

Multi-Indication Budget Impact Analysis of Subcutaneous IgPro20 Pre-filled Syringes for the Treatment of PID, SID, and CIDP in Italy

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CONCLUSIONS

- Introducing IgPro20 PFS for PID, SID, and CIDP in Italy is projected to save €31.5M over three years, with the greatest savings in CIDP due to high baseline vial use and efficiency gains from pre-filled syringes (PFS)
- Sensitivity and scenario analyses confirmed robustness, with cost-savings persisting under conservative dosing assumptions and alternative pricing scenarios
- Including indirect costs increased savings to €31.8M, reinforcing the economic value of IgPro20 PFS
- Beyond financial benefits, IgPro20 PFS supports patient-centric care by simplifying administration, reducing hospital reliance, and improving convenience and quality of life
- While limitations include reliance on proprietary data and dosing assumptions, findings suggest IgPro20 PFS offers a cost-saving, sustainable solution for managing immunodeficiencies and CIDP in Italy

BACKGROUND

- Primary and secondary immunodeficiencies (PID, SID) and immune-mediated neurological disorders (CIDP) impose a significant healthcare burden in Italy, where hospital capacity is often strained,^{1,2} leading to challenges in timely diagnosis and treatment^{3,4}
- PID: Rare, lifelong genetic disorders requiring continuous immunoglobulin (IG) therapy; delayed diagnosis increases costs and worsens outcomes^{5,6}
- SID: Acquired from malignancy, infection, immunosuppressive therapy;^{7,8} underuse of IG leads to preventable complications and economic burden^{4,9,10}
- CIDP: Autoimmune neuropathy causing progressive motor and sensory deficits;^{11,12} IG therapy is central, but diagnosis is often delayed¹²
- In Italy, standard care includes hospital-based IVIG and home-administered SCIG;^{5,7,13} however, IVIG reliance strains hospital resources, while vial-based SCIG can reduce burden¹⁴
- There is a critical need for treatment options that minimize wastage, shorten infusion time, improve healthcare system efficiency, and enhance patient satisfaction through convenient, patient-centric administration¹⁵⁻¹⁸
- IgPro20 PFS represent a new treatment option designed to address these unmet needs by reducing quantity of product consumed, simplifying home administration, and supporting more efficient and patient-friendly SCIG delivery, with the potential to improve overall cost efficiency

OBJECTIVE

This analysis aimed to estimate the budget impact of adding IgPro20 PFS to an Italian healthcare payer health plan over a three-year time horizon for the treatment of patients with PID, SID, or CIDP.

METHODS

- A budget impact model was developed in Microsoft Excel® from the Italian healthcare payer perspective to assess the financial impact of introducing IgPro20 PFS for PID, SID, and CIDP over a 3-year time horizon
- The model compared two scenarios: current treatment landscape without IgPro20 PFS vs. future scenario including IgPro20 PFS, calculating total costs for drug acquisition, administration, and AEs
- The analysis models IgPro20 PFS versus existing IVIG/SCIG products using CSL-informed population growth, current market share trends, AIFA drug costs (including a 17% dose reduction for PFS),¹⁹ administration costs, and published AE data,²⁰⁻²³ across chronic PID/CIDP treatment and an 8-month SID treatment duration
- Sensitivity analyses: One-way sensitivity analysis (OWSA; ±20%) and four scenario analyses tested alternative dosing, societal perspective (inclusion of indirect costs), and lower IVIG pricing

RESULTS

- In year 1, a total of 4,794 patients were eligible across PID, SID, and CIDP.
- Progressive introduction of IgPro20 PFS generated €31.5M in savings over three years.
- Savings by indication: PID €8.8M, SID €5.4M, CIDP €17.3M.
- OWSA: IgPro20 PFS/vial price was the main driver, with a budget impact ranging from –€60.7M to –€2.3M.
- Scenario analyses consistently reported cost savings under alternative settings:
 - 8.5% reduction in PFS dose compared to vials: €16.6M
 - Equivalent dosing for PFS and vials: €1.6M
 - Societal perspective including productivity and travel costs: €31.8M
 - Lower IVIG pricing assumptions: €29.9M

Key Drivers of Savings

- Improved dosing efficiency of IgPro20 PFS, resulting in reduced vial consumption and lower drug acquisition costs across all three indications.
- Reduced administration burden, as SCIG IgPro20 PFS replaces hospital-based IVIG infusions.
- Lower AE-related management costs of SCIG versus IVIG.

