

# Cost-Savings Analysis of Fitusiran Prophylaxis: Reducing Breakthrough Bleeding Treatment Expenditure in the Kingdom of Saudi Arabia

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## OBJECTIVE

To estimate the cost-savings associated with reduction in clotting factor concentrates (CFCs)/bypassing agents (BPAs) consumption for breakthrough bleeds management, when using fitusiran antithrombin (AT)-based dosing regimen (AT-DR) prophylaxis in the Kingdom of Saudi Arabia (KSA), using data from the ATLAS-OLE trial (NCT03754790).

## BACKGROUND

- Fitusiran is a subcutaneous AT-lowering therapeutic that increases thrombin generation to restore haemostasis in people with haemophilia (PwH).<sup>1</sup>
- Fitusiran received approval from the United States Food and Drug Administration (FDA) in March 2025 as a prophylactic treatment for people with haemophilia A or B (PwHA or PwHB) aged  $\geq 12$  years, irrespective of their inhibitor status.<sup>1</sup> This was followed by regulatory approval in United Arab Emirates in April 2025.<sup>2</sup>
- The findings from the ATLAS-OLE trial demonstrated that the fitusiran's AT-DR (targeting AT levels of 15%–35%) reduces the use of CFCs/BPAs in breakthrough bleed management compared with the use of CFCs/BPAs as prophylaxis in haemophilia.<sup>3</sup>

## METHODS

A cost analysis model was developed in Microsoft Excel.

### CFC/BPA episodic treatments used during breakthrough bleeds considered

- For PwHA without inhibitors: octocog alfa, efmorocog alfa, and ruriocog alfa pegol
- For PwHB without inhibitors: nonacog alfa, albutrepenonacog alfa, and eftrenonacog alfa
- For PwH with inhibitors: factor VIII inhibitor bypassing activity (FEIBA) and eptacog alfa

### Model inputs and assumptions

- Key inputs used for the calculation are presented in Table 1.
- An average patient weight of 70.00 kg was included.<sup>4</sup>
- The administration cost used was the cost of 500 Saudi riyal (SAR) per an intravenous drip session.<sup>5</sup>
- Published drug prices in the KSA were used in the analysis.<sup>6</sup>
- No vial sharing was assumed in the base case analysis.
- The reduction in CFC/BPA consumption with fitusiran AT-DR prophylaxis was derived directly from the ATLAS-OLE trial data (Figure 1).<sup>3</sup>

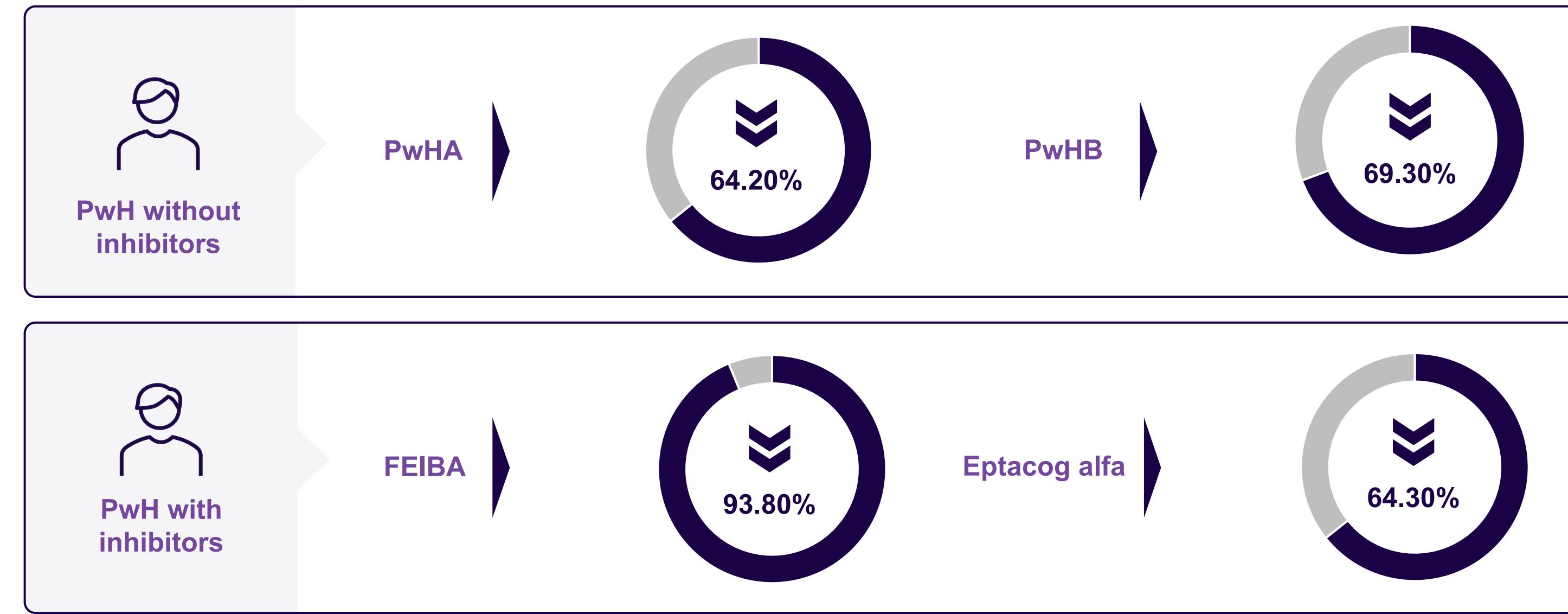
Table 1. Cost-calculation model inputs.

