

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Hormonal Contraception	P&T DATE:	5/9/2017
CLASS:	Endocrine	REVIEW HISTORY	2/16
LOB:	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 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). Qualified family planning professionals, pharmacists, and other providers may dispense these medications under the HPSJ pharmacy or medical benefit, where applicable.

Oral Hormonal Contraceptive Agent Formulary Positioning: (Current as of 5/2017)

Table 1: Monophasic Birth Control Agents:

GCN	Active Ingredients	Available Products	FDB Class	Form. Status	Average Cost per Rx
11534	Levonorgestrel/ Ethinyl Estradiol (28 Pack)	Lessina	Y	F	\$18.78
		Aviane	Y	F	\$17.62
		Orsythia	Y	F	\$17.83
		Falmina	Y	F	\$18.86
		Delyla	Y	F	\$18.80
		Aubra	Y	F	\$18.80
		Sronyx	Y	F	\$18.76
		Lutera	Y	F	\$18.80
		Levonorgestrel 0.1mg/ Ethinyl Estradiol 20mcg	Y	F	\$15.69
11471	Norethindrone/Ethinyl Estradiol (28 Pack)	Brevicon	O	NF	\$74.61
		Necon 0.5/35	Y	F	\$29.01
		Modicon	O	NF	\$69.98
		Nortrel 0.5/35	Y	F	\$27.59
		Wera 0.5/35	Y	F	\$23.98
11490	Ethinodiol Diacetate/Ethinyl Estradiol (28 Pack)	Zovia 1/35E	Y	F	\$27.11
		Kelnor 1/35	Y	F	\$24.69
11530	Levonorgestrel/ Ethinyl Estradiol (28 Pack)	Portia	Y	F	\$8.00
		Levora	Y	F	\$8.48
		Altavera	Y	F	\$7.13
		Chateal	Y	F	\$7.13
		Kurvelo	Y	F	\$7.46
		Marlissa	Y	F	\$8.81
		Levonorgestrel 0.15mg/Ethinyl Estradiol 30mcg	Y	F	\$7.27
	Norgestrel/Ethinyl Estradiol	Cryselle	Y	F	\$23.07

11500	(28 Pack)	Low-Ogestrel	Y	F	\$23.09
		Elinest	Y	F	\$23.12
11480	Norethindrone/ Ethinyl Estradiol (21 Pack)	Loestrin 1.5/30	Y	F	\$34.66
		Junel 1.5/30	Y	F	\$26.43
		Microgestin 1.5/30	O	F	\$25.97
		Gildess 1.5/30	Y	F	\$26.56
		Larin 1.5/30	Y	F	\$18.51
68101	Norethindrone/ Ethinyl Estradiol + Iron (28 Pack)	Loestrin FE 1.5/30	Y	F	\$18.52
		Junel FE 1.5/30	Y	F	\$18.52
		Blisovi FE 1.5/30	Y	F	\$18.52
		Microgestin FE 1.5/30	O	F	\$20.07
		Gildess FE 1.5/30	Y	F	\$18.15
		Larin FE 1.5/30	Y	F	\$18.15
11481	Norethindrone/ Ethinyl Estradiol (21 Pack)	Loestrin 1/20	Y	F	\$24.10
		Junel 1/20	Y	F	\$23.46
		Microgestin 1/20	Y	F	\$22.82
		Gildess 1/20	Y	F	\$22.74
		Larin 1/20	Y	F	\$22.82
		Norethindrone 1mg/Ethinyl Estradiol 20mcg	Y	F	\$9.10
68102	Norethindrone/ Ethinyl Estradiol + Iron (28 Pack)	Loestrin FE 1/20	Y	F	\$18.50
		Junel FE 1/20	Y	F	\$18.47
		Blisovi FE 1/20	Y	F	\$18.50
		Microgestin FE 1/20	O	F	\$20.13
		Gildess FE 1/20	Y	F	\$18.28
		Larin FE 1/20	Y	F	\$18.50
		Tarina FE	Y	F	\$18.50
		Norethindrone 1mg/Ethinyl Estradiol 20mcg/Fe 75mg	Y	F	\$18.50
--	Norethindrone/Ethinyl Estradiol (24) + Iron (Chewable)	Minastrin 24 FE	N	NF	\$170.24
--	Norethindrone/Ethinyl Estradiol (24) + Iron	Larin 24 FE	Y	NF	\$71.40
11300	Norgestimate/ Ethinyl Estradiol (28 Pack)	Ortho-Cyclen	O	NF	\$50.53
		Sprintec	Y	F	\$16.19
		Mononessa	O	F	\$23.98
		Previfem	Y	F	\$23.88
		Estarilla	Y	F	\$21.86
		Mono-linyah	Y	F	\$18.75
		Femynor	Y	F	\$12.83*
		Norgestimate 0.25mg/ Ethinyl Estradiol 35mcg	Y	F	\$16.60
11474	Norethindrone/ Ethinyl Estradiol (28 Pack)	Ortho Novum 1/35	O	NF	\$85.15
		Nortrel 1/35	Y	F	\$17.26
		Norinyl 1/35	O	NF	\$74.58
		Necon 1/35	Y	F	\$22.06
		Cyclafem 1/35	Y	F	\$21.75
		Alyacen 1/35	Y	F	\$22.10

		Dasetta 1/35	Y	F	\$20.96
		Pirmella 1/35	Y	F	\$16.27
11470	Norethindrone/ Ethinyl Estradiol (28 Pack)	Ovcon-35	O	NF	\$163.21
		Balziva	Y	F	\$30.70
		Zenchant	Y	F	\$31.84
		Briellyn	Y	F	\$35.63
		Philith	Y	F	\$30.23
		Gildagia	Y	F	\$31.85
		Vyfemla	Y	F	\$29.83
--	Norethindrone/ Ethinyl Estradiol + Iron	Femcon Fe (Chew and Swallow)	O	NF	153.57
		Zeosa	Y	NF	\$89.54
		Zenchant Fe	Y	NF	\$89.54
		Wymzya Fe	O	NF	\$89.54
11501	Norgestrel/ Ethinyl Estradiol (28 Pack)	Ogestrel	N	F	\$37.83
11461	Norethindrone/ Mestranol	Necon 1/50	N	F	\$25.07
		Norinyl 1 + 50 (no longer available)	N	F	\$81.31
11491	Ethinodiol diacetate/Ethinyl Estradiol (28 Pack)	Zovia 1/50E	N	F	\$28.51
--	Drospirenone 3mg/ Ethinyl Estradiol 30mcg	Yasmin	O	NF	\$123.84
		Ocella	O	NF	\$51.69
		Syeda	Y	NF	\$51.69
		Zarah	Y	NF	\$76.68
		Drosperinone 3mg /Ethinyl Estradiol 30mcg	Y	NF	\$76.68
--	Drospirenone/Ethinyl Estradiol	Safyral	N	NF	\$164.39
68811	Desogestrel/Ethinyl Estradiol (28 Pack)	Apri	Y	F	\$18.26
		Cyred	Y	F	\$20.42
		Desogen	O	NF	\$57.18
		Reclipsen	Y	F	\$18.54
		Enskyce	Y	F	\$16.69
		Emoquette	Y	F	\$16.60
		Juleber	Y	F	\$18.54
		Desogestrel/Ethinyl Estradiol (No longer Available)	Y	F	\$20.42

FDB Class - Generic Classification Y = Generic, O = Brand, N = Single Source Brand.

Table 2: Biphasic Birth Control Agents:

GCN	Active Ingredients	Available Products	FDB Class	For m. Statu s	Average Cost per Rx
--	Desogestrel 0.15mg/ Ethinyl Estradiol (20, 10mcg)	Kariva	Y	NF	\$59.58
		Mircette	Y	NF	\$121.68
		Bekyree	Y	NF	\$59.98
		Kimidess	Y	NF	\$59.98
		Azurette	Y	NF	\$59.58
		Viorele	Y	NF	\$59.98
		Pimtrea	Y	NF	\$44.64

		Desogestrel 0.15mg/ Ethinyl Estradiol (20, 10mcg)	Y	NF	\$59.98
11476	Norethindrone (0.5mg, 1mg)/Ethinyl Estradiol 0.035mg (28 Pack)	Necon 10/11	N	F	\$26.98

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
--	Norethindrone/ Ethinyl Estradiol + Iron Triphasic	Estrostep Fe	O	NF	\$176.13
		Tilia Fe	O	NF	\$54.87
		Tri-Legest Fe	Y	NF	\$85.68
11301	Norgestimate/ Ethinyl Estradiol Triphasic (28 Pack)	Ortho Tri-Cyclen	O	NF	\$44.71
		Tri-Sprintec	Y	F	\$15.36
		Tri-Previfem	Y	F	\$23.52
		Tri-Nessa	O	F	\$26.70
		Tri-Linyah	Y	F	\$20.09
		Tri-Estarylla	Y	F	\$12.68
		Norgestimate (0.18, 0.215, 0.25mg)/Ethinyl Estradiol 35mcg Triphasic	Y	F	\$26.51
18126	Norgestimate/ Ethinyl Estradiol Triphasic (28 Pack)	Ortho Tri-Cyclen Lo	O	NF	\$153.86
		Trinessa Lo	O	F	\$25.48
		Tri-Lo-Marzia	Y	F	\$11.64
		Tri-Lo-Estarylla	Y	F	\$22.24
		Tri-Lo-Sprintec	Y	F	\$11.83
		Norgestimate (0.18, 0.215, 0.25mg) / Ethinyl Estradiol 25mcg Triphasic	Y	F	\$11.97
11478	Norethindrone/ Ethinyl Estradiol Triphasic (28 Pack)	Tri-Norinyl	O	NF	\$81.31
		Aranelle	Y	F	\$33.45
		Leena	O	F	\$33.45
13094	Desogestrel/ Ethinyl Estradiol Triphasic (28 Pack)	Cyclessa	O	NF	\$69.19
		Velivet	Y	F	\$28.49
		Caziant	Y	F	\$27.13
11477	Norethindrone/ Ethinyl Estradiol Triphasic (28 Pack)	Ortho Novum 7/7/7	O	NF	\$37.88
		Nortrel 7/7/7	Y	F	\$22.96
		Necon 7/7/7	O	F	\$25.08
		Cyclafem 7/7/7	Y	F	\$22.01
		Alyacen 7/7/7	Y	F	\$22.96
		Dasetta 7/7/7	Y	F	\$22.90
		Pirmella 777	Y	F	\$10.19
11531	Levonorgestrel/ Ethinyl Estradiol Triphasic (28 Pack)	Enpresse	Y	F	\$19.60
		Trivora	Y	F	\$21.84
		Levonest	Y	F	\$20.39
		Myzilra	Y	F	\$22.42
		Levonorgestrel/Ethinyl Estradiol Triphasic	Y	F	\$22.40

