

PREVENTIVE SERVICES:

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

September 2014

Introduction

PHS Act section 2713 and the interim final regulations require non-grandfathered group health plans and health insurance coverage offered in the individual or group market to provide benefits for and prohibit the imposition of cost-sharing requirements for the following (with respect to the individual involved):

- Evidenced – based items or services that have in effect a rating of “A” or “B” in the current recommendations of the US Preventive Services Task Force (USPSTF)
- Immunizations for routine use in children, adolescents and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC)
- For infants, children, and adolescents, evidence – informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA)
- For women, evidence – informed preventive care and screening provided for in the comprehensive guidelines supported by HRSA, to the extent not already included in certain recommendations of the USPSTF

Aspirin

Aspirin to Prevent Cardiovascular Disease (CVD): Men

The U.S. Preventive Services Task Force (USPSTF) recommends the use of aspirin for men age 45 to 79 years when the potential benefit due to a reduction in myocardial infarctions outweighs the potential harm due to an increase in gastrointestinal hemorrhage

Aspirin to Prevent CVD: Women

The USPSTF recommends the use of aspirin for women age 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage.

CVS/caremark Recommendation

- Age limit ≥ 45 (men and women)
- No prior authorization
- Quantity limit of 100 units per fill
- Generic only
- OTC (requires prescription)

GPI Description*

**Single ingredient: All oral dosage forms ≤325mg
Includes dosage forms such as:**

- Aspirin tab 81mg & 325mg
- Aspirin chew tab 75mg & 81mg
- Aspirin tab delayed release 81mg, 162mg & 325mg
- Aspirin dispersible tab 81mg

*Products listed may be updated periodically. ‡For a complete listing of product names, contact your account representative.

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Iron Supplements

Iron Supplementation in Children

The USPSTF recommends routine iron supplementation for asymptomatic children aged 6 to 12 months who are at increased risk for iron deficiency anemia.

CVS/caremark Recommendation

- Age limit 6 to 12 months
- No prior authorization
- No quantity limit
- Brand and generic
- Rx or OTC (requires prescription)

GPI Description*

Single ingredient: Pediatric oral liquids

- Carbonyl Iron susp 15mg/1.25ml
- Iron susp. 15mg/1.5ml
- Ferrous sulfate elixir 220mg/5ml
- Ferrous sulfate syrup 300mg/5ml
- Ferrous sulfate soln 75mg/ml

Oral Fluorides

Chemoprevention of Dental Caries (Cavities)

The USPSTF recommends that primary care clinicians prescribe oral fluoride supplementation at currently recommended doses to preschool children older than 6 months of age whose primary water source is deficient in fluoride.

CVS/caremark Recommendation

- Age limit ≤ 6 yrs
- No prior authorization
- No quantity limit
- Brand and generic
- Rx products only

GPI Description*

Single ingredient: Oral dosage forms ≤ 0.5mg

- Sodium fluoride tab 0.5mg
- Sodium fluoride chew tab 0.25mg - 0.5mg
- Sodium fluoride soln 0.125mg/drop & 0.25mg/drop
- Sodium fluoride soln 0.25mg/0.6ml
- Sodium fluoride soln 0.5mg/ml

Folic Acid

Supplementation with Folic Acid

The USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8mg (400 to 800mcg) of folic acid.

CVS/caremark Recommendation

- Women only
- Age limit ≤ 55
- No prior authorization
- Quantity limit 100 units per fill
- Generic only
- OTC (requires prescription)

GPI Description*

Single ingredient

- Folic acid tab 0.4mg & 0.8mg

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Tobacco Cessation

Counseling for Tobacco Use: Adults

The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products.

