Targretin

Description

Targretin (bexarotene)

Background
Cutaneous T-cell lymphoma (CTCL) is a cancer of T-lymphocytes (white blood cells) that are involved in the body’s immune system. The disease usually appears first in the skin, but may spread to other organs. Targretin is a member of the subclass of retinoids and selectively binds and activates retinoid X receptors (RXRs), causing a biological cascade that eventually regulates the expression of genes that control cellular differentiation and proliferation (1-2).

Regulatory Status
FDA-approved indications:
Targretin gel 1% is indicated for the topical treatment of cutaneous lesions in patients with cutaneous T-cell lymphoma (CTCL) Stage 1A and 1B who have refractory or persistent disease after other therapies or who have not tolerated other therapies (1).

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 (2).

Off-Label Uses: (3)
1. Chronic Cutaneous T-cell lymphoma (CTCL)
2. Mycosis Fugoides (MF)
3. Sezary Syndrome (SS)
4. Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders
Targretin has a boxed warning for pregnancy due to being a member of the retinoid class of drugs because of the high association of these agents with birth defects. Therefore, this agent is considered category X, and a negative pregnancy test within one week before starting therapy and monthly throughout therapy should be obtained. Additionally, effective contraception must be used throughout therapy and for at least one month following discontinuation of therapy. Male patients with sexual partners that are pregnant or could become pregnant must use condoms during sexual intercourse during treatment and for one month after discontinuation of treatment (2).

Safety and effectiveness in pediatric patients have not been established (2).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Targretin capsules may be considered medically necessary in patients 18 years of age or older with cutaneous lesions of cutaneous T-cell lymphoma (CTCL), mycosis fungoides (MF), sezary syndrome (SS) or primary cutaneous CD30+ T-Cell Lymphoproliferative Disorders and Targretin gel may be considered medically necessary in patients 18 years of age or older for the treatment of cutaneous lesions of cutaneous T-cell lymphoma (CTCL), mycosis fungoides (MF), sezary syndrome (SS) or primary cutaneous B-Cell lymphoma and if the conditions indicated below are met.

Targretin is considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age

18 years of age or older

Diagnoses

Targretin capsules

Patient must have ONE of the following:

1. Cutaneous T-cell lymphoma (CTCL) including the following:
### Prior – Approval Renewal Requirements

**Age**

18 years of age or older

**Diagnoses**

**Targretin capsules**

Patient must have **ONE** of the following:

1. Cutaneous T-cell lymphoma (CTCL) including the following:
   a. Mycosis Fungoides (MF)
b. Sezary Syndrome (SS)

2. Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders

Targretin Gel

Patient must have ONE of the following:

1. Cutaneous T-cell lymphoma (CTCL) including the following:
   a. Mycosis Fungoides (MF)
   b. Sezary Syndrome (SS)

2. Primary Cutaneous B-Cell Lymphoma

AND the following:

a. Patient has had improvement with treatment based either on CAILS score or decrease in severity of scaling, plaque elevation or surface area.
b. For female patients (if of child bearing potential)
   i. Must not be pregnant
   ii. A negative pregnancy test must be obtained monthly throughout therapy
   iii. Agreement to use reliable contraception during therapy and for one month after discontinuation of therapy
c. For male patients
   i. If partner is pregnant or of child bearing potential an agreement to use condoms during therapy and for at least one month after discontinuation of therapy

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits
Duration 12 months

Prior – Approval Renewal Limits
Duration 12 months

Rationale
Summary

Targretin is a member of the subclass of retinoids 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 has a boxed warning for pregnancy due to being a member of the retinoid class of drugs because of the high association of these agents with birth defects. Therefore, this agent is considered category X (1-2).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Targretin while maintaining optimal therapeutic outcomes.

References


Policy History

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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.