

Drug Policy

Policy:	Targretin (bexarotene) and bexarotene capsules	Annual Review Date: 02/18/2021 Last Revised Date: 02/18/2021
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OVERVIEW

Bexarotene capsule is indicated for the treatment of cutaneous manifestations of cutaneous T-cell lymphoma (CTCL) in patients who are refractory to at least one prior systemic therapy. Bexarotene capsule has a Boxed Warning about birth defects and bexarotene must not be administered to a pregnant patient.

POLICY STATEMENT

This policy involves the use of bexarotene capsules. Requests for bexarotene topical gel are covered under the *Targretin (bexarotene) Gel Prior Approval Policy*. Prior authorization is recommended for pharmacy benefit coverage of bexarotene. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with bexarotene capsules as well as the monitoring required for adverse events and long-term efficacy, initial approval requires bexarotene capsules be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist, dermatologist, or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Targretin (bexarotene) capsules is recommended in those who meet the following criteria:

For all indications: if the request is for brand name Targretin capsules, the patient has tried generic bexarotene capsules per the prescribing physician OR bexarotene capsules are contraindicated or were not tolerated per the prescribing physician **[documentation required]**

1. **Cutaneous T-Cell Lymphomas (Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders or Mycosis Fungoides/Sezary Syndrome)**
Criteria. Approve if the patient is 18 years of age or older.
2. **Another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**

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Criteria. *Prescriber will provide specific diagnosis for documentation. Approve*

3. Patient has been started on Targretin (bexarotene) capsules (continuation of therapy)

Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.

A) Initial Approval: 1 year

B) Extended Approval: 1 year

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Targretin™ capsules (bexarotene) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; July 2015. Bexarotene capsules.
2. The NCCN Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on February 11, 2021.
3. The NCCN Primary Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (Version 2.2019) © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on February 13, 2019.
4. Bexarotene. In: DRUGDEX {online database}. Truven Health Analytics; Greenwood Village, CO. Last updated 4 December 2020. Accessed on 11 February 2021.