

Clinical Policy: Elexacaftor/Ivacaftor/Tezacaftor; Ivacaftor (Trikafta)

Reference Number: GA.PMN.04

Effective Date: 10/2021

Last Review Date: 9/2025

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Elexacaftor/ivacaftor/tezacaftor (Trikafta™) is a triple combination drug for cystic fibrosis (CF).

- Elexacaftor and tezacaftor bind to different sites on the cystic fibrosis transmembrane conductance regulator (CFTR) protein and have an additive effect in facilitating the cellular processing and trafficking of select mutant forms of CFTR (including F508del-CFTR) to increase the amount of CFTR protein delivered to the cell surface compared to either molecule alone.
- Ivacaftor potentiates the channel open probability (or gating) of the CFTR protein at the cell surface.
- The combined effect of elexacaftor, tezacaftor, and ivacaftor is increased quantity and function of CFTR at the cell surface, resulting in increased CFTR activity as measured both by CFTR mediated chloride transport *in vitro* and by sweat chloride in patients with CF.

FDA Approved Indication(s)

Trikafta is indicated for the treatment of cystic fibrosis (CF) in patients aged 2 years and older who have at least one *F508del* mutation in the *CFTR* gene or a mutation in the *CFTR* gene that is responsive based on *in vitro* data.

If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one indicated mutation.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Trikafta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cystic Fibrosis (must meet all):

1. Diagnosis of CF confirmed by all of the following (a, b, and c):
 - a. Clinical symptoms consistent with CF in at least one organ system, or positive newborn screen or genetic testing for siblings of patients with CF;
 - b. Evidence of CFTR dysfunction confirmed by one of the following (i or ii) (*see Appendix D*):
 - i. Elevated sweat chloride ≥ 60 mmol/L;

- ii. Genetic testing confirming the presence of two disease-causing mutations in CFTR gene, one from each parental allele;
- c. Confirmation of one of the following (i or ii):
 - i. Member has at least one *F508del* mutation in the CFTR gene;
 - ii. Member has a mutation in the CFTR gene that is responsive to Trikafta based on *in vitro* data (see Appendix E);
- 2. Age \geq 2 years;
- 3. Prescribed by or in consultation with a pulmonologist;
- 4. Trikafta is not prescribed concurrently with other CFTR modulators (e.g., Alyftrek[®], Orkambi[®], Kalydeco[®], Symdeko[®]);
- 5. Dose does not exceed one of the following (a, b, c, d, or e):
 - a. Age 2 to < 6 years and weight < 14 kg (both i and ii):
 - i. Elexacaftor 80 mg/tezacaftor 40 mg/ivacaftor 119.5 mg per day;
 - ii. One packet (elexacaftor 80 mg/tezacaftor 40 mg/ivacaftor 60 mg) of oral granules and one packet (ivacaftor 59.5 mg) of oral granules per day;
 - b. Age 2 to < 6 years and weight \geq 14 kg (both i and ii):
 - i. Elexacaftor 100 mg/tezacaftor 50 mg/ ivacaftor 150 mg per day;
 - ii. One packet (elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg) oral granules and one packet (ivacaftor 75 mg) oral granules per day;
 - c. Age 6 to < 12 years and weight < 30 kg (both i and ii):
 - i. Elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 150 mg per day;
 - ii. 2 tablets (elexacaftor 50 mg/tezacaftor 25 mg/ivacaftor 37.5 mg) and 1 tablet (ivacaftor 75 mg) per day;
 - d. Age 6 to < 12 years and weight \geq 30 kg (both i and ii):
 - i. Elexacaftor 200 mg/tezacaftor 100 mg/ivacaftor 300 mg per day;
 - ii. 2 tablets (elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg) and 1 tablet (ivacaftor 150 mg) per day;
 - e. Age \geq 12 years (both i and ii):
 - i. Elexacaftor 200 mg/tezacaftor 100 mg/ivacaftor 300 mg per day;
 - ii. 2 tablets (elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg) and 1 tablet (ivacaftor 150 mg) per day.

