

# ANALYSIS OF FUNDING CONDITIONS FOR ORPHAN MEDICINES IN SPAIN: TRENDS IN PRICING & REIMBURSEMENT

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## INTRODUCTION

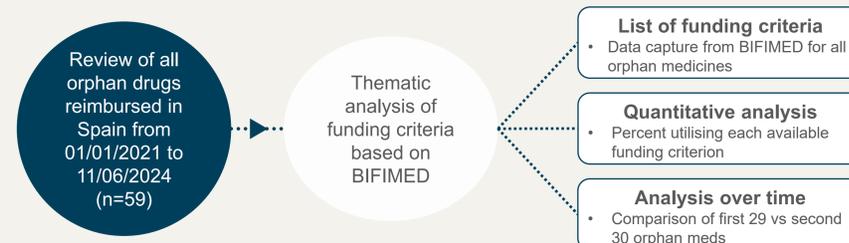
- ▶ As well as confidential discounts, pharmaceuticals in Spain are often subject to additional funding conditions, with the online platform Seguidimed used to monitor sales and consumption.
- ▶ Funding conditions in Spain can be categorised into broad groups, with some overlap between the two:
- ▶ **Clinical:** payment-by-results, implementation of a clinical protocol, reimbursement in a restricted population, data tracking through VALTARMED, trial at no cost to establish responder/non-responder
- ▶ **Financial:** expenditure ceiling, early access with the commitment to pay a rebate based on agreed price, maximum cost per patient, price/volume agreement, supply at lower cost, additional discount
- ▶ We note that a number of markets are moving away from clinically driven funding conditions, on account of their administrative burden, particularly for HCPs capturing the data
- ▶ For high-cost orphan medicines, utilisation of more simple financially driven funding conditions can be the easiest way to manage budget impact

## OBJECTIVE

- ▶ The objective of this analysis is to explore how use of funding conditions has developed in Spain over the past three years, specifically for orphan medicines

## METHODS

- ▶ All orphan medicines that achieved reimbursement in Spain between 1st January 2021 and 11th June 2024 were included in the analysis.
- ▶ The Spanish information system BIFIMED<sup>1</sup> was used to extract data on funding conditions for each medicine. The data was then analysed over time to explore trends emerging in the use of funding conditions.
- ▶ We split the 59 orphan medicines into two groups:
- ▶ **Group 1:** 29 orphan medicines reimbursed from 01/01/2021 through to 01/04/2023
- ▶ **Group 2:** 30 orphan medicines reimbursed from 02/04/2023 to 11/06/2024



## RESULTS

- ▶ In total, 59 orphan drugs achieved reimbursement in Spain between 01/01/2021 and 11/06/2024. On average (mean), each drug was subject to at least 2 funding conditions.
- ▶ Common funding conditions included: restrictions on eligible population (47.5%), maximum cost per patient (25.4%), and early access with the commitment to pay a rebate based on agreed price (23.7%).
- ▶ Notably, our analysis suggests use of clinical protocols and Valtarmed has reduced over time. On the other hand, use of early access, with a commitment to pay a rebate based on the ultimately agreed price, and trial of drug at no cost to establish responder status, has increased (Table 1).

**Table 1** Analysis of funding conditions over time for orphan medicines in Spain

Funding criterion	Utilisation (overall, n=59)	Utilisation (Group 1, n=29)	Utilisation (Group 2, n=30)
Early access with the commitment to pay a rebate based on agreed price	14 (23.7%)	1 (3.4%)	13 (43.3%)
Pharmacoclinical protocol	12 (20.3%)	10 (34.5%)	2 (6.7%)
Expenditure ceiling	18 (30.5%)	10 (34.5%)	8 (26.7%)
VALTARMED	10 (16.9%)	9 (31.0%)	1 (3.3%)
Maximum cost per patient	25 (25.4%)	8 (27.6%)	7 (23.3%)
Payment by results	5 (8.5%)	3 (10.3%)	2 (6.7%)
Price/volume agreement	4 (6.8%)	3 (10.3%)	1 (3.3%)
Supply at lower cost	3 (5.1%)	3 (10.3%)	0 (0.0%)
Trial at no cost	8 (13.6%)	1 (3.4%)	7 (23.3%)
Additional discount	6 (10.2%)	1 (3.4%)	5 (16.7%)
Restricted population	28 (47.5%)	15 (51.7%)	13 (43.3%)
Total number of funding criteria	2.1	2.2	2.0

