

CADTH REIMBURSEMENT REVIEW

Patient and Clinician Group Input

bimekizumab (Bimzelx)
(UCB Canada Inc.)

Indication: The treatment of adult patients with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy.

October 24, 2023

This document compiles the input submitted by patient groups and clinician groups for the file under review. The information is used by CADTH in all phases of the review, including the appraisal of evidence and interpretation of the results. The input submitted for each review is also included in the briefing materials that are sent to expert committee members prior to committee meetings.

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Patient Group Input

Patient input from Arthritis Consumer Experts

C/O: Canadian Agency for Drugs and Technologies in Health (CADTH)

Re: Patient Input for Bimzelx

Date of submission: October 24, 2023

Section 1 — General Information

Name of the drug: bimekizumab (Bimzelx®)

Indication of interest: treatment of ankylosing spondylitis

Name of patient group: Arthritis Consumer Experts

Name of the primary contact for this submission:

Cheryl Koehn, President

Name of author (if different):

Cheryl Koehn, President

Anita Chan, Director of Programs & Administration

Patient group's contact information:

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Vancouver, BC

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www.jointhehealth.org

Permission is granted to post this submission: Yes

Section 1 – About your Patient Group

Canada's largest, longest running national arthritis patient organization headquartered in Vancouver, BC, Arthritis Consumer Experts (ACE) provides free, science-based information and education programs in both official languages to people with arthritis. ACE and its team members acknowledge that they gather and work on the traditional, ancestral and unceded territory of the Coast Salish peoples - x^wməθk^wəyəm (Musqueam), Sk̓wx̓wú7mesh (Squamish), and Səlílwətaʔ/Selilwiltulh (Tsleil-Waututh) Nations.

ACE serves people living with all forms of arthritis by helping them take control of their disease and improve their quality of life through education and (em)powerment. Founded and led by people with arthritis, ACE also advocates on arthritis health policy and provides research-based education through ACE's JointHealth™ family of programs and the Arthritis Broadcast Network, directly to consumers/patients, media, and government. ACE operates as a non-profit in a fully transparent manner and is guided by a strict set of guiding principles, set out by an advisory board comprised of leading scientists, medical professionals, and informed arthritis consumers. Ultimately, we are guided by the needs of our members, who are people living with arthritis, and their caregivers.

Link to website: www.jointhehealth.org

Section 2 – Information Gathering

The following patient inputs were gathered from anonymous data collected from people living with ankylosing spondylitis who have completed previous ACE Surveys. The information was gathered in Canada on the SurveyMonkey platform from 2019 to 2022. We also followed up with patients who previously submitted patient input for ankylosing spondylitis; there are no updates to respondents' disease journeys or perspectives.

Section 3 — Disease Experience

3.1 How does the disease impact the patients' day-to-day life and quality of life?

- **Patient A** has been living with AS and rheumatoid arthritis for 30 years. They also have Crohn's Colitis, psoriatic arthritis, and psoriasis. They have limited mobility due to their AS.
- **Patient B** has been living with AS for 23 years. "I am aware that at any time, my back inflammation can flare up and severely limit my activity for a few days. So, I pace myself and pay attention to my posture."
- **Patient C** has been living with AS for 20 years. "Fatigue, pain, and subsequent deconditioning have led to other MSK issues (e.g. knee pain). The constant pain has also made me anxious and affects my mood when I am not able to go out to do things I would like to do, or sometimes even my daily activities."
- **Patient D** has been living with AS for 4 years. They experience unpredictable and disabling pain and fatigue.

3.2 How does the disease impact the caregivers' day-to-day life and quality of life?

- **Patient A:** "My caregiver has to help me dress, grocery shop, and help me with house chores."
- **Patient B** answered "Not applicable" to this question.
- **Patient C:** "It's hard for caregivers to understand what it is like when someone has inflammatory arthritis. They often don't know how best to provide emotional or physical support, and can be frustrating for them. I'm fairly high functioning, but for others who need more care, it would be draining on a caregiver in terms of both time and energy and stress."
- **Patient D** did not provide an answer to this section.

