ANALYSIS OF EVALUATIONS MADE BY THE UK CANCER DRUG FUND PANEL OF BREAST CANCER TREATMENTS IN RELATION TO OVERALL SCORES AND FINAL CDF DECISIONS

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Objectives

- To characterise UK Cancer Drug Fund (CDF) scoring of breast cancer drugs according to the CDF prioritisation tool.
- To assess final decisions made by the Chemotherapy Clinical Reference Group (CCRG) and the national CDF panel.

Background

- The CDF, run by National Health Service (NHS) England, provides additional funding for patients to access drugs that are not routinely available from the NHS.
- The fund was established in 2010 and is planned to run until the end of March 2016 with £340m made available in the financial year 2015-2016.
- Decisions are made based on the CDF Prioritisation Tool as well as the median drug cost per patient.
- Each evaluation result in an overall score based on a number of factors, including (NHS 2015a):
  - evidence of clinical benefit e.g. progression free survival (PFS) and overall survival (OS)
  - quality of life (QOL)
  - toxicity
  - unmet need
  - median drug cost per patient
  - strength of evidence
- Scoring criteria and the grades used for CDF evaluations are summarised in Table 1.
- Drugs whose aggregate score is below the threshold applicable will not be added/will be removed from the CDF list.

Methods

- The CDF decision summaries (NHS 2015b) record the formal decisions of the CCRG in relation to drugs and drug indications that are reviewed for inclusion on the national CDF list.
- We reviewed the individual scoring for each assessed treatment in the criteria outlined in the CDF prioritisation tool.
- Assessed criteria included: magnitude of survival benefit (progression free survival and overall survival), quality of life, toxicity compared with existing therapies, degree of unmet clinical need, strength of evidence and total score.
- The individual component scores, strength of evidence and the overall clinical scores were reviewed for evaluations between April 2013 and May 2015.
- Where drugs were re-evaluated, the most recent assessment was considered and historical decision summaries were excluded.

Results

- Since the initiation of this study another round of evaluations was published online in September 2015. Therefore, the analysis was extended to include these recent evaluations (start of April 2013 to end of September 2015).
- Eighteen decisions were published online in this time frame – 7/18 were excluded because more recent evaluations existed for the same intervention and indication, leaving 11 decision summaries in the final analysis.
- 2/11 decisions (18.2%) were positive resulting in the drug either entering the CDF or being retained on the list (Figure 1).
- 9/11 decisions (81.8%) were negative resulting in the drug not entering CDF or being delisted from the CDF (Figure 1).
- The mean clinical score was 4 in the group and ranged from 13 (highest) to 1 (lowest) (Table 2). The mean scores for each component are also presented.
- No treatment scored above zero for the level of “unmet need” in the group (Table 2).
- The “strength of evidence” in the included evaluations score was ‘B’ in 8 out of the 11 applications, all applications graded ‘D’ and the remaining 2 applications were not scored by the CDF panel.
- Figure 2 shows that overall clinical scores, overall survival, PFS and Qol were higher for positive decisions than for negative ones.
- Unmet need did not vary between evaluations as all included evaluations either scored 0 or were not scored in the category.

Table 1: Key to Cancer Drug Fund grading of strength of evidence (NHS 2015a)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two or more good quality phase II randomised controlled trials, both published</td>
<td>A</td>
</tr>
<tr>
<td>One good quality phase III randomised controlled trial, published</td>
<td>B</td>
</tr>
<tr>
<td>Comparative phase II trial, published</td>
<td>C</td>
</tr>
<tr>
<td>Non-Comparative phase II, published</td>
<td>D</td>
</tr>
<tr>
<td>Unpublished data (in abstract form only)*</td>
<td>U1</td>
</tr>
<tr>
<td>Unpublished data (in abstract form only)**</td>
<td>U2</td>
</tr>
</tbody>
</table>

*Appropriate methodology for treatment setting presented at an international meeting
**Methodology inappropriate for treatment setting and/or not presented at international meeting

Table 2: Descriptive statistics of overall CDF clinical score and individual components

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Mean</th>
<th>Highest score</th>
<th>Lowest score</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFS</td>
<td>2.2</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Overall Survival</td>
<td>1.7</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>QoL</td>
<td>0.8</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Toxicity</td>
<td>-0.4</td>
<td>1</td>
<td>-1</td>
</tr>
<tr>
<td>Unmet need</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Overall clinical score</td>
<td>4</td>
<td>13</td>
<td>1</td>
</tr>
</tbody>
</table>

Figure 1: Final decisions made by the CDF panel for breast cancer treatments between April 2013 and September 2015

Figure 2: Mean overall clinical scores and their individual components by CDF decision

Conclusion

- Understanding the way the UK CDF panel makes decisions on the provision of breast cancer treatments can help pharmaceutical companies prepare evidence in order to maximise market access.
- As a full statistical analysis was not conducted, conclusions cannot be made based on statistically significant differences. However, the results do suggest clinical scores were higher for positive decisions and generally higher in individual components such as overall survival.
- Future breast cancer submissions to the CDF should also focus on demonstrating unmet need with high quality supporting data.
- Identifying strengths and weaknesses in the scoring of previous submissions to the CDF can also optimise submissions to give patients with breast cancer the best chance of access to innovative medicines.

References