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

Requests for Thalomid (thalidomide) may be approved if the following criteria are met:

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

A. Multiple myeloma, as primary therapy or for relapsed or progressive disease;

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

OR

D. Histiocytic neoplasms, including Langerhans cell histiocytosis and Rosai-dorfman disease (NCCN 2A); **AND**

E. Individual is using as a single agent;

OR

F. Castleman's Disease, for active disease, progressive, or relapsed/refractory disease (NCCN 2A);

OR

G. Myelofibrosis associated anemia when used as monotherapy or in combination with prednisone (NCCN 2A);

OR

H. Cancer associated Cachexia (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.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. 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 10, 2023
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 10, 2023.
    a. B-Cell Lymphomas V5.2023. Revised July 7, 2023.
    b. Myeloproliferative Neoplasms V2.2023. Revised August 29, 2023.
    c. Kaposi Sarcoma V2.2023. Revised October 3, 2023.
    d. Histiocytic Neoplasms V1.2023. Revised August 11, 2023
    e. Multiple Myeloma V1.2024. Revised September 22, 2023.