MEDICATION POLICY:

Thalomid®

Generic Name: Thalidomide

Therapeutic Class or Brand Name: Thalomid

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 4/22/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of one of the following conditions A or B AND must meet criteria listed under applicable diagnosis:

FDA-Approved Indication(s)

A. Erythema Nodosum Leprosum (ENL) and meets one of the following 1 or 2:
    1. Documentation of moderate to severe disease
        a) Used for acute treatment of cutaneous manifestations.
    2. Used for prevention and suppression of cutaneous manifestations of ENL recurrence.
    3. Minimum age requirement: 12 years old.

B. Multiple myeloma
    1. Must be used in combination with dexamethasone.
    2. Minimum age requirement: 18 years old

Other Uses With Supportive Evidence

C. Castleman Disease

D. Langerhans Cell Histiocytosis

E. Rosai-Dorfman Disease

F. Kaposi Sarcoma

G. Pediatric Medulloblastoma

II. Treatment must be prescribed by or in consultation with an oncologist, hematologist, or dermatologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Pregnancy.
- If for ENL not indicated as monotherapy in presence of moderate to severe neuritis.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities of up to 60 capsules per 30 days (the quantity is limited to a maximum of a 30-day supply per fill).

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. Thalomid. Prescribing Information. Bristol-Myers Squibb Company. March 2023. Accessed April 22, 2025. www.accessdata.fda.gov/drugsatfda_docs/label/2023/020785s071lbl.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Multiple Myeloma. Version 2.2025. Updated April 11, 2025. Accessed April 22, 2025. www.nccn.org/ professionals/physician_gls/pdf/myeloma.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Castleman DIsease. Version 2.2025. Updated January 28, 2025. Accessed April 22, 2025. www.nccn.org/ professionals/physician_gls/pdf/castleman.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Histiocytic Neoplasms. Version 3.2024. Updated January 7, 2025. Accessed April 22, 2025. www.nccn.org/ professionals/physician_gls/pdf/histiocytic_neoplasms.pdf
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Kaposi Sarcoma. Version 2.2025. Updated January 14, 2025. Accessed April 22, 2025. www.nccn.org/ professionals/physician_gls/pdf/Kaposi.pdf

6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Pediatric Central Nervous System Cancers. Version 2.2025. Updated January 17, 2025. Accessed April 22, 2025. www.nccn.org/ professionals/physician_gls/pdf/ped_cns.pdf