

CADTH COMMON DRUG REVIEW

Patient Input

TAPENTADOL HYDROCHLORIDE (NUCYNTA)

(Paladin Labs Inc.)

Indication: For the management of pain severe enough to require daily, continuous, long-term opioid treatment, and: that is opioid-responsive; and for which alternative treatment options are inadequate

CADTH received patient input for this review from:

Action Atlantic Pain Society

Arthritis Consumer Experts

The Canadian Arthritis Patient Alliance

The Chronic Pain Association of Canada

Chronic Pain Support Group of Sarnia Lambton

Halton/Hamilton Chronic Pain Support Group

May 8, 2018

Disclaimer: 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.

1. About Your Patient Group

We are a not for profit grassroots organization called Action Atlantic Pain Society. We advocate for those who cannot advocate for themselves. We believe that anyone who suffers from Chronic Pain is entitled to first line treatment regardless of financial status. Action Atlantic manages Chronic Pain support groups across the Atlantic where people in pain can meet on a regular basis and learn, from each other, what it is like to live with unending pain. During National Pain Awareness Week we hold public forums in various communities in the hopes that families and friends of pain patients can learn and understand how this debilitating disease affects ones everyday life.

2. Information Gathering

Action Atlantic provides advocacy support for approximately 20 existing Chronic Pain support groups across the Atlantic Provinces. We also have a number of individual advocates who are not involved with the current running of support groups. They are located all across Canada, We are in daily communication, via e-mail, with a number of professionals who are interested in helping to advocate for those who are disabled by pain. The information enclosed is from a combination of personal experience gathered from facilitating support groups as well as surveys completed at past pain conferences held in the Atlantic region of Canada.

3. Disease Experience

Chronic Pain affects every aspect of a patient's life. Even though patients may not share the same illness, in most cases, they share the same symptoms. Pain impacts people emotionally, physically, mentally, and spiritually. Caregiving usually falls on the shoulders of a spouse, partner, or a family member. Most often than not we see the day to day caregiver suffering from being helpless in trying to understand what it is like to live with pain. Chronic Pain has no face as we consider it an invisible disease. Quite often we hear pain people say they feel isolated and alone even though they have family and friends around them.

For a person who suffers in pain it is terribly difficult to express the way one feels. This has a huge impact on how a pain doctor is able to effectively treat a patient's pain. We would have to say this is the most important aspect of a patient's illness because if a pain person is unable to express the severity of their pain, then it is likely they will not be successful in receiving treatment to its full potential. Currently, it is a challenge to find a doctor who will treat pain. In most cases, in Canada, there exists an 18-24 month wait to see a pain specialist. In Canada most all universities spend one day educating students on treating, living, and/or understanding this complex disease called Chronic Pain. We should all agree this is not acceptable in a 4 year post medical program. Ultimately, the one who suffers the most is the pain sufferer.

4. Experiences with Currently Available Treatments

The majority of our support group members, suffering in pain, are forced to live on very limited incomes. Many, if not all, have lost their jobs, retired earlier than expected and/or are unable to find gainful employment primarily due to their chronic illness of pain. A portion of our Chronic Pain patients within our support groups have had benefit from therapies such as Physiotherapy, Acupuncture, Psychological counselling, Qui gong, yoga, etc. Most, if not all, of these therapies have been extremely successful in combination with the use of medication. Having said that, a high percentage of these patients who do take medication, experience side effects. The number one side effect that is most often reported on a consistent basis, within our groups, is constipation. I am confident in saying that each of these

patients will put up with this side effect as long as they are able to reduce their daily pain. Dealing with constipation can be very costly. We have had some patients apply to pharmaceutical suppliers for compassion pricing and we have had patients write their provincial health departments for exception status.

In the past we have had an extremely small number of patients, in our groups, receive weekly Lidocaine infusions. This has proven to be an effective for most patients we know but most pain doctors do not offer this treatment. For example, in Nova Scotia, there are only 3 doctors who administer I.V. Lidocaine.

