Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

Clascoterone 1% cream (Winlevi)

Notes:

- Quantity Limits: Yes
- Adequate trial is defined as 3 months treatment duration
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- ** If benzoyl peroxide and topical retinoid products were ineffective as part of combination therapy, patient meets criteria for use of benzoyl peroxide and topical retinoid products

Initiation (new start) criteria, criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously, and criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary clascoterone 1% cream (Winlevi) will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber is a dermatologist
- Patient has a diagnosis of acne
- Patient is 12 years of age or older
- Patient has failed an adequate trial[^] or patient has an allergy, intolerance^{*}, or contraindication to the following medications:
 - Benzoyl peroxide**
 - At least one topical retinoid (adapalene or tretinoin)**
 - At least 1 combination therapy. Examples:
 - Benzoyl peroxide + topical antibiotic
 - Benzoyl peroxide + topical retinoid
 - Benzoyl peroxide + topical retinoid + topical antibiotic
 - Oral antibiotic + benzoyl peroxide + topical retinoid + topical antibiotic
 - Oral antibiotic + benzoyl peroxide + topical antibiotic
 - Oral antibiotic + benzoyl peroxide + topical retinoid
 - Spironolactone (if patient is female)
 - At least one combined oral contraceptive (if patient is female)
 - E.g. norgestimate/ethinyl estradiol, norethindrone/ethinyl estradiol, desogestrel/ethinyl estradiol, or drospirenone/ethinyl estradiol

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