

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE



POLICY:	Women's Health	P&T DATE:	01/12/2024
CLASS:	Endocrine	REVIEW HISTORY (MONTH/YEAR)	12/22, 12/21, 12/20, 12/19, 12/18, 5/17, 2/17, 2/16
LOB:	Medi-Cal		

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.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit <https://medi-calrx.dhcs.ca.gov/home/> for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit.

All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

The purpose of this coverage policy is to review the available agents (Table 1) and distinguish where the medications may be billed to. For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

OVERVIEW

This formulary document is intended to explain the HPSJ contraceptive pharmacy benefit. HPSJ covers implantable, injectable, and intrauterine birth control agents.

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 mid-trimester.

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

For a complete list of drugs and contraceptive supplies reimbursed by the Family PACT Program, refer to the Family PACT Pharmacy Formulary on the Medi-Cal Rx website (<https://medi-calrx.dhcs.ca.gov>) and the Clinic Formulary section in this manual: <https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/fpact/benfam.pdf>.

Oral Hormonal Contraceptive Agents:

Table 1: Monophasic Birth Control Agents:

CPT Code	GCN	Active Ingredients	Available Products	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
S4993 CONTRACEPTIV E PILLS FOR BIRTH CONTROL	11534	Levonorgestrel/ Ethinyl Estradiol (21/7)	Lessina	Yes	Yes
			Aviane	Yes	Yes
			Orsythia	Yes	Yes
			Falmina	Yes	Yes
			Delyla	Yes	Yes
			Aubra	Yes	Yes
			Sronyx	Yes	Yes
			Lutera	Yes	Yes
			Larissia	Yes	Yes
			Vienna	Yes	Yes
			Levonorgestrel 0.1mg/ Ethinyl Estradiol 20mcg	Yes	Yes
	98551	Levonorgestrel/Ethinyl Estradiol (28 active)	Amethyst	Yes	Yes
			Levonorgestrel 0.09mg/ Ethinyl Estradiol 20mcg	Yes	Yes
	11471	Norethindrone/Ethinyl Estradiol (21/7)	Brevicon	Yes	Yes
			Necon 0.5/35	Yes	Yes
			Modicon	Yes	Yes
			Nortrel 0.5/35	Yes	Yes
			Wera 0.5/35	Yes	Yes
	11490	Ethinodiol Diacetate/Ethinyl Estradiol (21/7)	Zovia 1/35E	Yes	Yes
			Kelnor 1/35	Yes	Yes
	11530	Levonorgestrel/ Ethinyl Estradiol (21/7)	Portia	Yes	Yes
			Levora	Yes	Yes
			Altavera	Yes	Yes
			Chateal	Yes	Yes
			Kurvelo	Yes	Yes
			Marlissa	Yes	Yes
			Lillow	Yes	Yes
			Levonorgestrel 0.15mg/Ethinyl Estradiol 30mcg	Yes	Yes
	20414	Levonorgestrel 0.15mg/Ethinyl Estradiol 0.03mg (84 active)	Quasense	Yes	Yes
			Setlakin	Yes	Yes
	11500	Norgestrel 0.3mg/Ethinyl Estradiol 0.03mg (21/7)	Cryselle	Yes	Yes
			Low-Ogestrel	Yes	Yes
Elinest			Yes	Yes	
11480	Norethindrone/ Ethinyl Estradiol (21 Pack)	Loestrin 1.5/30	Yes	Yes	
		Junel 1.5/30	Yes	Yes	
		Microgestin 1.5/30	Yes	Yes	
		Larin 1.5/30	Yes	Yes	