5. Improved Outcomes

For the most part patients in our groups are vulnerable and some very fragile. Patients are always looking for safer and more effective treatments for relief from their pain. We believe this to be of utmost importance to pain people, their friends and family members, when considering to introduce new therapies. Realistically, we tell our pain group members that they should not expect to be completely pain free with any treatments they receive. The more effective the treatment, the more quality of life is given back to the patient. We stress also that there is no guarantee for success when given new medication therapy.

If improvement on quality of life is achieved with new treatments, whether they are physical treatments or by medication treatments, then patients tend to accomplish more in an average day and gain self-worth as experienced before their life of pain.

Trade-offs : In trying new therapy there is, in most circumstances, trade-offs. More than likely we are talking about various side effects. In our experience with group members and their family members pain people will tend to tolerate side effects in order to lessen their pain. Constipation is the most talked about side effect of medication therapy

Appendix: Patient Group Conflict of Interest Declaration

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Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Canopy-Tweed				
Merck				
Purdue Pharma				

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: Terry Bremner

Position: Chair

Patient Group: Action Atlantic Pain Society

Date: May 3, 2018

1. About Your Patient Group

Arthritis Consumer Experts (ACE) is a national patient-led organization that provides science-based information, education and support programs in both official languages to people with arthritis. ACE serves consumers living with all forms of arthritis by helping them take control of their disease and improve their quality of life.

Arthritis Consumer Experts is committed to the following organizational objectives:

- To inform, educate and power people with arthritis to help them take control of their disease and improve their quality of life;
- To provide evidence-based information in reader-friendly language to people with arthritis, the public, governments and media;
- To provide research decision-making training to people with arthritis to help them participate meaningfully in research organizations and in consultations with government.

ACE's membership and program subscribers include people with arthritis, their families, their caregivers, rheumatologists, and other health professionals, elected officials, and senior government bureaucrats.

Link to website: www.jointhehealth.org.

2. Information Gathering

The information was gathered through Arthritis Consumer Experts' (ACE) call for patient input issued on March 23 and April 26, 2018 and day-to-day interactions with people living with severe pain and its work with clinical researchers in Canada, and through discussions with consumers and scientific members of the ACE Advisory Board. The data was gathered in Canada from January 2018 to May 2018. We had no patients who met the manufacturer requested reimbursement criteria "For the management of pain severe enough to require daily, continuous, long-term opioid treatment, and: that is opioid-responsive; and for which alternative treatment options are inadequate". However, we had four patients comment specifically on pain as a symptom of their arthritis in past submissions. They authorized the use of the data included below.

3. Disease Experience

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

Patients living with rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis have all indicated pain as a significant symptom of their disease.

- **Psoriatic arthritis:** Patient A has a baseline level of pain that she has learned to live with. She added: "When I am in a flare, my ability to cope collapses. I have nothing that controls the pain." Fatigue limits her day-to-day life and activities.
- **Ankylosing spondylitis and psoriatic arthritis:** Patient B has ankylosing spondylitis and psoriatic arthritis. The symptoms they experience include inflammation, pain, reduced range of motion in the shoulders, hips and elbows, and severe enthesitis that caused golf ball sized lumps on their Achilles tendons. Social activities are rare

as they always feel **pain** and fatigue. They added: “Lifting, pulling, pushing, carrying things hurt my arms. Driving and working at a desk are exhausting.”

- **Psoriatic arthritis:** Patient C’s ability to walk and stand is very limited. They can only walk for 10 minutes before feeling **pain**. They are sleep deprived. Emotionally, they feel depressed, helpless, and lose hope. As a result, they have gained 80 pounds in the last 4 years. Patient C can only work part-time.
- **Rheumatoid arthritis:** Patient D experiences swelling, inflammation and **pain** in her joints. She has a weakened immune system. She’s had ear and eye problems, in addition to getting lumps on her buttocks and neck.

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

Caregivers of patients living with arthritis have indicated that time management is a significant concern for them. They have to arrange their day according to the person living with arthritis. When patients are in **pain**, caregivers have to help with many aspects of their care and attempts at daily activities.

