

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to [Section H](#) of the Pharmaceutical Schedule. For community funding, see the [Special Authority Criteria](#).

PRESCRIBER

PATIENT:

Name:

Name:

Ward:

NHI:

Elxacaftor with tezacaftor, ivacaftor and ivacaftor

INITIATION

Prerequisites (tick boxes where appropriate)

- Patient has been diagnosed with cystic fibrosis
- and
- Patient is 6 years of age or older
- and
- Patient has two cystic fibrosis-causing mutations in the cystic fibrosis transmembrane regulator (CFTR) gene (one from each parental allele)
- or
- Patient has a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis or by Macroduct sweat collection system
- and
- Patient has a heterozygous or homozygous F508del mutation
- or
- Patient has a G551D mutation or other mutation responsive in vitro to elxacaftor/tezacaftor/ivacaftor (see note a)
- and
- The treatment must be the sole funded CFTR modulator therapy for this condition
- and
- Treatment with elxacaftor/tezacaftor/ivacaftor must be given concomitantly with standard therapy for this condition

Note:

- a) Eligible mutations are listed in the Food and Drug Administration (FDA) Trikafta prescribing information https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212273s004lbl.pdf

I confirm that the above details are correct:

Signed: Date: