PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Thalomid Prior Authorization Policy
- Thalomid® (thalidomide capsules – Celgene)

REVIEW DATE: 05/29/2024

OVERVIEW

Thalomid, an immunomodulatory agent, is indicated for the following uses:[1]

- **Erythema nodosum leprosum (ENL)**, acute treatment of cutaneous manifestations in moderate to severe disease. Thalomid is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.
- **ENL**, maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.
- **Multiple myeloma**, newly diagnosed, in combination with dexamethasone.

Other Uses with Supportive Evidence

Discoid Lupus Erythematosus or Cutaneous Lupus Erythematosus

Thalomid has been used for discoid lupus erythematosus and cutaneous lupus erythematosus. Patients usually had refractory disease after trial of other therapies and good responses were achieved for many patients given Thalomid.[2-12] A retrospective medical review was done that involved 29 patients with refractory cutaneous manifestations of cutaneous lupus erythematosus who received Thalomid. Of the 23 patients who took Thalomid for 1 month, 74% of patients (n = 17/23) had complete resolution of the cutaneous manifestations and 13% of patients (n = 3/23) had a 75% or greater partial improvement.[3] Another report involving patients with discoid lupus (n = 18), subacute cutaneous lupus (n = 6), and systemic lupus erythematosus with skin involvement (n = 24) who had been resistant to at least two other treatments found a response rate of 81% (n = 39/48) with use of Thalomid with 60% of patients (n = 29/48) achieving a complete cutaneous remission.[4] Other therapies used for these conditions include antimalarial agents (e.g. hydroxychloroquine), corticosteroids (oral, topical, intralesional), methotrexate, azathioprine, cyclosporine, dapsone, mycophenolate mofetil, topical calcineurin inhibitors (e.g., Elidel® [pimecrolimus 1% cream], Protopic® [tacrolimus 0.03% and 0.1% ointment]), and Soriatane® (acitretin capsules).[2,7,12]

Prurigo Nodularis

Thalomid has been studied in patients with prurigo nodularis, most of whom were refractory to other treatments or with adverse events from the other therapies.[2,13-15] A retrospective review assessed the medical records of 42 patients with prurigo nodularis who were refractory to other therapy and who received Thalomid.[13] Patients received Thalomid for an average of 105 weeks. Previous therapies tried included topical steroids, intralesional steroids, systemic steroids, topical tar, macrolides, cyclosporine, azathioprine, methotrexate, calcineurin inhibitors, antihistamines, dapsone, capsaicin, laser therapy, psoralen plus ultraviolet A therapy, ultraviolet B therapy, retinoids, hydroxyzine, and macrolides. With Thalomid, improvement was noted in approximately one-third of patients.

Aphthous Ulcers or Aphthous Stomatitis

Recurrent aphthous ulcers and recurrent aphthous stomatitis are associated with frequent and recurring symptoms that are painful and can lead to difficulty in speaking, eating, and swallowing.[16-27] Ulcers are larger and may persist for weeks to months. The conditions are noted in certain disease states such as in patients who are human immunodeficiency virus (HIV)-positive and Behcet's disease. In general, few adequately powered trials have assessed the efficacy of therapeutic agents for aphthous ulcers or aphthous

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stomatitis. Although the data are older and limited, Thalomid has led to rapid resolution of symptoms in patients with recurrent aphthous ulcers or aphthous stomatitis.[16-27] A double-blind, randomized, placebo-controlled study assessed Thalomid as a therapy for oral aphthous ulcers in patients infected with HIV. In total, 55% of patients (n = 16/29) given Thalomid had complete healing of their aphthous ulcers after 4 weeks compared with only 7% of patients (n = 2/28) who received placebo. Patients given Thalomid had symptom improvements in regards to discomfort that occurred while eating.[21] A retrospective cohort study involving patients with recurrent aphthous stomatitis found that Thalomid was rapidly effective as 85% of patients (n = 78/92) achieved a complete remission of the condition within 14 days.[25] Many other agents have been used for recurrent aphthous ulcers or stomatitis including topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics (lidocaine 2% viscous solution, benzocaine lozenges), antimicrobial mouth washes (tetracycline, chlorhexidine), topical sucralfate, acyclovir, pentoxifylline, dapsone, colchicine, and azathioprine.[16-27] Due to toxicities, use of Thalomid is generally reserved for patients who have not obtained satisfactory results with other agents.[26,27]

Guidelines

Thalomid is addressed in guidelines from National Comprehensive Cancer Network (NCCN):

- **Castleman's Disease:** NCCN guidelines (version 1.2024 – January 18, 2024) recommend use of Thalomid, with or without rituximab, for patients with Castleman's disease for those who have relapsed/refractory or progressive disease (category 2A).[28] Thalomid is cited as an "other recommended therapy" (when given with cyclophosphamide and prednisone) for patients with multi-centric Castleman's disease who are negative for HIV and human herpesvirus-8 (HHV-8) [category 2A].
- **Histiocytic Neoplasms:** NCCN guidelines (version 1.2024 – March 15, 2024) recommend Thalomid in a few clinical scenarios.[29] For Langerhans cell histiocytosis, Thalomid is recommended as first-line or as subsequent therapy for single system multifocal skin disease (including mucosa) and for relapsed/refractory disease (category 2A). Thalomid is also recommended as first-line or subsequent therapy for cutaneous skin disease associated with Rosai-Dorfman disease under "useful in certain circumstances", irrespective of mutation (category 2A) [e.g., those with relapsed/refractory disease, symptomatic multifocal disease, symptomatic unresectable unifocal disease].
- **Kaposi Sarcoma:** NCCN guidelines (version 1.2024 – November 7, 2023) recommended Thalomid as an agent "useful under certain circumstances" for subsequent systemic therapy options for relapsed/refractory therapy (category 2A) [for patients with corticosteroid-refractory immune reconstitution inflammatory syndrome].[30] This includes use when given alone (in patients without HIV) or with antiretroviral therapy for patients with HIV. First-line systemic therapy options include liposomal doxorubicin (preferred), and paclitaxel. Other subsequent systemic therapy options for relapsed/refractory therapy are also cited (e.g., Pomalyst® [pomalidomide capsules] {preferred}, lenalidomide, imatinib).
- **Multiple Myeloma:** NCCN guidelines (version 4.2024 – April 26, 2024) recommend use of Thalomid in various scenarios (category 2A).[31] It is considered "useful in certain circumstances" among patients with previously treated multiple myeloma, as well as for primary therapy for transplant candidates. Thalomid is always recommended to be used with at least two other therapies to comprise the regimen.
- **Myelofibrosis:** NCCN has guidelines regarding myeloproliferative neoplasms (version 1.2024 – December 21, 2023) that discuss myelofibrosis.[32] Thalomid is recommended in the management of anemia associated with myelofibrosis "useful in certain circumstances", with or without prednisone, for a variety of clinical scenarios (category 2A) including patients with erythropoietin levels ≥ 500 mU/mL and with erythropoietin levels < 500 mU/mL and no response or loss of response to erythropoietin stimulating agents.

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POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Thalomid. All approvals are provided for the duration noted below.

Automation: None.

Recommended Authorization Criteria
Coverage of Thalomid is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Erythema Nodosum Leprosum.** Approve for 1 year.

2. **Multiple Myeloma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Thalomid is being taken in combination with at least two other medications.
     Note: Examples of medications include bortezomib, dexamethasone, cisplatin, doxorubicin, cyclophosphamide, etoposide, and Kyprolis (carfilzomib intravenous infusion).

Other Uses with Supportive Evidence

3. **Castleman's Disease.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Patient has relapsed/refractory or progressive disease; OR
   - **B)** Patient meets BOTH of the following (i and ii):
     - **i.** Patient has multi-centric Castleman's disease; AND
     - **ii.** Patient is negative for the human immunodeficiency virus and human herpesvirus-8.

4. **Discoid Lupus Erythematosus or Cutaneous Lupus Erythematosus.** Approve for 1 year if the patient has tried at least two other medications.
   Note: Examples of medications include corticosteroids (oral, topical, intralesional), antimalarial agents (e.g., hydroxychloroquine), topical calcineurin inhibitors (e.g., Protopic [tacrolimus ointment], Elidel [pimecrolimus cream]), azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, dapsone, and Soriatane (acitretin capsules).

5. **Histiocytic Neoplasms:** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has Langerhans cell histiocytosis with single-system multifocal skin disease; OR
     - **ii.** Patient has Rosai-Dorfman cutaneous disease.

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Kaposi Sarcoma. Approve for 1 year if the patient meets BOTH of the following (A and B):
- **A)** Patient has tried at least one medication; AND
  Note: Examples include liposomal doxorubicin, paclitaxel, Pomalyst (pomalidomide capsules), lenalidomide, and imatinib.
- **B)** Patient has relapsed or refractory disease.

7. **Myelofibrosis.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** According to the prescriber the patient has anemia; AND
     - **iii.** Patient has serum erythropoietin levels ≥ 500 mU/mL; OR
   - **B)** Patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** According to the prescriber the patient has anemia; AND
     - **iii.** Patient has serum erythropoietin levels < 500 mU/mL; AND
     - **iv.** Patient has experienced no response or loss of response to an erythropoiesis-stimulating agent.

8. **Prurigo Nodularis.** Approve for 1 year if the patient has tried at least two other medications.
   Note: Examples of medications include topical steroids, intralesional steroids, systemic steroids, topical tar, cyclosporine, macrolides, azathioprine, methotrexate, topical calcineurin inhibitors (Elidel [pimecrolimus cream], Protopic [tacrolimus ointment]), retinoids, antihistamines, hydroxyzine, dapsone, capsaicin, psoralen plus ultraviolet A therapy, and ultraviolet B therapy.

9. **Recurrent Aphthous Ulcers or Aphthous Stomatitis.** Approve for 1 year if the patient has tried at least two other medications.
   Note: Examples of medications include topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics (e.g., lidocaine 2% viscous solution, benzocaine lozenges), antimicrobial mouthwashes (e.g., tetracycline, chlorhexidine), topical sucralfate, acyclovir, pentoxifylline, dapsone, colchicine, and azathioprine.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Thalomid is not recommend in the following situations:

1. **Cancer Cachexia.** Several small studies are available that have investigated Thalomid in the management of cancer cachexia related to various cancers.[33-37] A single center double-blind, controlled trial randomized patients with pancreatic cancer who had lost at least 10% of their body weight to receive Thalomid or placebo for 24 weeks (n = 50).[34] Of the 33 patients evaluable at 4 weeks, patients given Thalomid had gained an average of 0.37 kg compared with a loss of 2.21 kg in the patients given placebo.[34] A published review of data regarding use of Thalomid for the management of cancer cachexia concluded that there is inadequate evidence to recommend Thalomid in clinical practice.[37]

2. **Crohn's Disease.** Several publications report use of Thalomid in patients with Crohn's disease.[38-54] Thalomid was used as an adjunctive therapy, or in those refractory to other therapy, and usually involved children. The data were not of high quality and primarily consisted of open-label designs or retrospective reviews, without a placebo control, and involved very few patients.[38-54] Guidelines from the American College of Gastroenterology (2018) for the management of Crohn's disease in adults do not mention Thalomid as a therapeutic alternative.[49] Also, guidelines from the American Gastroenterological Association (2021) do not mention Thalomid in the guidelines for the medical management of moderate to severe luminal and perianal fistulizing Crohn's Disease.[55] Although some improvements were noted

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in published data with Thalomid, more definite data from randomized, controlled trials are required before this is a recommended therapy.[49] Consensus guidelines of the European Crohn's and Colitis Organization and the European society of Pediatric Gastroenterology, Hepatology and Nutrition (2014) state that even though some data are available that suggest efficacy of Thalomid in refractory pediatric Crohn's disease, there are insufficient data to recommended Thalomid therapy at this juncture.[54] Many other therapies are available for the management of Crohn's disease.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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