Reference number(s)
1795-A

SPECIALTY GUIDELINE MANAGEMENT

Targretin (bexarotene) capsules
bexarotene capsules (generic)
Targretin (bexarotene) gel 1%

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Targretin/bexarotene 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.
2. 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.

B. Compendial Uses
1. Targretin/bexarotene capsules
   a. Mycosis fungoides (MF)
   b. Sézary syndrome (SS)
   c. Primary cutaneous CD30+ T-cell lymphoproliferative disorders:
      i. Primary cutaneous anaplastic large cell lymphoma (ALCL)
      ii. Lymphomatoid papulosis (LyP)
2. Targretin gel
   a. Mycosis fungoides (MF)
   b. Chronic or smoldering adult T-cell leukemia/lymphoma (ATLL)
   c. Primary cutaneous B-cell lymphoma:
      i. Primary cutaneous marginal zone lymphoma
      ii. Primary cutaneous follicle center lymphoma

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Targretin/bexarotene Capsules

1. Mycosis Fungoides (MF)/Sézary Syndrome (SS)
Authorization of 12 months may be granted for treatment of MF or SS.

2. Primary Cutaneous Anaplastic Large Cell Lymphoma (ALCL)/Lymphomatoid Papulosis (LyP)
Authorization of 12 months may be granted for treatment of primary cutaneous ALCL or LyP as a single agent.

B. Targretin Gel

1. **Mycosis Fungoides (MF)** (excluding Sézary syndrome)
   Authorization of 12 months may be granted for treatment of MF.

2. **Adult T-cell Leukemia/Lymphoma (ATLL)**
   Authorization of 12 months may be granted for treatment of chronic or smoldering ATLL.

3. **Primary Cutaneous B-cell Lymphoma**
   Authorization of 12 months may be granted for treatment of primary cutaneous marginal zone lymphoma or primary cutaneous follicle center lymphoma.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Targretin capsules [package insert]. St. Petersburg, FL: Catalent Pharma Solutions LLC; April 2020.
2. Targretin gel [package insert]. San Antonio, TX: DPT Laboratories, Ltd.; February 2020.
3. Bexarotene capsule [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; December 2020.
4. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 4, 2022.