Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Danazol

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Danazol Oral Capsules

APPROVAL CRITERIA

Requests for danazol may be approved if the following criteria are met:

I. Individual has a diagnosis of endometriosis amenable to hormonal treatment; **AND**
II. Individual has had a trial of or contraindication to one of the following symptom management therapies (ACOG 2011):
    A. Oral contraceptives; **OR**
    B. Medroxyprogesterone; **OR**
    C. Norethindrone;

OR

III. Individual has a diagnosis of fibrocystic breast disease; **AND**
IV. Individual is using to decrease nodularity, pain, and tenderness; **AND**
V. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and insufficient response, intolerance or contraindication to one of the following symptom management therapies:
    A. Oral Contraceptives; **OR**
    B. Acetaminophen; **OR**
    C. Non-steroidal anti-inflammatory;

OR

VI. Individual has a diagnosis of hereditary angioedema; **AND**
VII. Individual is using to prevent cutaneous, abdominal, and/or laryngeal attacks;

OR

VIII. Individual has a diagnosis of myelofibrosis-associated anemia (NCCN 2A); **AND**
IX. One of the following:

Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

A. Serum erythropoietin (EPO) level of greater than or equal to 500 mU/mL; **OR**
B. Serum EPO level of less than 500 mU/mL and no response or loss of response to erythropoietic stimulating agents.

Danazol may not be approved for any of the following:

I. Individual has markedly impaired hepatic, renal, or cardiac function; **OR**
II. Individual has a diagnosis of porphyria; **OR**
III. Individual has an androgen-dependent tumor; **OR**
IV. Individual has a history of or an active thrombosis or thromboembolic disease.

Note: Danazol has black box warnings for use in pregnancy, thrombus formation, long-term therapy, and risk of pseudotumor cerebri. Use of danazol in pregnancy is contraindicated. A sensitive test capable of determining early pregnancy is recommended immediately prior to start of therapy. A non-hormonal method of contraception should be used during therapy. Androgenic effects on the female fetus exposed in utero have been reported. Thromboembolism, thrombotic and thrombophlebitic events have been reported. Experience with long-term therapy is limited. Physicians should be alert to the possibility of potentially silent peliosis hepatitis and benign hepatic adenoma with long-term use. Determine the lowest dose that will provide adequate protection. Attempt to decrease or withdraw therapy if initiated during exacerbation of hereditary angioneurotic edema due to trauma, stress, or other cause. Several cases of benign intracranial hypertension have been reported. Screen for papilledema and advise to discontinue immediately if symptoms are present.

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

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed January 30, 2017.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.