

Medical Policy



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***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: Contraception and Voluntary Sterilization

Description/Background

CONTRACEPTION

Contraception (ie, birth control, prevention of pregnancy) is the means by which an individual uses methods that will prevent pregnancy. Methods of contraception include barrier methods, non-hormonal contraception, hormonal contraception, and permanent surgical sterilization. Methods of contraception vary in their effectiveness, and some have associated complications.

Non-Hormonal Contraception

Barrier Methods

These methods physically prevent sperm from reaching the egg. Some methods may also protect against certain sexually transmitted diseases. Barrier methods include spermicides, condoms, diaphragm, cervical cap (Lea's Shield, FemCap), and a vaginal sponge with spermicide.

Intrauterine Device – Non-hormonal

The intrauterine device (IUD) is a small, T-shaped device that is placed inside the uterus to prevent pregnancy. Five IUDs are currently marketed in the United States: the copper-containing IUD, and four hormone-releasing intrauterine devices (see section below). The copper IUD is made of polyethylene wrapped with copper wire around the stem and arms. Studies indicate that the copper IUD disrupts sperm motility and viability. The U.S. Food and Drug Administration (FDA) has approved use of the copper IUD for up to 10 years.¹

Digital Fertility Applications

An FDA cleared digital application for contraception that provides user-specific fertility information for prevention of pregnancy. Ex: Natural Cycles.

Hormonal Contraception

Hormonal contraceptives include pills, injections, rings, patches, implants and intrauterine devices.

Oral Contraceptive Pills

The most common form of hormonal contraception is oral pills, which come in 2 varieties: a combined hormonal contraceptive pill, which contains estrogen and progesterone; and the progestin only pill which contains progesterone. The combination pill is composed of one type of estrogen (ethinyl estradiol), in various strengths; and many different forms and strengths of progestins. The progestin only pill is only available in one strength and one type of progestin.

Injection

The injection of depot-medroxyprogesterone acetate (DMPA) provides protection against pregnancy for up to 3 months.

Vaginal Ring

The vaginal ring is placed in the upper vagina. It releases estrogen and progesterone continuously. It is worn for 21 days, removed for 7, and then replaced with a new ring.

Skin Patch

The contraceptive skin patch is a weekly method of birth control that releases estrogen and progesterone through the skin and into the bloodstream. The patch follows a 28-day cycle. A patch is worn weekly for 3 weeks, then removed for a week.

Implant

The contraceptive implant is a flexible, thin, rod about the size of a matchstick that is placed under the skin of the upper arm. It releases a slow, steady dose of progesterone. The FDA has approved the implant for up to 3 years.

Intrauterine Device - Hormonal

The intrauterine device is a small, T-shaped device that is placed inside the uterus to prevent pregnancy. There are 4 IUDs that release levonorgestrel, a progestin, into the uterus. The FDA approves the use of these IUDs between 3 to 7 years, depending on the specific device. The IUD is more effective than most forms of birth control.¹

Emergency Contraception

Emergency contraception, also known as postcoital contraception, is therapy used to prevent pregnancy after unprotected or inadequately-protected sexual intercourse. Common indications for emergency contraception include contraceptive failure (eg, condom breakage or missed doses of oral contraceptives) and failure to use any form of contraception. Methods of emergency contraception include oral administration of combined estrogen-progestin, progestin only, or selective progesterone receptor modulators.²

Sterilization

Sterilization is the method of birth control that permanently prevents pregnancy.

- Sterilization in individuals with vasa deferentia is performed by a vasectomy, where the vas deferens tubes are most often cut and cauterized, to prevent the release of sperm into the semen.³
- Sterilization in individuals with a uterus is accomplished by tubal occlusion, in which transit of the egg from the ovary to the uterus is prevented by an interruption in the fallopian tubes. This is performed by removing a section of each tube or by closing off the tubes (clip or

band occlusion, or cauterization). Sterilization can also be accomplished by removal of both tubes. Complete removal of the tubes has the advantage to possibly reduce the risk of ovarian cancer. The procedure may be performed via laparoscopy, minilaparotomy, or at the time of a cesarean delivery.⁴

Regulatory Status

The U.S. Food and Drug Administration (FDA) has approved many birth control methods (eg, oral contraceptives, injectables, rings, patches, implants, diaphragms, and cervical caps). The FDA has also cleared a digital fertility application device, Natural Cycles.

