



Common Drug Review *Patient Group Input Submissions*

aripiprazole (Abilify Maintena) for Schizophrenia

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.

Schizophrenia Society of Canada — permission granted to post.

Schizophrenia Society of Ontario — permission granted to post.

CADTH received patient group input for this review on or before August 28, 2014

CADTH posts all patient input submissions to the Common Drug Review received on or after February 1, 2014 for which permission has been given by the submitter.

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.

Schizophrenia Society of Canada

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Abilify Maintena
Name of the patient group	Schizophrenia Society of Canada
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)	[REDACTED]
Patient group's contact information:	
Email	[REDACTED]
Telephone	1-204-786-1616
Address	100-4 Fort Street, Winnipeg, MB R3C1C4
Website	www.schizophrenia.ca
Permission is granted to post this submission	Yes

1.1 Submitting Organization

The Schizophrenia Society of Canada is a non-profit incorporated charity that serves both people living with schizophrenia and their family members. Our mission is to improve the quality of life of those affected by schizophrenia and psychosis through public education, support programs, advocacy and research. Working from a holistic perspective of a bio-psycho-social-recovery model we believe that medication plays a key role in the management of schizophrenia and helping people to return to a life of quality in the community. It is a cornerstone of treatment.

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:*

We did receive a grant from Otsuka Pharmaceuticals this year and also funding from Sunovion, Eli Lilly, Janssen, Roche, Bristol-Myers-Squib and Pfizer.

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 of interest to declare.

Section 2 — Condition and Current Therapy Related Information

2.1 Information Gathering

The SSC conducted an on-line survey during the months in which provincial schizophrenia societies and their members could fill out the survey as to issues and questions addressed in this template. As well, we conducted a Quality of Life Survey last year of nearly 1000 respondents. The writer, the CEO of the SSC regularly conducts focus groups and one-on-one discussion with people with lived experience of schizophrenia to stay aware of their concerns around treatment options.

2.2 Experience Patients Have with Their Condition

Schizophrenia interferes with a person's ability to live life as "typical" people. Our surveys reveal that the experience of non-reality (psychosis) is due to hallucinations or and delusions, difficulty in thinking, communicating, relating with others (socializing), fear of others due to paranoia, lack of energy to do tasks, poor concentration, memory problems, hopelessness, depression, anxiety and often a lack of insight that he/she has schizophrenia. Learning how to live with and managing the illness and his/her life are complicated by these symptoms. It affects people's lives in the following: disengagement from life, lack of maturation, lack of purpose and hope, communication problems with family and friends, loss of friends, educational and job opportunities. It has a disabling affect short or long term for people with significant impairment to engage in basic functions and activities: develop friends, take care of his/herself, and pursue hopes and dreams. Cognitive challenges are especially troublesome. Social prejudice and discrimination are generally society's response to people with schizophrenia because of lack of understanding, fear of symptoms and uncertainty regarding the recovery process. Those with severe schizophrenia often experience homelessness, incarceration, or "walking the streets." Cardiovascular and metabolic issues result in their dying on an average 20 years earlier than the rest of the population. Schizophrenia is treatable! Recovery of a quality of life (QOL) is possible. But that begins with having access to the best of treatment options and as early as possible. But enduring symptoms of schizophrenia get complicate the recovery process. QOL comes from meaningful work, feeling connected, contributing to community, having purpose, and being valued. Unfortunately, community is not always welcoming.

2.3 Patients' Experience with Current Therapy

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

- **What is the therapy that patients are using for this condition?**
95% of the patients in our survey are using medication howbeit the side-effects. Those who have stopped have done so because of side-effects. Most have tried numerous medications. The goal is to find a medication that addresses their particular symptoms, is effective, has no or minimal side-effects and is easy to take. Many are using self-help groups to learn how to manage the illness; spirituality as to the recovery process is meaningful to many. The support and understanding of family is highly important and most valuable. Many see recovery much more than symptom reduction but being able to live beyond the limitations of the illness and have a quality of life.
- **How effective is the current therapy in controlling the common aspects of this condition?**
As schizophrenia is so unique and individual to each person, so the response to medication is unique and individual to each person. Most have tried numerous medications. Most hate the side-effects ("zombied out", tiredness, interruption of sleep, weight gain, loss of a "sex life", etc.) There is no perfect medication on the market yet. Challenges are administration, adherence, side-effects and cognitive challenges not being addressed by medication. Many still hear voices even though they are

taking medication. A number of people still experience “lack of insight” and thus need a PACT Team, the benefit of a CTO, family member or others to help them with using medication.

