



Prior Authorization Approval Criteria Department of Pharmacy Services

- Generic Name:** Thalidomide
- Brand Name:** Thalomid
- Medication Class:** Immunosuppressive agent
- FDA Approved Uses:**
- Erythema nodosum leprosum (ENL) - acute treatment and maintenance therapy for prevention and suppression of moderate to severe ENL.
 - Multiple Myeloma- Newly diagnosed multiple myeloma in conjunction with dexamethasone.
- Usual Dose:**
- ENL: 100mg-400mg once daily at bedtime or in divided doses.
Multiple Myeloma with dexamethasone in 28 day treatment cycles:
Thalidomide 200mg once daily. The dose of dexamethasone is 40 mg once daily on days 1-4, 9-12, and 17-20 every 28 days.
Multiple Myeloma as monotherapy: 200mg to a maximum of 800mg daily
- Duration of Therapy:**
- ENL: Therapy is continued until signs and symptoms of active reaction have subsided (usually about 2 weeks) and then therapy should be tapered by 50mg every 2-4weeks.
For prolonged maintenance treatment to prevent recurrence of cutaneous ENL or for those who flare during tapering, they should be maintained on the minimum dose allowed and tapering should be attempted every 3-6 months, in 50mg decrements every 2-4 weeks.
Multiple Myeloma: Until relapse
- Criteria for use:** *(bullet points below are all inclusive unless otherwise noted)*
- Clinically diagnosed erythema nodosum leprosum (ENL).
- OR
- Clinically diagnosed multiple myeloma that is refractory to other chemotherapeutic regimens.
- OR
- Clinically newly diagnosed multiple myeloma when used in conjunction with dexamethasone.
 - Must be administered in compliance with all of the terms outlined in the S.T.E.P.S* program.
 - Must be prescribed by a physician that is registered with the S.T.E.P.S program.
 - Women of childbearing age must meet all of the following conditions:
 - Alternative therapies have failed or are considered inappropriate.



- Understands and can reliably carry out instructions
 - Must be capable of complying with the mandatory contraceptive measures, pregnancy testing, patient registration, and patient survey as described in the S.T.E.P.S. program.
 - Has received both oral and written warnings of the hazards of taking thalidomide during pregnancy and exposing a fetus to the drug.
 - Has received both oral and written warnings about the need to use two forms of contraception or continuous abstinence from sexual contact and she acknowledges in written of her understanding of this.
 - Has a negative pregnancy test within 24 hours prior to beginning therapy.
 - For patients between 12 and 18 years of age, her parent or legal guardian must agree to the above.
- Men who are sexually mature must meet all of the following conditions:
 - Alternative therapies have failed or are considered inappropriate.
 - Understands and can reliably carry out instructions
 - Must be capable of complying with the mandatory contraceptive measures, pregnancy testing, patient registration, and patient survey as described in the S.T.E.P.S. program.
 - Has received both oral and written warnings of the hazards of taking thalidomide and exposing a fetus to the drug.
 - Has received both oral and written warnings about the presence of thalidomide in semen. The need to use a latex condom during any sexual contact with women of childbearing potential, even if he has undergone a vasectomy.
 - For patients between 12 and 18 years of age, his parent or legal guardian must agree to the above.
 - Patient must be 12 years of age or older since the safety and effectiveness has not been established in children under 12 years of age.

Criteria for Continuation of Use:

- Women of childbearing age must have pregnancy testing done once weekly during the first 4 weeks of treatment and then once every 4 weeks if the menstrual cycle is regular and once every 2 weeks if the menstrual cycle is irregular and the results must be negative each time.
- White blood cell count and differential should be monitored. If ANC decreases to below 750/mm³ while on treatment, consideration should be given to discontinuing therapy if neutropenia persists.

Contraindications:

- Pregnant women
- Women capable of becoming pregnant (see number 4 under guidelines for criteria).
- Hypersensitivity to the use of thalidomide.
- ANC < 750/mm³



Cautions:

- The use of thalidomide in multiple myeloma results in an increased risk of venous thromboembolic events. This risk significantly increased when used in combination with standard chemotherapeutic agents including dexamethasone.

Not approved if:

- Patient is pregnant.
- Patient does not meet the above stated criteria.
- Patient has any contraindications to the use of thalidomide.

*** System for Thalidomide Education and Prescribing Safety (S.T.E.P.S)** - Because of the toxicity and in an effort to make the chance of fetal exposure to thalidomide as negligible as possible, thalidomide is approved by the FDA. 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.

Any suspected fetal exposure to Thalomid must be reported immediately to the FDA via the MedWatch number at 1-800-FDA-1088 and also to Celgene Corporation.

P&T Approval: _____ Date: _____