68101	Norethindrone/ Ethinyl Estradiol + Iron (21/7)	Loestrin FE 1.5/30	Yes	Yes
		Junel FE 1.5/30	Yes	Yes
		Blisovi FE 1.5/30	Yes	Yes
		Microgestin FE 1.5/30	Yes	Yes
		Larin FE 1.5/30	Yes	Yes
11481	Norethindrone/ Ethinyl Estradiol (21 Pack)	Loestrin 1/20	Yes	Yes
		Junel 1/20	Yes	Yes
		Microgestin 1/20	Yes	Yes
		Larin 1/20	Yes	Yes
		Norethindrone 1mg/Ethinyl Estradiol 20mcg	Yes	Yes
68102	Norethindrone/ Ethinyl Estradiol + Iron (21/7)	Loestrin FE 1/20	Yes	Yes
		Junel FE 1/20	Yes	Yes
		Blisovi FE 1/20	Yes	Yes
		Microgestin FE 1/20	Yes	Yes
		Larin FE 1/20	Yes	Yes
		Tarina FE	Yes	Yes
		Norethindrone 1mg/Ethinyl Estradiol 20mcg/Fe 75mg	Yes	Yes
29264	Norethindrone 1mg/Ethinyl Estradiol 10mcg (24 Pack)	Lo Loestrin Fe	Yes	Yes
26629	Norethindrone 1mg/Ethinyl Estradiol 20mcg/Fe 75mg	Blisovi 24 FE	Yes	Yes
34725	Norethindrone 1mg/Ethinyl Estradiol 20mcg (24) + Iron (Chewable)	Minastrin 24 FE	Yes	Yes
26629	Norethindrone 1mg/Ethinyl Estradiol 20mcg (24) + Iron	Larin 24 FE	Yes	Yes
11300	Norgestimate/ Ethinyl Estradiol (21/7)	Ortho-Cyclen	Yes	Yes
		Sprintec	Yes	Yes
		Mononessa	Yes	Yes
		Previfem	Yes	Yes
		Estarylla	Yes	Yes
		Mono-linyah	Yes	Yes
		Femynor	Yes	Yes
		Norgestimate 0.25mg/ Ethinyl Estradiol 35mcg	Yes	Yes
11474	Norethindrone/ Ethinyl Estradiol (21/7)	Ortho Novum 1/35	Yes	Yes
		Nortrel 1/35 (28)	Yes	Yes
		Nortrel 1/35 (21)	Yes	Yes
		Norinyl 1/35	Yes	Yes
		Necon 1/35	Yes	Yes
		Cyclafem 1/35	Yes	Yes
		Alyacen 1/35	Yes	Yes
		Dasetta 1/35	Yes	Yes
		Pirmella 1/35	Yes	Yes
		29719	Norethindrone 0.8mg/ Ethinyl Estradiol 0.035mg (24 Pack) (Chewable)	Kaitlib Fe

	11470	Norethindrone 0.4mg/ Ethinyl Estradiol 0.035mg (21/7)	Ovcon-35	Yes	Yes
			Balziva	Yes	Yes
			Zenchant	Yes	Yes
			Briellyn	Yes	Yes
			Philith	Yes	Yes
			Gildagia	Yes	Yes
			Vyfemla	Yes	Yes
	97167	Norethindrone 0.4mg/ Ethinyl Estradiol 0.035mg + Iron (21/7)	Femcon Fe (Chew and Swallow)	Yes	Yes
			Zeosa	Yes	Yes
			Zenchant Fe	Yes	Yes
			Wymzya Fe	Yes	Yes
	11501	Norgestrel/ Ethinyl Estradiol (21/7)	Ogestrel	Yes	Yes
	11461	Norethindrone/ Mestranol (21/7)	Necon 1/50	Yes	Yes
	11491	Ethynodiol diacetate/Ethinyl Estradiol (21/7)	Zovia 1/50E	Yes	Yes
	26737	Drospirenone 3mg/ Ethinyl Estradiol 20mcg (24 Pack)	Drospirenone 3mg/ Ethinyl Estradiol 20mcg	Yes	Yes
			Loryna	Yes	Yes
			Nikki	Yes	Yes
			Vestura	Yes	Yes
			Yaz	Yes	Yes
	13083	Drospirenone 3mg/ Ethinyl Estradiol 30mcg (21/7)	Yasmin	Yes	Yes
			Ocella	Yes	Yes
			Syeda	Yes	Yes
			Zarah	Yes	Yes
			Drosperinone 3mg /Ethinyl Estradiol 30mcg	Yes	Yes
	29382	Drospirenone 3mg/Ethinyl Estradiol 0.03mg + Levomefolate calcium (21/7)	Safyral	Yes	Yes
	49528	Drospirenone 3mg/Estetrol 14.2mg (24/4)	Nextstellis	Yes	Yes
	68811	Desogestrel 0.15mg/Ethinyl Estradiol 0.03mg (21/7)	Apri	Yes	Yes
			Cyred	Yes	Yes
Desogen			Yes	Yes	
Reclipsen			Yes	Yes	
Enskyce			Yes	Yes	
Emoquette			Yes	Yes	
Juleber			Yes	Yes	
Desogestrel 0.15mg/Ethinyl Estradiol 0.03mg			Yes	Yes	

