

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
 - i. Mycosis fungoides (MF)
 - ii. Sezary syndrome (SS)
 - iii. Primary cutaneous CD30+ T-cell lymphoproliferative disorders:
 - a. Primary cutaneous anaplastic large cell lymphoma (ALCL)
 - b. Lymphomatoid papulosis (LyP)
2. Targretin gel
 - i. Mycosis fungoides (MF)
 - ii. Adult T-cell leukemia/lymphoma (ATLL)
 - iii. 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 are not covered benefits.

II. CRITERIA FOR 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 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

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. REFERENCES

1. Targretin capsules [package insert]. St. Petersburg, FL: Catalent Pharma Solutions LLC; July 2015.
2. Targretin gel [package insert]. San Antonio, TX: DPT Laboratories, Ltd.; July 2013.
3. The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed December 08, 2016.