Mass General Brigham
Health Plan

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

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | 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 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.