

The Importance of Exclusive Enteral Nutrition:

Exclusive enteral nutrition (EEN) is a primary treatment prescribed by many Canadian paediatricians for children and young adults living with Crohn's disease – a life-long chronic condition that causes inflammation anywhere along the gastrointestinal tract. Enteral nutrition is a liquid formula taken orally or pumped through a nasogastric tube into the stomach. It is exclusive because no other food is taken during the treatment period, lasting from eight to twelve weeks.

Studies on children living with Crohn's disease have shown that EEN is an effective treatment used to induce mucosal healing while providing adequate nutrients for proper bone development and growth. It also helps to keep the condition in remission and can delay the need to go on other drugs and biologics. In the United Kingdom, Japan and in some European countries, EEN is a first line therapy for children with Crohn's disease. In fact, both Japan and the UK have established EEN clinical guidelines for the treatment of Crohn's disease in children.^{1,2} In Canada, there are no guidelines, however, it is common practice for paediatric gastroenterologists to prescribe liquid nutrition since it acts as a safe alternative to steroids and biologic drugs used to induce the remission of Crohn's disease.

In 2013, Crohn's and Colitis Canada has partnered with the IWK Health Centre and Nestle Health Sciences to jointly call on government and private insurers to **improve access to exclusive enteral nutrition (EEN) and supplies for children and adults living with Crohn's disease**. We want to inform representatives of the federal, provincial and territorial governments about the benefits of EEN and get public and private drug plans to recognize EEN as a viable first line treatment for Crohn's disease. Additionally, we call for coverage of the supplies and nutritional feeding from public and private insurance programs to help families get coverage for the cost of formula and tube feeding supplies, specifically the pump and feeding sets.

Background:

Crohn's disease (CD) and ulcerative colitis (UC) are the two main forms of inflammatory bowel disease (IBD). These are related but distinct diseases that can affect the gastrointestinal tract. When inflammation occurs people may experience pain, diarrhea, fecal incontinence and blood in the stool. People living with Crohn's disease or ulcerative colitis often face urgent and frequent need of accessing washrooms. On average an individual may visit the toilet between five and 20 times a day during active disease (flare-ups).

Crohn's and ulcerative colitis are chronic life-long conditions for which currently there is no cure. It can lead to episodic disabilities, and if left untreated it can increase the risk of developing colorectal cancer.

¹ Working Group of the Japanese Society for Pediatric Gastroenterology, Hepatology and Nutrition, (2006). Guidelines for the treatment of Crohn's Disease in Children. *Pediatrics International, Japan Today*, 48, 349-352.

² Lochs, H., Dejong, C., Hammarqvist, F., Hebuterne, X., Leon-Sanz, M., Schutz, T., van Gemert, W., (13 January 2006). ESPEN Guidelines on Enteral Nutrition: *Gastroenterology, Clinical Nutrition*, 25, 260-274.

Due to undetermined factors, the prevalence of both of these conditions has been increasing over recent years. Sadly, a quarter of those diagnosed are children.

The management of IBD in children and adolescents should go beyond the 'prevention' of inflammation to sustaining nutritional absorption for proper growth and development. For example, Crohn's disease in children and adolescents can lead to deficiencies in nutrition and weight loss. It can slow down the linear growth spurt, leading to a significant percentage of patients failing to achieve their predicted adult height (based on their genetic potential).

There are drug therapies available, including antibiotics, corticosteroids, azathioprine/methotrexate and biologics (e.g. adalimumab or infliximab) that minimize inflammation of the gut. Other drugs are used to maintain remission. However, these drugs may pose severe side effects. Long-term or high dose steroids may impair linear growth in children and teens, and impact bone development leading to osteopenia/osteoporosis in both children and adults. EEN has proven to be a safer alternative to induction and maintenance of remission.

The use of enteral nutrition as a treatment for Crohn's disease for children dates back to more than 40 years. This treatment option has been popular in Europe and has been proven successful in numerous studies of children and adults living with Crohn's Disease. Though the costs of EEN is higher than taking steroids, in the long-term there is a cost savings from lowered hospital visits, fewer gastroenterologists appointments needed and reduced need for surgery. Regardless of the costs, EEN improves the nutritional status and the quality of life for the majority of children and young adults that use it.

