The Regence *Group*

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Medication Policy Manual

Policy No: dru022

Topic: Self-administered Contraceptives for Medical Conditions

Date of Origin: January 1996

Revised/Effective Date: April 7, 2009

Next Review Date: March 2010

IMPORTANT REMINDER

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Contraceptives in the form of pills, vaginal rings, or transdermal patches are used to prevent pregnancy and also to treat other medical conditions.

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Policy/Criteria

I. Some contracts require prior authorization approval of self-administered contraceptives prior to coverage. Self-administered contraceptives containing estrogens and progestins (pills, vaginal rings and transdermal patches) may be prescribed for contraception or to treat certain medical conditions. Some contracts exclude coverage of contraceptive products.

II. Oral contraceptives containing estrogens and progestins may be considered medically necessary for non-contraceptive purposes for treatment of the following conditions:

A. Acne, which has not responded to other treatment methods or when condition worsens during menses.

B. Amenorrhea or absence of bleeding.

C. Dysfunctional uterine bleeding defined as abnormal or heavy bleeding caused by hormonal abnormalities in the absence of pregnancy, tumor, infection, or coagulopathy.

D. Dysmenorrhea/severe cramps.

E. Endometriosis (prophylaxis and treatment).

F. Hyperandrogenism.

G. Irregular Menses such as hypermenorrhea (abnormal **duration** of uterine bleeding) or menorrhagia (abnormal **amount** of bleeding).

H. Migraine headaches.

I. Osteoporosis or documented risk for osteoporosis.

J. Ovarian cyst.

K. Ovarian/endometrial cancer prevention.

L. Pelvic inflammatory disease (PID).

M. Perimenopause.

N. Polycystic ovary syndrome.

O. Premenstrual Dysphoric Disorder (PMDD).

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P. Premenstrual Syndrome (PMS).

III. Administration

Regence considers contraceptives in the form of pills, vaginal rings and transdermal patches to be self-administered medications.

IV. Use of contraceptive transdermal patches or vaginal rings containing estrogen and/or progestins, or oral progestin-only contraceptives, for non-contraceptive purposes is considered investigational.

Position Statement

- All self-administered contraceptives in the form of pills, vaginal rings, and transdermal patches (containing estrogens and progestins) have an efficacy rate of at least 90% in preventing pregnancy.[1,2]
- There is currently no evidence that estrogen/progestin contraceptives at doses administered as transdermal patches or vaginal rings provide similar non-contraceptive health benefits as oral contraceptives.

Health Benefits associated with Oral Contraceptives

- Oral contraceptives (OCs) have also been shown to provide other non-contraceptive health benefits. [1,39]
  - * Acne Vulgaris[2]
    - -- All combination oral contraceptives raise sex hormone binding globulin and decrease free testosterone concentrations, which are both known to decrease acne.
    - -- Combination OCs may be of benefit in females 15 years or older who need contraception and whose acne is unresponsive to other anti-acne therapy.

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* Endometriosis[10]

  -- The American College of Obstetricians and Gynecologists (ACOG) recommends medical management of endometriosis using oral contraceptives, progestins, danazol, nonsteroidal anti-inflammatory drugs and gonadotropin-releasing hormone (GnRH) agonists.

  -- All these medications effectively reduce the size and growth of endometrial tissue.

  -- Based on ACOG recommendations, oral contraceptives and oral/depot medroxyprogesterone acetate are effective in comparison to placebo and may be equivalent to other more costly regimens.

* Dysfunctional Uterine Bleeding/Dysmenorrhea/Amenorrhea[5-9]

  -- Treatment with combination norethindrone/mestranol and other estrogen-progestin combinations, are effective in managing unusual uterine bleeding problems such as amenorrhea, dysfunctional uterine bleeding, or hypermenorrhea.

  -- Oral contraceptives are effective in about 90% of patients with primary dysmenorrhea.

  -- NSAIDs are typically used for symptoms associated with dysmenorrhea. However, oral contraceptives may be of benefit for treatment of patients in whom contraception is necessary.

* Perimenopause[12-15]

  -- Oral contraceptives decrease the number and severity of hot flashes in perimenopausal women.

  -- Prospective studies of perimenopausal women have found that OC users can preserve bone mineral density, whereas bone loss has been observed in nonusers.

* Ovarian Cyst

  -- Women may receive oral contraceptives in an attempt to suppress ovarian activity and reduce complications from functional (benign) cysts.[16,20]

  -- A dose-related effect exists for this effect.[17-19,35]

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* Polycystic Ovary Syndrome (PCOS)[11]

  -- Treatment of PCOS is directed at managing the clinical symptoms of the condition, menstrual irregularities and hirsutism caused by anovulation and hyperandrogen secretion.

  -- Use of OCs for the sole purpose of treating hirsutism is considered cosmetic.

  -- Oral contraceptives are considered a first-line choice for treatment for prolonged or excessive menstrual bleeding in women that desires contraception.

  -- GnRH has similar effectiveness as oral contraceptives, with no added benefit when used in combination therapy.[24]

  -- Oral contraceptives, medroxyprogesterone, and antiandrogens are considered therapeutic options in the treatment of PCOS in women, that depends on the clinical picture as well as the wishes of the patient.

* Prevention of Ovarian Cancer

  -- There is compelling data to support the use of oral contraceptives in women at high risk based on family history, positive carrier status for BRCA mutations, or nulliparity, even if contraception is not required.[25-27] (The BRCA1 or BRCA2 gene mutation increases the lifetime risk of ovarian cancer 45% and 25%, respectively).

  -- The Cancer and Steroid Hormone Study (CASH) is the largest study of oral contraceptive-ovarian cancer relationship which demonstrated a 40% reduction in risk after as little as 3 to 6 months of oral contraceptive use, increasing up to 80% at 10 or more years of therapy.[26]

* Prevention of Endometrial Cancer

  -- A 1997 meta-analysis[28] and clinical studies[29-30] confirm the risk reduction of up to 50% with the use of oral contraceptives.

  -- The protection increases with longer duration of use, ranging from 56% after 4 years to 72% at 12 years or more.[28-30]

* Bone Mineral Density Maintenance

  -- Prospective studies demonstrate that perimenopausal women taking oral contraceptives maintain bone mineral density when compared with controls not taking the pill.[31-32]

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- -- Various studies found that the longer the oral contraceptive use, the greater the positive effects on bone mineral density.[33-36]
- -- The greatest protective effects were seen with oral contraceptive use of more than 5 years.

Safety

- OC use is associated with an increased risk of serious conditions including myocardial infarction, thromboembolic/thrombotic disorders, stroke, hepatic neoplasia and gall bladder disease.[4,21-23,33]
- Risk of serious morbidity and mortality is very small in healthy women without underlying risk factors.
- The risk of morbidity and mortality with OC use increases significantly in the presence of other underlying risk factors, such as hypertension, hyperlipidemias, obesity and diabetes.
- Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use.

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Cross References
Mirena®, levonorgestrel-containing Intrauterine System (LNG-IUS) for Medical Conditions dru079

Codes	Number	Description
N/A		

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