

09-J0000-60

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Subject: Contraceptive Drugs

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

[Position Statement](#)

[Billing/Coding](#)

[Reimbursement](#)

[Program Exceptions](#)

[Definitions](#)

[Related Guidelines](#)

[Other](#)

[References](#)

[Updates](#)

DESCRIPTION:

Contraception, or birth control, is the means by which the male or female can utilize methods that will prevent pregnancy. Such methods include oral contraceptives and medroxyprogesterone containing agents (i.e., Depo-Provera®) that are injected. Oral contraceptives (birth control pills) are medications that prevent pregnancy. They are one method of birth control. Oral contraceptives are hormonal preparations that may contain combinations of the hormones estrogen and progestin or progestin alone. Combinations of estrogen and progestin prevent pregnancy by inhibiting the release of the hormones luteinizing hormone (LH) and follicle stimulating hormone (FSH) from the pituitary gland in the brain. LH and FSH play key roles in the development of the egg and preparation of the lining of the uterus for implantation of the embryo. Progestin also makes the uterine mucus that surrounds the egg more difficult for sperm to penetrate and, therefore, for fertilization to take place. In some women, progestin inhibits ovulation (release of the egg).

DEPO-PROVERA Contraceptive Injection (CI) contains medroxyprogesterone acetate, a derivative of progesterone, as its active ingredient. Depo-Provera®, when administered at the recommended dose to women every 3 months, inhibits the secretion of gonadotropins which, in turn, prevents follicular maturation and ovulation and results in endometrial thinning. These actions produce its contraceptive effect.

POSITION STATEMENT:

Benefits vary by contract. Some contracts may exclude benefits for all or some methods of birth control.

Contraceptive drugs may be eligible for coverage when used for treatment of the following medical conditions:

- Acne, recalcitrant (resistant to treatment)
- [Amenorrhea](#)
- Contraception required by other therapies (i.e. teratogenic agents, etc.)
- Dysfunctional bleeding (e.g., hypermenorrhea, [menorrhagia](#), metrorrhagia, menometrorrhagia, oligomenorrhea, polymenorrhea, hypomenorrhea)
- [Dysmenorrhea](#)
- [Endometriosis](#)
- Follicular cyst of ovary
- [Hirsutism](#)
- Menopause
- Menorrhagia
- Perimenopausal symptoms
- [Polycystic ovarian syndrome](#)
- [Postcoital](#) contraception in rape victims
- Post menopausal osteoporosis (prophylaxis)
- Premenstrual dysphoric disorder (PMDD)
- [Turner's syndrome](#)

Medroxyprogesterone acetate **meets the definition of medical necessity** when administered for the following Orphan Drug Indication (<http://www.fda.gov/orphan/designat/list.htm>):

- Treatment of immune thrombocytopenic purpura.

PRECAUTIONS:

Contraindications

Levonorgestrel contraceptive injection

- Pregnancy or suspicion of pregnancy
- Congenital or acquired uterine anomaly if it distorts the uterine cavity
- Acute pelvic inflammatory disease (PID) or a history of PID unless there has been a subsequent intrauterine pregnancy
- Postpartum endometritis or infected abortion in the past 3 months
- Known or suspected uterine or cervical neoplasia
- Known or suspected breast cancer or other progestin-sensitive cancer
- Uterine bleeding of unknown etiology
- Untreated acute cervicitis or vaginitis or other lower genital tract infections
- Acute liver disease or liver tumor (benign or malignant)
- Increased susceptibility to pelvic infection
- A previous intrauterine device (IUD) that has not been removed

Medroxyprogesterone acetate contraceptive injection:

- Know or suspected pregnancy or as a diagnostic test for pregnancy.
- Active thrombophlebitis or current or past history of thromboembolic disorders, or cerebral vascular disease.
- Known or suspected malignancy of breast
- Significant liver disease
- Undiagnosed vaginal bleeding.

Oral contraceptives should not be used in women who currently have the following conditions.

