents are safer or more effective than monophasic birth control agents. In theory, multiphasic agents mimic a woman’s natural hormonal cycle more closely. In practice, this provides no clinically relevant benefit. Choice of progesterone agent may be more important due to varying receptor activity, which can affect cycle control and potential side effects.

Prevention of Preterm Birth:

Vaginal progesterone suppositories are recommended for women without a history of spontaneous preterm birth and develops a short cervix (< 25mm) during the mid-trimester. Prometrium, when administered as vaginal suppository, bypasses hepatic first pass effects to exhibit excellent bioavailability and is virtually without systemic side effects. Studies have used up to 400 mg of progesterone per day; thus, our quantity limit will be 2 capsules per day. Initiation as early as 16 gestational weeks has shown efficacy and safety in reducing the risk of preterm birth and prolonging gestation in high-risk pregnancies. First Progesterone VGS suppository compounding kit is non-formulary because it is not FDA approved and not subject to the FDA’s stringent Good Manufacturing Process (GMP). Guideline recommends either progesterone suppository or gel; thus, Crinone and Prochieve are non-formulary due to price differences.

Prior authorization for Makena (hydroxyprogesterone caproate) requires documented history of a singleton spontaneous preterm birth and current estimated due date (EDD) to ensure appropriate use. Unlike vaginal progesterone, Makena has not demonstrated efficacy in patients without history of preterm birth and cannot be used interchangeably. Therapy must be initiated between 16 weeks and 23 6/7 weeks.

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06). Formulary status is listed in the tables above. Agents without “PA” in the formulary status field are available to dispense up to 30 days’ supply at a time through the pharmacy benefit. Agents that require authorization are listed in the section below.

Transdermal Hormonal Contraceptive

Ortho Evra/Xulane

- Coverage Criteria:** None
- Limits:** Limited to 12 patches per year
- Required Information for Approval:** Clinical documentation or pharmacy fill history of treatment failure of 3 formulary first line oral/hormonal contraceptives.
- Other notes:** Xulane/Ortho Evra users experienced a 2-fold increase in incidence of VTE over users of alternative oral contraceptives. It is advised to use alternative agents as first line for contraception, such as Nuvaring or Depo-Provera, if once daily administration is not ideal.

Monophasic Oral Contraceptive

Brands Listed in Table 1

- Coverage Criteria:** None
- Limits:** 13 Cycles per Year.
- Required Information for Approval:** N/A
- Other Notes:** None

Biphasic Oral Contraceptive

Brands Listed in Table 2

- Coverage Criteria:** None
- Limits:** 13 Cycles per Year.
- Required Information for Approval:** N/A
- Other Notes:** None

Triphasic Oral Contraceptive

Brands Listed in Table 3

- Coverage Criteria:** None
- Limits:** 13 Cycles per Year.
- Required Information for Approval:** N/A
- Other notes:** None

Progestin-Only Oral Contraceptive

Brands Listed in Table 5

- Coverage Criteria:** None
- Limits:** 13 Cycles per Year.
- Required Information for Approval:** N/A
- Other notes:** None

Barrier Contraceptives

Brands listed in Table 6

- Coverage Criteria:** None
- Limits:**
 - Male condoms are limited to 24 per 30 days.
 - Female condoms are limited to 6 per 30 days.
- Required Information for Approval:** N/A
- Other Notes:** None

Emergency Contraception

Brands listed in Table 7

- Coverage Criteria:** Restricted to Females.
- Limits:** Two fills per 30 days and four fills per 365 days.
- Required Information for Approval:** N/A
- Other Notes:** This restriction is in place to ensure that members are not using emergency contraception chronically. Providers should counsel patients that the effectiveness of emergency contraception decreases when used multiple times within the same cycle. Members who frequently use emergency contraception should be started on oral contraceptives or alternative hormonal contraception.

Alternative Contraceptive Agents

Brands listed in Table 8

- Coverage Criteria:** None.
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** Items listed, as “MB” in table 7 are available through the Medical Benefit.

