BACKGROUND

Psoriatic arthritis (PsA) is a chronic inflammatory arthropathy. Anti-tumour necrosis factor (TNF) treatments for inflammatory arthritis, including PsA, have revolutionised therapeutic options in rheumatology.1

Apremilast is a new oral small molecule inhibitor of phosphodiesterase 4 that modulates a network of pro-inflammatory and anti-inflammatory mediators.

Apremilast has recently been approved by the European Commission for the treatment of PsA and psoriasis.

OBJECTIVE

This analysis was designed to estimate the budget impact following the introduction of apremilast in the treatment of adult patients in Spain with active PsA who have failed to respond to or are intolerant of conventional disease-modifying anti-rheumatic drugs (DMARDs).

METHODS

A budget impact model developed in Microsoft Excel was used to estimate healthcare costs for adult patients with PsA during a 3-year period, from the Spanish National Health System (NHS) perspective.

The target population was defined based on epidemiological criteria: The prevalence rates for PsA (0.2%)2 and proportion of PsA patients on biological treatment (13.5%)3 were applied to national adult population statistics (38,159,410 inhabitants) (Figure 1).

The prevalence of PsA was assumed to remain constant for the time horizon considered (€−3,131,597 for the third year).

The proportion of patients with PsA receiving treatment with DMARDs, non-steroidal anti-inflammatory drugs (NSAIDs)/steroids, or biologicals and the proportion of untreated patients with PsA were obtained by applying the market share data provided by Celgene Corporation to the estimated target population.

The analysis assumed that the proportion of patients in each treatment category would remain the same for the duration of the analysis.

RESULTS

The total budget for the scenario without apremilast was €101,104,837 for the first year, €1,082,349 for the second year, and €100,875,977 for the third year (Table 2). The pharmaceutical cost represented 95% of this total cost.

Incremental costs per patient in the scenario with apremilast, compared with the scenario without apremilast, were €−108.52 (−0.87%) for the first year, €−238.43 (−1.92%) for the second year, and €−385.59 (−3.10%) for the third year.

LIMITATIONS

Local price negotiations might have a significant effect on the budget impact.

Other variables not assessed in the present model, such as effectiveness and safety, could also have potential impact on the total drug expenditures.

CONCLUSION

Apremilast treatment for patients with active PsA, following conventional DMARD failure or contraindication, would imply a budget impact decrease upon overall healthcare expenditure for the Spanish NHS.

REFERENCES


This study was sponsored by Celgene Corporation.

Presented at: the ISPOR 18th Annual European Congress; 7–11 November 2015; Milan, Italy.
For intravenous (IV) drugs, a perfusion cost per dose was considered. For subcutaneous (SC) drugs, educational training (30-minute duration) by nursing personnel was applied to 100%, and 5-minute duration per administration was considered for the 3% of patients who were not able to self-administer.

- Monitoring costs, including laboratory tests and medical visits.

Apremilast has recently been approved by the European Commission for the treatment of PsA and psoriasis. Unit costs for health resources (€ 2014) were obtained from national databases (Table 1). No discounting of future costs was applied in the context of the budget impact analysis.

### OBJECTIVE

Ex-Factory Drug Price/Pack Annual Cost

- Apremilast (Otezla®) 30 mg, 56 tablets – oral €820.00 €9,860.50
- Adalimumab (Humira®) 40 mg, 2 injections 0.8 mL – SC €1,028.29 €12,365.19
- Etanercept (Enbrel®) 50 mg, 4 injections 1 mL – SC €947.22 €11,390.32
- Golimumab (Simponi®) 50 mg, 1 injection 0.5 mL – SC €1,117.00 €12,398.70
- Infliximab (Remsima®) 100 mg, 1 vial – IV €439.75 €10,576.99
- Ustekinumab (Stelara®) 45 mg, 1 injection 0.5 mL – SC €2,747.36 €11,012.33

### METHODS

- The target population was defined based on epidemiological criteria: The prevalence rates for PsA (0.2%) and national adult population statistics (38,159,410 inhabitants) were assumed to remain constant for the time horizon considered in the model.
- The proportion of patients with PsA receiving treatment with DMARDs, non-steroidal anti-inflammatory drugs (NSAIDs)/steroids, or biologicals and the proportion of untreated patients were estimated from a local expert panel.

### RESULTS

- Incremental costs per patient in the scenario with apremilast, compared with the scenario without apremilast, were €−108.52 (−0.87%) for the first year, €−238.43 (−1.92%) for the second year, and €−368.35 (−3.11%) for the third year.

### LIMITATIONS

- Other variables not assessed in the present model, such as effectiveness and safety, could also influence the budget impact analysis.
- Detailed information concerning resource consumption for disease management was obtained from a local expert panel.
- Estimation of total cost included: Drug cost, nurse personnel cost (€20.87/hour), and monitoring cost (€476.10).

### CONCLUSION

Apremilast treatment for patients with active PsA, following conventional DMARD failure or contraindication, would imply a budget impact decrease upon overall healthcare costs.
BACKGROUND

- Psoriatic arthritis (PsA) is a chronic inflammatory arthropathy. Anti-tumour necrosis factor treatments for inflammatory arthritis, including PsA, have revolutionised therapeutic options in rheumatology.¹
- Apremilast is a new oral small molecule inhibitor of phosphodiesterase 4 that modulates a network of pro-inflammatory and anti-inflammatory mediators.
- Apremilast has recently been approved by the European Commission for the treatment of PsA and psoriasis.

OBJECTIVE

- This analysis was designed to estimate the budget impact following the introduction of apremilast in the treatment of adult patients in Spain with active PsA who have failed to respond to or are intolerant of conventional disease-modifying anti-rheumatic drugs (DMARDs).

METHODS

- A budget impact model developed in Microsoft Excel was used to estimate healthcare costs for adult patients with PsA during a 3-year period, from the Spanish National Health System (NHS) perspective.
- The target population was defined based on epidemiological criteria: The prevalence rates for PsA (0.2%)² and proportion of PsA patients on biological treatment (13.5%)³ were applied to national adult population statistics (38,159,410 inhabitants)⁴ (Figure 1).
  - The prevalence of PsA was assumed to remain constant for the time horizon considered in the model.
  - The proportion of patients with PsA receiving treatment with DMARDs, non-steroidal anti-inflammatory drugs (NSAIDs)/steroids, or biologicals and the proportion of untreated patients with PsA were obtained by applying the market share data provided by Celgene Corporation to the estimated target population.
- The analysis assumed that the proportion of patients in each treatment category would remain the same for the duration of the analysis.

Figure 1. Patient Flow

![Patient Flow Diagram]

<table>
<thead>
<tr>
<th>Year</th>
<th>No treatment (7.1%)</th>
<th>Corticoid or NSAID treatment (8.6%)</th>
<th>DMARD treatment (70.8%)</th>
<th>Biological treatment (13.5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>First</td>
<td>4,281 patients</td>
<td>5,209 patients</td>
<td>42,680 patients</td>
<td>8,122 patients</td>
</tr>
<tr>
<td>Second</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Third</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

LIMITATIONS

- Other variables not assessed in the present model, such as effectiveness and safety, could also have potential impact on the total drug expenditures.
- Local price negotiations might have a significant effect on the budget impact.

REFERENCES

• The addition of apremilast to the current therapeutic arsenal (adalimumab, etanercept, golimumab, infliximab, and ustekinumab) was explored.

• From the annual eligible population (PsA patients: N=8,122), 5% (n=406), 11% (n=893), and 18% (n=1,462) were assumed to be treated with apremilast for the first, second, and third year, respectively (Figure 2). These market shares are estimations of Celgene Market Research based on benchmark golimumab in Spain (unit data converted to patients; source: IMS Health).

Figure 2. Proportions of Patients Using Therapies

• Detailed information concerning resource consumption for disease management was obtained from a local expert panel.

