PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Bexarotene (Topical) Prior Authorization Policy
- Targretin® (bexarotene 1% gel – Bausch Health, generic)

REVIEW DATE: 12/11/2024

OVERVIEW
Bexarotene gel is indicated for the topical treatment of cutaneous lesions in patients with **cutaneous T-cell lymphoma** (Stage 1A and 1B) who have refractory or persistent disease after other therapies or who have not tolerated other therapies.[1]

Guidelines
National Comprehensive Cancer Network (NCCN) Primary Cutaneous Lymphomas guidelines (version 1.2025 – November 11, 2024) recommend topical bexarotene as an option for the treatment of cutaneous lymphomas (e.g., mycosis fungoides, Sézary syndrome, T-cell lymphoma), as initial therapy and for relapsed/refractory cases (category 2A). NCCN notes there are case reports demonstrating efficacy of topical bexarotene in treating primary cutaneous B-cell lymphomas in children (category 2A). The NCCN T-Cell Lymphomas guidelines (version 1.2025 – November 11, 2024) recommend skin-directed therapies (refers to bexarotene in primary cutaneous lymphomas guidelines) for first-line therapy (category 2A) of smoldering symptomatic adult T-cell leukemia/lymphoma subtype.[4]

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of bexarotene gel. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with bexarotene gel as well as the monitoring required for adverse events and long-term efficacy, approval requires bexarotene gel to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Bexarotene gel is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Cutaneous T-Cell Lymphoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient has cutaneous manifestations/lesions; AND
   - **B)** The medication is prescribed by or in consultation with an oncologist or a dermatologist.

Other Uses with Supportive Evidence

2. **Adult T-Cell Leukemia/Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient has smoldering symptomatic subtype; AND
   B) The medication is used as first-line therapy; AND
   C) The medication is prescribed by or in consultation with an oncologist or a dermatologist.

3. **Primary Cutaneous B-Cell Lymphoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Medication is used as skin-directed therapy for ONE of the following (i or ii):
      i. Primary cutaneous marginal zone lymphoma; OR
      ii. Follicle center lymphoma; AND
   B) The medication is prescribed by or in consultation with an oncologist or a dermatologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of bexarotene gel is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Targretin® gel [prescribing information]. Bridgewater, NJ: Bausch Health; February 2020.
2. The NCCN Primary Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (version 1.2025 – November 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 6, 2024.
3. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 5, 2024. Search terms: bexarotene gel.
4. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 1.2025 – November 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 6, 2024.