Budget Impact Analysis of Apremilast in Patients With Moderate to Severe Psoriasis in Spain

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BACKGROUND

- Biological agents, including those that target tumour necrosis factor- α or interleukin (IL)-12/23 or IL-17, have greatly improved the treatment of psoriasis¹; however, some unmet needs remain.
- 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 psoriasis and psoriatic arthritis.

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- For intravenous (IV) drugs, a perfusion cost per dose was considered.
- For subcutaneous (SC) drugs, an educational training (5-minute duration) was applied (by nurse personnel in 70% of cases, and by a dermatologist in 30% of cases). In addition, it was assumed that 25% of patients were unable to self-administer, requiring administration by nurse personnel (5 minutes per administration).
- Monitoring costs, including laboratory tests and medical visits.
- Unit costs for health resources were obtained from national databases (Table 1).⁸
- No discounting of future costs was applied in the context of the budget impact analysis.

Table 1. Costs

• This analysis was designed to estimate the budget impact following the introduction of apremilast in the treatment of patients in Spain with moderate to severe psoriasis after failure, intolerance, or contraindication to previous conventional systemic treatment.

METHODS

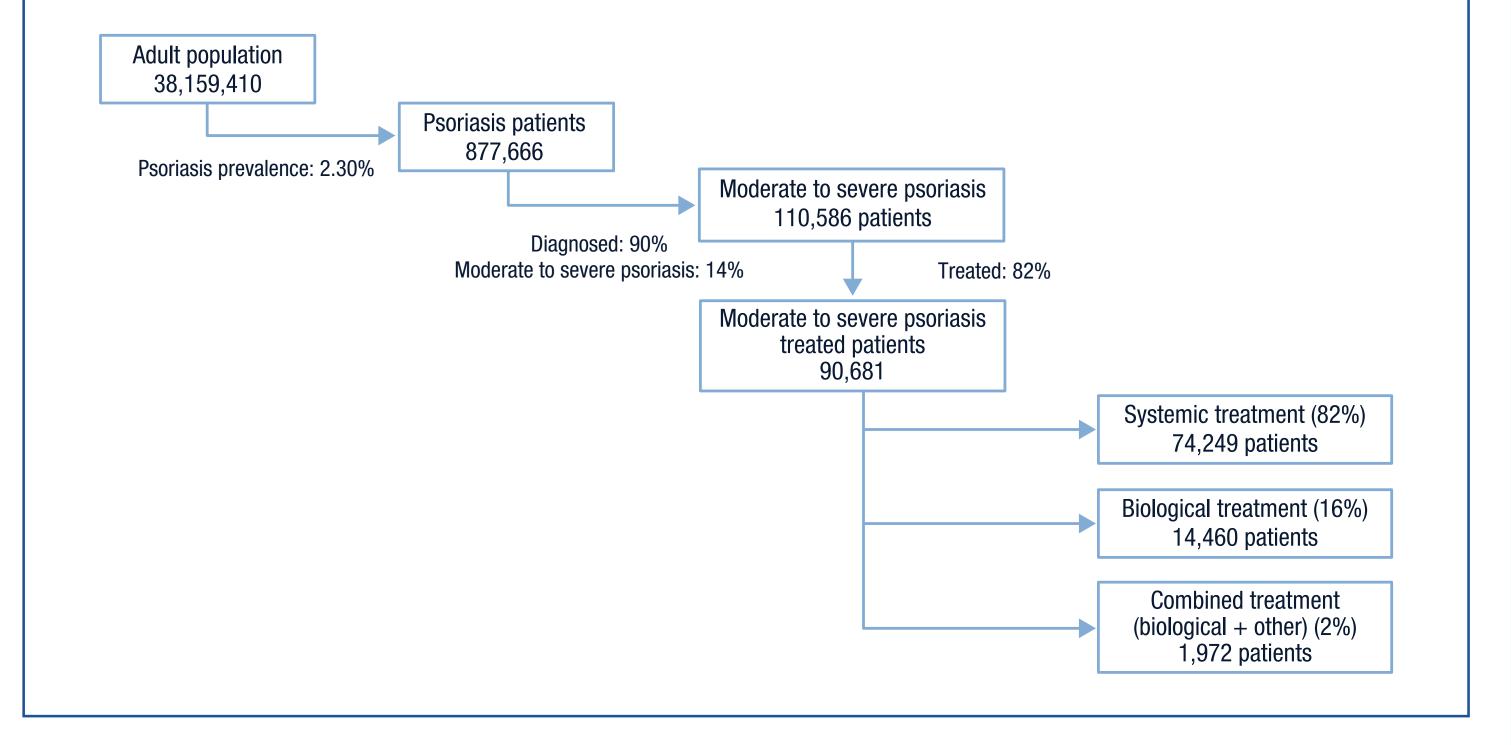
- A budget impact model developed in Microsoft Excel was used to estimate healthcare costs for adult patients with psoriasis during a 3-year period, from the Spanish National Health System (NHS) perspective.
- The target population was defined based on epidemiological criteria: The prevalence rate for psoriasis (2.30%),² proportion of diagnoses (90%) and moderate to severe cases (14%),³ percentage of treated patients (82%), and proportion of patients on biological treatment (18%, including monotherapies and combined treatments)⁴ were applied to national adult population statistics (38,159,410 inhabitants)⁵ (**Figure 1**).
 - The prevalence of psoriasis was assumed to remain constant for the time horizon considered in the model.
 - The proportion of patients with psoriasis in each treatment category and the proportion of untreated patients with psoriasis 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