Section 4 – Experiences with Currently Available Treatments

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

- **Patient A** takes Cimzia and methotrexate. They do not experience side effects from the therapy and finds it effective but notes that the medication is costly.
- **Patient B** is taking anti-inflammatories and Tylenol as needed. At night, they take an anti-depressant to help with their sleep. They also include exercise in their treatment plan. Their treatment therapy is "good right now" at controlling the common aspects of AS. "My liver and kidney blood tests become "out of range" if I take too many anti-inflammatories or Tylenol."
- **Patient C** is taking Humira. "It was previously very effective; however, it's effectiveness drastically decreased as of 3 months ago. I am still currently in a flare and awaiting to switch to Simponi." They do not experience side effects and have tolerated the biologic very well." Their extended medical insurance from work covers the cost of their biologics. They do not have a fear of needles so can take their medication fairly well and with ease.
- **Patient D** is taking adalimumab and anti-inflammatories. The medication is good at controlling fatigue; however, they still feel pain on some days.

Section 5 – Improved Outcomes

- **Patient A** hopes that the new medication will allow them to move with ease and with less pain.
- **Patient B** thinks it's very important to have medication that can control their back spasms.
- **Patient C** highlights that pain and inflammation are the source of fatigue and low mood for them. They would like to be able to exercise more. The following are unmet needs: "Better additional pain control when flaring (even if while on the biologic). NSAIDs have given me an ulcer and I am opioid sensitive so I don't have many options for pain management."
- **Patient D** would like medication to help more with their fatigue and weight gain. "Because I am overweight and a woman, I have sometimes felt disregarded. It took many years of intense pain before my then primary doctor referred me to a rheumatologist."

Section 6 – Experience with Drug Under Review

- None of the patients have had experience with the drug under review.

Section 7 – Companion Diagnostic Test

Not applicable to this submission.

Section 8 – Anything Else?

Arthritis Consumer Experts is providing this patient input submission based on patients have completed previous ACE Surveys. The information was gathered in Canada on the SurveyMonkey platform from 2019 to 2022. We also followed up with patients who have previously

submitted a patient input for ankylosing spondylitis. ACE made minor grammatical corrections to input where needed but in no way altered the meaning or intent of the input.

Appendix: Conflict of Interest Declaration

1) Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

This submission conducted and written solely by the staff of Arthritis Consumer Experts, free from consultation, advice, influence, or financial support from any outside individual, group, or company.

2) Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

No.

3) List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
UCB			X	

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Cheryl Koehn

Position: President

Patient Group: Arthritis Consumer Experts

Date: October 24, 2023

Name of Drug: bimekizumab

Indication: **Ankylosing spondylitis** (a form of spondyloarthritis)

Name of Patient Group: The Canadian Spondyloarthritis Association (CSA), Canadian Arthritis Patient Alliance (CAPA), Arthritis Society Canada (ASC) and CreakyJoints (CJ) collaborated on this joint submission.

Author of Submission:

Brenda Delodder, CSA, Margretha Gonzalez, ASC, Laurie Proulx, CAPA, Adam Kegley, CJ

1. About Your Patient Group

Canadian Spondyloarthritis Association is the only patient-led organization in Canada solely dedicated to supporting people living with spondyloarthritis (SpA). CSA is the voice for Canadians living with SpA, which includes Axial Spondyloarthritis and Peripheral Spondyloarthritis, Ankylosing Spondylitis (AS), Psoriatic Arthritis (PsA), Enteropathic Arthritis and related conditions. CSA develops and delivers innovative programs to educate, support, advocate and raise awareness for patients, caregivers, and healthcare professionals. www.sparthritis.ca

The Canadian Arthritis Patient Alliance (CAPA) is a grassroots, patient-driven and managed, 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. Our website is updated regularly and can be viewed at: www.arthritispatient.ca.

