Oncotype DX for Early Stage, Lymph Node-Positive Breast Cancer: A Review

Context
Breast cancer continues to be the most common cancer diagnosis in Canadian women older than 20 — accounting for 1 in 4 cancer diagnoses. It is one of the leading causes of cancer deaths in Canadian women, second only to lung cancer. Certain biological features of breast cancers can indicate whether the cancer is more or less likely to grow rapidly or return in another part of the body. Testing for these features can help guide treatment decisions such as whether to undergo adjuvant chemotherapy.

Technology
Oncotype DX (ODX) is a gene expression profiling test designed to measure the 10-year risk of tumour recurrence in early breast cancer following initial diagnosis. The risk of tumour recurrence is reported as a 21-gene signature or recurrence score (RS) on a scale of 0 to 100. The RS is translated into one of three categories of risk: low (RS <18), intermediate (RS 18 to 30), or high (RS >30). Initially developed in women with estrogen receptor-positive (ER+) and lymph node-negative (LN−) early invasive breast cancer, the use of ODX has since expanded into other settings, including the lymph node-positive (LN+) population.

Issue
Invasive breast cancer is LN− at diagnosis in 65% of patients. As a result, most of the evidence for ODX is for the LN− population. It is unclear to what extent, if any, the less commonly presenting LN+ population may benefit from ODX testing. A review of the clinical effectiveness of ODX in LN+ patients, together with a review of clinical guidelines will help to guide decisions about the use of ODX in these patients.

Methods
A limited literature search was conducted of key resources, and titles and abstracts of the retrieved publications were reviewed. Full-text publications were evaluated for final article selection according to predetermined selection criteria (population, intervention, comparator, outcomes, and study designs).

Key Messages
- It is uncertain whether ODX is effective in guiding decisions on adjuvant chemotherapy for patients with early invasive breast cancer that is LN+ (and ER+, but HER2−).
- Evidence on the use of ODX in patients with early invasive breast cancer that is LN+ is limited.

Results
The literature search identified 222 citations, 26 of which were potentially relevant, with 5 additional articles identified from other sources. Of these 31 articles, 29 were excluded after full-text screening, resulting in 2 meeting the criteria for inclusion in this review: 1 health technology report and 1 set of clinical practice guidelines.