CADTH

Common Drug Review

Patient Group Input Submissions

certolizumab pegol (Cimzia) for psoriatic arthritis

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

CADTH received patient group input for this review on or before September 22, 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 (ACE Planning and Consulting Inc.)

1. General Information

Name of the drug CADTH is reviewing and indication(s) of interest	certolizumab pegol (Cimzia) for Psoriatic Arthritis (PsA)
Name of the patient group	Arthritis Consumer Experts (ACE Planning and Consulting, Inc.)
Name of the primary contact for this submission:	[redacted]
Position or title with patient group	[redacted]
Email	[redacted]
Telephone number(s)	[redacted]
Name of author (if different)	
Patient group's contact information: Email	info@jointhealth.org
Telephone	606-974-1366
Address	200A - 1228 Hamilton Street Vancouver, BC V6B 6L2
Website	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, elected officials, and senior government bureaucrats.

1.2 Conflict of Interest Declarations

a) Regarding corporate members and joint working, sponsorship, or funding arrangements:

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, Canadian Institutes of Health Research, the Canadian Rheumatology Research Consortium, Celgene Inc., GlaxoSmithKline, Hoffman-La Roche Canada Ltd., Janssen Inc., Pfizer Canada, Purdue Pharma L.P., St. Paul's Hospital and the University of British Columbia. ACE also receives unsolicited donations from its community members (people with arthritis) across Canada.

b) 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.

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 submission is based on previous patient inputs and interviews we have conducted throughout ACE's 15 years as an organization.

2.2 Impact of Condition on Patients

a) What are the condition-related symptoms and problems that impact the patients' day-to-day life and quality of life?

The patients' day-to-day life is affected greatly by their PsA. Unlike most people who can take their physical/mobility abilities for granted, people living with psoriatic arthritis must always consider the state of their disease and decide what they can (and cannot) cope with or achieve, how they can go about it, and how much help they may need.

Examples of activities that those living with PsA have difficulty with, include:

- **Activities at home**: These include having difficulty getting out of bed due to morning stiffness; difficulty doing house chores because of a limited range of motion; difficulty getting up and down stairs and in and out of the bathtub; difficulty with cooking; and, difficulty getting dressed in the morning. House chores often require the use of modified tools that help extend the patient's reach.
- **Activities at work:** The feeling of fatigue and pain that is the norm with PsA and the unpredictable nature of the disease (some days the pain is more extreme than others) may prevent someone with PsA from going to work. It can be very stressful for a patient entering the workforce, as he would have to consider the benefit package and the flexibility of his workplace that can best accommodate his disease. Many patients have indicated to ACE they stopped working completely as a result of their arthritis pain and live on the limited income of disability pension.
- **Lifestyle activities:** PsA can affect a patient's lifestyle, including their sleep patterns, exercise routine, relationships with friends, significant others, and family, and parenting. Patients with PsA have to get up and stretch all the time to prevent muscle and joint stiffness. Friends and families of patients with PsA often have to sacrifice time and money to assist where necessary. For example, taking time off work to drive a patient to see their doctor.

It is important to note that an issue in PsA that is cross-cutting amongst the above domain is that of depression. Numerous published research studies show that depression has a tremendous negative impact on patients living with PsA. The skin manifestations associated with PsA are very visible and cause heightened anxiety and depression.

2.3 Patients' Experiences With Current Therapy

a) How well are patients managing their condition with currently available treatments?

In general, of the patients ACE has spoken with about their experiences of managing their PsA with currently available treatments, their comments and concerns included:

- Intolerance of methotrexate in combination with other medications.
- How their medication is administered.
- The loss of efficacy of their medication over time.
- Time commitment required from them as a patient (taking time off work, travel to and from clinics).

To summarize, patients believe that the more options there are, the better. Having more options could mean better access to medication, having a backup plan in case the current therapy treatment stops working, and having an economically sound solution in case the current therapy treatment is no longer covered under an insurance plan. As well, they feel that the best treatment is one that has the fewest adverse effects. Through ACE's research and education efforts, people with PsA who interact with our organization generally understand there is a high degree of variability of disease and that there is a need for increased research activity into the causes and possible cures for the disease.

2.4 Impact on Caregivers

a) What challenges do caregivers face in caring for patients with this condition? How do treatments impact on the caregivers' daily routine or lifestyle? Are there challenges in dealing with adverse effects related to the current therapy?

Caregivers of patients with PsA have indicated that time is always a concern for them. They need to arrange and plan their schedule to accommodate for sudden and emergency requests from the person living with PsA. They have to help with house chores when the patient is in extreme pain, as well as fulfill the financial responsibilities they owe to themselves and their household.

The patients expressed concerns of adverse effects over a prolonged period. Even though their medication(s) is successful in treating their PsA, a risk of developing other medical conditions is a strong possibility. All the patients agree that they will take the medication that is most effective in treating their PsA and that poses the least chance of adverse effects.