Natural Cycles is a class II Software application for contraception and was cleared by the FDA in 2021. A software application for contraception is a device that provides user-specific fertility information for preventing a pregnancy. This device includes an algorithm that performs analysis of patient-specific data (e.g., temperature, menstrual cycle dates) to distinguish between fertile and non-fertile days, then provides patient-specific recommendations related to contraception. Natural Cycles is a stand-alone software application, intended for women 18 years and older, to monitor their fertility. Natural Cycles can be used for preventing a pregnancy (contraception) or planning a pregnancy (conception).⁶

Table 1. Digital Fertility Applications Regulatory Table

Application	Manufacturer	FDA Cleared Indication	Description	FDA Product Code	FDA Marketing Clearance	Year
Natural Cycles	Natural Cycles Nordic, AB	Natural Cycles ⁵ is a stand-alone software application, intended for women 18 years and older, to monitor their fertility. Natural Cycles can be used for preventing a pregnancy (contraception) or planning a pregnancy (conception).	Natural Cycles is a class II Software application for contraception. Natural Cycles is a Software application for contraception. A software application for contraception is a device that provides user-specific fertility information for preventing a pregnancy. This device includes an algorithm that performs analysis of patient-specific data (e.g., temperature, menstrual cycle dates) to distinguish between fertile and non-fertile days, then provides patient-specific recommendations related to contraception. Natural Cycles is a stand-alone software application, intended for women 18 years and older, to monitor their fertility. Natural Cycles can be used for preventing a pregnancy (contraception) or planning a pregnancy (conception).	PYT	De Novo Classification	2017

Natural Cycles	Natural Cycles Nordic, AB	Natural Cycles ⁶ is a stand-alone software application, intended for women 18 years and older, to monitor their fertility. Natural Cycles can be used for preventing a pregnancy (contraception) or planning a pregnancy (conception)	Device, Fertility Diagnostic, Contraceptive, Software Application. Software application for contraception. Designed to monitor and provide fertility information to prevent pregnancy (contraception). Software application, the physical platform may vary (e.g., mobile phone, PC, tablet, etc...) Algorithm transforms user data into user-specific information regarding fertility and provides timeframes when pregnancy is unlikely. FDA 510K Indications:	PYT	510(k) premarket notification	2021
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Medical Policy Statement

Various contraceptive and sterilization methods are established for the prevention of unintended pregnancy. They may be a useful option when covered by the member's certificate.

Inclusionary and Exclusionary Guidelines

NOTE: Contraceptive or sterilization coverage is based on the member's certificate benefits. These services may not be covered on all certificates.

Inclusions:

- FDA approved contraceptive drugs or devices prescribed by a qualified health care provider
- FDA cleared digital fertility application for individuals 18 years and older prescribed by a qualified health care provider
- Vasectomy performed in the office setting
- Sterilization procedures in individuals with a uterus

Exclusions:

- Contraceptive drugs or devices that are not FDA approved
- Vasectomy in an outpatient facility
- Digital fertility application that is not FDA cleared or approved

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

11976	11981	11982	11983	55250	57170
58300	58301	58600	58605	58611	58615

58661

58670

58671

A9293

Other codes (investigational, not medically necessary, etc.):

N/A

Note: Code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

Rationale

Current medical literature has shown that the methods of contraception and sterilization included in this policy are considered safe and effective and are standard methods of care.

Government Regulations

National:

National Coverage Determination (NCD) for STERILIZATION (230.3)

Indications and Limitations of Coverage

A. Nationally Covered Conditions

- Payment may be made only where sterilization is a necessary part of the treatment of an illness or injury, e.g., removal of a uterus because of a tumor, removal of diseased ovaries.
- Sterilization of a mentally challenged beneficiary is covered if it is a necessary part of the treatment of an illness or injury, (bilateral oophorectomy, or bilateral orchidectomy in a case of cancer of the prostate). The Medicare Administrative Contractor denies claims when the pathological evidence of the necessity to perform any such procedures to treat an illness or injury is absent; and
- Monitor such surgeries closely and obtain the information needed to determine whether in fact the surgery was performed as a means of treating an illness or injury or only to achieve sterilization.