For more than two decades, CreakyJoints has served as a digital community for millions of arthritis patients and caregivers worldwide who seek education, support, advocacy, and patient-centred research. All of our programming and services are always provided free of charge. CreakyJoints is

part of the non-profit [Global Healthy Living Foundation](http://www.globalhealthylivingfoundation.org), whose mission is to improve the quality of life for people living with chronic illnesses. In keeping with our work at CreakyJoints USA, CreakyJoints Canada, available in English and French, inspires, empowers, and supports arthritis patients – and patients living with other chronic conditions – and their caregivers to put themselves at the centre of their care by providing evidence-based education and tools that help people make informed decisions about the daily and long-term management of arthritis and other chronic conditions. At the heart of CreakyJoints Canada is collaboration. We will continue and strengthen our work with Canadian arthritis organizations and patient advocates that you know, love and respect. We are all stronger together. For more information, please visit www.creakyjoints.ca.

Arthritis Society Canada is dedicated to extinguishing arthritis. We represent the six million Canadians living with arthritis today, and the millions more who are impacted or at risk. Fueled by the trust and support of our donors and volunteers, Arthritis Society Canada is fighting the fire of arthritis with research, advocacy, innovation, information and support. We are Canada's

largest charitable funder of cutting-edge arthritis research. We will not give up our efforts until everyone is free of the scorching pain of arthritis. Arthritis Society Canada is accredited under Imagine Canada's Standards Program. For more detailed information, please visit www.arthritis.ca.

2. Information Gathering

2.1. Data gathering

Information for this submission was obtained primarily through a survey hosted on Survey Monkey and made available through all of the collaborating organizations' communication channels (including websites, social media platforms, and e-newsletters) from September 27-October 11, 2023, in English and French.

The survey captured the experiences of people with psoriatic arthritis (PsA) and with ankylosing spondylitis (AS) as well as people who identified as caregivers of people with PsA or AS.

We received a total of 214 survey responses in total.

Similar to the separate PsA patient submission, this AS submission reflects the perspectives of the 114 survey participants (from a total of 214 who completed the joint PsA and AS survey) (53%) who identified as living with AS. A total of 5 survey participants identified as a caregiver of someone with AS.

2.2 Regional data

Survey responses from people with AS came from all provinces. Responses were not received from any of the territories. The majority (30.28%, n=33) of respondents were from Ontario, followed by Quebec (22.02%, n=24), and British Columbia (16.51%, n=18) and Alberta (14.68%, n=16). The remaining responses came from: New Brunswick (4.59%), Nova Scotia (3.67%), Manitoba (2.75%), Newfoundland and Labrador (2.75%), Prince Edward Island (1.83%) and Saskatchewan (0.92%).

For the caregiver respondents, responses were provided by residents from Quebec (60%, n=3%), Saskatchewan (20%, n=1) and Ontario (20%, n=1).

2.3. Survey demographics

Of the 109 survey participants living with AS who indicated their age, 40.91% (n=36) are aged 65+, 28.41% (n=25) are 55-64, 17.05% (n=15) are 45-54, almost 10% (n=8) are 35-44. Almost 60% (n=51) identified as female and 41% (n=36) as male with 1% (n=1) identifying as gender fluid.

Most survey participants who answered this question rate the severity of their AS right now as "moderate" (57.95%, n=51), with 20% (n=18) stating that it is "severe". Several survey participants with AS (n=80) reported living with additional conditions including another type of arthritis (36%, n=29), anxiety (34%, n=27), another inflammatory condition (31%, n=25), other (28%, n=22) which included crohns disease, depression (20% n=16), diabetes (11%, n=9), uveitis (26%, n=21). Fewer than 10% of respondents to this question also identified having liver disease, lung disease, kidney disease, and cancer.

When asked about social demographics, of the 78 people who answered this question, 62 (79.49%) said that they are "white", and one respondent each stated that they are "Indigenous", "East Asian", "Latino" and "Middle Eastern" respectively. Approximately 40% (n=31) of respondents identified as a person with a disability. Two people (3%) identified as LGBTQ2S+.

Most survey participants (24%, n=18) who answered this question stated that their household income is \$50,000-\$69,900; fourteen respondents (19%) stated \$150,000 or more; six people (8%) stated \$0-\$29,999; five people (7%) said \$30,000-49,999; with the rest falling in between.

