Common Drug Review
Patient Group Input Submissions

certolizumab pegol (Cimzia) for Ankylosing Spondylitis

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.
Arthritis Consumer Experts— permission granted to post.
Canadian Spondylitis Association — permission granted to post.
The Canadian Arthritis Patient Alliance — permission granted to post.

CADTH received patient group input for this review on or before August 28, 2014
CADTH posts all patient input submissions to the Common Drug Review received on or after February 1, 2014 for which permission has been given by the submitter. This includes patient input received from individual patients and caregivers as part of that pilot project.

The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations. While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

Arthritis Consumer Experts

Section 1 – General Information

Name of the drug CADTH is reviewing and indication(s) of interest	The use of IV form of certolizumab pegol (Cimzia®) for the treatment of ankylosing spondylitis
Name of the patient group	Arthritis Consumer Experts (ACE Planning and Consulting, Inc.)
Patient group's contact information:	info@jointhealth.org 606-974-1366 200A - 1228 Hamilton Street Vancouver, BC V6B 6L2 www.jointhealth.org
Permission is granted to post this submission	Yes

1.1 Submitting Organization

Arthritis Consumer Experts (ACE) is a national organization that provides science-based information, education and support programs in both official languages to people with arthritis. ACE serves consumers living with all forms of arthritis by helping them take control of their disease and improve their quality of life.

Arthritis Consumer Experts is committed to the following organizational objectives:

- To inform, educate and empower people with arthritis to help them take control of their disease and improve their quality of life;
- To provide evidence-based information in reader-friendly language to people with arthritis, the public, governments and media;
- To provide research decision-making training to people with arthritis to help them participate meaningfully in research organizations and in consultations with government.

ACE's membership and program subscribers include people with arthritis, their families, their caregivers, rheumatologists, and other health professionals.

1.2 Conflict of Interest Declarations

Arthritis Consumer Experts receives unrestricted grants-in-aid from the following private and public sector organizations: AbbVie Corporation, Amgen Canada, Arthritis Research Centre of Canada, BIOTECanada, Bristol-Myers Squibb Canada, the Canadian Rheumatology Research Consortium, Canadian Institutes of Health Research, Celgene Inc., GlaxoSmithKline, Hoffman-La Roche Canada Ltd., Janssen Inc., Pfizer Canada, Purdue Pharma L.P., Takeda Canada Inc., and the University of British Columbia. ACE also receives unsolicited donations from its community members (people with arthritis) across Canada.

a) Regarding those playing a significant role in compiling this submission:

This is not applicable, as it was solely the staff and advisory board of Arthritis Consumer Experts that aided in the compilation of this information.

Section 2 – Condition and Current Therapy Information

2.1 Information Gathering

The information was gathered through a request for patient input from JointHealth™ members and subscribers sent via email and posted on the JointHealth™ website. The response by the patients was given through telephone conversations and email correspondence.

2.2 Impact of Condition on Patients

The patients' day-to-day life is affected greatly by their AS. Patients have to consider what they can do for the day and how they will do it. The following are answers provided by the patients interviewed:

- **Interviewee A** indicates that she has trouble completing too many activities in one day. She has to plan ahead for each day. The main challenge is to pace herself accordingly so that she does not get too tired. Doing repetitive activities aggravates her AS symptoms. She had to stop playing tennis, one of her favourite sports, because it caused too much trauma to her joints. As well, she has difficulty participating in other impact sports. Luckily, she is able to participate in gentle sports like swimming and aqua aerobics.
- **Interviewee B** has lived with AS since an injury to her sacroiliac joint at the age of seventeen. She is now 63 years old. Her AS affects her cervical and lumbar spine. She also suspects her AS affects her thoracic vertebrae as her chest expansion is minimal. Most of time, she is without pain and has been since her neck became one long, curved bone. For her, the most important thing to control is the rate and degree of cervical spine fusion. She has difficulty looking up or down, left or right, without turning her whole body or leaning at precarious and slightly odd angles. Doing tasks above the head is next to impossible except through Braille-like manipulation of known objects, such as nuts, bolts, hammers, and screws. She can paint baseboards and floors but is not as efficient with crown mouldings and ceilings. Because of her AS, she can no longer enjoy stargazing and bird watching. Emotionally, knowing her body is permanently deformed causes a feeling of low self-esteem on some days.

