Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

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 (medication samples/coupons/discount cards are excluded from consideration as 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 for prophylaxis to prevent cutaneous, abdominal, and/or laryngeal attacks;

OR

VIII. Individual has a diagnosis of myelofibrosis-associated anemia (NCCN 2A); **AND**

Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

IX. One of the following:
   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.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. 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: June 30, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 30, 2020.
    a. Myeloproliferative Neoplasms. V1.2020. Revised May 21, 2020.

Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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.