CVS/caremark Recommendation

- No prior authorization of tobacco cessation products
 - Clients with existing prior authorization and quantity limits may choose to continue the requirement
- Limit of 168 day supply in one year of treatment with generic Nicotine replacement products (nicotine patch, gum and lozenges), Nicotrol (inhaler system) and Nicotrol NS (nasal spray)
- Limit of 168 day supply in one year of treatment with Chantix or generic Zyban
- Generics and Single Source Brands on nicotine replacement products
- Brands until generics become available on nicotine replacement products
- Limit to generic Zyban
- Rx or OTC (requires prescription)

GPI Description*

- Bupropion HCl tab SR 12hr 150mg
- Nicotine TD patch 24hr kit 21mg, 14mg, & 7mg/24hr
- Nicotine polacrilex gum 2 and 4mg
- Nicotine polacrilex lozenge 2mg and 4mg
- Nicotine inhaler system 10mg (4mg delivered)
 - Nicotrol brand
- Nicotine nasal spray 10mg/mL (0.5mg/spray)
 - Nicotrol NS brand
- Varenicline tartrate tab 0.5mg (base equiv) & 1mg (base equiv)
 - Chantix brand
- Varenicline tartrate tab 0.5mg X 11 tabs & 1mg X 42 pack
 - Chantix brand

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Immunizations

Immunizations: Vaccines

The USPSTF recommends immunizations for routine use in children, adolescents and adults that are recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC) on the CDC Immunization Schedules.

CVS/caremark Recommendation

- Children – birth through age 18
- Adults – covered age ≥ 19
- Rx Only
- Plans may choose to cover vaccines under the medical or pharmacy benefit
- If plans cover under the pharmacy benefit any vaccines which appear on the Immunization Schedules of the CDC, then the non-grandfathered or new start plans should apply \$0 copay for these vaccines‡
<http://www.cdc.gov/mmwr/preview/mmwrhtml/su6201a1.htm>
- No prior authorization

Children:

- Diphtheria, Tetanus, Pertussis
- Haemophilus influenzae type b
- Hepatitis A
- Hepatitis B
- Human Papillomavirus
- Inactivated Poliovirus
- Influenza
- Measles, Mumps, Rubella
- Meningococcal
- Pneumococcal
- Rotavirus
- Varicella

Adults:

Immunization vaccines for adults. Doses, recommended ages and recommended populations vary:

- Hepatitis A
- Hepatitis B
- Herpes Zoster
- Human Papillomavirus
- Influenza
- Measles, Mumps, Rubella
- Meningococcal
- Pneumococcal
- Tetanus, Diphtheria, Pertussis
- Varicella

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Prevention of Falls in Community-Dwelling Older Adults

Falls Prevention in older adults: Vitamin D

The USPSTF recommends vitamin D supplementation to prevent falls in community-dwelling adults age 65 years and older who are at increased risk for falls.

CVS/caremark Recommendation

- Age limit ≥ 65 (men and women)
- Brand and generic
- OTC (requires prescription)
- No prior authorization

GPI Description:

Single ingredient: Vitamin D dosing range: 600IU – 800IU (available products to meet dose range)

- Ergocalciferol tab 400 unit
- Cholecalciferol cap 400 unit
- Cholecalciferol tab 400 unit
- Cholecalciferol chewable tab 400 unit
- Cholecalciferol oral liquid 1200 unit/15ml
- Cholecalciferol oral liquid 1000 unit/10ml
- Cholecalciferol oral liquid 400 unit/ml
- Cholecalciferol drops 400 unit/0.03ml (per drop)

Bowel Preparation Medications

Screening for Colorectal Cancer

The USPSTF recommends screening for colorectal cancer (CRC) using fecal occult blood testing, sigmoidoscopy, or colonoscopy, in adults, beginning at age 50 years and continuing until age 75 years.

Since colonoscopy is an option for screening, and adequate bowel preparation is required prior to the procedure, coverage of medications that will provide adequate preparation should be provided.