On-demand treatment	Cost per pack (SAR)	CFC/BPA dose per kg	CFC/BPA doses to resolve one bleed	Total CFC/BPA dose per bleed with CFC/BPA prophylaxis	Total CFC/BPA dose per bleed with fitusiran AT-DR prophylaxis
<b>PwHA without inhibitors</b>					
Octocog alfa	618.20	30	1.5	3,150.00	1,127.70
Efmorocog alfa	739.30	20	1.5	2,100.00	751.80
Ruriocog alfa pegol	752.35	30	1.5	3,150.00	1,127.70
<b>PwHB without inhibitors</b>					
Nonacog alfa	1,333.85	30	1.7	3,570.00	1,095.99
Albutrepenonacog alfa	2,323.55	30	1.7	3,570.00	1,095.99
Eftrenonacog alfa	1,549.05	30	1.7	3,570.00	1,095.99
<b>PwH with inhibitors</b>					
FEIBA	1,645.30	75	3.7	19,425.00	1,204.35
Eptacog alfa	3,168.00	90	6.0	37,800.00	13,494.60

AT-DR, antithrombin-based dosing regimen; BPA, bypassing agent; CFC, clotting factor concentrate; FEIBA, factor VIII inhibitor bypassing activity; PwH, people with haemophilia; PwHA, people with haemophilia A; PwHB, people with haemophilia B; SAR, Saudi riyal; USPI: United States prescribing information.

The dose per kg for PwH on CFC/BPA prophylaxis was sourced from USPI<sup>7–14</sup>; The percentage reductions considered in factor consumption for PwH on fitusiran AT-DR prophylaxis are based on ATLAS-OLE data.<sup>3</sup>

Figure 1. Potential reduction in the mean annualised weight-adjusted consumption of on-demand CFC/BPA with fitusiran AT-DR prophylaxis compared with that with CFC/BPA prophylaxis for breakthrough bleeds management.



■ Reduction in CFC/BPA consumption for breakthrough bleeds management with fitusiran AT-DR compared with CFC/BPA prophylaxis

AT-DR, antithrombin-based dosing regimen; BPA, bypassing agent; CFC, clotting factor concentrate; FEIBA, factor VIII inhibitor bypassing activity;

PwH, people with haemophilia; PwHA, people with haemophilia A; PwHB, people with haemophilia B.

### Analysis

- The analysis calculated the total cost per bleed (including both medication and administration expenses) for patients on CFC/BPA prophylaxis compared with those on fitusiran AT-DR.
- The cost difference between these approaches represents the potential savings for people receiving fitusiran AT-DR.
- A scenario analysis assessed the impact of vial sharing.

