

Targretin[®] (bexarotene) (Oral and Topical)

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Date of Origin: 01/01/2012

Dates Reviewed: 12/2012, 11/2013, 08/2014, 07/2015, 07/2016, 08/2017, 07/2018, 07/2019

I. Length of Authorization

Coverage is provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

Oral:

- Targretin 75 mg capsule: 9 capsules per day

Topical:

- Targretin 1% gel 60 gram: 4 tubes per 30 days

B. Max Units (per dose and over time) [Medical Benefit]:

- N/A

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is 18 years old or older; **AND**

ORAL

Cutaneous T-cell lymphoma (CTCL) †

- Diagnosis of cutaneous manifestations of cutaneous T-cell lymphoma (e.g., Mycosis fungoides/Sezary Syndrome); **AND**
 - Used as primary therapy for stage IB or more advanced disease; **OR**
 - Patient is refractory to, or has progressed on, prior therapy; **OR**
 - Patient has relapsed or persistent disease

Primary Cutaneous T-Cell Lymphoproliferative Disorders ‡

- Patient is CD30-positive; **AND**
- Patient has cutaneous manifestations of disease; **AND**
- Must be used as a single agent; **AND**

- Used as primary therapy or for relapsed or refractory disease; **AND**
 - Patient has a diagnosis of primary cutaneous anaplastic large cell lymphoma (ALCL); **AND**
 - Patient has multifocal lesions; **OR**
 - Patient has a diagnosis of lymphomatoid papulosis (LyP); **AND**
 - Patient has extensive lesions

TOPICAL

Cutaneous T-cell lymphoma (CTCL) †

- Diagnosis of cutaneous manifestations of cutaneous T-cell lymphoma (e.g., Mycosis fungoides/Sezary Syndrome); **AND**
- Patient has limited/localized skin involvement; **AND**
 - Used as initial treatment for stage IA disease; **OR**
 - Patient has refractory or persistent disease following other therapies

Primary Cutaneous B-Cell Lymphoma ‡

- Topical therapy for primary cutaneous marginal zone or follicle center lymphoma

Adult T-Cell Leukemia/Lymphoma ‡

- Must be used as first-line topical therapy; **AND**
- Patient has chronic or smoldering disease

† FDA labeled indication(s); ‡ Compendia Recommended Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hyperlipidemia, pancreatitis, hepatotoxicity (greater than three times the upper limit of normal values for SGOT/AST, SGPT/ALT, or bilirubin), hematologic toxicities (leukopenia, neutropenia), hypothyroidism, hypoglycemia, cataracts, etc.

V. Dosage/Administration

Indication	Dose
Cutaneous T-cell lymphoma (CTCL)	ORAL <ul style="list-style-type: none"> ▪ Initial Dose: 300mg/m² once daily with meals. Dose should be rounded to the nearest 75mg.

	<ul style="list-style-type: none"> ▪ Maintenance dosage: Increase to 400 mg/m²/day if no tumor response after 8 weeks. ▪ Treatment should be continued as long as the patient is deriving benefit.
	<p><u>TOPICAL</u></p> <ul style="list-style-type: none"> ▪ Apply once every other day for the first week. The application frequency should be increased at weekly intervals to once daily, then twice daily, then three times daily and finally four times daily according to individual lesion tolerance. ▪ Sufficient gel should be applied to cover each lesion with a generous coating. ▪ Treatment should be continued as long as the patient is deriving benefit.

VI. Billing Code/Availability Information

Jcode:

- Oral: J8999 – Prescription drug, oral, chemotherapeutic, nos
- Topical: J3590 – unclassified biologics

NDC:

- Targretin 75 mg capsule*: 00187-5526-xx
 - Targretin 1% gel 60 grams: 00187-5525-xx
- *available generically

VII. References

1. Targretin capsules [package insert]. Bridgewater, NJ; Valeant Pharmaceuticals North America LLC; June 2016. Accessed May 2019.
2. Targretin gel [package insert]. Bridgewater, NJ; Valeant Pharmaceuticals North America LLC; Oct 2016. Accessed May 2019.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Bexarotene Gel. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2019.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Bexarotene. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2019.

