



www.canpku.org



FACT SHEET **Kuvan in Canada**

January 23, 2023

- The first prescription drug to treat PKU (phenylketonuria)
- PKU is a rare, brain-threatening genetic disorder; affects about 2,500 across Canada
- Thankfully, every province and territory test every newborn baby for PKU in the first days of life

Scientific name of drug: sapropterin dihydrochloride

Kuvan approved by all major Health regulators world-wide as safe, effective and of quality manufacturing

- USA FDA 2007, European Medicines Agency in 2008 and Health Canada 2010
- Wide recognition of unmet medical needs for therapies better than just severe protein restriction and synthetic protein substitution with medical formulas and medical foods
- Kuvan works for some but not all PKU patients
- Health Canada approved a second drug to treat PKU in 2021

Kuvan recommended by the two major health technology agencies in Canada

- CADTH (9 provinces) in 2016 and INESSS (Quebec) in 2013
 - o Canadian Agency for Drugs and Technology in Health (CADTH)
 - o Institute National of Excellence in Health and Social Services (INESSS)

Kuvan coverage recommended by agency that negotiates drug prices collectively for all drug plans of federal, provincial and territorial governments (2019)

- Pan Canadian Pharmaceutical Alliance (pCPA) letter of intent

Kuvan covered by 6 provinces and the federal government for Indigenous peoples

- Covered in BC, SK, ON, QC, NB, NS and Indigenous Services Canada, covering most Canadians
- ON, SK and QC began coverage in 2013
- Not covered yet, +12 years after Health Canada approval: AB, MB, NL, PEI

Kuvan Coverage Inconsistency:

All federal, provincial and territorial governments, including Alberta, cover Kuvan for an ultra-rare disorder even though it is not approved by Health Canada for that disorder: BH4 deficiencies (tetrahydrobiopterin deficiencies) in those jurisdictions with a diagnosed BH4 patient. Kuvan is the only known therapy for these disorders which can be life-threatening.

Author: John Adams, CEO, Canadian PKU and Allied Disorders – contact: john.adams@canpku.org

Canadian PKU & Allied Disorders Inc.

Because Knowledge Leads to Better Health

#180 - 260 Adelaide Street East, Toronto, ON, M5A 1N1, Canada

1-877-226-7581

PCU et maladies apparentées Canada inc.

Parce que la connaissance conduit à une meilleure santé

info@canpku.org