

Interim Final Rules for Non-Grandfathered Group Health Plans and Health Insurance Issuers Coverage of Preventive Services under the Patient Protection and Affordable Care Act

Women's Preventive Services

On August 1, 2011, the Department of Health and Human Services (HHS) adopted Guidelines for Women's Preventive Services – including well-woman visits, support for breastfeeding equipment, contraception, and domestic violence screening – that will be covered without cost sharing in non-grandfathered health plan years starting on or after August 1, 2012. The guidelines were recommended by the independent Institute of Medicine (IOM) and based on scientific evidence.

Oral Contraceptives

The IOM recommended as a preventive service for women: the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

CVS Caremark suggests a plan consider the following pharmacy-related recommendations when developing its coverage under these provisions. At this time until guidance and clarification becomes available and consistent with most government sponsored and large employer group plans, CVS Caremark recommends limiting coverage in most categories 1 to those FDA approved methods requiring a prescription.

CVS Caremark notes that previous HHS guidance enables plans to apply reasonable medical management techniques when developing Preventive Services coverage.

These Women's Health Preventive Services recommendations are an addendum to the initial CVS Caremark Preventive Services recommendations issued in October 2010.

¹Emergency contraception recommendation includes OTC products referenced in the IOM report. Regardless of OTC status a prescription is required for coverage.

CVS Caremark Recommendation

- Female
- Rx
- Generics and Single Source Brands
- Brands until generics become available

Product Description*

(Brand names in italics and in parenthesis are for reference only. Only generics and single source brands are recommended for coverage without cost sharing)

(Brand names in BOLD have no generic available and are recommended for coverage)

EE=Ethinyl Estradiol

LOW-DOSE MONOPHASIC PILLS

- EE 20 mcg/Levonorgestrel 0.1 mg (Aviane-2, Lessina, Lutera, Sronyx)
- EE 20 mcg/ Norethindrone1mg and/Fe (Junel 1/20 Junel FE 1/20, Loestrin-21 1/20, Loestrin FE 1/20, Microgestin 1/20, Microgestin FE 1/20)

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LOW-DOSE MONOPHASIC PILLS (cont.)

- EE 30 mcg/Levonorgestrel 0.15 mcg (Altavera, Levora, Nordette-28, Portia-28)
- EE 30mcg/Norgestrel .03mg (Cryselle-28, Low-Ogestrel, Lo/Ovral-28)
- EE 30 mcg/Norethindrone acetate 1.5 mg and /FE (Junel 1.5/30, Loestrin 21 1.5/30, Microgestrin 1.5/30)
- EE30 mcg/Desogestrel 0.15 mg (Desogen, Ortho-Cept)
- EE 30 mcg/Drospirenone 0.3 mg (Yasmin, Syeda)
- EE 35 mcg/Ethynodiol diacetate 1 mg (Kelnor 1/35, Zovia 1/35E)
- EE 35 mcg/Norgestimate 0.25 mg (Ortho-Cyclen-28, MoNessa, Previfem, Sprintec)
- Mestranol 50 mcg/Norethindrone 1 mg (Norinyl 1 + 50)
- EE 35 mcg/Norethindrone 0.4mg (Ovcon-35, Balziva-28, Briellyn, Femcon Fe, Zenchent, Zeosa)
- EE 35 mcg/ Norethindrone 0.5mg (Brevicon, Modicon, Nortrel 0.5/35)
- EE 35 mcg/Norethindrone 1 mg (Norinyl 1+35, Nortrel 1/35, Ortho-Novum 1/35)

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HIGH -DOSE MONOPHASIC PILLS

- OVCON-50 (EE 50 mcg/Norethindrone 1 mg)
- EE 50 mcg/Norgestrel 0.5 mg (Ogestrel0.5/50-28)
- EE 50mg/ Ethynodiol diacetate 1mg (Zovia 1/50E)

BIPHASIC PILLS

 EE 20 mcg / Desogestrel 0.15 mg (Azurette, Kaniva, Mircette)

TRIPHASIC PILLS

- EE 20 mcg, 30mcg, 35 mcg / Norethindrone 1 mg (Estrostep Fe, Tilia, Tilia Fe, Tri-Legest Fe)
- ◆ EE 25 mcg / Norgestimate 0.18 mg, 0.215 mg, 0.25mg (Ortho Tri-Cyclen Lo, Tri Lo Sprintec)
- ◆ EE 25 mcg / Desogestrel 0.1 mg, 0.125, 0.15 mg (Caziant, Cesia, Cyclessa, Velivet)
- EE 30 mcg, 40 mcg,30 mcg /Levonorgestrel 0.05 mg x 0.075 mg, 0.125 mg) (Enpress, Trivora)
- EE 35 mcg / Norgestimate 0.18 mg 0.215 mg, 0.25 mg (Ortho Tri-Cyclen, TriNessa, Tri-Previfem, Tri-Sprintec)
- ◆ EE 35 mcg / Norethindrone 0.5 mg x 1 mg, 0.5mg (Aranelle, Leena, Tri-Norinyl)
- EE 35 mcg / Norethindrone 0.5 mg, 0.75 mg, 1 mg (Ortho-Novum 7/7/7, Nortrel 7/7/7)

