Budget Impact Model to Evaluate the Inclusion of a Pre-Filled Syringe Compared to Vial Application of Denosumab in Patients with Four Cancer Types in Mexico

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BACKGROUND

Denosumab (XGEVA®) is used to prevent fractures, spinal cord compression, or the need for radiation or bone surgery in patients with malignant neoplasia and bone metastases (1). Until recently, the vial was the only presentation available in the market, which requires nursing staff for its administration. With the introduction of the prefilled syringe (PFS), the transition from vials to PFS may result in an improved allocation of resources for healthcare institutions, patients, and society as PFS can be administered at home by the patient or their caregiver.

OBJETIVES

To assess the economic impact on Mexican public health institutions by replacing denosumab vials for denosumab PFS in the treatment of four types of cancer, including both direct and indirect costs.

METHODS

Direct and indirect costs associated with the vial and PFS presentations of denosumab were identified from official public sources and literature. Annual costs were estimated assuming 13 cycles of 28 days per year (2). A deterministic sensitivity analysis (DSA) was performed, varying the costs of the vial, PFS, administration, and human resources by 10%. A probabilistic sensitivity analysis (PSA) was also conducted, using an inverse gamma distribution for the listed variables. Table 1 presents the characteristics included in the analysis.

Table 1. Inputs Included in the analysis

Cost per cycle	PFS	Vial
Direct costs	• Acquisition	• Acquisition • Administration supplies (3) • Nursing staff
Indirect Costs	• N/A	• Lost wages (4) • Time loss (5)

The number of patients with each type of cancer (breast, prostate, lung, and multiple myeloma) was estimated using data from the National Institute of Statistics and Geography (INEGI) (6) and GLOBOCAN. The number of patients eligible for denosumab in each public health institution (IMSS, ISSSTE, SSA, PEMEX, SEDENA, SEMAR) was based on INEGI data for population coverage.

The budget impact for Mexican health institutions was calculated estimating the annual costs and the number of patients, under a temporal horizon of 5 years. Two scenarios were analyzed: an immediate replacement from vials to PFS and a progressive replacement scenario, where vials decrease by 20% until only PFS are purchased.

RESULTS

Table 2. Annual cost of denosumab vial and PFS presentations

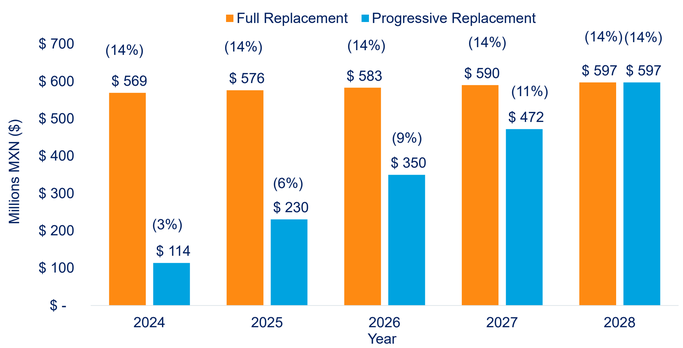
Annual Costs	Vial	PFS
Drug acquisition	$78,613 MXN	$78,094 MXN
Administration supplies	$37 MXN	$-
Nursing staff	$5,032 MXN	$-
Annual lost wage*	$7,456 MXN	$-
Total annual cost	**$91,139 MXN**	**$78,094 MXN**

* Wage reported by IMSS (Daily) (4)

The total annual cost (direct and indirect) of the vial presentation was $91,139 MXN compared to $78,094 MXN for the PFS presentation, resulting in **savings of $13,045 MXN per patient** (14% annual). These savings were primarily driven by the elimination of human resources required for vial administration and the avoidance of lost wages for patients and caregivers.

According to the DSA, the most sensitive variables were the cost of PFS and the cost of the vial, with maximum savings ranging between $ 1,604 and $1,608 MXN respectively. In the PSA, after 1,000 iterations, the total average cost was $91,297 for the vial presentation and $77,981 MXN for the PFS presentation, showing robust and consistent results against the base case scenario where PFS consistently remained the less costly option.

Graph 1. Savings generated by transitioning from vials to PFS for the total population with cancer and myeloma



Graph 1 illustrates the potential savings with both a full and a progressive replacement of the vial presentation with PFS for all eligible patients. Savings as a percentage of the total Mexican healthcare budget are shown in parentheses.