2.3 Patients' Experiences With Current Therapy

Interviewee A cannot take DMARDs because of liver problems, but she has been managing AS with the anti-inflammatory Celebrex® for about five years now. She notes that Celebrex® does not keep her AS under control as she continues to get back attacks. Sulphasalizine and methotrexate had no effect on her AS. She is not a candidate for Humira® because she has had a form of tuberculosis (TB) before and she also gets infections easily.

Interviewee B currently takes Enbrel® once a week and Celebrex® when needed. She has Tylenol-3's but rarely uses them. She thinks exercising more will improve her AS over time. Enbrel® is very effective at managing pain, allowing for increased flexibility and increased range of motion. The only challenge she experiences is the need for annual renewal of the special coverage approval via PharmaCare.

Patients interviewed agree that having more treatment options means a better access to medication. It is always safe to have a backup plan in case the current therapy loses its efficacy. It is also important to see all medications covered by insurance plans. The best treatment is one that has fewer adverse effects, eliminates pain, easy to self-administer and non-invasive.

In support of research, ACE recently conducted a survey with people living with arthritis. Patients ranked "being able to function and live a normal life" and "having affordable and accessible treatment options" as the top two priorities for them. ACE believes additional therapies will provide each patient with more

options for their unique circumstances, when considering which medication to take for their disease. This is especially true when indirect treatment costs far exceed medication cost

2.4 Impact on Caregivers

Interviewee A's husband has to help out with the housework, such as cleaning, grocery shopping, and doing the laundry. As the interviewee and her husband are both retired, her AS does not affect either of their work. She gets abdominal discomfort from Celebrex® and has to adjust the amount she takes according to her discomfort level.

Interviewee B has never relied on a caregiver. She is able to manage without one.

The patients interviewed expressed concerns of adverse effects over a prolonged period. The patients agree that they will take the medication that is most effective in treating their AS and that poses the least chance of adverse effects.

Section 3 – Information about the Drug Being Reviewed

3.1 Information Gathering

The information was gathered through a request for patient input from JointHealth™ members and subscribers sent via email and posted on the JointHealth™ website. The response by the patients was given through telephone conversations and email correspondence.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

a) Based on no experience using the drug:

Interviewee A expects IV certolizumab pegol would be less harmful on her liver. She also hopes that there will not be any contraindications, such as getting an infection easily. As she has had a type of TB, her liver is "extra sensitive". Although her arthritis presents mildly active, she thinks it will be great if she feels 100% better, but would be happy with 50% as long as she does not get her "back attacks".

Each person living with arthritis responds differently to each medication, and no single biologic therapy is effective in each person with ankylosing spondylitis. In the patients' opinion, access to IV certolizumab pegol means a new chance for them to have a treatment that will be more effective in managing their disease if another biologic(s) used before it, fails or stops working. Providing reimbursement to the medication can also give professionals the tools to help their patients achieve remission.

ACE recommends a well-rounded treatment plan for AS that includes medication, education, physiotherapy and occupational therapy, and a healthy diet. Initiation of the right medication in autoimmune arthritis is vital for helping someone gain back and maintain joint health. A patient's care team and support network can help the patient achieve an optimal response to therapy

b) Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:

None of the patients interviewed had experience with IV certolizumab pegol. A manufacturer's compassionate supply is difficult to obtain as it is typically only supplied to adults who are seriously ill or have failed 3 to 4 different therapies.

Arthritis Consumer Experts (ACE) is focused on connecting with, and helping, people who live with rheumatoid arthritis, among other forms of arthritis. It is on their behalf that ACE advocates for positive reimbursement recommendations. Doing so appropriately offers more medication options and creates and environment for the physician and patient to practice "personalized medicine" and possibly achieve disease remission. Focusing on remission as the treatment target delivers the best chance of a person with arthritis to gain back some semblance of a normal life and maximize their full potential as human beings.

ACE, like other arthritis organizations in Canada, believes clinical trials are extremely important to advancing research into new and effective treatments. As well, patients across the country who are refractory to current therapies rely on the emerging treatments being tested in clinical trials and post-marketing studies.

c) How is the new drug expected to change a patient's long-term health and well-being?
All the interviewees were open to trying IV certolizumab pegol and said they hoped that the medication would lessen their AS pain and allow them to manage/perform their day-to-day activities. They were, however, concerned that they would have to visit their rheumatologists to receive the IV certolizumab pegol treatment.

