

Specialty Pharmacy Program

Targretin[®] (bexarotene) Capsules Targretin[®] (bexarotene) Gel 1%

DESCRIPTION

Targretin 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 capsules may be used as primary therapy for advanced-stage CTCL, for early-stage CTCL with negative prognostic features (eg, blood involvement), and for early-stage CTCL that is progressive or refractory to skin-directed therapy.

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. Targretin gel may be used as primary therapy for early-stage CTCL, and for stage IIB MF and stage III MF, generally in combination with systemic therapy.

Targretin gel may also be used for the treatment of chronic or smoldering adult T-cell leukemia/lymphoma and primary cutaneous B cell lymphoma.

APPROVAL DURATION

Approval duration: 1 year

APPROVAL CRITERIA

Targretin Capsules may be approved when the following criteria have been met:

- I. Pregnancy has been excluded in female patients of childbearing potential **AND**
- II. Patient has been instructed on the importance of and proper utilization of contraception **AND**
- III. Patient has a diagnosis of CTCL (include mycosis fungoides [MF] and Sezary syndrome) **AND**
- IV. Patient has received prior systemic therapy, including but not limited to:
 - A. Retinoids (eg, bexarotene, all-trans retinoic acid) **OR**
 - B. Interferons **OR**
 - C. Histone deacetylase inhibitors **OR**
 - D. Extracorporeal photophoresis **OR**
 - E. Denileukin diftitox **OR**
 - F. Methotrexate **OR**
 - G. Doxorubicin, other chemotherapy agents**OR**
- V. Patient has advanced-stage MF (stage IIB, III, or IV) or Sezary syndrome **OR**
- VI. Patient has early-stage MF (stage IA, IB, or IIA) **AND**
 - A. There is blood involvement or folliculotropic/large cell transformation **OR**
 - B. MF is refractory or progressive to skin directed therapy.

Targretin Gel may be approved when the following criteria have been met:

- I. Pregnancy has been excluded in female patients of childbearing potential **AND**
- II. Patient has been instructed on the importance of and proper utilization of contraception **AND**
- III. Patient has a diagnosis of chronic or smoldering adult T-cell leukemia/lymphoma **OR**
- IV. Patient has a diagnosis of primary cutaneous B-cell lymphoma **OR**
- V. Patient has a diagnosis of CTCL (MF only) **AND**
 - A. Patient has early-stage MF (stage IA, IB, or IIA) **OR**
 - B. Patient has stage IIB MF **AND**
 - 1. Patch/plaque disease or limited extent tumor disease without blood involvement/transformation **AND**
 - a. Primary treatment or for relapsed/persistent disease **OR**
 - b. Refractory or progressive disease, in combination with systemic or combination therapy

OR

 - 2. Limited extent tumor disease with blood involvement/transformation **OR** generalized extent tumor disease
 - a. Primary treatment or for relapsed/persistent disease in combination with systemic or combination therapy

OR

- C. Patient has stage III MF with blood involvement
 - 1. Primary treatment or for relapsed/persistent disease, in combination with systemic therapy