



# Common Drug Review

## *Patient Group Input Submissions*

### **Secukinumab (Cosentyx®) for the treatment of ankylosing spondylitis (AS)**

**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.

Canadian Arthritis Patient Alliance — permission granted to post.

Canadian Spondylitis Association — permission granted to post.

#### **CADTH received patient group input for this review on or before March 11, 2016**

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.)

### Section 1 — General Information

<b>Name of the drug CADTH is reviewing and indication(s) of interest</b>	secukinumab (Cosentyx®) for the treatment of ankylosing spondylitis (AS).
<b>Name of the patient group</b>	Arthritis Consumer Experts (ACE Planning and Consulting, Inc.)
<b>Name of the primary contact for this submission:</b>	██████████
Position or title with patient group	██████████
Email	██████████
Telephone number(s)	██████████
<b>Name of author (if different)</b>	
<b>Patient group's contact information:</b> Email	<a href="mailto:info@jointhehealth.org">info@jointhehealth.org</a>
Telephone	604-974-1366
Address	#210 - 1529 West 6 <sup>th</sup> Avenue Vancouver, BC V6J 1R1
Website	<a href="http://www.jointhehealth.org">www.jointhehealth.org</a>
<b>Permission is granted to post this submission</b>	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 Canada, BIOTEC Canada, Canadian Institutes of Health Research, Celgene Inc., Hoffman-La Roche Canada Ltd., Janssen Inc., Pfizer

Canada, Sanofi Canada, UCB Canada Inc. and the University of British Columbia. ACE also receives donations from its community members (people with arthritis) across Canada.

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

This submission was expressly written by the staff and advisory board members of Arthritis Consumer Experts, free from advice or influence from any outside individual or party.

## 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 submission is based on previous patient input responses. ACE has provided additional organizational comments to augment the individual information.

### 2.2 Impact of Condition on Patients

***What are the disease-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 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 plans a schedule for each day. In order to complete all her activities for the day, she has to pace herself accordingly to avoid pain and stress. 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. "I have difficulty looking up or down, left or right, without turning my whole body or leaning at precarious and slightly odd angles," she explained. 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

**How well are patients managing their disease with currently available treatments?**

- **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. Sulphasalazine 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.

To summarize, patients believe that the more treatment options are needed. Having more options could mean starting on the best therapy for their disease from treatment onset, as well as offers more options available if current therapy fails to work or stops working. As well, they feel that the best treatment is one that has the fewest side effects. Through ACE's research and education efforts, people with AS 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.

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. Emerging therapies provides each unique patient a greater spectrum of treatment options from which to select for their unique circumstances as patients and as people.

## 2.4 Impact on Caregivers

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

- **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 submission is based on previous patient input responses. ACE has provided additional organizational comments to augment the individual information.

### 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:*

Each person living with arthritis responds differently to each medication, and no single therapy is effective in each person with ankylosing spondylitis. Access to secukinumab means a new chance for patients to have a treatment that will be more effective in managing their disease if another DMARD or biologic used before it fails or stops working. Allowing reimbursement access to the medication

can also give professionals the tools to help their patients achieve remission, the ultimate “treat-to-target” goal. A large body of evidence now exists showing the treat-to-target approach reduces the impact of the disease on patients and delivers optimal patient reported outcomes.

ACE recommends a well-rounded treatment plan for AS that includes medication, education, physiotherapy and occupational therapy, and a healthy diet and an active lifestyle as appropriate. 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 interviewed previously have been asked about their experience with secukinumab.

Arthritis Consumer Experts (ACE) is focused on connecting with, and helping, people who live with AS, among other forms of arthritis. It is on their behalf that ACE advocates for evidence- and experience-based reimbursement recommendations. Doing so appropriately offers more medication options and creates an 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 resemblance 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.