Table 2: Biphasic Birth Control Agents:

CPT Code	GCN	Active Ingredients	Available Products	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
S4993 CONTRACEPTIV E PILLS FOR	94868	Desogestrel 0.15mg/ Ethinyl Estradiol (20, 10mcg) (21/2/5)	Kariva	Yes	Yes
			Mircette	Yes	Yes
			Bekyree	Yes	Yes

BIRTH CONTROL		Kimidess	Yes	Yes
		Azurette	Yes	Yes
		Viorele	Yes	Yes
		Pimtrea	Yes	Yes
		Desogestrel 0.15mg/ Ethinyl Estradiol (20, 10mcg)	Yes	Yes

Table 3: Triphasic Oral Contraception:

CPT Code	GCN	Active Ingredients	Available Products	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
S4993 CONTRACEPTIVE PILLS FOR BIRTH CONTROL	68105	Norethindrone/ Ethinyl Estradiol + Iron Triphasic: 0.02mg-1mg (5), 0.03mg-1mg (7), 0.035mg-1mg (9)	Estrostep Fe	Yes	Yes
			Tilia Fe	Yes	Yes
			Tri-Legest Fe	Yes	Yes
	11301	Norgestimate/ Ethinyl Estradiol Triphasic (7/7/7)	Ortho Tri-Cyclen	Yes	Yes
			Tri-Sprintec	Yes	Yes
			Tri-Previfem	Yes	Yes
			Tri-Nessa	Yes	Yes
			Tri-Linyah	Yes	Yes
			Tri-Estarylla	Yes	Yes
			Norgestimate (0.18, 0.215, 0.25mg)/Ethinyl Estradiol 35mcg Triphasic	Yes	Yes
	18126	Norgestimate/ Ethinyl Estradiol Triphasic (7/7/7)	Ortho Tri-Cyclen Lo	Yes	Yes
			Trinessa Lo (obsolete 10/11/18)	Yes	Yes
			Tri-Lo-Marzia	Yes	Yes
			Tri-Lo-Estarylla	Yes	Yes
			Tri-Lo-Sprintec	Yes	Yes
			Norgestimate (0.18, 0.215, 0.25mg) / Ethinyl Estradiol 25mcg Triphasic	Yes	Yes
	11478	Norethindrone/ Ethinyl Estradiol Triphasic: 0.5mg/1mg/0.5mg-35mcg (7/9/5)	Tri-Norinyl	Yes	Yes
			Aranelle	Yes	Yes
			Leena	Yes	Yes
	13094	Desogestrel/ Ethinyl Estradiol Triphasic: 0.025mg-0.1mg, 0.025mg- 0.125mg, 0.025mg-0.15mg (7/7/7)	Cyclessa	Yes	Yes
			Velivet	Yes	Yes
			Caziant	Yes	Yes
	11477	Norethindrone/ Ethinyl Estradiol Triphasic: 0.035mg-0.5mg, 0.035mg-0.75mg, 0.035mg-1mg	Ortho Novum 7/7/7	Yes	Yes
			Nortrel 7/7/7	Yes	Yes
Necon 7/7/7			Yes	Yes	
Cyclafem 7/7/7			Yes	Yes	
Alyacen 7/7/7			Yes	Yes	
Dasetta 7/7/7			Yes	Yes	
Pirmella 777			Yes	Yes	
11531	Levonorgestrel/ Ethinyl Estradiol Triphasic: 0.03mg-0.05mg, 0.04mg-0.075mg, 0.03mg-0.125mg (6/5/10)	Enpresse	Yes	Yes	
		Trivora	Yes	Yes	
		Levonest	Yes	Yes	
		Myzilra	Yes	Yes	
		Levonorgestrel/Ethinyl Estradiol Triphasic	Yes	Yes	

Table 4: Quadriphasic Oral Contraception:

CPT Code	GCN	Active Ingredients	Available Products	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
S4993 CONTRACEPTIVE PILLS FOR BIRTH CONTROL	--	Dienogest (2mg, 3mg)/ Estradiol Valerate (3mg, 2mg, 2mg, 1mg) Quadriphasic (2/5/17)	Natazia	Yes	Yes

Table 5: Progestin Only Pills:

