Patient Group Input Submissions

BREXIPRAZOLE (Rexulti)
(Lundbeck Canada Inc. and Otsuka Canada Pharmaceutical Inc.)
Indication: Treatment of schizophrenia in adults
Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.

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<tr>
<th>Patient Group</th>
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<td>British Columbia Schizophrenia Society</td>
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**CADTH received patient group input for this review on or before February 23, 2017**

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.
Schizophrenia Society of Canada

General Information

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Patient group's contact information:

| Email | vvvvvvvvvvvvvvvvvvvvvvv |
| Telephone | vvv |
| Address | vvvvvvvvvvvvvvvvvvvvvvv |
| Website | www.schizophrenia.ca |

Permission is granted to post this submission: Yes

Submitting Organization

The Schizophrenia Society of Canada was formed in 1979 to improve the quality of life for those affected by schizophrenia and psychosis through education, support programs, public policy and research.

The Schizophrenia Society of Canada is a national registered charity that works with 10 provincial societies to help individuals with schizophrenia and their families have a better quality of life. At SSC we are committed to:

- Raising awareness and educating the public to help reduce mental disorders stigma and discrimination
- Supporting families and individuals
- Advocating for legislative change and improved schizophrenia treatment and mental health services
- Supporting research through the SSC Foundation and other independent efforts

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: Janssen, Lundbeck, and Otsuka.

b) We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission: Otsuka provided a grant for SSC to conduct a patient survey
Condition and Current Therapy Information

Information Gathering

The following information to complete Section 2 was obtained through personal experience, an online patient survey, and one-to-one conversations with a number of people living with schizophrenia.

Impact of Condition on Patients

What aspects of this condition are more important to control than others? For some the dominant symptoms are the positive symptoms of experiencing distressing voices and/or delusions of paranoia even while taking medication. These are most unsettling. For others the negative symptoms that affect cognition are problematic especially the limitations as regards executive skills and memory and verbalization skills. Patients say the following are important or very important:

| Reduces the frequency of disease symptoms (hallucinations, false beliefs, reduced facial expression and emotions, lack of drive and motivation, etc.) |
| Reduces hospitalizations due to relapse of disease symptoms |
| Minimizes weight gain |
| Reduces sexual problems (sex drive, intimacy, sexual functioning) |
| In men, reduce risk of growing breasts |
| In women, reduces menstrual cycle problems |
| Reduces the risk of akathisia (feeling restless with a compelling need to constantly be in movement) |
| Reduces the risk of sedation (feeling sleepy) |
| Reduces the feeling of anxiety (worry, stress, agitation) |
| Reduces the feeling of being too tired or slowed down |
| Reduces the risk of abnormal movements (for example tremors or muscle contraction) |
| Reduces the risk of elevated cholesterol, blood sugar and heart disease |

How does this condition affect day-to-day life? Potentially it interferes with socialization and integration in and acceptance by society. The onset of schizophrenia interferes with identity formation and results in delayed maturation due to the psychosis.

Are there activities that the patients are not able to do as a result of the condition? Many patients report having difficulty determining what is real and what is not real. Public stigma and self-stigma are difficult to live with. Maintaining relationships and working and continuing one’s education can be near impossible without effective treatments ranging from medication to “talk therapies,” and recovery-oriented mental health services.

Patients’ Experiences With Current Therapy

What is the therapy that patients are using for this condition? Antipsychotic medications, antidepressants, benzodiazepines, CBT and DBT for psychosis, psychiatric rehabilitation, and recovery-oriented services. 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? Many report that having to take multiple medications makes them “drowsy” and lethargic. CBT and DBT are virtually unavailable in many places as it is not covered by provincial health care plans. 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? Many report metabolic issues (weight gain and on set of diabetes).

Are there hardships in accessing current therapy? Yes, especially in rural and northern territories or where access to a psychiatrist and psychology is limited. 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, which are not being met by current therapy? What are these needs? Patients requests medications that do not have side-effects and do not interfere with personal goals (ex. returning to school). Negative symptoms seem to be a burden to many.

