



May 26, 2021

Institut national d'excellence en santé et en services sociaux (INESSS)
Direction de l'évaluation des médicaments et des technologies à des fins de remboursement
2535, boulevard Laurier, 5^e étage
Québec (Québec) G1V 4M3

Subject: Mandatory advance notice

As expected at least 2 months ahead of time, this letter is to inform INESSS of our intention to submit an evaluation request to the Direction de l'évaluation des médicaments et des technologies à des fins de remboursement.

The required information is provided in the following table.

Information concerning the evaluation request

*Target submission date	2021/07/29
*Type of evaluation requested (enter the number of the checklist concerned)	Checklist No. 3 - First request: New innovative drug that is a combination of drugs (each of which is listed) – With a Health Canada notice of compliance
*Manufacturer's name	Knight Therapeutics Inc.
*Brand name	BIJUVA™ Indicate if confidential <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
*Generic name	Estradiol and Progesterone capsule
*Indications submitted for evaluation by INESSS	For the treatment of moderate to severe vasomotor symptoms associated with menopause in women with intact uterus.
FOR A DRUG WITH A HEALTH CANADA NOTICE OF COMPLIANCE	
Date of issuance of the notice of compliance	2020/09/17 <input type="checkbox"/> Conditional <input checked="" type="checkbox"/> Unconditional
Indications recognized by Health Canada	For the treatment of moderate to severe vasomotor symptoms associated with menopause in women with intact uterus.
Dosage forms	Oral Capsules
Strengths	1 mg estradiol/ 100 mg progesterone
Other characteristics	N/A
Companion test ^a	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Name of the analysis Objective(s) of the analysis	



Formulary for which the request will be made	<i>List of Medications (basic plan):</i> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <i>List of Medications – Institutions:</i> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Expedited request being considered ^b	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<p>a. By companion test, INESSS means a diagnostic test (or a pharmacogenetic test, or a test which allows therapeutic monitoring) enabling the selection, according to their status for a predictive marker identified by this test, of the patients for whom the treatment is likely to provide benefit among those diagnosed for a given disease. The test is considered a "companion" to the use of the treatment.</p> <p>b. The prioritization request will be assessed, according to the applicable administrative procedures, if a waiting list is required for the assessment requests.</p>	

It is understood that we will inform INESSS as soon as possible of any change to the target date for submitting our evaluation request.

We authorize INESSS to use the information in this advance notice to plan its work and to initiate a consultation process involving citizens, patients and their caregivers, health professionals, and related groups and associations. For this purpose, we authorize INESSS to publish on its website the asked information in the above table.

Comments: N/A



 Signature

May 26, 2021

 Date

Jody Engel

 Name

Country Manager Canada

 Title

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