TITLE: Oncotype DX in Women and Men with ER-PR-Positive, HER2-Negative, Early Stage Breast Cancer with Lymph Node Micrometastasis: Clinical Effectiveness, Cost-Effectiveness, and Guidelines

DATE: 29 June 2016

RESEARCH QUESTIONS

1. In the adjuvant treatment setting, what is the clinical effectiveness of Oncotype DX in women and men with ER-PR-positive, HER2-negative early stage breast cancer with one lymph node micrometastasis?

2. In the adjuvant treatment setting, what is the cost-effectiveness of Oncotype DX in women and men with ER-PR-positive, HER2-negative early stage breast cancer with one lymph node micrometastasis?

3. What are the evidence-based guidelines regarding the use of Oncotype DX in women and men with ER-PR-positive, HER2-negative early stage breast cancer with one lymph node micrometastasis?

KEY FINDINGS

One evidence-based guideline was identified regarding the use of Oncotype DX in women and men with ER-PR-positive, HER2-negative early stage breast cancer with one lymph node micrometastasis.

METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were used to limit retrieval by publication type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between December 1, 2013 and June 27, 2016. Internet links were provided, where available.

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SELECTION CRITERIA

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

<table>
<thead>
<tr>
<th>Population</th>
<th>Women and men with early stage ER-PR-positive and HER2-negative breast cancer with micrometastasis in one lymph node (N1mic) in the adjuvant setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>Oncotype DX</td>
</tr>
<tr>
<td>Comparator</td>
<td>Other clinical or pathological prognostic indicators</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Q1: Clinical effectiveness (benefits and harms, safety); Q2: Cost-effectiveness; Q3: Evidence-based guidelines</td>
</tr>
<tr>
<td>Study Designs</td>
<td>Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic analyses, evidence-based guidelines</td>
</tr>
</tbody>
</table>

ER = estrogen receptor; HER2 = human epidermal growth factor receptor 2; PR = progesterone receptor.

RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, economic evaluations, and evidence-based guidelines.

One evidence-based guideline was identified regarding the use of Oncotype DX in women and men with ER-PR-positive, HER2-negative early stage breast cancer with one lymph node micrometastasis. No relevant health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, or economic analyses were identified.

Additional references of potential interest are provided in the appendix.

Health Technology Assessments
No literature identified.

Systematic Reviews and Meta-analyses
No literature identified.

Randomized Controlled Trials
No literature identified.

Non-Randomized Studies
No literature identified.

Economic Evaluations
No literature identified.
Guidelines and Recommendations

   See: R2, page 4 to 5;
       R7, page 6

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APPENDIX – FURTHER INFORMATION:

Previous CADTH Reports


Non-Randomized Studies

ER-positive and HER2-negative, PR Status Not Specified in Abstract


ER-positive

Oncotype DX Not Mentioned in Abstract


Economic Evaluations – ER-positive, PR Status Not Specified in Abstract


Review Articles