Figure 1. Base-case Three-year Budget Impact for the Total Population

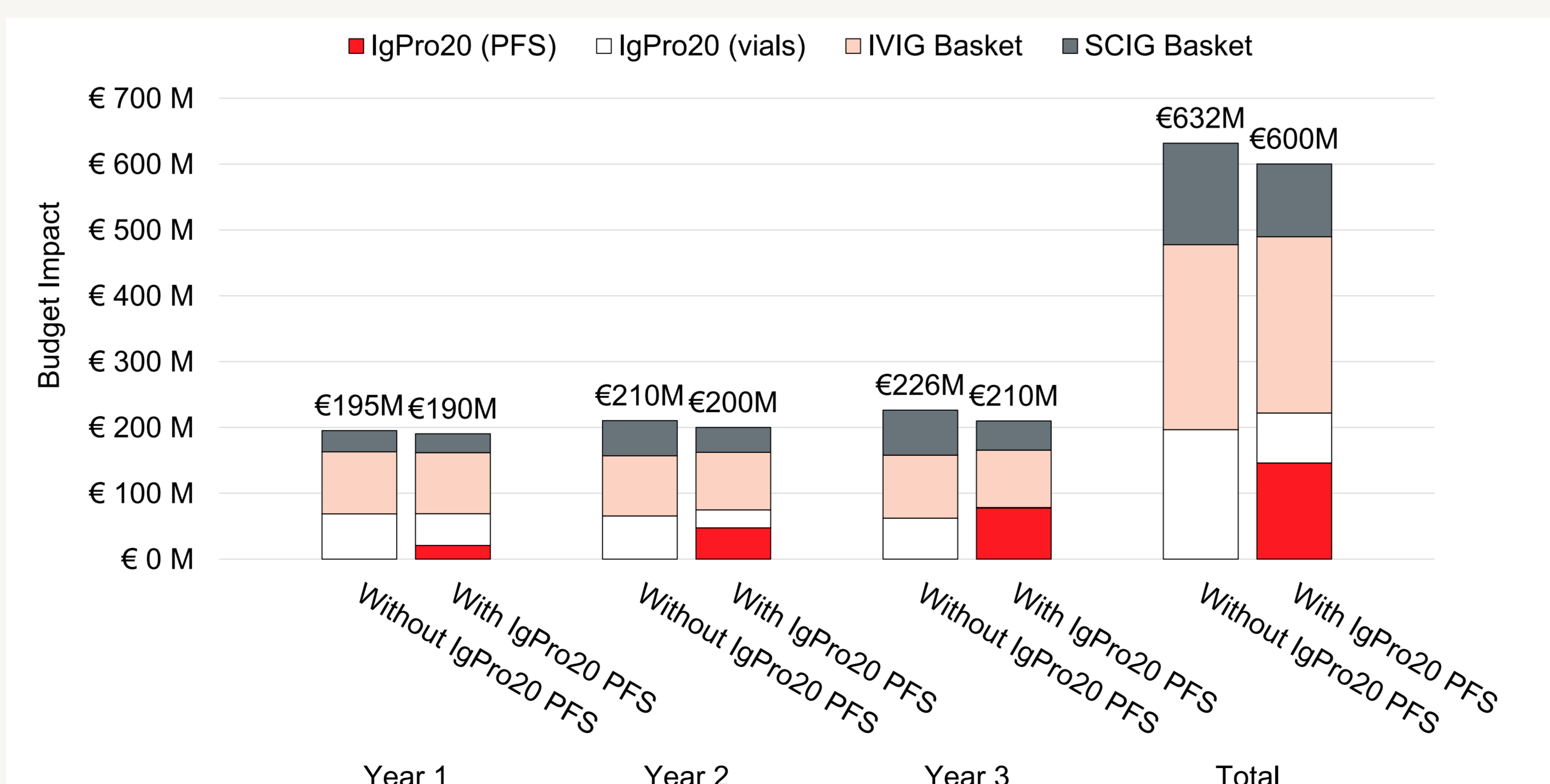


Figure 1 presents the costs associated with each year of the analysis, culminating in the total over three years. Due to cost offsets associated with switching from SCIG and IVIG to IgPro20 PFS, costs are lower when IgPro20 is incorporated into the market.

Table 1. Base Case Three-Year Annual Budget Impact

Treatment	Year 1 (€)	Year 2 (€)	Year 3 (€)	Total (€)
<i>Scenario without IgPro20 PFS</i>				
IgPro20 PFS	0	0	0	0
IgPro20 (vials)	68,695,142	65,530,148	62,344,339	196,569,630
IVIG Basket	94,275,890	91,329,561	95,489,610	281,095,060
SCIG Basket	32,161,383	53,458,485	68,423,260	154,043,128
Total	195,132,416	210,318,194	226,257,209	631,707,819
<i>Scenario with IgPro20 PFS</i>				
IgPro20 PFS	20,676,683	47,531,787	77,767,457	145,975,927
IgPro20 (vials)	48,212,959	27,113,581	575,274	75,901,814
IVIG Basket	92,813,464	87,562,980	87,352,961	267,729,406
SCIG Basket	28,622,655	37,800,930	44,152,599	110,576,184
Total	190,325,762	200,009,279	209,848,291	600,183,331
<i>Annual Budget Impact</i>				
IgPro20 PFS	20,676,683	47,531,787	77,767,457	145,975,927
IgPro20 (vials)	-20,482,183	-38,416,568	-61,769,065	-120,667,816
IVIG Basket	-1,462,426	-3,766,580	-8,136,648	-13,365,654
SCIG Basket	-3,538,728	-15,657,555	-24,270,661	-43,466,944
Total	-4,806,654	-10,308,916	-16,408,918	-31,524,488

The largest savings were generated by reduced use of IgPro20 vials, with additional decreases observed in both IVIG and SCIG basket utilization, reflecting a shift toward IgPro20 PFS as a more efficient treatment option.

