



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CLASCOTERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CLASCOTERONE	WINLEVI	46803		GPI-10 (9005001100)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acne vulgaris and meet **ALL** of the following criteria?
 - The patient is 12 years of age or older
 - Therapy is prescribed by or given in consultation with a dermatologist
 - The patient had a trial of or contraindication to **BOTH** of the following:
 - ONE oral acne agent (e.g. oral antibiotics or oral isotretinoin)
 - TWO topical acne agents (e.g. topical retinoids, topical antibiotics, benzoyl peroxide)

If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #60 grams (1 tube) per 30 days.**

APPROVAL TEXT: Renewal requires the patient had improvement of acne lesions.

If no, do not approve.

INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **CLASCOTERONE (Winlevi)** requires the following rule(s) be met for approval:

- A. You have acne vulgaris (skin condition in which hair follicles become plugged with oil and dead skin cells)
- B. You are 12 years of age or older
- C. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
- D. You have previously tried BOTH of the following unless there is a medical reason why you cannot (contraindication):
 1. ONE oral acne agent (such as oral antibiotics or oral isotretinoin)
 2. TWO topical acne agents (such as topical retinoids, topical antibiotics, benzoyl peroxide)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CLASCOTERONE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

- Does the patient have a diagnosis of acne vulgaris **AND** meet the following criterion?
 - The patient had improvement of acne lesions

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #60 grams (1 tube) per 30 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CLASCOTERONE (Winlevi)** requires the following rule(s) be met for approval:

- You have acne vulgaris (skin condition in which hair follicles become plugged with oil and dead skin cells)
- You had improvement of acne lesions

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Winlevi.

REFERENCES

- Winlevi [Prescribing Information]. Milan, Italy: Cosmo S.p.A.; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

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