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 supports and 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 trying to navigate the mental health system 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 and to be “functional” in society. 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.

Information about the Drug Being Reviewed

Information Gathering

The information to complete Section 3 was obtained by an online patient survey.

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

Based on no experience using the drug:

- Is it expected that the lives of patients will be improved by this new drug through improvement of cognitive performance and sleep patterns, as well as effects on affective states and potential to treat core symptoms in schizophrenia and major depressive disorder, including cognitive deficits with a low risk of adverse effects (extrapyramidal symptoms, metabolic complications, weight gain, akathisia potential) that are commonly encountered with other typical and second-generation antipsychotic drugs.
- Is there a particular gap or unmet patient need in current therapy that this drug will help alleviate? Cognitive impairments and depression.
• Would patients be willing to experience serious adverse effects with the new therapy if they experienced other benefits from the drug? No. Unless “made” to take it.

• How much improvement in the condition would be considered adequate? What other benefits might this drug have — for example, fewer hospital visits or less time off work? Better sleep pattern, less depression, and less cognitive challenges.

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

• What positive and negative effects does the new drug have on the condition? Unknown.

• Which symptoms does the new drug manage better than the existing therapy and which ones does it manage less effectively? Unknown.

• Does the new drug cause adverse effects? According to studies:
  - >10%
  - Akathisia (4-14%)
  - 1-10%
  - Headache (4-9%)
  - Weight increased (3-8%)
  - Nasopharyngitis (1-7%)
  - Extrapyramidal symptoms, excluding akathisia (5-6%)
  - Somnolence (4-6%)
  - Dyspepsia (2-6%)
  - Constipation (1-6%)
  - Tremor (2-5%)
  - Fatigue/sedation (2-5%)
  - Dizziness (1-5%)
  - Increased CPK blood levels (2-4%)
  - Decreased cortisol levels (2-4%)
  - Anxiety (2-4%)
  - Restlessness (2-4%)
  - Increased appetite (2-3%)
  - Diarrhea (1-3%)
  - Frequency Unknown
  - Dystonia

• Which adverse effects are acceptable and which ones are not? Patients do not like weight increase, akathisia, somnolence, and tremors.

• Is the new drug easier to use? The route of administration is oral. Most find this acceptable.

• How is the new drug expected to change a patient’s long-term health and well-being? Hopefully it results in a better quality of life and a return to “functionality.”
Additional Information

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 various 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 Canada

General Information

| Name of the drug CADTH is reviewing and indication(s) of interest | Brexpiprazole |
| Name of the patient group | Schizophrenia Society of Ontario |
| Name of the primary contact for this submission | [redacted] |

Patient group’s contact information:
- Email: [redacted]
- Telephone: [redacted]
- Address: [redacted]
- Website: [redacted]

Permission is granted to post this submission: Yes

Submitting Organization

The Schizophrenia Society of Ontario (SSO) is a charitable health organization that supports individuals, families, caregivers and communities affected by schizophrenia and psychosis across the province. For over 30 years we have made positive changes in the lives of people affected by schizophrenia, by building supportive communities, through services and education, advocating for system change and conducting research into the psychosocial factors that directly affect mental illness.

In Ontario, an estimated 136,000 individuals live with schizophrenia and over 405,000 individuals will experience at least one psychotic episode in their lifetime. The impact of schizophrenia is far-reaching, not only affecting the individual, but also families, caregivers and the community. This translates into thousands of people across the province in need of information, assistance and support.

Conflict of Interest Declarations

a) SSO has received some funding from pharmaceutical companies, including Janssen Inc., Novartis Pharmaceuticals Canada Inc., Otsuka-Lundbeck, Eli-Lilly Canada, Pfizer Canada, Hoffman-La Roche Limited, Bristol-Myers Squibb Canada Inc., and Sunovion Pharmaceuticals Canada Inc. In the last fiscal year, SSO received funding from Janssen Inc. and Novartis Pharmaceuticals Canada Inc.

b) We have no conflict of interest to declare in respect of those playing a significant role in compiling this submission.