3. Disease Experience

3.1 Disease experience

Survey participants were asked to identify the symptoms they experience. Their responses are captured in Table 1:

Table 1: Symptoms of AS identified by survey respondents (total of 92 respondents)

Symptom	Total (%)	Total (n)
Backpain	90.48%	95
Joint stiffness	79.05%	83
Fatigue	77.14%	80
Hip pain	71.43%	75
Difficulties concentrating	44.76%	47
Stress	41.90%	44
Anxiety	41.90%	44
Redness and pain in the eyes	32.38%	34
Other (please specify)	27.62%	28
Changes in fingernails or toes	26.67%	28
Sore heels	26.67%	28

3.2 Impact on day-to-day life and quality of life

Survey participants were asked about the impacts of AS on various areas of their lives. Their responses are captured in Table 2.

Table 2: Impacts of AS on Survey Respondents Lives (total of 92 respondents)

Area of Life that is Impacted	Total (%)	Total (n)
Difficulties exercising/being active	80.77%	84
Challenges with sleep	73.08%	76
Ability to work	57.69%	60
Social connections	53.85%	56
Self-esteem	48.08%	50
Family life	45.18%	47
Mental health	43.27%	45
Intimacy	43.27%	45
Strain on finances	40.38%	42
Friendships	39.42%	41
Parenting	15.38%	16
Other (please specify)	9.62%	10
Participation in school	5.77%	6

Respondents who answered “Other” shared the following:

- Finding knowledgeable medical caregivers
- Fatigue impacts all social and family events
- To go out, I usually depend on friends for physical support and rides
- Difficult to maintain pace of work
- Unable to go into stores w/o discomfort

When asked how many days of work survey participants miss per month, on average, 90 people answered as follows in Table 3.

Table 3: Number of days of work missed each month on average by AS survey participants due to symptoms or side effects

Number of days of work missed each month on average	Total (%)	Total (n)
I do not work or attend school for other reasons	24.00%	24
I do not typically miss school or work because of symptoms or side effects of AS	30.00%	30
I cannot work or attend school due to AS	18.00%	18
1-5 days	22.00%	22
6-10 days	5.00%	5
11-15 days	0.00%	0
>20 days	1.00%	1
16-20 days	0.00%	0

3.3 Experiences with barriers to accessing care and treatment

When asked if the cost of medication, travel to and from appointments, or time involved to receive medication limited one's use, or one's doctor's ability to prescribe a particular treatment option, some of the 78 respondents said "no", however we also heard the following:

- Yes the cost has been a problem on some medications before approval was given. Traveling to specialist costs time and money. There was a time I needed to travel 700km for my appointments. We could only proceed at a slow rate of speed due to pain caused by rough AB highways.
- I am being moved from Enbrel to Brenzy's due to the high cost to the government.
- Yes. Dosages are restricted by insurance. Will not reimburse quickly takes months even when previously approved.
- Non, mais j'ai des assurances. Toutefois je dois voir un médecin à l'extérieur de ma région aux 3 mois pour le suivi. Je dois prendre une journée de congé min à chaque fois.
- Plus ou moins car mon assureur privé, Desjardins, refuse de couvrir de plus en plus de médicaments. C'est correct pour Idacio, un générique d'Humira.
- I have private insurance that covers 100%
- No. BC has PharmaCare which pays for my biologic and I have extended health which covers my drugs.
- Worked at a hospital and penalized for taking 1/2 day for IV treatment. Dr letter, Human Resources, meetings for 18 months for treatment accommodation. "Absenteeism" threatened my job so went part time to schedule around shifts. Rheumatologist can't prescribe steroid eye drops for iritis! 2008 Green Shield wouldn't cover [drug] - wanted me to go to a lower tier med. Not what was best choice for my treatment. Now, the pt support program declined my Rheumatologist and my choice of switching to a biosimilar this May. Mind boggling that insurance co. can dictate the drug. Travel- outside my area & needed spouse to miss work to do drop off & pick up- gravel for nausea during treatment, too tired to drive.
- My medications are covered by Alberta Retired Teachers' Benefit Plan and Alberta Blue Cross.

