MEDICAL MUTUAL®

Drug Policy

Policy:	Thalomid (thalidomide)	Annual Review Date: 01/21/2021 Last Revised Date: 01/21/2021

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, categorized in pregnancy category X, and venous thromboembolism. 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 in which patients (male and female) must follow the required reproductive precautions.

POLICY STATEMENT

This policy involves the use of Thalomid. Prior authorization is recommended for pharmacy benefit coverage of Thalomid. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Thalomid as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Thalomid be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist, dermatologist, or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1) Erythema Nodosum Leprosum (ENL)

Criteria. *Patient must meet the following criteria*

A. The patient meets one of the following:

i) Acute treatment of the cutaneous manifestations of moderate to severe ENL; OR

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ii) Maintenance therapy for prevention and suppression of cutaneous manifestations of ENL recurrence; AND

B. Thalomid is not being used as monotherapy for ENL in the presence of moderate to severe neuritis.

2) Multiple Myeloma

Criteria. *Patient must meet the following criteria*

A. Diagnosed with active (symptomatic) myeloma; OR

B. Disease relapse after 6 months following primary induction therapy with the same regimen; OR

C. Therapy for previously treated myeloma for relapse or progressive disease.

3) Myelofibrosis-Associated Anemia

Criteria. *Patient must meet the following criteria*

A. Serum EPO ≥500 mU/mL; OR

B. Serum EPO <500 mU/mL and no response or loss of response to erythropoietic stimulating agents

4) Castleman's Disease (CD)

Criteria. *Patient must meet ONE of the following criteria (A or B):*

A. The patient meets BOTH of the following:

i) The patient has been diagnosed with multicentric CD; AND

ii) Thalomid is being used as subsequent therapy for disease that has progressed following treatment of relapsed/refractory or progressive disease; OR

B. The patient meets ALL of the following:

i) The patient has been diagnosed with active idiopathic multicentric CD with no organ failure; AND

ii) Thalomid will be used in combination with cyclophsophamide and prednisone; AND

iii) The patient has hyaline vascular histology; AND

iv) The patient is HIV-negative and human herpes virus-8-negative

5) AIDS-Related Kaposi Sarcoma

Criteria. *Patient must meet the following criteria*

A. Thalomid is administered with antiretroviral therapy (ART); AND

B. The patient has relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; AND

C. Patient meets both of the following criteria:

i) Disease has progressed on or has not responded to first-line systemic therapy as defined by NCCN guidelines; AND

ii) Disease progressed on alternate first-line systemic therapy as defined by NCCN guidelines

6) 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

7) Patient has been started on Thalomid (continuation of therapy)

Approve for an indication or condition addressed as an approval in this document.

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Initial Approval/ Extended Approval
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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