**Submission for companion diagnostic tests evaluation**

As part of the synchronized evaluation process for companion diagnostic tests, the manufacturer is required to file a Submission for companion diagnostic tests evaluation with the Direction de l’évaluation des médicaments et des technologies à des fins de remboursement – secteur biologie médicale et génomique.

Please fill out the information below.

**Information on an application for companion diagnostic tests evaluation**

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| **Identification of drug requiring one or more companion diagnostic tests** | |
| Drug name |  |
| Manufacturer |  |
| Indication(s) requested in application to INESSS |  |
| **Information required for companion diagnostic tests evaluation** | |
| Context   * *Describe how the requested indication, the drug and the companion diagnostic test are related;* * *Describe the target population for this test.* |  |
| Objective(s) of companion diagnostic test   * *Specify what is measured by the test (protein level, gene expression, presence of a mutation, etc.) and define how it is related to the disease (signalling pathway, altered phenotype, etc.).* * *How will this result be used/interpreted?* |  |
| Recommended technique(s)   * *What type of analytical procedure (NGS, PCR, ELISA, IHC, FISH, etc.) is recommended for this test?* * *Is more than one technique required for the companion diagnostic test (e.g., screening followed by confirmation)? If “yes,” describe the diagnostic algorithm.* |  |
| Current status of laboratory service   * *Is the test currently available in Quebec’s public health system?* * *If “yes,” which laboratories are able to perform the test? Do they use certified methods or in-house protocols? What are these certified methods or protocols?* * *If “no,” what certified method or protocol is being considered? What laboratories would be able to offer the test?* |  |
| **Regarding the budgetary aspects section related to the companion test below :**  **May be completed at the time of advance notice but mandatory with the assessment request.** |  |
| Budgetary aspects related to the companion diagnostic test (from a Quebec perspective)   * *How many patients will need to be tested in order to target potential recipients of the drug?* * *How many target patients could be given the drug?* * *If the test is available in Quebec’s public system, do you anticipate any change in the volume of analyses for the requested indication?* * *If the test is not available in Quebec’s public system, what is your estimate of the per-unit cost of use (equipment and labour)?* * *Provide an economic model.* |  |

We agree to inform INESSS, as promptly as possible, of any change to the above information.

We authorize INESSS to use the information provided in this document to plan its work and to advise the MSSS of any issues related to the companion diagnostic tests. Thus, in the event a notice recommanding the inscription of a drug associated with a companion test is forwarded to the Minister, the authorities responsible for adapting laboratory services can take the necessary steps to ensure the availability of said analysis upon listing of the drug.

Comments:

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| --- |
| Signature |
| Date |
| Name |
| Title |
| Telephone number |