- **Are there adverse effects that are more difficult to tolerate than others?**
Any side-effect that interferes with the person pursuing their personal goals is most troubling. It depends on the individual. Common are feeling tired, loss of libido, inability to concentrate and persistent symptoms.
- **Are there hardships in accessing current therapy?**
Finding the right medication for the person; restrictions of provincial drug plans, lack of training by GPs to prescribe, etc.
- **Are there needs, experienced by some or many patients, that are not being met by current therapy? What are these needs?**
Many due to the difficulty of their illness need a medication that can be administered quickly, timely and does not have to be taken every day because the dosage and delivery last a long time. Adherence can thus be problematic.

2.4 Impact on Caregivers

Families are the primary caregivers or support persons of those living with schizophrenia. 70 percent live with families, often due to lack of appropriate housing, community services and non-recovery-oriented mental health services. They carry a significant burden which is rooted in society’s social prejudice towards those with severe mental illness. They feel blamed and shame. They are often frustrated by the “mental health maze” and the difficulty in accessing treatment. If symptoms persist and the medication does not address these, it creates fear, hopelessness and frustration. Families are looking for newer and better medications as are patients. They want their loved one to have a quality of life. Families worry about side-effects impacting on quality of life and interfering with personal goals. Adherence is critical to family. There is no respite for families. They want the doctor to be able to prescribe the very best medication based upon the unique needs of their loved one. They do not want the doctor’s choice limited by provincial drug plan decisions. Families worry most about their loved one becoming so ill he/she winds up on the streets, homeless or in jail. The mental health and quality of life of family members are compromised due to the above.

Section 3 — Related Information about the Drug Being Reviewed

3.1 Information Gathering

No one identified as having used Ability Maintena.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had To Date with the New Drug?

- **Is it expected that the lives of patients will be improved by this new drug, and how?**
Yes, it is hoped so for those in which current medication does not work as effectively or has significant side-effects for the person. A once-monthly injection can help some people manage their symptoms better with a less chance of the symptoms coming back longer-term. It means for many having one less medication to remember to take every day.

- **Is there a particular gap or unmet patient need in current therapy that this drug will help alleviate?**
Adherence issues and side-effects.
- **Would patients be willing to experience serious adverse effects with the new therapy if they experienced other benefits from the drug?**
Some would. To be or not to be: whether it be better to live with the consequences of the illness or the side-effects of the medication. It is a personal choice between the doctor and the patient.
- **How much improvement in the condition would be considered adequate?**
That is a personal decision. Most would take any improvement, period!
- **What other benefits might this drug have — for example, fewer hospital visits or less time off work?**
This is what would be hoped for plus enhanced quality of life due to its effectiveness for both patient and family members.

Section 4 — Additional Information

Our survey respondents said the TOP QOL MEASURES are:

Being seen as capable - 96%

Acceptance by family - 96%

Belief in recovery - 96%

Peace & contentment - 94%

Support & information – 94%

Feeling safe in their community – 93%

Involvement of friends – 92%

Medications - 90%

Hope & Optimism -90%

Sense of belonging – 90%

Social & recreational activities – 90%

Positive relations with professionals – 89%

Support of family – 87%

Schizophrenia can be the cruelest of illnesses. Often striking young people at a critical stage of life when the promise of their future is unfolding. It can bring to a crashing halt the pursuit of learning, thoughts of love and dreams for the future. The symptoms of psychosis can pummel the very core of ones being, confuse the mind, disorient perceptions, and unsettle important relationships with family and friends.

