

Drug Policy

Policy:	Androgen – Anabolic Steroid and Danazol <ul style="list-style-type: none"> • Danazol 	Annual Review Date: 10/19/2023 Last Revised Date: 10/19/2023
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OVERVIEW

Anabolic steroids have high abuse potential and safety concerns. However, appropriate clinical indications do exist. The word “anabolic” refers to muscle building. Anabolic are used to treat muscle loss, anemia, and hormone related conditions. Anabolics also have androgenic properties which can lead to increased male sex characteristics. Danazol suppresses the pituitary-ovarian axis and has weak androgenic activity. For the treatment of hereditary angioedema, danazol corrects primary biochemical abnormalities of HAE by increasing levels of C1 esterase inhibitor and thus increase C4 serum levels.

POLICY STATEMENT

This policy involves the use of Anabolic steroids and danazol. Prior authorization is recommended for pharmacy benefit coverage of Anabolic steroids and danazol. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Prior approval is recommended for the specified medication to evaluate for cosmetic/athletic enhancement or excluded uses. For testosterone products, please refer to MMO Testosterone Injection, Oral, Topical and Pellet Prior Criteria.

1. Hereditary Angioedema

Criteria. *Approve for duration noted below*

2. Endometriosis

Criteria. *Approve for duration noted below*

3. Fibrocystic Breast Disease

Criteria. *Approve for duration noted below*

4. Adjunctive therapy for weight gain after surgery, chronic infection, severe trauma or pathophysiologic reason

Criteria. *Approve for duration noted below*

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5. Anemia/Stimulation of erythropoiesis

Criteria. *Patient must have tried and failed, or is intolerant to erythropoiesis stimulating agents*

Initial Approval/ Extended Approval.

A) *Initial Approval:* 365 days (1 year)

B) *Extended Approval:* 365 days (1 year)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Anabolic steroids and danazol has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Performance enhancement.** Testosterone products are not recommended for approval because this indication is excluded from coverage in a typical pharmacy benefit.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

- Danazol [package insert]. Lannett Company, Inc. Philadelphia, PA. April 20, 2020 .
- Oxandrolone [package insert]. Par Pharmaceutical Inc. Woodcliff Lake, NJ. August 22, 2018.
- Nandrolone decanoate injection [package insert]. Watson Laboratories, Inc. Gurnee, IL. February 8, 2007.
- Androl- 50 [package inert]. Alaven Pharmaceutuical. Marietta, GA. October 2, 2012.
- DrugFacts: Anabolic Steroids. National Institute on Drug Abuse. Updated March 2016. Available at: <https://www.drugabuse.gov/publications/drugfacts/anabolic-steroids>.