- I cannot afford the [biosimilar] prescription and must rely on the drug company's help to supply monthly medication. I worry that at some point their funding will be finished.
- I have a drug plan otherwise cost would be a big problem
- Luckily [drug] is covered for me under pharma program, their patient support program as I have no coverage for it.
- No, as I cannot go without my medications, so I'm forced to find a way to travel 5 hours round trip for appts. Medication thankfully is shipped to my community.
- This is very expensive, also buying CBD is very expensive
- Le coût des médicaments a toujours été un problème pour moi. Vu ma situation financière, le moindre coût de médicaments est excessif. Je dois emprunter à mon entourage pour payer la base de mes médicaments.
- I avoided biologics for many years until we figured out a program that would support it.
- I have to travel 3 hours to another province once a year to my in person appointment. I do another appointment via phone.
- On fixed income, 65 yrs old. Full of pain. Dr. appointments and all tests have to be in another town. Everything about AS is costly and expensive.
- No, I have private health insurance in addition to provincial coverage and my infusion clinic is nearby.
- My specialist comes from Toronto and he often cannot be here when he wants to because he has other duties in Toronto.
- My rheumatologist has stated I do not meet the current parameters (positive bloodwork, positive imaging) for biological or biosimilar coverage from the Ontario government....
- Fortunately I am covered under pharamacare and the drug supplier otherwise it would not be avoidable
-

When asked specifically about how people pay for their treatments, most people (40%, n=36) indicated that they have private insurance through their employer, union or professional association; 38% (n=34) said that they are covered through a public (provincial/territorial/federal) program; 23%

(n=21) indicated that they have coverage through their partner/spouse; 18% (n=16) say they receive coverage through a Patient Support Program or compassionate access; and 16% (n=14) say they pay for their medications out of pocket. Some shared they did not know 5% (n=5) while 12% (n=11) noted other. We also heard:

- I need to maintain a second personal plan to help cover for the full year
- Le Biologique est couvert mais pas les traitements de la douleur
- Privée+je paie aussi
- Biologics are not covered under my private insurance plans
- I have received assistance from the patient support program
- Je dois payer les premiers 96\$ des coûts mensuels de médicaments.
- I pay 11\$ for every prescription. The NB Medication Plan pays the balance.
- I have my own out of pocket insurance plan
- Public funded pharmacare
- Combination of above
- Extra costs paid through patient support program

We also heard from 26% (n=23) of survey participants who answered this question, that they have had trouble paying for medications, but they managed; 7% (n=6) said that they have stopped taking their medication when they could not afford it; and 14% (n=14) said that they have not filled their prescription or took less medication than prescribed when they have had trouble paying for medications.

3.4 Impact on Caregivers

When asked about caregiving support that people receive from family and/or friends, 80 survey participants responded to this question. Many indicated “N/A”, “No”, and “I did it all on my own”. Many others provided insights into the various ways that families/caregivers support them including:

- Un soutien émotionnel serais bien
- I am in need of help with heavy projects. Also with climbing, carrying, long distance walking, or crawling jobs.
- Mon mari m'aide énormément avec les taches ménagères et les enfants. Il sait quand je suis trop fatigué et m'encourage à aller me reposer
- I receive a bit of help, a bit
- My immediate family are my only support and reason I keep going. They are the single reason I afford my medications, supplements and travelling to appointments, along with my other living expenses.
- I get emotional support but not really enough caregiving support. I am overwhelmed at times not being able to keep up with housework.
- Conjoint, enfants et fratrie tous aidants et compréhensif
- Assist with shopping; can't walk distances in large stores to find items. Can't reach items nor carry items. Help with paying for medication. Need assistance dressing sometimes and cleaning tasks. Very slow complete my daily tasks.
- I live by myself and do not receive any assistance from anyone other than drug company sending monthly [drug]
- Avec le traitement biologique, je suis fonctionnelle
- Oui - aide a la maison et surtout avec les animaux
- I have a cleaning lady as I work full time out of the home
- I have three children, 14, 11 and 4. My children have had to care for the four year old far more than they should have too. My husband helps me immensely at home....
- Pick up prescriptions when not able. Do need help with maintaining house but do it anyways - space it out, do few tasks at a time. Emotional support lacking... “you don't look sick” mentality.
- A homecare person comes once a week to help me take a bath
- Emotional support Help if temporarily can't do something that is time dependent
- Le CLSC me fourni une personne pour mon entretien ménager toutes les deux semaines. C'est TRÈS apprécié, car il y a des tâches que je suis incapable de faire. Et ma famille s'offre de temps à autres, de m'accompagner pour mes rendez-vous, lorsqu'ils sont à l'extérieur de la ville.
- I feel like they don't believe me most of the time when I say I am in pain. My wife picks up my meds for me
- My wife provides excellent support to me.
- Toutes ces réponses plus en étant un soutien financier
- Work medical plan still pays for the stomach b protectant I have been on for almost 40 years.
- No support. If having a bad day things just don't get done.
- Running errands, housework, preparing meals, helping to pay for treatments, providing emotional support
- housework

