Cystic Fibrosis Canada | FURTHER

Updated: April 2022

Improve access to life-changing cystic fibrosis medicines now

Cystic Fibrosis Canada's Recommendations

We're urging all Members of Provincial Parliament (MPPs) to call on the Minister of Health and Premier to:

1) Provide unrestricted access to Health Canada-approved cystic fibrosis modulators Trikafta, Orkambi, and Kalydeco, and to commit to expanding access to Trikafta for eligible patients who are six and older.
2) Make Ontario public drug programs more affordable for Ontario families affected by cystic fibrosis by reducing the cost of deductibles to be in line with Canada's more affordable provinces and territories.
3) Take a leadership role by working with your provincial and territorial counterparts and the federal government to follow-through on earlier commitments to develop a nation-wide rare disease strategy.

Background

- Accelerated and affordable access to medications is crucial to maintaining and improving the health and well-being of Canadians with cystic fibrosis. There are new highly effective medicines that treat the basic defect of cystic fibrosis, rather than just the symptoms, and which significantly improve the health outcomes and quality of life of people diagnosed with CF.

- There are over 2,000 mutations associated with cystic fibrosis. First-in-kind, genetically tailored disease-modifying therapies such as Trikafta, Kalydeco, Orkambi and Symdeko are precision medicines approved by Health Canada that have been shown to work well in some people with cystic fibrosis. Trikafta is the newest disease-modifying therapy and can treat up to 90% of the cystic fibrosis population. It was approved by Health Canada and reimbursed in Ontario for people aged 12 and above in 2021.

- Recently published real-world evidence from *the PROMISE Study* shows that Trikafta has significant health benefits to those who have lung function of 90% or greater. Trikafta has recently been approved by Health Canada for use in children aged 6-11 years old.

- Despite a promise from Health Minister Christine Elliott to *"ensure all cystic fibrosis patients will have more timely access to the effective and lifechanging treatments they need"*[1], only some Ontarians who could benefit from these drugs can access them. Not all Ontarians are eligible for full or partial public coverage.

- While Trikafta – and other CF disease-modifying drugs – are being funded in Ontario, too many people are falling through the cracks due to unnecessary red tape. With the new Health Canada indication for 6-11 year olds, the situation will only get worse: if the 90% lung function requirement is applied to these children, at least 70 % would not be able to access this life-changing drug.

Unrestricted Access

- Unlike some other provinces, such as Alberta, Saskatchewan, Manitoba and New Brunswick, Ontario is using non-binding CADTH recommendations to limit access to Trikafta. Ontario is also limiting access to other modulators Orkambi and Kalydeco. For example, Ontario currently requires people with cystic fibrosis to have lung function that is 90% or less in order to access Trikafta.

- Although Ontario has committed to reviewing anyone with a lung function greater than 90% on a case-by-case basis through its Exceptional Access Program (EAP), this requirement could prevent almost 30% of those currently indicated for the drug, aged 12 years or older, from accessing it. With the new Health Canada approval for children aged 6-11 years, at least 70% of these children could be left behind. This would be similar to denying a stage 2 cancer patient from access to medicine because they are not in stage 3 or worse.

- Cystic Fibrosis Canada has published standardized care guidelines for modulator use in Canada. Developed and endorsed by Canadian cystic fibrosis clinicians, these guidelines provide important information on best practice use of the modulator drugs when treating cystic fibrosis patients in Canada. Cystic fibrosis clinicians are experts in cystic fibrosis care and in partnership with their patients should decide who needs access to these therapies, not government.

[1] Government of Ontario. (2021, September 24). *Ontario Providing Access to Lifechanging Treatment for Cystic Fibrosis Patients*

Affordability of medicines

- Too many Ontarians do not have access to Trikafta and other modulators because they simply cannot afford the drugs, either through public or private drug plans. The Ontario Trillium Drug Program was designed to support people and families that spend a large part of their income on prescription medications, 4% or more of after-tax household income. Compared to other Canadian jurisdictions with similar drug programs, Ontario has one of the least affordable programs of this kind in Canada.

- Moreover, many Canadian jurisdictions are providing access to Trikafta for free for eligible patients who meet the required clinical criteria. Among those provinces that do charge a deductible, Ontario is the second highest as detailed.

Comparable public drug program deductibles for CFTR modulators		
Province	**Annual household income – $25K**	**Annual household income – $125K**
Manitoba	~ $1,180/year	~ $8,723/year
Ontario	~ $1,008/year	~ $5,008/year
New Brunswick	~ $460/year	~ $4,120/year
Quebec	~ $1,803/year	~ $1,803/year
Alberta	~ $1,091/year	~ $1,506/year

- For the first time in the history of CFTR modulators, Canada's public drug plans have moved faster to cover Trikafta than most private drug plans. This has created some unintended consequences for Ontarians with private insurance plans.

- For example, Ontario's OHIP+ has created inequities in the system. OHIP+ does not provide coverage to people under the age of 25 if they have private insurance. This forces those with private insurance to be formally denied coverage in order to access cystic fibrosis treatments through the Trillium Drug Program. These families are then left with difficult choices that can require a family to pay unaffordable deductibles, cancel their private insurance, wait months or years for private coverage, or forego treatments altogether.

- It is unacceptable that Ontario can't provide more affordable access to these medicines to more people when so many other Canadian jurisdictions do. Ontario's approach to funding these therapies is costing people their health and, in some cases, potentially their lives. The longer people wait to access these medicines, the more irreversible damage is done.

Nation-wide strategy for rare disease drugs

- Canada and Ontario's broken drug access system fails to prioritize precision medicines for rare diseases, like cystic fibrosis, which is limiting and delaying access to disease modifying therapies. Except Trikafta, the current drug access pathway can take years, is duplicative, and onerous for precision medicines and drugs for rare diseases. Our governments should commit to developing and implementing a shared strategy to improve access to medicines for rare diseases immediately.

- In 2017, Ontario began to implement a rare disease framework – however, to date, little of this work has progressed. Similarly, the federal government announced in 2019 that it would partner with provinces and territories to develop a national strategy for high-cost rare diseases. We need Ontario to build on this momentum, play a leadership role, and provide rare disease therapies to those who need them.

- Such a strategy must create an accelerated and affordable drug access pathway for rare disease drugs like Trikafta, reduce duplication in the health system, and ensure timely and equitable patient access to new life-changing and life-saving rare disease medicines that Canadians need.