



Feedback on Draft Recommendation

Interested party information	
Project number	PC0401-000
Brand name (generic)	Trastuzumab deruxtecan (enhertu)
Indication(s)	For treatment of adult patients with unresectable or metastatic HR - positive, HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining) breast cancer who have received at least one endocrine therapy in the metastatic setting and are not considered suitable for endocrine therapy as the next line of treatment.
Organization	REAL Breast Cancer Alliance of Canada
Contact information ^a	Name: Dr. Christine Brezden-Masley
Interested party agreement with the draft recommendation	
1. Does the interested party agree with the committee's recommendation.	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
<p>We agree with the draft recommendation to reimburse trastuzumab deruxtecan (T-DXd) for adult patients with unresectable or metastatic HR-positive, HER2-low or HER2-ultralow breast cancer who have received at least one endocrine therapy in the metastatic setting and are no longer suitable for further endocrine therapy. The proposed initiation, discontinuation, and prescribing criteria outlined in Table 1 are aligned with the DESTINY-Breast06 trial design and appropriately reflect the evidence reviewed.</p> <p>While we agree with the initiation criteria as written, we would like to highlight an area where evidence is rapidly evolving and may warrant future reconsideration. Specifically, condition 3 currently excludes patients with "<i>clinically active CNS metastases</i>", reflecting the DESTINY-Breast06 eligibility criteria. However, we note that T-DXd is increasingly generating prospective evidence of intracranial activity, including in HER2-low disease, from dedicated phase II trials and brain-metastasis-focused cohorts. These include studies such as DEBBRAH, TUXEDO-4, and other investigator-initiated trials showing promising responses in untreated or progressing brain metastases. Although these data were not part of DB06 and are not intended to alter the scope of this recommendation at this time, they underscore that this exclusion criterion may merit future reassessment as the CNS evidence base for T-DXd continues to mature—particularly for HER2-low and HER2-ultralow patients who currently have limited therapeutic options.</p> <p>This comment is offered to support long-term alignment between reimbursement criteria and the evolving clinical landscape, rather than as a critique of the current draft recommendation.</p>	
Expert committee consideration of the input	
2. Does the recommendation demonstrate that the committee has considered the input that your organization provided?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

If not, please provide details regarding the information that requires clarification.		
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"/>
If not, please provide details regarding the information that requires clarification.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.		

^a CDA-AMC 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 CDA-AMC 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.
- CDA-AMC may contact your group with further questions, as needed.
- Please see the *Procedures for 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		
1. 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.		
2. 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		
3. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the 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"> Dr. Jean-Francois Boileau Dr. Nathaniel Bouganin Dr. Christine Brezden-Masley Dr. Jeffrey Cao Dr. Stephen Chia Dr. Scott Edwards Dr. Karen Gelmon Dr. Nayyer Iqbal Dr. Anil Abraham Joy Dr. Aalok Kumar Dr. Nathalie Levasseur Dr. Mita Manna Dr. Callista Phillips Dr. Daniel Rayson 		



- Dr. Maged Salem
- Dr. Sandeep Sehdev
- Dr. Christine Simmons

C. New or Updated Conflict of Interest Declarations

NONE