Approval duration: 6 months

B. Other diagnoses/indications

- 1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Cystic Fibrosis (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy as evidenced by one of the following (a or b, *see Appendix D*):
 - a. Stabilization or improvement (e.g., increase) in ppFEV1 from baseline;
 - b. For age < 6 years: Stabilization or improvement (e.g., decrease) in LCI from baseline;
3. Trikafta is not prescribed concurrently with other CFTR modulators (e.g., Alyftrek®, Orkambi®, Kalydeco®, Symdeko®);
4. If request is for a dose increase, new dose does not exceed (a, b, c, d, or e):
 - a. Age 2 to < 6 years and weight < 14 kg (both i and ii):
 - i. Elexacaftor 80 mg/tezacaftor 40 mg/ivacaftor 119.5 mg per day;
 - ii. One packet (elexacaftor 80 mg/tezacaftor 40 mg/ivacaftor 60 mg) of oral granules and one packet (ivacaftor 59.5 mg) of oral granules per day;
 - b. Age 2 to < 6 years and weight ≥ 14 kg (both i and ii):
 - i. Elexacaftor 100 mg/tezacaftor 50 mg/ ivacaftor 150 mg per day;
 - ii. One packet (elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg) of oral granules and one packet (ivacaftor 75 mg) of oral granules per day;
 - c. Age 6 to < 12 years and weight < 30 kg (both i and ii):
 - i. Elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 150 mg per day;
 - ii. 2 tablets (elexacaftor 50 mg/tezacaftor 25 mg/ivacaftor 37.5 mg) and 1 tablet (ivacaftor 75 mg) per day;
 - d. Age 6 to < 12 years and weight ≥ 30 kg (both i and ii):
 - i. Elexacaftor 200 mg/tezacaftor 100 mg/ivacaftor 300 mg per day;
 - ii. 2 tablets (elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg) and 1 tablet (ivacaftor 150 mg) per day;
 - e. Age ≥ 12 years (both i and ii):
 - i. Elexacaftor 200 mg/tezacaftor 100 mg/ivacaftor 300 mg per day;
 - ii. 2 tablets (elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg) and 1 tablet (ivacaftor 150 mg) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information*Appendix A: Abbreviation/Acronym Key*

ACFLD: advanced cystic fibrosis lung disease

CF: cystic fibrosis

CFF: Cystic Fibrosis Foundation

CFTR: cystic fibrosis transmembrane conductance regulator

FDA: Food and Drug Administration

ppFEV1: percent predicted forced expiratory volume in 1 second

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- The Cystic Fibrosis Foundation (CFF) Mutation Analysis Program (MAP) available here: <https://www.cff.org/medical-professionals/mutation-analysis-program>. The MAP is a free and confidential genetic testing program for people with a strongly suspected or confirmed diagnosis of CF.
- Regarding the diagnostic criteria for CF:
 - The Cystic Fibrosis Foundation (CFF) guidelines state that CFTR dysfunction needs to be confirmed with an elevated sweat chloride ≥ 60 mmol/L.

- “Genetic testing confirming the presence of two disease-causing mutations in CFTR gene” is used to ensure that whether heterozygous or homozygous, there are two disease-causing mutations in the CFTR gene, one from each parental allele. One of those two mutations must be an *F508del* mutation but does not necessarily require both.
- Most children can do spirometry by age 6, though some preschoolers are able to perform the test at a younger age. Some young children aren’t able to take a deep enough breath and blow out hard and long enough for spirometry.

