Cost comparison of rFVIIA and plasma-derived factor VII for bleeding management in Colombia

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Aim

To compare pharmacological treatment costs of rFVIIa and pd-FVII for the management of bleeding events and surgical procedures in patients with Factor VII Deficiency[10,11] in Colombia, from a third-party payer perspective.

Introduction

Management of acute bleeding events in patients with Factor VII Deficiency requires use of **procoagulant therapies** that are **associated with substantial pharmaceutical costs.** In Colombia, recombinant activated factor VII **(rFVIIa)** and plasma-derived factor VII concentrate **(pd-FVII)** are therapeutic options used across different bleeding severities and surgical settings.

Comparative cost evidence across clinically relevant scenarios is needed to **support efficient resource allocation within the health system.**

Key Words

Factor VII deficiency: presents with a wide spectrum of symptoms related to low levels of factor VII. The most common symptoms are excessive bleeding after invasive procedures; heavy menstrual bleeding; and bleeding in the mucous membranes, joints and muscles.[10,11]

Mild or moderate bleeding: includes bleeding episodes that can be controlled with low to intermediate doses of recombinant factor VII (15-30 mcg/kg) or plasma derivative (15-20 IU/kg). They generally require repeated administration every 4-6 hours until clinical control.[4,6,7,8]

Severe bleeding: hemorrhages that are life-threatening, compromise vital organs, or do not resolve with initial treatment. They are treated with similar doses of recombinant factor VII (15-30 mcg/kg), but with greater intensity of administration of plasma concentrate (30-40 IU/kg), initially every 2-4 hours and then every 4-6 hours depending on clinical evolution.[5,6,7, 8]

Major surgery: includes large surgical procedures, with a high risk of bleeding. Management is comparable to that of severe bleeding, using recombinant factor VII (15-30 mcg/kg) or plasma concentrate (30-40 IU/kg), administered every 4-6 hours to maintain perioperative hemostasis.[5,6,7,8]

Minor surgery: surgical procedures with low bleeding risk. Recombinant factor VII (15-30 mcg/kg) or plasma concentrate (15-30 IU/kg) is recommended, usually in a single dose, with the possibility of repeating it if bleeding persists.[5,6,7,8]

Key considerations

The dosages of each technology from their pivotal studies were considered, according to the type of bleeding and the equivalence to vials was carried out, contemplating the waste of doses due to the indication of mg and/or iu per kilogram of the patient's weight.

Table 1: *Dosage by type of bleeding rFVIIa[1]*

Types of bleeding	rFVIIa					Dosage Frecuency
	Indication	Minimum	Average	Maximum	Unit of measurement	
Mild or moderate bleeding	15-30	15	22.5	30	mcg/Kg	every 4-6 hours
Severe bleeding	15-30	15	22.5	30	mcg/Kg	every 2-4 hours initially, then every 4-6 hours
Major surgery	15-30	15	22.5	30	mcg/Kg	every 4-6 hours
Minor surgery	15-30	15	22.5	30	mcg/Kg	in one dose and repeat if bleeding continues

Table 2: *Dosage by type of bleeding plasma-derived factor VII[6]*

Types of bleeding	pd-FVII					Dosage Frecuency
	Indication	Minimum	Average	Maximum	Unit of measurement	
Mild or moderate bleeding	15-20	15	17.5	20	UI/kg	every 4-6 hours
Severe bleeding	15-20	30	35	40	UI/kg	every 2-4 hours initially, then every 4-6 hours
Major surgery	15-20	30	35	40	UI/kg	every 4-6 hours
Minor surgery	15-20	15	22.5	30	UI/kg	in one dose and repeat if bleeding continues

The unit cost of medications was carried out following the recommendations of the IETS economic evaluation manual. Sales reports from the institutional channel corresponding to the 4 quarters of the year of analysis were obtained. With this information, the minimum, average and maximum weighted price per minimum unit of concentration for the medications in their different presentations was calculated.[2,3]

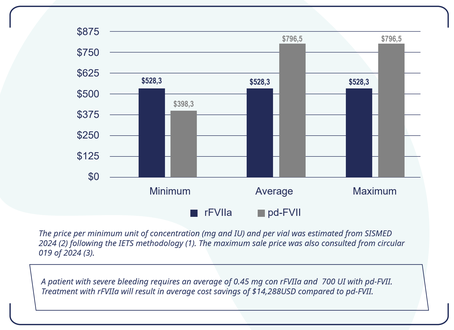
Methods

1. **Cost comparison analysis** following IETS methodological recommendations[1]
2. **Perspective:** Colombian General Social Security Health System
3. **Clinical scenarios:** Mild or moderate bleeding, Severe bleeding, Minor surgery, Major surgery
4. **Unit prices and dosing** ranges derived from product labels and clinical practice.
5. **Costs calculated** by patient body weight, dosing regimen, and number of doses

Results

In severe bleeding or major surgery, **rFVIIa was associated with lower pharmacological costs compared with pd-FVII** in patients weighing more than 18 kg under single-dose regimens.

Table 1: *The cost of treating severe bleeding in a man weighing 20Kg is between*

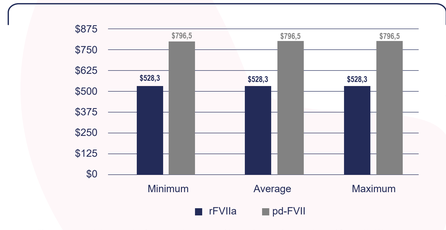


The price per minimum unit of concentration (mg and IU) and per vial was estimated from SISMED 2024 (2) following the IETS methodology (1). The maximum sale price was also consulted from circular 019 of 2024 (3).

