PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 11/22/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 1.2023 – January 5, 2023) 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. NCCN notes there are case reports demonstrating efficacy of topical bexarotene in treating primary cutaneous B-cell lymphomas in children. The NCCN T-Cell Lymphomas guidelines (version 1.2023 – January 5, 2023) recommend skin-directed therapies (refers to bexarotene in primary cutaneous lymphomas guidelines) for first-line therapy (category 2A) of chronic/smoldering 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.

- **Targretin® (bexarotene 1% gel – Bausch Health, generic) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

FDA-Approved Indication

1. **Cutaneous T-Cell Lymphoma.** Approve for 1 year if the patient meets 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 the following (A, B, and C):
   A) Patient has chronic/smoldering 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.

CONDITIONS NOT COVERED

- **Targretin® (bexarotene 1% gel – Bausch Health, generic) is(are) considered experimental, investigational or unproven for ANY other use(s)**

REFERENCES

1. Targretin® gel [prescribing information]. Bridgewater, NJ: Bausch Health; February 2020.
2. The NCCN Primary Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (version 1.2023 – January 5, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 20, 2023.
3. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 20, 2023. Search terms: bexarotene gel.
4. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 1.2023 – January 5, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 20, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Cutaneous T-Cell Lymphoma.** Generic bexarotene gel is now available. Added requirement that generic bexarotene gel is requested or patient had previously tried the generic product. For patients who had previously tried the generic, added requirement that the patient is unable to use to the generic product due to a formulation difference in inactive ingredient(s) [e.g., difference in buffers, emollients, emulsifiers, preservatives, surfactants] between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or a serious adverse reaction [documentation required]. **Policy name change**: Policy name was changed from Oncology – Targretin (Topical) PA to Oncology – Bexarotene (Topical) PA with Step Therapy.	11/02/2022
Selected Revision	**Cutaneous T-Cell Lymphoma.** Criterion "Patient has cutaneous lesions" was revised to "Patient has cutaneous manifestations/lesions". The requirements for use of generic bexarotene gel before brand Targretin was removed. Policy name is changed to remove "with Step Therapy" from the title.	01/25/2023 Effective date – to be determined
Annual Revision	**Adult T-Cell Leukemia/Lymphoma.** Added new indication and approval criteria under "Other Uses with Supportive Evidence".	11/22/2023