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 submission is based on previous patient inputs and interviews we have conducted throughout ACE's 15 years as an organization.

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:

According to all of the patients, it is difficult to determine with certainty that patients' lives will be improved by certolizumab pegol, but they are all willing to try certolizumab pegol. The patients expect any success story to parallel the results from the data and studies of previous treatment methods for other similar medication.

Each person living with arthritis responds differently to each medication, and no single biologic therapy is effective in everyone with a particular condition. In the patients' opinion, access to 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. Allowing access to the medication can also give professionals the tools to help their patients achieve remission.

ACE recommends a well-rounded treatment plan for PsA 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 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 have experience with using certolizumab pegol to treat PsA. 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.

c) How is the new drug expected to change a patient's long-term health and well-being?

The patients hope that certolizumab pegol will lessen their PsA pain so that they can manage to do day-to-day activities. The patients concluded with a plea to the healthcare system to find medications that help people with PsA 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.

4. Additional Information

We have no additional information for CADTH, CDEC, and participating drug plans.

The Canadian Arthritis Patient Alliance

1. General Information

Name of the drug CADTH is reviewing and indication(s) of interest		Certolizumab Pegol/Cimzia for Psoriatic Arthritis
Name of the patient group		The Canadian Arthritis Patient Alliance
Name of the primary contact for this submission:		[redacted]
Position or title with patient group		[redacted]
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	Website	www.arthritispatient.ca
Permission is granted to post this submission		Yes

1.1 Submitting Organization

CAPA is a grass-roots, patient-driven, independent, national education and advocacy organization with members and supporters across Canada. CAPA creates links between Canadians with arthritis, assists them to become more effective advocates and seeks to improve the quality of life of all people living with the disease. CAPA believes the first expert on arthritis is the individual who has the disease, as theirs is a unique perspective. We assist members to become advocates not only for themselves but all people with arthritis. CAPA welcomes all Canadians with arthritis and those who support CAPA's goals to become members.

1.2 Conflict of Interest Declarations

a) *We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:*

In the past year, CAPA has received both restricted and unrestricted funding and in-kind support from: Abbvie, Amgen, Hoffman-La Roche, Janssen, Novartis, Pfizer Canada, UCB Pharma, Rx&D, The Ontario Rheumatology Association, The Canadian Rheumatology Association, and The Arthritis Society.

Additionally, CAPA has also received support in the past from: Canadian Institutes for Health Research, Schering Canada, Scleroderma Society, and STA Communications

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

No conflict.

2. Condition and Current Therapy Information

2.1 Information Gathering

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

Psoriatic Arthritis (PsA) is a type of inflammatory arthritis (IA) that is a serious, debilitating auto-immune disease affecting every aspect of a patient’s day to day life. Patients often experience psoriasis first, and then experience the onset of PsA symptoms usually between the ages of 20 and 50. PsA affects men and women relatively equally and as with other forms of IA, there is currently no cure, only ways to help alleviate symptoms and hopefully slow the progression of disease. PsA is a chronic disease that one lives with from the onset of symptoms until death. The disease is characterized by inflammation in the joints that destroys the lining and ultimately the surrounding bone resulting in the need for a total joint replacement. Once damage occurs, it is not reversible and can cause significant pain and disability. There are 5 well-documented patterns of PsA and it can be very different from person to person.

PsA is a challenging disease to manage. Physicians and patients work together to suggest and try different drugs to find one that works well for each patient and their PsA. There are currently no methods to help physicians predict which patients will respond best to which therapies. In addition, a patient’s immune system may adapt to a drug, requiring them to switch to another when one becomes ineffective based on their immune system’s adaption. As a result, patients may require many medication options, changing medications a number of times during their lifetime.

For those whose PsA is not well controlled, day to day activities, such as participating in post secondary education, becoming and remaining employed, taking care of oneself (bathing, dressing, activities of daily living) and one’s family, and other activities that the healthy general population simply take for granted, become very difficult. It is vital that inflammation be controlled early and well so that patients can continue to be productive members of society. We know the economic benefits to society of keeping people living with PsA in the work force and productive are greater than those required of the healthcare and long term disability if patients do not receive treatments for their disease.

2.3 Patients’ Experiences With Current Therapy

Both small molecule and biologic disease- modifying anti-rheumatic drugs (DMARDS) are available to treat PsA. The biology of a patient’s response to PsA medications is not well understood or predicted, necessitating a trial and error approach to find the most suitable treatment for their disease with minimal side effects and maximum efficacy. Some patients experience long periods of responding well to a drug while others, for unknown reasons, will need to try numerous drugs before finding one that works to control their symptoms (if at all).

While patients may require many medication options throughout their lifetime for the reasons mentioned above, they take only one biologic medication at a time. Which specific one is prescribed does not have a huge impact on cost, as they are all approximately the same, however it is important **to** pay and provide access for the specific one that works for a specific patient. Unfortunately, patients are not all the same and thus may have different responses to different drugs.

