Title: Cost-effectiveness of using the 21-gene breast cancer assay in France

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Cost-effectiveness analyses have proven to be useful to inform reimbursement decisions, as they raise the question of the value for money of alternative health technologies. However, to be relevant to individual decision makers, these analyses need to reflect local clinical practices and to incorporate local costs. The objective of this study was to assess the long-term cost-effectiveness of using the 21-gene breast cancer assay (Onco*type* DX®) in French clinical practice.

Markov model structures are particularly well suited to the modelling of chronic diseases such as cancer. Such a model was developed to evaluate the long-term costs and clinical outcomes associated with the introduction of Onco*type* DX® to inform decisions on adjuvant chemotherapy for patients with ER+, node-negative early-stage breast cancer in France. The model projected life expectancy, and costs, based on recurrence rates for low, intermediate and high-risk patients (NSABP 20 study) as well as French mortality data. Annual cycles were modelled across three health states: *recurrence-free* (in which all patients start the simulation), *recurrence* (following a distant recurrence event) and *dead* (following a mortality event**)**. In the absence of French specific decision impact data, the model compared the assignment of adjuvant chemotherapy based on the conventional approach or based on the Onco*type* DX® Recurrence Score using data from a meta-analysis of nine decision impact studies (Hornberger et al, 2011). Costs associated with chemotherapy were collected through a retrospective study at Tenon hospital. Costs associated with long term recurrence were collected from the literature. The study was conducted in the perspective of the French social security. According to French pharmaco-economic guidelines, costs and outcomes were discounted at 5% per annum. One-way sensitivity analyses were conducted to test the robustness of key inputs and assumptions.

When compared to the conventional approach, using Onco*type* DX® is expected to decrease chemotherapy cost (- €1,540 per patient) through patients who are spared unnecessary chemotherapy, and to increase outcomes (0.13 life years gained per patient) through patients reclassified towards chemotherapy following Recurrence Score assessment. Onco*type* DX® is therefore expected to be cost-saving in French clinical practice. Details of one-way sensitivity analyses, conducted on all key model parameters, are presented and confirm the robustness of the base case results.

In conclusion, using Onco*type* DX® in French clinical practice is expected to save money from the social security perspective. Further work is needed to confirm these results once further French specific data becomes available, such as the decision impact study results from the Switch study.