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 covered benefits 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. Sezary syndrome (SS)
   c. Primary cutaneous CD30+ T-cell lymphoproliferative disorders:
      a. Primary cutaneous anaplastic large cell lymphoma (ALCL)
      b. 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:
      a. Primary cutaneous marginal zone lymphoma
      b. 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 the treatment of MF or SS.

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

B. Targretin Gel

1. Cutaneous T-cell Lymphoma (CTCL): Mycosis Fungoides (MF) (excluding Sézary syndrome)

Authorization of 12 months may be granted for the treatment of MF.

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

3. **Primary Cutaneous B-cell Lymphoma**
   Authorization of 12 months may be granted for the 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 who have not experienced disease progression or an unacceptable toxicity.

IV. REFERENCES

1. Targretin capsules [package insert]. St. Petersburg, FL: Catalent Pharma Solutions LLC; June 2016. .
2. Targretin gel [package insert]. San Antonio, TX: DPT Laboratories, Ltd.; October 2015.
3. Bexarotene capsules [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; June 2018.
4. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 27, 2019.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas (Version 2.2019). https://www.nccn.org. Accessed January 27, 2019.
6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas (Version 2.2019). https://www.nccn.org. Accessed January 27, 2019.