



# Evolut Clinical Guideline 3221 for Thalomid™ (thalidomide)

<b>Guideline Number:</b> Evolut_CG_3221	<b><u>Applicable Codes</u></b>	
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## STATEMENT

### Purpose

To define and describe the accepted indications for Thalomid (thalidomide) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

## INDICATIONS

**Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided**

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

### Multiple Myeloma

- The member has multiple myeloma and Thalomid (thalidomide) is being used in any ONE of the following clinical situations:
  - In combination with Velcade (bortezomib) + Dexamethasone +/- Darzalex/Darzalex Faspro (daratumumab) as primary/initial line of therapy for transplant-eligible newly diagnosed multiple myeloma
  - As a part of VTD-PACE (bortezomib, dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen for relapsed/refractory multiple myeloma or as subsequent line of therapy
  - In DT-PACE (dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen for relapsed/refractory multiple myeloma.

## CONTRAINDICATIONS/WARNINGS

- Contraindications
  - Hypersensitivity to thalidomide or any component of the formulation
  - Pregnancy

- US Boxed Warning
  - Embryo-Fetal Toxicity
    - If thalidomide is taken during pregnancy, it may cause severe birth defects or embryo-fetal death. Thalidomide should never be used by females who are pregnant or who could become pregnant while taking thalidomide. Even a single dose (1 capsule [regardless of strength]) taken by a pregnant woman during pregnancy may cause severe birth defects.
    - Pregnancy must be excluded before start of treatment. Prevent pregnancy thereafter by the use of two reliable methods of contraception.
    - Because of this toxicity and in an effort to make the chance of embryo-fetal exposure to thalidomide as negligible as possible, thalidomide is approved for marketing only through a special restricted distribution program: Thalomid REMS program
  - Venous Thromboembolism
    - The use of thalidomide in multiple myeloma results in an increased risk of venous thromboembolism, such as deep venous thrombosis and pulmonary embolism. This risk increases significantly when thalidomide is used in combination with standard chemotherapeutic agents including dexamethasone.
    - Patients and physicians are advised to be observant for the signs and symptoms of thromboembolism. Instruct patients to seek medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Consider thromboprophylaxis based on an assessment of individual patients' underlying risk factors.

## EXCLUSION CRITERIA

- Member has disease progression on or after taking Thalomid (thalidomide).
- Dosing exceeds single dose limit of Thalomid (thalidomide) 200 mg.
- Treatment exceeds the maximum limit of Thalomid (thalidomide) 28 (50 mg), 28 (100 mg), 28 (150 mg), or 28 (200 mg) capsules/month.
- Investigational use of Thalomid (thalidomide) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3

months.

- Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
- That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
- That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
- That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

## **CODING AND STANDARDS**

### **Codes**

- J8999 - thalidomide

### **Applicable Lines of Business**

<input type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

## POLICY HISTORY

Date	Summary
November 2025	<ul style="list-style-type: none"> <li>● Converted to new Evolent guideline template</li> <li>● This guideline replaces UM ONC_1391 Thalomid (thalidomide)</li> <li>● Updated exclusion criteria</li> <li>● Updated references</li> </ul>
November 2024	<ul style="list-style-type: none"> <li>● Updated NCH verbiage to Evolent</li> <li>● Updated maximum dosage form quantities in exclusion criteria</li> </ul>

## LEGAL AND COMPLIANCE

### Guideline Approval

#### Committee

**Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee**

### Disclaimer

*Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.*

## REFERENCES

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