Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

Trikafta™ (Elexacaftor/ivacaftor/tezacaftor; ivacaftor) PA

Trikafta is indicated for the treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one F508del mutation in the CFTR gene.

CRITERIA:

Select the diagnosis:

☐ Cystic fibrosis (CF); ICD-10 code(s): _____

Initial authorization: 6 months

Prior authorization will be considered for patients when **ALL** the following criteria are met:

☐ Yes ☐ No Age of patient is within the age range as recommended by the FDA label; ***AND***

☐ Yes ☐ No Diagnosis of CF; ***AND***

☐ Yes ☐ No Prescribed by or in consultation with a CF specialist/pulmonologist specializing in treating CF patients.

a. Name of CF treating or consulting specialist/pulmonologist:

_____

b. Provide chart documentation from consulting provider including name, strength and dosing instructions of CF drug:

_____

AND

☐ Yes ☐ No Patient has at least one *F508del* mutation in the CFTR gene.

- If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of at least one F508del mutation; ***AND***

☐ Yes ☐ No Trikafta is not prescribed concurrently with other CFTR modulators (e,g., Orkambi®, Kalydeco®, Symdeko®); ***AND***

☐ Yes ☐ No Baseline measures submitted by provider of **ALL** of the following:

a. For age appropriate patients, percent predicted expiratory volume in 1 second (ppFEV1):_____

b. Body mass index (BMI):_____

c. Pulmonary exacerbations- number in preceding 6 months: _____

AND

☐ **Yes** ☐ **No** Dose does not exceed elexacaftor 200 mg/tezacaftor 100 mg/ivacaftor 300mg (2 tablets elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg and 1tablet ivacaftor 150 mg) per day

<u>Reauthorization</u>: 12 months with evidence of appropriate clinical response to therapy

□ Yes □ No Prescribed by or in consultation with a CF specialist/ pulmonologist who specializes in treating CF patients.

a. Name of CF treating/consulting specialist/pulmonologist:

_____

b. Provide chart documentation from consulting provider including name, strength, and dosing instruction of CF drug:

AND

□ Yes □ No Trikafta is not prescribed concurrently with other CFTR modulators (e,g., Orkambi®, Kalydeco®, Symdeko®);

_____

AND

□ Yes □ No Provider attests that the patient has achieved a clinically meaningful response while on Trikafta based on **ALL** of the following:

a. For age appropriate patients, improved or stable lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1): _____

b. Body mass index (BMI):_____

c. Pulmonary exacerbations- number of exacerbations compared to number of exacerbations prior to medication initiation:_____

AND

□ Yes □ No If request is for a dose increase, new dose does not exceed 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.

<u>How Supplied:</u>

<u>84-count tablet carton</u>

<u>(4 wallets, each wallet containing 14 tablets of elexacaftor, tezacaftor and ivacaftor and 7 tablets of ivacaftor)</u>