



## **Arthritis Consumer Experts**

# **Election 2008 Briefing Document on the Non-Insured Health Benefits (NIHB) Drug Benefit Plan**

**September 2008**

## **Executive Summary:**

The stated goal of the Non-Insured Health Benefits plan is to ensure that First Nations and Inuit Canadians reach an overall health status that is comparable with other Canadians. This is simply not what is occurring; in fact, NIHB policies are working against this very goal.

According to the NIHB, “Optimal drug use means providing the right drug to the right client in the right dose at the right time”. Tragically, this is far from the reality being presented to its clients.

- For First Nations and Inuit people with rheumatoid arthritis, the NIHB dictates which biologic response modifier a person is able to access, rather than allowing the physician and patient to choose the best of the five available based on the patient’s disease, ability to self-administer the medication, cultural beliefs, and a host of other considerations.
- For those First Nations and Inuit Canadians living with ankylosing spondylitis and psoriatic arthritis, the NIHB goes even further and simply denies coverage for necessary medications – in effect, creating a second-class of Canadian citizens.

On behalf of its First Nations and Inuit Canadian members living with inflammatory arthritis, Arthritis Consumer Experts recommends that government immediately address the restrictive medication reimbursement policies within the NIHB by listing the full class of biologic response modifiers for First Nations and Inuit Canadians living with inflammatory arthritis on the NIHB drug benefit plan. *This will ensure that the discriminatory reimbursement practices of the NIHB are eliminated and will allow First Nations and Inuit Canadians who rely on the NIHB for medication reimbursement to receive the same quality of care and treatment that other Canadians living with inflammatory arthritis receive in this country.*

## **Introduction – What is arthritis?**

There are more than 100 different types of arthritis, falling into two major groups: osteoarthritis and inflammatory arthritis. The most common type of arthritis in Canada is osteoarthritis, which affects 3 million Canadians or approximately one in ten<sup>1</sup>. Osteoarthritis is caused by a breakdown of cartilage in joints causing bones to rub together resulting in pain, stiffness and eventual loss of use. In inflammatory arthritis, the body’s own immune system attacks healthy joints and tissues, causing inflammation and joint damage. The most common type of inflammatory arthritis is rheumatoid arthritis, which affects approximately 300,000 Canadians or one in 100<sup>2</sup>. Other forms of inflammatory arthritis include juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis, lupus, and many others.<sup>3</sup>

## Treating inflammatory arthritis effectively

There is no cure for the over 100 types of arthritis. However, there are treatments proved by research to slow or stop the disease process. Research has shown that in order to reduce or delay the joint damage associated with arthritis, particularly inflammatory forms of arthritis, early diagnosis, as well as timely and appropriate treatment is critical. Research has shown that early treatment can<sup>4, 5, 6, 7</sup>:

- Control aggressive forms of the disease
- Minimize the need for on-going tests and procedures
- Reduce the need for hospitalizations and visits to physicians
- Delay or eliminate the need for some joint replacement surgeries, relieving pressure on our growing waitlists.
- Decrease costs associated with intermediate and long-term care

Until recently, arthritis treatments focused on pain relief, with doctors using acetaminophen (Tylenol®) or non-steroidal anti-inflammatory drugs (NSAIDs) for a long period of time before trying more aggressive treatments. Today, the approach to treatment has changed, with new pharmacological treatment coming to the forefront. Currently, arthritis treatment includes analgesics, corticosteroids and non-steroidal anti-inflammatory drugs (NSAIDs) to treat the symptoms of arthritis, with disease-modifying anti-rheumatic drugs (DMARDs) and biologic response modifiers (also known as biologics) to treat the underlying disease.

Biologic response modifiers or ‘biologics’ are the newest type of medication to treat forms of inflammatory arthritis. These medications, in combination with others, are considered the “gold standard” in treatment for severe inflammatory arthritis. There is irrefutable evidence supporting the use of biologic response modifiers in this disease state, with research demonstrating that biologics are particularly effective for reducing disease activity and enabling management of the physical aspects that lead to disability and deformity.<sup>8, 9, 10</sup>

Currently, there are five biologics approved for and generally used in the treatment of inflammatory arthritis. Each biologic targets different molecules that cause or promote the inflammatory process—the one symptom that is so devastating and damaging to joints in rheumatoid arthritis; three of them target a molecule called TNF, one targets b cells and one targets t cells.

