Submission to the Canadian Drug Agency (CDA) Consultation on the Proposed List of Essential Prescription Drugs and Related Products

Canadian Pulmonary Fibrosis Foundation

Breathing should never be hard work©

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Overview

The Canadian Pulmonary Fibrosis Foundation (CPFF) is pleased to submit this response to the Canadian Drug Agency's consultation on the proposed list of essential prescription drugs and related products. This submission focuses on the critical case for **supplementary oxygen therapy**—a life-sustaining treatment for people living with pulmonary fibrosis and other chronic respiratory diseases—which is currently excluded from the essential medicines list due to legacy classification challenges.

CPFF supports the CDA's commitment to developing a focused, evidence-informed, and phased list guided by principles of transparency, equity, sustainability, and patient-centeredness. We present a detailed case for including supplementary oxygen on the essential medicines list, drawing on clinical guidelines, international standards, public funding realities, and patient experience.

The Case for Supplementary Oxygen

Supplementary oxygen is a life-sustaining therapy for individuals with pulmonary fibrosis and other chronic respiratory conditions. Despite its routine prescription by healthcare professionals, oxygen therapy is notably excluded from most provincial drug formularies and from the CDA's proposed list of essential medicines.

A key driver of this exclusion is oxygen's current **classification as a medical device rather than a drug**, despite its prescription-based use, dose titration, monitoring, and therapeutic necessity. This classification has prevented oxygen from undergoing traditional drug benefit reviews and from being listed on formularies—even though it functions as a medically essential therapy.

The legacy of this classification is evident in past Canadian assessments. For example, the **Canadian Agency for Drugs and Technologies in Health (CADTH) 2013 health technology assessment**, "Optimal Timing and Frequency of Follow-Up Care for Patients Receiving At-Home Supplemental Oxygen," focused on clinical monitoring and service delivery rather than oxygen's fundamental therapeutic role. It identified significant variation in access, a lack of standardized protocols, and the need for more coordinated, evidence-based approaches to oxygen therapy coverage across jurisdictions (CADTH, 2013). This reinforces the systemic gap oxygen currently faces in Canadian drug policy.

International Recognition and WHO Model List Inclusion

Importantly, supplementary oxygen is **explicitly included on the World Health Organization's (WHO) Model List of Essential Medicines (23rd edition, 2023)** under

the **Core list**—the subset of medicines deemed essential for a functioning basic health system (WHO, 2023). Medical oxygen is listed as a critical, life-saving therapy for the treatment of hypoxemia and respiratory conditions requiring oxygen support.

The WHO Core list comprises medicines that satisfy priority healthcare needs, must be continuously available in adequate amounts, in appropriate dosage forms, and at affordable prices. *The global consensus reflected by the WHO Model List is clear: oxygen therapy is indispensable and should be universally accessible within all health systems.*

By contrast, Canada's current approach—treating supplementary oxygen primarily as a medical device outside traditional drug formularies—diverges from this internationally recognized standard. Aligning Canada's national formulary with WHO's classification would ensure equitable and consistent access to oxygen therapy, fulfilling a fundamental healthcare need for Canadians living with pulmonary fibrosis and other chronic lung and respiratory diseases.

Alignment with CDA's Conservative Approach

The CDA's discussion paper endorses a **"conservative approach"** to inclusion, recommending that products already funded by one or more provincial programs be prioritized for initial inclusion to allow real-world evaluation prior to broader expansion.

Supplementary oxygen clearly meets this threshold. It is currently funded by **all provincial and territorial governments across Canada**, though primarily under **home oxygen or other health service programs rather than traditional drug plans**. This patchwork funding highlights that oxygen is already recognized as a medically necessary therapy, just not yet treated as an essential medicine in the formal drug benefit system.

Inclusion on the national essential medicines list would unify this fragmented funding model, promote equitable access, and facilitate consistent data collection and evaluation across jurisdictions—the kind of real-world implementation the CDA's advisory panel envisions.

This is particularly relevant in the context of renewed national interest in improving economic integration and reducing interprovincial barriers. With the current federal government pursuing a policy agenda that includes growing interprovincial trade and harmonizing standards across provinces, health system harmonization—including consistent access to essential therapies like oxygen—will be a crucial enabler. A national essential medicines list that includes oxygen would not only advance health equity, but also support economic and administrative efficiency, patient mobility, and a more unified Canadian health system.

