

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Depo-Estradiol (estradiol cypionate) injection

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Depo-Estradiol (estradiol cypionate) injection

APPROVAL CRITERIA

Requests for Depo-Estradiol (estradiol cypionate) injection may be approved when the following criteria are met:

- I. Individual is using to treat moderate to severe vasomotor symptoms associated with menopause; **OR**
- II. Individual has been diagnosed with hypoestrogenism due to hypogonadism;

OR

- III. Individual has a diagnosis of gender dysphoria or gender identity disorder (WPATH 2012, Endocrine Society 2017) ; **AND**
- IV. Individual is 16 years of age or older; **AND**
- V. The goal of treatment is male-to-female gender reassignment.

Requests for Depo-Estradiol (estradiol cypionate) injection may not be approved for any of the following:

- I. Individual has undiagnosed abnormal genital bleeding; **OR**
- II. Individual has known or suspected cancer of the breast; **OR**
- III. Individual has known or suspected estrogen-dependent neoplasia; **OR**
- IV. Individual has active deep vein thrombosis, pulmonary embolism or history of these conditions; **OR**
- V. Individual has active or recent (within the past year) arterial thromboembolic disease (such as stroke or myocardial infarction); **OR**
- VI. Individual has liver dysfunction or disease.

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: December 5, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Hembree WC. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. The journal of clinical endocrinology and metabolism. 2009-09;94:3132-3154.
6. The 2017 hormone therapy position statement of The North American Menopause Society. *Menopause*. 2017 Jun 22; 24(17): p. 728-753.
7. Cobin RH, Goodman NF, AACE Reproductive Endocrinology Scientific Committee. American Association of Clinical Endocrinologists and American College of Endocrinology Position Statement on Menopause-2017 update. *Endocr Pract*. 2017 Jul; 23(7): 869-880.
8. ACOG Practice Bulletin No. 141: management of menopausal symptoms. *Obstet Gynecol*. 2014 Jan; 123(1):202-16.
9. Coleman E, Bockting W, Botzer M, et al. World Professional for Transgender Health (WPATH). Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. *Int J Transgen*. 2012; 13:165-232. Available at: http://www.wpath.org/site_page.cfm?
10. Hembree WC, Cohen-Kettenis PT, Gooren L. et.al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrin Metab*; 2017 Nov; 102(11):3869-3903. Available at: <https://academic.oup.com/jcem/article/102/11/3869/4157558>.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.