STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

THALIDOMIDE

Generic	Brand	HICL	GCN	Exception/Other
THALIDOMIDE	THALOMID	11465		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma?

   If yes, continue to #2.
   If no, continue to #3.

2. Is Thalomid being used in combination with dexamethasone or prednisone?

   If yes, **approve for 12 months by HICL for #1 capsule per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of erythema nodosum leprosum (ENL)?

   If yes, **approve for 12 months by HICL for #2 capsules per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to myelodysplastic syndrome that has been previously treated?

   If yes, **approve for 12 months by HICL for #2 capsules per day.**
   If no, continue to #5.

5. Does the patient have a diagnosis of Waldenström's Macroglobulinemia?

   If yes, **approve for 12 months by HICL for #1 capsule per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Approval requires a diagnosis of multiple myeloma and that Thalomid is being used in combination with dexamethasone or prednisone; or a diagnosis of erythema nodosum leprosum (ENL); or a diagnosis of anemia due to myelodysplastic syndrome that has been previously treated; or a diagnosis of Waldenström's Macroglobulinemia.

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RATIONALE

To ensure appropriate use aligned with FDA approved indications and NCCN guidelines.

The FDA approved dose for multiple myeloma is 200mg once daily along with dexamethasone 40mg daily on days 1-4, 9-12, and 17-20 every 28 days. For cutaneous erythema nodosum leprosum the dosage is 100 to 300mg daily and up to 400mg daily for severe cases.

NCCN multiple myeloma treatment guidelines consider primary induction therapy for stem cell transplant candidates with lenalidomide in combination with dexamethasone, and thalidomide in combination with bortezomib and dexamethasone to have the strongest evidence. Other combinations involving bortezomib, lenalidomide or thalidomide are also considered effective. For primary induction therapy for non-transplant candidates in patients with newly diagnosed multiple myeloma, NCCN considers thalidomide and melphalan in combination prednisone, melphalan in combination with prednisone and bortezomib, and lenalidomide in combination with low-dose dexamethasone to have the strongest evidence. Other combinations involving melphalan, lenalidomide or thalidomide are also considered effective. For maintenance therapy following disease response in patients with newly diagnosed multiple myeloma who undergo stem cell transplant, NCCN considers thalidomide monotherapy to have the strongest evidence. Lenalidomide monotherapy, thalidomide in combination with prednisone and interferon monotherapy are also considered effective. For salvage therapy in patients who did not respond to or were ineligible for stem cell transplant, re-induction with the same regimen can be considered if the relapse occurs at greater than 6 months after completion of the initial induction therapy. NCCN considers lenalidomide in combination with dexamethasone to have the best evidence. Other therapies involving lenalidomide, thalidomide or bortezomib may be considered.

The NCCN myelodysplastic syndrome guidelines recognize thalidomide as a non-chemotherapy, low-intensity agent that has demonstrated efficacy in a phase II trial.

NCCN guidelines for Waldenström's Macroglobulinemia state that primary treatment options include oral alkylators, nucleoside analogs, rituximab alone or in combination with cyclophosphamide, bortezomib, nucleoside analogues, thalidomide, or bendamustine.

FDA APPROVED INDICATIONS

Thalomid in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myelomas. Thalomid is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL). Thalomid is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis. Thalomid is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

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REFERENCES

- Celgene Corporation. Thalomid package insert. Summit, NJ. February 2012.
- National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Multiple Myeloma. (Version 1.2012).
- National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Myelodysplastic Syndromes. (Version 1.2012).
- National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Waldenström's Macroglobulinemia / Lymphoplasmacytic Lymphoma. (Version 1.2012).

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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