BEXAROTENE

Generic	Brand	HICL	GCN	Exception/Other
BEXAROTENE SOFTGEL	TARGRETIN		92373	
BEXAROTENE 1% TOPICAL GEL	TARGRETIN		89921	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cutaneous T-cell lymphoma (CTCL) refractory to systemic therapy; (**Note:** Systemic therapy to treat CTCL may include, but is not limited to, gemcitabine, methotrexate, liposomal doxorubicin, Velcade, and other agents.)?

   If yes, **approve for 12 months by GPID as follows:**
   - **75mg Capsules: quantity of up to #14 capsules per day.**
   - **1% Gel: quantity of #1 tube (60g) per month.**

   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. Pregnancy Category X. For more information please ask your doctor or pharmacist.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of cutaneous T-cell lymphoma that is refractory to prior systemic therapy.

RATIONALE
Promote appropriate utilization of Targretin based on FDA approved indication.

FDA APPROVED INDICATIONS
Targretin (bexarotene) capsules are indicated for the treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.

(Systemic therapy to treat CTCL may include gemcitabine, methotrexate, liposomal doxorubicin, Velcade, and other agents.)

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OTHER INFORMATION

Capsules (weight-based dosing of 4 to 14 capsules per day).

Gel (applications may be titrated from every other day up to four times daily; typical application varies from twice daily up to four times daily).

Targretin capsules should be administered once daily with a meal. The initial dose is 300mg/m^2/day. The dose may be increased up to 400mg/m^2/day when there is no tumor response after 8 weeks.

OTHER INFORMATION (CONTINUED)

In clinical trials oral Targretin was administered for up to 97 weeks and topical Targretin gel was administered for up to 172 weeks.

Dosing information from http://us.eisai.com/pdf_files/prescribing_caps_information.pdf

Initial Dose Level (300 mg/m^2/day)		
Body Surface Area (m^2)	**Total Daily Dose (mg/day)**	**Number of 75 mg Targretin Capsules**
0.88 - 1.12	300	4
1.13 - 1.37	375	5
1.38 - 1.62	450	6
1.63 - 1.87	525	7
1.88 - 2.12	600	8
2.13 - 2.37	675	9
2.38 - 2.62	750	10

Targretin contains a **black box warning** that this product is a member of the retinoid class of drugs and should not be administered to pregnant women (Pregnancy Category X).

REFERENCES

- Eisai Inc. Targretin prescribing information. Woodcliff Lake, NJ. April 2011. Accessed online February 2012 at: http://us.eisai.com/pdf_files/prescribing_caps_information.pdf

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/14
Created: 05/12
Client Approval: 11/13
P&T Approval: 11/13