

## Thalomid<sup>®</sup>

To initiate a Coverage Review, Call 1 800 753-2851

<b>Covered Medication</b>
Thalidomide ( <i>Thalomid</i> <sup>®</sup> )

<b>What It Does and How It's Used</b>
<ul style="list-style-type: none"> <li>➤ 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-<math>\alpha</math>).</li> <li>➤ Thalidomide is indicated for use in the treatment of newly diagnosed multiple myeloma in combination with dexamethasone. Multiple myeloma is a blood cancer effecting 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.</li> <li>➤ 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).</li> <li>➤ Conditions for which use of thalidomide may have benefit include:       <ul style="list-style-type: none"> <li>• Treatment of Crohn's disease. Crohn's disease is characterized by inflammation of the gastrointestinal tract.</li> <li>• Treatment of aphthous ulcers associated with HIV/AIDS. Aphthous ulcers are painful lesions/sores of the mouth or esophagus that are caused by bacterial, viral, or fungal infections.</li> </ul> </li> <li>➤ Additionally, thalidomide has been tried in the treatment of the following:       <ul style="list-style-type: none"> <li>• Treatment of AIDS-related cachexia or wasting syndrome to promote weight gain.</li> <li>• Treatment of ulcers or lesions associated with Behcet's syndrome which is characterized by a combination of oral ulcerations, genital ulcerations, skin lesions and inflammatory eye lesions.</li> <li>• Treatment of discoid lupus erythematosus (chronic condition characterized by inflammation and skin lesions).</li> <li>• 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).</li> <li>• Treatment of prurigo nodularis (skin condition characterized by hard sores and intense itching).</li> <li>• Treatment of rheumatoid arthritis. Thalidomide is believed to decrease the generation of inflammatory mediators such as superoxide and hydroxyl radicals thus preventing tissue damage.</li> </ul> </li> </ul> <p>Thalidomide is available for oral administration as 50-mg, 100-mg, and 200-mg capsules through the special restricted distribution program called the <i>S.T.E.P.S.</i><sup>®</sup> 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 <i>S.T.E.P.S.</i><sup>®</sup> program are able to prescribe and dispense the product to patients who are registered and meet all the conditions of this program. In the <i>S.T.E.P.S.</i><sup>®</sup> 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 furnished with a 28-day supply of thalidomide for each fill.</p>

<b>Rationale for Prior Authorization</b>
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 associated with HIV/AIDS, Crohn's disease, or multiple myeloma).

<b>Benefit Design</b>
Coverage for thalidomide is determined through a prior authorization process for every claim.

<b>Prior Authorization Criteria</b>
➤ 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, in patients able to receive corticosteroids.
- Coverage is provided for use in the treatment of Crohn's disease, multiple myeloma, or aphthous ulcers associated with HIV/AIDS disease.
- Coverage duration: 6 months. Benefit may be renewed.

### References

Bellomo A, Schorr-Lesnick B. Thalidomide treatment for idiopathic esophageal ulcers in patients with HIV. *Gastrointestinal Endoscopy*. 1996;44(6):729-30.

Eisenbud L. Recurrent aphthous stomatitis of Behcet's type: successful treatment with thalidomide. *Oral Medicine*. 1987;64:289-92.

Guitierrez-Rodriguez O. Thalidomide-A promising New Treatment for Rheumatoid Arthritis. *Arthritis and Rheumatism*. 1984;27(10):1118-21.

Guetierrez-Rodriguez O et al. Treatment of Refractory Rheumatoid Arthritis-The Thalidomide Experience. *The Journal of Rheumatology*. 1989;16(2):158-62.

Gunzler V. Thalidomide-A Therapy for the Immunological Consequences of HIV Infection? *Medical Hypotheses*. 1989;30:150-9.

Heney D, Bailey CC, Lewis IJ. Thalidomide in the treatment of graft-versus-host disease. *Biomed & Pharmacotherapy*. 1990;44:199-204.

Jasper MF. Chronic Cutaneous Lupus Erythematosus. *Arch Dermatology*. 1983;119:812-5.

Knop J et al. Thalidomide in the treatment of sixty cases of chronic discoid lupus erythematosus. *British Association of Dermatologists*. 1983;108:461-6.

Laine L, Bonacini M. Esophageal Disease in Human Immunodeficiency Virus Infection. *Arch Intern Med*. 1994;154:1577-82.

Larsson H. Treatment of severe colitis in Behcet's syndrome with thalidomide (CG-217). *Journal of Internal Medicine*. 1990;228:405-7.

Multiple Myeloma Research Foundation. Intro to Myeloma.  
[http://www.multiplemyeloma.org/about\\_myeloma/index.html](http://www.multiplemyeloma.org/about_myeloma/index.html) Accessed June 2, 2006

Naafs B et al. Thalidomide treatment of subacute cutaneous lupus erythematosus. *British Journal of Dermatology*. 1982;107:83-6.

Product Information: Thalidomide Capsules (*Thalomid*<sup>®</sup> - Celgene Corp.) 2006.

Ramselaar CG. Thalidomide in the treatment of neuro-Behcet's syndrome. *British Journal of Dermatology*. 1986;115:367-70.

Revus J et al. Crossover Study of Thalidomide vs Placebo in Severe Recurrent Aphthous Stomatitis. *Arch Dermatol*. 1990;126:923-7.

Sharpstone D et al. Thalidomide: A Novel Therapy for Microsporidiosis. *Gastroenterology*. 1997;112:1823-9.

Singhal S et al. Antitumor activity of Thalidomide in refractory multiple myeloma. *New England Journal of Medicine*. 1999;341:1565-71.

Soler RA et al. Regression of AIDS-Related Kaposi's Sarcoma During Therapy with Thalidomide. *Clinical Infectious Diseases*. 1996;23:501-3.

Vasiliauskas E. An Open-Label Pilot Study of Low-Dose Thalidomide in Chronically Active, Steroid-Dependent Crohn's Disease. *Gastroenterology*. 1999;177:1278-87.

Wanke C. Single-Agent/Combination Therapy of Human Immunodeficiency Virus-Related Wasting. *Seminars in Oncology*. 1998;25(2,6):98-103

Waters MFR. An internally-controlled Double Blind Trial of Thalidomide in Severe Erythema Nodosum Leprosum. *Lepr Rev*. 1971;42:26-42.

Yazici H, Barnes CG. Practical Treatment Recommendations for Pharmacotherapy of Behcet's Syndrome. *Drugs*. 1991;42(5):796-804.