



Authorization & Appeals Kit

Supporting Patient Access to WINLEVI® (clascoterone) cream, 1%

Sun Pharmaceuticals cannot guarantee insurance coverage or reimbursement. Coverage or reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to ensure the accuracy of all statements made in seeking coverage and reimbursement for an individual patient.

INDICATION

WINLEVI (clascoterone) cream 1% is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

Local Irritation: Pruritus, burning, skin redness or peeling may be experienced with WINLEVI cream. If these effects occur, discontinue or reduce the frequency of application of WINLEVI cream.

Hypothalamic-pituitary-adrenal (HPA) axis suppression may occur during or after treatment with WINLEVI. In the PK trial, HPA axis suppression was observed in 5% of adult subjects and 9% of adolescent subjects at Day 14. All subjects returned to normal HPA axis function at follow-up 4 weeks after stopping treatment. Conditions which augment systemic absorption include use over large surface areas, prolonged use, and the use of occlusive dressings. Attempt to withdraw use if HPA axis suppression develops.

Pediatric patients may be more susceptible to systemic toxicity.

Hyperkalemia: Elevated potassium levels were observed in some subjects during the clinical trials. Shifts from normal to elevated potassium levels were observed in 5% of WINLEVI-treated subjects and 4% of vehicle-treated subjects.

Please see Important Safety Information for WINLEVI throughout and on page 14, as well as the full Prescribing Information [here](#).

Resource Overview

This kit has been created to provide information and sample letters that can be used to help you communicate with health plans about prior authorization (PA) or appeal issues related to WINLEVI.

This kit includes:



Checklists to help ensure you have provided all needed information



Sample letters with information that will usually be required

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Clinical Considerations for WINLEVI and Diagnosis Code

The First and Only Topical Androgen Receptor Inhibitor Indicated for the Treatment of Acne Vulgaris, Addressing a Long-Standing Gap in Acne Treatment^{1,2}

Clinical Efficacy of WINLEVI in Patients With Acne Vulgaris at Week 12²

		Trial 1		Trial 2	
		WINLEVI (n=342)	VEHICLE (n=350)	WINLEVI (n=367)	VEHICLE (n=362)
IGA Success*		18.8%	8.7%	20.9%	6.6%
<i>Difference From Vehicle (95% CI)</i>		10.1% (4.1%, 16.0%)		14.3% (8.9%, 19.7%)	
Noninflammatory Lesions	Mean Absolute Reduction	20.4	13.0	19.5	10.8
	<i>Difference From Vehicle (95% CI)</i>	7.3 (3.5, 11.1)		8.7 (4.5, 12.4)	
	Mean Percent Reduction	32.6%	21.8%	29.6%	15.7%
	<i>Difference From Vehicle (95% CI)</i>	10.8% (3.9%, 17.6%)		13.8% (7.5%, 20.1%)	
Inflammatory Lesions	Mean Absolute Reduction	19.3	15.4	20.1	12.6
	<i>Difference From Vehicle (95% CI)</i>	3.9 (1.3, 6.5)		7.5 (5.2, 9.9)	
	Mean Percent Reduction	44.6%	36.3%	47.1%	29.7%
	<i>Difference From Vehicle (95% CI)</i>	8.3% (2.2%, 14.4%)		17.5% (11.8%, 23.1%)	

Study Design: The safety and efficacy of WINLEVI applied twice daily for 12 weeks for the treatment of acne vulgaris were assessed in two identically designed, multicenter, randomized, double-blind, vehicle-controlled clinical trials. A total of 1421 patients 12 years and older with facial acne vulgaris were enrolled. At baseline, patients had a mean inflammatory lesion count of 42.4 and a mean noninflammatory lesion count of 61.4. Additionally, approximately 83% of patients has an IGA score of 3 (moderate).² WINLEVI was statistically superior over vehicle for all 3 coprimary endpoints, including IGA success* and absolute change from baseline in inflammatory and noninflammatory lesion counts. Mean percent change from baseline in total, inflammatory, and noninflammatory lesion counts, and absolute change from baseline in total lesion counts were secondary endpoints.¹

*IGA success was defined as at least a 2-point reduction in IGA compared to baseline and an IGA score of 0 (clear) or 1 (almost clear).²