• Estimation of total cost included:
  – Drug acquisition cost based on drug doses from each summary of product characteristics (€ 2015, ex-factory price with 7.5% of mandatory deduction).
– Administration cost associated with parenteral drugs.
  - For intravenous (IV) drugs, a perfusion cost per dose was considered.
  - For subcutaneous (SC) drugs, educational training (30-minute duration) by nursing personnel was applied to 100%, and 5-minute duration per administration was considered for the 3% of patients who were not able to self-administer.
– Monitoring costs, including laboratory tests and medical visits.
• Unit costs for health resources (€ 2014) were obtained from national databases (Table 1).7
• No discounting of future costs was applied in the context of the budget impact analysis.

Table 1. Costs

<table>
<thead>
<tr>
<th>Drug</th>
<th>Ex-Factory Price/Pack5</th>
<th>Annual Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apremilast (Otezla®) 30 mg, 56 tablets – oral</td>
<td>€820.00</td>
<td>€9,860.50</td>
</tr>
<tr>
<td>Adalimumab (Humira®) 40 mg, 2 injections 0.8 mL – SC</td>
<td>€1,028.29</td>
<td>€12,365.19</td>
</tr>
<tr>
<td>Etanercept (Enbrel®) 50 mg, 4 injections 1 mL – SC</td>
<td>€947.22</td>
<td>€11,390.32</td>
</tr>
<tr>
<td>Golimumab (Simponi®) 50 mg, 1 injection 0.5 mL – SC</td>
<td>€1,117.00</td>
<td>€12,398.70</td>
</tr>
<tr>
<td>Infliximab (Remsima®) 100 mg, 1 vial – IV</td>
<td>€439.75</td>
<td>€10,576.99</td>
</tr>
<tr>
<td>Ustekinumab (Stelara®) 45 mg, 1 injection 0.5 mL – SC</td>
<td>€2,747.36</td>
<td>€11,012.33</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Administration for Parenteral Drug</th>
<th>Unit Cost7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug perfusion (0.5–2 hours)</td>
<td>€156.10</td>
</tr>
<tr>
<td>Nurse personnel</td>
<td>€20.87/hour</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitoring (Detailed Consumption Provided for Expert Panel)</th>
<th>Annual Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apremilast</td>
<td>€418.02</td>
</tr>
<tr>
<td>Adalimumab, etanercept, golimumab, infliximab, and ustekinumab</td>
<td>€476.10</td>
</tr>
</tbody>
</table>

RESULTS

• The total budget for the scenario without apremilast was €101,104,837 for the first year, €101,082,349 for the second year, and €100,875,977 for the third year (Table 2). The pharmaceutical cost represented 95% of this total cost.
• Following the introduction of apremilast, the total budget was reduced by €881,331 for the first year, €1,936,455 for the second year, and €3,131,597 for the third year.
• Incremental costs per patient in the scenario with apremilast, compared with the scenario without apremilast, were €−108.52 (−0.87%) for the first year, €−238.43 (−1.92%) for the second year, and €−385.59 (−3.10%) for the third year.
Table 2. Budget Impact Results

<table>
<thead>
<tr>
<th></th>
<th>Without Apremilast</th>
<th>With Apremilast</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First Year</td>
<td>Second Year</td>
</tr>
<tr>
<td>Drug cost</td>
<td>€96,221,878</td>
<td>€96,109,397</td>
</tr>
<tr>
<td>Administration and monitoring cost</td>
<td>€4,882,959</td>
<td>€4,972,952</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>€101,104,837</strong></td>
<td><strong>€101,082,349</strong></td>
</tr>
<tr>
<td>Incremental total cost (scenario with vs. scenario without apremilast)</td>
<td>€−881,331</td>
<td>€−1,936,455</td>
</tr>
<tr>
<td>Incremental cost per patient (scenario with vs. scenario without apremilast)</td>
<td>€−108.52</td>
<td>€−238.43</td>
</tr>
</tbody>
</table>

**LIMITATIONS**

- Local price negotiations might have a significant effect on the budget impact.
- Other variables not assessed in the present model, such as effectiveness and safety, could also have potential impact on the total drug expenditures.

**CONCLUSION**

- Apremilast treatment for patients with active PsA, following conventional DMARD failure or contraindication, would imply a budget impact decrease upon overall healthcare expenditure for the Spanish NHS.

**REFERENCES**


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