CPT Code	GCN	Active Ingredients	Available Products	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
S4993 CONTRACEPTIVE PILLS FOR BIRTH CONTROL	11520	Norethindrone	Camila	Yes	Yes
			Ortho Micronor	Yes	Yes
			Nor-QD	Yes	Yes
			Nora-BE	Yes	Yes
			Errin	Yes	Yes
			Heather	Yes	Yes
			Jencycla	Yes	Yes
			Jolivette	Yes	Yes
			Deblitane	Yes	Yes
			Sharobel	Yes	Yes
			Lyza	Yes	Yes
			Norlyroc	Yes	Yes
			Norlyda	Yes	Yes
Norethindrone 0.35mg	Yes	Yes			

Table 6: Barrier Contraceptives:

CPT Code	Active Ingredients	Available Products	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
A4267 CONTRACEPTIVE SUPPLY, CONDOM, MALE, EACH	Condoms, latex	Condoms lubricated	Yes	Yes (PA for facility based)
		Condoms, non-lubricated	Yes	
A4268 CONTRACEPTIVE SUPPLY, CONDOM, FEMALE, EACH	Condoms, female	FC2 female condom	Yes	Yes (PA for facility based)
A4269 CONTRACEPTIVE SUPPLY, SPERMICIDE (E.G., FOAM, GEL), EACH	Spermicide	Foam, gel, cream, film, suppository, sponge	Yes	Yes (PA for facility based)
A4266 DIAPHRAGM FOR CONTRACEPTIVE USE	Diaphragm	Diaphragm	Yes	Yes (PA for facility based)
A4261 CERVICAL CAP FOR CONTRACEPTIVE USE	Cervical cap	Cap	Yes	Yes (PA for facility based)

Table 7: Emergency Contraception:

CPT Code	GCN	Active Ingredients	Available Products	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
--	23549	Levonorgestrel 1.5mg	Aftera	Yes	No
--			Econtra EZ	Yes	No
--			Fallback SOLO	Yes	No
--			My Way	Yes	No
--			Next Choice One Dose	Yes	No
--			Opcicon One-Step	Yes	No
--			Plan B One-Step	Yes	No
--			Take Action	Yes	No
--			Levonorgestrel 1.5mg	Yes	No
--			27585	Ulipristal acetate 30 mg	Ella

Table 8: Alternative Hormonal Contraceptive Agents:

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Intravaginal				
J7295 ETHINYL ESTRADIOL AND ETONOGESTREL 0.015 MG, 0.12 MG PER 24 HOURS; MONTHLY VAGINAL RING, EA	Ethinyl Estradiol/Etonogestrel (Nuvaring, EluRyng)	0.015 mg/ 0.12 mg	Yes	Yes (PA for facility based)
J7294 SEGESTERONE ACETATE AND ETHINYL ESTRADIOL 0.15 MG, 0.013 MG PER 24 HOURS; YEARLY VAGINAL SYSTEM, EA	Segesterone acetate/ Ethinyl estradiol (Annovera)	103 mg/ 17.4 mg		
Intrauterine				
J7298 LEVONORGESTREL-RELEASING INTRAUTERINE CONTRACEPTIVE SYSTEM (MIRENA), 52 MG	Levonorgestrel 52mg (20mcg/day) (Mirena)	52 mg IUD	Yes	Yes (auth not required)
J7297 LEVONORGESTREL-RELEASING INTRAUTERINE CONTRACEPTIVE SYSTEM (LILETTA), 52 MG	Levonorgestrel 52mg (18.6mcg/day) (Liletta)	52 mg IUD	Yes	Yes (auth not required)
J7301 LEVONORGESTREL-RELEASING INTRAUTERINE CONTRACEPTIVE SYSTEM (SKYLA), 13.5 MG	Levonorgestrel 13.5mg (14mcg/day) (Skyla)	13.5 mg IUD	Yes	Yes (auth not required)
J7296 LEVONORGESTREL-RELEASING INTRAUTERINE CONTRACEPTIVE SYSTEM, (KYLEENA), 19.5 MG	Levonorgestrel 19.5mg (Kyleena)	19.5 mg IUD	Yes	Yes (auth not required)
J7300 INTRAUTERINE COPPER CONTRACEPTIVE	Copper IUD (Paragard)	--	Yes	Yes (auth not required)