Incidence of New or Worsening Local Skin Reactions Reported by ≥5% of Subjects Treated With WINLEVI After Day 1 in 12-Week Controlled Clinical Trials²

	WINLEVI (n=674 [†])	VEHICLE (n=656 [†])
Erythema/redness	82 (12.2%)	101 (15.4%)
Pruritus	52 (7.7%)	54 (8.2%)
Scaling/dryness	71 (10.5%)	68 (10.4%)

ICD-10 Diagnosis Code³: L70.0: Acne vulgaris

[†]The denominators for calculating the percentages were the 674 of 709 subjects treated with WINLEVI and 656 of 712 subjects treated with vehicle in these trials who had local skin reaction results reported after Day 1.²

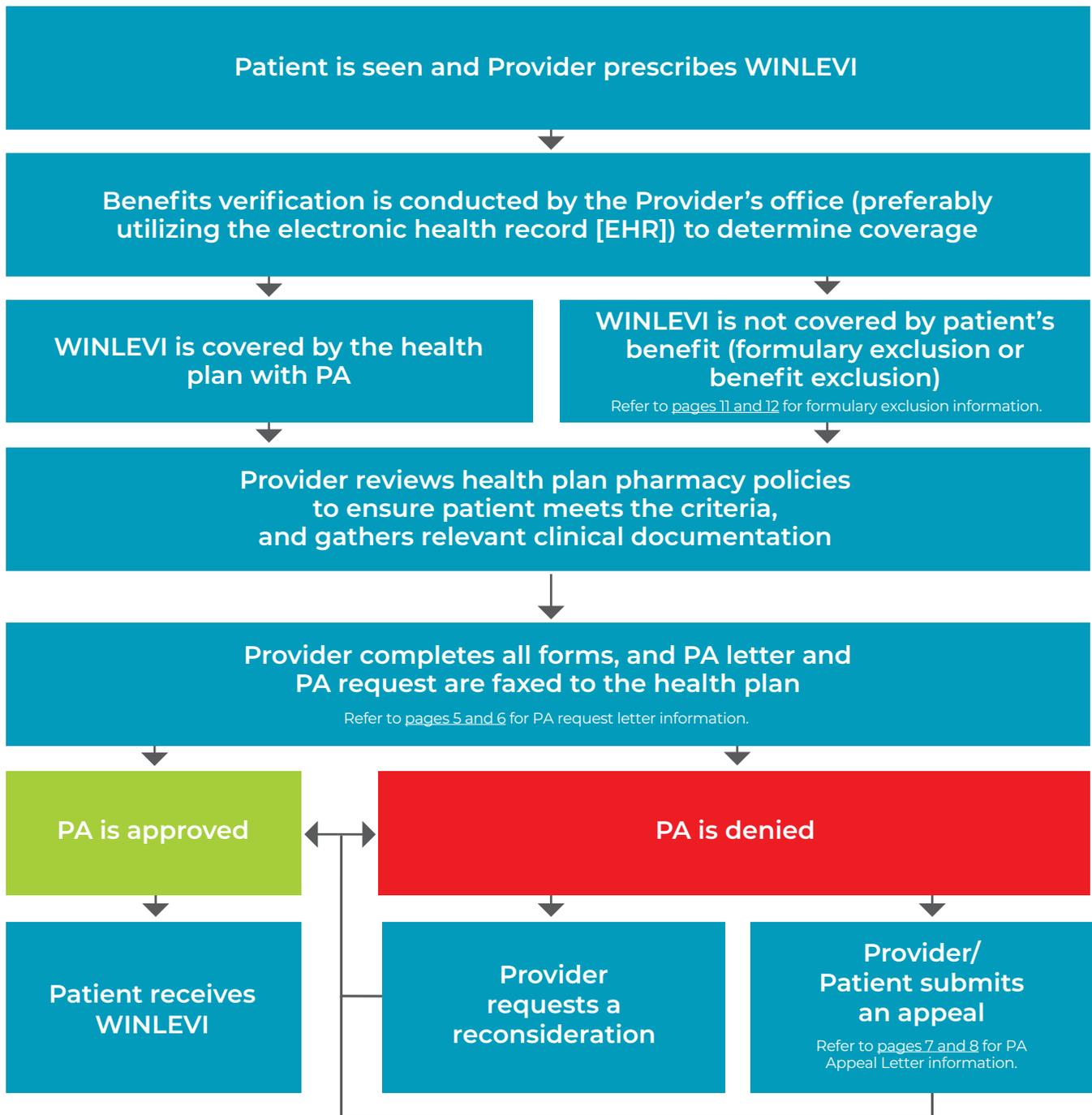
SELECT IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