Appendix E: CFTR Gene Mutations that are Responsive to Trikafta

List of CFTR Gene Mutations that are Responsive to Trikafta				
Mutations responsive to Trikafta based on clinical data*				
2789+5G→A	D1152H [†]	L206W [†]	R1066H [†]	S945L [†]
3272-26A→G	F508del [†]	L997F [†]	R117C [†]	T338I [†]
3849+10kbC→T	G85E [†]	M1101K [†]	R347H [†]	V232D [†]
A455E [†]	L1077P [†]	P5L [†]	R347P [†]	
Mutations responsive to Trikafta based on in vitro data [‡]				
N1303K	F200I	I1139V	P574H	S1045Y
1507 1515del9	F311del	I125T	P67L	S108F
2183A→G	F311L	I1269N	P750L	S1118F
3141del9	F508C	I1366N	Q1291R	S1159F
546insCTA	F508C;S1251N	I148N	Q1313K	S1159F
A1006E	F575Y	I148T	Q237E	S1235R
A1067P	F587I	I175V	Q237H	S1251N
A1067T	G1047R	I331N	Q359R	S1255P
A107G	G1061R	I336K	Q372H	S13F
A120T	G1069R	I502T	Q493R	S341P
A234D	G1123R	I506L	Q552P	S364P
A309D	G1244E	I556V	Q98R	S492F
A349V	G1247R	I601F	R1048G	S549I
A46D	G1249R	I618T	R1070Q	S549N
A554E	G126D	I807M	R1070W	S549R
A62P	G1349D	I980K	R1162L	S589N
C491R	G178E	K1060T	R117C;G576A;R668C	S737F
D110E	G178R	K162E	R117G	S912L
D110H	G194R	K464E	R117H	S977F
D1270N	G194V	L1011S	R117L	T1036N
D1445N	G27E	L1324P	R117P	T1053I
D192G	G27R	L1335P	R1283M	T1086I
D443Y	G314E	L137P	R1283S	T1246I
D443Y;G576A;R668C	G424S	L1480P	R170H	T1299I

List of CFTR Gene Mutations that are Responsive to Trikafta				
D565G	G463V	L15P	R258G	T351I
D579G	G480C	L165S	R297Q	V1153E
D614G	G480S	L320V	R31C	V1240G
D836Y	G551A	L333F	R31L	V1293G
D924N	G551D	L333H	R334L	V201M
D979V	G551S	L346P	R334Q	V392G
D993Y	G576A	L441P	R347L	V456A
E116K	G576A;R668C	L453S	R352Q	V456F
E116Q	G622D	L619S	R352W	V562I
E193K	G628R	L967S	R516S	V603F
E292K	G970D	M1137V	R553Q	V754M
E403D	G970S	M150K	R555G	W1098C
E474K	H1054D	M152V	R668C	W1282R
E56K	H1085P	M265R	R709Q	W361R
E588V	H1085R	M952I	R74Q	Y1014C
E60K	H1375P	M952T	R74W	Y1032C
E822K	H139R	N1088D	R74W;D1270 N	Y109N
E92K	H199Y	N1303I	R74W;V201M	Y161D
F1016S	H620P	N186K	R74W;V201M ;D1270N	Y161S
F1052V	H620Q	N187K	R751L	Y301C
F1074L	H939R	N418S	R75L	Y563N
F1099L	H939R;H949L	P140S	R75Q	
F1107L	I1027T	P205S	R792G	
F191V	I105N	P499A	R933G	
Mutations responsive to Trikafta based on extrapolation from Trial 5 [§]				
4005+2T→C	2789+2insA	3849+40A→G	5T;TG13	
1341G→A	296+28A→G	3849+4A→G	621+3A→G	
1898+3A→G	3041-15T→G	3850-3T→G	711+3A→G	
2752-26A→G	3600G→A	5T;TG12	E831X	

* Clinical data obtained from Trials 1, 2, and 5.

† This mutation is also predicted to be responsive by FRT assay.

‡ The N1303k mutation is predicted to be responsive by HBE assay. All other mutations predicted to be responsive with in vitro data are supported by FRT assay.

§ Efficacy is extrapolated from Trial 5 to non-canonical splice mutations because clinical trials in all mutations of this subgroup are infeasible and these mutations are not amenable to interrogation by FRT system.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CF	Pediatric patients age 2 to less than 6 years weighing less than 14 kg: <ul style="list-style-type: none"> <u>Morning dose</u>: One packet (containing elexacaftor 80 mg/tezacaftor 40 mg/ivacaftor 60 mg oral granules) 	Age 2 to 6 years weighing less than 14 kg: elexacaftor 80 mg/tezacaftor 40 mg

