

APPLICANT (stamp or sticker acceptable) **PATIENT NHI:** **REFERRER** Reg No:

Reg No: First Names: First Names:

Name: Surname: Surname:

Address: DOB: Address:

..... Address:

.....

Fax Number: Fax Number:

Elexacaftor with tezacaftor, ivacaftor and ivacaftor

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

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 the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:
Post application to Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz