JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS020
		Effective Date	07/01/2007
		Review Date	01/14/2009
	Subject **Zolinza**	*Revision Date*	11/12/2020
		Page	1 of 2

This document applies to the following Participating Organizations:

Priority Partners

Keywords: Zolinza

Table of Contents		Page Number
I.	POLICY	1
II.	POLICY CRITERIA	1
III.	AUTHORIZATION PERIOD/LIMITATIONS	1
IV.	EXCLUSIONS	1
V.	REFERENCES	2
VI.	APPROVALS	2

I. POLICY

A. Zolinza will require prior authorization to ensure appropriate use for outpatient prescription drug benefit coverage to ensure this medication is used only when clinically appropriate. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. The following criteria must be met for consideration of drug coverage:
   1. Patient must be 18 years of age or older
   2. Documented diagnosis of cutaneous T-cell lymphoma (CTCL) that is progressive, persistent, or recurrent on or following two systemic chemotherapeutic therapies.
   3. Documented treatment plan including laboratory monitoring tests of blood glucose, serum electrolytes, serum creatinine, and complete blood count; to be performed at baseline, every two weeks for the first two months of therapy, and monthly thereafter.
   4. Documented treatment plan including baseline and periodic electrocardiogram (ECG) to be performed throughout Zolinza therapy.

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be restricted to 6 months of therapy.

B. Approval for continuation of therapy may be extended in 12-month intervals with documentation showing that the patient has had a beneficial response to treatment.

IV. EXCLUSIONS

A. If the request is for a diagnosis not listed above, a letter may be sent to the requesting physician to provide additional information.
   1. Zolinza is pregnancy category D and can cause fetal harm when administered to a pregnant woman.

2. If Zolinza is used during pregnancy, or if the patient becomes pregnant while taking Zolinza, the patient should be apprised of the potential hazard to the fetus.
3. The safety and efficacy of Zolinza in patients less than 18 years of age have not been established.
4. Severe thrombocytopenia and gastrointestinal bleeding have been reported with concurrent use of Zolinza and other HDAC inhibitors (e.g. valproic acid).
5. Patients concurrently taking Zolinza and coumarin derivatives (e.g. warfarin) should be regularly monitored for prolongation of prothrombin time (PT) and International Normalized Ratio (INR).
6. Patient should be instructed to take Zolinza with food and at least two liters of fluid per day to prevent dehydration.
7. Patients should be instructed about the signs and symptoms of deep vein thrombosis (DVT) and pulmonary embolism (PE) which can occur coincident with Zolinza therapy.

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Zolinza product information. Whitehouse Station, NJ: Merck & Co., Inc.; July 2007.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2016	Removed background information and updated LOB, removed process of initiation of request
07/27/2017	Updated Exclusion section regarding physician samples
11/12/2020	Clarified continuation of therapy criteria

Review/Revision Dates: 01/16/2008, 01/14/2009, 04/20/2016, 07/27/2017, 07/01201/, 11/12/2020