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BACKGROUND

- Nilotinib is a tyrosine kinase inhibitor (TKI) for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myeloid leukaemia (CML) in chronic phase.
- The ENESTnd phase III trial demonstrated that nilotinib has clinical superiority over current standard treatment of first-line imatinib in patients with chronic phase Ph+ CML, on the basis that fewer patients progressed to accelerated phase/blast crisis.[2]
- Within this trial, significantly fewer patients progressed on nilotinib 300 mg BD (0.7% patients, p=0.003) or nilotinib 400 mg BD (1.8% patients, p=0.009) compared to imatinib 400 mg OD (6.0% patients).[2]
- Whilst the clinical benefits of nilotinib have been demonstrated, the cost-effectiveness of first-line nilotinib has not been explored.

OBJECTIVES

- To evaluate the cost-effectiveness of first-line nilotinib compared to first-line imatinib for patients newly diagnosed with chronic phase Ph+ CML.
- Population: Adult patients with Ph+ CML diagnosed in chronic phase and who do not initially receive a stem cell transplant (SCT).
- Intervention: First-line nilotinib 300 mg BD, second-line dasatinib 100 mg OD.
- Comparator: First-line imatinib 400 mg OD, second-line dasatinib 100 mg OD.
- Outcomes: Costs, life-years (LY), quality-adjusted life-years (QALYs), incremental cost-effectiveness ratios (ICERs).

RESULTS

- Overall survival is estimated to be consistently greater in the nilotinib arm than the imatinib arm for all time points.
- Figure 2 presents the modelled overall survival of patients in the nilotinib arm and depicts the transition of patients through each of the health states. The orange area represents the number of patients alive on first-line nilotinib, with the blue dashed portion of the orange area representing the difference in numbers alive on first-line nilotinib compared to first-line imatinib.
- It can be seen that nilotinib has a slower rate of progression to worse disease health states. The overall effect is that nilotinib extends life in comparison to imatinib.
- Patients receiving first-line nilotinib followed by second-line dasatinib are estimated to live an additional 0.64 years (53 weeks) compared to the imatinib arm, with an associated cost saving of £10,700 over a lifetime (Table 2).
- The mean undiscounted survival in the nilotinib arm is estimated to be 13.96 years compared to 13.32 years in the imatinib arm.
- After adjusting for quality of life, patients are estimated to gain an additional 0.49 QALYs in the nilotinib arm compared to the imatinib arm.
- After discounting, patients are estimated to accrue an additional 0.35 LYs and 0.28 QALYs in the nilotinib arm compared to the imatinib arm. Expected lifetime (discounted) costs in the nilotinib arm are £220,416 compared to £232,941 in the imatinib arm.

CONCLUSIONS

- Our analysis suggests that first-line nilotinib provides a cost-effective use of NHS resources for the treatment of chronic phase Ph+CML.
- This is in line with recent guidance from the Scottish Medicines Consortium (SMC) and the National Institute for Health and Clinical Excellence (NICE), both of whom have recommended nilotinib as an option for the first-line treatment of adults with chronic phase Ph+CML in Scotland and England respectively.[B,9]

REFERENCES


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Table 1. Treatment costs, utilities and disutilities included in the model

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nilotinib 300 mg BD (28 days)</td>
<td>£12,432.85</td>
<td>[3]</td>
</tr>
<tr>
<td>Imatinib 400 mg OD (30 days)</td>
<td>£1,274.39</td>
<td>[4]</td>
</tr>
<tr>
<td>Dasatinib 100 mg OD (30 days)</td>
<td>£2,504.96</td>
<td>[4]</td>
</tr>
<tr>
<td>HU 50mg (25 days)</td>
<td>£10.47</td>
<td>[4]</td>
</tr>
<tr>
<td>Allogeneic SCT</td>
<td>£199,224.58</td>
<td>[5,6]</td>
</tr>
</tbody>
</table>

Table 2. Cost-effectiveness results

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Life-years</th>
<th>QALYs</th>
<th>Lifetime costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undiscounted</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nilotinib</td>
<td>13.96</td>
<td>10.71</td>
<td>£279,000</td>
</tr>
<tr>
<td>Imatinib</td>
<td>13.32</td>
<td>10.22</td>
<td>£288,700</td>
</tr>
<tr>
<td>Difference</td>
<td>0.64</td>
<td>0.49</td>
<td>£10,700</td>
</tr>
<tr>
<td>ICER</td>
<td>Dominated</td>
<td>Dominated</td>
<td></td>
</tr>
</tbody>
</table>

| Discounted | | | |
| Nilotinib | 10.52 | 8.18 | £220,500 |
| Imatinib | 10.17 | 7.90 | £233,000 |
| Difference | 0.35 | 0.28 | £12,500 |
| ICER | Dominated | Dominated |

**Patients may die from other causes at any time. CP = chronic phase; AP = accelerated phase; BC = blast crisis; allo-SCT = allogeneic stem cell transplantation; HU = hydroxyurea.**