CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

secukinumab (Cosentyx)

(Novartis Pharmaceuticals Canada Inc.)

Indication: COSENTYX is indicated for the treatment of adult patients with moderate to severe hidradenitis suppurativa (acne inversa) who have responded inadequately to conventional systemic hidradenitis suppurativa therapy.

August 29, 2024

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	**SR0781-000**
Brand name (generic)	**Cosentyx (secukinumab)**
Indication(s)	**Hidradenitis suppurativa**
Organization	Canadian Skin Patient Alliance
Contact information[a]	Name: Sabrina Ribau

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☒

The Canadian Skin Patient Alliance (CSPA) agrees with the draft recommendation for secukinumab. However, for the reimbursement conditions and reasons outlined in Table 1, page 3 of the recommendation, we recommend that the initiation criteria be adjusted from a total abscess and nodule count of 5 or greater to 3 or greater due to the following reasons:

- Quality of life impacts of hidradenitis suppurativa (HS) for people living with HS,
- The chronic, cyclic, painful nature of HS flares and the impact healthcare wait times can have on receiving care from a practitioner with expertise in the management of patients with HS when the condition is at its worst, and
- To provide practitioners with a wider range of treatment options so that they can support patients as effectively as possible, in line with other second-line biologics and the expert recommendations outlined in the draft recommendation.

Quality of life impacts of hidradenitis suppurativa (HS) for people living with HS. HS is a chronic inflammatory skin condition with physically and emotionally debilitating symptoms, such as painful boils and abscesses in skin folds (i.e., armpits, groin, under breasts, between buttocks). During a flare, these lesions produce purulent and malodorous discharge followed by healing of lesions with significant scarring and formation of fistulas. Fistulas are abnormal connections between two surfaces, with a common example being a connection between the anal canal and perianal skin leading to uncontrollable leakage of stool. Consequently, more than 80% of respondents to the 2020 National Report of Patient's Experiences Living with HS survey reported that HS negatively impacted their work performance (81%), social interactions, and intimacy with their partner. Fifty-nine percent of respondents missed at least 2 days of work every month and spent a median of 14 hours per month on HS-related tasks, such as wound care. Patients constantly worry about the odor, staining of clothes, and the unpredictable onset of disease flares, which are often very painful. These anxieties make social life challenging, with symptoms also impacting physical activity levels. For 68% of survey respondents, family life is also affected, and intimacy in 87%. As a result of a wide variety of stressors, nearly 70% of respondents reported feelings of depression. Moreover, one of the major manifestations of HS is debilitating pain associated with the lesions in the skin folds that persist for many years on daily basis. Nearly all patients experience some degree of pain daily that is moderate on average (5.3 out of 10) as per the 2020 National Report. Pain is difficult to control in patients with HS making physical activity and wearing comfortable clothing very challenging. Most patients still do not have report not having a successful pain management regimen, with only 11% of all respondents

considering pain well-controlled and 46% reporting poorly controlled pain. It is also troubling that 51% of patients report self-managing with difficulty accessing prescriptions. There is, therefore, much room for improvement for pain control.

Respondents to the 2023 patient survey identified severe impact of HS on day-to-day life with drainage, severe pain, lesions that make it challenging to walk, challenges to find clothes. The costs of wound care and treatments are high, anxiety and irritation from living with HS are high. All patients report that HS lesions are chronic with majority of patients constantly having active HS lesions.

The chronic, cyclic, painful nature of HS flares and the impact healthcare wait times can have on receiving care from a practitioner with expertise in the management of patients with HS when the condition is at its worst. For people living with HS, the chronic cycle of painful flares can and often does significantly impact many aspects of their life. Due to unpredictable pattern of HS flares, accessing care while having a set number of nodules or abscesses present at the time of the appointment may impact their ability to receive the best and most appropriate care available. For example, a patient may book their appointment when they have several painful nodules and abscesses present, but due to specialist wait times, it may be months before they are able to be in front of a practitioner, and when the day comes, they may present with only 4 nodules. However, for patients with HS, even just 2 or 3 nodules/abscesses can cause significant quality of life impacts if they are in in sensitive areas that lead to stool leakage or significant impacts on a person's ability to walk. Due to factors outside of patient's control, like healthcare wait times and the cyclic nature of HS flares, HS patients can be back into a flare shortly after leaving the office, leaving them once again without adequate care and management for their condition. Under these current recommendations, this would leave HS patients without many options for managing their care, highlighting another reason for reducing the nodule/abscess count from 5 to 3.

