

## CADTH REIMBURSEMENT REVIEW

# Stakeholder Feedback on Draft Recommendation

**Brentuximab vedotin (Adcetris)  
(Seagen Canada Inc.)**

**Indication:** Brentuximab vedotin in combination with doxorubicin, vincristine, etoposide, prednisone and cyclophosphamide in previously untreated high-risk HL in the pediatric population. Brentuximab vedotin in combination with doxorubicin, vinblastine, and dacarbazine for the treatment of previously untreated patients with advanced stage Hodgkins Lymphoma

**August 16, 2024**

**Disclaimer:** The views expressed in this submission are those of the submitting organization or individual. As such, they are independent of CADTH and do not necessarily represent or reflect the view of CADTH. No endorsement by CADTH is intended or should be inferred.

By filing with CADTH, the submitting organization or individual agrees to the full disclosure of the information. CADTH 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 identifying personal information or personal health information is included in the submission. The name of the submitting stakeholder group and all conflicts of interest information from individuals who contributed to the content are included in the posted submission.

## CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information		
CADTH project number	PC0371-000	
Brand name (generic)	Adcetris (brentuximab vedotin)	
Indication(s)	in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide in previously untreated high-risk HL in the pediatric population. Brentuximab vedotin in combination with doxorubicin, vinblastine, and dacarbazine for the treatment of previously untreated patients with advanced stage HL.	
Organization	The Leukemia & Lymphoma Society of Canada (LLSC)	
Contact information <sup>a</sup>	Name: Colleen McMillan [REDACTED]	
Stakeholder agreement with the draft recommendation		
<b>1. Does the stakeholder agree with the committee's recommendation.</b>	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
We agree that there is a need for new treatments for HL that control disease symptoms, prolong remission, prolong survival, and improve quality of life. We also agree there is a need to avoid further therapies and late effects in the pediatric population.		
Expert committee consideration of the stakeholder input		
<b>2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?</b>	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
The LLSC did not submit input toward this initial submission. However, our organization fully supports the input submitted by Lymphoma Canada on behalf of those affected by Hodgkin Lymphoma.		
Clarity of the draft recommendation		
<b>3. Are the reasons for the recommendation clearly stated?</b>	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.		
<b>4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?</b>	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.		
<b>5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?</b>	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.		

<sup>a</sup> 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				
<b>Name</b>	Colleen McMillan			
<b>Position</b>	Advocacy Lead			
<b>Date</b>	13-08-2024			
<input checked="" type="checkbox"/>	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	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?			No	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
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	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
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
Seagen Canada Inc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add or remove rows as required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0371-000
Brand name (generic)	Adcetris (Brentuximab vedotin)
Indication(s)	Brentuximab vedotin in combination with doxorubicin, vincristine, etoposide, prednisone and cyclophosphamide in previously untreated high-risk HL in the pediatric population. Brentuximab vedotin in combination with doxorubicin, vinblastine, and dacarbazine for the treatment of previously untreated patients with advanced stage Hodgkins Lymphoma
Organization	Lymphoma Canada
Contact information <sup>a</sup>	Name: Gurjot Basra [REDACTED]
Stakeholder agreement with the draft recommendation	
<b>1. Does the stakeholder agree with the committee's recommendation.</b>	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.	
We agree with the committee's overall recommendation that Adcetris be reimbursed if the conditions are met. From our patient surveys, it is clear that HL patients want access to novel lymphoma therapies which control disease symptoms, bring a longer disease remission, allow them to live longer and improve quality of life. Hence, lymphoma patients with aggressive subtypes, such as advanced HL, deserve access to novel treatment options including Brentuximab vedotin.	
Expert committee consideration of the stakeholder input	
<b>2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?</b>	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
If not, what aspects are missing from the draft recommendation?	
Yes, the committee has demonstrated that it has recognized the importance of the preferences of the surveyed patient population, namely that patients need access to more therapeutic options that allow them to live longer, with less symptoms and an improved quality of life.	
Clarity of the draft recommendation	
<b>3. Are the reasons for the recommendation clearly stated?</b>	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.	
The reasons for the recommendations are clearly stated. However, reimbursement condition 6 stating that Adcetris should not be reimbursed when given in combination with other chemotherapy drugs,	

may be limiting for patients as this can hinder the ability to tailor treatment plans to individual patient needs, compromising the chances of optimal outcomes. Instead, the decision for combination therapy should be left to the discretion of the treating clinician (hematologists or oncologists) with expertise in the management of HL.

<b>4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?</b>	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>

If not, please provide details regarding the information that requires clarification.

<b>5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?</b>	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>

Most conditions have been listed clearly, however, condition 7 seems to suggest that despite Adcetris being a viable option for patients, feasibility of adoption is solely dependent on the submitted price. We feel the feasibility of adoption should not be tied strictly to budgetary impacts and rather that the focus be on the manageable toxicity profile, improvement in QoL and prolonged response should take precedence. We would like to flag the need to have Adcetris funded quickly, as there is currently inequitable access for stage III/pediatric patients versus stage IV.

