

Applicable Drugs: Thalomid (thalidomide)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 2/27/2026

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of one of the following FDA-approved diagnoses 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 National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

- 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

- 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. 2023. Accessed February 27, 2026. www.accessdata.fda.gov/drugsatfda_docs/label/2023/020785s071lbl.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Multiple Myeloma. Version 5.2026. Updated January 9, 2026. Accessed February 27, 2026. www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Castleman Disease. Version 1.2026. Updated November 24, 2025. Accessed February 27, 2026. www.nccn.org/professionals/physician_gls/pdf/castleman.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Histiocytic Neoplasms. Version 2.2025. Updated November 21, 2025. Accessed February 27, 2026. www.nccn.org/professionals/physician_gls/pdf/histiocytic_neoplasms.pdf
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Kaposi Sarcoma. Version 2.2026. Updated September 16, 2025. Accessed February 27, 2026. 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 1.2026. Updated February 27, 2026. www.nccn.org/professionals/physician_gls/pdf/ped_cns.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.