Arthritis Consumer Experts (ACE) is focused on connecting with, and helping, people who live with rheumatoid arthritis, among other forms of arthritis. It is on their behalf that ACE advocates for positive reimbursement recommendations. Doing so appropriately offers more medication options and creates and environment for the physician and patient to practice "personalized medicine" and possibly achieve disease remission. Focusing on remission as the treatment target delivers the best chance of a person with arthritis to gain back some semblance of a normal life and maximize their full potential as human beings.

The patients concluded with a plea to the healthcare system to find medications that help people with AS achieve remission. When a patient achieves remission, they are able to live a normal life free from adverse effects and maximize their full potential as human beings.

Section 4 – Additional Information

Throughout the CADTH Patient Input Template, the term "condition" is used. Since CADTH reviews products that are largely for people living with diseases, and that are being developed to treat debilitating, possibly life ending diseases such as ankylosing spondylitis, which is a serious incurable autoimmune form of arthritis.

Using the word "condition" is not medically accurate, nor is it respectful of patients living with serious chronic diseases. Please see
www.rheumatology.org/Practice/Clinical/Diseases_And_Conditions/Rheumatoid_Arthritis/

ACE requests that the term "condition" be replaced with "disease"—or at least "disease and/or condition"— consistently throughout the document.

Canadian Spondylitis Association

Section 1 – General Information

Name of the drug CADTH is reviewing and indication(s) of interest	CIMZIA, (Certolizumab pegol) For Ankylosing Spondylitis.
Name of the patient group	CANADIAN SPONDYLITIS ASSOCIATION
Name of the primary contact for this submission:	[redacted]
Name of author (if different)	
Patient group's contact information:	info@spondylitis.ca (416) 694-5493 18 LONG CRESCENT, TORONTO, ON. M4E 1N6 WWW.SPONDYLITIS.CA
Permission is granted to post this submission	Yes

1.1 Submitting Organization

The Canadian Spondylitis Association was formed in 2006 as a volunteer-run patient support and advocacy association for those living with Spondyloarthritis, a group of related diseases that includes Ankylosing Spondylitis (AS) and Psoriatic Arthritis (PsA).

The aims of the Association are:

- To promote the growth of CSA membership in Canada
- To be a voice for advocacy for SpA patients across Canada nationally and provincially.
- To support and advocate for research into SpA in Canada.
- To provide a national resource centre for information relevant to the SpA community.
- To provide a national forum for partnerships between the medical and patient communities to further research into the causes and management of SpA.
- To facilitate a pool of willing volunteer patients who may make themselves available for professional training programs such as medical student undergraduate teaching, post-graduate training programs.
- To participate in the international SpA community.
- To promote public awareness of SpA through the media, public forums and other means.

Our membership is comprised of individuals, the majority of whom have Ankylosing Spondylitis but also including individuals with other forms of Spondyloarthritis, and some of their family members.

1.2 Conflict of Interest Declarations

The Canadian Spondylitis Association receives both unrestricted and restricted grants from pharmaceutical industry partners. We have received funding from Abbvie (unrestricted and restricted grants), Janssen (restricted educational grants) and UCB Canada (restricted travel grant).

We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:

No conflicts. All Directors are volunteers.

Section 2 – Condition and Current Therapy Information

2.1 Information Gathering

Information was gathered from our general membership and from the Board of Directors. We interact frequently with our membership through patient forums, newsletters, our website and our Facebook pages, which are in both English and French. Our Directors all have AS and speak with many years of experience with different treatments.

2.2 Impact of Condition on Patients

The onset of Ankylosing Spondylitis is often in the teenage years or early 20s. Onset after the age of 45 is unusual. There is no cure and while people experience different levels of severity, the symptoms of the disease are generally pain in the sacroiliac joints, hips, lower back spreading up to and including the neck, morning stiffness, fatigue and depression. Progression of the disease causes fusion in the vertebra and spinal deformity. Other joints such as the knees, ankles and wrists can become involved. Iritis and uveitis are frequently experienced.

The chronic pain of Ankylosing Spondylitis together with fatigue and depression significantly reduces the quality of life for patients, making work or study difficult or impossible. Individuals find that normal activities such as carrying one's baby, walking, participating in athletic and recreational activities, even sitting and driving, become limited.

It is devastating for young individuals to find themselves diagnosed with AS. They become struck down in the prime of life and also suffer because of the lack of awareness and understanding of AS, even though it is almost as common as Rheumatoid Arthritis.

