DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Anti-Influenza – Oseltamivir Drug Quantity Management Policy – Per Rx
- Tamiflu® (oseltamivir capsules, powder for oral suspension – Genentech, generic)

REVIEW DATE: 03/11/2025

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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

Oseltamivir (Tamiflu, generic), a neuraminidase inhibitor, is indicated for the following uses:[1]
- **Treatment of influenza A and B infection**, for patients with acute, uncomplicated illness who are ≥ 2 weeks of age and who have been symptomatic for ≤ 48 hours.
- **Prophylaxis of influenza A and B infection**, in patients ≥ 1 year of age.

Limitations of Use: Oseltamivir is not recommended for patients with end-stage renal disease not undergoing dialysis.

Dosing

Treatment[1]

- Patients ≥ 13 years of age: 75 mg twice daily (BID) for 5 days.
- Patients 2 weeks of age through 12 years of age: weight-based dose administered BID. Refer to the table below for weight-based dosing.

Prophylaxis[1]

- Patients ≥ 13 years of age: 75 mg once daily (QD) for at least 10 days for household exposure and up to 6 weeks for community outbreak. Oseltamivir may be used for up to 12 weeks in immunocompromised patients.
- Patients 1 year to 12 years of age: weight-based dose administered QD. Use for 10 days for household exposure and up to 6 weeks during a community outbreak.

Of note, dose adjustments are required for patients with renal dysfunction for both treatment and prophylaxis with oseltamivir.[1]

Table 1. Oseltamivir Dosage Recommendations for Treatment and Prophylaxis of Influenza.[1]

Weight	Treatment Dosage for 5 days	Prophylaxis Dosing for 10 days	Volume of Oral Suspension (6 mg/mL) for each dose	Number of Bottles of Oral Suspension Needed to Complete Course	Number of Capsules needed to Complete Course
2 weeks to < 1 year of age					
Any weight	3 mg/kg BID	NA	0.5 mL/kg	1 bottle	NA
1 to 12 years of age					
15 kg or less	30 mg BID	30 mg QD	5 mL	1 bottle	10 x 30 mg capsules
15.1 kg – 23 kg	45 mg BID	45 mg QD	7.5 mL	2 bottles	10 x 45 mg capsules
23.1 kg – 40 kg	60 mg BID	60 mg QD	10 mL	2 bottles	20 x 30 mg capsules
≥ 40.1 kg	75 mg BID	75 mg QD	12.5 mL	3 bottles	10 x 75 mg capsules
≥ 13 years of age					
Any weight	75 mg BID	75 mg QD	12.5 mL	3 bottles	10 x 75 mg capsules

BID – Twice daily; NA – Not applicable; QD – Once daily.

Availability

Oseltamivir (Tamiflu, generic) is available as 30 mg, 45 mg, and 75 mg capsules in blister packs containing 10 capsules each.[1] It is also available as an oral suspension that is supplied as a powder, which after reconstitution delivers a total usable volume of 60 mL (6 mg/mL).

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of oseltamivir (Tamiflu, generic). 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 the duration noted below. "One-time" overrides are provided for 30 days in duration.

Drug Quantity Limits

Product	Strength	Retail and Home Delivery Maximum Quantity per Rx
Tamiflu® (oseltamivir capsules, generic)	30 mg capsules	20 capsules[α]
	45 mg capsules	10 capsules[†]
	75 mg capsules	10 capsules[†]
Tamiflu® (oseltamivir powder for oral suspension, generic)	6 mg/mL (60 mL bottles)	180 mL (3 bottles)[β]

[α] Twenty of the 30 mg capsules is a quantity sufficient for 5 days of treatment or 10 days of prophylaxis for patients who need a 30 mg or 60 mg dose; [†] Ten of the 45 mg or 75 mg capsules is quantity sufficient for 5 days of treatment or 10 days of prophylaxis; [β] Three 60 mL bottles of oral suspension is a quantity sufficient for 5 days of treatment or 10 days of prophylaxis for a patient who requires up to a 75 mg dose.

Anti-Influenza – Oseltamivir 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

1. Approve a one-time override for up to a total of 6 weeks of therapy at retail or home delivery if the patient meets ALL of the following (A, B, and C):
Note: Refer to the table below for override quantity.
A) Request for oseltamivir is between November 1st and March 31st; AND
B) According to the prescriber, there has been a CDC-confirmed outbreak in the patient's community; AND
C) Patient requires more than 10 days of influenza prophylaxis.

Product	Strength	Retail or Home Delivery Override Quantity
Tamiflu® (oseltamivir capsules, generic)	30 mg capsules	84 capsules
	45 mg capsules	42 capsules
	75 mg capsules	42 capsules
Tamiflu® (oseltamivir powder for oral suspension, generic)	6 mg/mL oral suspension (60 mL bottles)	540 mL (9 bottles)

2. Approve a one-time override for up to a total of 6 weeks of therapy at retail or home delivery if the patient meets ALL of the following (A, B, and C):
Note: Refer to the table below for override quantity.
A) Request for oseltamivir is between November 1st and March 31st; AND
B) Patient resides in a long-term care facility; AND
C) Patient requires more than 10 days of influenza prophylaxis.

Product	Strength	Retail or Home Delivery Override Quantity
Tamiflu® (oseltamivir capsules, generic)	30 mg capsules	84 capsules
	45 mg capsules	42 capsules
	75 mg capsules	42 capsules
Tamiflu® (oseltamivir powder for oral suspension, generic)	6 mg/mL oral suspension (60 mL bottles)	540 mL (9 bottles)

3. Approve a one-time override for up to a total of 12 weeks of therapy at retail or home delivery if the patient meets BOTH of the following (A and B):
Note: Refer to the table below for override quantity.
A) According to the prescriber, the patient is immunocompromised; AND
B) Patient requires more than 10 days of influenza prophylaxis.

Product	Strength	Retail or Home Delivery Override Quantity
Tamiflu® (oseltamivir capsules, generic)	30 mg capsules	168 capsules
	45 mg capsules	84 capsules
	75 mg capsules	84 capsules
Tamiflu® (oseltamivir powder for oral suspension, generic)	6 mg/mL oral suspension (60 mL bottles)	1,080 mL (18 bottles)

EXCLUSIONS

Approval of additional quantities of oseltamivir (Tamiflu, generic) is NOT recommended in the following situations:

1. No overrides are recommended for the treatment of influenza.
Note: The initial quantity limits allow for a quantity sufficient for one standard treatment course.

REFERENCES

1. Tamiflu® capsules, oral suspension [prescribing information]. South San Francisco, CA: Genentech; August 2019.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. **Oseltamivir 30 mg capsules (Tamiflu, generic):** Home delivery quantity limit changed from 60 capsules per dispensing to 20 capsules per dispensing. **Oseltamivir 45 mg and 75 mg capsules (Tamiflu, generic):** Home delivery quantity limit changed from 30 capsules per dispensing to 10 capsules per dispensing. **Oseltamivir 6 mg/mL powder for oral suspension (Tamiflu, generic):** Home delivery quantity limit changed from 9 bottles (540 mL) per dispensing to 3 bottles (180 mL) per dispensing.	03/29/2023
Annual Revision	No criteria changes.	03/28/2024
Annual Revision	Policy statement was updated to note that "one-time" approvals are provided for 30 days in duration.	03/11/2025

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