So disturbing can its symptoms be that many will hide the cruelty of its impact, withdraw from a confusing, rejecting, and often frightening world to retreat inward. Sometimes alcohol and drugs replace medication with disastrous effect. Family and friends can be left confused and frightened as they struggle to make sense of what is happening, search for answers, hunt for help, rail against the illness or withdraw in despair. Their dreams and hopes for the future may also darken and the quality of life of the family may slip away. But it does not have to be this way. Schizophrenia and psychosis are treatable and recovery of quality of life is possible when people are able to find the right door that opens up options for treatment, support, and hope. Until there is a cure patients and families pray for better medication to be developed and come to the market.

Schizophrenia Society of Ontario

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Abilify Maintena (aripiprazole)
Name of the patient group	Schizophrenia Society of Ontario
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)	[REDACTED]
Patient group's contact information:	Schizophrenia Society of Ontario
Email	sso@schizophrenia.on.ca
Telephone	1-800-449-6367
Address	130 Spadina Ave, suite 302, Toronto, ON M5V 2L4
Website	www.schizophrenia.ca
Permission is granted to post this submission	Yes

1.1 Submitting Organization

The Schizophrenia Society of Ontario (SSO) is a non-profit charitable organization dedicated to making a positive difference in the lives of people, families and communities affected by schizophrenia and psychotic illnesses. With a mandate to educate, support and advocate, we are the largest organization representing people affected by these conditions in Ontario. SSO has been providing assistance, information and support to individuals and families living with schizophrenia since 1979 and today we have five regional offices and over 300 active volunteers, allowing us to provide programs and services throughout the province.

1.2 Conflict of Interest Declarations

SSO receives some funding from pharmaceutical companies. These include: Janssen Inc., Novartis Pharmaceuticals Canada Inc., Otsuka Canada Pharmaceutical, Hoffman-La Roche Limited, Bristol-Myers Squibb Canada Inc., Lundbeck Canada Inc., and Sunovion Pharmaceuticals Canada Inc.

b) We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission: None

Section 2 — Condition and Current Therapy Related Information

2.1 Information Gathering

The information presented here is based on two surveys and two focus groups:

The first survey was completed by 40 individuals living with schizophrenia. This survey was available in August 2014 and included questions about people's experiences with the illness, medications and treatment in general.

The second survey was completed by 56 caregivers of people with schizophrenia. This survey was made available in August 2014 and included questions about their relative/friend's experience with the illness, medications and treatment in general.

The two in-depth focus groups were held in July 2014 and focused on access to treatments and quality of life. There were 8 participants in the focus groups and they included individuals living with schizophrenia/psychosis and caregivers of individual with schizophrenia/psychosis

2.2 Experience Patients Have with Their Condition

Based on August 2014 individual survey: Many respondents identified that they experienced the following symptoms: lack of energy, anxiety, depressed mood, difficulty with social interaction, hallucinations, difficulty with concentration, suicidal thoughts, loss or increase in appetite, sleeping difficulties, confused or racy thoughts, and delusions. Majority of respondents (82%) were currently taking antipsychotic medications, yet still experienced numerous symptoms.

With regards to individuals' quality of life and social well-being, the results of the 2014 individual survey showed that:

- Majority of respondent were on social assistance or working part time; and had annual family income of \$25,000 or less.
- Many respondents experienced challenges with gaining meaningful employment, accessing secure and affordable housing, and accessing treatments and supports for their mental health needs. As noted by one respondent: "I have difficulty taking public transit on my own and this makes it hard to find supports and employment options and access recreation".
- Many respondents reported having more than one mental health issue and at least one co-morbid physical disability. Top co-morbid health conditions were: chronic physical illness such as diabetes or heart disease, developmental disability, learning disability, sensory deficit, and addictions

Responses from the 2014 Caregiver survey, further highlighted that many individuals with schizophrenia were socially isolated, due to stigma and the illness itself; and experienced major challenges with obtaining services from mental health providers and family doctors, which not only compromised their mental health, but their overall quality of life as well.