To provide practitioners with a wider range of treatment options so that they can support patients as effectively as possible. At present, there are not many treatment options tailored for HS, leaving patients and their healthcare providers with few options for managing this debilitating, chronic condition. With only one biologic currently available in Canada for the treatment of HS (adalimumab), patients and their practitioners lack options for safely and effectively managing HS. In CDA's draft recommendation for secukinumab (outlined in Initiation, Table 1, and in Considerations for prescribing of therapy, Table 2), CDA does not place adalimumab as a treatment that patients must try and receive an inadequate response from first before beginning secukinumab, but outlines secukinumab as being a second-line biologic therapy like adalimumab, being offered prior to adalimumab or offered after a patient did not have success with adalimumab. As such, to provide practitioners with HS expertise as many tools as possible to improve the quality of life of HS patients, we recommend that this initiation reimbursement condition be adjusted from a total abscess and nodule count of 5 down to 3 so that the initiation can be in line with the initiation criteria of adalimumab and clinical expert input can guide the treatment plans for HS patients, allowing them to select the most suitable treatments for their patients' health and wellbeing.

In short, CSPA agrees with the draft recommendation, with the following revision implemented: reducing the Initiation criteria down to 3 abscesses or nodules from the 5 in the current draft recommendation. We make this suggestion to provide practitioners with expertise in HS management more options for improving health outcomes for HS patients, allowing their clinical expert input and clinician judgment to guide prescription and treatment plans for people impacted by the debilitating, chronic condition that is HS, as outlined in the implementation guidance and responses of the draft recommendation Tables.

Expert committee consideration of the stakeholder input

2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☒
	No	☐
If not, what aspects are missing from the draft recommendation?		
Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☐
	No	☒
They have been clearly articulated, however CSPA feels that they have not been adequately addressed in the recommendation, specifically the alignment of the Reimbursement Conditions (Table 1) and Reasons and the Considerations for prescribing therapies (Table 2, page 9). With only one biologic currently available in Canada for the treatment of HS (adalimumab), patients and their practitioners lack options for safely and effectively managing HS. In CDA's draft recommendation for secukinumab, the reasons and considerations do not place adalimumab as a treatment that patients must try and receive an inadequate response from first before beginning secukinumab, but instead outline secukinumab as being a second-line biologic therapy in line with adalimumab (Initiation, Table 1; Considerations for prescribing of therapy, Table 2). As such, to provide practitioners with HS expertise as many tools as possible to improve the quality of life of HS patients, we recommend that this initiation reimbursement condition be adjusted from a total abscess and nodule count of 5 down to 3, aligning it with the initiation criteria of adalimumab so that clinical expert input can guide the treatment plans for HS patients, allowing them to select the most suitable treatments for their patients' health and wellbeing. As outlined in the responses in Table 2, this reduction from 5 to 3 would place the decision to use one biologic over the another into the hands of the clinician and their clinician judgment.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☐
	No	☒
The reimbursement conditions are clearly stated, however CSPA feels the rationale provided does not fully align with the initiation recommendations presented in the draft recommendation, specifically alignment between the Reimbursement Conditions (Table 1) and Reasons and the Considerations for prescribing therapies (Table 2, page 9). With only one biologic currently available in Canada for the treatment of HS (adalimumab), patients and their practitioners lack options for safely and effectively managing HS. In CDA's draft recommendation for secukinumab, the reasons and considerations do not place adalimumab as a treatment that patients must try and receive an inadequate response from first before beginning secukinumab, but outlines secukinumab as being a second-line biologic therapy like adalimumab (Initiation, Table 1; Considerations for prescribing of therapy, Table 2). As such, to provide practitioners with HS expertise as many tools as possible to improve the quality of life of HS patients, we recommend that this initiation reimbursement condition be adjusted from a total abscess and nodule count of 5 down to 3, aligning it with the initiation criteria of adalimumab so that clinical expert input can guide the treatment plans for HS patients, allowing them to select the most suitable treatments for their patients' health and wellbeing.		