CVS/caremark Recommendation

- Age limit 50 through 74 years (men and women)
- No prior authorization or quantity limits
- Rx Only
- Brands until generics become available

GPI Description*

- MoviPrep
- Prepopik
- Suclear
- Suprep

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WOMEN'S PREVENTIVE SERVICES:

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

Introduction

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 breast feeding 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. FDA approved over the counter (OTC) contraceptive methods are also recommended if prescribed for a woman by her health care provider.¹

CVS/caremark suggests a plan consider the following pharmacy-related recommendations when developing its coverage under these provisions.

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.

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

CVS/caremark Recommendation

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

Product Description*

(Brand names in *italics* and in parentheses are for reference only. Only generics and single source brands are recommended for coverage without cost sharing) (Brand names in **BOLD/BLUE** have no generic available and are recommended for coverage).

EE=Ethinyl Estradiol

HIGH – DOSE MONOPHASIC PILLS

- EE 50mcg/Norgestrel 0.5mg (*Ogestrel 0.5/50*)
- EE 50mg/Ethinodiol diacetate 1mg (*Zovia 1/50E*)

BIPHASIC PILLS

- EE 20mcg/Desogestrel 0.15mg (*Azurette, Kariva, Mircette, Pimtreea, Viorele*)
- **NECON 10/11**(EE 35mcg/Norethindrone 0.5mg, 1mg)

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Oral Contraceptives (cont.)

LOW-DOSE MONOPHASIC PILLS

- EE 20mcg/Drospirenone 3mg
(*Yaz, Gianvi, Loryna, Nikki, Vestura*)
- EE 20mcg/Levonorgestrel 0.1mg
(*Aubra, Aviane-2, Delyla, Falmina, Lessina, Lutera, Orsythia, Sronyx*)
- EE 20mcg/Norethindrone 1mg and/FE
(*Gildess 1/20, Gildess FE 1/20, Junel 1/20 Junel FE 1/20, Larin 1/20, Larin FE 1/20 Loestrin1/20-21, Loestrin FE 1/20, Microgestin 1/20, Microgestin FE 1/20*)
- **MINASTRIN 24 FE**
(EE 20mcg/Norethindrone 1mg/FE)
- **GENERESS FE**
(EE 25mcg/Norethindrone 0.8mg/FE)
- EE 30mcg/Levonorgestrel 0.15mcg
(*Altavera, Chateal, Kurvelo, Levora, Marlissa, Nordette-28, Portia-28*)
- EE 30mcg/Norgestrel .03mg
(*Cryselle-28, Elinest, Low-Ogestrel*)
- EE 30 mcg/Norethindrone acetate 1.5mg and /FE
(*Gildess 1.5/30, Gildess FE 1.5/30, Junel 1.5/30, Junel FE, Loestrin 1.5/30 -21, Loestrin FE 1.5/30, Microgestrin 1.5/30, Microgestin FE 1.5/30*)
- EE 30mcg/Desogestrel 0.15mg
(*Apri, Desogen, Emoquette, Enskyce, Ortho-Cept, Reclipsen, Solia*)
- EE 30mcg/Drospirenone 3mg
(*Ocella, Syeda, Yasmin, Zarah*)
- EE 35mcg/Ethinodiol diacetate 1mg
(*Kelnor 1/35, Zovia 1/35E*)
- EE 35mcg/Norgestimate 0.25mg
(*Ortho-Cyclen-28 Estarylla,, Mono-lyyah, Mononessa, Previfem, Sprintec*)
- Mestranol 50mcg/Norethindrone 1mg
(*Norinyl 1 + 50, Necon 1/50*)
- EE 35mcg/Norethindrone 0.4mg and /FE
(*Ovcon-35, Balziva-28, Briellyn, Femcon Fe, Gildagia, Philith Vyfemla, Wymzya Fe, Zenchent, Zenchent Fe*)
- EE 35mcg/Norethindrone 0.5mg
(*Brevicon, Modicon, Necon 0.5/35, Nortrel 0.5/35, Wera*)
- EE 35mcg/Norethindrone 1 mg
(*Alyacen 1/35, Cyclofem 1/35, Dasetta 1/35, Norinyl 1+35, Necon 1/35, Nortrel 1/35, Pirmella 1/35, Ortho-Novum 1/35*)
- EE 20mcg/Norethindrone 1mg(LoMedia 24 FE)
- **BEYAZ** (EE 20mcg/Drospirenone 3mg + Calcium 0.451mg)
- **SAFYRAL** (EE 30mcg/Drospirenone 3mg + Calcium 0.451mg)

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Oral Contraceptives (cont.)

