Arthritis Consumer Experts

Who we are

Arthritis Consumer Experts (ACE) provides research-based education, advocacy training, advocacy leadership and information to Canadians with arthritis. We help empower people living with all forms of arthritis to take control of their disease and to take action in healthcare and research decision making. ACE activities are guided by its members and led by people with arthritis, leading medical professionals and the ACE Advisory Board. To learn more about ACE, visit **www.jointhealth.org**

Guiding principles and acknowledgement

Guiding Principles

Healthcare is a human right. Those in healthcare, especially those who stand to gain from the ill health of others, have a moral responsibility to examine what they do, its long-term consequences and to ensure that all may benefit. The support of this should be shared by government, citizens, and non-profit and for-profit organizations. This is not only equitable, but is the best means to balance the influence of any specific constituency and a practical necessity. Any profit from our activities is re-invested in our core programs for Canadians with arthritis.

To completely insulate the agenda, the activities, and the judgments of our organization from those of organizations supporting our work, we put forth our abiding principles:

- ACE only requests unrestricted grants from private and public organizations to support its core program.
- ACE employees do not receive equity interest or personal "in-kind" support of any kind from any health-related organization.
- ACE discloses all funding sources in all its activities.
- ACE identifies the source of all materials or documents used.
- ACE develops positions on health policy, products or services in collaboration with arthritis consumers, the academic community and healthcare providers and government free from concern or constraint of other organizations.
- ACE employees do not engage in any personal social activities with supporters.
- ACE does not promote any "brand", product or program on any of its materials or its web site, or during any of its educational programs or activities.

Thanks

ACE thanks the Arthritis Research Centre of Canada (ARC) for its scientific review of JointHealth™.

Arthritis Research Centre of Canada

Acknowledgement

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Disclaimer

The material contained in this newsletter is provided for general information only. It should not be relied on to suggest a course of treatment for a particular individual or as a substitute for consultation with qualified health professionals who are familiar with your individual medical needs. Should you have any healthcare related questions or concerns, you should contact your physician. You should never disregard medical advice or delay in seeking it because of something you have read in this or any newsletter.

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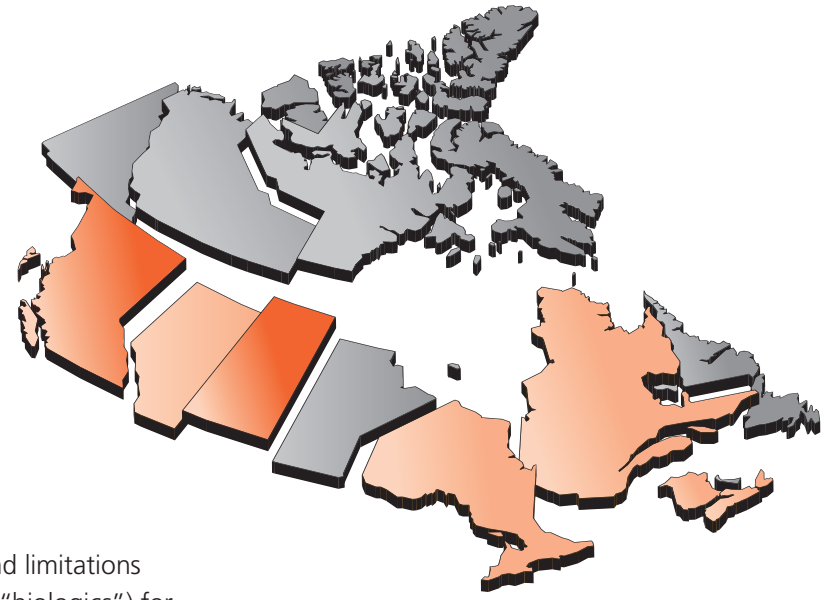
JointHealth™ monthly
Arthritis research, education and advocacy news : September 2010

Leveling the Field in Canada:

Moving Toward Reimbursement Equality in Biologic Therapy for Canadians with Rheumatoid Arthritis.



Today, across Canada there exist significant restrictions and limitations around the prescribing of biologic response modifiers (or "biologics") for rheumatoid arthritis (RA) through provincial public drug plans.

A recently released national paper entitled *Leveling the Field in Canada: Moving Toward Reimbursement Equality in Biologic Therapy for Canadians with Rheumatoid Arthritis ("Leveling the Field in Canada")* reviews this issue from the perspective of physicians, who specialize in treating rheumatoid arthritis (RA) – rheumatologists – and ACE, the leading provider of research-based information on arthritis in Canada.

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The primary objective of *Leveling the Field in Canada* is to provide a rationale allowing rheumatologists to prescribe the most appropriate biologic therapy, one that is most suited to an individual RA patient whenever it is recognized that the particular biologic would provide the best possible health outcome for the patient. The secondary objective is to highlight to government decision-makers the lack of equitable access and patient/physician choice in treating RA with biologics.

Rheumatoid arthritis is a severe form of autoimmune arthritis. It occurs in 1 percent of the population, which means approximately 300,000 Canadian adults live with the disease. A debilitating disease, RA most often affects people in the prime of their lives (20-50 years of age), but can hit a person at any age. Two-thirds of those diagnosed are women.

Biologics are a class of medication used to treat people with moderate to severe RA. This class of therapies is engineered to target and block specific disease pathways responsible for the inflammation and joint destruction characteristics of RA.

Biologics (in most cases, along with methotrexate) are the standard of care world-wide for the treatment of patients with severe RA. However, no one biologic therapy is effective in all RA patients. Each patient's disease is different and requires a unique treatment plan. The clinician and patient must weigh the potential risk-benefit ratio for each biologic treatment. It is therefore critical that clinicians have access to different biologics, in order to best treat their patients.

There are no studies that have compared biologics to one another. However, the best research data has shown that no one biologic is superior to the other. This may be because RA behaves differently in every patient, and therefore each patient has a different response to each biologic.

Arthritis Consumer Experts believes that rheumatologists should be allowed to prescribe the biologic therapy most suited for an individual RA patient whenever it is recognized that the particular biologic would provide the best possible outcome for that patient. Unfortunately, that is not what happens today in Canada.

Currently, the majority of biologics available for the treatment of RA in Canada are available only on a "case-by-case" basis in most of the provinces and territories through their public formularies. Reimbursement for a biologic is approved in those patients with RA where treatment criteria have been met. In many provinces and territories, the "case-by-case"

review process can take weeks, when patients are experiencing severe pain and while irreversible joint damage is occurring. Often, the government review process does not include the expertise of a rheumatologist. In addition, the public reimbursement process is not equal across all of the provinces and territories, which leaves serious gaps in care.

The authors of *Leveling the Field in Canada* found that because of various restrictions and limitations within respective provincial formularies, public reimbursement coverage for biologics varies greatly across Canada. In fact, each province/territory has different coverage of biologics. There is no uniform public reimbursement across Canada.

For example, Manitoba and Prince Edward Island have the poorest public reimbursement coverage. On a case-by-case basis, these provinces provide reimbursement for 4 of the biologic therapies approved by Health Canada. Their reimbursement criteria is overly restrictive, they have the longest wait times for processing applications, and no appeal mechanism in place.

One tier above these lowest ranking jurisdictions, we find Alberta, Quebec and Nova Scotia have only average reimbursement coverage. They provide reimbursement for 5 of the 7 biologics, but have somewhat restrictive criteria and longer wait times than some of the other provinces/territories. Furthermore, there is no transparent appeal process for denied reimbursement coverage.

British Columbia and Saskatchewan have the best public reimbursement coverage for biologics. On a case-by-case basis, they provide reimbursement for 5 out of 7 biologic therapies approved by Health Canada, they have the least restrictive reimbursement criteria, and the shortest wait times for initial processing for reimbursement. They have the fewest number of reimbursement renewal applications required and an appeal mechanism is in place for case-by-case reimbursement coverage denials.

Equal coverage throughout Canada and in each of the provinces and territories is vitally important because rheumatoid arthritis is a debilitating autoimmune disease that aggressively and progressively attacks and damages joints and the surrounding tissues. If left untreated, it causes irreversible damage, chronic pain, and loss of joint function, all of which result in a profound loss of quality of life and a decreased life expectancy. Joint damage begins within six weeks of RA initiation. It is therefore imperative that all Canadians have quick access to these drugs without having to combat the uneven public drug plan requirements.

Response to biologic agents is commonly assessed in Canada by clinical outcome measures. While many patients respond quickly to biologics, there are others that do not respond as quickly, but do show significant benefit somewhat later on in the course of therapy. Eighty-five percent of patients who will show such a response have done so by three months, but about 15% of late-responders will be missed.

ACE recommends that if there is evidence of a fair response, but one not quite meeting the criteria set by the clinical outcome measures, an extension for re-assessment of response at six months be permitted.

Earlier treatment of RA has been shown to better maintain function than later treatment of advanced disease. So, after stopping one drug for an inadequate response, it is inappropriate to have to wait for a person's disease to significantly worsen before starting the next course of therapy.

ACE recommends that if a patient has been deemed initially eligible for a biologic, there should be a seamless process when switching to a second or third biologic (if needed) without the necessity of repeating the initial formal application and clinical pro forma.

Specialist physicians can provide the appropriate prerequisites for the use of biologics in rheumatoid arthritis, including the development of specific criteria for each medication and within the case-by-case request process. An open communication process between rheumatologists and government must be developed to ensure that comprehensive information is available to public formulary decision-makers. This results in the best quality of patient care, delivered in a cost-effective manner.

ACE recommends that the provincial and territorial governments seek advice from rheumatologists through a formal advisory framework in determining indication prerequisites.