### Key observed trends

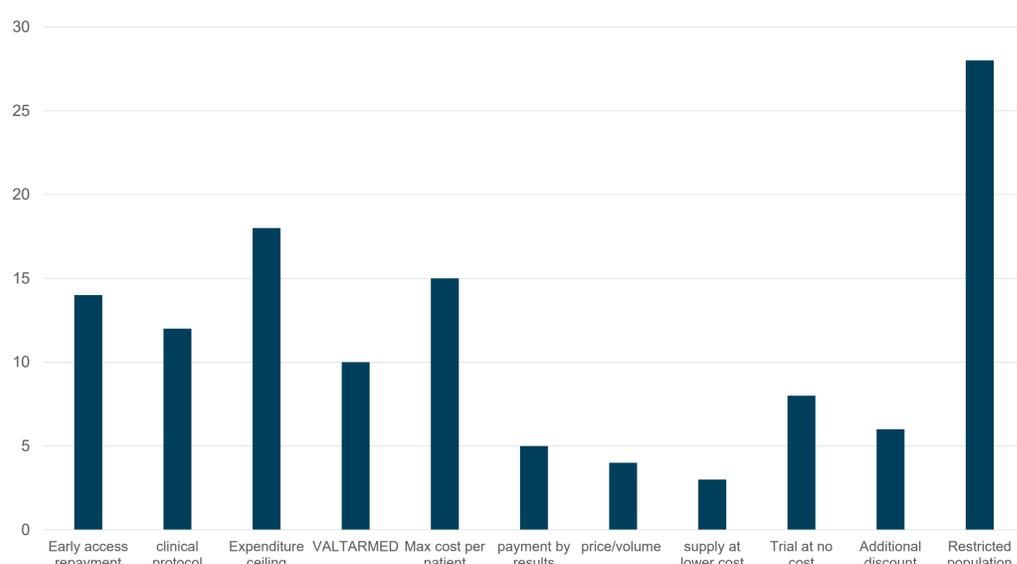
#### Increasing utilisation over time

- ▶ **Early access with rebates:** perhaps looking to address perceived delays in access, use of early access with rebate repayments has increased over time, with almost half (43.3%) of products in Group 2 including this funding condition, compared to just 3.4% of Group 1
- ▶ **Trial of drug at no cost:** usage of free drug to establish responder status has increased from 3.4% of Group 1, to 23.3% of Group 2

#### Reduced utilisation over time

- ▶ **Pharmacoclinical protocols:** use of clinical protocols to manage prescriptions reduced from 34.5% of products in Group 1, to just 6.7% of products in Group 2
- ▶ **VALTARMED:** use of the VALTARMED database to determine therapeutic value of medicines reduced from 31% in Group 1, to only 3.3% of Group 2

**Figure 1** Use of each funding condition for orphan medicines tracked as part of this analysis (N=59)



## REFERENCES

1. <https://www.sanidad.gob.es/profesionales/medicamentos.do?metodo=buscarMedicamentos>

## CONCLUSIONS

- ▶ Funding conditions remain a commonly used tool to manage spending on pharmaceuticals in Spain. Our analysis shows that almost half of orphan medicines are reimbursed in a restricted population.
- ▶ In addition, an increase in the use of early access with the commitment to pay a rebate based on agreed price suggests Spanish payers are trying to speed up time to access.
- ▶ Our analysis of trends over time suggests a move away from funding conditions that may tangentially reduce budget impact (e.g. tracking real-world evidence & use of clinical protocols) towards funding conditions with a very immediate & direct reduction in budget impact, such as trial of drug at no cost
- ▶ This is consistent with trends in other markets, where payers are looking to address two key objectives:
  1. Reduction in overall budget impact
  2. Management of administrative burden for clinicians & payer bodies
- ▶ To this end, we expect these trends to continue, with complex, clinically driven managed access agreements increasingly reserved for exceptional circumstances