

Clinical Policy: Bexarotene (Targretin) Capsules

Reference Number: PA.CP.PHAR.75

Effective Date: 09/11

Last Review Date: 04/18

[Revision Log](#)

Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness[®] clinical policy for bexarotene (Targretin[®]) capsules

FDA Approved Indication(s)

Targretin 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.

Policy/Criteria

It is the policy of Pennsylvania Health and Wellness that Targretin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cutaneous T-Cell Lymphoma (must meet all):

1. Diagnosis of cutaneous T-cell lymphoma (CTCL) (see Appendix B for CTCL subtypes);
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Dose does not exceed 400mg/m² daily;

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. Cutaneous T-Cell Lymphoma (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Dose does not exceed 400mg/m² daily;

Approval duration: 6months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Targretin (bexarotene) is a member of a subclass of retinoids that selectively activate retinoid X receptors (RXRs). These retinoid receptors have biologic activity distinct from that of retinoic acid receptors (RARs). RXRs can form heterodimers with various receptor partners such as retinoic acid receptors (RARs), vitamin D receptor, thyroid receptor, and peroxisome proliferator activator receptors (PPARs). Once activated, these receptors function as transcription factors that regulate the expression of genes that control cellular differentiation and proliferation. Bexarotene inhibits the growth *in vitro* of some tumor cell lines of hematopoietic and squamous cell origin. It also induces tumor regression *in vivo* in some animal models. The exact mechanism of action of bexarotene in the treatment of CTCL is unknown.

Formulations:

Capsule, oral administration

Targretin: 75 mg

Generic: 75 mg

Appendices

Appendix A: Abbreviation Key

ALCL: anaplastic large cell lymphoma

ATLL: adult T-cell leukemia/lymphoma

CTCL: cutaneous T-cell lymphoma

LyP: lymphomatoid papulosis

MF: mycosis fungoides

NK cells: natural killer cells

RAR: retinoid acid receptor

RXR: retinoic X receptors

Appendix B: WHO-EORTC Classification of Cutaneous T-Cell Lymphomas (CTCLs) with Primary Cutaneous Manifestations

- Mycosis fungoides (MF)
- MF variants and subtypes
 - Folliculotropic MF
 - Pagetoid reticulosis
 - Granulomatous slack skin
- Sezary syndrome
- Adult T-cell leukemia/lymphoma (ATLL)
- Primary cutaneous CD30+ lymphoproliferative disorders
 - Primary cutaneous anaplastic large cell lymphoma (ALCL)
 - Lymphomatoid papulosis (LyP)
- Subcutaneous panniculitis-like T-cell lymphoma
- Extranodal NK*/T-cell lymphoma, nasal type
- Primary cutaneous peripheral T-cell lymphoma, unspecified
 - Primary cutaneous aggressive epidermotropic CD8+ T-cell lymphoma
 - Cutaneous gamma/delta T-cell lymphoma
 - Primary cutaneous CD4+ small/medium-sized pleomorphic T-cell lymphoma

**Extranodal NK-cell lymphoma is considered a CTCL subtype under the policy criteria.*

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: added age; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	02.13 .18	

References

1. Targretin (capsules) Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; July 2015. Available at <http://www.valeant.com/Portals/25/PDF/TargretinCapsules-PI.pdf?ver=2016-05-11-044521-020>. Accessed January 2018.
2. Bexarotene. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed January 2018.
3. T-cell lymphomas (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed January 2018.
4. Willemze R, Jaffe ES, Burg G, et al. WHO-EORTC classification for cutaneous lymphomas. *Blood*. May 2005; 105(10): 3768-85.
5. Olsen EA. Evaluation, diagnosis and staging of cutaneous lymphoma. *Dermato Clin*. October 2015; 33(4): 643-54. doi: 10.1016/j.det.2015.06.001.