CALL TO ACTION: ODB PROGRAM AMENDMENTS TO SUPPORT INFANTS AND CHILDREN WITH A MEDICAL DIAGNOSIS* REQUIRING STRICT AVOIDANCE OF STANDARD SOY AND MILK PROTEINS

ISSUE

The Ontario Drug Benefit (ODB) Program does not cover the cost of specialized infant formulas required for infants and children 0-24 months of age with a medical diagnosis* requiring strict avoidance of standard soy and milk proteins.

Not covering these specialized infant formulas jeopardizes infant and child growth and development as well as perpetuates health inequities amongst Ontario residents.

RECOMMENDATIONS

To support and optimize infant and child growth and development, reduce health inequities, and help the sustainability of Ontario's health care system, it is recommended that:

- The Government of Ontario expand coverage for specialized infant formulas through the Ontario Drug Benefit Program;

And that:

- Infants and children 0-24 months of age who are partially breastfed or non-breastfed with a medical diagnosis* requiring strict avoidance of standard soy and milk proteins qualify for this coverage.

BACKGROUND

British Columbia, Alberta, and Manitoba have programs that cover specialized infant formula (i.e., extensively hydrolyzed and elemental/amino acid-based nutritional products), when medically required for food allergies.

While specialized infant formulas are currently included in the ODB formulary, infants and children 0-24 months of age needing to avoid standard soy and milk proteins are excluded from the medical criteria[1] whether it is their sole source of nutrition or not.

CURRENT STATUS

An estimated 5,125 infants and children 0-24 months of age in Ontario have a medical diagnosis* requiring strict avoidance of standard soy and milk proteins[2,3] and must have specialized infant formula to meet nutrient needs, if not receiving breastmilk.

> "We have not been able to contribute to RESP's or savings for [our child] because we currently cannot afford to do so. For [their] birthday and Christmas, family members have given money to help with the cost of formula since [their] nutrition is much more important than any new toys or clothes."
>
> *Parent of a child with the dual diagnoses of cow milk protein and soy protein allergies*

ECONOMIC IMPACT ON FAMILIES

The Government of Ontario states that the "health care system should be guided by a commitment to equity and to the promotion of equitable health outcomes" (Connecting Care Act, S.O. 2019, preamble). Health equity "involves the fair distribution of resources needed for health, fair access to the opportunities available, and fairness in the support offered to people when ill".[4] **Due to the high cost of specialized infant formulas (see Tables 1 and 2), these infants and children face inequitable access to resources needed for their health, and their families are at an economic disadvantage.**

In response to the extreme cost of specialized infant formulas, families may make homemade infant formula, which can cause severe malnutrition and potentially fatal illness.[5]

> "[Our child] struggled with breastfeeding and because [they were] fairly lethargic and not gaining much weight, we were told to give formula. The cost of our [their] formula has been financially draining for us, but we need to give [them] this formula so that [they] can thrive. While other babies over 1 year get to drink milk that the rest of our household drinks, [our child] still needs the special, extremely expensive formula, because without it, [they] would have nothing."
>
> *Parent of a child with the dual diagnoses of cow milk protein and soy protein allergies*

Table 1: Cost comparison between volume of specialized infant formula and standard infant formula recommended to meet nutrient needs of infants 0-12 months of age

Standard cow milk-based	Standard soy-based	Extensively hydrolyzed cow milk-based (for allergies)	Elemental/amino acid-based (for severe allergies)
$175 /month	$223 /month 1.3 x more†	$292 /month 1.7 x more†	$743 /month 4.3 x more†

†Than standard cow milk-based infant formula.

Table 2: Cost comparison between volume of specialized infant formula and fluid cow milk recommended to meet nutrient needs of infants 12-24 months of age

Standard 3.25% M.F. fluid cow milk	Standard soy-based	Extensively hydrolyzed cow milk-based (for allergies)	Elemental/amino acid-based (for severe allergies)
$39 /month	$139 /month 3.6 x more‡	$183 /month 4.7 x more‡	$705 /month 18.1 x more‡

‡Than standard 3.25% M.F. (milk fat) fluid cow milk.