4. Experiences With Currently Available Treatments

We asked survey participants to rate the effectiveness of the treatments that they have used. Their responses (n=85) are outlined in Table 4 below.

Table 4: Rating of effectiveness of treatment used by survey participants

Type of treatment	Very effective	Effective	Ineffectiv e	Very ineffecti ve	N/A
Non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)	1.16%	60.47%	18.60%	10.47%	9.30%
Disease-modifying antirheumatic drugs (DMARDs) (e.g., methotrexate, azathioprine, cyclosporine, sulphasalazine)	1.25%	26.25%	11.25%	5.00%	56.25%
Leflunomide	0.00%	0.00%	1.35%	0.00%	98.65%
Apremilast (Otezla)	0.00%	0.00%	0.00%	0.00%	100%
Tofacitinib (Xeljanz)	0.00%	1.35%	0.00%	0.00%	98.65%
Upadacitinib (Rinvoq)	0.00%	3.95%	0.00%	1.32%	94.74%
Hydroxychloroquine	1.35%	5.40%	5.41%	0.00%	87.84%
Biologics (e.g., adalimumab-Humira, infliximab-Remicade, etc.)	28.57%	45.24%	3.57%	3.57%	19.05%
Steroid injections	2.60%	36.37%	3.9%	3.90%	53.25%
Oral steroids	4.00%	21.33%	2.67%	5.33%	66.67%
Medical cannabis	4.00%	25.33%	5.33%	2.67%	62.67%

Biologics were found to have the highest proportion as “effective” with 73.81% (n=62). NSAIDs saw the largest spread with 62% (n=53) of respondents noting effective while another 29% (n=25) of respondents ranked as “ineffective.”. DMARDs also saw a split with 27.5% (n=22) of respondents indicating that they are “effective” and 16.25% (n=13) stating that they are “ineffective”.

When asked about their experiences with current treatments, 16% (n=15) strongly agreed and 41% (n=37) agreed that the dosing schedule is convenient; 29% (n=26) strongly agreed and 38% (n=35) agreed that their prescriber can prescribe the preferred/appropriate treatment for their circumstances;

16% (n=15) strongly agreed and 41% agreed that treatment allows them to resume daily activities, like work, parenting, household tasks; and 18% (n=16) strongly agreed and 39% (n=35) agreed that any side effects caused by treatment are tolerable.

When asked if treatment was affordable, 9% (n=8) strongly disagree and 20% (n=18) disagree. Moreover, almost 20% (n=16) disagreed and strongly disagreed that their current treatment allows them to resume daily activities. Overall, more than a quarter (26%) either disagreed or strongly disagreed with the statement “my needs are met with the treatment I receive”.

In the general comments about experiences with treatments, we heard:

- Licensed Medical worker had to reduce full time job to part time thereby losing benefit coverage. Rely on spouse + patient support program and trillium for a year Future medical coverage is unknown. No one health provider can provide answers for continuity and go long stretches without assessment for pain.
- I have been prescribed all the arthritis medications on the market; because of side effects I can no longer take any of them. I currently take [drug] but because of the side effects can take it only twice a week.
- It helps to have a drug plan to pay for the treatment otherwise it would be very unaffordable
- Travel expenses to appts. are weighing
- I can afford my prescription with help from pharmacare, my prescription coverage and assistance from the drug company
- Biologics are not covered by my insurance
- I often have to wait weeks, sometimes months for my treatment because of backlog due to lack of specialists.

