Clinical Policy: Bexarotene (Targretin) Capsules

Reference Number: ERX.SPA.79
Effective Date: 03.01.14
Last Review Date: 05.18 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Bexarotene (Targretin® capsules) 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
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 CTCL (see *Appendix C* for CTCL subtypes);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Pregnancy test within the past 30 days is negative;
5. Dose does not exceed 400 mg/m^2/day.

Approval duration: Length of Benefit

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Targretin capsules for CTCL and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 400 mg/m^2/day.

Approval duration: Length of Benefit

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. 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: 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.*

V. Dosage and Administration

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

VI. Product Availability

Capsule: 75 mg

VII. 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 www.nccn.org. Accessed January 2018.
3. T-cell lymphomas (Version 2.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	02.14	03.14
Policy converted to new template. Added NCCN compendial uses. Reduced approval period to 3 months as monitoring is required at least every two months. Added appendix B (subtypes of cutaneous T-cell lymphoma), drawing from WHO-EORTC categories presented in Willenze 2005.	08.16	09.16
Converted to new template. Age added. Maximum dose added. Dosing guidance for off-label use added. Approval periods lengthened from 3/3 to 6/12 months. References updated.	07.17	08.17
2Q 2018 annual review: NCCN and FDA approved uses summarized for improved clarity; specialist involvement in care added; continuity of care statement added; approval durations increased to length of benefit; references reviewed and updated.	02.13.18	05.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.