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## CONCLUSIONS

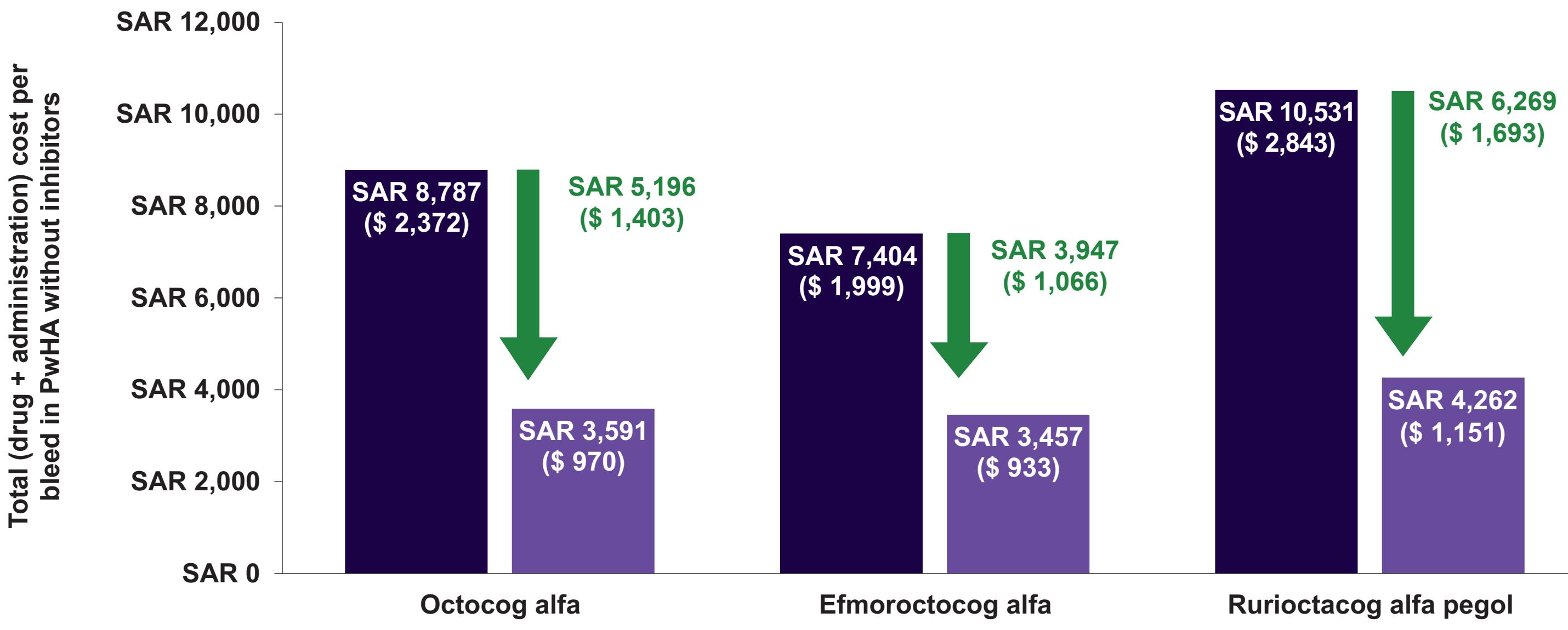
- In the KSA, fitusiran AT-DR prophylaxis may considerably reduce breakthrough bleed management costs for PwH compared with those with CFC/BPA prophylaxis.
- Cost-savings are anticipated to be more substantial (SAR 60,581 [\$ 16,357] to SAR 77,961 [\$ 21,049]) for PwH with inhibitors than for those without inhibitors.
- For payers and healthcare systems, fitusiran may substantially reduce annual haemophilia bleed management budgets in the KSA.

## RESULTS

### PwH without inhibitors

- For PwHA without inhibitors, fitusiran AT-DR prophylaxis resulted in savings ranging from SAR 3,947 (\$ 1,066) to SAR 10,531 (\$ 2,843) per bleed (Figure 2).

