### Thalomid®
#### Covered Medication

**Thalidomide (Thalomid®)**

#### What it does and How it's used

- Thalidomide is an immunomodulatory drug that exerts its actions through inhibiting angiogenesis (the formation of new blood vessels) and the production of an inflammatory protein known as tumor necrosis factor alpha (TNF-α).
- Thalidomide is indicated for use in the treatment of newly diagnosed multiple myeloma in combination with dexamethasone. Multiple myeloma is a blood cancer affecting plasma cells. Plasma cells are an essential part of the immune system and aid in fighting off infections. Multiple myeloma causes plasma cells to be ineffective in supporting normal immune system function.
- Thalidomide is also used for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (a.k.a. ENL; i.e., leprosy) and maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence. Thalidomide is used in combination with corticosteroids in leprosy patients to treat moderate to severe neuritis (inflammation of nerves).
- Conditions for which use of thalidomide may have benefit include:
  - Treatment of Crohn’s Disease. Crohn’s disease is characterized by inflammation of the gastrointestinal tract.
  - Treatment of myelofibrosis with myeloid metaplasia (MMM). MMM is a severe chronic myeloproliferative disorder.
  - Treatment of aphthous ulcers. Aphthous ulcers are painful lesions/sores of the mouth or esophagus that are caused by bacterial, viral, or fungal infections and have been associated with HIV/AIDS among other conditions.
- Additionally, thalidomide has been tried in the treatment of the following:
  - Treatment of AIDS-related cachexia or wasting syndrome to promote weight gain.
  - Treatment of ulcers or lesions associated with Behçet's syndrome which is characterized by a combination of oral ulcerations, genital ulcerations, skin lesions and inflammatory eye lesions.
  - Treatment of discoid lupus erythematosus (chronic condition characterized by inflammation and skin lesions).
  - Treatment of graft vs. host disease from bone marrow transplantation which is a condition where the donor bone marrow cells mount an immune attack against the recipient cells. Thalidomide can decrease IgM (antibody) synthesis causing a reduction in antibody production in response to antigenic stimuli (transplanted organ).
  - Treatment of prurigo nodularis (skin condition characterized by hard sores and intense itching).
  - Treatment of rheumatoid arthritis. Thalidomide is believed to decrease the generation of inflammatory mediators such as superoxide and hydroxyl radicals thus preventing tissue damage.
- Thalidomide is available for oral administration as 50 mg, 100 mg, 150 mg and 200 mg capsules through the special restricted distribution program called the S.T.E.P.S.® program. This program was developed due to the potential of severe, life-threatening birth defects associated with thalidomide use during pregnancy. Only providers and pharmacists registered with the S.T.E.P.S.® program are able to prescribe and dispense the product to patients who are registered and meet all the conditions of this program. In the S.T.E.P.S.® program, women of child-bearing age are required to take a pregnancy test on a monthly basis to certify they are not pregnant to avoid potentially severe birth defects. Patients are given a 28-day supply of thalidomide for each fill.
- Thalidomide may increase HIV RNA levels in HIV-seropositive patients. Viral load should be measured after the first and third months of treatment and every 3 to 4 months thereafter.
- Patients should be examined for the development of neuropathy at monthly intervals during the first 3 months of thalidomide therapy and periodically thereafter. Therapy should be discontinued in the presence of symptoms suggesting drug induced neuropathy if clinically appropriate.
What it costs

<table>
<thead>
<tr>
<th>How Supplied</th>
<th>AWP per capsule</th>
<th>Cost Per Month*</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mg capsule</td>
<td>$180</td>
<td>$8370-$19,080</td>
</tr>
<tr>
<td>100 mg capsule</td>
<td>$279</td>
<td></td>
</tr>
<tr>
<td>150 mg capsule</td>
<td>$298</td>
<td></td>
</tr>
<tr>
<td>200 mg capsule</td>
<td>$318</td>
<td></td>
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</tbody>
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*range based on dosage for all indications

- Recommended doses are 100 – 300 mg/day for an episode of cutaneous ENL. In patients with a severe cutaneous ENL reaction, a dose can be titrated up to 400 mg/day. Average treatment costs for cutaneous ENL per month at the recommended doses range from $ 8370 - $ 19,080.
- The recommended dose for treatment of multiple myeloma is 200 mg/day. Average treatment cost for multiple myeloma per month at the recommended dose (given every 28 days) is $9,540.

Rationale for Prior Authorization

To reduce exposure to cost associated with use for conditions for which the effectiveness of thalidomide is not known (conditions other than erythema nodosum leprosum, aphthous ulcers, Crohn's disease, myelofibrosis, or multiple myeloma).

Benefit Design

Coverage for thalidomide is determined through a prior authorization process for every claim

Prior Authorization Criteria

- Coverage is provided for the treatment or prevention of the cutaneous lesions associated with erythema nodosum leprosum (i.e., leprosy).
- Coverage is provided in leprosy patients with moderate to severe neuritis when thalidomide is used with concurrent corticosteroid therapy unless the patient is not a candidate to receive corticosteroids.
- Coverage is provided for use in the treatment of Crohn’s disease, multiple myeloma, myelofibrosis, or aphthous ulcers
- Coverage duration: 12 months. Benefit may be renewed.

References


Hello M, Barbarot S, Bastuji-Garin S et al. Use of thalidomide for severe recurrent aphthous stomatitis.
Medicine 2010; 89:176-182.


Thalidomide Capsules (Thalomid®) Prescribing Information. Summit, NJ.- Celgene Corp. 2/2012.


Wanke C. Singe-Agent/Combination Therapy of Human Immunodeficiency Virus-Related Wasting. Seminars in Oncology 1998;25(2,s):98-103