| Drug | Ex-Factory Price ⁶ |
|--|-------------------------------|
| Apremilast (Otezla®) 30 mg, 56 tablets – oral | €820.00 |
| Adalimumab (Humira®) 40 mg, 2 injections 0.8 mL – SC | €1,028.29 |
| Etanercept (Enbrel®) 50 mg, 4 injections 1 mL – SC | €947.22 |
| Infliximab (Remsima®) 100 mg, 1 vial – IV | €439.75 |
| Ustekinumab (Stelara®) 45 mg, 1 injection 0.5 mL – SC | €2,747.36 |
| Administration for Parenteral Drug | Unit Cost ⁸ |
| Drug perfusion (0.5–2 hours) | €156.10 |
| Nurse personnel | €20.87/hour |
| Dermatologist | €27.16/hour |
| Monitoring* (Medical Visits/Laboratory Tests for Applicable Cases) | Annual Cost |
| Apremilast | €115.40 |
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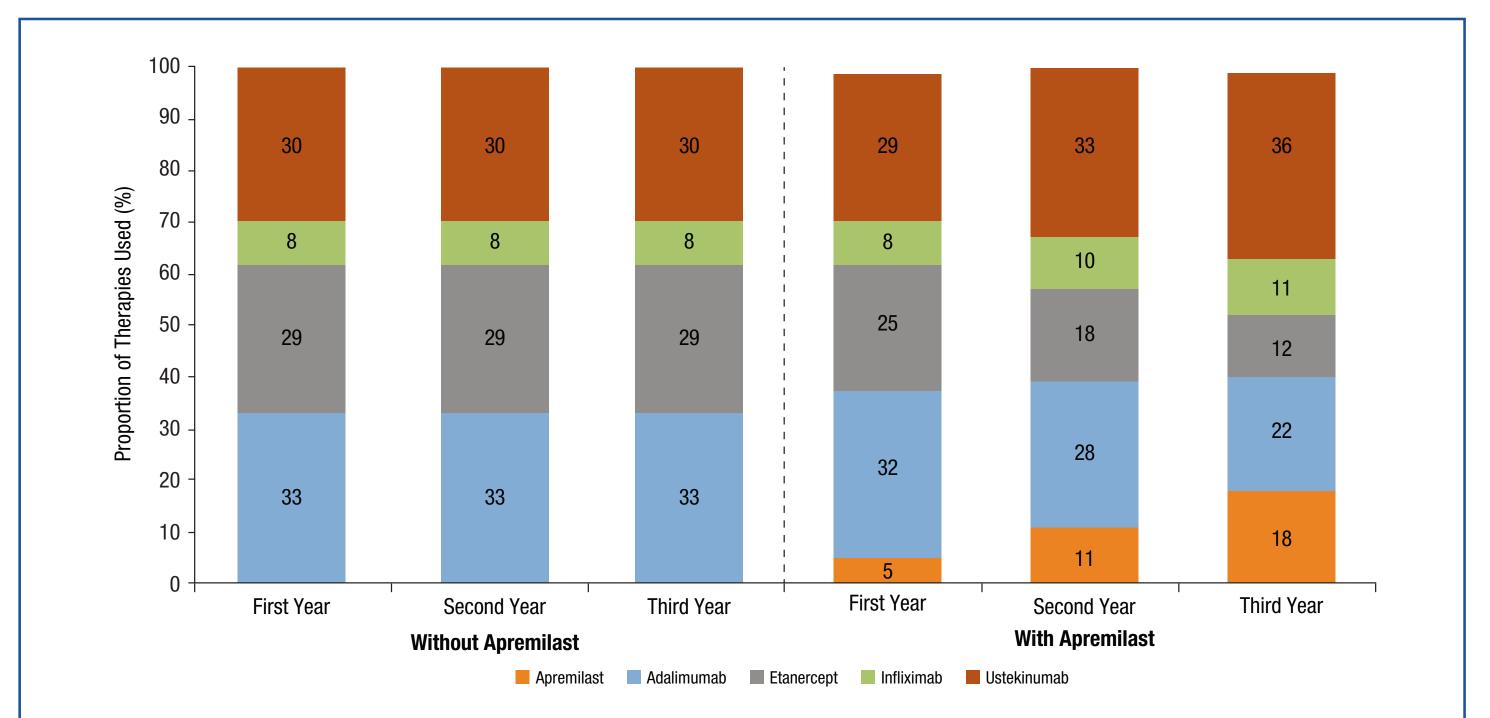
RESULTS

