Analysis of the Clinical Impact of the Time to Reimbursement of New Oncology Drugs in Spain: A Case Study in Breast Cancer

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INTRODUCTION AND OBJECTIVES

- According to the **WAIT Indicator**, in Spain it is estimated that oncology drugs approved by EMA between 2019 and 2022 took an average of **701 days to become available in the National Health System** (NHS), and by early 2024, 40% were still not accessible[1]. This may be due to **factors** such as the **lack of initiation** of the commercialization process, **funding under negotiation**, or **non-funding**.
- These metrics are essential, but do **not allow to estimate the impact on patients** from **a clinical point of view.** In this context, **Fundación ECO** aims to **assess** metrics to evaluate the contribution that a better access to innovation could have on public health. With this objective, **the clinical impact** in Spain of the time between EMA authorization of a new indication and its availability in the NHS **has been estimated.**

METHODS

- As a **case study** including two innovative molecules, **trastuzumab deruxtecan** and **sacituzumab govitecan**, were analyzed. These were authorized by the EMA for three breast cancer (BC) indications as of the cut-off date for this study, March 2023:
  i. Unresectable or metastatic **HER2+ BC** (trastuzumab deruxtecan)
  ii. Unresectable or metastatic **HER2 low BC** (trastuzumab deruxtecan)
  iii. Unresectable or metastatic **triple-negative BC** (sacituzumab govitecan)
- The clinical impact was estimated in terms of **potential years of overall survival lost** (YOSL) and **years of progression-free survival lost** (YPFSL) in patients due to the time until the availability of an innovative drug for a specific indication, a methodology **previously described** in the literature[2,3].
- To estimate YOSL and YPFSL, the following were considered:
  - **Time until reimbursement**: days elapsed between published EMA authorization date and its inclusion date in *Nomenclátor de Facturación*[4] in Spain.
  - The estimation of **affected patients** was obtained from the IQVIA-Oncology Dynamics database[5].
  - The **incremental clinical benefit** per patient was calculated as the difference in the median of overall survival and progression-free survival between the assessed drug and its comparator in the RCT that supported their authorization.
- The previous variables are related through the **following formula** to obtain the YOSL and YPFSL:

$$\text{Potential years lost} = \frac{\text{Time to reimbursement (months)} \times \text{Affected patients (per month)} \times \text{Incremental clinical benefit (in months)}}{12}$$

- A **sensitivity analysis** (SA) was performed considering only 85% and 70% of potential affected patients and discounting 180 days for administrative tasks.

RESULTS

Trastuzumab deruxtecan – Unresectable or metastatic HER2+ BC

- **Time to reimbursement** for trastuzumab deruxtecan in unresectable or metastatic HER2+ BC was 17.7 months for the 3L+ indication, and 4.7 months for the 2L+ indication.
- Time to reimbursement had an **impact** of 1,715 YOSL in 3L+ (SA: 1,142-1,458) and 3,446 YPFSL in 2L+ (SA: 980-2,929) (Table 1).
- **For each day** that time to reimbursement could have been reduced, an estimated clinical benefit of **3 potential YOSL** gained in 3L+ and **17 potential YPFSL** gained in 2L+ is projected.

Table 1. Results for trastuzumab deruxtecan in HER2+ BC in terms of patients, YOSL and YPFSL

	Eligible patients	YOSL in 3L+	YPFSL in 2L+
Base case	2,697	1,715	3,446
SA: 85% eligible	2,293	1,458	2,929
SA: 70% eligible	1,888	1,200	2,412
SA: 180 days deduction	1,079	1,142	980

Trastuzumab deruxtecan – Unresectable or metastatic HER2 low BC

- Given that, at the time of the analysis, trastuzumab deruxtecan was not reimbursed for HER2 low, the date that the Interministerial Commission on Medicine Prices and Health Products (CIPM) communicated its positive decision for reimbursement was used as the index date. Therefore, **time to reimbursement** for trastuzumab deruxtecan in unresectable or metastatic HER2 low BC was 20.1 months.
- Time to reimbursement had an **estimated impact** of 2,286 YOSL (SA: 1,600-1,943) (Table 2).
- **For each day** that time to reimbursement could have been reduced, an estimated clinical benefit of **4 potential YOSL** gained is projected.

Table 2. Results for trastuzumab deruxtecan in HER2 low BC in terms of patients, YOSL and YPFSL

	Eligible patients	YOSL	YPFSL
Base case	4,157	2,286	1,663
SA: 85% eligible	3,534	1,943	1,413
SA: 70% eligible	2,910	1,600	1,164
SA: 180 days deduction	2,934	1,614	1,174

Sacituzumab govitecan – Unresectable or metastatic triple-negative BC

- **Time to reimbursement** for sacituzumab govitecan in unresectable or metastatic triple negative BC was 12.3 months.
- Time to reimbursement had an **estimated impact** of 833 YOSL (SA: 458-751) (Table 3).
- **For each day** that time to reimbursement could have been reduced, an estimated clinical benefit of **2 potential YOSL** gained is projected.

Table 3. Results for trastuzumab deruxtecan in triple negative BC in terms of patients, YOSL and YPFSL

	Eligible patients	YOSL	YPFSL
Base case	2,164	883	559
SA: 85% eligible	1,839	751	475
SA: 70% eligible	1,514	618	391
SA: 180 days deduction	1,122	458	290

CONCLUSION

These analysis provide possible metrics to quantify the benefits of minimizing time through better coordination of all the agents involved in the different phases leading to the availability of the drug in the healthcare system

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