In terms of side effects that they found intolerable or difficult to manage, survey participants reported the following experiences with their current medications. Many reported nausea, GI issues and fatigue.

- None other than they all quit working after a while, so something new always needs to be in the pipeline.
- Yes and no, each time this is discussed with family doctor, he does not understand well enough this SpA, as for rheumatologist, see her once a year as she is 2hr away and difficult to get appointment
- The instant nausea, followed by intolerable fatigue and weakness add to the debilitating symptoms I already deal with living with A.S.
- Headaches, gastrointestinal
- I get an allergic reaction but 5mg of prednisone 24hrs before injecting relieved the problem.
- Oui, les infections de toutes sortes et les complications
- Oui car ne suppriment en rien la douleur
- Previous rash but had improved
- Headaches. Too many side effects increasing that had to discontinue. 'transfusions reaction' type response. Blood pressure drop, hives, stomach cramping, aura
- I have developed side effects to all the medications prescribed.
- Anti inflammatory drug was not a good option because I have ulcerative colitis
- Shingles reoccurrences were difficult to control and to deal with
- Oui, douleur dans la zone, fatigue, l'immunité après application est très faible et j'ai des infections
- Not really, but I do have to carefully manage my cold sores or they get out of control. My biologics controls my iritis was a big problem before going on biologics
- Just feel tired all the time
- La prise de poids et la perte de cheveux étaient difficile à accepter.
- The methotrexate makes me feel ill.
- NSAIDs are very hard on your stomach so only use in absolute need. I manage my AS with diet and exercise. I haven't had luck with biologics.
- Humira, hands and feet were raw
- NSAIDS caused my kidneys to deteriorate and I was without medication until biologics came on the market.
- Stomach problems
- No but have no benefits either
- Infection
- Yes, humira allergy
- Concerned about effect on heart

- Yes, both Sulfasalazine and Methotrexate had intolerable and constant side effects that did not decrease much during 3 month trials of each and were discontinued due to side effects (brain fog, headaches, dizziness, 24/7 nausea, mouth sores, yeast infections, hair loss, general malaise and lack of energy, etc.)
- Les anti-inflammatoires n'aident pas beaucoup et les effets secondaires sont difficiles à tolérer lorsqu'on doit en prendre longtemps. Simponi aidait aussi le Crohn et les uvéites si je me souviens bien et surtout était efficace à prévenir les crises et la fatigue. Après une névrite optique j'ai dû arrêter Simponi et n'était plus éligible aux médicaments du même type . On m'a prescrit Cosentix, j'avais plus d'uvéites et de symptômes de Crohn sans être non gérante.
- Accelerated myopia
- I found the side effects worse at the beginning but now seem to be more tolerable

5. Improved Outcomes

When asked what they want in a new treatment, most respondents who answered this question – 71% (n=63) – said “improves my symptoms”, and 67% (n=60) said “better quality of life (e.g., return to work, able to socialize more, mental well-being)”. Several respondents – 66% (n=59) said “affordable” and 69% (n=62) said, “helps with the symptoms I still have”.

With regard to what they would like to see in a new treatment, respondents also expressed:

- If it makes me feel even better then please bring it on.
- Si efficace aussi pour l'arthrite sporiasis
- je nai pas connaissance de ce traitement
- I don't like having infusions every 9 weeks. It wrecks my veins.
- New medications expands the range of treatments available and is good for patients.
- Better energy/stamina. If a med is working for me, I have energy to do more. I will always have some pain and fatigue, but having less pain and more energy is a winning combo for me.
- Pas d'effet secondaires graves comme un cancer
- Occasional Psoriasis on my feet and shoulder issues, calcific tendonopathy

When asked about what survey participants would like to see as the biggest improvement in AS treatment, we heard several insights from the 89 respondents to this question.

