Clinical Policy: Bexarotene (Targretin) Capsules

Reference Number: PA.CP.PHAR.75
Effective Date: 09/11
Last Review Date: 04/19

Revision Log

Description
Bexarotene (Targretin®) is a retinoid X receptor activator.

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 D for CTCL subtypes);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 400 mg/m^2 per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

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. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 400 mg/m^2 per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

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.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALCL: anaplastic large cell lymphoma
ATLL: adult T-cell leukemia/lymphoma
CTCL: cutaneous T-cell lymphoma
FDA: Food and Drug Administration
LyP: lymphomatoid papulosis
MF: mycosis fungoides
NK cells: natural killer cells
RAR: retinoid acid receptor
RXR: retinoic X receptors

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): Pregnancy; known hypersensitivity to bexarotene
- Boxed warning(s): Birth defects

Appendix D: 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.*

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CTCL	300-400 mg/m^2/day PO	400 mg/m^2/day

V. Product Availability

Capsules: 75 mg

VI. References

1. Targretin (capsules) Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; June 2016. Available at http://www.valeant.com/Portals/25/PDF/TargretinCapsules-PI.pdf?ver=2016-05-11-044521-020. Accessed February 7, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 7, 2019.
3. National Comprehensive Cancer Network Guidelines. T-Cell Lymphomas Version 2.2019. Available at www.nccn.org. Accessed February 7, 2019.
4. National Comprehensive Cancer Network Guidelines. Primary Cutaneous Lymphomas Version 2.2019. Available at www.nccn.org. Accessed February 7, 2019.
1. Willemze R, Jaffe ES, Burg G, et al. WHO-EORTC classification for cutaneous lymphomas. *Blood*. May 2005; 105(10): 3768-85.
2. 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.

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	
2Q 2019 annual review: no significant changes; references reviewed and updated.	04/19	