KEY CONSIDERATIONS

Nutrition is fundamental for growth and development in the early years of life.[6] While breastfeeding is recommended for up to two years and beyond, many families offer infant formula for a variety of reasons, including medical conditions of the baby or mother, separation of the baby and mother or the informed decision to feed infant formula. These families should be supported as per the Baby-Friendly Initiative.[7]

IMPORTANCE OF SPECIALIZED INFANT FORMULA

For those with a medical diagnosis* requiring strict avoidance of standard soy and milk proteins, there is no substitute for breastmilk other than a specialized commercial infant formula.

Breastmilk is the only food needed during the first six months of life. Between 6-12 months of age, breastmilk still provides up to half of nutrients needs and between 12-24 months of age, it provides up to one third of nutrient needs.[8,9]

Plant-based milks are not recommended under 24 months of age so when an infant or child under 24 months of age with a medical diagnosis* requiring strict avoidance of standard soy and milk proteins is not fed specialized infant formula, it can result in protein-energy malnutrition and micronutrient deficiency diseases, such as iron deficiency anemia and rickets.[10-16]

> "The road to expensive formula is not going to be ending in the foreseeable future. This is unfortunate because there are so many other ways we could be saving money for [our child'[s] future, but this will have to wait until the cost of formula is no longer dictating our finances."
>
> *Parent of a child with the dual diagnoses of cow milk protein and soy protein allergies*

Early childhood malnutrition presents a considerable burden to the health care system in Ontario. The long-term effects of malnutrition during early childhood include increased risk of overweight and obesity, hypertension, dyslipidemia, insulin resistance in adulthood, poor school achievement due to impaired cognitive development and increased risk of mental illness.[17] These conditions cost millions of dollars in health care expenditures.

OPTIONS AND IMPLICATIONS

One option is to provide coverage for specialized infant formulas through the existing ODB Program as has been established in British Columbia and Alberta. This would include:

- For infants 0-12 months of age, provide coverage equal to the cost of specialized infant formula minus the cost of standard cow milk-based infant formula.
- For children 12-24 months of age, provide coverage equal to the cost of specialized infant formula minus the cost of standard 3.25% MF fluid cow milk.

Alternatively, the Government of Ontario can establish a separate benefit program for specialized infant formulas as has been established in Manitoba, with the same coverage as the previous option.

Eligibility criteria should align with the programs in British Columbia, Alberta, and Manitoba:

- Partially breastfed and non-breastfed infants and children 0-24 months of age with a medical diagnosis* requiring strict avoidance of standard soy and milk proteins.

While coverage for these specialized infant formulas requires a financial investment from the Government of Ontario, the implication of either option promotes:

- Optimal growth and development of infants and children who must avoid standard soy and milk proteins by providing them medically required nutrition without placing undue financial burden on the family; and
- A sustainable health care system by reducing future health care costs resulting from early childhood malnutrition.

*Medical diagnosis can include an IgE mediated food allergy and/or a non-IgE mediated food allergy, such as food protein-induced enterocolitis syndrome (FPIES), food protein-induced enteropathy (FPE), allergic proctocolitis (AP), eosinophilic esophagitis (EoE) and several others. Due to the variability in clinical presentation and lack of validated diagnostic tests, a diagnosis relies on a detailed medical history, physical examination and a trial elimination of the suspected food allergen.

The recommendations in this policy brief are supported by Ontario Dietitians in Public Health (ODPH) and Food Allergy Canada. It is the hope of these organizations that the Government of Ontario will implement change to the coverage of specialized infant formula for infants and children 0-24 months of age with a medical diagnosis* requiring strict avoidance of standard soy and milk proteins.

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