July 214 focus group participants echoed the above noted challenges. Many stated that because of their or their relative/friend's diagnosis of schizophrenia, they were treated as less than human and experienced tremendous stigma from others. Focus group participants further indicated that because of inability to access the necessary treatments and supports, individuals and caregivers felt "abandoned", experienced increased emotional stress, and had to rely on emergency services more often.

2.3 Patients' Experience with Current Therapy

Based on 2014 individual survey: Respondents indicated that they use anti-psychotic medications, other mental health medications, and a number of formal and informal treatments and supports to manage their mental illness. Respondents indicated that they experience barriers with accessing psychiatrists, professional group counseling, case management services, supportive housing, peer support, and employment counseling. For instance, when asked about unmet needs, survey respondents stated:

“After first episode was treated I was released to find my own care. My parents help me but it is not easy to find help.”

“I currently do not have a psychiatrist, and I am on a long waiting list for one. I would also really, really like to engage in some talk therapy, but I cannot afford it.”

“Would like to see psychologist but he costs \$175 per session.”

“I am not followed up with in the community very much.”

Only area of support that individuals noted as easy to access was informal support from family. At the same time, majority of respondents indicated that they believe that psychosocial treatments are more effective than pharmacological ones and that pharmacological treatments are most effective when provided in conjunction with psychosocial ones.

With regards to medications, 82% of individual respondents indicated that they were currently taking antipsychotic medication(s), majority using this form of treatment for 5 or more years. Individual and caregiver respondents and focus group participants noted that medications are a “trial and error” process, often requiring individuals to try numerous types, dosages and combinations of treatments before the most effective one is found, a process which can take months or years. As put by a survey respondent: “Every person is different and what works well for some people may be really bad for others which is why there should be as many choices available for them to try until they find what works best.” Some respondents further indicated that their doctors refused to prescribe medications if they were “too new” or not listed on the formulary.

The most prevalent and distressing symptoms identified by respondents were anxiety, depressed mood, lack of energy, difficulty concentrating, and difficulty with social interactions. Many individual and caregiver survey respondents stated that even when using antipsychotic medications, many of these symptoms were not controlled fully and many individuals had to take other psychiatric and health medications to manage the symptoms and side-effects. Survey respondents identified following advantages of taking antipsychotic medications: control of symptoms; decrease the need to go to the hospital; fewer episodes of psychosis. Identified disadvantages included: having to take the medications everyday (e.g. most respondents indicated that they take medications in pill format once per day, although some would prefer if it was less regularly, such as once every 6 months), and having to visit health professional for regular monitoring.

Survey respondents were also very concerned about the side effects of current medications, and the majority of respondents indicated that the best way to improve the ease of use of antipsychotic medications is to reduce side effects. Weight gain, drowsiness, restlessness and muscle spasms were noted as most commonly experienced side-effects. One caregiver respondent noted: “Visible side effects such as weight gain, involuntary movements and feeling lethargic is the main reason my relative is reluctant to take medication – these are noticed and commented on by strangers and my relative is likely not to disclose they are taking antipsychotics as cause of these side effects”. Another caregiver stated “He had problems with irregular heart beat due to the medication and I worry the side effects

that the medications will have on him either heart or stroke issues in his 40s. He feels dizzy when he wakes up and has no energy.” Lack of accessible and transparent information about potential side-effects was noted as big concern as well: “I wasn’t told about appetite changes, seizures, tardive dyskinesia, or the debilitating drowsiness when I started taking meds. New medications often have dangerous side effects that aren’t discovered until the medications has been prescribed widely e.g. diabetes, birth defects.”

Another theme throughout survey and focus groups was increasing access to other treatments, such as ‘talk therapy’, supportive housing, and naturopathic remedies. As noted by one respondent: “I know that certain kinds of talk therapy can be effective for psychosis. Why not fund them instead and stop focusing so much on medications that have unwanted side effects such as blunting the emotions.” Many respondents further indicated preference to have control over their treatment, with one respondent indicating “I wish I had control about how often I took my medications (every 6 months) and by what method (injection)”.

Major concern noted by individuals and caregivers in both surveys and focus groups was the cost of medications:

“As an individual living below the poverty line and not currently on assistance, I find the cost to be a burden and a source of frustration”.

“Injections are very expensive so I don’t think everyone gets them.”

2.4 Impact on Caregivers

According to 2014 focus group participants, caregivers experienced challenges with navigating the mental health system, and felt like they were unable to get information about their relative/friend’s health care to effectively support them. Caregivers described having few resources for understanding the medications used by their relative/friend and feeling like adjustment periods for new, or adjusted medications can be long and distressing. This often increased caregiver burnout, created tensions between family members, and increased stress.

Section 3 — Related Information about the Drug Being Reviewed

3.1 Information Gathering

The information presented here is based on two surveys:

The first survey was completed by 40 individuals living with schizophrenia. This survey was available in August 2014 and included questions about people’s experiences with the illness, medications, Abilify Maintena (aripiprazole), and treatment in general. 14 respondents indicated that they were currently taking, or previously used Abilify Maintena (aripiprazole).

The second survey was completed by 56 caregivers of people with schizophrenia. This survey was made available in August 2014 and included questions about their relative/friend’s experience with the illness, medications, Abilify Maintena (aripiprazole), and treatment in general. 17 respondents indicated that their relative/friend was currently taking, or previously used Abilify Maintena (aripiprazole).

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had To Date with the New Drug?

a) *Based on no experience using the drug :*

Please refer to the above section for information on general experience with antipsychotic medications.

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

Based on the 2014 individual survey, 9 respondents were currently using Abilify Maintena (aripiprazole) and 5 have tried it but discontinued using it. Based on 2014 caregiver survey, 17 respondents commented on their relative/friend's experience with this medication (either currently using or tried and discontinued). From these respondents, responses for how this medication affected individuals varied. Majority of respondents experienced lack of energy, anxiety, depressed mood, difficulty with social interactions, hallucinations, suicidal thoughts, loss or increase in appetite, sleeping difficulties, confused or racy thoughts, delusions, and irritability. When asked about whether these symptoms changed after using aripiprazole, half of the respondents indicated that symptoms improved, other half stated that there was no change or that some symptoms improved, while others got worse, and 1 individual stated that their symptoms got worse. When asked to specify, respondents indicated "a marked improvement in suicidal thoughts" while another indicated a significant increase in anxiety.

Side effects impacted respondents differently, with some individuals noticing an improvement from other medications, and others noticing no change, or that some side effects got worse. When asked to specify, weight gain (6-10 pounds for most and over 21 pounds for one), dry mouth, restlessness, anxiety, dizziness, muscle spasms, and sexual dysfunction were noted as most common side-effects. At the same time, majority of respondents (77%) indicated that since taking Abilify Maintena (aripiprazole), they take their medication more regularly, and 58% reported keeping in greater contact with their doctor and/or psychiatrist. The majority of respondents also noted that their physical activity increased since taking Abilify Maintena (aripiprazole). The majority of respondents indicated that the following either improved, or that they did no notice any changes since taking this medication: quality of life; cognitive abilities; mood; self-esteem, and engagement in volunteer or community activities. Respondents reported no major change to social interactions, feelings of hopelessness about life, employment opportunities, or housing.

When asked about advantages of Abilify Maintena (aripiprazole), respondents indicated: symptom control, and fewer episodes of psychosis. Caregiver respondents also noted decreased hospitalizations and fewer side effects. The biggest disadvantage noted by both individual and caregiver respondents was that the medication was difficult to access. Individual respondents also indicated that main disadvantage was that it did not control all symptoms well and caregivers noted that injections made individual patients feel uncomfortable. When asked what would make the medication better, the majority of respondents answered 'reducing side effects' and 'increasing ability to control symptoms'.

Overall majority of survey respondents (individual and caregiver) noted that they would prefer for the medications to be "easier to access" and expressed concern about costs of medications. Those who are currently paying for medication noted that it is a major financial burden. As put by one individual respondent, "it is very expensive, and I do not have drug coverage."

Section 4 — Additional Information

SSO strongly believes that individuals and caregivers directly affected by schizophrenia and psychotic illnesses should be allowed to make their own submissions into the patient input process.