A patient with severe bleeding requires an average of 0.45 mg con rFVIIa and 700 UI with pd-FVII. Treatment with rFVIIa will result in average cost savings of $14,288USD compared to pd-FVII.

For mild or moderate bleeding and minor surgery, cost advantages for rFVIIa were observed primarily in higher-weight patients (>30 kg).

Table 2: *The cost of treating severe bleeding in a man weighing 30Kg is between*



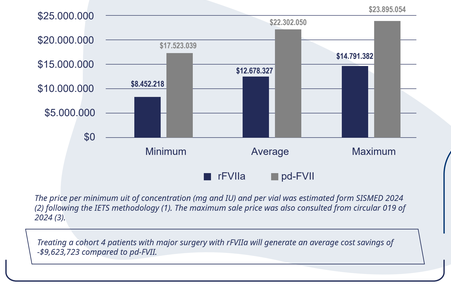
The price per minimum unit of cocentration (mg and IU) and per vial was estimated from SISMED 2024 (2) following the IETS methodology (1). The maximum sale price was also consulted from circular 019 of 2024 (3).

A patient with severe bleeding requires an average of 0.45 mg with rFVIIa and 700 IU with pd-FVII. Treatment with rFVIIa will result in an average cost savings of $14,288USD compared to pd-FVII.

The body weight threshold at which rFVIIa became cost-saving decreased as dosing frequency increased.

Finally, the assumption of treating a cohort of 4 patients in need of management in major surgery was analyzed, and it was concluded that avoided costs were generated with the use of rFVIIa.

Table 3: *The total cost of treating 4 patients with major surgery*



The price per minimum uit of concentration (mg and IU) and per vial was estimated form SISMED 2024 (2) following the IETS methodology (1). The maximum sale price was also consulted from circular 019 of 2024 (3).

Treating a cohort 4 patients with major surgery with rFVIIa will generate an average cost savings of -$9,623,723 compared to pd-FVII.

Summary

For **mild or moderate bleeding and minor surgery, cost advantages for rFVIIa were observed primarily in higher-weight patients (>30 kg).**

In **severe bleeding** or major surgery, **rFVIIa was associated with lower pharmacological costs compared with pd-FVII** in patients weighing more than 18 kg under single-dose regimens.

The body weight threshold at which rFVIIa became cost-saving decreased as dosing frequency increased.

Conclusion

From the Colombian payer perspective, **rFVIIa demonstrates lower pharmacological costs than pd-FVII in patients with Factor VII deficiency: - Higher body weight - Multiple-dose regimens - Management of severe bleeding or major surgical procedures.**

1. Instituto de Evaluación Tecnológica en Salud - IETS. Manual para la elaboración de evaluaciones económicas en salud. 2014. Bogotá D.C.: IETS. 2. Ministerio de Salud y Protección Social. Sistema de Información de Precios de Medicamentos - SISMED. Período de consulta: Q2 2024-Q1 2025 [Consultado en agosto de 2025]. 3. Comisión nacional de percios de medicamentos y dispositivos médicos. Circular 19 de 2024. 4. U.S. Food and Drug Administration. NovoSeven RT (Coagulation Factor VIIa [Recombinant]): Full Prescribing Information [Internet]. Silver Spring (MD): U.S. Food and Drug Administration; revised July 2014 [cited 2025 Aug 8]. Available from: U.S. FDA. .5. Novo Nordisk. NovoSeven RT dosing tools reference — congenital factor VII deficiency; Recommended dosing for treatment of bleeding episodes and surgery section [Internet]. Copenhagen: Novo Nordisk; [cited 2025 Aug 8]. Available from: https://www.novomedlink.com/rare-bleeding-disorders/products/treatments/novoseven/dosing-administration/dosing-tools-reference.html#tailored-dosing. 6. Bernardi, F., & Mariani, G. (2024). Clinical, laboratory, and molecular aspects of factor VII deficiency. In Seminars in Thrombosis and Hemostasis. Thieme Medical Publishers, Inc.. 7. Bernardi, F., & Mariani, G. (2021). Biochemical, molecular and clinical aspects of coagulation factor VII and its role in hemostasis and thrombosis. haematologica, 106(2), 351. 8. Napolitano, M., Siragusa, S., & Mariani, G. (2017). Factor VII deficiency: clinical phenotype, genotype and therapy. Journal of clinical medicine, 6(4), 38. 9. De Moerloose, P., Schved, J. F., & Nugent, D. (2016). Rare coagulation disorders: fibrinogen, factor VII and factor XIII. Haemophilia, 22, 61-65. 10. Mannuci PM, Rare inherited coagulation disorders. In: UpToDate. Waltham (MA): UptoDate; [cited 2025 Sep 12]. Available from: https://www.uptodate.com/contents/rare-inherited-coagulation-disorders?search=factor%20vii%20deficiency&source=search_result&selectedTitle=1~30&usage_type=default&display_rank=1#H3092954501 11. Herrmann FH, et al; Factor FVII Deficiency Study Group. Factor VII deficiency: clinical manifestation of 717 subjects from Europe and Latin America with mutations in the factor 7 gene. Haemophilia. 2009 Jan;15(1):267-80. doi: 10.1111/j.1365-2516.2008.01910.x. Epub 2008 Oct 30. PMID: 18976247.

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