Alignment with CDA's Guiding Principles

The CDA advisory panel's June 2022 report, *Building Toward a Potential Pan-Canadian Formulary: A Report From the Advisory Panel,* outlines six guiding principles underpinning the proposed national drug list:

- Universality and Integration
- Equity
- Effectiveness and High Quality
- Sustainability
- Efficiency and Timeliness
- Inclusivity with Transparent and Fair Processes

Supplementary oxygen aligns strongly with each principle:

- *Universality and Integration:* Oxygen therapy is an established, medically necessary treatment for pulmonary fibrosis and chronic respiratory diseases, yet there is significant variability in funding and delivery across provinces. CPFF research documents these disparities in access and care pathways (CPFF Oxygen Access Reports, 2023).
- *Equity:* Access challenges disproportionately affect vulnerable populations—rural and remote residents, Indigenous peoples, and low-income Canadians—leading to delays and out-of-pocket costs. CPFF patient and caregiver surveys highlight financial strain and geographic barriers (CPFF Reports).
- *Effectiveness and High Quality:* Oxygen's clinical benefit is well-established in national and provincial respiratory guidelines, and its inclusion on the WHO Essential Medicines List affirms its therapeutic importance (CTS Guidelines, WHO EML).
- *Sustainability and Efficiency:* The current fragmented, provincial program structure leads to duplicated assessments and inefficiencies. A unified essential medicines listing would streamline coverage and facilitate evidence-based improvements.
- *Timeliness:* Patient-reported delays in oxygen approval correlate with worsening symptoms and avoidable hospital admissions. Prioritizing oxygen access aligns with timely care delivery goals.
- *Inclusivity and Transparency:* Recognizing oxygen as an essential medicine formally acknowledges patient and clinician experiences and supports fair, evidence-informed decision-making.

Alignment with CDA Criteria for Commonly Prescribed Drugs

The CDA advisory panel applies criteria to determine "commonly prescribed" drugs for inclusion, such as:

- Presence on the **Canadian Institute for Health Information (CIHI) Top 100 Drugs List** or ranking in the top three within its drug class.
- Recognition as **first-line treatment** based on Health Technology Assessment (HTA) recommendations or clinical practice guidelines.
- Adoption by **seven or more public drug plans or cancer agencies** demonstrating widespread use.

Supplementary oxygen aligns with these criteria:

- While not appearing on CIHI's Top 100 due to device classification, oxygen is widely prescribed for pulmonary fibrosis, COPD, and interstitial lung disease.
- It is a first-line treatment endorsed by Canadian clinical guidelines (e.g., Canadian Thoracic Society).
- Oxygen is funded by **multiple provincial drug and health programs**, reflecting broad public sector adoption, albeit outside standard drug formularies.
- *The lack of a formal HTA recommendation for oxygen as a drug reflects legacy classification; however, CADTH's 2013 health technology assessment affirms its clinical importance and need for improved policy alignment.*

Addressing Access and Equity for Vulnerable Subpopulations

The advisory panel did not limit inclusion decisions to drugs listed on seven or more formularies alone, recognizing that some excluded products serve vulnerable groups with high unmet needs (e.g., ADHD medications for children).

Oxygen therapy exemplifies a treatment excluded due to device classification but critical to a vulnerable population living with chronic respiratory disease. CPFF's research and patient data reveal inequities in access, including:

- Delays in oxygen approval.
- Geographic disparities affecting rural, remote, and Indigenous patients.
- Financial burdens due to incomplete coverage or administrative hurdles.

Inclusion of oxygen on the essential medicines list would improve equitable access and reliability for these patients, advancing the panel's equity goals.

Patient and Caregiver Perspectives

The barriers to oxygen access are not abstract—they are deeply personal, profoundly disruptive, and consistently reported across Canada. Data from CPFF's national patient and caregiver surveys, as well as qualitative studies published in peer-reviewed journals, reveal stories of delay, distress, and systemic failure. As one patient shared, "Thousands of Canadian PF patients do NOT have access to timely oxygen deliveries, while others have NO access at all" (CPFF Oxygen Access Reports, 2023). A caregiver recalled the logistical and emotional strain: "He had to go through a whole bunch of tests in order for the government to pay for it… He just couldn't do it. He was very exhausted by the time he finished it" (Marques et al., 2023).

These stories are not isolated. They illustrate widespread themes: rigid eligibility criteria, inconsistent provincial guidelines, rural inaccessibility, and financial hardship. A healthcare professional observed that "two-thirds of healthcare professionals say their provincial guidelines do NOT allow them to prescribe oxygen therapy to all who need it," resulting in under-treatment and preventable deterioration (CPFF, 2023). Another noted, "The hoop jumping can be a bit of a headache… the process itself… is quite tedious for these patients" (Smith et al., 2025). A patient poignantly described the emotional toll: "You're not free, can't laugh or cry fully because if you do you won't be able to breathe even with oxygen – that is terrible and upsetting" (Marques et al., 2023). These quotes are drawn from national-level surveys, direct CPFF engagement, and studies published in journals such as the Canadian Journal of Respiratory Therapy and Canadian Journal of Health Technologies. Collectively, they underscore the human cost of fragmented policy—and the urgent need for national action.