Condition and Current Therapy Information

Information Gathering

The information presented in this submission is from two online surveys distributed between February 3-14, 2017 in Ontario; of the two surveys, one targeted people with lived experience of mental illness* and the other targeted people who identify as caregivers of individuals with mental illness. Seven people with lived experience of mental illness and twenty-eight people who identified as caregivers responded to the surveys; of these, none has experience with Rexulti (Brexpiprazole).
The questions in the surveys focused on peoples’ experience with various forms of antipsychotic medications, including the impact of antipsychotic medications and other treatments and supports on their lifestyle and quality of life. In addition, the surveys asked people about what they see as the most important things they would like addressed by treatments and how treatments can be improved. Direct quotes in this submission have been provided with consent from respondents.

SSO does not make claims about particular medications but serves as a conduit for sharing experiences of individuals living with mental illness and their families and caregivers when medications are under review. This submission reflects a synthesis of survey responses and trends, and as a result does not include the full scope of each individual response received.

*In this submission, the term “mental illness” refers to symptoms and conditions which may take the form of changes in thinking, mood or behavior, or some combination of all three, that impact a person’s ability to function effectively over a period of time. This term was chosen because it is the closest in aligning to the language used by various stakeholders affected by issues related to access to medications. It should be clarified that not all individuals living with a mental health issue would identify with this label.

Impact of Condition on Patients

Information gathered from people with lived experience of mental illness indicates that many of the respondents experience symptoms such as anxiety, irritability or anger, depressed mood, lack of energy, difficulty with concentration, difficulty with social interactions and sleeping difficulties. In addition, some respondents also experience workload stress, challenges with memory, loss of appetite or increased appetite and confused or racing thoughts.

Of the four people with lived experience of mental illness who responded to this particular question, the majority (75%) are currently taking antipsychotic medications or had in the past (25%). Many had been taking antipsychotic medication for five years or more.

Out of 26 responses by caregivers, 73 per cent indicate that, to their knowledge, their relative/friend experiences difficulty with social interaction (73%), anxiety (65%), difficulty with concentration (61%), hallucinations (58%), lack of energy (58%), depressed mood (54%), over-sleeping (50%) and trouble with memory (46%), to highlight the most prevalent symptoms cited.

Out of four people with lived experience who responded to questions about employment, two indicated that they are employed full-time and two are working part-time. Two respondents earn between $10,000 and $24,999 per year, one earns between $25,000 and $49,999, and another earns between $50,000 and $74,999. Two respondents indicated that they own their homes, one rents and another lives in supportive housing.

Of the caregiver respondents, some indicated that to their knowledge, their relative/friend has used substances other than prescribed medications to help them cope with symptoms of mental illness. For instance, of the 25 respondents to this particular question, 48 per cent stated they used recreational drugs such as marijuana or cocaine; 44 per cent indicated they used alcohol; and one person shared that their relative/friend has taken prescription medications for reasons other than prescribed. Twenty-one respondents indicated that, to their knowledge, their relative/friend was using these substances to cope with symptoms such as depression (38%), anxiety (38%), difficulty with social interaction (38%), difficulty with concentration (24%) and sleeping difficulties (24%).

Several respondents also highlighted systemic barriers people face such as long wait times for housing, minimal financial assistance and supports from the Ontario Disability Support Program (ODSP), and lack of employment opportunities. Four out of 10 Ontario caregivers indicated that their relative/friend was also living with a chronic physical illness.

Patients’ Experiences With Current Therapy

Overall, the majority of respondents with lived experience of mental illness reported significant benefits associated with taking antipsychotic medications including four out of five stating that current antipsychotic medications effectively control symptoms overall, with only one respondent indicating otherwise; three out of five indicated that these medications improve quality of life, including improving ability to attend school or work; and three out of five stating that the use of antipsychotics results in less visits to the hospital.