Most common adverse reactions occurring in 7% to 12% of patients are erythema/reddening, pruritus and scaling/dryness. Additionally, edema, stinging, and burning occurred in >3% of patients and were reported in a similar percentage of subjects treated with vehicle.

Please see Important Safety Information for WINLEVI throughout and on page 14, as well as the full Prescribing Information [here](#).

Prior Authorization Process Overview



- Claims may reject for PA, step therapy, or non-formulary reasons. Some plans may exclude coverage for acne treatments for patients over a certain age (eg, 25)
- Many payers will allow up to 3 levels of appeals for PA denials. A third level of appeal may include an external review*
- Formulary exclusions may be appealed while appeals for benefit exclusions are generally not available

*An external review can also be requested at any point when there are extenuating circumstances.

Please see Important Safety Information for WINLEVI throughout and on page 14, as well as the full Prescribing Information [here](#).

Suggestions for a PA Request Letter

All PA forms should be completed and submitted to the plan by your office. Benefits verifications performed by the customer service center of the patient's plan can identify PA requirements, step therapies, and form requirements.

A PA letter comes from the patient and/or the physician. Fax the PA request to the health plan. Many payers will allow up to 3 levels of appeals for PA denials. Refer to pages 7 and 8 for PA Appeal Letter information.

Checklist

- **Use the health plan's website to locate their PA form**
- **Include the patient's information: name, DOB, sex, policy information**
- **List previous therapies, if applicable**
Explain why each therapy was discontinued and give the duration of therapy for each agent
- **Document that all PA requirements of the plan have been met, if applicable**
Provide evidence that the patient is an appropriate candidate for WINLEVI, including, but not limited to:
 - Diagnosis of acne vulgaris
 - Patient is 12 years of age or older
- **Provide rationale and clinical support for your recommendation.**
Information can include:
 - Efficacy and safety data for WINLEVI
 - Adverse events/contraindications with other treatment options
 - Applicable treatment guidelines (American Academy of Dermatology)
- **Review sample letter format on the next page for additional information**

◀ PA Process Overview

Please see Important Safety Information for WINLEVI throughout and on page 14, as well as the full Prescribing Information [here](#).


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Sample PA Request Letter for WINLEVI

[INSERT ON PROVIDER LETTERHEAD]

[Date]
[Claims department]
[Name of health plan]
[Mailing address]

RE: [Patient name]
Policy number: [Policy number]
Claim number: [Claim number]

Dear [Medical director],

This letter is sent on behalf of [patient's name] to request coverage for WINLEVI for the treatment of acne vulgaris (diagnosis code, L70.0).

[Patient's name] is [a/an] [age]-year-old [male/female] who was diagnosed with acne vulgaris on [date]. [Patient's name] has been in my care since [date] and has previously tried and failed on multiple other treatments including [list any previous treatments].

[Patient's name] meets your prior authorization criteria of:

- Diagnosis of acne vulgaris
- Patient is 12 years of age or older
- [other applicable authorization criteria, including trial and failure of previous therapies and/or other contraindicated therapies]

[Provide a summary of the patient's medical history and current condition, and what factors led you to recommend the use of WINLEVI.] Enclosed you will find other relevant supporting documentation.

Please contact my office by calling [phone number] for any additional information you may require. I look forward to your timely approval.

Enclosures: [WINLEVI Prescribing Information, clinical notes/medical records, American Academy of Dermatology clinical practice guidelines, other supporting documentation]

Sincerely,

[Physician signature]
[Insert name]

◀ PA Process Overview

Please see Important Safety Information for WINLEVI throughout and on page 14, as well as the full Prescribing Information [here](#).


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Suggestions for a PA Appeal Letter

This type of letter can be used when a PA request for WINLEVI has been denied. There can be multiple levels of appeals. Please refer to the plan's specific appeal guidelines.