2.3 Patients' Experiences With Current Therapy

Existing therapies include NSAIDs, analgesics, DMARDs, biologics and exercise. Many patients with milder disease will do well on NSAIDs and appropriate exercise. DMARDs are effective only with peripheral, not axial, disease. For patients with more severe disease, biologics have proved to be very effective in many cases. However, some patients who go on a specific biologic will find that it is ineffective for them and will have to try another biologic. In addition, the efficacy of a specific biologic for a patient may wear off, resulting in the need to switch to another biologic. This points to the fact that existing biologics do not work for everyone and that it is important to have as large an arsenal of biological drugs as possible for AS patients because of the failure rates after starting on biologics.

There are hardships in accessing current biological therapies. Aside from the need to first fail on NSAIDs and the costs of the biologics, not all biologics that are approved for Rheumatoid Arthritis are approved or effective for AS, reducing the amount of choice. There is also the serious matter of time to diagnosis, which is notoriously long for AS patients. It is known that the earlier the diagnosis and the earlier treatment starts, the better the outcome. However, biologics may not be prescribed until AS shows up

radiographically, which may be many years after onset. There is a need to recognise Axial Spondyloarthritis as a precursor to AS and for the ability to use biologics from the time of diagnosis.

2.4 Impact on Caregivers

AS is an insidious disease. The long time to diagnosis can be very demanding for both the patient and their caregiver. Patients can feel that along with the pain, fatigue and depression, they are losing their minds. Caregivers find it hard to understand what is happening when faced with someone who looks healthy but has unexplained health issues, who can be normal and active one day and the next sleep all day.

Because AS commonly appears in the teenage years or 20s, the onset places a physical and mental burden on parents and caregivers. A great deal of patience is required in dealing with young AS patients because of the ups and downs of their disease and their inability to maintain activities in which they were involved. The symptoms of the disease have an adverse effect on their social, educational and business lives, all things that the caregiver will concern themselves with too.

Biologics offer not only relief and slowing of disease progression for those with AS, but relieve the mental anguish and physical burden of caregivers.

Section 3 – Information about the Drug Being Reviewed

3.1 Information Gathering

Information was gathered from our general membership and from the Board of Directors. We interact frequently with our membership through patient forums, newsletters, our website and our Facebook pages, which are in both English and French. Our Directors all have AS and speak with many years of experience with different treatments.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

a) Based on no experience using the drug:

It is clearly the case that patients on biologics that work for them are productive members of society. They are in the work force, paying taxes and living a life of quality. On the other hand, there are those patients who are revolving through different biologics trying to find one that works for them (and their co-morbidities because AS patients can also suffer from Inflammatory Bowel Disease). The choice is limited. Additional choices are welcome and desirable and this is the expectation of the new drug.

Every patient who starts on a biologic has some worries about adverse side effects. However, the informed consumer does a risk/reward analysis about their own unique circumstances. Generally this means that patients will trade having adverse side effects from biologics for a better quality of life than not being on them. The patient who fails on a biologic or finds that their biologic treatment loses its efficacy has a difficult time with first, the failure of the drug to improve symptoms and second, the ordeal of switching within a very limited number of treatment options.

b) Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:

We are unable to comment due to the difficulty of finding any significant commentary from individuals who have already been on Cimzia for AS. However, Cimzia does offer an additional choice, which is important to the patient community. It is desirable that more biologics are available to allow all patients suffering from AS to lead productive and normal lives.

Section 4 – Additional Information

We question the fact that this drug is "Queued" and what that means? Your review should be subject to strict time frames so that patients know when new drugs will be available. Why is patient input called for now if the review is not proceeding? Does the fact that the review is queued mean that there are queue jumpers? Your process should be much more transparent.

The Canadian Arthritis Patient Alliance

Section 1 – General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Cimzia for Ankylosing Spondylitis
Name of the patient group	The Canadian Arthritis Patient Alliance
Name of the primary contact for this submission:	[redacted]
Name of author (if different)	
Patient group's contact information:	[redacted] Address: Virtual www.arthritispatient.ca
Permission is granted to post this submission	Yes

1.1 Conflict of Interest Declarations

Sources of grants and support received by CAPA in the last year include: AbbVie, Amgen Canada, Arthritis Alliance of Canada, The Arthritis Society, Canadian Rheumatology Association, Janssen, Novartis, Ontario Rheumatology Association, and UCB Pharma.

Additionally, CAPA has also received support in the past from: Canadian Institutes for Health Research, Hoffman-La Roche, Pfizer Canada, Rx&D, Schering Canada, Scleroderma Society, and STA Communications.

We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:

No conflict.