It is critical to have a diversity of treatment options because different people respond very differently to biologics, even those targeting the same molecule. Research shows that there continues to be a significant unmet need for new treatments, with more than half of people with inflammatory arthritis not having their symptoms alleviated with the current biologics.<sup>11, 12, 13</sup> The real-world consequence of listing some but not all treatment options are that some people can have their health and lives back while others cannot.

It is important to recognize that the economic impact of not providing these medications is far greater than the cost of providing them. **Every dollar invested in new medicines saves the health care system seven times that amount in other medical areas**<sup>14, 15</sup>. Spending on medications is associated with improved health outcomes for Canadian citizens.<sup>16</sup> For example, the consequences of untreated or under-treated ankylosing spondylitis, such as spinal rigidity, increased risk of fractures and other joint problems, are irreversible and result in higher use of health services and work disability.<sup>17, 18</sup>

### Impact of inflammatory arthritis on Aboriginal Canadians

In First Nations peoples, arthritis is one of the most prevalent chronic diseases; 19% of Aboriginal people living off-reserve report having arthritis. If the Aboriginal population had the same age composition as the overall Canadian population, this rate would be 27%.<sup>19</sup> In addition, for Aboriginal Canadians living off-reserve the prevalence of serious inflammatory arthritis is approximately 5%, compared to 1% of the total population of Canada. Moreover, the arthritis occurring in Aboriginal people is more severe, more debilitating, and more likely to be life-threatening than arthritis in non-aboriginals.<sup>20</sup>

Significantly higher rates of inflammatory arthritis, in the context of poverty and other health concerns facing Aboriginal Canadians, are cause for great concern for health professionals who work in Aboriginal communities. These concerns are compounded by the fact that many Aboriginal Canadians cannot access reimbursement coverage for the medications their specialists are prescribing for their arthritis, as the medication reimbursement coverage provided by the federal Non-Insured Health Benefit (NIHB) plan is some of the most restrictive in Canada. For example, unlike almost every other provincial drug plan, Aboriginal Canadians who live with ankylosing spondylitis and psoriatic arthritis, who rely on the NIHB formulary do not have coverage for any of the newest class of gold-standard medications to treat their disease.<sup>21</sup>

This means that First Nations and Inuit people who rely on the NIHB do not have the same coverage for biologic medications for this disease as other Canadians. This is despite the fact that First Nations and Inuit peoples experience higher rates of inflammatory arthritis, and likely a more debilitating disease process, than other Canadians.

#### **NIHB overview: What is the NIHB?**

The Non-Insured Health Benefits Program (NIHB) is a supplemental benefit program that “provides a range of medically necessary goods and services to registered Indian and recognized Inuit and Innu when they are not otherwise insured”<sup>22</sup>, in addition to provincial, territorial or private health benefit programs. While provinces and territories are responsible for delivering health care services to all Canadian citizens in accordance with the Canada Health Act, a number of health-related goods and services are not covered through provincial and territorial programs. In these cases, the NIHB may cover some, or all of the costs of these services. These include:

- Pharmacy (including approved prescription, over-the counter drugs and medical supplies/equipment);
- Dental services;
- Transportation to access medically required services;
- Glasses and other vision care aids and services;
- Health care premiums in Alberta and British Columbia only; and
- Other health care services including short-term crisis intervention mental health counselling.

The program policies and practices follow the 1979 Indian Health Policy and the 1997 NIHB Renewed Mandate, with the goal: “To support First Nations people and Inuit in reaching an overall health status that is comparable with other Canadians”.<sup>23</sup> The objectives of the program are to provide benefits to eligible First Nations and Inuit in a manner that:

- is suitable to their unique health needs
- helps eligible First Nations and Inuit to reach an overall health status on par with other Canadians
- is cost effective
- will maintain health, prevent disease and assist in detecting and managing illnesses, injuries, or disabilities

A benefit will be considered for coverage when:

- The item or service is on a NIHB Program benefit list or NIHB schedule;
- It is intended for use in a home or other ambulatory care settings;
- Prior approval or predetermination is obtained (if required);
- It is not available through any other federal, provincial, territorial, or private health or social program;
- The item is prescribed by a physician, dental care provider, or other health professional licensed to prescribe; and
- The item is provided by a recognized provider.

An eligible recipient must be identified as a resident of Canada and one of the following<sup>24</sup>:

- A registered Indian according to the *Indian Act*;
- An Inuk recognized by one of the Inuit Land Claim organizations; or
- An infant less than one year of age, whose parent is an eligible recipient.”

