Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Danazol***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***September 2013 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Danazol.

Danazol is indicated for the treatment of endometriosis amenable to hormonal management, the treatment of fibrocystic breast disease, and the prevention of attacks of hereditary angioedema of all types (cutaneous, abdominal, laryngeal) in males and females.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002

Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Danazol, is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. **For all diagnoses:**
   - Must not have abnormal genital bleeding, impaired hepatic, renal, or cardiac function, or porphyria
   - Must have a confirmed negative pregnancy test prior to starting therapy and must not be breastfeeding OR must be post-menopausal

2. **Endometriosis amenable to hormonal management:**
   - Must be prescribed by or in consultation with a gynecologist
   - Must have a diagnosis of endometriosis confirmed by laparoscopy
     - If the diagnosis is not confirmed by surgery, then chart documentation of an adequate work-up and the clinical rationale for the diagnosis must be provided.
   - Must have had an adequate trial of oral contraceptives and/or progestins with an inadequate response or significant side effects or must have a contraindication to these therapies

3. **Fibrocystic breast disease:**
   - Must be prescribed by or in consultation with a gynecologist
   - Must have a diagnosis of fibrocystic breast disease
   - Must have symptomatic disease (such as pain, tenderness, discomfort)
   - Must have had an adequate trial of at least one non-pharmacologic therapy (such as padded brassieres) with inadequate response AND at least one analgesic therapy with an inadequate response or significant side effects /toxicity or must have a contraindication to all analgesic therapies.

4. **Hereditary angioedema:**
   - Must be prescribed by or in consultation with an allergist/immunologist
   - Must be used as prophylactic therapy for the prevention of hereditary angioedema attacks

Reauthorization Criteria:

All prior authorization renewals are reviewed on a 6-month or annual basis, depending on diagnosis, to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 6-month or 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Endometriosis: up to 6 months • Fibrocystic breast disease: up to 1 year • Hereditary angioedema: up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Danocrine [prescribing information]. New York, NY: Sanofi, Inc. February 2003.
2. Lapp T. Practice Guidelines: ACOG Issues Recommendations for the Management of Endometriosis. Am Fam Physician. 2000 Sep;62(6):1431.
3. Craig T, Aygören-Pürsün E, Bork K, et al. WAO Guideline for the Management of Hereditary Angioedema. *World Allergy Organ J*. 2012 Dec;5(12):182-199.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*