Clinical Policy Title:	elexacaftor/ivacaftor/tezacaftor; ivacaftor
Policy Number:	RxA.523
Drug(s) Applied:	Trikafta®
Original Policy Date:	09/05/2020
Last Review Date:	10/19/2023
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. Age ≥ 2 years;
4. Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center;
5. Trikafta® is not prescribed concurrently with other CFTR modulators (e.g., Orkambi®, Kalydeco®, Symdeko®);
6. Dose does not exceed any of the following (a, b, c or d)):
   a. 2 years to less than 6 years weighing less than 14 kgs: elexacaftor 80 mg/tezacaftor 40 mg/ivacaftor 119.5 mg;
   b. 2 years to less than 6 years weighing 14 kgs or more: elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 150 mg;
   c. 6 years to less than 12 years weighing less than 30 kgs: elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 150 mg (2 tablets elexacaftor 50 mg/tezacaftor 25 mg/ivacaftor 37.5 mg and 1 tablet ivacaftor 75 mg) per day;
   d. 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 (2 tablets elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg and 1 tablet ivacaftor 150 mg) per day;

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Trikafta® is not prescribed concurrently with other CFTR modulators (e.g., Orkambi®, Kalydeco®, Symdeko®);
4. If request is for a dose increase, new dose does not exceed any of the following (a, b, c or d):

a. 2 years to less than 6 years weighing less than 14 kgs: elexacaftor 80 mg/tezacaftor 40 mg/ivacaftor 119.5 mg;
b. 2 years to less than 6 years weighing 14 kgs or more: elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 150 mg;
c. 6 years to less than 12 years weighing less than 30 kgs: elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 150 mg (2 tablets elexacaftor 50 mg/tezacaftor 25 mg/ivacaftor 37.5 mg and 1 tablet ivacaftor 75 mg) per day;
d. 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 g (2 tablets elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg and 1 tablet ivacaftor 150 mg) per day;

Approval Duration
Commercial: 12 months
Medicaid: 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 following mutations in the CFTR gene (a or b)…". 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".	07/08/2021	09/14/2021

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.		
Policy was reviewed: 1. References were reviewed and updated.	04/05/2022	07/18/2022
Policy was reviewed: 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:	04/28/2023	07/13/2023

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.		
Policy was reviewed.	10/19/2023	10/19/2023