Additionally, two out of five respondents identified other advantages to taking current medications such as the fact that they do not experience significant side effects and that their mood and self-esteem are improved. At the same time, other respondents reported a number of side effects to medications with weight gain, drowsiness and dizziness identified as some of the most difficult to manage.
Many of the caregiver respondents indicated that their relative/friend’s current antipsychotic medications significantly help to manage symptoms, however a few noted that they still experience intermittent symptom relapse and some symptoms, including anxiety and memory challenges, are not fully allayed.

In addition, out of 26 caregiver respondents, the majority (65%) identified weight gain as a side effect of antipsychotic medications; other common side effects listed included drowsiness (50%), dry mouth (46%), constipation (42%), muscle spasms or involuntary muscle movements (31%) and restlessness (26%). One caregiver pointed out that often people have to take additional medications to manage the side effects of current antipsychotics. Only four per cent reported that their relative/friend experiences no side effects, to their knowledge.

In terms of adverse effects, caregiver respondents shared their views on those which are most difficult to tolerate. One stated that there needs to be more medication options for treatment-resistance schizophrenia as current treatment has “many and risky side effects”. Another shared, “Antipsychotics have pulled my son out of his psychoses several times, and he is compliant with his drug protocol. I’m thankful for the meds, but resent the strong side-effects. He has had heart ‘episodes’, has spent several months sleeping 18 hrs/day…he’s had akathisia, tardive dyskinesia, black/green tongue, skin rashes….and still, his depression and suicidal ideation persist”.

A few respondents with lived experience of mental illness indicated that, in addition to medications, they also use other therapies such as counselling, employment counselling, short-term crisis care and peer support groups and clubhouses, as well as informal supports, such as family and friends.

Four out of five respondents to this question indicated that the main benefits to these other types of treatments and support are that they improve quality of life (100%); that they improve ability to maintain education and employment; that they control symptoms well (75%); and that they improve mood and self-esteem (75%).

In addition, twenty-six caregivers provided information about other types of psychosocial treatment and supports which their relative/friend use – the majority (84%) indicated that their relative/friend uses family support to help them with their mental health needs and fifty-four per cent access counselling services. Of the three caregiver respondents who indicated that their relative/friend do not use psychosocial treatments or supports, two indicated that costs and long wait times were the reasons why they did not.

Costs associated with medications and other psychosocial treatments were identified as a hardship in accessing current therapy by both people with lived experience and caregivers. According to one caregiver respondent, “Antipsychotics should be covered by OHIP because those using it are often on ODSP and in financial difficulty”. Another shared their opinion that “The government must play a role in ensuring those who, by no fault of their own developed a mental illness, are supported in society”. Echoing similar sentiments, another caregiver shared, “Luckily he qualifies for ODSP so there is no cost. If that situation should change we couldn't afford his medications” and yet another observed, “The most challenging part of the process is [that] he does not get assistance with his medication and it is very expensive. He does not want to tax the system and ask for assistance as he feels the process to receive assistance is too onerous”.

Further feedback from caregiver respondents about how current medications can be improved includes the opinion that, “It [antipsychotic medication] could be improved if it was used as an ADJUNCT to talk therapy. THIS HAS BEEN THE KEY PIECE THAT HAS BEEN MISSING IN HIS TREATMENT since his first hospitalization, several years ago. We cannot expect a pill to cure everything. We are still on a waiting list for therapy/CBT. This, in my opinion, is how antipsychotic medication can be improved”.

The needs which caregiver respondents identified as being unmet for their relative/friend include: opportunities for meaningful, paid work; greater opportunity and means for socializing; better navigation support and pathways to care; increased access to affordable treatment, services and supports including supportive housing, adequate income from ODSP, talk therapy, peer support and medications. Many Ontario caregivers surveyed also cited social isolation and lack of friends as unmet needs for their relative/friend. Once caregiver shared, “Social needs are not being met. He is socially isolated. Family and health professionals he sees are his only social contact”.