Supplementary Oxygen as a Related Product

The CDA discussion paper defines related products as devices supporting drug delivery, administration, or dose management and requiring funding by one or more provincial programs.

Supplementary oxygen fits this definition. It is prescribed, requires dose titration and monitoring, and is essential to safe respiratory disease management. Oxygen is funded by multiple provinces through diverse programs.

Therefore, whether classified as a drug or related product, oxygen meets inclusion criteria and plays a critical role in patient safety and care quality.

Response to CDA Exclusion Criteria

Supplementary oxygen does **not** meet any exclusion criteria outlined by the CDA advisory panel:

- It has no major safety concerns.
- It is actively prescribed for chronic respiratory disease.
- It is publicly funded across all provinces and territories, though outside traditional drug plans.
- It has not received any negative HTA assessments for clinical reasons.
- It remains standard of care and recommended in guidelines.
- It is a long-standing, first-line therapy.
- It aligns with CDA's inclusion criteria when considering international standards and public funding realities.

The current exclusion arises from historical classification rather than evidence or clinical merit.

Phased Inclusion Approach

CPFF acknowledges the CDA panel's recommendation to begin with a focused list emphasizing overlap between the CLEAN Meds and WHO EML Core lists and commonly prescribed products.

Although oxygen is absent from CLEAN Meds, it is on the WHO EML Core list, underscoring its global foundational role. It is widely prescribed, requires a prescription, and funded publicly across Canada.

Oxygen should be prioritized for inclusion in Phase 1 or an early phase of the list development. Delaying inclusion would perpetuate inequities and fail to recognize oxygen's life-saving role.

Suggestions for Updating the List Over Time

CPFF supports the CDA's life-cycle approach and recommends:

- Establishing a reassessment pathway for therapies excluded initially due to legacy classification, including oxygen.

- Prioritizing reassessment for products critical to vulnerable subpopulations experiencing access barriers.
- Including patient and clinician voices in topic selection for updates.
- Aligning reassessment cycles with WHO EML updates, fast-tracking additions relevant to Canada.
- Ensuring transparency in decision-making with public rationale and timelines.

Patient and Caregiver Perspectives and Research Evidence

CPFF draws on its own reports documenting patient and caregiver experiences, demonstrating barriers in access, affordability, and consistency of oxygen therapy across Canada (CPFF Oxygen Access Reports).

A 2024 narrative review published by the *Annals of the American Thoracic Society* underscored similar concerns from the clinical community, highlighting the limitations of rigid SpO_2-based eligibility protocols and calling for more individualized assessment (AnnalsATS, 2024). A 2025 U.S. study found significant underutilization of oxygen therapy among patients with fibrosing interstitial lung disease and documented wide variation in prescribing patterns—further emphasizing the consequences of inconsistent access criteria across health systems (Respiratory Research, 2025). A 2024 systematic review and meta-analysis of randomized controlled trials confirmed that oxygen therapy significantly improves exercise capacity in individuals with fibrotic interstitial lung disease—reinforcing its clinical value and importance for maintaining quality of life in this population (PubMed, 2024).

This evidence highlights how fragmented policies contribute to health inequities and poorer outcomes, underscoring the urgency of including oxygen as an essential medicine.

Final Recommendation

CPFF strongly urges the CDA to include **supplementary oxygen therapy** on the proposed essential medicines list, either as a drug or related product. Inclusion in Phase 1 or an early update would embody the CDA's guiding principles of universality, equity, effectiveness, and inclusivity.

This step will ensure Canadians with pulmonary fibrosis and other chronic lung diseases receive timely, equitable, and standardized access to a life-sustaining therapy—aligning national policy with international best practices and patient-centered care.

References

- World Health Organization. WHO Model List of Essential Medicines – 23rd List (2023). https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.01
- Canadian Agency for Drugs and Technologies in Health (CADTH). Optimal Timing and Frequency of Follow-Up Care for Patients Receiving At-Home Supplemental Oxygen (2013). https://www.cadth.ca/sites/default/files/pdf/htis/feb-2013/RB0563%20Supplemental%20Oxygen%20Final.pdf
- CPFF Oxygen Access Reports. https://cpff.ca/understanding-pf/treatment-and-care/cpff-oxygen-access-canada-reports/
- Understanding facilitators and barriers to oxygen therapy for patients with interstitial lung disease. https://pubmed.ncbi.nlm.nih.gov/39222968/
- Harmonizing domiciliary oxygen therapy in Canada https://www.tandfonline.com/doi/full/10.1080/24745332.2025.2467038

Appendix 1: Responses to CDA Consultation Questions

Question 1: Suggestions to Enhance Inclusion/Exclusion Process

Do you have suggestions that could enhance the process for including and excluding products?

