OFFICE of the DEPUTY PRIME MINISTER
MINISTRY for HEALTH
15, PALAZZO CASTELLANIA, MERCHANTS STREET, VALLETTA, MALTA

DH CIRCULAR No. 38/2021
DH 646/2021

5th July 2021

Attention All: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: New Cystic Fibrosis Treatment

As part of Government's strategy to continue increasing the accessibility of medicines, it is being brought to your attention that the following cystic fibrosis treatment is now available on the Government Formulary List for in-patient and out-patient use:

- Ivacaftor 150mg Tablets
- Ivacaftor 188mg + Lumacaftor 150mg Granules
- Ivacaftor 150mg + Tezacaftor 100mg Tablets
- Ivacaftor 75mg + Tezacaftor 50mg + Elexacaftor 100mg Tablets

All the medicines above are protocol regulated and can be prescribed by Consultant Paediatric Respiratory Medicine and/or Consultant Respiratory Physicians. Requests should also be counter-signed by 2 other physicians as described in the respective protocols attached (Annex 1, 2, 3 and 4).
Treatment will be strictly monitored and audited.

For your attention please.

Dr Denis Vella Baldacchino
Chief Medical Officer

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Ivacaftor 150mg Tablets

Prescriber Criteria: Consultant Paediatric Respiratory Medicine
Consultant Respiratory Physician

Outpatient and Inpatient use:

1. Cystic Fibrosis

To be used:

- In patients aged 6 months and over, with cystic fibrosis who have a CFTR gene mutation.
- In conjunctive with Ivacaftor/Tezacaftor/Elexacaftor for Cystic fibrosis patients aged 12 years and over, who are either homozygous or heterozygous for *F508del* with a minimal function mutation.

Request should be counter-signed by the Lead Respiratory Physician or delegated specialist nominated by the Lead Clinician, and a second Consultant Respiratory Physician or Consultant Paediatrician as applicable.

Duration of Approval:
1 year

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Ivacaftor 188mg + Lumacaftor 150mg Granules

Prescriber Criteria: Consultant Paediatric Respiratory Medicine

Outpatient and Inpatient use:

1. Cystic Fibrosis

To be reserved for paediatric cystic fibrosis patients aged 2 years and above who are homozygous for the *F508del* mutation in the CFTR gene.

Request should be counter-signed by the Lead Respiratory Physician or delegated specialist nominated by the Lead Clinician, and a second Consultant Respiratory Physician or Consultant Paediatrician as applicable.

Duration of Approval:
1 year

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Ivacaftor 150mg + Tezacaftor 100mg Tablets

Prescriber Criteria: Consultant Paediatric Respiratory Medicine
Consultant Respiratory Physician

Outpatient and Inpatient use:

1. Cystic Fibrosis

To be used in combination with Ivacaftor 150mg tablets for Cystic Fibrosis patients aged 6 years and older who are:

- Homozygous for the *F508del* mutation in the CFTR gene
- Heterozygous for *F508del* mutation in the CFTR gene and have a mutation in the CFTR gene*: P67L, R117C, L206W, R352Q, A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G,* and *3849+10kbC→T.*

Request should be counter-signed by the Lead Respiratory Physician or delegated specialist nominated by the Lead Clinician, and a second Consultant Respiratory Physician or Consultant Paediatrician as applicable.

Duration of Approval:
1 year

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Ivacaftor 75mg + Tezacaftor 50mg + Elexacaftor 100mg Tablets

Prescriber Criteria: Consultant Paediatric Respiratory Medicine
Consultant Respiratory Physician

Outpatient and Inpatient use:

1. Cystic Fibrosis

To be used in combination with Ivacaftor 150mg tablets for Cystic Fibrosis patients aged 12 years and older who are:

- Homozygous for the *F508del* mutation in the CFTR gene.
- Heterozygous for *F508del* mutation in the CFTR gene with a minimal function mutation.

Request should be counter-signed by the Lead Respiratory Physician or delegated specialist nominated by the Lead Clinician, and a second Consultant Respiratory Physician or Consultant Paediatrician as applicable.

Duration of Approval:
1 year