- Thrombophlebitis or thromboembolic disorders
- A past history of deep vein thrombophlebitis or thromboembolic disorders
- Cerebral vascular or coronary artery disease (current or history)
- Valvular heart disease with complications
- Severe hypertension
- Diabetes with vascular involvement
- Headaches with focal neurological symptoms
- Major surgery with prolonged immobilization
- Known or suspected carcinoma of the breast
- Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
- Undiagnosed abnormal genital bleeding
- Cholestatic jaundice of pregnancy or jaundice with prior pill use
- Acute or chronic hepatocellular disease with abnormal liver function
- Hepatic adenomas or carcinomas
- Known or suspected pregnancy

Warnings:

Levonorgestrel contraceptive injection

- Remove if pregnancy occurs
- Uterine perforation may occur and may reduce contraceptive effectiveness or require surgery. Risk is increased if inserted in lactating women and may be increased if inserted in women with fixed retroverted uteri and postpartum
- Evaluate persistent enlarged ovarian follicles or ovarian cysts
- Bleeding patterns become altered, may remain irregular and amenorrhea may ensue

Medroxyprogesterone acetate contraceptive injection:

- Thromboembolic Disorders: Discontinue in individuals who develop thrombosis
- Cancer Risks: Monitor women with breast nodules or a strong family history of breast cancer carefully.

- Ectopic Pregnancy: Consider ectopic pregnancy if a woman using medroxyprogesterone acetate becomes pregnant or complains of severe abdominal pain.
- Anaphylaxis and Anaphylactoid Reactions: Provide emergency medical treatment.
- Liver Function: Discontinue medroxyprogesterone acetate if jaundice or disturbances of liver function develop
- Carbohydrate Metabolism: Monitor diabetic individuals carefully.

Oral Contraceptives:

- Myocardial Infarction: An increased risk of myocardial infarction has been attributed to oral contraceptive use.
- Thromboembolism: An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well established.
- Cerebrovascular diseases: Oral contraceptives have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes).
- Carcinoma of the breasts and reproductive organs: In spite of many studies of the relationship between oral contraceptive use and breast and cervical cancers, a cause-and-effect relationship has not been established.
- Hepatic neoplasia: Benign hepatic adenomas are associated with oral contraceptive use.
- Ocular lesions: There have been clinical case reports of retinal thrombosis associated with the use of oral contraceptives.
- Carbohydrate and lipid metabolic effects: Oral contraceptives have been shown to cause a decrease in glucose tolerance in a significant percentage of users.
- Elevated blood pressure: Women with significant hypertension should not be started on hormonal contraception.
- Headache: The onset or exacerbation of migraine or development of headache with a new pattern which is recurrent, persistent or severe requires discontinuation of oral contraceptives and evaluation of the cause.
- Ectopic pregnancy: Ectopic as well as intrauterine pregnancy may occur in contraceptive failures.

BILLING/CODING INFORMATION:

HCPSC Coding:

J2675	Injection, progesterone, per 50 mg
J3490	Unclassified drug (for Depo-Provera, Depo-SubQ Provera ONLY)
S4993	Contraceptive pills for birth control

ICD-10 Diagnosis Codes That Support Medical Necessity for contraceptives used for non-contraceptive indications:

D39.0	Neoplasm of uncertain behavior of uterus
D69.3	Immune thrombocytopenic purpura
D69.42	Congenital and hereditary thrombocytopenia purpura
E28.2	Polycystic ovarian syndrome
E28.8	Other ovarian dysfunction

