

David Ramsden
Chief Executive
Cystic Fibrosis Trust

Specialised Commissioning
NHS England
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30 June 2020

Dear David

Triple Combination Therapy: Interim Access Agreement

I am writing to confirm that NHS England has reached a commercial agreement with Vertex Pharmaceuticals that extends the existing interim access agreement for ivacaftor (Kalydeco®), lumacaftor-ivacaftor (Orkambi®) and tezacaftor-ivacaftor (Symkevi®) to include the triple combination therapy, elexacaftor-tezacaftor-ivacaftor, expected to be licensed under the name Kaftrio.

Clinicians will be free to start prescribing the triple combination therapy to English NHS patients from the point that the European marketing authorisation is granted. NHS England has also ensured that Vertex will offer equivalent terms for cystic fibrosis patients in Wales, Northern Ireland and Scotland should those devolved administrations wish to adopt them.

As well as ensuring that all patients can access the therapy in its European licensed indications (including any future licence extensions), the terms of the deal also mean that clinicians will be free to start prescribing the triple combination therapy and other drugs in the portfolio for certain patients with rare mutations that are covered by the U.S. Food & Drug Administration's licensing decisions. This makes the deal we have secured amongst the most comprehensive access arrangements of any country in Europe.

The deal is supported by the National Institute for Health & Care Excellence (NICE)- the internationally renowned body for assessing the clinical and cost effectiveness of new treatments and technologies. It will last for 4 years and allow for further data to be collected to better understand the impact for patients of this new treatment option, as well as Orkambi® and Symkevi®. Prices of all three products will then be adjusted as necessary, following full NICE appraisal, to ensure that tax payers and the NHS continue to get a fair deal and there is continued access for patients.

Because the European licence for the triple combination therapy will only cover patients who are 12 years and older at this stage, younger children will continue to benefit from the previous deal struck by NHS England, giving them continued access to Kalydeco®, Orkambi® and Symkevi® where clinically appropriate. If and when the licence for the triple combination therapy is extended to younger age groups, access will be automatic.



This agreement is the latest in a growing catalogue of commercial access deals benefiting thousands of patients that have been put in place over the past 18 months following NHS England's establishment of a new commercial medicines function, led by Blake Dark.

I know for the thousands of people living every day with cystic fibrosis and who have been shielding throughout the COVID-19 pandemic that this medicine cannot receive its licence soon enough.

I look forward to catching up with you very soon as we begin an exciting new chapter in our shared goal of improving outcomes and quality of life for people with CF in this country. The CF Trust will, of course, have a critical role to play in supporting the data collection aspects of this agreement through the CF Registry.

Yours sincerely



John Stewart

National Director, Specialised Commissioning
NHS England