CPS10278

MEDICATION MANAGEMENT OF COMBINATION THERAPY IVACAFTOR, TEZACAFTOR AND ELEXACAFTOR FOR CYSTIC FIBROSIS PATIENTS WITH THE F508del MUTATION BY THE HOSPITAL PHARMACY IN A CENTRAL GENERAL HOSPITAL

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WHAT WAS DONE?

A Phase 3, open-label clinical trial (CT) with 3 enrolled patients runs since April 2019 and two early access (EA) programs with 23 enrolled patients run since the end of July 2020 to permit the access of cystic fibrosis (CF) patients with the F508del mutation in **the innovative combination therapy of ivacaftor, tezacaftor and elexacaftor (IVA/TEZA/ELEXA)** in our hospital.

WHY WAS IT DONE?

In our hospital is located **the main CF Unit for Adults in Greece**. Ensuring that as many as possible young patients benefit from accessing the new and crucial treatment, even during COVID-19 period, reflects our commitment to improve patients' outcomes and overall survival.

HOW WAS IT DONE?

• For **3 outpatients** that enrolled **in the CT** and procedures regarding the protocol have been followed strictly. Medication dispensing is conducted every 12 weeks.

• **In the EA procedure**, **2 parallel programs** have been approved by authorities, one for the heterozygous including 19 patients and one for the homozygous including 4 patients. Dispensing is programmed every 4 weeks, although an initial stock for 3 months was shipped to pharmacy.

•The role of HPs was decisive for the quick start of the EA programs during COVID-19 period.

•Roadmap was designed at the beginning by HPs in collaboration with the physicians
• **to accelerate approval and shipment procedures**
•licensing for each patient,
•drug receipt, storage, dispensing, accountability,
•electronic registry in designated EA platform
•and additional electronic recording and follow up in the electronic Pharmacy platform for both **the IVA/TEZA/ELEXA and supporting therapies (e.g. inhaled antibiotics, a-dornase)**

•For 17 EA patients with chronic obstructive pulmonary disease in exacerbation, hospitalization before starting the IVA/TEZA/ELEXA therapy was necessary. HPs monitored closely their medication cards to avoid adverse reactions and delays in therapy.

•HPs served all outpatients on personal afternoon appointments, to avoid overcrowding in the hospital during the pandemic.

WHAT WAS ACHIEVED?

Critically ill patients have been able to receive in priority the IVA/TEZA/ELEXA treatment, without cost and with optimal safety standards, as well as valuable scientific experience has been gained.

WHAT IS NEXT?

• EA programs have received 3 months extension until reimbursement negotiations are completed by authorities.

• In the meantime, we design a cost affordable procedure to ensure continuity of access for our patients.

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