Appendix 1 – Covered Diagnosis Codes

ORAL:

ICD-10	ICD-10 Description
C84.00	Mycosis fungoides, unspecified site
C84.01	Mycosis fungoides, lymph nodes of head, face and neck
C84.02	Mycosis fungoides, intrathoracic lymph nodes
C84.03	Mycosis fungoides, intra-abdominal lymph nodes
C84.04	Mycosis fungoides, lymph nodes of axilla and upper limb
C84.05	Mycosis fungoides, lymph nodes of inguinal region and lower limb
C84.06	Mycosis fungoides, intrapelvic lymph nodes
C84.07	Mycosis fungoides, spleen
C84.08	Mycosis fungoides, lymph nodes of multiple sites
C84.09	Mycosis fungoides, extranodal and solid organ sites
C84.10	Sezary disease, unspecified site
C84.11	Sezary disease, lymph nodes of head, face and neck
C84.12	Sezary disease, intrathoracic lymph nodes
C84.13	Sezary disease, intra-abdominal lymph nodes
C84.14	Sezary disease, lymph nodes of axilla and upper limb
C84.15	Sezary disease, lymph nodes of inguinal region and lower limb
C84.16	Sezary disease, intrapelvic lymph nodes
C84.17	Sezary disease, spleen
C84.18	Sezary disease, lymph nodes of multiple sites
C84.19	Sezary disease, extranodal and solid organ sites
C86.6	Primary cutaneous CD30-positive T-cell proliferations

TOPICAL:

ICD-10	ICD-10 Description
C82.60	Cutaneous follicle center lymphoma, unspecified site
C82.61	Cutaneous follicle center lymphoma, lymph nodes of head, face and neck
C82.62	Cutaneous follicle center lymphoma, intrathoracic lymph nodes
C82.63	Cutaneous follicle center lymphoma, intra-abdominal lymph nodes
C82.64	Cutaneous follicle center lymphoma, lymph nodes of axilla and upper limb
C82.65	Cutaneous follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.66	Cutaneous follicle center lymphoma, intrapelvic lymph nodes
C82.67	Cutaneous follicle center lymphoma, spleen
C82.68	Cutaneous follicle center lymphoma, lymph nodes of multiple sites
C82.69	Cutaneous follicle center lymphoma, extranodal and solid organ sites
C83.80	Other non-follicular lymphoma, unspecified site

C83.81	Other non-follicular lymphoma, lymph nodes of head, face and neck
C83.82	Other non-follicular lymphoma, intrathoracic lymph nodes
C83.83	Other non-follicular lymphoma, intra-abdominal lymph nodes
C83.84	Other non-follicular lymphoma, lymph nodes of axilla and upper limb
C83.85	Other non-follicular lymphoma, lymph nodes of inguinal region and lower limb
C83.86	Other non-follicular lymphoma, intrapelvic lymph nodes
C83.87	Other non-follicular lymphoma, spleen
C83.88	Other non-follicular lymphoma, lymph nodes of multiple sites
C83.89	Other non-follicular lymphoma, extranodal and solid organ sites
C84.00	Mycosis fungoides, unspecified site
C84.01	Mycosis fungoides, lymph nodes of head, face and neck
C84.02	Mycosis fungoides, intrathoracic lymph nodes
C84.03	Mycosis fungoides, intra-abdominal lymph nodes
C84.04	Mycosis fungoides, lymph nodes of axilla and upper limb
C84.05	Mycosis fungoides, lymph nodes of inguinal region and lower limb
C84.06	Mycosis fungoides, intrapelvic lymph nodes
C84.07	Mycosis fungoides, spleen
C84.08	Mycosis fungoides, lymph nodes of multiple sites
C84.09	Mycosis fungoides, extranodal and solid organ sites
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue (MALT-lymphoma)
C91.50	Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission
C91.51	Adult T-cell lymphoma/leukemia (HTLV-1-associated), in remission

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC