



CADTH REIMBURSEMENT REVIEW

Patient and Clinician Group Input

Dupilumab (Dupixent)
sanofi-aventis Canada Inc.

Indication: Dupixent is indicated for the treatment of adult patients with moderate-to-severe prurigo nodularis (PN) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.

January 10, 2025

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

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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 identifying personal information or personal health information is included in the submission. The name of the submitting group and all conflicts of interest information from individuals who contributed to the content are included in the posted submission.

Patient Input Template for CADTH Reimbursement Reviews

Name of Drug: Dupilumab (Dupixent)

Indication: Prurigo Nodularis

Name of Patient Group: Canadian Skin Patient Alliance

Author of Submission: Sabrina Ribau, Programs Manager (CSPA), Zahra Rehan, MD, Dana Gies, Executive Director (CSPA)

1. About Your Patient Group

This submission is supported by the [Canadian Skin Patient Alliance \(CSPA\)](https://canadianskin.ca/en/). CSPA is a national charity organization that improves the health and well-being of people across Canada affected by skin, hair, and nail conditions through collaboration, advocacy, and education. For more information, please visit: <https://canadianskin.ca/en/>.

2. Information Gathering

2.1 Data gathering

Information for this submission was compiled from a patient and caregiver survey shared on CSPA's communications channels from September 12 to November 29, 2024, and on CSPA's website, in both English and in French. In this submission we report on combined English and French survey responses. A total of 9 survey responses were received, 8 in English and 1 in French. Personal experience from people living with prurigo nodularis involved in the project was also gathered and included for this submission. We had two survey respondents with experience with the drug under review.

2.2 Regional data

The patient and caregiver survey contained 9 respondents from Canada, with the largest number being from Ontario (55.56%, n=5). A smaller proportion of respondents also came from Alberta (11.11%, n=1), Northwest Territories (11.11%, n=1), Quebec (11.11%, n=1), and New Brunswick (11.11%, n=1). There were no survey respondents from Yukon, Nunavut, British Columbia, Saskatchewan, Manitoba, Nova Scotia, Prince Edward Island or Newfoundland and Labrador.

2.3 Survey Demographics

When asked about their age, the respondents (n=5) were all over 35 years old, with more than half of respondents being over 55. 20% (n=1) were 35-44 years old, 60% (n=3) were 55-64 years old, 20% (n=1) were over 65 years old. There were four individuals who did not provide their age for the survey. For those who answered the question (n=5), 100% (n=5) of respondents have had prurigo nodularis for less than five years. Most respondents reported having severe (75%, n=3) or moderate (25%, n=1) prurigo nodularis, no respondent reported their prurigo nodularis as mild.

The most common comorbidities were mental health conditions (e.g., depression, anxiety) in 100% (n=2) of respondents who completed that survey question. One respondent listed iron deficiency anemia, another autoimmune condition and hypothyroidism. The second respondent shared having diabetes and allergic rhinitis. Regarding sex and gender, 100% (n=5) reported being female, and none identified as male. One respondent reported that they were a caregiver. When asked how they best described themselves, 80% (n=4) described themselves as White/Caucasian and 20% (n=1) described themselves as Eastern European.

3. Disease Experience

Prurigo nodularis (PN) is a chronic skin condition characterized by the development of firm, itchy nodules on the skin. These nodules typically appear on the arms, legs, and trunk but can occur anywhere on the body. The intense itchiness associated with PN often leads to repeated scratching, which can worsen the condition and result in secondary infections, scarring, hypopigmentation and hyperpigmentation of the skin.

For the areas of body affected, 100% of survey responses reported their arms and back being affected by their condition. 75% of respondents mentioned an impact on their legs. 50% of respondents shared that buttocks were an area impacted by PN.

In terms of skin symptoms and side effects experienced, all patients reported the following signs: itchy skin, itchy bumps (nodules), burning or stinging skin, scratching, pain, and hyperpigmentation (dark spots). Three patients (75%) reported skin symptoms of scarring because of PN. One patient (25%) reported experiencing side effects of flares and hypopigmentation (light spots).