***How is the new drug expected to change a patient’s long-term health and well-being?***

Patients expressed that they want medications that would lessen their AS pain and allow them to manage/perform their day-to-day activities. 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

Arthritis Consumer Experts is providing this patient input submission based on patients who have responded to our previous patient input requests for the treatment of ankylosing spondylitis.

Based on a large body of peer-reviewed evidence, ACE recommends a well-rounded treatment plan for AS that includes education (both disease and self management), appropriate immunosuppressive medication(s), therapeutic and recreational exercise, appropriate amounts of rest during flares, physical therapy, healthy diet and an overall healthy lifestyle. Paramount among these is the timely initiation of the most suitable medication, chosen by the patient in consultation with their rheumatologist and free from external pressures such as public formulary special authority criteria leading to “trial and error” prescribing. Getting it right quickly in AS means life or death to the joints and quality of life, if not life itself, so barriers to effective treatment must be minimized where at all possible.

# Canadian Arthritis Patient Alliance

## Section 1 — General Information

<b>Name of the drug CADTH is reviewing and indication(s) of interest</b>	Cosentyx (Secukinimab) for Ankylosing Spondylitis (AS)
<b>Name of the patient group</b>	Canadian Arthritis Patient Alliance
<b>Name of the primary contact for this submission:</b>	[REDACTED]
Position or title with patient group	[REDACTED]
Email	[REDACTED]
Telephone number(s)	[REDACTED]
<b>Name of author (if different)</b>	N/A
<b>Patient group's contact information:</b>	
Email	[REDACTED]
Telephone	416-358-5377
Address	204 Gerrard Street East, Unit 3, Toronto, Ontario, M5A 2E6
Website	<a href="http://www.arthritispatient.ca">www.arthritispatient.ca</a>
<b>Permission is granted to post this submission</b>	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 to assist them in becoming more effective advocates and to improve their quality of life. We assist members to become advocates not only for themselves but for all people with arthritis. CAPA believes the first expert on arthritis is the person who lives with arthritis - ours is a unique perspective. 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:*

Sources of grants and support received by CAPA in the last year include: AbbVie, Amgen Canada, Hoffman-La Roche, Janssen, Novartis, and UCB Pharma.

Additionally, CAPA has received support in the past from: Arthritis Alliance of Canada, The Arthritis Society, Canadian Institutes for Health Research (Institute for Musculoskeletal Health & Arthritis), Canadian Rheumatology Association, Ontario Rheumatology Association, Pfizer Canada, Rx&D, Schering Canada, the 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:

None to declare.

## Section 2 — Condition and Current Therapy Information

### 2.1 Information Gathering

Information here 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

Though not as common as Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS) is another type of inflammatory arthritis that is a serious, debilitating auto-immune disease, affecting every aspect of a patient's day-to-day life. Patients can feel the onset of symptoms in their late teens to early 20s, and often times live for many years in extreme pain without an accurate diagnosis. Most patients have their own stories about their painful and often debilitating journeys to seek a correct diagnosis. Unlike RA, AS affects predominantly men, a pattern that is not well understood. As with other forms of inflammatory arthritis, there is currently no cure for AS – only ways to help alleviate symptoms and hopefully slow the progression of disease – it is a chronic illness that one lives for from the onset of symptoms until death.

The disease is characterized by inflammation in the joints of the spine. This inflammation can spread to involve other parts of the spine and, in the most severe cases, involves the entire spine. As the inflammation continues and the body attempts to repair itself, new bone forms. This results in bones of the spine growing together (fusing), causing the spine to become very stiff and inflexible. Even though new bone has formed, the existing bone may become thin, which increases the risk of fractures.

AS is a challenging disease to manage and physicians and patients often have to try different drugs to find something that works well – there are currently no methods that help physicians predict which patients will respond best to which therapies. In addition, a patient's immune system can adapt to a drug making it necessary to switch to another treatment when one becomes ineffective. As a result, patients require many medication options as treatment response is not possible to predict and changes over time.

For those whose AS is not well controlled, day to day activities, such as participating in post-secondary education, becoming and staying employed, taking care of oneself 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 can imagine that the economic benefits to society of keeping people living with AS in the work force and as productive members of society are greater than those required of the healthcare system if patients do not receive treatments for their disease.

### **2.3 Patients' Experiences With Current Therapy**

Since the biology of a person's AS response to medications is not currently well understood or able to be predicted, patients with AS undergo trial and error in finding the most suitable treatment for their AS. Some patients experience long periods of responding well to a drug (meaning that their symptoms are well-controlled), while others, for reasons unknown, will need to be exposed to many different drugs over their lifetime to achieve the best treatment of their AS.

With the advent of biologics for the treatment of AS, there has been a need for either infusions or injections. Some patients have vein scarring and scar tissue from numerous infusions and injections. In the most extreme case, a patient would have been giving themselves injections or receiving infusions for over a decade (since biologics were first approved in 2000) – a reality faced by many patients living with AS. Patients may also face scheduling issues for infusions and need to take time off work or find someone to deal with family commitments (e.g. babysitting young children).

All biologics suppress the patient's immune system. Infections are a concern for patients with AS on biologics since even a common cold can quickly turn into something more serious, such as pneumonia.

Biologics are extremely costly for patients – while some patients have extended health insurance, others do not, and either rely on their own resources or those of their provincial Ministries of Health for assistance.

### **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 AS 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 toilet. 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 need to take over family responsibilities while the patient is receiving their infusion. Living with a chronic condition as potentially debilitating as AS can affect a person profoundly psychologically – including caregivers. Additionally, when patients do not have drug coverage options, if one's spouse is their caregiver, this adds to the burden of disease in ways nearly unimaginable.

It is important to highlight that AS affects patients and caregivers and family members profoundly, in all aspects of their lives – and does so from before their diagnosis, throughout their lives.

## **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, in addition to many years of interfacing with our membership.

### **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:*

Cosentyx represents a medication for a new target for AS (i.e. it targets IL-17A) – this presents a significant advance in treatment possibilities for patients with AS. All other biologic therapies for AS are currently anti-TNF targeted, so there is a potential that if/when patients no longer respond to those medications, they would have success with Cosentyx. This is a very important differentiating factor for Cosentyx over other medications that are currently available.

To reiterate the points made in section 2:

- Patients require a number of medication options (including Cosentyx) in order to manage their disease effectively over their lifetime;
- Vein scarring and infusion site reactions may be a significant issue for patients who need to receive their medications via transfusion;
- Current therapies often pose a number of side effects that patients unfortunately simply have to deal with because of a lack of other options;
- The availability of another self-administered monthly medication would reduce the amount of time spent by patients and their families on infusions, allowing them increased independence, and decreased time spent ‘as a patient.’

### **Section 4 — Additional Information**

We would reiterate the comments made on previous submissions here. As a patient organization, we have provided numerous submissions, and since we submit for the same inflammatory arthritis conditions (rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis), it would be great if we could simply reference large portions of those previous submissions for new submissions, if they correspond appropriately. While it may not seem like a lot of work, re-writing and re-working Sections 2.2, 2.3, and 2.4 is quite burdensome for individuals who are primarily volunteers. We again ask that CADTH and CDEC consider allowing us to simply point to those sections of previous submissions unless something has changed dramatically since the last submission.

# Canadian Spondylis Association

## Section 1 — General Information

<b>Name of the drug CADTH is reviewing and indication(s) of interest</b>	Secukinumab for Ankylosing Spondylitis
<b>Name of the patient group</b>	Canadian Spondylis Association
<b>Name of the primary contact for this submission:</b>	██████████
Position or title with patient group	██████████
Email	██
Telephone number(s)	██████████
<b>Name of author (if different)</b>	
<b>Patient group's contact information:</b> Email	<a href="mailto:info@spondylitis.ca">info@spondylitis.ca</a>
Telephone	(416) 694-5493
Address	18 Long Cres., Toronto, ON. M4E 1N6
Website	<a href="http://www.spondylitis.ca">www.spondylitis.ca</a>
<b>Permission is granted to post this submission</b>	Yes

### 1.1 Submitting Organization

The Canadian Spondylitis Association is an all-volunteer run patient organization to support, educate and advocate for those living with Spondyloarthritis. The aims of the Association are to create awareness of Spondyloarthritis with the objective of reducing the time from onset of disease until diagnosis, to provide information and education (mainly through patient forums with expert speakers) to those living with Spondyloarthritis, including caregivers and family, to enable them to better manage their disease, and to advocate for equal access to treatment options. The Association also facilitates discussion amongst its members and support for each other through its use of social media.

The Association's membership is comprised of individuals from all Provinces and Territories who live with Axial or Peripheral Spondyloarthritis, which includes Ankylosing Spondylitis and Psoriatic Arthritis. Since inception ten years ago, the Association has grown to a membership of over 1,600.

### 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 has received restricted educational and developmental grants from AbbVie, Amgen and Janssen, and restricted travel grants from UCB Canada.

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

The President, Michael Mallinson, has received honoraria from AbbVie (indirectly) and Novartis.

## Section 2 — Condition and Current Therapy Information

### 2.1 Information Gathering

Information was gathered through lived experiences. All members were invited to submit stories of their journeys with Ankylosing Spondylitis and answers to the specific questions outlined in this template. The information so gathered was complemented by information gleaned from our Facebook group discussions and from many conversations amongst the Board members (all of whom live with Spondyloarthritis) and with patients, particularly at our forums.

### 2.2 Impact of Condition on Patients

Symptoms of Ankylosing Spondylitis (AS) vary greatly from one individual to another. However, common symptoms are pain in the back, neck, hips and legs, with many experiencing pain in the shoulders, eyes, and feet. Stiffness, particularly in the morning, which can take up to an hour to relieve, is universal. Limited motion due to stiffness and fusing of the vertebrae is often reported. Fatigue, depression and anxiety are typical.

Patients report difficulty with completing household chores, participating in sports, lifting up children, sleeping, being in bed, standing for long periods, walking, and sitting for long periods. They also report a host of co-morbidities such as uveitis and Inflammatory Bowel Disease, stomach issues possibly caused by medications as well as social isolation brought on by pain and depression.

Many patients report the impact of being hit by this disease when they are young and active. AS typically strikes individuals, men and women, between the ages of 15 and 45. As one patient said “My daily activities went from always on the go to can’t get up and go.” The cause of this (pain, stiffness, discomfort in sitting, walking, standing) results in severely affected patients going on disability and leaving the work force. For others, it means giving up much-loved recreational activities, particularly sports, or struggling to get through daily routines such as dressing and cooking.

A typical quality of life issue that comes up repeatedly is the ability to function well on one day but feel totally exhausted and incapacitated the next. This is a fact that is not well understood by employers, family and caregivers, nor, indeed, by patients themselves. The inability to fulfill plans because of painful episodes adds to the frustration of living with the disease.

If pain can be better managed many people with AS would be able to lead fuller lives and feel that they have a better quality of life even if they are still somewhat restricted in their activities.

## 2.3 Patients' Experiences With Current Therapy

Typically, patients start on NSAIDs and analgesics and these medications may be sufficient for those with relatively mild disease. They are not effective for those with more severe disease, who end up being prescribed TNF-inhibitors (TNFi). Because everyone is different and everyone's disease is different, TNF-inhibitors are reported to be everything from 'miraculous' to ineffective. For those for whom they work well, TNF-inhibitors significantly slow the progress of disease and fully treat the symptoms of inflammation, pain and stiffness. It allows them to enjoy a near-normal life without many limitations and certainly a better quality of life than they experienced before going on the biologic.