[a] CADTH may contact this person if comments require clarification.

Appendix 1. Conflict of Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

A. Patient Group Information	
Name	*Sabrina Ribau*
Position	*Programs Manager*
Date	*29-08-2024*
☒	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.

B. Assistance with Providing Feedback		
1. Did you receive help from outside your patient group to complete your feedback?	No	☒
	Yes	☐
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?	No	☐
	Yes	☒
This submission draws on evidence in CSPA's 2020 HS Report, for which funding was received from a pharmaceutical company. That company did not see any data or drafts prior to its publication by CSPA. For that report, data was purchased by CSPA from the Canadian Institute for Health Information. The three organizations (CSPA, HS Heroes and Hidradenitis & Me Support Group) who prepared the initial patient input submission requested contact information for the principal investigators of clinical trials in Canada from Novartis, which was provided. CSPA then reached out to those principal investigators with an invitation for their clinical trial participants to complete a survey about their experiences, and the data collected is also mentioned in this feedback submission. No funding or other support was received to complete this submission.		

C. Previously Disclosed Conflict of Interest		
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.	No	☐
	Yes	☒

D. New or Updated Conflict of Interest Declaration

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
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0781
Brand name (generic)	Cosentyx
Indication(s)	Hidradenitis Suppurativa
Organization	Dermatology Association of Ontario
Contact information[a]	Name: Dr. Melinda Gooderham

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐
Yes, we agree with the secukinumab criteria and consider that the draft recommendation is fair. However, we consider that more flexibility should be allowed to the clinician to facilitate the implementation of the criteria for reasons highlighted in 4.		

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☐
	No	☐
Not applicable		

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
If not, please provide details regarding the information that requires clarification – N/A		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐

We acknowledge the secukinumab criteria recommended by CDEC and consider that the draft recommendation is fair and would improve the care of HS patients by offering an alternative option. However, we consider that more flexibility should be allowed to facilitate the implementation for one of the recommendations that is presented in Table 1.1:

In patients with moderate to severe HS only if the following criteria are met: 1.1 The patient currently has a total abscess and nodule count of 5 or greater. This criterion would create a care gap that would limit the use for some patients who could benefit from treatment for the following reasons:

- The criteria for moderate HS used since adalimumab approval by Health Canada are a total abscess and nodule count of 3 or greater; and lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III. These are different from the definition in Sunshine & Sunrise where the requirement is a total of five or more inflammatory lesions affecting at least two distinct anatomical areas. There is no requirement of Hurley II or III lesions in the latter and therefore 3-4% of the patients were Hurley I. Dermatologists are now accustomed to staging HS based on the adalimumab criteria, and we believe based on the rationale stated above that this criteria should be replicated for secukinumab to avoid creating the positioning of one biologic over another. Even if this could be considered a minimal difference, this would limit the

use of secukinumab in patients with 3 or 4 nodules that have failed on adalimumab and limit use in patients with 3 or 4 nodules that have contraindications to the use of adalimumab. As there are no other therapies available for these patients, these moderate to severe patients will be left without therapeutic options. Our comment is aligned with the one pointed out by the experts consult in the critical appraisal section: "Although some potential candidates for treatment (identified by the experts) were excluded from the trials, the experts indicated the results would likely be applicable in those patients (e.g., patients with less than 5 inflammatory lesions)".

- The Canadian Hidradenitis Suppurativa Foundation (CHSF) produced a position paper in 2016 regarding the definition of moderate-to-severe HS (of which two of us are authors)[1]. It includes patients with 5 inflammatory nodules on two distinct locations. However, a distinction is made for lesions on the genitalia where a count of only 3 inflammatory nodules would be required. This position reflects the complexity that dermatologists are facing when treating HS patients. Some patients with only two lesions may be good candidate for a biologic if lesions have a significant impact on their daily activities. Two lesions could be severe and painful. Depending on the location, they can cause the patient to have trouble walking, sitting and could impair many aspects of patient social life (for example, my patient who is a truck driver with buttock lesions who cannot work when even one nodule is flared up). Our clinical observations are supported by the literature that showed a weak correlation with disease severity and work impairment & quality of life [2,3].

