Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Thalomid (thalidomide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Thalomid (thalidomide)	May be subject to quantity limit

APPROVAL CRITERIA

Thalomid may be approved if the following criteria are met:

I. Individual has a diagnosis of one of the following:

A. Multiple myeloma
   1. For primary therapy in combination with a steroid, if tolerated; **OR**
   2. For relapsed or progressive disease (NCCN 2A);

OR

B. Erythema nodosum leprosum (ENL)
   1. For acute treatment of moderate to severe disease; **OR**
   2. Prophylaxis therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence;

OR

C. AIDS-Related Kaposi Sarcoma, for progressive disease in subsequent therapy (AHFS, NCCN 2A);

OR

D. Castleman's Disease, for progressive or relapsed/refractory disease in subsequent therapy (NCCN 2A);

OR

E. Myelofibrosis
   1. For myelofibrosis-associated anemia when used as monotherapy or in combination with prednisone (NCCN 2A); **OR**

F. Erosive lichen planus (AHFS); **OR**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

G. Erythema multiforme (AHFS); **OR**

H. Lupus erythematosus (AHFS); **OR**

I. Prurigo nodularis (AHFS); **OR**

J. Actinic prurigo (AHFS); **OR**

K. Cutaneous Langerhans cell histiocytosis (AHFS); **OR**

L. Uremic pruritus (AHFS); **OR**

M. Porphyria cutanea tarda (AHFS); **OR**

N. Pyoderma gangrenosum (AHFS); **OR**

O. Cachexia (AHFS); **OR**

P. Graft vs host disease (AHFS); **OR**

Q. Recurrent Aphthous Stomatitis (AHFS); **OR**

R. Sarcoidosis (AHFS).

Thalomid (thalidomide) may **not** be approved for the following:

I. Use as monotherapy for ENL treatment in the presence of moderate to severe neuritis.

Note: Thalomid (thalidomide) has a black box warning for embryo-fetal toxicity and venous thromboembolism. Thalomid can cause severe birth defects or embryo-fetal death if taken during pregnancy. Thalomid should never be used by women who are pregnant or who could become pregnant while taking the drug. Thalomid distribution is restricted through the THALOMID REMS program (formerly known as the S.T.E.P.S. program). The use of Thalomid in multiple myeloma results in an increased risk of venous thromboembolism, such as DVT and pulmonary embolism. This risk is increased when used in combination with standard chemotherapeutic agents including dexamethasone. Thromboprophylaxis should be considered based on individual risk assessment.

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: 4/2018.

DrugPoints® System [Internet Database]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

The NCCN Drugs & Biologics Compendium (NCCN Compendium™) © 2018 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.