Clinical Policy: Clascoterone (Winlevi)

Reference Number: ERX.NPA.152
Effective Date: 03.01.21
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Clascoterone (Winlevi®) is an androgen receptor inhibitor.

FDA Approved Indication(s)
Winlevi is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Winlevi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acne Vulgaris (must meet all)**:**

1. Diagnosis of acne vulgaris;
2. Age ≥ 12 years;
3. Failure of ≥ 2 of the following topical preparations, each from different medication classes, each used for ≥ 2 months, unless clinically significant adverse effects are experienced or all are contraindicated:
   a. Topical antibiotics: clindamycin, erythromycin;
   b. Topical anti-infectives: benzoyl peroxide;
   c. Topical retinoids: tretinoin, tazarotene;
4. Dose does not exceed 60 grams (1 tube) per month.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Acne Vulgaris (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 60 grams (1 tube) per month.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
clindamycin (Cleocin T®)	Apply a thin film BID	BID
erythromycin (Erygel®, Ery®)	Apply a thin film BID	BID
benzoyl peroxide (Benzac®, BPO®, Brevoxyl®, PanOxyl®)	Apply or wash QD or BID	BID
tretinoin (Retin-A®)	Apply QD	QD
tazarotene (Tazorac®)	Apply QD	QD

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Acne vulgaris	Apply approximately 1 gram topically to the affected area twice daily	2 gm/day

VI. Product Availability

Cream: 1% (60 g tube)

VII. References

1. Winlevi Prescribing Information. San Diego, CA: Cassiopea Inc.; August 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213433s000lbl.pdf. Accessed October 1, 2021.
2. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol 2016;74:945-73.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.22.20	02.21
1Q 2022 annual review: no significant changes; added generic tazarotene as an option; references reviewed and updated.	10.01.21	02.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of

medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.