This letter comes from the patient and the physician. It should be submitted along with a copy of the patient's relevant medical records and a Letter of Medical Necessity (see pages 9 and 10). Many payers will allow up to 3 levels of appeals for PA denials.

Checklist

- ❑ **Include the patient's information: name, DOB, sex, policy information**
- ❑ **Acknowledge that you are familiar with the company's policy and state the reason for the denial**
- ❑ **Document that all PA requirements of the plan have been met, if applicable**
 - Diagnosis of acne vulgaris
 - Patient is 12 years of age or older
- ❑ **List previous therapies, if applicable**

Explain why each therapy was discontinued and give the duration of therapy for each agent
- ❑ **If other agents/treatments are not appropriate for this patient, explain why not (if they have not already been listed as previous therapies)**
- ❑ **Provide rationale and clinical support for your recommendation. Information can include:**
 - Efficacy and safety data for WINLEVI
 - Adverse events or contraindications with other treatment options
 - Applicable treatment guidelines (American Academy of Dermatology)
- ❑ **Attach a Letter of Medical Necessity (see pages 9 and 10)**

For second- and third-level appeals, it may be helpful to include:

- ❑ **The original letter of denial**
- ❑ **Specific medical notes in response to the denial**

A third level of appeal may include review by an independent noninsurance-affiliated external review board or hearing

◀ PA Process Overview

Sample Letter of Appeal for WINLEVI

[INSERT ON PROVIDER LETTERHEAD]

[Date]
[Claims department]
[Name of health plan]
[Mailing address]

RE: [Patient name]
Policy number: [Policy number]
Claim number: [Claim number]

Dear [Medical director],

This letter is sent on behalf of [patient's name] to request an appeal of a denied prior authorization for WINLEVI. According to the denial letter, [name of health plan] denied this prior authorization because [reason from denial letter]. I am asking that you reconsider your denial of coverage for WINLEVI for the treatment of acne vulgaris for [patient's name].

[Patient's name] meets your prior authorization criteria of:

- Diagnosis of acne vulgaris
- Patient is 12 years of age or older
- [other applicable authorization criteria, including trial and failure of previous therapies and/or other contraindicated therapies]

[Provide a summary of the patient's medical history and current condition, and what factors led you to recommend the use of WINLEVI.] Enclosed you will find other relevant supporting documentation.

Please contact my office by calling [phone number] for any additional information you may require in support of this appeal. I look forward to your timely approval.

Enclosures: [WINLEVI Prescribing Information, clinical notes/medical records, American Academy of Dermatology clinical practice guidelines, other supporting documentation]

Sincerely,

[Physician signature]
[Insert name]

◀ PA Process Overview

Suggestions for a Letter of Medical Necessity

Some plans require that a Letter of Medical Necessity be submitted along with a PA Appeal Letter (see pages 7 and 8) to support the choice of WINLEVI over agents that are on formulary.

The information provided below and the sample letter on the next page may be helpful to consider as you prepare the letter.

A Letter of Medical Necessity should also accompany a Formulary Exception Request Letter (see pages 11 and 12).

Checklist

- ❑ **Include the patient's information: name, DOB, sex, policy information**
- ❑ **Include specific diagnosis code for acne vulgaris (L70.0) where appropriate**
- ❑ **Clearly state the rationale for treatment with WINLEVI and why it is appropriate for your patient**
- ❑ **Be sure to include all the listed documents with the letter when you send it to your patient's insurance provider**
- ❑ **List previous therapies, if applicable**
Explain why each therapy was discontinued and give the duration of therapy for each agent
- ❑ **Explain why formulary-preferred agents are not appropriate if they have not already been listed as previous therapy**
- ❑ **Provide rationale and clinical support for your recommendation. Information can include:**
 - Efficacy and safety data for WINLEVI
 - Adverse events/contraindications with other treatment options
 - Applicable treatment guidelines (American Academy of Dermatology)
- ❑ **To close the letter, summarize your recommendation, and provide a phone number should any additional information be required**

◀ PA Process Overview

Please see Important Safety Information for WINLEVI throughout and on page 14, as well as the full Prescribing Information [here](#).