- **Psoriatic arthritis:** Patient A’s family is frustrated with her constant **pain** and fatigue. She added: “They have given up on trying to help or understand my condition.”
- **Ankylosing spondylitis and psoriatic arthritis:** When Patient B feels fatigued, their family members feel stressed and cannot do work or other activities because they would have to look after or help Patient B.
- **Psoriatic arthritis:** Like Patient A, Patient C expressed that their caregivers feel frustrated because they do not understand what’s wrong.
- **Rheumatoid arthritis:** Patient D requires her family and friends to help her with house chores when she is experiencing flares, ear and eye problems.
- **Ankylosing spondylitis:** Patient E has been living with AS since March 2013. He experiences stiffness and **pain** in his low back, hand, foot, and neck. He is unable to sit down on a chair for more than 30 minutes.

3.3 Are there any aspects of the illness that are more important to control than others?

Patients universally commented that they would like to take the most effective medications and that pose the least chance of experiencing side effects.

4. Experiences with Currently Available Treatments

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

Psoriatic arthritis: Patient A is currently taking a phosphodiesterase 4 inhibitor. She has tried one anti-TNF biologic but had serious side effects from it – demyelination of her temporal lobes. Her neurologist has forbidden her from going on another anti-TNF biologic.

Ankylosing spondylitis and psoriatic arthritis: Patient B is currently taking methotrexate, Humira and folic acid.

Psoriatic arthritis: Patient C is currently taking Simponi and sulfasalazine Celebrex. They also live with Type 2 Diabetes. They added: “Only side effect seems to be terrible dry mouth but not sure which meds cause it.”

Rheumatoid arthritis: Patient D is taking Xeljanz for her RA. She experiences headaches and swelling but is not sure if it is from her medication or from her disease.

Ankylosing spondylitis: Patient E took anti-inflammatory drugs until July 2014. Along with his medication therapy, he would do yoga and swim. However, the medication did not help his AS. From July 2014, he took Humira, while

continuing to swim and do yoga. He Started with taking two shots per month and is currently taking one per month. He thinks that his is back to 75% normal.

5. Improved Outcomes

The patients we interviewed did not submit responses for this section.

ACE response: In general, arthritis patients believe that the “best” treatment is one that has the fewest side effects, rather than thinking about or having a good understanding of the treatment’s benefits. Through ACE’s research and education efforts, we know that people with arthritis who interact with our organization generally understand there is a high degree of variability of disease and that there is a need for increased research activity into the causes and possible cures for them. Patients want new treatments that completely stop or control their symptoms, allowing them to return to “normal” living.

6. Experience with Drug Under Review

None of the patients interviewed have experience using Nucynta to treat their severe pain.

7. Anything Else?

Arthritis Consumer Experts is providing this patient input submission based on patients who responded to current and past calls for patient inputs for the treatment of rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis and specifically referred to their symptom of **pain**. Our organization believes that a new, cost-effective therapy with an acceptable safety and efficacy profile to treat severe pain can improve the quality of life for people living with severe arthritis.

Appendix: Patient Group Conflict of Interest Declaration

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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 was expressly researched and written by the staff of Arthritis Consumer Experts, free from advice or influence from any outside individuals, public or private organization or company

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? No
If yes, please detail the help and who provided it.
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.

Arthritis Consumer Experts does not receive any funding or grants-in-aid from Paladin Labs Inc.

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: May 8, 2018

1. About Your Patient Group

CAPA is a grass-roots, patient-driven, volunteer, independent, national education, advocacy organization with members and supporters across Canada. CAPA creates links between Canadians with arthritis to assist them in becoming more effective advocates and to improve their quality of life. CAPA believes the first expert on arthritis is the person who lives with arthritis, and is an organization for patients run by patients. CAPA welcomes all Canadians with arthritis, and those who support CAPA's goals, to become members.

www.arthritispatient.ca

2. Information Gathering

CAPA gathers our input from our board members who are people living with daily pain from inflammatory arthritis. We have extensive experience with the healthcare system, the limitations of currently available treatments and current research in the area of pain through involvement with the Strategy for Patient Oriented Research Chronic Pain Network. In this instance a patient felt so strongly about her need to provide input she reached out to us before we put out a call on social media for patients to contact us with their experiences on Nucynta.

