

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

Duavee (conjugated estrogens/bazedoxifene)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Duavee (conjugated estrogens/bazedoxifene) 0.45mg/20mg tablets	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Duavee (conjugated estrogens/bazedoxifene) may be approved if the following criteria are met:

- I. Individual is age 18 through age 75; **AND**
- II. Individual has an intact uterus; **AND**
- III. Individual is using for one of the following conditions:
 - A. Treatment of moderate to severe vasomotor symptoms associated with menopause;

OR

 - B. Prevention of postmenopausal osteoporosis; **AND**
 - C. If individual is using solely for prevention of osteoporosis, individual has had a trial of and inadequate response or intolerance or has a contraindication to non-estrogen agents for osteoporosis.

Duavee (conjugated estrogens/bazedoxifene) may **not** be approved for the following:

- I. If individual had a hysterectomy; **OR**
- II. Individual has undiagnosed abnormal uterine bleeding; **OR**
- III. Individual has known, suspected, or past history of breast cancer; **OR**
- IV. Individual has known or suspected estrogen-dependent neoplasia; **OR**
- V. Individual has active or past history of venous thromboembolism; **OR**
- VI. Individual has active or past history of arterial thromboembolism; **OR**
- VII. Individual has known hepatic impairment or disease; **OR**
- VIII. Individual has known protein C, protein S, or antithrombin deficiency or other known thrombophilic disorders.

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

Note:

Duavee (conjugated estrogens/bazedoxifene) has black box warnings for endometrial cancer, cardiovascular disorders, and probable dementia. Women taking Duavee should not take additional estrogens. There is an increased risk of endometrial cancer in women with a uterus that use unopposed estrogens. Estrogen therapy should not be used for the prevention of cardiovascular disease or dementia. The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT) with daily conjugated estrogens therapy compared with placebo. The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older with daily conjugated estrogens therapy compared with placebo.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL:. 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.

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.