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Sample Letter of Medical Necessity for WINLEVI

[INSERT ON PROVIDER LETTERHEAD]

[Date]
[Claims department]
[Name of health plan]
[Mailing address]

RE: [Patient name]
Policy number: [Policy number]
Claim number: [Claim number]

Dear [Medical director],

This letter is sent on behalf of [patient's name] to document that [he/she] has been diagnosed with acne vulgaris (diagnosis code, L70.0) and requires topical treatment with WINLEVI. I am writing to document my patient's medical history and diagnosis and summarize my treatment rationale. Treatment with WINLEVI is medically appropriate and necessary for this patient.

[Patient's name] is [a/an] [age]-year-old [male/female] who was diagnosed with acne vulgaris on [date]. [Patient's name] has been in my care since [date] and has previously tried and failed on multiple other treatments including [list any previous treatments].

[Provide a summary of the patient's medical history and current condition, contraindications to other treatments, and what factors led you to recommend the use of WINLEVI.]

WINLEVI [was/will be] prescribed to [patient's name] for the treatment of acne vulgaris. Enclosed you will find other relevant supporting documentation.

Please contact my office by calling [phone number] for any additional information you may require. I look forward to your timely approval.

Enclosures: [WINLEVI Prescribing Information, clinical notes/medical records, American Academy of Dermatology clinical practice guidelines, other supporting documentation]

Sincerely,

[Physician signature]
[Insert name]

◀ PA Process Overview

Please see Important Safety Information for WINLEVI throughout and on page 14, as well as the full Prescribing Information [here](#).


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Suggestions for a Formulary Exception Request Letter

This type of letter can be used when WINLEVI is not listed on a formulary or if it has an NDC block. While the plan may provide a form on its website that can be used to apply for an exception, you can refer to the information in this kit to see what is typically required.

This letter is written and sent by the patient, with the help of their physician. The letter should also be signed by the physician. It should be submitted along with a copy of the patient's relevant medical records and a Letter of Medical Necessity (see pages 9 and 10).

The following is an example outline for information that should be included within the Formulary Exception Request Letter. If your patient is requesting an exception to the formulary to fill their prescription for WINLEVI, ensure they include the following information:

- Patient's name, DOB, sex, and policy information at the top of the letter
- The patient is requesting an exception to your formulary to fill [his/her] prescription for WINLEVI
- Patient has been diagnosed with acne vulgaris (diagnosis code, L70.0)
- Past treatments include [list previous treatments and drugs]. Enclosed are medical records and a Letter of Medical Necessity from [physician name] supporting the request for the formulary exception approval of WINLEVI

(Note: Medical records should include the records from the date WINLEVI was first prescribed to the patient)

- The main reasons for requesting this exception are [main medical necessity points]
- [Physician name] can be contacted at [phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of providing a formulary exception for the use of WINLEVI for this patient
- Include physician and patient signature at the bottom of the letter
- If this is a second- or third-level appeal for formulary exception, include level of appeal, letter of denial, and medical notes in response to denial

◀ PA Process Overview

NDC, National Drug Code.

Please see Important Safety Information for WINLEVI throughout and on page 14, as well as the full Prescribing Information [here](#).


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Sample Formulary Exception Request Letter for WINLEVI

[INSERT ON PROVIDER LETTERHEAD]

[Date]
[Claims department]
[Name of health plan]
[Mailing address]

RE: [Patient name]
Policy number: [Policy number]
Claim number: [Claim number]

Dear [Medical director],

This letter is sent on behalf of [patient's name] to request an exception to your formulary for WINLEVI. [Patient's name] is [a/an] [age]-year-old [male/female] who was diagnosed with acne vulgaris (diagnosis code, L70.0) on [date]. I am writing to document my patient's medical history and diagnosis and summarize my treatment rationale. Treatment with WINLEVI is medically appropriate and necessary for this patient.

[Provide a summary of the patient's medical history and current condition, tried and failed treatments, contraindications to other treatments, what factors led you to recommend the use of WINLEVI, and reasons for requesting this exception.]

I hope you will agree WINLEVI is appropriate and medically necessary to treat [patient's name] and will support this request for a formulary exception. Enclosed you will find other relevant documentation that supports this request.