3. Disease Experience

It is well documented that there are insufficient treatments available for chronic pain. For many patients opioids are an important part of their treatment regime. Despite being a contributing factor to the current opioid crisis, many patients use these drugs safely, appropriately and effectively.

Beyond pharmaceutical options there are treatments available that can be helpful for patients but many of these; acupuncture, massage therapy, yoga, exercise programs, physiotherapy are either not available in the public health care system or the wait times are so long patients give up on them. The primary care environment, for the most part is ill equipped to treat chronic pain patients. Pain patients need access to specialized, multi-disciplinary treatment clinics but the wait time for the few clinics we have in Canada are measured in years. There is no magic bullet, patients must learn to be active self-managers and to use multiple treatments to achieve some quality of life. Some manage to accomplish this with little support from the healthcare system, others are not able to do this. Living a life with severe pain affects every aspect your day; getting out of bed in the morning can feel like climbing a mountain, then you must get dressed, bathe, perhaps care for children, make meals, do household tasks all while trying to remain employed and a functioning member of society. It becomes too much for many patients and they end up depressed and isolated.

Patient on Nucynta reports to CAPA:

Pain has affected every part of my daily routine. I lost my career several years ago due to inflammatory arthritis and chronic pain, and have difficulties with daily activities such as cooking, housework and recreational activities.

While I am an active volunteer and patient advocate, I am very limited in terms of shoulder pain when on the keyboard. I am waiting for my third shoulder surgery and hope that this problem is improved with this intervention.

4. Experiences with Currently Available Treatments

It is well known that there are insufficient treatments for chronic pain. The pharmaceutical options, both prescription and non-prescription have the potential for serious risks with side effects that are often difficult to manage. The non-pharmacological, complementary treatments are difficult to access in the health care system with some not being available at all unless you have good private health insurance.

Reported to CAPA by patient on Nucynta

I go to our community- based therapy pool every second day, walk 10,000 steps most days, and closely follow the recommendations made by my medical team.

My pain is not well managed without my current medication regimen, and when pain management becomes poor, I get discouraged and have trouble staying active. This leads to more pain.

I often run out of private funding for Physiotherapy and would love to have access to a Psychologist periodically to help with relaxation techniques for pain. Wait times for the only Pain specialist in my region is five years, and waiting time to access Orthopaedic Specialist care and surgery is measured in years.

We currently have a private drug plan, but this is expensive for our family. My husband is retired so the premium has gone up markedly.

Chronic pain has been part of our family life now for almost 20 years. It has affected every element of our family in terms of finances, activities and relationships. Our children are now grown so it is easier for us to manage.

5. Improved Outcomes

With few treatment options for pain every new therapy is important and can return some quality of life to a patient allowing them to resume daily activities that healthy individuals take for granted.

Patient on Nucynta reports to CAPA

I have experienced far fewer side effects with Nucynta versus other pain medications. In addition to Nucynta, I take Lyrica, low-dose Amitriptyline, Humira and a small dose of Cannabis oil at night.

The treatment goal for me when taking Nucynta is to manage pain well enough to carry-on with every day activities At home and in the community.

I have been taking this medication for several years and it is the first opioid that I have been able to tolerate. It has given me my life back.

6. Experience with Drug Under Review

Patient on Nucynta Reports

Without Nucynta, I have no doubt that I would not have been able to stay active and this would have had a profound impact on my life and the life of my family members

Before starting Nucynta, I had tried several other opioids. All had intolerable side effects in terms of severe constipation. I had to take laxatives and other treatments for the constipation and this was a real problem for me. My doctor told me that Nucynta has fewer G.I. side effects than other opioids and this has made the world of difference for me in terms of my ability to take this medication and stay active.

