Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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 one of the following FDA approved or off-label oncology diagnoses:

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. Cancer associated Cachexia (AHFS).

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

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 5, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 5, 2019.
    a. AIDS-Related Kaposi Sarcoma. V2.2019. Revised November 29, 2018.
    b. B-Cell Lymphomas. V5.2019. Revised September 23, 2019.
    c. Multiple Myeloma V1.2020. Revised September 6, 2019.
    d. Myeloproliferative Neoplasms V3.2019. Revised September 4, 2019.