Injectable				
J1050 INJECTION, MEDROXYPROGESTERONE ACETATE, 1 MG	Medroxyprogesterone Acetate DepoProvera, Depo-SubQ Provera)	150 mg/ml IM syringe/vial, 400 mg/ml IMJ vial, 104 mg/0.65 mL SQ syringe	Yes	Yes (auth not required)
Implantable				
J7307 ETONOGESTREL (CONTRACEPTIVE) IMPLANT SYSTEM, INCLUDING IMPLANT AND SUPPLIES	Etonogestrel 68mg Implant (Nexplanon)	68 mg implant	No	Yes (PA for facility based)
J7306 LEVONORGESTREL (CONTRACEPTIVE) IMPLANT SYSTEM, INCLUDING IMPLANTS AND SUPPLIES	Levonorgestrel 150mg Implant (Norplant)	150 mg implant	Discontinued	Discontinued
Transdermal				
J7304 CONTRACEPTIVE SUPPLY, HORMONE CONTAINING PATCH, EACH	Ethinyl Estradiol/ Norelgestromin (Xulane)	35 mcg/ 150 mcg patch	Yes	Yes (PA for facility based)
	Ethinyl estradiol/ Levonorgestrel (Twirla)	30 mcg/ 120mcg patch	Yes	Yes (PA for facility based)

Table 9: Agents for Menopause:

CPT Code	GCN	Drug Name	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Estrogen Agents				
--	69123	Estradiol 0.05mg-Norethindrone 0.14mg patch (Combipatch)	Yes	No
--	15567	Norethindrone 0.5mg-Ethinyl Estradiol 2.5 mcg tablet	Yes	No
--	92296	Norethindrone 1mg-Ethinyl Estradiol 5mcg tablet	Yes	No
		Jinteli 1mg-5mcg tablet	Yes	No
--	19739	Estrogen, conjugated 0.45mg-Medroxyprogesterone 1.5mg (Prempro)	Yes	No
--	20769	Estrogen, conjugated 0.3mg-Medroxyprogesterone 1.5mg (Prempro)	Yes	No
--	55731	Estrogen, conjugated 0.625mg-Medroxyprogesterone 2.5mg (Prempro)	Yes	No
--	55730	Estrogen, conjugated 0.625mg-Medroxyprogesterone 5mg (Prempro)	Yes	No
--	55733	Estrogen, conjugated 0.625mg-Medroxyprogesterone 5mg (Premphase)	Yes	No
--	10943	Estrogen, conjugated 0.3mg tablet (Premarin)	Yes	No
--	19975	Estrogen, conjugated 0.45mg tablet (Premarin)	Yes	No
--	10942	Estrogen, conjugated 0.625mg tablet (Premarin)	Yes	No
--	10944	Estrogen, conjugated 0.9mg tablet (Premarin)	Yes	No
--	10945	Estrogen, conjugated 1.25mg tablet (Premarin)	Yes	No
--	28410	Estrogen, conjugated 0.625mg/gram vaginal cream (Premarin)	Yes	No
--	11051	Estrogens (esterified) 0.625mg tablet (Menest)	Yes	No
--	10772	Estradiol 0.5mg tablet	Yes	No