ACE recommends that some form of appeal mechanism be set up that is satisfactory to patients, physicians, and government to review both approval applications for general approval of a specific drug as well as the needs of specific patients where required.

What can you do to help level the field in Canada?

If you are a rheumatologist,

there are several things you can do to equalise coverage of biologics across Canada. You can write a letter to the Minister of Health and the elected representative in your province or territory to advocate for better and equal coverage. You can also put up a "*Leveling the Field in Canada*: Moving Toward Reimbursement Equality in Biologic Therapy for Canadians with Rheumatoid Arthritis" poster in your offices, urging your patients to visit www.jointhealth.org for more information.

If you are a Canadian living with arthritis,

there are numerous things you can do to equalise coverage of biologics across Canada. Primarily, you can write a letter to the Minister of Health and your elected representative in your province or territory to advocate for better and equal coverage. Also, patients interested in further advocacy options could go to www.jointhealth.org for more information.

ACE would like to acknowledge its co-authors and supporters of the Leveling the Field in Canada paper:

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We would also like to acknowledge the contributions of Advocacy Solutions.

Questions & Answers

Question: What are biologics?
Answer: Biologics are a class of medication used to treat patients with moderate to severe rheumatoid arthritis (RA). They are therapies that have been engineered to target and block specific disease pathways responsible for the inflammation and joint destruction characteristics of RA.

Question: Is there one biologic for all patients with RA?
Answer: No, no one biologic therapy is effective for all patients. Each patient's disease is different and requires a unique treatment plan. The clinician and patient must weigh the potential risk-benefit ratio for each biologic treatment. It is therefore critical that clinicians have access to different biologics, in order to best treat their patients.

Question: Has one biologic proved to be more effective than the others?
Answer: There are no studies that have compared biologics to one another. However, statistical data has shown that no one biologic is superior to the other. This may be because RA behaves differently in every patient, and therefore each patient has a different response to each biologic.

Question: What is the process for receiving public reimbursement coverage for the cost of a biologic?
Answer: Reimbursement for a biologic is approved in those patients with RA where treatment criteria have been met. However, the public reimbursement process is not equal across all of the provinces and territories, which leaves serious gaps in care.

Question: What is public reimbursement coverage like for biologics across Canada; is it the same?
Answer: Each province/territory has different coverage of biologics. There is no uniform public reimbursement across Canada.

Question: Which provinces or territories have the worst public reimbursement coverage for biologics?
Answer: Manitoba and Prince Edward Island have the poorest public reimbursement coverage. On a case-by-case basis, these provinces provide reimbursement for 4 of the biologic therapies approved by Health Canada. Their reimbursement criteria is overly restrictive, they have the longest wait times for processing, and no appeal mechanism in place.

Question: Which provinces or territories have average public reimbursement coverage for biologics?
Answer: Alberta, Quebec and Nova Scotia rank as having average reimbursement coverage. They provide reimbursement for 5 of the 7 biologics, but have somewhat restrictive criteria and longer wait times than some of the other provinces/territories. Furthermore, there is no transparent appeal process for denied reimbursement coverage.

Question: Which provinces or territories have the best public reimbursement coverage for biologics?
Answer: British Columbia and Saskatchewan have the best coverage. On a case-by-case basis, they provide reimbursement for 5 out of 7 biologic therapies approved by Health Canada, they have the least restrictive reimbursement criteria, and the shortest wait times for initial processing for reimbursement. They have the fewest number of reimbursement renewal applications required and formal or informal appeal mechanisms in place for case-by-case reimbursement coverage denials.

Question: Why is equal coverage throughout the provinces and territories so important?
Answer: Rheumatoid arthritis is a debilitating autoimmune disease that progressively erodes the synovial joints and the surrounding tissues. If left untreated, it causes irreversible joint damage, chronic pain, and loss of joint function all of which result in the profound loss of quality of life and a decreased life expectancy. Joint damage begins within six weeks of RA initiation. It is therefore imperative that all Canadians have quick access to these drugs without having to combat the uneven public drug plan requirements.

Question: What can you do as a physician to level the playing field in Canada?
Answer: As a physician, there are several things you can do to equalise coverage of biologics across Canada. You can write a letter to the Minister of Health and your elected representative in your province or territory to advocate for better and equal coverage. You can also put up a "*Leveling the Field in Canada*: Moving Toward Reimbursement Equality in Biologic Therapy for Canadians with Rheumatoid Arthritis" poster in your offices, urging your patients to visit www.jointhealth.org for more information.

Question: What can you do as a patient to level the playing field in Canada?
Answer: As a patient, there are numerous things you can do to equalise coverage of biologics across Canada. Primarily, you can write a letter to the Minister of Health and your elected representative in your province or territory to advocate for better and equal coverage. Also, patients interested in further advocacy options should go to www.jointhealth.org for more information.