PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**CONTRACEPTIVES**
BRAND NAME (generic)	**ANNOVERA (segesterone/ethinyl estradiol vaginal system)** **DEPO-SUBQ PROVERA 104 (medroxyprogesterone acetate injectable suspension)** **NUVARING (etonogestrel/ethinyl estradiol vaginal ring)**
DOSAGE FORM*	**ORAL Contraceptives (all) excluding emergency contraceptives** **TRANSDERMAL Contraceptives (all)**
Status: CVS Caremark® Criteria	
Type: Initial Prior Authorization	

POLICY

FDA-APPROVED INDICATIONS

Contraception

Oral contraceptives, transdermal contraceptives, Annovera, Depo-subQ provera 104 and NuvaRing are indicated for the prevention of pregnancy in women who elect to use these products as a method of contraception.

Heavy Menstrual Bleeding

Natazia is also indicated for the treatment of heavy menstrual bleeding in women without organic pathology who choose to use an oral contraceptive as their method of contraception.

Acne

Beyaz, Tri-Estarylla, Tri-Legest, and Yaz are indicated for the treatment of moderate acne vulgaris in women/females at least 14 (Beyaz, Yaz) or 15 (Tri-Estarylla, Tri-Legest) years of age who have no known contraindications to oral contraceptive therapy and have achieved menarche and for Tri-Legest who are unresponsive to topical anti-acne medications. Beyaz, Tri-Estarylla, Tri-Legest, and Yaz should be used for the treatment of acne only if the patient desires an oral contraceptive for birth control and for Tri-Legest only if the patient plans to stay on it for at least 6 months.

Premenstrual Dysphoric Disorder (PMDD)

Beyaz and Yaz are indicated for the treatment of symptoms of premenstrual dysphoric disorder (PMDD) in women who choose to use an oral contraceptive as their method of contraception. The effectiveness of Beyaz and Yaz for PMDD when used for more than three menstrual cycles has not been evaluated. Beyaz and Yaz have not been evaluated for the treatment of premenstrual syndrome (PMS).

Folate Supplementation
Beyaz and Safyral are indicated in women who choose to use an oral contraceptive as their method of contraception, to raise folate levels for the purpose of reducing the risk of a neural tube defect in a pregnancy conceived while taking the product or shortly after discontinuing the product.

Management of endometriosis-associated pain
Depo-subQ provera 104 is indicated in females of reproductive age for the management of endometriosis-associated pain.

Limitations of Use:
The use of depo-subQ provera 104 is not recommended as a long-term (i.e., longer than 2 years) birth control method or medical therapy for endometriosis-associated pain unless other options are considered inadequate.

Compendial Uses
Dysfunctional Uterine Bleeding[30,31]
Dysmenorrhea[32-34]
Endometriosis[32,33]
Female Hirsutism[35]
Polycystic Ovary Disease[36]
Premenstrual dysphoric disorder[37]

COVERAGE CRITERIA

Authorization may be granted for the requested drug when ONE of the following criteria is met:

- The request is for depo-subQ provera 104 and the patient meets ONE of the following criteria:
  - The requested drug is being prescribed for the management of endometriosis-associated pain
  - The patient is taking a drug that should NOT be taken during OR after pregnancy (e.g., acitretin, isotretinoin, Revlimid, Ribavirin, Thalomid, etc.)
- The requested drug is being prescribed for ANY of the following:
  - Dysfunctional uterine bleeding (e.g., amenorrhea, hypermenorrhea, oligomenorrhea, polymenorrhea, menorrhagia, metrorrhagia, menometrorrhagia)
  - Dysmenorrhea in a patient who had an inadequate treatment response with analgesics
  - Endometriosis
  - Hirsutism
  - Polycystic ovary disease
  - Premenstrual dysphoric disorder
- The patient is taking a drug that should NOT be taken during OR after pregnancy (e.g., acitretin, isotretinoin, Revlimid, Ribavirin, Thalomid, etc.)

DURATION OF APPROVAL (DOA)

- 55-A:
  - Depo-subQ provera 104: DOA: 24 months
  - All other target drugs: DOA: 36 months

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