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Circular 019/17 1 June 2017.

Ref: Centralised Approval Process for Orkambi/Kalydeco

Dear Pharmacist,

The purpose of this circular is to highlight the centralised approval process put in place for a newly approved High Tech Medicine, Orkambi and for additional presentations of Kalydeco. This is a very significant investment in Cystic Fibrosis treatments for patients and requires prudent stewardship to ensure avoidable expenses are not incurred.

As with Ivacaftor (Kalydeco), hospitals have been requested to forward all High Tech Prescriptions for Ivacaftor/Lumacaftor (Orkambi) to the HSE PCRS High Tech Co-ordination Unit for prior authorisation. Please note that Local High Tech Liaison Officers are not involved with this centralised process.

When approved by the HSE PCRS High Tech Co-ordination Unit, the patient nominated pharmacy will be informed when they can order the product using a specific patient authorisation number provided by the HSE PCRS High Tech Co-ordination Unit.

Vertex has been informed that they cannot deliver Orkambi to a community pharmacy unless the patient specific authorisation code is referenced.

If a patient presents to you with a prescription and you have not already been contacted by the HSE, please forward a copy to the High Tech Co-ordination Unit at PCRS.HiTech@hse.ie (preferred mechanism) or alternatively fax the prescription to 01 891 4899 ensuring the Pharmacy Contractor number and telephone contact details are provided to enable as timely a response as possible.

It is probable that this manual process will become more IT enabled in the coming months and we will keep you updated in this regard.

The codes for the new additions to the High Tech List of Reimbursable Items are as follows:

PROPRIETARY NAME INDEX	NON-PROPRIETARY NAME	
		CODE
Kalydeco Sachets, Oral Granules 50 mg. 56 (A)	Ivacaftor	88797
Code the number of sachets dispensed		
Kalydeco Sachets, Oral Granules 75 mg. 56 (A)	Ivacaftor	88799
Code the number of sachets dispensed		
Orkambi Film Coated Tabs. 200 mg./125 mg. 112 (A)	Ivacaftor and Lumacaftor	88791

Yours faithfully,

Anne Marie Hoey,

Que Marie Droy

Primary Care Reimbursement & Eligibility.