Reference number(s)
1795-A

Specialty Guideline Management bexarotene-Targretin

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Targretin capsules	bexarotene capsules
Targretin gel 1%	bexarotene gel 1%

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.

FDA-Approved Indications[1-4]

- 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.
- Targretin/bexarotene 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.

Compendial Uses[5]

Targretin/bexarotene capsules

- Mycosis fungoides (MF)

- Sézary syndrome (SS)
- Subcutaneous panniculitis-like T-cell lymphoma
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders:
    - Primary cutaneous anaplastic large cell lymphoma (ALCL)
    - Lymphomatoid papulosis (LyP)

Targretin/bexarotene gel

- Mycosis fungoides (MF)
- Sézary syndrome (SS)
- Smoldering adult T-cell leukemia/lymphoma (ATLL)
- Primary cutaneous B-cell lymphoma:
    - Primary cutaneous marginal zone lymphoma
    - Primary cutaneous follicle center lymphoma

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

Coverage Criteria

Targretin/bexarotene Capsules

Mycosis Fungoides (MF)/Sézary Syndrome (SS)[1,2,5]

Authorization of 12 months may be granted for treatment of MF or SS.

Subcutaneous Panniculitis-like T-cell Lymphoma[1,2,5]

Authorization of 12 months may be granted for treatment of subcutaneous panniculitis-like T-cell lymphoma as a single agent or in combination with prednisone.

Primary Cutaneous Anaplastic Large Cell Lymphoma (ALCL)/Lymphomatoid Papulosis (LyP)[5]

Authorization of 12 months may be granted for treatment of primary cutaneous ALCL or LyP as a single agent.

Targretin Gel

Mycosis Fungoides (MF)/Sézary syndrome (SS) [1,2,5]

Authorization of 12 months may be granted for treatment of MF or SS.

Adult T-cell Leukemia/Lymphoma (ATLL)[5]

Authorization of 12 months may be granted for treatment of smoldering ATLL.

Primary Cutaneous B-cell Lymphoma[5]

Authorization of 12 months may be granted for treatment of primary cutaneous marginal zone lymphoma or primary cutaneous follicle center lymphoma.

Continuation of Therapy

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

References

1. Targretin capsules [package insert]. St. Petersburg, FL: Catalent Pharma Solutions LLC; April 2020.
2. Bexarotene capsule [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; December 2022.
3. Targretin gel [package insert]. San Antonio, TX: DPT Laboratories, Ltd.; February 2020.
4. Bexarotene gel [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; December 2023.
5. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed December 17, 2024.