- Finally, we agree with the experts consult by the CDA regarding the **generalizability** of the inclusion criteria: "the clinical experts noted that patients with fewer than 5 inflammatory lesions who have a history of numerous lesions may be candidates for treatment in clinical practice as HS fluctuates in disease severity independent of treatment". We consider this comment highly relevant in clinical practice as some patients will come to their medical appointment with a lower count of nodules that what triggered the need for a consultation. Even if we agree with the expert comment overall, we consider that the requirement of 3 inflammatory lesions, as for adalimumab, would be easier to implement in practice.

For these reasons, we feel strongly that the adalimumab criteria should also be used for secukinumab to facilitate implementation and that an inflammatory lesion count of 3 should be met or left to clinical expert opinion of those patients severely impacted (like my patient, the truck driver).

1. Alavi A, Adam DN, Alhusayen R, Boucier M, Brassard A, Coutts P, Gooderham M. Definition of Moderate to Severe Hidradenitis Suppurativa: A Position Paper by the Canadian Hidradenitis Suppurativa Foundation (CHSF) Journal of Cutaneous Medicine and Surgery. 2016, Vol. 20(6) 613–615
2. Schneider-Burrus S , Kalus S , Fritz B , Wolk K , Gomis-Kleindienst S, and Sabat R. The impact of hidradenitis suppurativa on professional life. Br J Dermatol. 2023 Jan 23;188(1):122-130. doi: 10.1093/bjd/ljac
3. H.H. van der Zee, M. van de Bunte, and K.R. van Straalen. Management of mild hidradenitis suppurativa: our greatest challenge yet. Br J Dermatol. 2022 Feb; 186(2): 355–356.

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐

[a] CADTH may contact this person if comments require clarification.

Appendix 2. Conflict of Interest Declarations for Clinician Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.
- For conflict of interest declarations:
  - Please 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.
  - Please note that declarations are required for each clinician that contributed to the input.
  - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
  - Please add more tables as needed (copy and paste).
  - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
2. Did you receive help from outside your clinician group to complete this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
3. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☒
	Yes	☐
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Clinician 1 • Clinician 2 • *Add additional (as required)*		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Melinda Gooderham MSc MD FRCPC*
Position	*Dermatologist, Vice President, Dermatology Association of Ontario*
Date	*28 AUG 2024*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.
Conflict of Interest Declaration	

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**
Novartis	☐	☐	☒	☐
Abbvie	☐	☐	☐	☒
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 2	
Name	*Maxwell Sauder, MD, FRCPC*
Position	*Dermatologist, Secretary, Dermatology Association of Ontario*
Date	*28 Aug 2024*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration				
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**
Novartis	☐	☒	☐	☐
Abbvie	☐	☐	☒	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 3	
Name	*David Adam MD FRCPC DABD*
Position	*Dermatologist, President, Dermatology Association of Ontario*
Date	*28 AUG 2024*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration				
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**
Novartis	☐	☐	☒	☐
Abbvie	☐	☐	☒	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0781-000
Name of the drug and Indication(s)	Secukinumab (Cosentyx) For the treatment of adult patients with moderate to severe hidradenitis suppurativa
Organization Providing Feedback	

1. Recommendation revisions Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.		
Request for Reconsideration	**Major revisions:** A change in recommendation **category** or patient **population** is requested	☐
	Minor revisions: A change in reimbursement **conditions** is requested	☐
No Request for Reconsideration	**Editorial revisions:** Clarifications in recommendation **text** are requested	X☐
	No requested revisions	☐

2. Change in recommendation category or conditions Complete this section if major or minor revisions are requested
Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation.

3. Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
Please provide details regarding the information that requires clarification.
b) Reimbursement conditions and related reasons
Please provide details regarding the information that requires clarification.
c) Implementation guidance
Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here.

Guidance is needed regarding a definition for "conventional therapy" as it relates to reimbursement condition 2.

