

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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz