

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Zyclara (imiquimod)

Override(s)	Approval Duration
Prior Authorization – Age Quantity Limit	56 days of treatment per year

Medications	Quantity Limit
Zyclara 2.5% cream (pump)	1 pump bottle (28 actuations) per 28 days; 56 days of treatment per year
Zyclara 3.75% cream (packets)	14 packets per 28 days; 56 days of treatment per year
Zyclara 3.75% cream (pump) Imiquimod 3.75% cream (pump) – Single Source Brand	1 pump bottle (28 actuations) per 28 days; 56 days of treatment per year

APPROVAL CRITERIA

Requests for Zyclara (imiquimod) may be approved when the following criterion is met:

- I. Individual has had a trial of and inadequate response or intolerance to one preferred topical anogenital wart agent. Preferred agents are as follows: fluorouracil 5% cream, fluorouracil 2% topical solution, fluorouracil 5% topical solution, imiquimod 5% cream packets, podofilox solution.
- II. If Zyclara (imiquimod) packets are requested for individuals with actinic keratosis, 28 packets per 28 days may be approved, if two packets per day are needed to cover the treatment area.
- III. If Zyclara (imiquimod) 3.75% packets are requested for external genital warts, 28 packets per 28 days may be approved.
- IV. If Zyclara (imiquimod) is requested to treat additional actinic keratosis lesions or episodes of external genital warts, an additional course of treatment may be approved.

Requests for Zyclara (imiquimod) for individuals LESS than 12 years of age will be reviewed on a case-by-case basis.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Note: Zyclara (imiquimod) is NOT indicated for the treatment of common warts (verruca vulgaris).

Note: Preferred agents also cover diagnoses of external genital warts (imiquimod 5% cream) along with actinic keratosis (all listed preferred agents)

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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