

# MEDICATION COVERAGE POLICY

## PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

<b>POLICY:</b>	Women's Health	<b>P&amp;T DATE:</b>	12/10/2019
<b>CLASS:</b>	Endocrine	<b>REVIEW HISTORY</b>	12/18, 5/17, 2/17, 2/16
<b>LOB:</b>	Medi-Cal	(MONTH/YEAR)	

*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 1<sup>st</sup>, 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).<sup>1</sup> 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.<sup>2</sup> 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.<sup>3-5</sup>

### 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

		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	NF	\$49.73
		Setlakin	Y	NF	\$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

		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

	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	NF	\$16.22
		Mircette	Y	NF	--
		Bekyree	Y	NF	--
		Kimidess	Y	NF	--
		Azurette	Y	NF	--
		Viorele	Y	NF	--
		Pimtrea	Y	NF	\$17.33
		Desogestrel 0.15mg/ Ethinyl Estradiol (20, 10mcg)	Y	NF	\$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

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	--
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
	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
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	<b>Progesterone (First- Progesterone Vgs)</b>	100mg suppository 200mg suppository	NF	\$320.36	Non-formulary. Formulary alternative = Progesterone capsules.
	<b>Micronized Progesterone Gel (Crinone)</b>	4% vaginal gel 8% vaginal gel	NF	--	
	<b>Micronized Progesterone (Prometrium)</b>	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.
	<b>Progesterone in Oil</b>	50mg/ml intramuscular oil	PA	--	Reserved for women with $\geq 2$ consecutive miscarriages
Progestin	<b>Hydroxyprogesterone caproate (Makena)</b>	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**

*Necon 10/11*

- 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 intramuscular oil**

- Coverage Criteria:** Singleton pregnancy with history of spontaneous preterm birth (less than 37 weeks). Therapy must be initiated between 16 and 23 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 continue 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
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*Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy*

 Agents used to <b>promote fertility</b> are excluded from coverage. This is based on <b>Title XIX, Social Security Act, Section 1927(d)(2)</b> .
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This coverage policy was approved by the P&T Committee on December 10, 2019.