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Amgen			X	
Abbvie				
Janssen		X		
Lilly	X			
Manulife	X			
Novartis	X			
Pfizer (Including PfizerHospira)			X	
Purdue		X		
Roche			X	
Sanofi			X	
UCB		X		

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Name: Linda Wilhelm

Position: President

Patient Group: The Canadian Arthritis Patient Alliance

Date: April 28, 2018

1. About Your Patient Group

The Chronic Pain Association of Canada (CPAC) is an extensive patient group across Canada serving people with pain. Our mission is improving the quality of life of people with pain through support, raising public awareness concerning the impact of pain on people's lives, providing practical information, promoting research, improving education, advocating for the removal of barriers and increase access to timely, effective pain management. Our network of support groups across Canada is one of the keys to our efforts. Membership in CPAC is open to everyone, but does consist largely of people with pain, family members and professionals.

2. Information Gathering

The knowledge we have concerning the treatment and management of pain is from personal experience, from personal contact we have with the large number of people with pain that are part of our network, through the personal contact we have with pain sufferers who contact us on a daily basis, through ongoing research of various journals, via e-mail correspondence we receive from many others who make up our huge constituency, through professional contacts, through our relationships with other patient groups and via our contacts with groups in other countries.

3. Disease Experience

Chronic pain impacts virtually every aspect of a pain sufferers' life, from family relationships, social outings, workplace settings, and even the simple ability to carry out everyday activities that most others take for granted. Many people with pain also lose the will to live because of their unbearable pain, with suicide being more prevalent in this population than in the general public. This situation has become even more prevalent in the climate that prevails in Canada today. Even though chronic pain greatly impacts our health care system it remains woefully undertreated, mistreated and misunderstood due to existing misconceptions, fears and stigma surrounding pain management. Side effects of medication that many people experience also impact the lives of people with pain, which is one of the reasons we support approving this medication as it appears to be far more tolerable than some of the other medications presently used. This improves pain control and compliance.

4. Experiences with Currently Available Treatments

There are obviously a number of therapies used in efforts to manage a person's pain. They appear to be broken down into four basic areas: cognitive behavioural, rehabilitative, surgery, and pharmaceutical. All four areas can play a part in a successful pain management program, but are often ignored or simply set aside because of the lack of education of professionals in pain management or indeed the sheer ignorance that is often promulgated about pain. This is extremely frustrating to a pain sufferer. So, although these therapies, used within an interdisciplinary setting, can be successful for some they are not utilized to the extent they should be. The one area that is perhaps the most misunderstood and maligned is that of the use of medication, especially opioids. This is often due to the lack of understanding, misunderstanding, false information and education about the use of medication. As patients we find there is a definite lack of balance in the area of medication use when treating pain, which only, in the final analysis affects the legitimate pain patient. The recent hysteria concerning illicit fentanyl analogues smuggled in from China has really compounded this for people with pain and has turned many lives upside down. This is another reason we feel this medication must be approved as it has fewer gastrointestinal effects, has a lower abuse potential, and overall has

a positive effect on a person with pain quality of life. Approving it also makes it more accessible to those covered under public sector insurance plans.

5. Improved Outcomes

CADTH should consider the accessibility and costs related to new therapies. A large number of people with pain often do not have the means to access new therapies and by covering them under public plans would enhance their ability to obtain them. New therapies with fewer side effects also impact a person's life and this particular medication has that ability. This medication will positively affect people with pain because of the fewer side effects people would be able to maintain its use. With fewer side effects compliance improves, pain control is more consistent and for some even smaller doses come into play. With the present climate in Canada and the misconceptions about pain and opioids being expressed this medication may help allay some of the fears, misunderstandings about misgivings concerning their use by many professionals.

6. Experience with Drug Under Review

Information we gathered on this medication is based on the personal experience of many who have already had access to it as it has been on the market for some time. We have also found through these personal contacts that side effects are far less than some of the other medications, including non-opioid substances that many are now forced to take. As with any medication some have not tolerated it, but in general the overall consensus is it has been beneficial for most. Families and caregivers in a number of instances have reported relief that something had been found that helped.