<sup>a</sup> 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				
<b>Name</b>	<i>Gurjot Basra</i>			
<b>Position</b>	<i>Manager of Patient Programs, Research, and Advocacy</i>			
<b>Date</b>	<i>August 16, 2024</i>			
<input checked="" type="checkbox"/>	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	<input checked="" type="checkbox"/>		
	Yes	<input type="checkbox"/>		
If yes, please detail the help and who provided it.				
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?	No	<input checked="" type="checkbox"/>		
	Yes	<input type="checkbox"/>		
If yes, please detail the help and who provided it.				
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	<input type="checkbox"/>		
	Yes	<input checked="" type="checkbox"/>		
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
<i>Pfizer/Seagen</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<i>Roche</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Incyte</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

# CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0371-000
Brand name (generic)	Brentuximab vedotin
Indication(s)	Brentuximab vedotin in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide in previously untreated high-risk HL in the pediatric population. Brentuximab vedotin in combination with doxorubicin, vinblastine, and dacarbazine for the treatment of previously untreated patients with advanced stage HL.
Organization	OH (CCO) Hematology Cancer Drug Advisory Committee
Contact information <sup>a</sup>	Name: Dr. Tom Kouroukis
Stakeholder agreement with the draft recommendation	
<b>1. Does the stakeholder agree with the committee's recommendation.</b>	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.	
Expert committee consideration of the stakeholder input	
<b>2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?</b>	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
If not, what aspects are missing from the draft recommendation?	
Clarity of the draft recommendation	
<b>3. Are the reasons for the recommendation clearly stated?</b>	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.	
<b>4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?</b>	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
If not, please provide details regarding the information that requires clarification.	
Please clarify availability of BV with AVD in patients with isolated CNS Hodgkin's or with advanced stage disease including CNS.	
<b>5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?</b>	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
If not, please provide details regarding the information that requires clarification.	
Refer to #4.	

<sup>a</sup> 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.
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- 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	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
If yes, please detail the help and who provided it.  OH (CCO) provided a secretariat function to the group.		
3. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
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	<input type="checkbox"/>
	Yes	<input type="checkbox"/>
If yes, please list the clinicians who contributed input and whose declarations have not changed: <ul style="list-style-type: none"> <li>Dr. Tom Kouroukis</li> </ul>		

### C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	Dr. Vighnesh Bharath
Position	Member, OH (CCO) Hematology Cancer Drug Advisory Committee
Date	13-08-2024
<input checked="" type="checkbox"/>	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
Pfizer	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add or remove rows as required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### New or Updated Declaration for Clinician 2

<b>Name</b>	Dr. Joanna Graczyk
<b>Position</b>	Member, OH (CCO) Hematology Cancer Drug Advisory Committee
<b>Date</b>	13-08-2024
<input checked="" type="checkbox"/>	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
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add or remove rows as required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

# CADTH Reimbursement Review

## Feedback on Draft Recommendation

Stakeholder information		
CADTH project number	PC0371-000	
Brand name (generic)	Adcetris (Brentuximab vedotin)	
Indication(s)	Newly Diagnosed High Risk Hodgkin Lymphoma	
Organization	Pediatric Oncology Group of Ontario	
Contact information <sup>a</sup>	Name: Paul Gibson [REDACTED]	
Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
We support the recommendation as it reflects the current standard of care of pediatric centers in Ontario.		
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	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
We were happy to see the consideration of the AHOD 1331 data, however we think its important to highlight how much LESS BV is used in this pediatric approach.		
Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Note: The Budget Impact Analysis presumes 13 patients treated per year. We feel this is a significant underestimation of eligible patients nationally, even when Quebec is excluded.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
While we understand that a fulsome pharmacoeconomic model was not used in assessing the pediatric data, we do think its important that payors recognize that the results of AHOD 1331 were accomplished with almost 60% LESS BV (5 total doses vs 12) which suggests pediatric patients gain significant benefit at a far lower cost.		

<sup>a</sup> CADTH may contact this person if comments require clarification.

## Appendix 2. Conflict of Interest Declarations for Clinician Groups

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  - 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	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
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	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
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	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
If yes, please list the clinicians who contributed input and whose declarations have not changed: <ul style="list-style-type: none"> <li>Clinician 1</li> <li>Clinician 2</li> <li>Add additional (as required)</li> </ul>		

### C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	Please state full name
Position	Please state currently held position
Date	Please add the date form was completed (DD-MM-YYYY)
<input type="checkbox"/>	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	

# CADTH Reimbursement Review

## Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0371-000
Name of the drug and Indication(s)	Brentuximab vedotin (Adcetris) for Hodgkin's Lymphoma
Organization Providing Feedback	PAG
<b>1. Recommendation revisions</b>	
Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.	
Request for Reconsideration	<b>Major revisions:</b> A change in recommendation <b>category</b> or patient <b>population</b> is requested <input type="checkbox"/>
	<b>Minor revisions:</b> A change in reimbursement <b>conditions</b> is requested <input type="checkbox"/>
No Request for Reconsideration	<b>Editorial revisions:</b> Clarifications in recommendation <b>text</b> are requested <input checked="" type="checkbox"/>
	<b>No requested revisions</b> <input type="checkbox"/>
<b>2. Change in recommendation category or conditions</b>	
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.	
<b>3. Clarity of the recommendation</b>	
Complete this section if editorial revisions are requested for the following elements	
<b>a) Recommendation rationale</b>	
Please provide details regarding the information that requires clarification.	
<b>b) Reimbursement conditions and related reasons</b>	
Please provide details regarding the information that requires clarification.	
<ul style="list-style-type: none"> <li>• Under Discontinuation criteria where one of the criteria includes reaching maximum dose/cycle, PAG suggested adding a statement that the dose of brentuximab vedotin is same for stage III and IV disease in adults.</li> <li>• Under Prescribing, PAG suggested the following statement instead:               <ul style="list-style-type: none"> <li>○ "Brentuximab vedotin should be used in combination with chemotherapy drugs AVD in adults or AVPEC in pediatric patients"</li> </ul> </li> </ul>	

- On page 8 pertaining to the statement: “pERC agreed with the clinical experts that patients with CNS involved could be eligible.” PAG suggested to review if there is alignment with Table 1 3.3, where the condition indicates that patients with Cerebral or meningeal disease should not be treated with brentuximab.

### 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.

## 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. Rapid algorithm update for stage 3 adult population (PAG lead NB)
- 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.