DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Thalomid Drug Quantity Management Policy – Per Rx
- Thalomid® (thalidomide capsules – Celgene)

REVIEW DATE: 09/18/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Thalomid, an immunomodulatory agent, is indicated for the following uses:[1]
- **Erythema nodosum leprosum (ENL)**, as acute treatment of cutaneous manifestations in moderate to severe disease. Thalomid is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.
- **ENL**, as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.
- **Multiple myeloma**, newly diagnosed, in combination with dexamethasone.

Dosing

For cutaneous ENL the recommended dose of Thalomid is 100 mg to 300 mg once daily (QD).[1] For severe cutaneous ENL reactions, doses up to 400 mg once daily may be used. Continue Thalomid until signs and symptoms of active reaction have subsided, usually a period of 2 weeks. Patients may then be tapered off Thalomid in 50 mg decrements every 2 to 4 weeks.

For multiple myeloma the recommended dose of Thalomid in combination with dexamethasone is 200 mg QD.[1]

To manage adverse events, dose reductions/modifications or discontinuation may be required in patients who develop Grade 3 or 4 adverse reactions.[1] Permanently discontinue Thalomid for angioedema, anaphylaxis, Grade 4 rash, skin exfoliation, bullae, or any other severe dermatologic reactions.

Availability

Thalomid is available as 50 mg and 100 mg capsules.[1] Thalomid capsules are supplied in blister packs of 28 capsules each. Previously, 150 mg capsules and 200 mg capsules were also available, but have been discontinued.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Thalomid. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Thalomid® (thalidomide capsules)	50 mg capsules	28 capsules	84 capsules
	100 mg capsules	112 capsules	336 capsules
	150 mg capsules (discontinued)	60 capsules	180 capsules
	200 mg capsules (discontinued)	60 capsules	180 capsules

Oncology – Thalomid Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Thalomid 50 mg capsules

1. If the patient has cutaneous erythema nodosum leprosum, approve the requested quantity, not to exceed 196 capsules per dispensing at retail and 588 capsules per dispensing at home delivery.
Note: The approval quantity allows for a dose of 350 mg once daily for 28 days at retail and 350 mg once daily for 84 days at home delivery.

Thalomid 100 mg capsules

No overrides recommended.

Thalomid 150 mg capsules (discontinued)

No overrides recommended.

Thalomid 200 mg capsules (discontinued)
No overrides recommended.

REFERENCES

1. Thalomid® capsules [prescribing information]. Summit, NJ: Celgene Corporation; March 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	A new policy was created to provide overrides to existing quantity limits. **Thalomid 50 mg capsule:** Quantity limits were changed to 28 capsules per dispensing at retail and 84 capsules per dispensing at home delivery (previous limits were 30 capsules per dispensing at retail and 90 capsules per dispensing at home delivery). An override for 196 capsules per dispensing at retail and 588 capsules per dispensing at home delivery is provided if the patient has cutaneous erythema nodosum leprosum. **Thalomid 100 mg capsule:** Quantity limits were changed to 112 capsules per dispensing at retail and 336 capsules per dispensing at home delivery (previous limits were 30 capsules per dispensing at retail and 90 capsules per dispensing at home delivery). No clinical overrides apply.	09/18/2024