7. Companion Diagnostic Test

We have had no experience with any companion diagnostic tests. When it was first introduced some had experience through RCT, but we have had no reports of any negative aspects anyone experienced at the time.

8. Anything Else?

The evidence continues to grow that chronic pain is a huge burden on those who suffer with it, their families, and our health care systems making it more and more imperative this devastating disease be addressed more aggressively and fully. Over the past few years the number of myths and half truths based on illicit drug use that have been written about the use of opioids have turned the lives of people with pain up-side-down, destroyed the lives of many and pushed back the treatment of pain decades. This must stop. Research from many areas tell us that pain affects more people than diabetes, heart disease and cancer combined, yet remains on the periphery of care, causing enormous costs to society as a whole. As our population ages the problem will only become worse and it is time to look at this situation differently. People with pain are the only population that are now treated the way they are and by approving this medication will hopefully work to change some of that. People with pain are fully aware that medication, and opioids are not the panacea they would like, we also know they play an important role in the lives of many, giving them some quality of life.

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Purdue Pharma			xxx	

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Name :Barry D. Ulmer

Position: Executive Director

Patient Group: The Chronic Pain Association of Canada

Date: May 3, 2018

1. About Your Patient Group

If you have not yet registered with CADTH, describe the purpose of your organization. Include a link to your website.

CHRONIC PAIN SUPPORT GROUP OF SARINIA-LAMBTON
MEET MONTHLY.
ANY CHRONIC PAIN SUFFERER IS FREE TO ATTEND.

2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus groups, or survey; personal experience; or a combination of these. Where possible, include **when** the data were gathered; if data were gathered in **Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

WE MET IN PERSON AND ANSWERED THE
INFORMATION TOGETHER

3. Disease Experience

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient's perspective. Describe how the disease impacts patients' and caregivers' day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

IT IMPACTS EVERY SINGLE ASPECT OF OUR LIVES AND EVERYONE IN OUR LIFE.

4. Experiences With Currently Available Treatments

CADTH examines the clinical benefit and cost-effectiveness of new drugs compared with currently available treatments. We can use this information to evaluate how well the drug under review might address gaps if current therapies fall short for patients and caregivers.

Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

NO TWO PEOPLE OR TWO DAYS ARE EVER THE SAME. DRUGS, IV LIDOCAINE INJECTIONS & TRIGGER POINT INJECTIONS. EPIDURALS.

5. Improved Outcomes

CADTH is interested in patients' views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements? What trade-offs do patients, families, and caregivers consider when choosing therapy?

QUALITY OF LIFE. PAIN RELIEF THAT IS NOT A OPIOID.
IT WOULD BE A WHOLE NEW WORLD.
FINANCIAL AND FREEDOM.

6. Experience With Drug Under Review

CADTH will carefully review the relevant scientific literature and clinical studies. We would like to hear from patients about their individual experiences with the new drug. This can help reviewers better understand how the drug under review meets the needs and preferences of patients, caregivers, and families. *NO ONE IN ATTENDANCE HAS BEEN ON THE DRUG.*

How did patients have access to the drug under review (for example, clinical trials, private insurance)? Compared to any previous therapies patients have used, what were the benefits experienced? What were the disadvantages? How did the benefits and disadvantages impact the lives of patients, caregivers, and families? Consider side effects and if they were tolerated or how they were managed. Was the drug easier to use than previous therapies? If so, how? Are there subgroups of patients within this disease state for whom this drug is particularly helpful? In what ways?

ANYONE TAKING THE DRUG WOULD HAVE TO PAY IN CASH.

7. Companion Diagnostic Test

N.A. If the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies, or monitor clinical responses to optimally guide treatment adjustments.

N.A. What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with regarding the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.
- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?
- N.A.* • Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?
- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

8. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

EVERY PATIENT SHOULD HAVE THE RIGHT TO HAVE ACCESS TO ANY MEDICATION THAT MAY BE RIGHT FOR THEM.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, 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.

No, we did ourselves

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.