Section 2 – Condition and Current Therapy Information

2.1 Information Gathering

Please briefly identify how the information to complete Section 2 was obtained. Was it obtained, for example, through personal experience, focus groups, one-to-one conversations with a number of patients using the current therapy, printed sources, etc.?

The information was obtained through personal experiences of the Board of The Canadian Arthritis Patient Alliance in living with inflammatory arthritis, in addition to many years of interfacing with our membership.

2.2 Impact of Condition on Patients

Ankylosing Spondylitis (AS) is not as common a form of inflammatory arthritis as the more prevalent Rheumatoid Arthritis (RA). Although most types of inflammatory arthritis (IA) affect women more than men, AS is the exception to this. Onset of AS symptoms can occur during the teenage years, lasting a lifetime as there is no cure and impacting the ability to continue to receive an education, as well as launch and maintain a career. There are far fewer treatments available to treat AS; not all the medications that are approved and available to treat RA are shown to be effective in AS. In addition, not every medication that is approved and available works for everyone. AS is a challenging disease to manage; physicians and patients often have to try different drugs to find something that works well for a particular person. In addition, a patient's immune system can adapt to a drug making it necessary to switch to another treatment when one becomes ineffective. We would like to highlight to the review committee (since we understand that the members may not be experts in inflammatory arthritis) that it is not sufficient to only have one or two drugs available to treat AS, patients require as many options as possible since everyone's response to these biologics are different. Perhaps in the future tests may exist that will be better able to predict response to therapies but that point has not yet arrived. AS that is unresponsive to treatments is extremely debilitating and can result in serious, long term disability as well as a major burden to the health care system. This has a disastrous effect on a patient's and their family's quality of life, including both physical and psychological manifestations. It is vital that inflammation be controlled early and well so that patients can continue to be productive members of society.

2.3 Patients' Experiences With Current Therapy

As stated in 2.2, not all drugs approved for the more common form of inflammatory arthritis, rheumatoid arthritis are approved for ankylosing spondylitis. These patients have fewer options, AS is a rarer form of IA so there are also more challenges in receiving a diagnosis and accessing treatment as early as possible which is crucial for an optimum health outcome. Evidence has clearly shown that in order to avoid joint damage patients should be diagnosed and inflammation controlled with six months of onset of symptoms.

Patients who are being considered for treatment with a biologic have generally failed on conventional, less expensive therapies or they were unable to tolerate them because of adverse reactions. Existing therapies include Non-Steroidal Anti-inflammatory Drugs (NSAIDS), analgesics, Disease Modifying Anti-Rheumatic Drugs (DMARDS), biologics and exercise. Many patients with milder disease will do well on NSAIDs and appropriate exercise. DMARDs are effective only with peripheral, not axial, disease and are not effective for all patients.

2.4 Impact on Caregivers

AS is a disease that can appear during late teenage into young adult years and then is a chronic illness (there is no cure), every therapeutic tool available is needed to assist an individual through this period in their life when education and interaction with their peers is so vital to future success.

For those patients whose AS is not well controlled day to day activities such post-secondary education, becoming employed, taking care of oneself, walking, cooking, grocery shopping, house work, being in a relationship, getting married, having and caring for children and social activities can be extremely difficult and in some cases, impossible to undertake. All of the above causes extreme stress not only on the person living with the illness but on their families and caregivers.

Section 3 – Information about the Drug Being Reviewed

3.1 Information Gathering

The information was obtained through personal experiences of the Board of The Canadian Arthritis Patient Alliance in living with inflammatory arthritis, including anklylosing spondylitis. Our Board members have facilitated educational programs for people living with arthritis and CAPA has been interfacing with its membership since 2002.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

a) Based on no experience using the drug:

It is expected that patients living with Ankylosing Spondylitis, a rarer form of inflammatory arthritis will have another treatment option to consider that will help alleviate the severe, disabling symptoms of their disease for which some patients develop an immunogenicity response. We strongly believe that patients require access to all approved and available treatment options that have been demonstrated to be safe and effective so that they are able to continue to live full and productive lives as tax paying, productive and contributing citizens.

b) Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:

Nothing to add that has not already been stated

Section 4 – Additional Information

The Canadian Arthritis Patient Alliance finds it unconscionable that CADTH would put out a call for patient input on a drug that is currently in a queue with no time frame for review by CDEC. Patients living with severe, disabling inflammatory arthritis who have exhausted all their options for treatment are waiting for new therapies with the hope that they will regain some measure of quality of life. CADTH should not be asking for input from patients on potential new treatment options until the option is actually going to be considered by the review committee.