Please contact my office by calling [phone number] for any additional information you may require or to participate in a peer-to-peer review discussing the necessity of providing a formulary exception for the use of WINLEVI for this patient. I look forward to your timely approval of this formulary exception request.

Enclosures: [WINLEVI Prescribing Information, clinical notes/medical records, American Academy of Dermatology clinical practice guidelines, other supporting documentation]

Sincerely,

[Physician signature]
[Insert name]

[Patient signature]
[Insert name]

◀ PA Process Overview

Please see Important Safety Information for WINLEVI throughout and on page 14, as well as the full Prescribing Information [here](#).


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PA Determinations, Faster.

PA SUPPORT IS AVAILABLE FOR WINLEVI THROUGH COVERMYMEDS.

Through an online platform and integrations with 75% of EHRs, more than 750,000 providers use CoverMyMeds to electronically submit PA requests to every health plan.

Submit requests for any medication and all plans

Receive faster PA determinations, often in real time

Automatically renew previously submitted PA requests

Use the solution at no cost

HOW TO INITIATE A PA REQUEST AT THE PROVIDER OFFICE:

- 01** Create an account with CoverMyMeds, or log into your existing account at covermymeds.com.
- 02** Shorten time to therapy by creating a PA request required for treatment.
- 03** Fill in medical details and then **click one button to electronically submit the request** to any plan for determination.

HOW TO COMPLETE A PHARMACY INITIATED REQUEST:

- 01** Create an account with CoverMyMeds, or log into your existing account at covermymeds.com.
- 02** On your CoverMyMeds dashboard, click **“Enter Key.”**
- 03** Enter the access key, as well as **your patient’s last name and DOB**, as indicated on the fax. You’ll see that most of the request is already completed.
- 04** Fill in any remaining fields and click **“Send to Plan.”**
- 05** **Mark determinations directly** in your CoverMyMeds account. Once it’s determined by the plan, the pharmacy will be notified of the outcome.

Questions? CoverMyMeds can help.

Live support: call 1-866-452-5017 or chat at covermymeds.com
FAQ and webinar registration: go.covermymeds.com/help

Please see Important Safety Information for WINLEVI throughout and on page 14, as well as the full Prescribing Information [here](#).



INDICATION and IMPORTANT SAFETY INFORMATION

INDICATION

WINLEVI (clascoterone) cream 1% is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Local Irritation: Pruritus, burning, skin redness or peeling may be experienced with WINLEVI cream. If these effects occur, discontinue or reduce the frequency of application of WINLEVI cream.

Hypothalamic-pituitary-adrenal (HPA) axis suppression may occur during or after treatment with WINLEVI. In the PK trial, HPA axis suppression was observed in 5% of adult subjects and 9% of adolescent subjects at Day 14. All subjects returned to normal HPA axis function at follow-up 4 weeks after stopping treatment. Conditions which augment systemic absorption include use over large surface areas, prolonged use, and the use of occlusive dressings. Attempt to withdraw use if HPA axis suppression develops.

Pediatric patients may be more susceptible to systemic toxicity.

Hyperkalemia: Elevated potassium levels were observed in some subjects during the clinical trials. Shifts from normal to elevated potassium levels were observed in 5% of WINLEVI-treated subjects and 4% of vehicle-treated subjects.

ADVERSE REACTIONS

Most common adverse reactions occurring in 7% to 12% of patients are erythema/reddening, pruritus and scaling/dryness. Additionally, edema, stinging, and burning occurred in >3% of patients and were reported in a similar percentage of subjects treated with vehicle.

To report SUSPECTED ADVERSE REACTIONS, contact Sun Pharmaceutical Industries, Inc. 1-800-818-4555 or FDA at 1-800-FDA-1088 or <http://www.fda.gov/medwatch>.

Please see [full Prescribing Information](#).

References: 1. Hebert A et al. *JAMA Dermatol.* 2020;156(6):621-630. doi:10.1001/jamadermatol.2020.0465 2. Winlevi® [Package Insert]. Cassiopea. 2021. 3. Centers for Medicare & Medicaid Services. 2022 ICD-10-CM. Accessed January 18, 2022. <https://www.cms.gov/medicare/icd-10/2022-icd-10-cm>