



THALIDOMIDE (THALOMID[®]) UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS:	Immunomodulators
Generic (Brand) Name:	Thalidomide (Thalomid) 50mg; 100mg;150mg; 200mg capsules

FDA-APPROVED INDICATIONS:

- **Multiple Myeloma:** newly diagnosed multiple myeloma, in combination with dexamethasone
- **Erythema Nodosum Leprosum:** acute and maintenance therapy for cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL)
 - Thalidomide is not indicated as monotherapy for ENL treatment in the presence of moderate to severe neuritis.

COVERAGE AUTHORIZATION CRITERIA for thalidomide (Thalomid):

Thalidomide (Thalomid) is covered for the following conditions:

- Treatment or prevention of cutaneous lesions associated with erythema nodosum leprosum
- Treatment of leprosy with moderate to severe neuritis when thalidomide is used with concurrent corticosteroid therapy, in patients able to receive corticosteroids
- Treatment of multiple myeloma in combination with dexamethasone
- Treatment of Crohn's disease after failure of conventional therapy (e.g., corticosteroids, 5-aminosalicylates, azathioprine, 6-mercaptopurine, metronidazole, methotrexate) and/or TNF inhibitor
- Treatment of aphthous ulcers associated with HIV/AIDS disease.

BOXED WARNING:

SEVERE, LIFE-THREATENING HUMAN BIRTH DEFECTS

If thalidomide is taken during pregnancy, it can cause severe birth defects or death to an unborn baby. Thalidomide should never be used by women who are pregnant or who could become pregnant while taking the drug. Even a single dose [1 capsule (regardless of strength)] taken by a pregnant woman during her pregnancy can cause severe birth defects. Because of this toxicity and in an effort to make the chance of fetal exposure to thalidomide as negligible as possible, Thalomid is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called the "System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.[®])." Under this restricted distribution program, only prescribers and pharmacists registered with the program are allowed to prescribe and dispense the product. In addition, patients must be advised of, agree to, and comply with the requirements of the S.T.E.P.S. program in order to receive product. Please see the

prescribing information for additional information.

VENOUS THROMBOEMBOLIC EVENTS

The use of Thalomid in multiple myeloma results in an increased risk of venous thromboembolic events, such as deep venous thrombosis and pulmonary embolus. This risk increases significantly when thalidomide is used in combination with standard chemotherapeutic agents including dexamethasone. Patients and physicians are advised to be observant for the signs and symptoms of thromboembolism. Patients should be instructed to seek medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Preliminary data suggest that patients who are appropriate candidates may benefit from concurrent prophylactic anticoagulation or aspirin treatment.

DOSAGE:

Multiple Myeloma: 200 mg orally, once daily with water, preferably at bedtime, and at least 1 hour after the evening meal. May lower the dose as needed for intolerable side effects.

Erythema Nodosum Leprosum: 100 to 300 mg/day, once daily with water, preferably at bedtime, and at least 1 hour after the evening meal.

REFERENCES:

Drug Facts and Comparisons eAnswers. Wolters Kluwer. Accessed March 2011.

Thalomid. DRUGDEX Evaluations. Micromedex 2.0. Thomson Reuters. March 2011.

Thalomid ® (thalidomide) prescribing information. Celgene Corporation. Summit, NJ. August 2010.