Unfortunately, any individual TNFi is known to be effective in only approximately 70% of patients. Furthermore the efficacy of any individual TNFi can wear off after a period, sometimes months, sometimes years, in an individual patient. This means that about 30% of patients given any particular TNFi will fail on it and of the 70% who do well on it, some will not experience lasting efficacy.

It is known that some AS patients who started on infliximab or adalimumab had to switch to the other or golimumab or entcept. Rotating through the available biologics because one or two are ineffective or their effect soon wears off, is now almost commonplace. Different options are required for a more efficaciously long-lasting, safe drug.

There are side-effects to TNFi therapy. Infections, cold-like symptoms and dizziness as well as injection site allergic reactions were most reported by patients to us. One patient reported the onset of cancer (follicular lymphoma) while on a biologic.

The biologic drugs are very expensive. While there is access to them through private and public drug plans and manufacturers' support programs, getting access to the drugs on a timely basis is an issue. The cost of the drugs is a deterrent to workplace mobility; some people are fearful of leaving an employer because of worries that a new workplace will not have an adequate drug plan or that they may be refused coverage because of their health and medications.

Some of the patient comments we have received regarding current TNFi therapy include: "I have severe AS and have been on a biologic for the past 15 years. Unfortunately, the disease has continued to progress even with all the attempts at mitigating its effects". "Then I was on adalimumab for a few months, without any positive results. Since November 2015 I have been on golimumab, with negative results to date". "I started using adalimumab two years ago. It may or may not be working. It is hard to tell". "I started adalimumab injections two years ago. This medication has helped tremendously with the pain and also my state of mind". "The golimumab is working. I'm 80% better". "Since going on biologics a few years ago, I have zero stiffness now – just restricted head and neck mobility". These specific comments are included because they reflect common experiences with existing treatments.

## 2.4 Impact on Caregivers

Caregivers have to be very understanding. Patients report parents who are unwilling to acknowledge their disease and spouses who have left them because of the burden of caregiving. In the case of parents, it can be devastating to see their child struck by the disease when the child is young and active. It causes a lot of anxiety and sometimes financial hardship if the child has not yet left home and is unable to work, compounded by the fact that the time from onset to diagnosis can be so long (an average of seven to eight years).

Perhaps the biggest challenge caregivers face is not understanding the disease and seeing the patient well one day but incapacitated the next. They also see people who by and large do not look unwell and are relatively young adults who cannot do the things that might be expected of them if they were healthy. This is frustrating to the patient and caregiver and places extra burdens on the caregiver, in the case of, say, a spouse, who has to care for the household and children unassisted.

Current TNFi therapies work well for many people allowing them a relatively normal life. If drug therapies do not work well, the caregiver can be distressed at how they are unable to help their patient as limited treatment options are exhausted. Depending on the Province, only four or five TNF-inhibitors are approved for use in AS. More treatment options are required.

## Section 3 — Information about the Drug Being Reviewed

### 3.3 Information Gathering

Information was gathered through lived experiences. All members were invited to submit stories of their journeys with Ankylosing Spondylitis and answers to the specific questions outlined in this template. The information so gathered was complemented by information gleaned from our Facebook group discussions and from many conversations amongst the Board members (all of whom live with Spondyloarthritis) with patients, particularly at our forums.

### 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:*

Given the information that has been made available about secukinumab and its clinical trials, there is an expectation that this new drug will be more efficacious than TNFi therapy, as safe, possibly cheaper and hopefully effective in AS patients who have had an inadequate response to TNFi biologics.

As mentioned, a proportion of patients, about 30%, have an inadequate or no response to TNF-inhibitors. New treatment options are desperately needed for these patients. Even for those patients who are on TNFi therapy but whose response may be less than optimal (some patients report feeling better but not by much, on biologics), additional treatment options are required.

All patients who start a biologic drug have concerns about side effects and personally weigh the risks and rewards of taking the drug. On balance, patients will put up with side effects if their sense of overall wellbeing improves for most of the time after they go on the drug.