

Revlimid™

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

Covered Medication
Lenalidomide (<i>Revlimid</i> ™)
What It Does and How It's Used
<ul style="list-style-type: none"> ➤ Myelodysplastic syndromes (MDS) are a group of diseases in which the bone marrow does not function normally, resulting in the production of malformed or immature blood cells. MDS eventually lead to transfusion dependence, increased risk of infection or hemorrhage, and increased potential for transformation to acute myeloid leukemia (AML). Adult acute myeloid leukemia (AML) is a cancer of the blood and bone marrow. It is a quickly progressing disease in which too many immature white blood cells are found in the blood and bone marrow. ➤ MDS has emerged as one of the most common groups of hematologic disorders effecting older adults. An estimated 7,000 to 12,000 new cases are diagnosed each year in the U.S. In the general population the occurrence of MDS is 5 per 100,000, while in those aged 70 and older, the incidence increases to 22 – 45 per 100,000. ➤ Patients with MDS present with dyspnea (difficulty breathing) due to anemia, infection due to neutropenia (decrease in specific white blood cells), or less frequently, with bleeding due to thrombocytopenia (decrease in platelets (clotting cells)) or a combination of all these. ➤ <i>Revlimid</i>™ has been shown to decrease the need for blood transfusions, the main treatment for MDS. Response is greatest in a certain type of MDS involving the deletion of chromosome 5q. ➤ Multiple myeloma is a cancer of the blood in which malignant plasma cells (white blood cells that help produce immunoglobulins that fight infections and disease) are overproduced in the bone marrow. Patients with multiple myeloma have plasma cells that produce an immuno-globulin called paraprotein (M protein) which has no benefit to the body. The malignant plasma cells will also begin to replace normal plasma cells and white blood cells in the body leading to infections and disease. The disease is also known to attach to other tissues in the body, like bone, and can lead to tumors in these locations. ➤ Multiple myeloma is the second most common blood cancer in the U.S. and affects approximately 50,000 people. An estimated 14,600 new cases are diagnosed each year in the U.S. Average survival time for patients with multiple myeloma is approximately 3 to 4 years. ➤ <i>Revlimid</i>™ possesses immunomodulatory and antiangiogenic properties. It is an analog of thalidomide thus it carries similar warnings of potentially causing severe, life-threatening human birth defects. ➤ The recommended initial dose of <i>Revlimid</i>™ for MDS is 10 mg once daily. The recommended dosage for multiple myeloma is 25 mg per day taken days 1-21 of repeated 28-day cycles. Dexamethasone 40 mg per day is used in combination with <i>Revlimid</i>™ for multiple myeloma taken on days 1-4, 9-12, and 17-20 of each 28 day cycle. <i>Revlimid</i>™ is available in 5-mg and 10-mg capsules for MDS and 15-mg and 25-mg capsules for multiple myeloma which is only available through the special restricted distribution program called <i>RevAssist</i>™. Providers and pharmacists registered with this program are able to prescribe and dispense the product to patients who are registered and meet all of the conditions of the <i>RevAssist</i>™ program.

Rationale for Coverage Authorization
To reduce costs associated with the use of <i>Revlimid</i> ™ for conditions other than MDS or multiple myeloma for which the effectiveness of <i>Revlimid</i> ™ is not known.

Benefit Design
Coverage for <i>Revlimid</i> ™ is determined through a traditional prior authorization process for every claim

Coverage Criteria

Coverage is provided for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS).

Coverage is provided for the treatment of patients with multiple myeloma in combination with dexamethasone.

Coverage duration: 6 months for MDS. Coverage may be renewed for MDS for and additional 6 months in situations where treatment with *Revlimid*TM is providing reductions in transfusion requirements.

Duration for multiple myeloma is 4 months. Coverage may be renewed for multiple myeloma.

References

Product Information: Lenalidomide (*Revlimid*TM) Celgene Corporation, 2006.

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National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology – v.3.2006. Myelodysplastic syndromes. Available from: http://www.nccn.org/professionals/physician_gls/PDF/mds.pdf. Accessed July 10, 2006.

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