“Not realizing I’m itching my legs is the worst. I will wake myself up in the middle of the night scratching so bad that my legs will be bloody and feeling raw.”

PN is far more than a skin condition; it impacts patients’ psychological well-being, social interactions, and day-to-day functioning. While the physical manifestation of prurigo nodularis may seem to be the primary issue from the outside, the reality is that the disorder can profoundly disrupt the emotional, mental, and social aspects of patients’ lives. Persistent and severe itching (pruritus) is the predominant symptom, which significantly disrupts daily activities and sleep. The visible nodules and scars may lead to embarrassment and reduced self-esteem. The chronic nature of PN can result in emotional distress, anxiety and depression.

When asked to list all aspects impacted by a PN diagnosis, survey respondents included the following: family relationships, intimate relationships), work life, mental health, social life, daily activities, sleep, self-esteem, finance and sex life. 100% of respondents reported that PN affected their intimate relationships. 75% of respondents shared a disturbance in their family relationships, mental health and sleep. 50% of respondents recounted an impact on their social life and daily activities.

“My sex life has been declining and my social life has become non-existent. Also, I can’t wear shorts during the hot summer months because of the scared looks I get like I’m nasty and contagious.”

The psychological impact of PN is profound, as the chronic nature and intense symptoms of this condition significantly affect mental health and emotional well-being. The psychological impact can include sleep disruption, emotional distress, body-image issues and experiencing social isolation or stigma. Particularly, constant itching and discomfort can lead to feelings of frustration, irritability and embarrassment. Compounding the psychological impacts with the impacts of constant itching and discomfort, PN has profound physical, emotional, mental, and social impacts on patients and their loved ones.

One patient quoted the following when asked how their PN experience has affected their family or caregiver: “Agitation, annoyed by my scratching, embarrassment”

Regarding impact on daily activities, 25% of respondents shared missing work 5-10 times monthly due to PN. Twenty-five percent (25%) of patients surveyed reported missing work 1-5 times monthly. Fifty percent (50%) of survey respondents communicated not missing work due to PN or missing work as a non-applicable factor in their situation.

Caregivers are also impacted, often witnessing their loved ones endure emotional pain, insecurity, and social withdrawal. The psychological burden on caregivers can be immense, as they provide ongoing emotional support and encouragement, while often feeling helpless themselves.

The caregiver responding to our survey observed their loved one being impacted in the following areas by PN: family balance/relationships, mental health and intimate relationships. For their loved one who lives with PN, the caregiver relayed their intimate relationships are impacted by PN. Additionally, the caregiver shared it is difficult to encourage their loved one to continue to use and take treatments for PN.

4. Experiences With Currently Available Treatments

Currently, PN patients and their caregivers navigate a range of treatments with varying degrees of effectiveness and accessibility challenges. Many patients report limited success with existing therapies, highlighting the need for new and more effective treatments. In our survey, all respondents indicated trying multiple treatments to manage their PN; 100% have tried topical corticosteroids, 80% have tried topical capsaicin, oral antihistamines and methotrexate, and 60% have tried topical calcineurin inhibitors, narrowband UVB phototherapy (NBUVB), and medical cannabis. The responses emphasize the limited efficacy of these treatments: despite all five having used topical corticosteroids in the past, none of the surveyed patients found them to work “well” or “very well”. Instead, patients rated their experience as “did not work very well” (60%) or “no change” (40%). As topical corticosteroids are often the first-

line therapy for many skin conditions, including PN, this underscores the need for new and effective treatments that are accessible to patients.

Other treatments such as topical capsaicin, oral antihistamines and methotrexate also showed minimal effectiveness, with all respondents noting they “did not work very well” or there was “no change”. Further, there were two patients (40%) who reported having used all the treatments included in the survey in the past, including intralesional corticosteroids, topical vitamin D derivatives, psoralen plus UVA photochemotherapy (PUVA), oral cyclosporine, Dupixent, thalidomide, tricyclic depressants and anticonvulsants. Both patients shared that these treatments were minimally effective and there was “no change” in their condition. An interesting thing to note with both patients is that they currently use topical corticosteroids, oral antihistamines and topical capsaicin for their PN, despite both sharing these treatments are minimally efficacious with “no change” or do “not work very well”. This demonstrates the fatigue and frustration among patients, further underscoring the importance of new and effective treatments becoming available for patients so that they are able to have more and better options for managing their condition.

