



RATIONALE FOR INCLUSION IN PA PROGRAM

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 requires 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).



**BlueCross
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TARGRETIN (bexarotene)

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

1. Targretin gel [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; February 2020.
2. Targretin capsules [package insert]. Bridgewater, NJ: Bausch Health US, LLC; April 2020.
3. NCCN Drugs & Biologics Compendium® Bexarotene 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.