TRIPHASIC PILLS

- EE 20mcg, 30mcg, 35mcg/Norethindrone 1mg
(Estrostep Fe, Tilia Fe, Tri-Legest Fe)
- **ORTHO TRI-CYCLEN LO**
(EE 25mcg/Norgestimate 0.18mg, 0.215mg, 0.25mg)
- EE 25mcg/Desogestrel 0.1mg, 0.125, 0.15mg
(Caziant, Cesia, Cyclessa, Velivet)
- EE 30mcg, 40mcg, 30mcg /Levonorgestrel 0.05mg, 0.075mg, 0.125mg
(Enpresse, Levonest, Myzilra, Trivora)
- EE 35 mcg/Norgestimate 0.18mg 0.215mg, 0.25mg
(Ortho Tri-Cyclen, Tri-Estarylla, Tri-Linyah, TriNessa, Tri-Previfem, Tri-Sprintec)
- EE 35 mcg/Norethindrone 0.5mg, 1mg, 0.5mg
(Aranelle, Leena, Tri-Norinyl)
- EE 35 mcg/Norethindrone 0.5mg, 0.75mg, 1mg
(Alyacen 7/7/7, Cyclofem 7/7/7, Dasetta7/7/7, Necon 7/7/7, Ortho-Novum 7/7/7, Nortrel 7/7/7, Pirmella 7/7/7)

FOUR-PHASIC

- **NATAZIA**
(Estradiol valerate/Dienogest)

EXTENDED – CYCLE PILLS

- EE 30mcg/Levonorgestrel 0.15mg
(Jolessa, Quasense, Introvale)
- EE 30, 10mcg/Levonorgestrel 0.15mg
(Amethia, Camrese, Daysee, Seasonique)
- EE 20mcg/Levonorgestrel 0.1mg
(Amethia Lo, Camrese Lo, LoSeasonique)
- **LO LOESTRIN FE** (EE 10mcg/Norethindrone 1mg)
- **QUARTETTE**
(levonorgestrel/EE 0.15mg/20mcg, 0.15mg/25mcg, 0.15mg/30mcg and EE 10mcg)

CONTINUOUS – CYCLE PILLS

- EE 20mcg/Levonorgestrel 90mcg (Amethyst)

PROGESTIN-ONLY PILLS “Mini-Pills”

- Norethindrone 0.35mg
(Camila, Errin, Heather, Jencycla, Jolivette, Lyza, Nor-QD, Nora-BE, Norlyroc)

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Emergency 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. FDA approved over the counter (OTC) contraceptive methods are also recommended if prescribed for a woman by her health care provider.¹

CVS/caremark suggests a plan consider the following pharmacy-related recommendations when developing its coverage under these provisions.

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.

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

CVS/caremark Recommendation

- Female
- Rx
- OTCs (requires a prescription)

Product Description*

(Brand names in *italics* and in parentheses are for reference only. Only generics and single source brands are recommended for coverage without cost sharing) (Brand names in **BOLD/BLUE**) have no generic available and are recommended for coverage).