Indication	Dosing Regimen	Maximum Dose
	<ul style="list-style-type: none"> <u>Evening dose</u>: One packet (containing ivacaftor 59.5 mg oral granules) <p>Pediatric patients age 2 to less than 6 years weighing 14 kg or more:</p> <ul style="list-style-type: none"> <u>Morning dose</u>: One packet (containing elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg oral granules) <u>Evening dose</u>: One packet (containing ivacaftor 75 mg oral granules) <p>Pediatric patients age 6 years to less than 12 years weighing less than 30 kg:</p> <ul style="list-style-type: none"> <u>Morning dose</u>: 2 tablets (each containing elexacaftor 50 mg/tezacaftor 25 mg/ivacaftor 37.5 mg) <u>Evening dose</u>: 1 tablet of ivacaftor 75 mg <p>Adults, pediatric patients age 12 years and older, or pediatric patients age 6 years to less than 12 years weighing 30 kg or more:</p> <ul style="list-style-type: none"> <u>Morning dose</u>: 2 tablets (each containing elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg) <u>Evening dose</u>: 1 tablet of ivacaftor 150 mg <p>Morning and evening dose should be taken PO approximately 12 hours apart with fat-containing food</p>	<p>mg/ivacaftor 119.5 mg per day</p> <p>Age 2 to 6 years weighing 14 kg or more and pediatric patients, or age 6 years to less than 12 years weighing less than 30 kg: elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 150 mg per day</p> <p>Adults, pediatric patients age 12 years and older, or pediatric patients age 6 years to less than 12 years weighing 30 kg or more: elexacaftor 200 mg/tezacaftor 100 mg/ivacaftor 300 mg per day</p>

VI. Product Availability

- Tablets: co-packaged fixed dose combination containing elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg and ivacaftor 150 mg; co-packaged fixed dose combination containing elexacaftor 50 mg/tezacaftor 25 mg/ivacaftor 37.5 mg and ivacaftor 75 mg
- Unit-dose packets containing oral granules: fixed dose combination containing elexacaftor 100 mg, tezacaftor 50 mg, and ivacaftor 75 mg co-packaged with ivacaftor 75 mg; fixed dose combination containing elexacaftor 80 mg, tezacaftor 40 mg, ivacaftor 60 mg co-packaged with ivacaftor 59.5 mg

VII. References

- Trikafta Prescribing Information. Boston, MA: Vertex Pharmaceuticals, Inc.; April 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217660s000lbl.pdf. Accessed May 4, 2023.

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3. Farrell PM, White TB, Ren CL, et al. Diagnosis of cystic fibrosis: consensus guidelines from the Cystic Fibrosis Foundation. *J Pediatr*. 2017 Feb;181S:S4-S15.e1.
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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10/2021	10/2021
4Q 2022 annual review. No changes made. References reviewed and updated.	10/2022	10/2022
Template changes applied to other diagnoses/indications and continued therapy section; revised criteria to include pediatric expansion and new granule formulation; updated Appendix D to include information on LCI; references reviewed and updated.	7/2023	7/2023
4Q 2023 annual review. No changes made.	10/2023	10/2023
Revised Appendix D to remove information on advanced Cystic Fibrosis disease.	4/2024	4/2024
4Q 2024 annual review: for continued therapy, clarified positive response as an “improvement” (e.g., decrease) of LCI and improvement of ppFEV1 as an “increase from baseline”; for Appendix D, updated LCI supplemental information; references reviewed and updated.	9/2024	9/2024
4Q 2025 annual review: Removed lung clearance index from criteria to align with competitor analysis and standard of care; for initial approval criteria, updated approval duration from 4 months to 6 months. RT4: added new indication to criteria for non-F508del	9/2025	9/2025

Reviews, Revisions, and Approvals	Date	P&T Approval Date
mutation responsive to Trikafta based on clinical data; for Appendix E, updated list of CFTR gene mutations responsive to Trikafta per prescriber information. Added Alyftrek to list of CFTR modulator concurrent exclusion criteria; references reviewed and updated.		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

CLINICAL POLICY

Elexacaftor/Ivacaftor/Tezacaftor; Ivacaftor



Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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