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 | PATIENT: | |
|------------|----------|--|
| Name: | Name: | |
| Ward: | NHI: | |

Elexacaftor with tezacaftor, ivacaftor and ivacaftor

INITIATION

| requis | ites | (tick boxes where appropriate) | | |
|--------|---|--|--|--|
| and | 0 | Patient has been diagnosed with cystic fibrosis | | |
| and | 0 | Patient is 6 years of age or older | | |
| | or | O Patient has two cystic fibrosis-causing mutations in the cystic fibrosis transmembrane regulator (CFTR) gene (one from each parental allele) | | |
| | | O Patient has a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis or by Macroduct sweat collection system | | |
| and | and | | | |
| | or | O Patient has a heterozygous or homozygous F508del mutation | | |
| | | O Patient has a G551D mutation or other mutation responsive in vitro to elexacaftor/tezacaftor/ivacaftor (see note a) | | |
| and | O The treatment must be the sole funded CFTR modulator therapy for this condition | | | |
| and | Ο | Treatment with elexacaftor/tezacaftor/ivacaftor must be given concomitantly with standard therapy for this condition | | |
| e: | | | | |
| | | stations are listed in the Food and Drug Administration (FDA) Trikafta prescribing information -crs.fda.gov/fdalabel/services/spl/set-ids/f354423a-85c2-41c3-a9db-0f3aee135d8d/spl-doc | | |