OVERVIEW
Thalomid is indicated for use in combination with dexamethasone for the treatment of patients with newly diagnosed multiple myeloma. It is also indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL). It is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis. Thalomid is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence. Thalomid is usually given once daily and it is recommended to be given at bedtime and at least 1 hour after the evening meal. Thalomid has a Boxed Warning regarding embryo-fetal toxicity and venous thromboembolism. Thalomid is in Pregnancy Category X. The safety and effectiveness in pediatric patients < 12 years of age have not been established. Thalomid is available only through the THALOMID Risk Evaluation Mitigation Strategy (REMS) program. Males and females must follow the required reproductive precautions.

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Thalomid. In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist, oncologist, or dermatologist.

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

1) **Erythema Nodosum Leprosum (ENL).** Approve.

2) **Multiple Myeloma.** Approve.

3) **Discoid Lupus Erythematous or Cutaneous Lupus Erythematous.** Approve if the patient has tried two other therapies (e.g., corticosteroids [oral, topical, intralesional], antimalarial agents [e.g., hydroxychloroquine], topical calcineurin inhibitors [e.g., Protopic {tacrolimus ointment}, Elidel {pimecolimus cream}], azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, dapsone, and Soriatane [acitretin capsules]).

4) **Myelofibrosis and Post-PV or Post-ET MF.** Approve if patient meets the following criteria (a **and** b) **or** c:

   a) Patient with serum EPO <500 mU/mL; AND
   b) Patient has no response or loss of response to erythropoietic stimulating agents; OR
   c) Patient with serum EPO of ≥500 mU/mL
5) **Prurigo Nodularis.** Approve if the patient has tried two other therapies (e.g., topical steroids, intralesional steroids, systemic steroids, topical tar, cyclosporine, macrolides, azathioprine, methotrexate, topical calcineurin inhibitors [Elidel, Protopic], retinoids, antihistamines, hydroxyzine, dapsone, capsaicin, psoralen plus ultraviolet A [PUVA] therapy, ultraviolet B [UVB] therapy).

6) **Recurrent Aphthous Ulcers or Aphthous Stomatitis.** Approve if the patient has tried two other therapies and is immunocompromised (such as HIV or Bechet’s) (e.g., topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [e.g., lidocaine 2% viscous solution, benzocaine lozenges], antimicrobial mouthwashes [e.g., tetracycline, chlorhexidine], topical sulcralfate, acyclovir, pentoxifylline, dapsone, colchicine, and azathioprine).

7) **Waldenström’s Macroglobulinemia/Lymphoplasmacytic Lymphoma.** Approve.

8) **Systemic Light Chain Amyloidosis.** Approve.

9) **Castleman’s Disease.** Approve if the patient has relapsed/refractory or advanced disease.

10) **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation.** Prescriber will provide specific diagnosis for documentation. Approve.

11) **Patient has been started on Thalomid.** Approve for an indication or condition addressed as an approval in this document.

**Approval Duration**
Approval = 365 days (1 year)

**References**
1. Thalomid® capsules [prescribing information]. Summit, NJ: Celgene Corporation; August 2015.