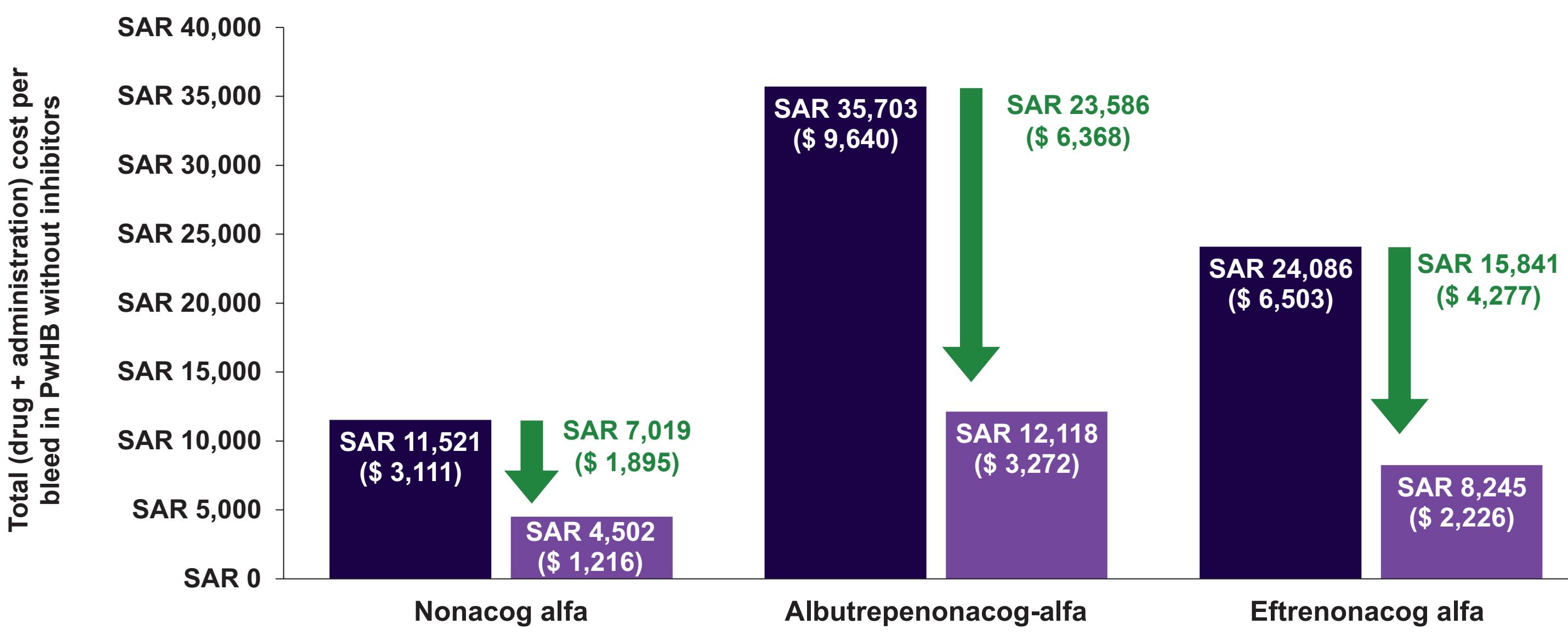
Figure 2. Treatment cost of breakthrough bleeds management with CFC prophylaxis and fitusiran AT-DR prophylaxis among PwHA without inhibitors.



AT-DR, antithrombin-based dosing regimen; CFC, clotting factor concentrate; PwHA, people with haemophilia A; SAR, Saudi riyal.

- In PwHB without inhibitors, the savings ranged from SAR 7,019 (\$ 1,895) to SAR 23,586 (\$ 6,368) per bleed (Figure 3).

Figure 3. Treatment cost of breakthrough bleeds management with CFC prophylaxis and fitusiran AT-DR prophylaxis among PwHB without inhibitors.

