

<b>Clinical Policy Title:</b>	CFTR Modulators
<b>Policy Number:</b>	RxA.887
<b>Drug(s) Applied:</b>	Alyftrek, Trikafta
<b>Original Policy Date:</b>	6/19/2025
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Cystic Fibrosis (must meet all):

1. Diagnosis of cystic fibrosis confirmed by sweat chloride  $\geq 30$ mmol/L;
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.

#### Approval duration

**All Lines of Business (except Medicare):** 12 months

### II. Continued Therapy Approval

#### A. Cystic Fibrosis (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

#### Approval duration

**All Lines of Business (except Medicare):** 12 months

## References

1. Farrell PM, et al. Diagnosis of Cystic Fibrosis: Consensus Guidelines from the Cystic Fibrosis Foundation. J Pediatr. 2017.
2. HIGHLIGHTS of PRESCRIBING INFORMATION.  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2024/218730s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218730s000lbl.pdf)

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	6/19/2025	6/19/2025
Policy reviewed	12/11/2025	12/11/2025

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.