Figure 2. Tornado Diagram of One-Way Sensitivity Analyses

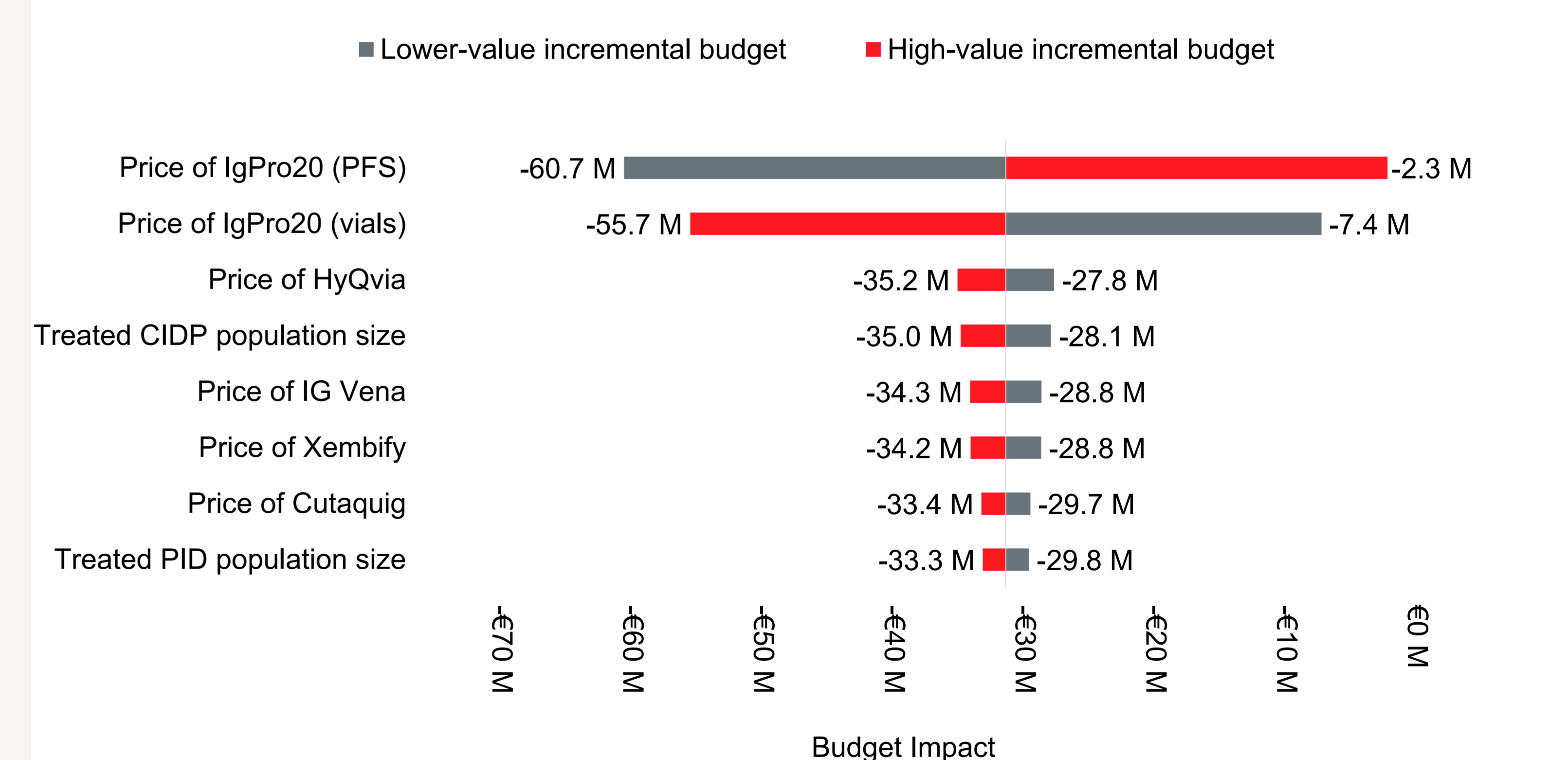


Figure 2 presents the key drivers associated with the model's outcomes. Prices of IgPro20 PFS and vials are key cost drivers, where varying the price of IgPro20 PFS by 20% results in a range of €60.7M to €2.3M in savings. All sensitivity analyses remained cost saving.

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ABBREVIATIONS: AE = adverse event; AEs = Adverse Events; AIFA = Agenzia Italiana del Farmaco; CIDP = chronic inflammatory demyelinating polyneuropathy; IG = immunoglobulin; IVIG = intravenous immunoglobulin; M = million; OWSA = one-way sensitivity analysis; PID = primary immunodeficiency; JG, and SV are employees of CSL. BK, MIT, and JG hold stocks at CSL.