

EE413: Budget Impact Analysis of macimorelin, an oral growth hormone stimulation test, as a diagnostic test for adult growth hormone deficiency (AGHD) across 5 European countries

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Background & Objective

Background

Diagnosis of adult growth hormone deficiency (AGHD) can be challenging and remains a barrier to the initiation of growth hormone treatment due to the clinical presentation of the symptoms often being nonspecific. Macimorelin is a novel, oral growth hormone stimulation test approved by the EMA and FDA for the diagnosis of AGHD. Macimorelin requires considerably less clinical time to administer compared with alternative tests and is associated with a more favorable safety profile when compared with current diagnostic tests. As a result, introducing macimorelin into clinical practice may result in reduced medical resource costs and time savings for hospital nurses and clinical specialists.

Objective

The objective of this study is to investigate the budget impact arising from the introduction of macimorelin as a diagnostic test for AGHD across France, Germany, Italy, Spain and the United Kingdom.

Table 1: Cost of AGHD diagnosis test by country

| | Spain | Italy | France | UK | Germany |
|---------------|---------|---------|---------|-----------|---------|
| Macimorelin | €581.40 | €503.97 | €555.00 | €695.51 | €516.15 |
| ITT | €749.38 | €561.12 | €777.41 | €1,001.76 | €757.01 |
| GHRH-arginine | €768.08 | €538.70 | €658.93 | €1,204.24 | €661.93 |

Methods

A budget impact model was developed from the healthcare perspective, using only direct costs, over a 5-year time horizon. Analyses were run to compare the macimorelin test against two separate comparators: the insulin tolerance test (ITT) and the GHRH-arginine test. The weighting of each comparator was dependent upon local guidelines. It was further assumed that macimorelin would displace 14, 33, 60, 80 and 100 percent of the market share during the first five years of its introduction. A micro-costing approach was taken to calculate the total cost of each test; estimates of resource utilisation for each test were based on clinical guidelines. Costs included were drug acquisition, treatment administration, nurse time, clinical specialist time and adverse event management. The total amount of time taken to conduct the macimorelin test was 1.5 hours. For the ITT and the GHRH-arginine tests, the total time taken was 3.5 and 5 hours, respectively. A doctor and a nurse were assumed to be present for the entirety of the time taken to conduct the tests. Cost inputs were sourced from national databases and, where available, literature.

Patient populations were based on European incidences of AGHD, the incidence estimate of 10 – 16.5 (average 13.25) cases per million was used to calculate the number of cases per year for each individual country. With around 50% of tests showing a negative diagnosis, this figure was doubled to calculate target population. Child onset GHD (cGHD) patients transitioning to adulthood were also considered in the population, the prevalence of cGHD in reported studies is within the range of 180 to 290 per million in Europe (average 235 per million). This prevalence was applied to the population of each country between the ages of 0 to 17 years of age and divided by 17 to calculate annual rates of patients requiring re-testing. Based on market research it is estimated that only 80% of patients who transition to adulthood are retested for GHD, the cGHD population was therefore weighted by 0.8

Table 2: Results from budget impact analysis across EU 5

| | Spain | Italy | France | UK | Germany |
|-----------------------------------|----------------|--------------|----------------|-----------------|----------------|
| Without Intervention | | | | | |
| ITT | € 6,287,275.36 | € 138,597.70 | € 3,125,174.66 | € 4,312,553.38 | € 2,025,767.86 |
| GHRH-arginine | - | € 532,231.49 | € 882,966.20 | € 2,221,823.54 | € 1,180,885.26 |
| With Intervention | | | | | |
| Macimorelin | € 2,799,941.00 | € 357,259.29 | € 1,707,535.20 | € 2,455,212.79 | € 1,321,364.65 |
| ITT | € 2,678,379.30 | € 236,170.48 | € 1,331,324.41 | € 1,837,147.73 | € 862,977.11 |
| GHRH-arginine | - | € 56,682.65 | € 376,143.60 | € 946,496.82 | € 503,057.12 |
| 5 Year Impact (excluding offset) | € 5,478,320.31 | € 650,112.42 | € 3,415,003.21 | € 5,238,857.36 | € 2,687,398.87 |
| 5 Year Savings (including offset) | -€ 808,955.05 | -€ 20,716.76 | -€ 593,137.66 | -€ 1,295,519.56 | -€ 519,254.24 |

Results

The results from the budget impact analysis suggest that the introduction of the macimorelin test is associated with reduced resource utilisation and therefore cost-savings for healthcare systems across all countries included in the analysis. This is the case when compared against both the ITT and the GHRH-arginine test. The total cost of each test is displayed in Table 1, macimorelin is the least costly across all five countries included in the analysis. The introduction of macimorelin leads to savings ranging between €20,716.76 and €1,295,519.56 across the five-year period. Cost savings are driven primarily by reductions in clinical time taken to administer the test, leading to lower clinical resource utilisation and savings in staff costs. However, savings also arise from an improved safety profile leading to fewer mild and transient adverse events.

Conclusion

From a financing perspective, the adoption of macimorelin for AGHD diagnosis represents the best alternative to reduce costs to healthcare systems across the countries considered. The macimorelin test is also associated with fewer adverse events, leading to a potentially better patient experience. Finally, the macimorelin test requires less clinical staff time and may ultimately increase hospital capacity through efficient resource utilisation.