--	10770	Estradiol 1mg tablet	Yes	No
--	10771	Estradiol 2mg tablet	Yes	No
--	28842	Estradiol 0.025mg patch	Yes	No
		Alora 0.025mg patch	Yes	No
--	28848	Estradiol TDS 0.025mg/day patch	Yes	No
--	20069	Estradiol TDS 0.0375mg/day patch	Yes	No
--	28846	Estradiol 0.0375mg patch	Yes	No
		Minivelle 0.0375mg patch	Yes	No
--	28840	Estradiol 0.05mg patch	Yes	No
		Minivelle 0.05mg patch	Yes	No
--	28845	Estradiol TDS 0.05mg/day	Yes	No
--	20068	Estradiol 0.06mg/day patch	Yes	No
--	28843	Estradiol 0.075mg patch	Yes	No
		Minivelle 0.075mg patch	Yes	No
--	28853	Estradiol TDS 0.075mg/day patch	Yes	No
--	28841	Estradiol 0.1mg patch	Yes	No
		Alora 0.1mg patch	Yes	No
		Minivelle 0.1mg patch	Yes	No
		Vivelle-Dot 0.1mg patch	Yes	No
--	67170	Estradiol 0.01% cream	Yes	No
		Estrace 0.01% cream	Yes	No
--	28844	Estradiol TDS 0.1mg/day	Yes	No
--	98723	Estradiol 1.53mg/spray (Evamist)	Yes	No
--	28107	Estradiol 10 mcg vaginal insert	Yes	No
		Yvafem 10 mcg vaginal insert	Yes	No
--	22606	Estradiol 1.25 gram/actuation (0.06%) transdermal gel pump (EstroGel)	Yes	No
J1000 INJECTION, DEPO- ESTRADIOL CYPIONATE, UP TO 5 MG	10660	Estradiol cypionate 5mg/ml IM vial	Yes	Yes (auth not required)
J1380 INJECTION, ESTRADIOL VALERATE, UP TO 10 MG	10692	Delestrogen 10mg/ml vial	Yes	Yes (auth not required)
	10690	Estradiol valerate 20mg/ml IM vial		
			Delestrogen 20mg/ml IM vial	
--	20849	Estradiol 0.045mg-Levonorgestrel 0.015mg/24 hour (Climara Pro Patch)	Yes	No
Selective Serotonin Reuptake Inhibitor				
--	34876	Paroxetine mesylate 7.5mg capsule (Brisdelle)	Yes	No
Selective Estrogen Receptor Modulator (SERM)				
--	34336	Ospemifene 60mg tablet (Osphena)	Yes	No

Table 10: Agents for Abnormal Uterine Bleeding:

CPT Code	GCN	Drug Name	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
--	11261	Medroxyprogesterone 2.5mg tablet	Yes	No
--	11262	Medroxyprogesterone 5mg tablet	Yes	No
--	11260	Medroxyprogesterone 10mg tablet	Yes	No
--	11280	Norethindrone 5mg tablet	Yes	No
--	28578	Tranexamic Acid 650mg tablet	Yes	No

Table 11: Preterm Birth Prevention Agents:

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
--	Progesterone (First- Progesterone Vgs)	100mg suppository 200mg suppository	Yes	No
--	Micronized Progesterone Gel (Crinone)	4% vaginal gel 8% vaginal gel	Yes	No
--	Micronized Progesterone (Prometrium)	100mg capsules 200mg capsules	Yes	No
J2675 INJECTION, PROGESTERONE, PER 50 MG	Progesterone in Oil	50mg/ml intramuscular oil	Yes	Yes (auth not required)
J1726 INJECTION, HYDROXYPROGESTERONE CAPROATE, (MAKENA), 10	Hydroxyprogesterone caproate (Makena)	1250mg/5mL vial 250mg/ml vial 275mg/1.1 ml autoinjector	No	No
J1729 INJECTION, HYDROXYPROGESTERONE CAPROATE, NOT OTHERWISE SPECIFIED, 10 MG				No

PA = Prior Authorization

Clinical Justification:**Table 12: Female Hormones**

Progestins				Estrogens
<u>Testosterone Derived</u>			<u>Spirolactone Derived</u>	--
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. 50 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.

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. 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. Note that the First Progesterone VGS suppository compounding kit is not FDA approved and not subject to the FDA’s stringent Good Manufacturing Process (GMP). The guideline recommends either progesterone suppository or gel.

On April 6th, 2023 the FDA announced the withdrawal of approval of Makena which was approved under the accelerated approval pathway back in 2011. Effective that day, Makena and its generics are no longer approved and cannot lawfully be distributed in interstate commerce.⁵³ ACOG shortly released a statement on the FDA withdrawal of 17-OHP and no longer recommends its use for the primary prevention of preterm birth in patients with a history of spontaneous preterm birth. They also state that while compounded HPC may remain available, compounded products do not undergo FDA premarket review for safety, effectiveness, or quality.⁵⁴ Therefore, HPSJ will no longer cover Makena.

✚ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, HPSJ will make the determination based on Medical Necessity criteria as described in HPSJ Medical Review Guidelines (UM06).

Progestin
<i>Hydroxyprogesterone caproate (Makena)</i>

- ❑ **Coverage Criteria:** Requests for hydroxyprogesterone caproate will not be approved for the prevention of pre-term delivery due to FDA withdrawal.

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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
Review of Policy	Women’s Health	12/2021	Matthew Garrett, PharmD
Review of Policy	Women’s Health	12/2022	Matthew Garrett, PharmD
Review of Policy	Women’s Health	1/2024	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)**.