

Availability and Reimbursement of Multiple Myeloma Drug Regimens in Spain

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OBJECTIVES

To analyse the availability in the Spanish National Health System (NHS) of multiple myeloma (MM) drug regimens authorised in Europe and the time elapsed from authorisation to reimbursement.

METHODS

All drug regimens approved by the European Commission (EC) for the treatment of MM between 01/06/2007 and 01/06/2022 were included in the analysis. Immunoestimulants and regimens based on a chemotherapy agent and a corticoid, without other type of drugs, were excluded. For each regimen we collected the date of EC authorisation from EC website, and the Spanish NHS reimbursement status as of 01/06/2022 and the date of reimbursement decision from the Spanish Ministry of Health website.

Collected data (source)

- Authorisation date (EC website)
- Spanish NHS reimbursement status as of 01/06/2022 (Spanish Ministry of Health website)
- Date of reimbursement decision (Spanish Ministry of Health website)

Outcomes

- Reimbursement status: reimbursed/excluded of reimbursement/pending of decision
- Type of reimbursement: full/restricted
- Time elapsed from authorisation to reimbursement decision

RESULTS

Thirty-two drug regimens were included in the analysis: 21 (65,6%) were reimbursed, 8 (25%) were excluded of reimbursement and 3 (9,4%) were pending of decision (Figure 1). One regimen based on a foreign drug was excluded. Reimbursement of 4 out of 21 regimens (19,0%) was restricted to a subgroup of patients within the authorised indication. Negative and restricted reimbursements have been decided between 2014 and 2022. The time elapsed from EC authorisation to reimbursement decision was 427 days $\pm$ 216 (mean $\pm$ standard deviation): 377 days $\pm$ 206 for reimbursed regimens and 559 $\pm$ 195 for regimens excluded of reimbursement (Figure 2). This is consistent with the mean time reported for oncologic drugs altogether (416 days, of which 147 days are spent by companies before presenting an initial offer, and 269 days are spent in the negotiation period).