Outstanding Implementation Issues

In the event of a positive draft recommendation, drug programs can request further implementation support from CADTH on topics that cannot be addressed in the reimbursement review (e.g., concerning other drugs, without sufficient evidence to support a recommendation, etc.). Note that outstanding implementation questions can also be posed to the expert committee in Feedback section 4c.

Algorithm and implementation questions
1. Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)
1. 2.
2. Please specify other implementation questions or issues that should be addressed by CADTH
1. 2.
Support strategy
3. Do you have any preferences or suggestions on how CADTH should address these issues?
May include implementation advice panel, evidence review, provisional algorithm (oncology), etc.

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0781-000
Brand name (generic)	secukinumab
Indication(s)	Cosentyx is indicated for the treatment of adult patients with moderate to severe hidradenitis suppurativa (acne inversa) who have responded inadequately to conventional systemic hidradenitis suppurativa therapy.
Organization	Novartis Pharmaceuticals Canada Inc.
Contact information[a]	Name: [redacted]

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐

Novartis Pharmaceuticals Canada agrees with the committee's draft recommendation.

In the reimbursement conditions and reasons table, Novartis proposes to add the following language under the implementation guidance section (see below in red). This addition would allow for more clarity and completeness as it relates to the implementation of the initiation criteria:

Table 1. Reimbursement Conditions and Reasons

Reimbursement condition	Reason	Implementation guidance
Initiation		
1. In patients with moderate to severe HS only if the following criteria are met: 1.1 The patient currently has a total abscess and nodule count of 5 or greater 1.2 Lesions in at least 2 distinct anatomical areas 1.3 Hurley Stage II or III	The SUNNY trials demonstrated that treatment with secukinumab likely resulted in clinical benefit in patients with moderate to severe HS, defined as patients with a total of at least 5 inflammatory lesions (i.e., abscesses and/or inflammatory nodules) affecting at least 2 distinct anatomic areas. Additionally, most patients (94% to 98% of patients across treatment groups) enrolled in the SUNNY trials had HS at Hurley Stage II or III at baseline.	'According to the experts, the inclusion and exclusion criteria used in the trials were considered standard in HS. Although some potential candidates for treatment (identified by the experts) were excluded from the trials, the experts indicated the results would likely be applicable in those patients (e.g., patients with less than 5 inflammatory lesions).' 'The clinical experts noted that patients with fewer than 5 inflammatory lesions who have a history of numerous lesions may be candidates for treatment in clinical practice as HS fluctuates in disease severity independent of treatment.... CDEC defers to the expertise of the clinical experts.'

The following statements are taken from the body of the draft recommendation, and relate to the initiation criteria regarding the total abscess and nodule count:

- The 4th paragraph of Critical Appraisal section on page 16: *'According to the experts, the inclusion and exclusion criteria used in the trials were considered standard in HS. Although some potential candidates for treatment (identified by the experts) were excluded from the trials, the experts indicated the results would likely be applicable in those patients (e.g., patients with less than 5 inflammatory lesions).'*
- CDEC response to Generalizability Implementation Issues flagged by drug plans in Table 2. Responses to Questions from the Drug Programs on page 10: *'The clinical experts noted that patients with fewer than 5 inflammatory lesions who have a history of numerous lesions may be candidates for treatment in clinical practice as HS fluctuates in disease severity independent of treatment…… CDEC defers to the expertise of the clinical experts.'*

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☐
	No	☐
N/A		

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐
The implementation issues were clearly articulated and addressed in the draft recommendation. However, as mentioned in section 1 above, including the experts' statement from the Critical Appraisal section (4th paragraph, page 16), and the CDEC response to the Drug Plans (Generalizability Implementation Issues, page 10) in Table 1 of the draft recommendation would allow for more clarity and completeness as it relates to the implementation of the initiation criteria.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐
The reimbursement conditions were clearly stated. The only additional clarification requested is for condition 1, where no implementation guidance was stated (please see our previous comments); while for the other reimbursement conditions especially conditions 4 and 6, implementation guidance was included based on experts' suggestions.		

[a] CADTH may contact this person if comments require clarification.