The NIHB does not cover<sup>25</sup>:

- Ineligible spouses
- Ineligible children over one year of age

As of 2007, the NIHB provides supplemental coverage to approximately 792,600 (as of March 31, 2007) registered First Nations and recognized Inuit.

## **NIHB Drug Benefits Program**

“It is the goal of the NIHB Program to develop a comprehensive list of cost-effective drugs which will allow practitioners to prescribe an appropriate course of therapy for NIHB clients” (NIHB, 2007: 94).

According to the NIHB website, “the objective of the drug benefit program is to provide eligible clients with access to pharmacy services that will contribute to optimal health outcomes in a fair, equitable and cost-effective manner and will:

- Contribute to improving the overall health status of First Nations and Inuit clients recognizing their unique health needs and the context of health service delivery; and
- Fund drug benefits and services based on professional judgment, consistent with the current best practices of health services delivery and evidence-based standards of care”.

The NIHB Program covers prescription drugs listed on the Non-Insured Health Benefits Drug Benefit List and approved over-the-counter medication. NIHB policy is to fund the ‘lowest cost alternative drug’, and to reimburse only the best price alternative or equivalent product in a group of interchangeable drug products.

## **Current state of the NIHB: Obstacles to effective treatment and care for inflammatory arthritis**

While the NIHB program includes five benefit areas, the treatment and care of arthritis is mainly influenced by the programs “pharmacy” or drug benefits, as well as “medical transportation”. Arthritis Consumer Experts has identified several problematic issues around the NIHB drug benefit plan.

### **Problems:**

#### ***1. Rigid and lengthy criteria for access to coverage for biologic response modifiers for the treatment of rheumatoid arthritis***

While the NIHB drug reimbursement formulary lists all the current biologics for the treatment of rheumatoid arthritis, the criteria needed to gain access to these medications is rigid and results in delayed treatments. Health professionals have repeatedly commented on the fact that for First Nations or Inuit patients to get access to one of the biologics, they must fail more medications than is required on other provincial and territorial formularies.

It is critically important that people with rheumatoid arthritis have access to the full range of treatment options; just like in treatment for HIV and cancer, doctors must be given the opportunity to find the ideal “cocktail” of medications for each patient. As well, research has shown that 28-58% of these patients do not respond to anti-TNF drugs<sup>26</sup>. In addition to varying response rates, patients with rheumatoid arthritis also experience issues of drug resistance with anti-TNF therapy over time<sup>27</sup>. Finally, it is also important to note that listing more medications will not increase treatment costs, as a patient with rheumatoid arthritis will never be on two biologic response modifiers at one time.

**Recommendation: First Nations and Inuit Canadians who rely on the NIHB should have the same criteria for reimbursement coverage as other Canadians covered under other federally-funded drug plans.**

## ***2. No biologic is included on the NIHB drug reimbursement formulary for the treatment of ankylosing spondylitis and psoriatic arthritis***

The NIHB has no biologic response modifiers listed on their drug reimbursement formulary for the treatment of ankylosing spondylitis and psoriatic arthritis. In fact, the NIHB has formally declined to list many of the biologics for these two types of arthritis. The NIHB declined etanercept (Enbrel®) and infliximab (Remicade®) for the treatment of ankylosing spondylitis. They also declined infliximab (Remicade®) and adalimumab (Humira®) for the treatment of psoriatic arthritis.

The decision to decline these medications goes against scientific research and stands in contrast to evidenced-based treatment. There is strong scientific evidence demonstrating the value of infliximab (Humira®) for the management of the physical aspects of ankylosing spondylitis such as spinal rigidity, increased risk of fracture and joint problems<sup>28,29</sup>. In fact, the Common Drug Review (CDR) has recommended that the provinces and territories list this biologic for the treatment of ankylosing spondylitis.<sup>30</sup>

Research has shown that infliximab (Remicade®) provides significant benefit in the management of psoriatic arthritis, as well as in managing the skin aspects of this disease<sup>31</sup>. This means the medication provides a dual benefit by improving the physical function of patients as well as their quality of life<sup>32</sup>.

