

**THALOMID
(thalidomide)**

Pre - PA Allowance

None

Prior-Approval Requirements

Age 12 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Newly diagnosed multiple myeloma (MM)
 - a. Used in combination with dexamethasone
2. Erythema nodosum leprosum (ENL) **AND ONE** of the following:
 - a. Used for the acute treatment of the cutaneous manifestations of moderate to severe ENL
 - b. Used as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL

AND ALL of the following:

- a. Patient and prescriber must be enrolled and compliant with the **Thalomid REMS** program
- b. Females of reproductive potential **only**: patient must have **TWO** negative pregnancy tests before initiating Thalomid
- c. Females of reproductive potential **only**: patient will be advised to abstain continuously from heterosexual sexual intercourse or to use **TWO** methods of reliable birth control simultaneously for 4 weeks prior to initiation of Thalomid therapy, during therapy, during dose interruptions, and continuing for 4 weeks following the last dose
- d. Males with female partners of reproductive potential **only**: patient will be advised to use a latex or synthetic condom during treatment with Thalomid and for 4 weeks after the last dose, even if they have undergone a successful vasectomy
- e. Prescriber agrees to monitor for signs and symptoms of thromboembolism

Prior - Approval Limits

Quantity

Diagnosis	Dose Limit
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**THALOMID
(thalidomide)**

Multiple myeloma (MM)	200 mg per day OR
Erythema nodosum leprosum (ENL)	400 mg per day

Duration 12 months

Prior – Approval *Renewal* Requirements

Age 12 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Multiple myeloma (MM)
 - a. Used in combination with dexamethasone
 - b. **NO** disease progression or unacceptable toxicity
2. Erythema nodosum leprosum (ENL) **AND ONE** of the following:
 - a. Used for the acute treatment of the cutaneous manifestations of moderate to severe ENL
 - b. Used as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL

AND ALL of the following:

- a. Patient and prescriber must be enrolled and compliant with the **Thalomid REMS** program
- b. Females of reproductive potential **only**: patient will be advised to abstain continuously from heterosexual sexual intercourse or to use **TWO** methods of reliable birth control simultaneously during therapy, during dose interruptions, and for 4 weeks after the last dose
- c. Males with female partners of reproductive potential **only**: patient will be advised to use a latex or synthetic condom during treatment with Thalomid and for 4 weeks after the last dose, even if they have undergone a successful vasectomy
- d. Prescriber agrees to monitor for signs and symptoms of thromboembolism

Prior - Approval *Renewal* Limits

Same as above