Pharmacy Policy Bulletin: J-0550 Targretin (bexarotene) - Commercial and Healthcare Reform	
Number: J-0550	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0550-013	**Original Date:** 05/24/2017
Effective Date: 08/23/2024	**Review Date:** 08/07/2024

Drugs Product(s):	• Targretin (bexarotene)
FDA-Approved Indication(s):	• Targretin oral capsule o Treatment of cutaneous manifestations of cutaneous T-cell lymphoma (CTCL) in patients who are refractory to at least one prior systemic therapy. • Targretin topical gel o 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.

Background:	• Bexarotene is a synthetic retinoid agent that activates retinoid X receptor (RXR) subtypes RXR-alpha, RXR-beta, and RXR-gamma. • Prescribing considerations: o Targretin carries a black box warning for birth defects. Targretin must not be administered to a pregnant woman due to it belonging to the retinoid drug class, which is associated with human birth defects.

Approval Criteria

I. Initial Authorization

A. Targretin (bexarotene) oral capsules

When a benefit, coverage of Targretin (bexarotene) oral capsules may be approved when all of the following criteria are met **(1. through 4.)**:

1. The member is 18 years of age or older.

2. The member has a diagnosis of cutaneous manifestations of CTCL (ICD-10: C84.A)

3. The member has experienced therapeutic failure, contraindication, or intolerance to at least one (1) guideline-directed systemic therapy **(a. through e.)**:

a. Interferon-α-2b or interferon-γ-1b

b. Extracorporeal photochemotherapy

c. Systemic retinoids (e.g., acitretin, isotretinoin)
d. Methotrexate
e. Single agent or combination chemotherapies

4. If the request is for brand Targretin oral capsules, the member has experienced therapeutic failure or intolerance to generic oral bexarotene.

B. Targretin (bexarotene) topical gel

When a benefit, coverage of Targretin (bexarotene) topical gel may be approved when all of the following criteria are met **(1. through 4.)**:

1. The member is 18 years of age or older.
2. The member will be using Targretin gel for cutaneous lesions associated with one (1) of the following stages of CTCL (ICD-10: C84.A) **(a. or b.)**:
  a. Stage IA
  b. Stage IB
3. The member has experienced therapeutic failure, contraindication, or intolerance to at least one (1) other guideline-directed therapy **(a. through h.)**:
  a. Topical corticosteroids
  b. Topical chemotherapy (e.g., carmustine)
  c. Local radiation
  d. Topical retinoid (e.g., tazarotene)
  e. Phototherapy
  f. Topical imiquimod
  g. Topical mechlorethamine
  h. Total skin electron beam radiation (TSEBT)
4. If the request is for brand Targretin topical gel, the member has experienced therapeutic failure or intolerance to generic topical bexarotene gel.

II. Reauthorization

When a benefit, reauthorization of Targretin (bexarotene) oral capsules or topical gel may be approved when all of the following criteria are met **(A. and B.)**:

A. The prescriber attests that the member is tolerating therapy and has experienced a therapeutic response defined as one (1) of the following **(1. or 2.)**:
  1. Disease improvement
  2. Delayed disease progression
B. If the request is for brand Targretin oral capsules or topical gel, the prescriber provides documentation that the AB-rated generic is ineffective or not tolerated.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

IV. Coverage of oncology drug(s) listed in this policy may be approved on a case-by-case basis per indications supported in the most current NCCN guidelines.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Targretin capsules [package insert]. St. Petersburg, FL: Valeant; July 2015.
2. Targretin 1% gel [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; October 2016.
3. NCCN Guidelines. Primary Cutaneous Lymphomas. v.2.2024. National Comprehensive Cancer Network. Available at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed June 3, 2024.