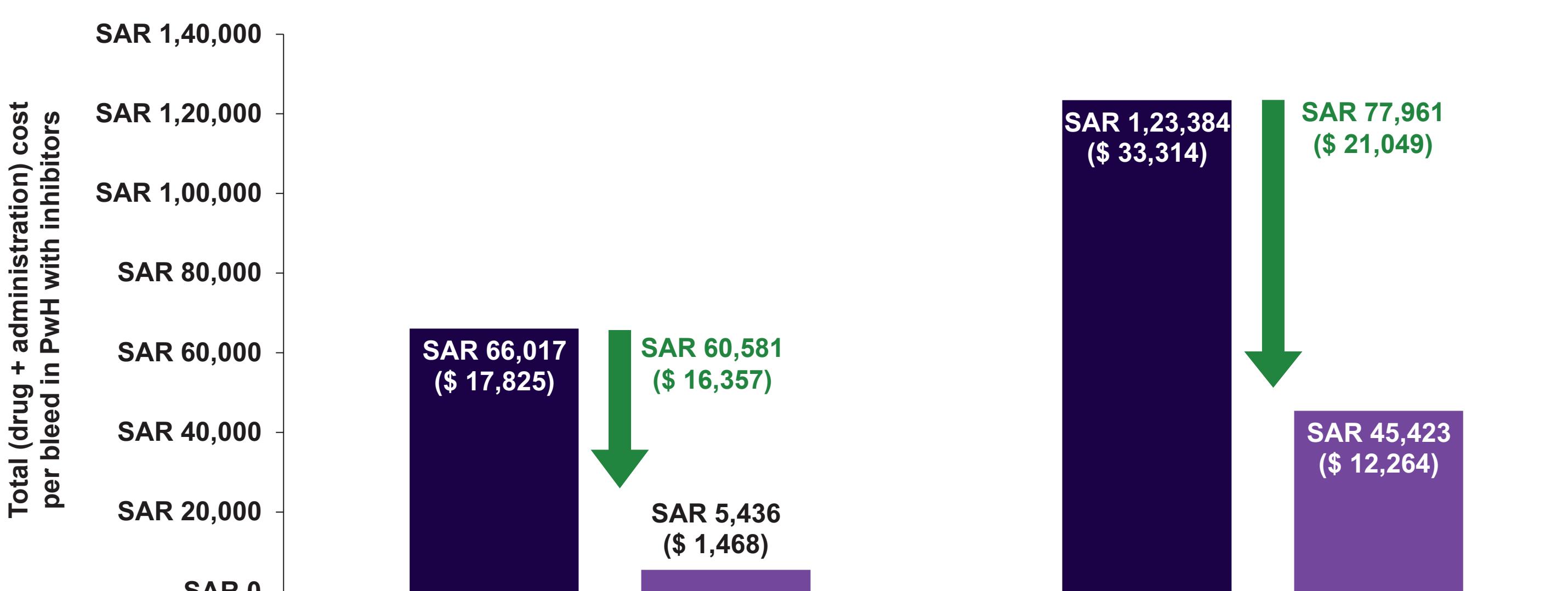


AT-DR, antithrombin-based dosing regimen; CFC, clotting factor concentrate; PwHB, people with haemophilia B; SAR, Saudi riyal.

### PwH with inhibitors

- Notably, most substantial savings were observed among PwH with inhibitors, ranging from SAR 60,581 (\$ 16,357) to SAR 77,961 (\$ 21,049) per bleed (Figure 4).

Figure 4. Treatment cost of breakthrough bleeds management with BPA prophylaxis and fitusiran AT-DR prophylaxis among PwH with inhibitors.



AT-DR, antithrombin-based dosing regimen; BPA, bypassing agent; FEIBA, factor VIII inhibitor bypassing activity; PwH, people with haemophilia; SAR, Saudi riyal.

### Scenario analysis considering vial sharing

- The cost-savings associated with fitusiran AT-DR prophylaxis remained substantial.
  - For PwH without inhibitors, the cost savings per bleed ranged from SAR 4,237 (\$ 1,144) to SAR 6,336 (\$ 1,711) in PwHA and from SAR 6,950 (\$ 1,877) to SAR 23,344 (\$ 6,303) for PwHB.
  - For PwH with inhibitors, the savings per bleed ranged from SAR 61,307 (\$ 16,553) to SAR 78,929 (\$ 21,311).