Market Applicability/Effective Date

| Market | FL & FHK | FL MMA | FL LTC | GA | IND | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
|--------|----------|--------|--------|----|-----|----|----|----|----|----|----|----|----|----|----|----|
| Applicable | X | NA | NA | X | X | NA | X | X | X | X | X | X | X | NA | NA | X |

*FHK- Florida Healthy Kids

**Thalomid (thalidomide)**

<table>
<thead>
<tr>
<th>Override(s)</th>
<th>Approval Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization, Quantity Limit</td>
<td>1 year</td>
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<table>
<thead>
<tr>
<th>Medications</th>
<th>Strength</th>
<th>Quantity Limit</th>
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</thead>
<tbody>
<tr>
<td>Thalomid (thalidomide)</td>
<td>50mg, 100mg</td>
<td>1 capsule per day</td>
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<tr>
<td></td>
<td>150mg, 200mg</td>
<td>2 capsules per day</td>
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**APPROVAL CRITERIA**

Thalomid may be approved for the following indications, when accompanying criteria are met:

I. Multiple myeloma, when used in combination with a steroid, if tolerated;

II. Erythema nodosum leprosum (ENL):
   a. Acute treatment of moderate to severe disease; **OR**
   b. Prophylaxis therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence;

III. Non-Hodgkin Lymphoma (NHL) – Castleman’s Disease (NCCN);

IV. Waldenstrom’s macroglobulinemia/Lymphoplasmacytic Lymphoma (NCCN);

V. Systemic Light Chain Amyloidosis (NCCN);

VI. Erosive lichen planus (AHFS);

VII. Erythema multiforme (AHFS);

VIII. Lupus erythematosus (AHFS);

IX. Prurigo nodularis (AHFS);

X. Actinic prurigo (AHFS);

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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XI. Cutaneous Langerhans cell histiocytosis (AHFS);

XII. Uremic pruritus (AHFS);

XIII. Porphyria cutanea tarda (AHFS);

XIV. Pyoderma gangrenosum (AHFS);

XV. Cachexia (AHFS);

XVI. Graft vs host disease (AHFS);

XVII. Recurrent Aphthous Stomatitis (AHFS).

Thalomid (thalidomide) may not be approved for the following:

I. Use as monotherapy for ENL treatment in the presence of moderate to severe neuritis.

Note: Thalomid (thalidomide) has a black box warning for embryo-fetal toxicity and venous thromboembolism. Thalomid can cause severe birth defects or embryo-fetal death if taken during pregnancy. Thalomid should never be used by women who are pregnant or who could become pregnant while taking the drug. Thalomid distribution is restricted through the THALOMID REMS program (formerly known as the S.T.E.P.S. program). The use of Thalomid in multiple myeloma results in an increased risk of venous thromboembolism, such as DVT and pulmonary embolism. This risk is increased when used in combination with standard chemotherapeutic agents including dexamethasone. Thromboprophylaxis should be considered based on individual risk assessment.
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