L85.0	Acquired ichthyosis
L85.1	Acquired keratosis [keratoderma] palmaris et plantaris
L87.0	Keratosis follicularis et parafollicularis in cutem penetrans
M81.0	Age-related osteoporosis without current pathological fracture
N80.00 – N80.9, N80.A0 – N80.D9	Endometriosis of uterus, ovary, fallopian tube, pelvic peritoneum, rectovaginal septum and vagina, intestine, cutaneous scar, other areas and unspecified
N83.0	Follicular cyst of ovary
N83.00	Follicular cyst of ovary, unspecified side
N83.01	Follicular cyst of right ovary
N83.02	Follicular cyst of left ovary
N91.2	Amenorrhea, unspecified
N91.5	Oligomenorrhea, unspecified
N92.0	Excessive and frequent menstruation with regular cycle
N92.2	Excessive menstruation at puberty
N92.3	Ovulation bleeding
N92.4	Excessive bleeding in the premenopausal period
N92.5	Other specified irregular menstruation
N93.8	Other specified abnormal uterine and vaginal bleeding
N94.6	Dysmenorrhea, unspecified
N95.0	Postmenopausal bleeding
N95.1	Menopausal and female climacteric states
Q55.4	Other congenital malformations of vas deferens, epididymis, seminal vesicles and prostate
Q96.9	Turner's syndrome, unspecified
Y04.8XXA	Assault by other bodily force, initial encounter

REIMBURSEMENT INFORMATION:

Refer to the section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline revised date.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

DEFINITIONS:

Amenorrhea: absence of menstruation or stoppage of the menses; also called amenia.

Dysmenorrhea: painful menstruation.

Endometriosis: benign condition where endometrial tissue is present outside the uterine cavity.

Hirsutism: abnormal hair-growth, especially an adult male pattern of hair distribution in women.

Menorrhagia: excessive menstrual bleeding.

Polycystic ovary syndrome (PCOS): a mild hormone imbalance that can cause irregular periods, unwanted hair growth, and acne. This is a common condition that begins during the teenage years.

Postcoital: following sexual intercourse between a male and female.

Subcutaneous: beneath the skin.

Turner's syndrome: an endocrine disorder in which amenorrhea is an indication in girls.

RELATED GUIDELINES:

None applicable.

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 10/11/16.

GUIDELINE UPDATE INFORMATION:

06/15/00	New Medical Coverage Guideline.
04/01/02	Quarterly HCPCS code update.
06/15/02	Reviewed; added information regarding Mirena® contraceptive systems; revise name of policy.
07/15/02	Additional procedure codes added.
01/01/03	HCPCS coding update.
02/15/03	Description section revised to include “contraceptive patches”.
06/15/04	Scheduled review; no change in coverage statement. Additional related procedure codes added.
01/01/06	HCPCS update, deleted A4260, added new code J7306.
07/01/06	Updated MCG number from 09-A9140-09 to 09-J0000-60.
09/15/06	Biennial review, updated references.
12/15/06	Revised: added new implantable rod called Implanon® and added new HCPCS code S0180.
07/15/07	Reviewed guideline: Reformatted guideline, maintain current coverage and limitations, added the word “medical” to conditions that may be covered, updated links and updated references.
01/01/08	Annual coding update. Added HCPCS code J7307 and removed S0180.
08/15/09	Review and revision to guideline; consisting of review of literature, added menorrhagia as a covered diagnosis and definition, updated description section, removal of devices and changed name of guideline.
12/15/10	Review and revision to guideline; consisting of updating coding, update references and added Acne, recalcitrant (resistant to treatment) and Perimenopausal symptoms as covered diagnoses.
12/15/11	Review and revision to guideline; consisting of updating references.
12/15/12	Review and revision to guideline; consisting of revising position statement to include premenstrual dysphoric disorder, updating references.
01/01/13	Annual HCPCS Update; added HCPCS code J1050, removed J1055 and J1056
09/15/13	Review and revision to guideline; consisting of updating position statement, precautions, references, program exceptions, and coding.
11/01/15	Revision: ICD-9 Codes deleted.
11/15/16	Revision to guideline; consisting of revising contraindications, precautions/warnings, coding.
07/01/17	Addition of HCPCS code Q9984.
01/01/18	Annual HCPCS coding update: added HCPCS code J7296 and deleted code Q9984.
06/15/21	Removal of HCPCS code J7296.
10/01/22	Update to ICD-10 coding.

