

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)

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