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FOUR-PHASIC

NATAZIA (Estradiol valerate / Dienogest)

EXTENDED - CYCLE PILLS

- EE 30 mcg / Levonorgestrel 0.15 mg (Seasonale, Jolessa, Quasense, Introvale)
- EE 30, 10mcg/Levonorgestrel 0.15mg (Amethia, Camrese, Seasonique)
- EE 20 mcg / Drospirenone 3 mg (Yaz, Gianvi, Syeda)
- EE 20 mcg / Levonorgestrel 0.1 mg (LoSeasonique)
- Lo LOESTRIN FE (EE 10mcg /Norethindrone 1 mg)
- LOESTRIN-24 (EE 20 mcg / Norethindrone 1 mg)
- **BEYAZ** (EE 20 mcg / Drospirenone 3 mg + Calcium 0.451mg)
- SAFYRAL (EE 30mg/Drospirenone 3mg + Calcium 0.451mg)

CONTINUOUS - CYCLE PILLS

EE 20 mcg/Levonorgestrel 90 mcg (Amethyst, Lybrel)

PROGESTIN-ONLY PILLS "Mini-Pills

 Norethindrone 0.35mg (Camila, Errin, Heather, Jolivette, Micronor, Nor-QD, Nora-BE)

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EMERGENCY CONTRACEPTION

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CVS Caremark notes that previous HHS guidance enables plans to apply reasonable medical management techniques when developing Preventive Services coverage.

These Women's Health Preventive Services recommendations are an addendum to the initial CVS Caremark Preventive Services recommendations issued in October 2010.

CVS Caremark Recommendation

- Female
- Rx
- OTCs (requires a prescription)

Product Description*

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- ELLA (Ulipristal 30 mg tablet) (progesterone receptor modulator)
- Levonorgestrel 0.75 mg x 2 tablets (Next Choice) OTC
- PLAN B ONE STEP (Levonorgestral 1.5mg tablet) (RX & OTC)

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INJECTABLES

The IOM recommended as a preventive service for women: the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

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CVS Caremark Recommendation

- Female
- Quantity limit (4 Injections/year)
- Rx
- Brands until generics become available

Product Description*

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- Medroxyprogesterone acetate 150 mg IM x q3 months-(Depo- Provera)
- DEPO-SUBQ-PROVERA 104
 (Medroxyprogesterone acetate 104 mg SQ X q3 months)

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IMPLANTABLE DEVICES & VAGINAL RING

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CVS Caremark Recommendation

- Female
- Rx
- Quantity Limits

Sub-dermal Rod 1/year

IUD 1/year

Vaginal Ring 1 per month / 12 per year

Product Description*

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Single ingredient

- IMPLANON, NEXPLANON Subdermal Rod (Etonogestrel 68mg -release rate varies over time)
- MIRENA Intrauterine device IUD (Levonorgestrel 20 mcg/day
- NUVA RING Vaginal Ring (Ethinyl estradiol/ Etonogestrel 15 mcg/day)

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TRANSDERMAL PATCH

The IOM recommended as a preventive service for women: the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

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CVS Caremark Recommendation

- Female
- Rx

Product Description*

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 ORTHO EVRA Transdermal Patch weekly (Ethinyl estradiol 35 mcg/ Norelgestromin 200 mcg)

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BARRIER METHODS**

The IOM recommended as a preventive service for women: the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

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CVS Caremark Recommendation

- Female
- Quantity Limit 1/year
- Rx Only

Product Description*

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(Brand names in BOLD have no generic available and are recommended for coverage)

Diaphragms

ORTHO-ALL FLEX
OMNIFLEX COIL SPRING SILICONE
MILEX WIDE-SEAL
REFLEXIONS FLATSPRING

Cervical Cap
 FEMCAP

**OTHER BARRIER METHODS (Currently under consideration) - Although barrier methods are identified as FDA approved contraceptive methods, there are varied interpretations of the IOM recommendations on coverage. At this point in time further guidance is needed to provide a recommendation for inclusion of other OTC products (i.e. condoms, spermicides, sponges).

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