Winlevi (clascoterone) Prior Authorization Program Summary

This program applies to FlexRx Closed, FlexRx Open, GenRx Closed, GenRx Open, and Health Insurance Marketplace formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
04-01-2024	07-01-2021

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Winlevi® (clascoterone) Cream	Topical treatment of acne vulgaris in patients 12 years of age and older		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Acne Vulgaris	The American Academy of Dermatology suggests several options for treatment of acne vulgaris in adolescents and young adults. Recommendations for topical acne therapies include benzoyl peroxide or combination with topical antibiotics (e.g., erythromycin or clindamycin) as monotherapy for mild acne, or in conjunction with topical retinoid, or systemic antibiotic therapy for moderate to severe acne. Clindamycin 1% solution or gel is currently the preferred topical antibiotic for acne therapy. Erythromycin 2% available in multiple formulations but has reduced efficacy compared to clindamycin due to resistance of cutaneous Staphylococci and P acnes.(2) Topical adapalene, tretinoin, and benzoyl peroxide can be safely used in the management of preadolescent acne in children. Azelaic acid is useful as an adjunctive acne treatment and is recommended in the treatment of post-inflammatory dyspigmentation. Topical dapsone 5% gel is recommended for inflammatory acne, particularly in adult females with acne. There is limited data to support sulfur, nicotinamide, resorcinol, sodium sulfacetamide, aluminum chloride, and zinc in the treatment of acne.(2) If topical antibiotic treatment is to be prolonged for more than a few weeks, topical benzoyl peroxide should be added, or used in combination products.(3) Topical androgen receptor inhibitors, such as Winlevi, are not addressed in guidelines at this time and do not have a place in therapy.
Safety (1)	Winlevi has no FDA labeled contraindications for use.

REFERENCES

Number	Reference
1	Winlevi prescribing information. Sun Pharmaceutical Industries, Inc. July 2022.
2	Zaenglein, Andrew L. MD, et al. American Academy of Dermatology. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2016;74:945-73.

Number	Reference
3	Eichenfield L, Krakowski A, Piggott C, et al. Evidence-based recommendations for the diagnosis and treatment of pediatric acne. *Pediatrics*. 2013;131;S163-S186.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Winlevi	clascoterone cream	1 %	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Winlevi	clascoterone cream	1 %	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Winlevi (clascoterone) will be approved when BOTH of the following are met:

1. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

      1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
      2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

   B. The patient has a diagnosis of acne vulgaris AND ONE of the following:
      1. The patient's medication history includes use of at least ONE generic topical antibiotic agent OR at least ONE generic topical retinoid agent as indicated by:
         A. Evidence of a paid claim(s) **OR**
         B. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) AND the required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR**
      2. The patient has an intolerance or hypersensitivity to generic topical antibiotic OR generic topical retinoid therapy **OR**
      3. The patient has an FDA labeled contraindication to ALL generic topical antibiotic AND generic topical retinoid agents **OR**
      4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
         A. A statement by the prescriber that the patient is currently taking the requested agent **AND**

Module	Clinical Criteria for Approval
	B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL generic topical antibiotic AND generic topical retinoid agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age **Length of Approval:** 12 months

