



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMIQUIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMIQUIMOD	ZYCLARA		28216 31436 32958	GPI-14 (90773040003715) (90773040003710)	

GUIDELINES FOR USE

- Does the patient have a diagnosis of actinic keratosis (AK) of the full face or balding scalp and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient is immunocompetent
 - The patient had a trial of **TWO** generic topical agents indicated for AK (e.g., fluorouracil, imiquimod, diclofenac 3%)

If yes, **approve the requested strength for 4 months by GPID or GPI-14 with the following quantity limits:**

- 3.75% packet: #28 packets per 28 days.**
- 2.5% or 3.75% pump: #7.5g per 28 days.**

If no, continue to #2.

- Does the patient have a diagnosis of external genital or perianal warts and meet **ALL** of the following criteria?
 - The patient is 12 years of age or older
 - The patient had a trial of or contraindication to generic imiquimod 5% topical cream

If yes, **approve the requested strength for 2 months by GPID or GPI-14 with the following quantity limits:**

- 3.75% packet: #28 packets per 28 days.**
- 2.5% or 3.75% pump: #7.5g per 28 days.**

If no, do not approve.

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 **IMIQUIMOD (Zyclara)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following diagnoses:

- Actinic keratosis (AK: rough, scaly patch on the skin caused by years of sun exposure) of the full face or balding scalp
- External genital or perianal (around the anus) warts

(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

B. If you have actinic keratosis of the full face or balding scalp, approval also requires:

1. You are 18 years of age or older
2. You are immunocompetent (healthy immune system)
3. You had a trial of TWO generic topical agents for AK (such as fluorouracil, imiquimod, diclofenac 3%)

C. If you have external genital or perianal warts, approval also requires:

1. You are 12 years of age or older
2. You have tried or have a contraindication (harmful for) to generic imiquimod 5% topical cream

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 Zyclara.

REFERENCES

- Zyclara [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

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