2.4 Impact on Caregivers

Depending on a person's ability to cope with activities of daily living and their ability to still be employed, caregivers of people living with PsA are relied upon in varying capacities. In some cases, caregivers are required to assist with simple tasks such as bathing, getting in and out of bed, getting dressed, even using the bathroom. The emotional toll on both patients and caregivers in this type of situation cannot be underscored enough. In other situations, a caregiver's burden may not be as great, perhaps giving the patient their injection or assuming more of the family responsibilities. Living with a severe chronic disease that is as potentially debilitating as PsA can affect a person profoundly, it makes no sense for governments to deny patients access to any medication that could keep them productive and contributing members of society.

3. Information about the Drug Being Reviewed

3.1 Information Gathering

As Cimzia is a relatively new product to Canada, CAPA has had no patients come forward with their experience. We are anticipating needs based on our Board's and membership's history of living with inflammatory arthritis. We have seen nothing that shows the experience of patients will change in the foreseeable future.

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:

As Cimzia is a relatively new product to Canada, CAPA has had no patients come forward with their experience. We are anticipating needs based on our Board's and membership's history of living with inflammatory arthritis. We have seen nothing that shows the experience of patients will change going forward. The answers to the above questions have been previously addressed in this submission.

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

See above 3.2 (a)

4. Additional Information

None.

The Canadian Spondylitis Association

1. General Information

Name of the drug CADTH is reviewing and indication(s) of interest		Cimzia (Certolizumab) for Psoriatic Arthritis (PsA)
Name of the patient group		CANADIAN SPONDYLITIS ASSOCIATION
Name of the primary contact for this submission:		[redacted]
Position or title with patient group		[redacted]
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Name of author (if different)		
Patient group's contact information:	Email	info@spondylitis.ca
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	Website	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

a) We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:

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).

b) 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.

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 Spondyloarthritis including PsA and speak with many years of experience with different treatments.

2.2 Impact of Condition on Patients

PsA is a type of inflammatory arthritis and an autoimmune disease, which usually starts slowly and gradually spreads from one joint to others. The onset of PsA is often in the teenage years or early 20s and is often preceded by Psoriasis (30% of patients with Psoriasis develop PsA). There is no cure and while people experience different levels of severity (there are five general patterns of PsA), the symptoms of the disease are generally pain and swelling in the peripheral joints, particularly the fingers and toes (dactylitis), but including the knees, ankles and lower back pain, pitted and discoloured fingernails and toenails, discoloured and scaly skin, and extreme fatigue. Iritis and uveitis are frequently experienced.

The chronic pain of PsA together with fatigue and depression significantly reduces the quality of life for patients, making work or study difficult or impossible for those individuals whose disease is not well controlled. PsA has no cure and is difficult to diagnose.
It is devastating for young individuals to find themselves diagnosed with PsA. They become struck down in the prime of life and also suffer because of the lack of awareness and understanding of PsA, a not uncommon disease. At best, treatment options will slow the progression of the disease by controlling inflammation and making life somewhat more normal for the patient. An early diagnosis and start of treatment is imperative to reduce the risk of irreversible damage to joints. This damage can be very painful and debilitating and can cause disability.

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 with peripheral disease. For patients with more severe disease, biologics have proved to be very effective in many cases. Many patients are on the biologics approved for PsA, Remicade (Infliximab), Enbrel (Entanercept), Humira (Adalimumab) and Simponi (Golimumab).

Many patients do well on a biologic but experience has shown that any particular biologic is not effective in all patients and furthermore, that the efficacy of a particular biologic may wear off over time as the patient's immune system adapts to it. 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 PsA patients because of the failure rates after starting on biologics.

Side effects reported for biologics are most commonly allergic reactions, infections and cold-like symptoms. Many patients worry about going on biologics because of possible side-effects. On balance, the positive effects of biologics outweigh the side effects for those patients for whom the biologic is effective. There are hardships, not all cost related, in accessing current biological therapies. Aside from the need to first fail on NSAIDs, we note that the need for infusion or injection treatments is disruptive and time-consuming, requiring travel to an infusion/injection site or the discipline for self-injecting. The cost of a biologic drug therapy is expensive and for those patients without a health insurance plan or one that only partially covers drug costs, or only access to their provincial health insurance, the cost can be demanding, not only on their own financial resources but in some cases, on the resources of their caregiver also.

2.4 Impact on Caregivers

The long time to diagnosis of PsA can be very demanding for both the patient and their caregiver. Patients can feel that along with the pain and fatigue, they are losing their minds. Caregivers find it hard to understand what is happening when faced with someone who has undiagnosed health issues, who can be normal and active one day and the next sleep all day. Because PsA appears in young adults, the onset places a physical and mental burden on parents and caregivers. A great deal of patience is required in dealing with young PsA patients because of the progression 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

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 Spondyloarthritis including PsA 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 PsA. 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 PsA to lead productive and normal lives.

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.