- **ELLA**
(*Ulipristal 30mg tablet*) (progesterone receptor modulator)
- Levonorgestrel 0.75mg x 2 tablets
(*Plan B*) RX
- Levonorgestrel 1.5mg tablet
(*My Way, Next Choice One Dose, Take Action*) RX & OTC

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Injectables

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CVS/caremark Recommendation

- Female
- Quantity limit
(1 injection/75 days) or (4 injections/300days)
- Rx
- 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)
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- Medroxyprogesterone acetate 150mg IM x q3 months
(*Depo-Provera*)
- **DEPO-SUBQ-PROVERA 104**
(Medroxyprogesterone acetate 104mg SQ X q3 months)

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Miscellaneous – Intrauterine Devices, Subdermal Rods & Vaginal Rings

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CVS/caremark suggests a plan consider the following pharmacy-related recommendations when developing its coverage under these provisions.

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.

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

CVS/caremark Recommendation

- Female
- Rx
- Plans may choose to cover these items under the medical or pharmacy benefit
- Quantity Limits
 - Sub-dermal Rod (1/300 days)
 - Intrauterine Device (IUD) (1/300 days)
 - Vaginal Ring (13/300 days)

Product Description*

(Brand names in italics and in parentheses are for reference only. Only generics and single source brands are recommended for coverage without cost sharing) (Brand names in (BOLD/BLUE) have no generic available and are recommended for coverage).

- **IMPLANON, NEXPLANON**
Subdermal Rod
(Etonogestrel 68mg -release rate varies over time)
- **MIRENA**
IUD
(Levonorgestrel 20mcg/day)
- **SKYLA**
IUD
(Levonorgestrel 14mcg/day)
- **PARAGARD T 380A**
IUD
(Copper 309mg/day)
- **NUVA RING**
Vaginal Ring
(Ethinyl estradiol 15mcg/Etonogestrel 12mcg)

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Transdermal Patch

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CVS/caremark Recommendation

- Female
- Rx

Product Description*

(Brand names in *italics* and in parentheses are for reference only. Only generics and single source brands are recommended for coverage without cost sharing) (Brand names in (**BOLD/BLUE**) have no generic available and are recommended for coverage).

- Ethinyl estradiol 20mcg/Norelgestromin 150mcg (**Ortho Evra, Xulane**)

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Barrier Methods

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CVS/caremark suggests a plan consider the following pharmacy-related recommendations when developing its coverage under these provisions.

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

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

CVS/caremark Recommendation

- Female
- Quantity Limit (1/300 days)
- Rx

Product Description*

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

(Brand names in (**BOLD/BLUE**) have no generic available and are recommended for coverage).

- Diaphragms
 - **ORTHO-ALL FLEX**
 - **OMNIFLEX COIL SPRING SILICONE**
 - **MILEX WIDE-SEAL**
 - **REFLEXIONS FLATSPRING**
- Cervical Caps
 - **FEMCAP**

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OTC - Contraceptives

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

CVS/caremark Recommendation

- Female
- OTC (requires prescription)

Product Description*

(Brand names in *italics* and in parentheses are for reference only. Only generics and single source brands are recommended for coverage without cost sharing) (Brand names in **BOLD/BLUE** have no generic available and are recommended for coverage).

- Female Condoms
 - **FC-2**
- Vaginal Sponge
 - **TODAY (Nonoxynol-9)**
- Spermicides
 - **VCF VAGINAL FOAM**
 - **VCF VAGINAL FILM 28%**
 - **ENCARE VAGINAL SUPPOSITORIES**
 - **GYNOL II GEL 3%**
 - **CONCEPTROL GEL 4%**
 - **SHUR-SEAL GEL 2%**

Primary Prevention of Breast Cancer

Medications for risk reduction of primary breast cancer in women:

The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians engage in shared, informed decision making with women who are at increased risk for breast cancer about medications to reduce their risk. For women who are at increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene.

CVS/caremark Recommendation

- Female
- Age limit ≥ 35
- No prior authorization²
- Generic only
- RX

² May be subject to certification process.

GPI Description*

- Raloxifene HCl tab 60 mg
- Tamoxifen citrate tab 10mg (base equiv) & 20mg (base equiv)

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