DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Cystic Fibrosis – Trikafta Drug Quantity Management Policy – Per Rx
- Trikafta® (elexacaftor/tezacaftor/ivacaftor tablets; ivacaftor tablets [co-packaged] and elexacaftor/tezacaftor/ivacaftor oral granules; ivacaftor oral granules [co-packaged] – Vertex)

REVIEW DATE: 06/03/2024

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

Trikafta is a combination of ivacaftor, a cystic fibrosis transmembrane regulator (CFTR) potentiator, tezacaftor, and elexacaftor. It is indicated for the **treatment of cystic fibrosis (CF)** in patients ≥ 2 years of age who have:
- At least one F508del mutation in the CFTR gene; OR
- A mutation in the CFTR gene that is responsive to Trikafta based on in vitro data.[1]

Dosing

The recommended dosage of Trikafta for adult and pediatric patients ≥ 2 years of age is provided in Table 1.[1] The morning and the evening dose should be taken approximately 12 hours apart. Dose reductions may be needed to manage hepatic impairment.

The entire contents of each packet of Trikafta oral granules should be mixed with one teaspoon (5 mL) of age-appropriate soft food or liquid that is at or below room temperature for administration.

Table 1. Recommended Dosage of Trikafta.[1]

Age	Weight	Morning Dose	Evening Dose	Quantity Needed per 28 Days	Quantity Needed per 84 Days
2 to < 6 years	< 14 kg	elexacaftor 80 mg/tezacaftor 40 mg/ivacaftor 60 mg (1 packet of oral granules)	ivacaftor 59.5 mg (1 packet oral granules)	56 packets	168 packets
	≥ 14 kg	elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg (1 packet of oral granules)	ivacaftor 75 mg (1 packet oral granules)	56 packets	168 packets
6 to < 12 years	< 30 kg	elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg (2 x 50 mg/25 mg/37.5 mg tablets **or** 1 x 100 mg/50 mg/75 mg packets)	ivacaftor 75 mg (1 tablet **or** 1 packet)	84 tablets **or** 56 packets	252 tablets **or** 168 packets
	≥ 30 kg	elexacaftor 200 mg/tezacaftor 100 mg/ ivacaftor 150 mg (2 x 100 mg/50 mg/75 mg tablets **or** 2 x 100 mg/50 mg/75 mg packets)	ivacaftor 150 mg (1 tablet **or** 2 x 75 mg packets)	84 tablets **or** 112 packets	252 tablets **or** 336 packets
≥ 12 years		elexacaftor 200 mg/tezacaftor 100 mg/ ivacaftor 150 mg (2 x 100 mg/50 mg/75 mg tablets **or** 2 x 100 mg/50 mg/75 mg packets)	ivacaftor 150 mg (1 tablet **or** 2 x 75 mg packets)	84 tablets **or** 112 packets	252 tablets **or** 336 packets

Availability

Trikafta is available as the following dosage forms:

- Fixed-dose tablets:
  - Elexacaftor 50 mg/tezacaftor 25 mg/ivacaftor 37.5 mg tablets co-packaged with ivacaftor 75 mg tablets. Each carton contains 84 tablets (56 combination tablets and 28 single tablets).
  - Elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg tablets co-packaged with ivacaftor 150 mg tablets. Each carton contains 84 tablets (56 combination tablets and 28 single tablets).
- Unit dose packets of oral granules:
  - Elexacaftor 80 mg, tezacaftor 40 mg, and ivacaftor 60 mg packets and ivacaftor 59.5 mg packets. Each carton contains 56 packets (28 combination packets and 28 single packets).
  - Elexacaftor 100 mg, tezacaftor 50 mg, and ivacaftor 75 mg packets and ivacaftor 75 mg packets. Each carton contains 56 packets (28 combination packets and 28 single packets).

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Trikafta. 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	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Trikafta® (elexacaftor/tezacaftor/ivacaftor tablets; ivacaftor tablets, co-packaged)	• Elexacaftor 50 mg/tezacaftor 25 mg/ivacaftor 37.5 mg tablets co-packaged with ivacaftor 75 mg tablets. • Each carton contains 84 tablets (56 combination tablets and 28 single tablets).	84 tablets	252 tablets
	• Elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg tablets co-packaged with ivacaftor 150 mg tablets. • Each carton contains 84 tablets (56 combination tablets and 28 single tablets).	84 tablets	252 tablets
Trikafta® (elexacaftor/tezacaftor/ivacaftor oral granules; ivacaftor oral granules, co-packaged)	• Elexacaftor 80 mg, tezacaftor 40 mg, and ivacaftor 60 mg packets co-packaged with ivacaftor 59.5 mg packets. • Each carton contains 56 packets (28 combination packets and 28 single packets).	56 packets	168 packets
	• Elexacaftor 100 mg, tezacaftor 50 mg, and ivacaftor 75 mg packets co-packaged with ivacaftor 75 mg packets. • Each carton contains 56 packets (28 combination packets and 28 single packets).	56 packets	168 packets

Cystic Fibrosis – Trikafta 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

Trikafta Oral Granules (elexacaftor 80 mg, tezacaftor 40 mg, ivacaftor 60 mg packets co-packaged with ivacaftor 59.5 mg packets)
No overrides recommended.

Trikafta Oral Granules (elexacaftor 100 mg, tezacaftor 50 mg, ivacaftor 75 mg packets co-packaged with ivacaftor 75 mg packets)

1. If the patient is 6 to 11 years of age and weighs ≥ 30 kg, approve the requested quantity, not to exceed 112 packets per dispensing at retail or 336 packets per home delivery.

2. If the patient is ≥ 12 years of age, approve the requested quantity, not to exceed 112 packets per dispensing at retail or 336 packets per home delivery.

Trikafta Tablets (elexacaftor 100 mg, tezacaftor 50 mg, ivacaftor 75 mg tablets co-packaged with ivacaftor 75 mg tablets)
No overrides recommended.

Trikafta Tablets (elexacaftor 50 mg/tezacaftor 25 mg/ivacaftor 37.5 mg tablets co-packaged with ivacaftor 75 mg tablets)
No overrides recommended.

REFERENCES

1. Trikafta® tablets and oral granules [prescribing information]. Boston, MA: Vertex; August 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	Quantity limits with no overrides were previously approved for Trikafta tablets. This policy creates new quantity limits for the Trikafta oral granules with overrides provided.	05/31/2023
Annual Revision	No criteria changes.	06/03/2024