At this time, there are only two Health Canada approved treatments for prurigo nodularis: Dupixent and Nemolizumab. For PN, these treatments are not covered/approved on public or private insurance plans. In our survey, two patients reported trying Dupilumab in the past but both patients found there to be “no change” in their condition. It is difficult to conclude that Dupixent is not an efficacious treatment due to the small sample size of survey respondents. Dupilumab is also an expensive biologic medication, and our survey results demonstrate financial cost can be a barrier to accessing medications. When asked about aspects of a new PN treatment that are most important to patients, survey respondents indicated the top three factors to be effectiveness, affordability and lack of side effects. Other less important aspects included the treatment being easy to take or apply and conducive to the patient’s schedule. In our survey, the caregiver disclosed that the cost of medication is the most important aspect of a new treatment for them.

One patient quoted the following price for a treatment recommendation: “One recommendation was 12,000.00!?!?”

Regarding side effects, patients reported experiencing a racing heart (n=1), skin irritation (n=3), nausea (n=2), vomiting (n=1), hypopigmentation (n=1) and hyperpigmentation (n=2). Only one respondent shared that they stopped treatment for PN because of side effects and three respondents shared that they stopped treatments because of a lack of efficacy. This highlights the importance of new treatments that are effective and have minimal side effects to better support patients in their treatment goals.

The psychological toll of repeatedly undergoing ineffective treatments cannot be overstated. Many respondents expressed frustration and emotional distress from trying multiple therapies with little to no improvement. When asked, participants overwhelmingly strongly agreed that they would be interested in a new treatment for PN (4 out of 5 respondents) and that they wish there was a better PN treatment option for them (4 out of 5 respondents). On the other side, three respondents (3/5) disagreed, and two respondents (2/5) strongly disagreed that they felt satisfied with their current treatment for PN. These patient experiences highlight the need for new, effective, accessible treatments for patients so that they can manage their condition and reduce the mental health burdens so often experienced by people impacted by prurigo nodularis.

5. Improved Outcomes

When asked about what aspects of a new treatment for prurigo nodularis are important to them, patients shared that effectiveness (4/5), affordability (3/5), lack of side effects (3/5) were their top priorities. They are also looking for treatments that are easy to take/apply (2/5) and are conducive to their schedule (2/5). Four of five patients who responded to the survey question reported that they strongly agreed that they would be interested in a new treatment for prurigo nodularis and that they wish there was a better PN treatment option for them, and one disagreed. All five patients felt that they strongly disagreed or disagreed that they felt satisfied with their current treatment for PN, highlighting a need for new, effective treatments. When asked about their reasons for stopping their treatments, ¾ who replied to the question shared that it was being it was not effective, and the fourth shared it was due to side effect, further emphasizing the desire for safe, effective, affordable treatments. A treatment that is simple to administer and integrates smoothly into daily life reduces the logistical and psychological burden on patients. This is particularly relevant for individuals managing the emotional and burdensome weight of prurigo nodularis, as well as any coexisting conditions or family responsibilities.

Patients also shared that they have experienced financial challenges that have affected their access to PN treatments, with one patient sharing that “paying for over-the-counter anti-itch, moisturizers, ointments, etc.” contributed to the burden of disease, and this patient used a public drug plan for their insurance coverage for their medications. Another shared that they had received the following suggestion, “one recommendation was 12,000.00!?!?” and this patient did not have insurance coverage and paid out of pocket for treatments, highlighting the financial burden of living with PN when there are not affordable options indicated for PN. When paired with some of the other quality of life impacts reportedly experienced by patients and their loved ones living with PN, including

negative impacts on intimate relationships, family relationships, mental health, work life, social life, daily activities, and sleep, it's instrumental that new therapies indicated for PN are accessible and affordable to improve health outcomes and the quality of life of patients and their caregivers.