Figure 1. Reimbursement status
32 drug regimens

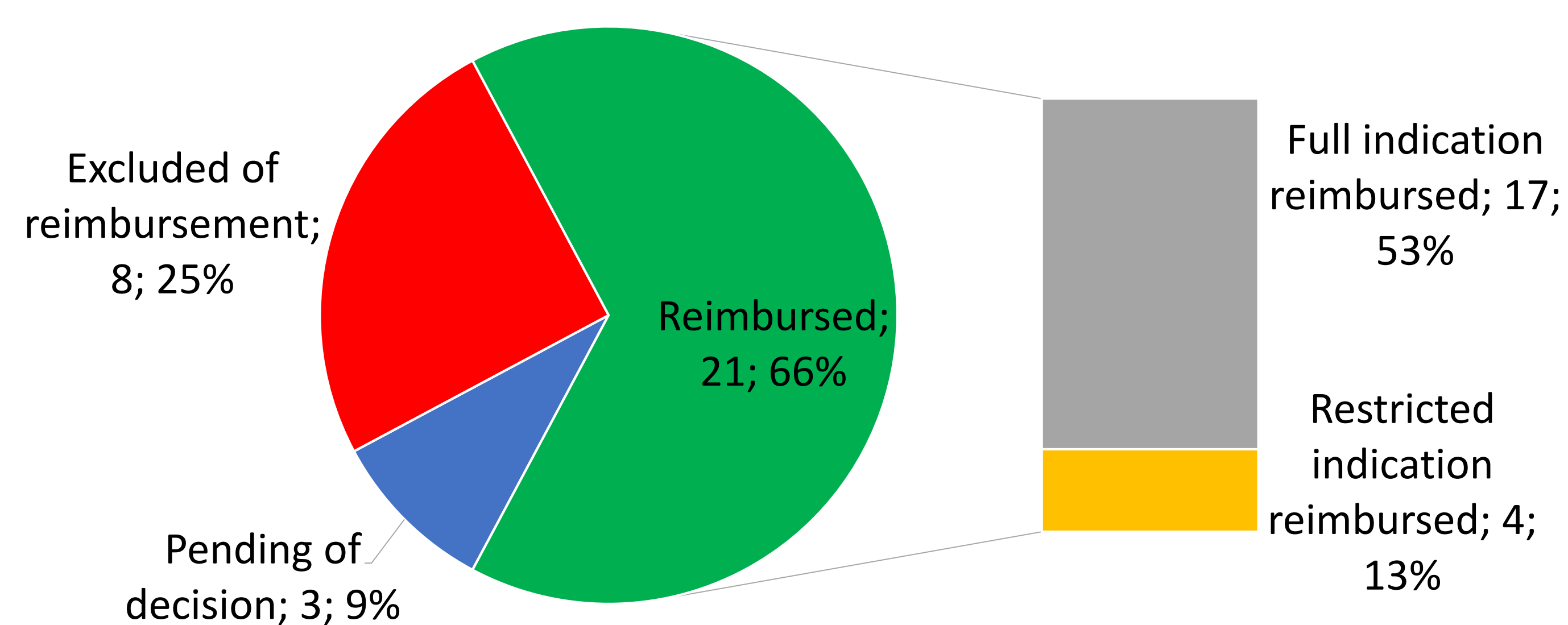
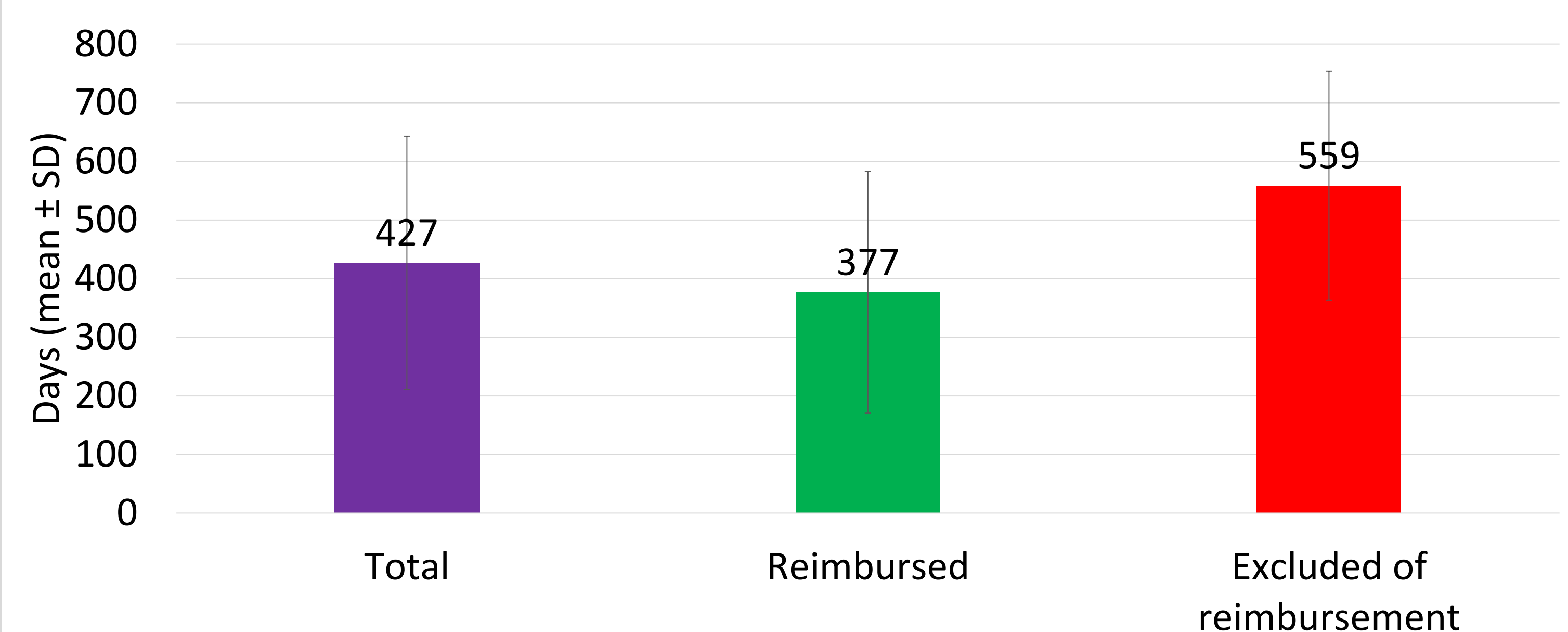


Figure 2. Time elapsed from authorisation to
reimbursement decision



CONCLUSIONS

Almost two-thirds of drug regimens approved in Europe for the treatment of MM are reimbursed in the Spanish NHS and one-quarter is excluded of reimbursement. All negative and restricted decisions have been made during the last eight years. Mean time elapsed from authorisation to reimbursement for MM regimens was similar to that of oncologic drugs, and was shorter for reimbursed regimens than for not reimbursed ones.