# Budget impact analysis of pegaspargase for the treatment of acute lymphoblastic leukemia in Greece.

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## Introduction

- Acute Lymphoblastic Leukemia (ALL) is a rare cancer with approximately 6,150 new cases each year in United States (US) and approximately 5,800 in Europe [1, 2]. The incidence rate of ALL is 1.7 per 100,000 persons in US [3] (2013–2017 data) and 1.28 per 100,000 individuals per year in Europe [2].
- Asparaginase constitutes a cornerstone chemotherapeutic agent in ALL [4, 5]. Clinical experience with asparaginase treatment as a component of multi-agent chemotherapy showed improved clinical outcomes in patients with ALL [6-8].
- Pegaspargase is a pegylated form of asparaginase that has showed better clinical profile due to its lower hypersensitivity reactions (one injection every other week) [9, 10], compared to the current first-line treatment of L-Asparaginase derived from Escherichia coli (one injection every other day).
- To assist health technology assessment and reimbursement decision-making, it is important to quantify the economic value of pegaspargase relative to L-Asparaginase for ALL patients in Greece.

## Objective

The aim of present study was to estimate the budgetary impact of the introduction of pegaspargase as treatment option for pediatric, adolescents and adult patients with ALL in Greece from a public payer perspective.

## Methods (1/2)

- A 5-year budget impact model was developed to delineate the financial implications of the introduction of pegaspargase as treatment option for pediatric, adolescents and adult patients with ALL (Figure 1).
- Epidemiological data were modelled after synthesizing the cross-validated data retrieved from literature and local clinical experts (Table 1).
- Market share scenarios with and without pegaspargase as first-line treatment, switch to Erwinase as second line treatment in case of hypersensitivity applied to the eligible Greek patient population. Pharma's projection estimates were used for building up the market shares of the analysis (Table 2).
- The risk of hypersensitivity leading to a treatment switch was from first to second-line asparaginase therapy was considered in the model. The risk of hypersensitivity for both population (pediatric and adult patients), were extracted from published study and validated by local experts.

**Figure 1. Budget impact model structure**

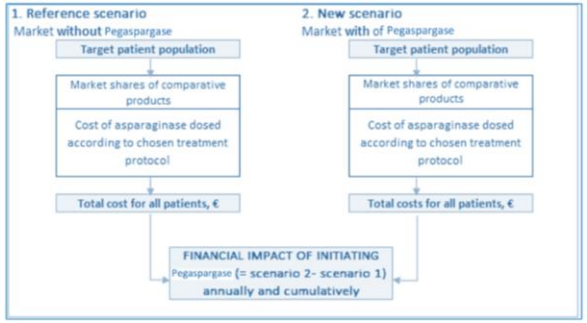



**Table 1. Eligible patient population inputs**

| Parameters | | | | Number of patients | | Source |
|---|---|---|---|---|---|---|
| Annual incidence of ALL | | | | 170 | | Local experts |
| Proportion of ALL patients eligible to receive asparaginase (%) | | | | 88% | | Local experts |
| Number of eligible patient population | | | | 149 | | |
| Patient groups | Pediatric & AYA | | | Adults | | |
| Population distribution (%) | 75% (112) | | | 25% (37) | | Local experts |
| | HR | IR | SR | Aged ≤ 40y | Aged ≥41 y | |
| Risk/age group (%) | 13% (15) | 66% (74) | 21% (23) | 30% (11) | 70% (26) | Local experts |
| Eligible for transplant (%) | | - | | 50% | 50% | |
| Median age | | 7 years | | 31 years | 53 years | |
| BSA | | 0.999 | | 1.790 | | |

ALL, Acute Lymphoblastic Leukemia; AYA, Adolescence and Young Adult; BSA, Body Surface Area; HR, high-risk; IR, intermediate-risk; SR, standard-risk; y, years

- Costs related to drug acquisition were considered in the model from a public payer perspective (Table 3) and unit costs were retrieved from Greek official sources (€, 2020).

## Methods (2/2)

**Table 2. Market share with and without Pegaspargase**

| Market share in current market scenario | | | | | |
|---|---|---|---|---|---|
| Treatment sequence | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
| Pegaspargase followed by Erwinase | 0% | 0% | 0% | 0% | 0% |
| L-asparaginase followed by Erwinase | 100% | 100% | 100% | 100% | 100% |
| **Market share in new market scenario** | | | | | |
| Treatment sequence | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
| Pegaspargase followed by Erwinase | 70% | 60% | 46% | 30% | 24% |
| L-asparaginase followed by Erwinase | 30% | 40% | 54% | 70% | 76% |

**Table 3. Drug acquisition cost considered in the model**

| | Unit cost (€) | Source |
|---|---|---|
| Drug acquisition cost | | |
| Pegaspargase 3,750 IU/vial x 1vial | 1,540 | Greek Ministry of Health [11] |
| L-asparaginase 10,000 IU/vial x 1 vial | 339 | Pharmaceutical Research and Technology Institution [12] |
| Erwinase 10,000 IU/vial x 5 vial | 4,411 | |

- Key outcomes were total incremental costs, calculated by comparing the respective total budget expenditures with and without the introduction of pegaspargase.

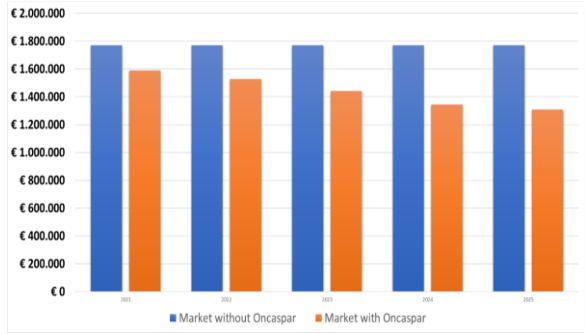
## Results

- Over the 5-year time horizon, adding pegaspargase treatment sequence to the Greek ALL market share mix resulted in considerable cost-savings, with a budget impact of - €1,644,357 (-19%) (Table 4).
- Through the years, the gradual increasing of market share of pegaspargase treatment sequence in each calendar year was associated with the gradual increasing of cost-savings for public payer ending up with the highest total cost-savings (€462,856 [-26%]) in the last year of analysis (2025) (Table 4 & Figure 2).

**Table 4. Base-case budget impact analysis results**

| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Cumulative budget impact |
|---|---|---|---|---|---|---|
| Current market share scenario | | | | | | |
| Total cost without Pegaspargase in the market | €1,770,805 | €1,770,805 | €1,770,805 | €1,770,805 | €1,770,805 | **€8,854,026** |
| Projected market share scenario | | | | | | |
| Total cost with Pegaspargase in the market | €1,588,099 | €1,527,197 | €1,441,934 | €1,344,490 | €1,307,949 | **€7,209,669** |
| Annual incremental cost of introduction of Pegaspargase | -€182,706 | -€243,609 | -€328,871 | -€426,315 | -€462,856 | **-€1,644,357** |
| Budget Impact (%) | -10% | -14% | -19% | -24% | -26% | **-19%** |

**Figure 2. Total Annual Costs with and without pegaspargase in the market**




## Conclusion

This budget impact analysis suggests that the inclusion of pegaspargase for ALL treatment was predicted to be associated with short and long-term cost-savings for Greek payers.

## Acknowledgments

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