In addition to managing itch, psychological and social relief are underlying motivations behind these desired outcomes. With a treatment that offers tangible improvement and restores a sense of normalcy, patients anticipate a significant enhancement in quality of life, self-confidence, and social participation. Ultimately, our survey responses reveal that patients desire treatments that are not only clinically effective but also supportive of their holistic well-being. Effective, accessible treatments like Dupilumab have the potential to address the physical and emotional gaps in the current treatment landscape, allowing patients to regain a sense of agency over their condition and their lives.

6. Experience With Drug Under Review

As a national patient organization, CSPA recognizes and emphasizes the importance of providing access to effective and affordable treatments to people across Canada. As there are no currently available treatments indicated for PN covered by public drug plans in Canada, it's incredibly important that more treatments tailored to PN become available, accessible, and affordable for patients. From the survey conducted among PN patients and caregivers, two (2) participants reported having used the drug under review, and both reported no change. With that being said, this is a small sample size and this information on the drug under review was asked in relation to other treatments used for PN, mostly off-label, in a survey that was not designed for patients who used dupilumab. We also do not know the treatment protocol followed by these patients or prescribed by their providers, how they adhered to it, and if it's in line with the recommendations under review. It is therefore difficult to conclude that Dupixent is not an efficacious treatment due to the small sample size of survey respondents. Dupilumab is also an expensive biologic medication, and our survey results demonstrate financial cost can be a barrier to accessing medications.

One thing that was consistent across survey respondents was that patients and their loved ones shared their frustration with a lack of treatments available in Canada for PN and the need for safe, effective, and affordable options. "It is very disappointing that there is a medication for prurigo nodularis, a devastating skin condition, but is unavailable for patients," shared one patient in the survey. Another simply implored, "Please approve it so I can afford it," highlighting the significant need for treatments that are affordable and covered under drug plans across the country so that PN patients can seek effective care for their condition. One other patient shared, "I need to find a treatment that actually works long term and that is effective and has little side effects," echoing the feelings of the other PN patients and caregivers who participated in the survey. Dupilumab is one of only two treatments approved for use in prurigo nodularis in Canada. Of the two treatments, access to both is currently costly and difficult (both nemolizumab and dupilumab are currently under review for recommendation by CDA), impacting the ability for PN patients and their families to seek treatment via medications that are both indicated and covered under public drug plans for their incredibly uncomfortable condition.

7. Companion Diagnostic Test

Not applicable.

8. Anything Else?

Given such a significant impact of prurigo nodularis on the lives of individuals living with the condition, it is important to explore effective and safe treatment options to improve the quality of life of those affected by prurigo nodularis. There remains a great need for effective treatment options for prurigo nodularis. Access to new and promising treatments is critical to helping patients gain a sense of control over their disease and begin to regain their quality of life. Presently, there are no treatments indicated for PN covered under public drug plans in Canada, leaving a significant need for new treatments for.

Individuals with PN have often attempted numerous treatments, therapies, and other strategies off-label to manage the signs of their condition. When their PN is well-treated, it becomes more manageable, and the physical, psychological, and social impacts they experience because of this disease are reduced.

The nature of this disease requires ongoing care and a constellation of different approaches. Individuals with prurigo nodularis incur considerable monetary expenses on products and treatments to manage their condition, as well as significant psychosocial costs of living with or being in a family with someone who has a debilitating condition like PN, considerably impacting mental and physical health and wellbeing for the individual and their family. CSPA supports the advancement of treatments for PN and is encouraged by the possibility of improving access to new, effective treatments for PN patients and their families to improve their health outcomes and quality of life.

Appendix: Patient Group Conflict of Interest Declaration

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

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

No. CSPA worked with staff and volunteers to complete this report. No funding was received to complete this submission.

6. 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. CSPA worked with staff and volunteers to complete this report. No funding was received to complete this submission.

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

Table 1: Financial Disclosures

Check Appropriate Dollar Range With an X. Add additional rows if necessary.

Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Sanofi			X	
Galderma		X		

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

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Position: Programs Manager

Patient Group: Canadian Skin Patient Alliance

Date: January 10, 2024