Considering the total population of patients with breast cancer (19,178), prostate cancer (17,900), lung cancer (5,068), or multiple myeloma (1,502) at the beginning of 2024, the projected **savings could amount to $2,916 million MXN in the full replacement scenario**. This amount is 65% higher than the savings accumulated in the progressive replacement scenario ($1,763 million MXN) over a five-year period.

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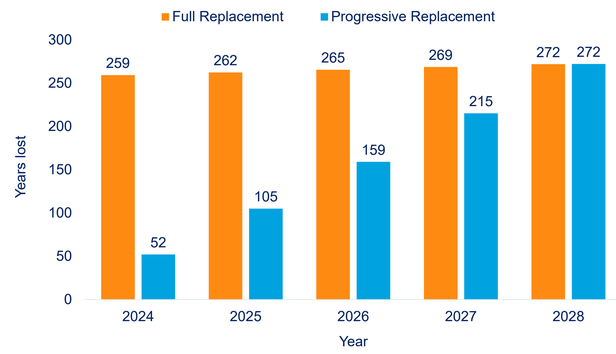
Table 3. Average 5-year savings (in MXN) per institution for each type of cancer

Cancer type	IMSS	ISSSTE	SSA	PEMEX, SEDENA and SEMAR
Breast	-$57,971,648	-$10,002,951	-$40,352,814	-$1,477,709
Prostate	-$54,109,491	-$9,336,540	-$37,664,450	-$1,379,262
Lung	-$15,318,709	-$2,643,228	-$10,663,023	-$390,477
Multiple Myeloma	-$4,538,877	-$783,179	-$3,159,414	-$115,697
Total	**-$131,938,725**	**-$22,765,898**	**-$91,839,701**	**-$3,363,144**

Table 3 shows the average 5-year savings resulting from the full replacement of denosumab vials with PFS for each public health institution, considering direct costs only.

The institutions that would save the most resources are IMSS (0.19% of its medications budget) **followed by SSA** (0.55% of its medications budget), due to the size of the population they cover. Due to the smaller population coverage, the savings in ISSSTE and PEMEX, SEDENA and SEMAR would be lower (0.22 and 0.10% of its medications budget, respectively).

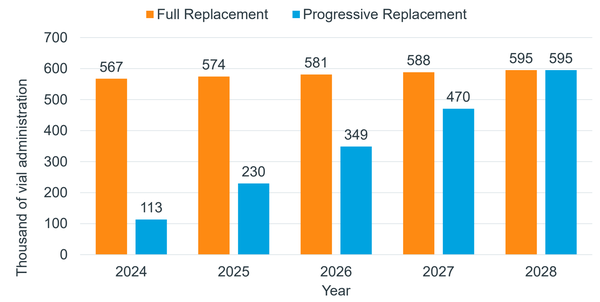
Graph 2. Years lost to commuting due to vial administration



The PFS denosumab presentation can save both patients and caregivers up to 52 hours each year by eliminating the need for commuting to receive vial administration.

As shown in Graph 3, **the full replacement of vials with PFS delivers an immediate and significant reduction in commuting time**, far surpassing the reduction seen with a progressive replacement in the cohort of patients analyzed.

Graph 3. Number of vial administrations saved with PFS denosumab presentation



The PFS presentation of denosumab also optimizes personnel time by eliminating the nursing team's need to administer the vial. As shown in Graph 3, a **full replacement of vials with PFS results in a significant reduction in vial administrations**, compared to a progressive replacement.

This allows healthcare institutions to reallocate its human resources, increasing system efficiency and reducing the demand for healthcare services.

CONCLUSIONS

- **The innovative presentation of denosumab in PFS has the potential to add significant value to patients, healthcare institutions and society by optimizing economic, human and physical resources.**
- **Pre-filled denosumab syringes allow public health institutions to optimize financial resources, as their use would generate savings of up to $1,250 million MXN over a 5–year period. These resources could either be reallocated to other healthcare needs or used to treat 16,000 new patients with multiple myeloma and bone metastases from solid tumors with denosumab PFS.**
- **Pre-filled denosumab syringes reduce productivity and income losses caused by commuting and work absenteeism for patients and their caregivers. In the full replacement scenario, Mexico would save 1,327 years in commuting and $1,666 million MXN in absenteeism over a 5-year period, improving economic efficiency.**
- **Denosumab in PFS enhances healthcare efficiency by removing 2.9 million vial administrations over a 5-year period, freeing nursing staff to focus on other priorities and reducing the demand on healthcare services.**
- **Investing in an innovative alternative that simplifies patient treatment impacts the patients and the healthcare ecosystem positively, ultimately benefiting the society.**

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