Several indicated affordability, less fatigue, less pain, less stiffness. Many stated that they wanted to see earlier diagnosis. We also heard the following:

- I need something that works. To date there has been nothing.
- Knowledge about what is going on.
- Understanding the disease process and related comorbidities
- Earlier diagnosis. I waited 7 years before I was finally referred to a rheumatologist who diagnosed me in one visit.
- A more prompt ability to have the disease diagnosed in order prevent the damage it causes
- Generally, a treatment that could stop disease progression, decrease inflammation, and decrease pain which in turn, increases energy. Specifically, any new medication to treat AS should also be approved to treat NR-AxSpA.

6. Experience With Drug Under Review

In the survey, 2 respondents indicated they used Bimzelx. One of these individuals commented they did not have any issues.

We made several attempts to contact clinical trial participants that had taken bimekizumab (Bimzelx) for AS but were unable to speak with anyone directly. The survey responses provided insights into the expectations of people with AS with regards to new therapies which are expressed below as a percentage of total respondents:

- Improves symptoms (70.79%, n=63)
- Better quality of life, e.g., return to work, able to socialize more, mental wellbeing, fewer doctor visits (67.42%, n=60)
- Affordable to purchase (66.29%, n=59)
- Reduced side effects (48.31%, n=43)
- Treatments are easier to take, e.g., dosing schedules are simpler, pill easier to swallow (35.96%, n=32)

Quality of life most impacted by AS (expressed as a percentage of total respondents) includes difficulties exercising/being active (80.77%), challenges with sleep (73.08%), ability to work (57.69%), social connections (53.85%), self-esteem (48.08%), family life (45.18%), mental health

(43.27%), intimacy (43.27%), strain on finances (40.38%), friendships (39.42%), parenting

(15.38%), and participation in school (5.77%).

7. Companion Diagnostic Test

N/A.

8. Anything Else?

AS is painful and debilitating for many – particularly for those with disease progression. Individuals living with AS are greatly impacted both physically and mentally, and it takes a toll on their loved ones and caregivers as well. Most patients begin experiencing symptoms between the ages of 17 and 45.

CSA's 2020/2021 Quality of Life Survey <https://spondylitis.ca/quality-of-life-survey-2021/> highlights the many difficulties and complications that SpA patients face.

The impact of living with AS on patients and caregivers is far-reaching and complicated. Those living with AS reported an average of more than three complications. Many live with inflammatory bowel disease. Other complications include uveitis, weight issues, migraine, vertebral disc herniations and hypertension.

Complicating the situation for people with AS is the fact that it takes 7-10 years on average for Canadians to be diagnosed from the onset of symptoms, during which time patients experience a significantly impacted quality of life and frustration. Delayed diagnosis and treatment can lead to irreversible damage as well as a negative impact on mental health.

Further complicating matters, approximately 50% of all patients become resistant to their treatments within five years. As a result, access to new treatment options is essential.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH reimbursement review process, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

N/A

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

N/A

2. List any companies or organizations that have provided your group with financial payment over the past 2 years AND who may have direct or indirect interest in the drug under review.

Table 1: Financial Disclosures Check Appropriate Dollar Range

Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
AbbVie Canada			X	
Amgen Canada			X	
Bristol Myers Squibb				
Boehringer Ingelheim International				
Boehringer Ingelheim Canada				
Janssen Canada			X	
LEO Pharma Canada				
Novartis Canada			X	
Organon			X	
Pfizer			X	
UCB Canada			X	

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Brenda Delodder
Position: Executive Director

Patient Group: Canadian Spondyloarthritis Association Date: October 18, 2023

Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
AbbVie Corporation			X	

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Adam Kegley

Position: Manager, Global Partnership Patient

Group: CreakyJoints Canada Date: October 18, 2023

Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Abbvie			X	
Amgen		X		
Boehringer Ingelheim		X		
BMS		X		
Eli Lilly	X			
Fresenius Kabi	X			
Innovative Medicines Canada		X		
J+J Shared Services				X
JAMP Pharma		X		
Janssen			X	
Nordic Pharma				X
Novartis	X			
Organon			X	

Pfizer				X
UCB		X		
Valeo		X		

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Joanne Di Nardo and Kelly Gorman

Position: Senior Director, Public Policy and Government Affairs (job-share) Patient Group: Arthritis Society Canada

Date: October 18, 2023

Clinician Group Input

No clinician group input was submitted for this review.