Progesterone

Micronized Progesterone (Crinone 8%, Prometrium), Progesterone in Oil

Micronized Progesterone (Prometrium capsules)

- Coverage Criteria:** Reserved for women with history of preterm birth, short cervix (< 25 mm), history of 2 miscarriages, or for the prevention of endometrial hyperplasia in postmenopausal women with a uterus who are receiving conjugated estrogen.
- Limits:** Limited to 2 capsules per day.
- Required Information for Approval:** Diagnosis of short cervical length (CL < 25mm) before 24 weeks and documentation of prior birth terms
- Non-Formulary:** First-Progesterone Vgs, Endometrin, Prochieve, Crinone
- Other Notes:** Therapy may be continued until 37 gestational weeks.

Micronized Progesterone (Crinone Vaginal Gel Suppository)

- Coverage Criteria:** Reserved for pregnancy with history of pre-term birth, short cervix (< 25mm after 16 gestational weeks), or history of 3 consecutive miscarriages.
- Limits:** 34 grams per 30 days (each applicator delivers 1.125 g of gel containing 90 mg progesterone)
- Required Information for Approval:** Diagnosis of cervical length and documentation of prior birth terms are required for progesterone agents.
- Other Notes:** Maximum duration of all progesterone therapy for PTB is 21 weeks
- Non-Formulary:** progesterone vaginal suppository (First-Progesterone Vgs)

Progesterone in oil (50mg/mL)

- Coverage Criteria:** Reserved for women with history of 2 miscarriages.
- Required Information for Approval:** Documentation of gestational age and outcome of all prior births.
- Other Notes:** None

Progestin

Hydroxyprogesterone caproate (Makena)

Hydroxyprogesterone caproate (Makena®) 250mg/ml vials, 1250mg/5ml vials

- Coverage Criteria:** Singleton pregnancy with history of spontaneous preterm birth (less than 37 weeks). Therapy should be initiated between 16 and 20 weeks, 6 days.
- Limits:** 5 mL per 35 days.
- Required Information for Approval:** Documented history of preterm birth with gestational age and current estimated due date (EDD)
- Other Notes:** Therapy may be continued until 37 gestational weeks.
- Non-Formulary:** Makena auto-injector

Agents for Abnormal Uterine Bleeding

Tranexamic Acid (Lysteda)

- Coverage Criteria: None
- Limits: None
- Required Information for Approval: N/A
- Other Notes: None

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REVIEW & EDIT HISTORY

| Document Changes | Reference | Date | P&T Chairman |
|--------------------|--|--------|-----------------------|
| Creation of Policy | Contraceptives May09_JHP01 draft from MI.doc | 4/2009 | Allen Shek, PharmD |
| Update to Policy | Contraceptives May09_JHP01 5-11-09.doc | 5/2009 | Allen Shek, PharmD |
| Update to Policy | OC Class Review 9-20-11.docx | 9/2011 | Allen Shek, PharmD |
| Update to Policy | Formulary Realignment 9-18-12.xlsx | 9/2012 | Allen Shek, PharmD |
| Update to Policy | Oral Contraceptive Formulary Realignment 2-2016_update.docx | 2/2016 | Johnathan Yeh, PharmD |
| Update to Policy | HPSJ Coverage Policy – Endocrine – Hormonal Contraception 2016-05.docx | 5/2016 | Johnathan Yeh, PharmD |

| | | | |
|--------------------|---|---------|-------------------------|
| Creation of Policy | HPSJ Coverage Policy – Women’s Health – Preterm Birth Prevention 2017-02.docx | 2/2017 | Johnathan Yeh, PharmD |
| Update to Policy | HPSJ Coverage Policy – Endocrine – Hormonal Contraception 2017-05.docx | 5/2017 | Johnathan Yeh, PharmD |
| Update to Policy | HPSJ Coverage Policy – Endocrine – Women’s Health 2018-12.docx | 12/2018 | Matthew Garrett, PharmD |
| Update to Policy | HPSJ Coverage Policy – Endocrine – Women’s Health 2019-12.docx | 12/2019 | Matthew Garrett, PharmD |
| Update to Policy | HPSJ Coverage Policy – Endocrine – Women’s Health 2020-12.docx | 12/2020 | Matthew Garrett, PharmD |

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy

 Agents used to **promote fertility** are excluded from coverage. This is based on **Title XIX, Social Security Act, Section 1927(d)(2)**.

This coverage policy was approved by the P&T Committee on December 8, 2020.