

## What is cystic fibrosis?

Cystic fibrosis (CF) is the most common fatal genetic disease affecting children and young adults in Canada. Around 4400 Canadians living with this disease. There is no cure. On average, we will lose one Canadian with CF per week, with a median age of 30.

## What is Trikafta?

Trikafta is a gene modulator with the potential to treat up to 90% of Canadians with cystic fibrosis. It represents the single biggest advancement in treating CF in the history of the disease and has been proven to significantly improve health outcomes. The drug has received regulatory approval in 32 countries and public reimbursement in the United States, United Kingdom, Ireland, Austria, Denmark, Germany, and Slovenia. However, the drug is still not available on Canadian public plans.

## Where is Trikafta in the drug approval and reimbursement process?

Trikafta is currently undergoing an aligned review by Health Canada and Health Technology Assessment agencies. This means that the Canadian Agency for Drugs and Technologies in Health (CADTH) and The Institut national d'excellence en santé et en services sociaux (INESSS) are assessing it while Health Canada is performing a priority review of the drug for safety and efficacy. This is helping expedite the regulatory approvals in order to make sure the drug gets to patients as soon as possible. Health Canada's priority review means Health Canada is committed to finalize their process by June 22 of this year. CADTH has announced that they will have their draft recommendation completed by June 30.

## What is next?

For Trikafta to be added to the public formulary, it needs to be negotiated by the pan-Canadian Pharmaceutical Alliance. If successful, a letter of intent (LOI) is created. The LOI lists the terms and conditions for funding a drug which are used to create a product listing agreement (PLA) between each participating member jurisdiction and the manufacturer. The pCPA has been re-negotiating with the manufacturer since June 2020 for two earlier generation of modulator drugs: Orkambi and Kalydeco.

## THE ROAD TO ACCESS



## What you can do to help...

Raise the importance of quick access to Trikafta with the Minister of Health (*Question Period is a good opportunity*).  
Ask them to commit to listing Trikafta on **public record**.

Ask the Minister to acknowledge the urgency that this file deserves and use their position and influence at the pCPA level to make sure Trikafta is negotiated **quickly**.

Work with your colleagues to build on the **all-party support** that we have to date.