• The total budget for the scenario without apremilast was €193,677,634 for the first year, €192,945,426 for the second year, and €192,077,291 for the third year (**Table 2**). The pharmaceutical cost represented 95% of this total cost.



- Economic consequence of the addition of apremilast to the current therapeutic arsenal (adalimumab, etanercept, infliximab, and ustekinumab) was explored.
- From the annual eligible population (psoriasis patients: N=16,322), 5% (n=816), 11% (n=1,795), and 18% (n=2,938) were assumed to be treated with apremilast for the first, second, and third year, respectively (**Figure 2**).

Figure 2. Proportions of Therapies Used



- Following the introduction of apremilast, total costs were reduced by €1,464,885 for the first year, $\in 3,222,748$ for the second year, and $\in 5,273,587$ for the third year.
- Incremental drug costs per patient in the scenario with apremilast, compared with the scenario without apremilast, were $\in -89.75$ (-0.76%) for the first year, $\notin -197.44$ (-1.67%) for the second year, and $\in -323.09 (-2.75\%)$ for the third year.

Table 2. Budget Impact Results

| | Without Apremilast | | | With Apremilast | | |
|--|--------------------|----------------|---------------|-----------------|----------------|---------------|
| | First Year | Second Year | Third Year | First Year | Second Year | Third Year |
| Drug cost | €188,272,794 | €187,265,230 | €186,249,039 | €186,895,996 | €184,236,274 | €181,292,566 |
| Administration and monitoring cost | €5,404,840 | €5,680,196 | €5,828,252 | €5,316,753 | €5,486,404 | €5,511,138 |
| TOTAL | €193,677,634 | €192,945,426 | €192,077,291 | €192,212,749 | €189,722,678 | €186,803,704 |
| Incremental total cost (scenario with vs. scenario without apremilast) | | | –€1,464,885 | –€3,222,748 | –€5,273,587 | |
| Incremental cost per patient (scenario with vs. scenario without apremilast) | | | –€89.75 | –€197.44 | €–323.09 | |

LIMITATIONS

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

- 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 price⁶ with 7.5% of mandatory deduction⁷).
 - Administration cost associated with parenteral drugs.

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 moderate to severe plaque psoriasis, following failure, intolerance, or contraindication to conventional systemic treatment, would imply a budget impact decrease upon overall healthcare expenditure for the Spanish NHS.



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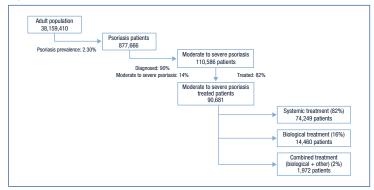
OBJECTIVE

 This analysis was designed to estimate the budget impact following the introduction of apremilast in the treatment of patients in Spain with moderate to severe psoriasis after failure, intolerance, or contraindication to previous conventional systemic treatment.

METHODS

- A budget impact model developed in Microsoft Excel was used to estimate healthcare costs for adult patients with psoriasis during a 3-year period, from the Spanish National Health System (NHS) perspective.
- The target population was defined based on epidemiological criteria: The prevalence rate for psoriasis (2.30%),² proportion of diagnoses (90%) and moderate to severe cases (14%),³ percentage of treated patients (82%), and proportion of patients on biological treatment (18%, including monotherapies and combined treatments)⁴ were applied to national adult population statistics (38,159,410 inhabitants)⁵ (Figure 1).
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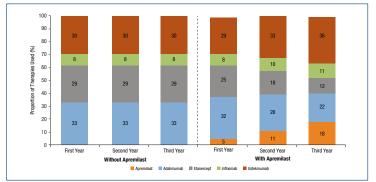


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- · Local price negotiations might have a significant effect on the budget impact.
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