HOSPITAL MEDICINES LIST
RESTRICTIONS CHECKLIST

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

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Elexacaftor 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 elexacaftor/tezacaftor/ivacaftor (see note a)

and

- ○ The treatment must be the sole funded CFTR modulator therapy for this condition

and

- ○ Treatment with elexacaftor/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://nctr-crs.fda.gov/fdalabel/services/spl/set-ids/f354423a-85c2-41c3-a9db-0f3aee135d8d/spl-doc

I confirm that the above details are correct:

Signed: ..... Date: .....