Market Applicability					
Market	**GA**	**KY**	**MD**	**NJ**	**NY**
Applicable	X	X	X	X	X

Aldara (imiquimod)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	112 days of treatment per year (actinic keratosis and external genital warts) 42 days (superficial basal cell carcinoma) for criteria in quantity section below

Medications	Comments	Quantity Limit
imiquimod 5% cream (packets) – generic*	Preferred	12 packets per 28 days
podofilox 0.5% solution – generic	Preferred	N/A
Aldara 5% cream (packets) – brand*	Non-Preferred	12 packets per 28 days

* If Aldara (brand) or generic imiquimod is requested to treat additional actinic keratosis lesions or additional episodes of external genital warts, an additional course of treatment may be approved.

*If Aldara (brand) or generic imiquimod is requested for superficial basal cell carcinoma, 30 packets for 42 days of treatment may be approved.

APPROVAL CRITERIA

Requests for brand Aldara may be approved when the following criteria are met:

I. Documentation is provided that individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one preferred topical anogenital wart agent.

Preferred agents: generic imiquimod 5% cream packets, generic podofilox solution;

OR

II. Documentation is provided that individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial of and inadequate response or intolerance to one preferred topical actinic keratosis agent.

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.

Market Applicability					
Market	**GA**	**KY**	**MD**	**NJ**	**NY**
Applicable	X	X	X	X	X

Preferred agents: fluorouracil 5% cream, fluorouracil 2% topical solution, fluorouracil 5% topical solution, generic imiquimod 5% cream packets.

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

Requests for generic imiquimod may be approved when the following criteria are met:

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

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

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 9, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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