Basic Facts:

- In previous studies conducted, children with CD were shown to ingest 55% to 80% less of expected caloric intake when compared to a controlled group of children without IBD.
- The most common nutrient deficiencies are iron, vitamin D and calcium. These nutrient deficiencies lead to adverse effects on growth, bone development and wellbeing.
- Nutritional deficits aside, just the underlying inflammation seen with Crohn's disease can directly impact growth and bone development.
- Studies have shown that enteral nutrition induces remission in 80% to 85% of newly diagnosed CD in children. For the number of children who failed to achieve remission they were still observed as having a clinical response, with a decrease in disease activity and an improvement in nutritional status.
- Mucosal healing has been demonstrated to occur in children treated with enteral nutrition therapy.
- For the family of a child with Crohn's disease it can cost up to \$3,400 for formula plus \$300 for equipment for an 8 week course of therapy of EEN.

Opportunities for Change:

As of May 2014, EEN is covered on three public formularies: the Ontario Drug Benefits (ODB), Quebec's public program la Régie de l'assurance maladie du Québec (RAMQ) and the Alberta Blue Cross provincial program. However, each person must qualify for these programs to be covered, and for the most part, a needs assessment is required.

The absence of an identification number can prove challenging for private insurance coverage since private insurers may look at provincial formularies to approve coverage for listed treatments. For provinces that do not list EEN on public formularies, some plan sponsors may deny claims

Exclusive enteral nutrition does not fall within the criteria to receive a drug identification number (DIN) nor is it considered a contender for a Natural Product Number (NPN). Current nutrition products and formula fall within the 'food for special dietary use' part of the Food and Drug Act. They are not drugs, nor do they qualify as Natural Health products.

There are exceptions where DINs or NPNs are not required to get coverage and place treatments onto public formularies. Below are some examples found across Canada:

- In Alberta, the government has launched the Insulin Therapy Program that covers the \$7,000 cost for insulin pump and supplies for people with Type 1 diabetes. The pumps infuse insulin continuously, eliminating the need to give frequent regulars.³
- The Ontario Ministry of Health and Long-Term Care through its Special Drugs Program cover the full cost of certain drugs used for specific conditions.⁴ Specifically it covers:
 - Specific drugs for the treatment of cystic fibrosis;
 - Amoxicillin, ascorbic acid (Vitamin C), deferoxamine, folic acid, hydrocortisone injection, penicillin and trimethoprim/sulfamethoxazole for the treatment of thalassaemia;
 - Zidovudine (AZT) for the treatment of HIV infection;
 - Erythropoietin (EPO) for people with end stage renal disease
 - Cyclosporine for people who have had a solid organ or bone marrow transplant
 - Human growth hormone for children with growth failure
 - Clozapine for treatment of schizophrenia
 - Alglucerase for people with Gaucher's Disease

General Recommendations:

Crohn's and Colitis Canada and its partners call on federal, provincial, territorial governments and private insurers to:

- Recognize exclusive enteral nutrition (EEN) and list it on provincial/territorial formularies as a viable and primary treatment option for children living with Crohn's disease.
- Provide financial assistance for children and adolescents who wish to take exclusive enteral nutrition to maintain their Crohn's disease. Cover the costs of taking EEN, including the cost of formula and the pump and feeding set.
- Call upon the Canada Revenue Agency (CRA) to include EEN formula and equipment as eligible medicaments or other preparations or substances under the Medical Expense Tax Credit. As such this therapy will be considered for coverage under Private Extended Health Plans.⁵

³ Government of Alberta, The Insulin Therapy Program (2013), Albertahealth.ca , accessed on 24 October 2014: <http://www.health.alberta.ca/services/insulin-pump-therapy-program.html>

⁴ Government of Ontario, Publicly Funded Drug Programs - Special Drugs Program, health.gov.on.ca, (21 March 2013), accessed on 24 October 2014: http://www.health.gov.on.ca/en/pro/programs/drugs/funded_drug/fund_special.aspx

⁵ Canada Revenue Agency, IT-519R2: Income Tax Act – Medical Expense and Disability Tax Credits and Attendant Care Expense Deduction, cra-arc.gc.ca, (18 October 2013), accessed on 07 April 2014: <http://www.cra-arc.gc.ca/tx/tchncl/ncmtx/fls/s1/f1/s1-f1-c1-eng.html>