Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 05/01/2021**
Policy Number: PA.CP.PHAR.75	**Effective Date: 01/2018** **Revision Date: 04/2021**
Policy Name: Bexarotene (Targretin Capsules, Gel)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

2Q 2021 annual review: added off-label indication for Mycosis Fungoides/Sezary Syndrome; added generic redirection language to "must use" since oral oncology product; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Bexarotene (Targretin Capsules, Gel)

Reference Number: PA.CP.PHAR.75
Effective Date: 01/2018
Last Review Date: 04/2021

Revision Log

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

FDA Approved Indication(s)
Targretin capsules are 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.

Targretin gel is indicated for the topical treatment of cutaneous lesions in patients with CTCL (Stage IA and IB) who have refractory or persistent disease after other therapies or who have not tolerated other therapies.

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. Member must use generic bexarotene, unless contraindicated or clinically significant adverse effects are experienced;
5. 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. Primary Cutaneous Lymphomas of the Skin (must meet all):
1. Request is for Targretin gel;
2. Diagnosis of CTCL or cutaneous B-cell lymphoma (CBCL) *(see Appendix D for CTCL and CBCL subtypes)*;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Disease manifestation is localized to skin only;
6. Request meets one of the following (a of b):
   a. Dose does not exceed application of four times 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

C. Off-Label Indications (must meet all)**:**

1. Diagnosis of Mycosis Fungoides/Sezary Syndrome;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following:
   a. For Targretin capsule request, member must use generic bexarotene, unless contraindicated or clinically significant adverse effects are experienced;
   b. For Targretin gel request, disease is limited and localized to skin involvement only;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

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

II. Continued Approval

A. Primary Cutaneous 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. Bexarotene capsules: New dose does not exceed 400 mg/m^2 per day;
   b. Bexarotene gel: New dose does not exceed application of four times per day;
   c. New 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 (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
C-ALCL: primary cutaneous anaplastic large cell lymphoma
CBCL: cutaneous B-cell lymphoma
CTCL: cutaneous T-cell lymphoma
EBV: Epstein-Barr virus
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 primary cutaneous lymphomas
- CTCL
  - 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 (C-ALCL)
    - Lymphomatoid papulosis (LyP)
  - Subcutaneous panniculitis-like T-cell lymphoma
  - Extranodal NK*/T-cell lymphoma, nasal type
  - Chronic active EBV infection
  - Primary cutaneous peripheral T-cell lymphoma, not otherwise specified
  - Primary cutaneous peripheral T-cell lymphoma, rare subtypes
    - Primary cutaneous gamma/delta T-cell lymphoma
    - Primary cutaneous aggressive epidermotropic CD8+ T-cell lymphoma (provisional)
    - Primary cutaneous CD4+ small/medium T-cell lymphoproliferative disorder (provisional)
    - Primary cutaneous acral CD8+ T-cell lymphoma (provisional)
- CBCL
  - primary cutaneousmarginal zone lymphoma
  - primary cutaneous follicle center lymphoma
  - primary cutaneous large B-cell lymphoma, leg type
  - Epstein-Barr virus mucocutaneous ulcer (provisional)
  - Intravascular large B-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	Oral	Oral

Indication	Dosing Regimen	Maximum Dose
	300-400 mg/m^2/day PO Topical Initially applied once every other day for the first week. The application frequency should be increased at weekly intervals to once daily, then twice daily, then three times daily and finally four times daily according to individual lesion tolerance	400 mg/m^2/day Topical Four times daily

V. Product Availability

Drug Name	Availability
Bexarotene capsules (Targretin)	Capsules: 75 mg
Bexarotene 1% gel (Targretin)	Gel: 600 mg active bexarotene per 600 g

VI. References

1. Targretin (capsules) Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; July 2015. Available at https://www.targretin.com/. Accessed February 21, 2021..
2. Targretin (gel 1%) Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; October 2016. Available at https://www.targretin.com/. Accessed February 21, 2021.
3. Bexarotene. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 21, 2021.
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.
6. Willemze R, Cerroni L, Kempf W, et al. The 2018 update of the WHO-EORTC classification for primary cutaneous lymphomas. *Blood*. 2019; 133(16): 1703-1714.

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	
2Q 2020 annual review: added bexarotene gel formulation and criteria; updated appendix D primary cutaneous lymphoma classification; references reviewed and updated.	04/2020	

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2021 annual review: added off-label indication for Mycosis Fungoides/Sezary Syndrome; added generic redirection language to "must use" since oral oncology product; references reviewed and updated.	04/2021	