Trikafta® (elexacaftor/tezacaftor/ivacaftor; ivacaftor), Symdeko® (tezacaftor/ivacaftor; ivacaftor), Kalydeco® (ivacaftor) – Expanded indication, label updates

- On December 21, 2020, Vertex announced the FDA approval of Trikafta (elexacaftor/tezacaftor/ivacaftor; ivacaftor), for the treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (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 *F508del* mutation or a mutation that is responsive based on *in vitro* data.
- Trikafta was previously only approved for people with at least one *F508del* mutation and is now approved for 177 additional mutations.
- In addition, Symdeko (tezacaftor/ivacaftor; ivacaftor) and Kalydeco (ivacaftor) also received approvals to include additional responsive mutations in people with CF ages 6 years and older and age 4 months and older, respectively.
    - Symdeko is now approved for 127 additional mutations, for a total of 154 Symdeko-responsive mutations; and Kalydeco is now approved for an additional 59 mutations, for a total of 97 Kalydeco-responsive mutations.
    - In addition, for certain people with CF who are currently eligible for Kalydeco, this approval allows them to also be eligible for Symdeko or Trikafta; and similarly, for those who are currently eligible for Symdeko, this approval allows them to also be eligible for Trikafta.
- The full list of mutations for Trikafta, Symdeko and Kalydeco can be found within the updated full drug labels for each respective product.
- According to Vertex, over 600 more people with CF are now eligible for treatment based on these approvals.
- The recommended dosage of Trikafta is two tablets (each containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg) taken in the morning and one ivacaftor tablet (containing ivacaftor 150 mg) taken in the evening, administered orally, approximately 12 hours apart.
- Refer to the drug labels for Symdeko and Kalydeco for their respective dosage recommendations.

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