

Clinical Policy Title:	Elexacaftor/ivacaftor/tezacaftor
Policy Number:	RxA.523
Drug(s) Applied:	Trikafta®
Original Policy Date:	09/05/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Cystic Fibrosis (must meet all):

1. Diagnosis of CF;
2. Member has at least one of the following mutations in the CFTR gene (a or b);
 - a. At least one F508del mutation;
 - b. A mutation that is responsive based on in vitro data;
3. Trikafta® is not prescribed concurrently with other CFTR modulators (e.g., Orkambi®, Kalydeco®, Symdeko®);

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Cystic Fibrosis (must meet all):

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met initial approval criteria;
2. Trikafta® is not prescribed concurrently with other CFTR modulators (e.g., Orkambi®, Kalydeco®, Symdeko®);

Approval Duration

All Lines of Business (except Medicare): 12 months

References

Not Applicable

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	09/05/2020	09/14/2020
Policy was reviewed: 1. Initial Approval Criteria I.A.1 was updated to remove "...with genetic testing confirming the presence of two disease causing mutations in CFTR gene." 2. Initial Approval Criteria I.A.2 was updated to include "Member has at least one of the	07/08/2021	09/14/2021

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>following mutations in the CFTR gene (a or b)...”.</p> <ol style="list-style-type: none"> 3. Initial Approval Criteria I.A.2.a was updated to include “At least one F508del mutation;”. 4. Initial Approval Criteria I.A.3 was updated from “Age ≥ 12 years” to “Age ≥ 6 years”. 5. Initial Approval Criteria I.A.7.a was updated to include “6 years to less than 12 years weighing less than 30 kgs: elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 150 mg per day”. 6. Initial Approval Criteria I.A.7.b was updated to include “6 years to less than 12 years weighing 30 kgs or more & 12 years and older: elexacaftor 200 mg/tezacaftor 100 mg/ivacaftor 300 mg per day”. 7. Initial Approval Criteria I.A.7 was updated to remove “Moderate hepatic impairment: elexacaftor 200 mg/tezacaftor 100 mg/ivacaftor 150 mg per day”. 8. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 9. Continued Therapy Criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance...”. 10. Continued Therapy Approval Criteria II.A.2 was updated to include “...both of the following (a and b)...”. 11. Continued Therapy Approval Criteria II.A.2.a was updated to include “Stabilization in ppFEV1 if baseline was ≥ 70% or increase in ppFEV1 if baseline was < 70%”. 12. Continued Therapy Approval Criteria II.A.2.b was updated to include “Increase in chloride transport ≥ 10% since baseline”. 13. Continued Therapy Approval Criteria II.A.4.a was updated to include “6 years to less than 12 years weighing less than 30 kgs...”. 14. Continued Therapy Approval Criteria II.A.4.b was updated to include “6 years to less than 12 years weighing 30 kgs or more & 12 years and older...”. 15. References were reviewed and updated. 		
<p>Policy was reviewed: 1. References were reviewed and updated.</p>	<p>04/05/2022</p>	<p>07/18/2022</p>
<p>Policy was reviewed:</p>	<p>04/28/2023</p>	<p>07/13/2023</p>

<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.3: Updated age criteria from Age ≥ 6 years to Age ≥ 2 years. 2. Initial Approval Criteria I.A.4: Updated to add prescriber requirement for a specialist affiliated with a CF care center. 3. Initial Approval Criteria, I.A.5: Updated to remove prior criteria pertaining to indication “cystic fibrosis, Chart notes indicate that pulmonary function tests, performed within the last 90 days, show a percent predicted forced expiratory volume in 1 second (ppFEV1) that is between 40-90%.” 4. Initial Approval Criteria, Commercial and Medicaid Approval duration were updated from 6 months to 12 months. 5. Continued Therapy Criteria II.A.2.b: Updated to remove increase in chloride transport ≥ 10% since baseline. 6. Continued Therapy Approval Criteria, II.A.2: Updated pertaining to indication “cystic fibrosis” from Member is responding positively to therapy; as evidenced by the stabilization in ppFEV1 if baseline was ≥ 70% or increase in ppFEV1 if baseline was < 70% to Member is responding positively to therapy. 7. References were reviewed and updated. 		
<p>Policy was reviewed.</p>	<p>10/19/2023</p>	<p>10/19/2023</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed prescriber criteria. 2. Removed age criteria. 3. Removed dosing criteria. 4. Updated continuation of therapy language. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 	<p>03/20/2025</p>	<p>04/10/2025</p>
<p>Policy reviewed.</p>	<p>12/11/2025</p>	<p>12/11/2025</p>