B. Nationally Non-covered Conditions

- Elective hysterectomy, tubal ligation, and vasectomy, if the primary indication for these procedures is sterilization.
- A sterilization that is performed because a physician believes another pregnancy would endanger the overall general health of the woman is not considered to be reasonable and necessary for the diagnosis or treatment of illness or injury within the meaning of §1862(a) (1) of the Social Security Act. The same conclusion would apply where the sterilization is performed only as a measure to prevent the possible development of, or effect on, a mental condition should the individual become pregnant; and sterilization of a mentally retarded person where the purpose is to prevent conception, rather than the treatment of an illness or injury.

Local:

There is no local coverage determination on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Pregnancy Terminations

References

1. The American College of Obstetricians and Gynecologists. Long-acting reversible contraception: implants and intrauterine devices. Practice Bulletin Number 186, November 2017(reaffirmed 2021).
<https://www.acog.org/en/clinical/clinical-guidance/practice-bulletin/articles/2017/11/long-acting-reversible-contraception-implants-and-intrauterine-devices> Accessed 5/15/24.
2. The American College of Obstetricians and Gynecologists. Emergency contraception. Practice Bulletin Number 152, September 2015. (reaffirmed 2022)
<https://www.acog.org/en/clinical/clinical-guidance/practice-bulletin/articles/2015/09/emergency-contraception> Accessed 5/15/24.
3. The American Urological Association. Vasectomy Guideline 2015.
<https://www.auanet.org/guidelines/guidelines/vasectomy-guideline> Accessed 5/15/24.
4. The American College of Obstetricians and Gynecologists. Benefits and risks of sterilization. Practice Bulletin Number 208, March 2019. [Benefits and Risks of Sterilization | ACOG](#) accessed 5/15/24
5. FDA De Novo Classification Request for Natural Cycles September 20, 2017 [DE NOVO CLASSIFICATION REQUEST FOR NATURAL CYCLES \(fda.gov\)](#) assessed 5/14/2024
6. FDA 510(k) Classification Request for Natural Cycles June 6, 2021 [510\(k\) Premarket Notification \(fda.gov\)](#) accessed 5/15/24
7. Centers for Medicare and Medicaid Services, The Center for Consumer Information & Insurance Oversight, Affordable Care Act Implementation FAQs - Set 12.
http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html Accessed 5/15/24.
8. Centers for Medicare and Medicaid Services. Medicare National Coverage Database. NCD for Sterilization, Manual Section 230.3. <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=13&ncdver=1&bc=AgAAQAAAAAAAAAA%3d%3d&> Accessed 5/15/24.
9. U.S. Food and Drug Administration. Birth Control. Updated 05/10/24.
<http://www.fda.gov/ForConsumers/ByAudience/ForWomen/FreePublications/ucm313215.htm> Accessed 5/15/24.
10. World Health Organization. Family planning/Contraception method. Updated Sept 5, 2023.
<http://www.who.int/mediacentre/factsheets/fs351/en/> Accessed 5/15/24.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/15/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
4/24/02	4/24/02	4/24/02	Joint policy established
6/15/05	6/15/05	5/20/05	Routine maintenance
11/1/07	8/21/07	10/31/07	Routine maintenance
3/1/09	12/9/08	12/21/08	Routine maintenance
3/1/12	12/13/11	2/2/12	Routine maintenance, CPT codes 11975 and 11977 deleted effective 12/31/11
7/1/15	4/24/15	5/8/15	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
7/1/17	4/18/17	4/18/17	Routine maintenance
1/1/18	10/19/17	10/26/17	Routine maintenance
1/1/19	10/16/18	10/18/18	Routine maintenance
1/1/20	10/15/19		Routine maintenance
1/1/21	10/20/20		Routine maintenance
1/1/22	10/19/21		Routine maintenance Delete 11980, 58565 Add 58661
1/1/23	10/18/22		Routine maintenance (ls) Added gender-neutral language
1/1/24	10/17/23		Routine maintenance (jf) Vendor Managed: NA
11/1/24	8/20/24		Routine Maintenance (jf) HCPCS Code Update <ul style="list-style-type: none"> • Added A9293 HCPCS code update Natural Cycles as established. • Added information about Natural Cycle in description section. Edits to the inclusions, exclusions and FDA section. • Vendor Managed: NA Added Ref: 5,6

Next Review Date: 3rd Qtr, 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 4/1/99	Revised: 1/12/00
BCBSM: N/A	Revised: N/A

**BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: CONTRACEPTION AND VOLUNTARY STERILIZATION**

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Policy criteria apply. Refer to individual contracts and certificates to determine coverage of contraceptives and/or sterilization.
BCNA (Medicare Advantage)	See Government Regulations Section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.