

**Imiquimod Agents:**  
**Imiquimod 3.75%, Zyclara 2.5% (imiquimod)**  
**Effective 07/01/2025**

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange		Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit			<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A			
Contact Information	Medical Benefit Pharmacy Benefit		Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A			

### Overview

Imiquimod 5% cream is indicated for the topical treatment of:

- Clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses (AK) on the face or scalp in immunocompetent adults
- External genital and perianal warts/condyloma accuminata in patients 12 years of age and older.
- Imiquimod 5% has not demonstrated efficacy for molluscum contagiosum in children 2 to 12 years of age.

Imiquimod 3.75% cream and pump are indicated for the topical treatment of:

- Clinically typical, visible or palpable actinic keratoses (AK) of the full face or balding scalp in immunocompetent adults
- External genital and perianal warts/condyloma accuminata in patients 12 years of age and older.
- Imiquimod 3.75% not demonstrated efficacy for molluscum contagiosum in children 2 to 12 years of age.

Imiquimod 5% cream is covered without prior authorization.

### Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

**OR**

Authorization may be granted when all of the following criteria are met:

1. Member has had an inadequate response or intolerance to imiquimod 5% cream or clinical rationale why imiquimod 5% cream is not appropriate for the member
2. **Zyclara 2.5% cream:** Member has had an inadequate response or intolerance to imiquimod 3.75% cream or clinical rationale why imiquimod 3.75% cream is not clinically appropriate for the member

### Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Member has had a positive response to therapy

**Limitations**

1. Initial and reauthorization approvals will be granted for 12 months.

**References**

1. Imiquimod 3.75% cream [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; September 2020.
2. Zyclara (imiquimod) cream [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; September 2024.

**Review History**

12/13/2023 - Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024

04/09/2024 – Reviewed and Updated at April P&T. Removed fluorouracil products from the policy due to product discontinuation or coverage updates. Updated policy to indicate the imiquimod 5% cream is covered without prior authorization. Criteria for 3.75% cream and 2.5% cream require trial and failure with 5% cream, and 2.75% cream requires trial and failure with 3.75% cream. Added reauthorization criteria to the policy. Effective 07/01/2025.

