

Specialty Guideline Management

Thalomid

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Thalomid	thalidomide

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

- Thalomid in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).
- Erythema Nodosum Leprosum (ENL)
 - Acute treatment of the cutaneous manifestations of moderate to severe ENL
 - Maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence
 - Thalomid is not indicated as monotherapy for ENL treatment in the presence of moderate to severe neuritis

Compendial Uses²⁻⁶

- Multiple Myeloma
- Crohn's Disease
- Kaposi Sarcoma

Reference number(s)
2368-A

- Chronic Graft-versus-Host Disease
- Multicentric Castleman Disease
- Aphthous Stomatitis
- Histiocytic Neoplasms
 - Langerhans Cell Histiocytosis
 - Rosai-Dorfman Disease
- Pediatric Medulloblastoma
- POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome
- Plasma cell-related Monoclonal Immunoglobulin Deposition Disease (MIDD)
- Plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Multiple Myeloma¹⁻⁵

Authorization of 12 months may be granted for treatment of multiple myeloma.

Erythema Nodosum Leprosum¹

Authorization of 12 months may be granted for treatment and prevention of erythema nodosum leprosum.

Crohn's Disease²

Authorization of 12 months may be granted for treatment of Crohn's disease.

Kaposi Sarcoma³

Authorization of 12 months may be granted for treatment of Kaposi sarcoma when any of the following criteria are met:

- The requested medication will be used in combination with antiretroviral therapy for the treatment of HIV-related relapsed or refractory advanced Kaposi sarcoma
- Member is HIV-negative and the requested medication will be used as a single agent for relapsed or refractory advanced Kaposi sarcoma
- The requested medication will be used in combination with rituximab for the treatment of Kaposi-sarcoma associated herpesvirus (KSHV)-Associated Inflammatory Cytokine Syndrome (KICS)

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Chronic Graft-versus-Host Disease^{2,5}

Authorization of 12 months may be granted for treatment of refractory chronic graft-versus-host disease.

Multicentric Castleman Disease³

Authorization of 12 months may be granted for treatment of multicentric Castleman disease.

Aphthous Stomatitis^{2,5}

Authorization of 12 months may be granted for treatment of AIDS-related aphthous stomatitis and recurrent severe aphthous stomatitis.

Histiocytic Neoplasms³

Authorization of 12 months may be granted for treatment of histiocytic neoplasms, including Langerhans cell histiocytosis and Rosai-Dorfman disease, as a single agent.

Pediatric Medulloblastoma³

Authorization of 12 months may be granted for treatment of recurrent or progressive pediatric medulloblastoma as part of MEMMAT (thalidomide, celecoxib, fenofibrate, etoposide, cyclophosphamide, bevacizumab) regimen.

POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome, plasma cell-related Monoclonal Immunoglobulin Deposition Disease (MIDD), and plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)^{3,6}

Authorization of 12 months may be granted for treatment of POEMS syndrome, plasma cell-related MIDD, and plasma cell-related MGRS.

Continuation of Therapy

Multiple Myeloma, Multicentric Castleman Disease, Histiocytic Neoplasms, Kaposi sarcoma, Pediatric Medulloblastoma, POEMS Syndrome, plasma cell-related MIDD, and plasma cell-related MGRS

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for multiple myeloma, multicentric Castleman Disease, histiocytic neoplasms, Kaposi sarcoma, pediatric medulloblastoma, POEMS syndrome, plasma cell-related MIDD, or plasma cell-related MGRS when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

All Other Indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section, other than multiple myeloma, multicentric Castleman disease, histiocytic neoplasms, Kaposi sarcoma, pediatric medulloblastoma, POEMS syndrome, plasma cell-related MIDD, or plasma cell-related MGRS who have improvement in symptoms and no unacceptable toxicity.

References

1. Thalomid [package insert]. Princeton, NJ: Celgene Corporation; March 2023.
2. AHFS Drug Information. (Adult and Pediatric) Bethesda, MD. American Society of Health System Pharmacists, Inc. Electronic version. Updated September 17, 2025. Available with subscription. URL: <http://online.lexi.com/lco>. Accessed October 2, 2025.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed October 2, 2025.
4. Micromedex® (electronic version). Ann Arbor, Michigan, USA. Available at: <http://www.micromedexsolutions.com>. Accessed October 2, 2025.
5. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; Updated October 1, 2025. <https://online.lexi.com>. Accessed October 2, 2025.
6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma. Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed September 25, 2025.