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

Table 4: Quadriphasic Oral Contraception:

GCN	Active Ingredients	Available Products	FDB Class	Form. Status	Average Cost per Rx
--	Dienogest/ Estradiol Valerate Quadriphasic	Natazia	N	NF	\$149.58

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

Table 5: Progestin Only Pills:

Active Ingredients	Available Products	FDB Class	Form. Status	Average Cost per Rx
Norethindrone (GCN = 11520)	Camila	Y	F	\$18.90
	Ortho Micronor	O	NF	\$55.28
	Nor-QD	O	NF	\$74.57
	Nora-BE	O	F	\$18.85
	Errin	Y	F	\$15.65
	Heather	Y	F	\$18.83
	Jencycla	Y	F	\$7.00
	Jolivette	O	F	\$18.92
	Deblitane	Y	F	\$18.85
	Sharobel	Y	F	\$18.74
	Lyza	Y	F	\$21.32
	Norlyroc	Y	F	\$21.32
	Norethindrone 0.35mg	Y	F	\$15.68

Table 6: Emergency Contraception:

Active Ingredients	Available Products	FDB Class	Form. Status	Average Cost per Rx
Levonorgestrel 1.5mg (GCN = 23549)	Aftera	O	NF	\$15.18
	Econtra EZ	Y	F	\$29.25
	Fallback SOLO	Y	F	\$26.59
	My Way	O	F	\$31.83
	Next Choice One Dose	Y	F	\$26.84
	Opcicon One-Step	Y	F	\$19.87
	Plan B One-Step	O	NF	\$39.00
	Take Action	O	NF	\$39.00
	Levonorgestrel 1.5mg	Y	F	\$26.33

Table 7: Alternative Hormonal Contraceptive Agents:

Therapeutic Class	Drug Name	Form Status	Notes
Intravaginal	Ethinyl Estradiol/Etonogestrel (Nuvaring)	F	Provides 1 month of contraception.
Intrauterine	Levonorgestrel 52mg (20mcg/day) (Mirena)	MB	Provides 5 years of contraception
	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 (DepoProvera)	F, MB	Provides 3 months of contraception
Implantable	Etonogestrel 68mg Implant (Nexplanon)	MB	Provides 3 years of contraception
Transdermal	Ethinyl Estradiol/ Norelgestromin (Ortho Evra/Xulane)	F, PA	Reserved for treatment failure or contraindication of 3 oral contraceptive products due to the increased risk of clotting disorders.

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.

Clinical Justification:

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.

HPSJ covers at least one progestin from each generation of progestin products, with the exception of drospirenone. While the use of any hormonal contraceptive products carry an increased risk of thromboembolism, some data suggests that drospirenone containing oral contraceptives may carry a higher risk of VTE. While the risk is low, some studies report an approximately 1.5 to 2 fold higher risk than other available oral contraceptives according to an FDA press release. With so many available oral contraceptive agents and formulations, HPSJ chooses to maintain drospirenone containing oral contraceptive agents as non-formulary for public health concerns.

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 Cyklaferm 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 effect cycle control and potential side effects.

⊕ 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 HSPJ 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 4

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

Emergency Contraception

Brands listed in Table 6

- 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 7

- 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.

REFERENCES

1. Shah DS. Monophasic versus multiphasic oral contraceptives: RHL commentary (last revised: 23 June 2009). *The WHO Reproductive Health Library*; Geneva: World Health Organization.
2. van Vliet HAAM, Grimes DA, Helmerhorst FM, Schulz KF. Biphasic versus monophasic oral contraceptives for contraception. *Cochrane Database of Systematic Reviews*; Issue 3, 2006.
3. van Vliet HAAM, Grimes DA, Lopez LM, Schulz KF, Helmerhorst FM. Triphasic versus monophasic oral contraceptives for contraception. *Cochrane Database of Systematic Reviews*; Issue 3, 2006.
4. van Vliet HAAM, Grimes DA, Helmerhorst FM, Schulz KF. Biphasic versus triphasic oral contraceptives for contraception. *Cochrane Database of Systematic Reviews*; Issue 3, 2006.
5. Belsey EM, Farley TMM. The analysis of menstrual bleeding patterns: a review. *Contraception* 1988;38:129-156.

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
Update to Policy	HPSJ Coverage Policy – Endocrine – Hormonal Contraception 2017-05.docx	5/2017	Johnathan Yeh, PharmD

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