Yes

Suggested Changes:
CPFF recommends refining the inclusion/exclusion process to ensure it captures the full scope of clinically essential therapies, especially those excluded due to legacy classification issues. A prominent example is **supplementary oxygen**, a prescription-based, life-sustaining therapy currently excluded because it is classified as a medical device rather than a drug. Despite this, oxygen is:

- Routinely prescribed for pulmonary fibrosis and other chronic lung diseases.
- Funded across all provinces and territories.
- Included on the **WHO Model List of Essential Medicines (Core)**.
- Endorsed in Canadian clinical guidelines (e.g., Canadian Thoracic Society).

To enhance fairness and effectiveness, CPFF recommends:

- Establishing a pathway for reassessment of products excluded due to outdated classifications.
- Including therapies based on clinical practice realities and public funding patterns, not only HTA reviews.
- Enabling case-by-case exceptions for widely used therapies serving vulnerable populations.

Question 2: Suggestions to Support Updating the List

Do you have specific suggestions to support the process of updating the proposed list over time?

Yes

Suggested Changes:

CPFF supports a dynamic, life-cycle approach to list management and recommends:

- A dedicated reassessment stream for excluded products with high clinical utility but outdated classifications, such as supplementary oxygen.
- Synchronizing major update cycles with the **WHO Essential Medicines List**, updated every two years.
- Involving patients and clinicians in identifying and prioritizing topics for review.
- Accelerated inclusion pathways for therapies addressing major gaps in equity, such as rural and respiratory care.
- Transparent reporting on why a product was excluded, with public timelines for potential reconsideration.

These steps will ensure the list remains responsive, inclusive, and reflective of current evidence and needs.

Question 3: Missing Commonly Prescribed Drugs or Related Products

Can you identify any commonly prescribed drugs in Canada not already assessed by the advisory panel?

Yes

Suggested Product: Supplementary Oxygen Therapy

Though excluded from the current list due to classification as a device, supplementary oxygen clearly meets the CDA's criteria for inclusion:

- Routinely prescribed across Canada for conditions like **pulmonary fibrosis**, **COPD**, and **interstitial lung disease**.
- Publicly funded by all provinces and territories through home oxygen or related programs.
- Included in the **WHO Model List of Essential Medicines**.
- Recommended in national respiratory guidelines and CADTH reports.
- Frequently cited in CPFF surveys as essential but inconsistently available.

It should be considered either as a **drug** or a **related product**, in accordance with the CDA's own definition and international standards. Its inclusion would address a long-standing equity gap in access to essential respiratory care.

Appendix 2: Accessing Oxygen Therapy in Canada: Quotes from Patients, Caregivers, and Healthcare Professionals

Patient & Caregiver Quotes

1. "Thousands of Canadian PF patients do NOT have access to timely oxygen deliveries, while others have NO access at all."
2. "Two thirds of healthcare professionals say their provincial guidelines do NOT allow them to prescribe oxygen therapy to all who need it, resulting in 20 percent of patients not getting oxygen therapy when needed."
3. "Accessibility Statement… 20 % of pulmonary fibrosis patients experience delays in accessing oxygen when they need it."
4. "I was just not ready to live my life trapped at home … Without liquid oxygen, I could not leave the house, because I needed more than five litres of oxygen per minute whenever I'm walking around."

Healthcare Professional Quotes (from CPFF & Qualitative Studies)

5. "If you're in rural Alberta and you need help, you're probably not going to get it and that's a shame, but I think it's a well-known thing."
6. "The hoop jumping can be a bit of a headache, to kind of hit one test, get denied to move to the next. So, the process itself, to try to get the funding is quite tedious for these patients."
7. "And then when we got home [from hospital] we had to pay the first month because he had to go through a whole bunch of tests in order for the government to pay for it … He just couldn't do it. … He was very exhausted by the time he finished it."

Emotional & Daily-Life Barriers (from ILD qualitative study)

8. "You're not free, can't laugh or cry fully because if you do you won't be able to breathe even with oxygen – that is terrible and upsetting. Also, being tied to oxygen makes you feel like you're stuck inside the cage."
9. "…there are areas that you need a plane to physically get there, or an ice road. … Some of these extremely high flow patients, I don't know if their health centre would have the ability to provide them with their oxygen needs if their power went out as well."
10. "Everything was an expedition if we were going out"

Appendix 3: CPFF Video Resources

Respirologists weigh in on the vital role of oxygen (video): https://youtu.be/wuGWUTM-Sp8

Stan Hendriksen's journey with PF : speaks to how hard it is to breathe - its like someone is standing on your chest and your suffocating : https://youtu.be/uABb0iMlM24

Talking about PF and Oxygen (Todd Georgieff & speaks about what CPFF is doing and how his father in law suffered) https://youtu.be/7cdy9-df-lU