**Recommendation: The NIHB must take the immediate necessary steps to list all three medications that make up the class of biologic response modifiers on the drug benefit plan for First Nations and Inuit peoples living with ankylosing spondylitis and psoriatic arthritis.**

## ***3. Differences in drug spending***

In the 2007-2008 Health Canada budget, Minister of Health Tony Clement highlighted four strategic outcomes, with one focused on ensuring better health outcomes and reduction of health inequalities for First Nations Canadians<sup>33</sup>. Despite this stated goal, the Canadian Institute for Health Information, in their 2006 yearly report stated that First Nations Canadians suffer discrimination by receiving less health care than the general population. This is strongly evidenced by comparing drug spending. The average per person spending on drugs for First Nations peoples is \$419, compared to \$770 for non-Aboriginal Canadians. Furthermore, provincial funding of health benefits is 6%, whereas Health Canada has capped NIHB funding at 3%.<sup>34</sup>

The lack of drug spending is echoed by the Assembly of First Nations. In a review of the NIHB program, the Assembly of First Nations compared the drug spending of the NIHB program of the FNIHB to that of veterans. In doing so they found that in 2004-2005, Health Canada spent approximately \$320.6 million on drug benefits for the 765,000 eligible First Nations and Inuit Canadians, which results in an average of \$419 per person. In comparison, for Canada's 133,000 veterans, the average spent on drugs is \$843 per person; the Department of Defense spends \$3519 for their 67,000 members and; \$6492 per person is spent for the 21,255 federal prison inmates.<sup>35</sup>

**Recommendation: Funding for the NIHB drug benefit plan must be in line with that for other federal and provincial health programs.**

#### **4. Restrictive appeal process**

When a benefit has been denied by the NIHB program, recipients may initiate an appeal to have the decisions reversed. While an appeal process is important, the one established within the NIHB Program results in lengthy delays and restrictive access for many First Nations and Inuit Canadians as all appeals must be initiated by the patient (recipient) or their guardian, with supporting information from the provider or prescriber. This information includes<sup>36</sup>:

1. The condition for which the benefit is being requested.
2. The diagnosis and prognosis, including what other alternatives have been tried.
3. Relevant diagnostic test results.
4. Justification for the proposed treatment and any additional supporting information.

The need for patients to write the initial letter of appeal ignores the reality of many First Nations and Inuit Canadians lives. For many people within these populations, the level of literacy required to write an appeal would not exist. As shown in the International Adult Literacy and Skills Survey 2003, First Nations people have lower levels of literacy than other Canadians<sup>37</sup>, with less than 39% having graduated from high school<sup>38</sup>.

In addition, as many First Nations and Inuit people do not live in urban centers, being able to gather the required accompanying information from their health care providers would be very difficult and may entail travelling long distances. Not only does this take people out of their communities, but also may require financial resources that are not available.

This is the only public appeal process that requires the recipient, or person living with disease, to initiate. Why is it that in a population with lower than average literacy rates, higher than average poverty rates, and geographical barriers, the patient is required to initiate the appeal and write the letter of appeal?

**Recommendation: The appeal process must be re-vamped to ensure that the ability to appeal a decision about medication coverage is not affected by geographic, economic or social factors.**

### ***5. Lack of compliance with the recommendations of the Common Drug Review***

As noted above, the NIHB had not included biologics on their drug reimbursement list for the treatment of ankylosing spondylitis despite having been “recommended to list” by the Common Drug Review (CDR)<sup>39</sup>. The NIHB’s failure to comply with the recommendations of the CDR are further highlighted in a study commissioned by the Canadian Association of Retired Persons (CARP) that compared the prescription drug coverage of elected and public officials to public drug plans in British Columbia, Alberta, Ontario and those managed by the Federal government for Aboriginal Canadians, veterans and soldiers. In this study, they showed there exists a large discrepancy between the drug coverage and CDR compliance of the privately provided, publically funded benefits plans provided to politicians and bureaucrats and those of provincially or federally-funded public drug plans. For example, of 27 drugs recommended to list by the CDR, only 15 these drugs are reimbursed through the NIHB, yet all 27 are reimbursed for politicians and bureaucrats.<sup>40</sup>

The lack of compliance with the CDR recommendations is surprising. As this is a review process that takes place at the federal level, with reviewers chosen by Health Canada, it seems that the NIHB could reduce costs associated with doing an in house review by automatically listing those medications recommended by the CDR. (we could add a point about cost effectiveness)

**Recommendation: The NIHB should list all medications recommended by the Common Drug Review to treat forms of inflammatory arthritis.**

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