N.A

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

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: *Lorie Chevalier*
 Position: *Facilitator*
 Patient Group: *Chronic Pain Support Group*
 Date: *March 28, 2018*

1. About Your Patient Group

The Halton/Hamilton Chronic Pain Support Group provides a support system, a social and meaningful cushion to isolation, loneliness, sadness and pathos for the person living with chronic pain. It is a vehicle where people who feel isolated and disenfranchised from family, friends, work and the health care system, can come and feel comfortable among peers who understand.

The support group does not provide any medical services and it is not attached to any health services. There are no expectations, no registration required, no cost to participants. These events are all free of any charge and there is no membership fee.

Monthly meetings typically include a time for peer-to-peer social networking, a presentation by a speaker on a topic of interest and relevance to people in pain, a period of light refreshments and further social networking, ending with light exercises, breathing exercises and often a period of quiet facilitator-led meditation.

This group has been running since 2005 and is funded by the Ontario Pain Foundation, an independent not-for-profit organization incorporated in the Province of Ontario with the purpose to advance education and awareness for the benefit of people who live with debilitating pain.

The website is: <http://ontariopainfoundation.ca>.

2. Information Gathering

The information provided in this document was captured the evening of the 10th of April, at the monthly meeting of the Halton/Hamilton Chronic Pain Support Group, where a total of 61 people were in attendance. The discussion was led by James L. Henry, Ph.D., President of the Ontario Pain Foundation. Those present were simply asked to comment on each of Questions 3, 4 and 5 of this form without any guidance or input from Dr. Henry. Notes were taken at the time by hand.

3. Disease Experience

The following were comments from those present about the pain experience:

- pain interferes with sleep
- it decreases energy
- it is depressing
- it is tiring
- medications do not get rid of the pain
- pain decreases mood
- pain is physically and emotionally restrictive
- it is frustrating when it doesn't work
- pain affects relationships
- meds are addictive, often need higher doses

- some meds are allergic
- pain causes a person to withdraw
- pain can be on and off
- pain is different for different people

4. Experiences with Currently Available Treatments

Those present were asked to describe benefits seen, side effects experienced and their management, including difficulties in accessing treatment.

Current different treatments cause:

- constipation
- tiredness
- drowsiness
- nausea
- stomach upset
- kidney and liver damage
- weight gain or loss
- loss of appetite
- anxiety
- hyperactivity
- feelings of being unwell
- dizziness
- headache
- dry mouth
- mood swings
- brain fog
- insomnia
- irritability
- paranoia

Difficulties in accessing were described as follows:

- some drugs not on the drug benefit plan
- difficult if a prescription runs out on the weekend, when the doctor is not available
- public transport does not go near my pharmacy
- can't afford my medications

5. Improved Outcomes

The following were mentioned as what would be improvements in new pain medications:

- improve functionality
- decrease pain
- be affordable
- have fewer side effects
- be non-addictive and won't cause withdrawal
- take only when needed
- longer lasting
- easier to swallow
- does not cause anxiety
- targeted result for my specific type of pain
- continued effectiveness over years
- no effect on the immune system
- improves my quality of life
- non-drowsy
- affordable
- socially acceptable without controversy
- dissolvable/absorbable
- easily taken

6. Experience with Drug Under Review

People in the group did not have access to the drug and all were unfamiliar with the drug.

7. Companion Diagnostic Test

This drug was not evaluated under the circumstances of the meeting of the Halton/Hamilton Chronic Pain Support Group.

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

There was no help of any type in completing this submission

- 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.

Other than funding from the Ontario Pain Foundation, which supports all the activities of the Halton/Hamilton Chronic Pain Support Group, here was no outside funding for the meeting at which the opinions were solicited, or in the collection or analysis of the contents of this submission.

- 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

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: James L. Henry, Ph.D.

Position: Co-organizer of the Halton/Hamilton Chronic Pain Support Group; President of the Ontario Pain Foundation

Patient Group: the Halton/Hamilton Chronic Pain Support Group

Date: 30 April, 2018