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CADTH COMMON DRUG REVIEW Patient Group Input Submissions for Rexulti
Impact on Caregivers

Of the respondents who identify as caregivers, about 95 per cent are caring for a person who is currently taking antipsychotic medications with the majority (61%) having used antipsychotic medications for more than five years.

Caregivers identified a multitude of ways in which they help their relative/friend and the resulting impact on their own lives. Common examples include helping with self-care (i.e., laundry, cleaning, meals), assisting with managing appointments and other schedules (e.g., work), providing a place to live, providing emotional support, and being involved in committees in one’s own local mental health community to work with and support other families and caregivers.

Examples of resources that caregivers identified would help them in their role include improved access to supports such as psychiatrists, social workers and peers for their relative/friend as well as professional and peer support for themselves. One respondent indicated that caregivers need information on how to help a person with adhering to their medication plan.

In terms of the impact of treatments on caregivers’ daily routine or lifestyle, one respondent observed that managing the symptoms of the illness makes the biggest difference and that they worry about depression setting in again. Another observed that when their relative/friend becomes unwell, it in turn affects their own mental health.

Information about the Drug Being Reviewed

Information Gathering

See Information Gathering on page 8.

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

Of respondents who identify as having lived experience of mental illness, the side effect that the majority find most difficult include weight gain (80%), followed by drowsiness (20%), dizziness (20%), sexual dysfunction (20%), parkinsonism (20%) and “too much sedation” (20%). The respondent with concerns about “sedation” stated that they “could not function in any way while on any kind of antipsychotics”.

The following disadvantages of current medication therapies were also identified: they do not control symptoms well; they have too many side effects; and that they do not allow the person to have control over if and how they take their medication.

Of 26 caregivers, weight gain was also identified by the majority (65%) as a side effect of current medications with one stating that their relative/friend acquired diabetes related to their medications as well as significant problems with dental issues, including having to have their teeth pulled. Other significant side effects identified include social anxiety, loss of initiative to engage in activities, involuntary muscle movements, allergic reactions and challenges with memory, with one caregiver describing memory loss as a “crippling” side effect.

When asked how antipsychotic medication could be improved, 76 per cent of the 26 caregivers who responded to this question indicated that they could be improved by reducing the side effects; sixty-two per cent indicated they could be improved by increasing their ability to treat symptoms; thirty-five per cent said it would be an improvement if people could take them less frequently; and 35 per cent stated antipsychotics would be improved if they were made more affordable.

One caregiver observed that current therapies do not completely control symptoms and medication does not help with motivation and ability to partake in life activities. Other caregivers indicated that it would be helpful if medications could “control negative symptoms” and one caregiver shared “I hope that you’re offering a medication that is safe and helps in the treatment of depression”. Yet another stated, “Antipsychotic medication allows my relative/friend to have a chance at a life of his choosing…because he still has residual symptoms and suffers side effects, any new options for medication should be fully explored”.

CADTH COMMON DRUG REVIEW Patient Group Input Submissions for Rexulti
A common theme which emerged from both individual and caregiver respondents is captured in the comment, "medication is necessary, but it is only part of a treatment that should be far more holistic......therapy, meds, exercise, diet, etc".

**Additional Information**

In addition to the information provided, we recommend that the Canadian Agency for Drugs and Technologies in Health accept input directly from the individuals and families, rather than from patient groups.

The current method for patient input creates a two-step process for gathering feedback where input is filtered, first through the consolidation of input by the patient group, and again when submissions are consolidated for the Common Drug Review process. There is significant variation in individual responses to medications; variation which may be missed during this two-step consolidation process.
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The patient group has not granted permission to post its patient input submission. As announced in *CDR Update — Issue 99*, when permission is not granted, CADTH will post on its website that a patient submission was received, but it was not posted at the request of the submitter.

The patient input that was provided in this submission, along with all other patient input received for this drug, is included in the summary of patient input that is contained in the posted *CDR Clinical Review Report*. 

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**British Columbia Schizophrenia Society**