Budget Impact Analysis of the Anti-Vascular Endothelial Growth Factors Injections for treating Diabetic Macular Oedema, assessing their affordability in the UK healthcare system

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Introduction

Study Background

Diabetic macular oedema (DMO) is a severe complication of uncontrolled diabetes that results in gradual visual deterioration and blindness.

Since anti-vascular endothelial growth factor (VEGF) intravitreal injections interventions have widely replaced other regimens, the use of anti-VEGF intravitreal injections has resulted in a rigorous injection and follow-up schedule that is assumed to increase financial burden.

A budget impact model, from a payer perspective, was developed to analyse the financial effects of the four anti-VEGF interventions on the DMO population in the UK.

In the **United Kingdom**, **6 %** of the **total adult population** is affected by **Diabetes**[1]

£10 billion are spent **per year** for **Diabetes** by the **NHS**[2]

80% of NHS expenditures are directed towards **Diabetic Complications**[3]

DMO emerged as the **most prevalent diabetic complication**, that **affected patients' eyesight,** many of whom are in their **prime working years**[4,5]

Objective

The objective of this research was to assess whether the novel anti-VEGF intravitreal injections **(Brolucizumab and Faricimab)** addition to the market with the established anti VEGFs **(Ranibizumab and Aflibercept)** would benefit the UK healthcare system and decrease its expenditures.

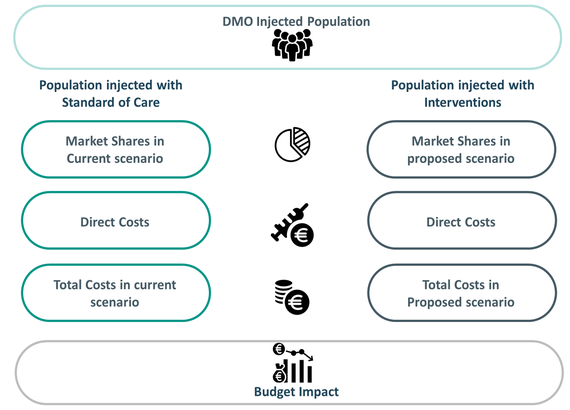
Methodology

Study Specifications

Study scope	UK healthcare system - payer perspective.
Population	Publicly insured adult diabetic patients within the UK healthcare system above 18 years old with unilateral and bilateral centre involving DMO of central retinal thickness greater or equal to 400 mm.
Interventions	Novel Anti-VEGFs (Brolucizumab and Faricimab).
Comparators	Current Standard of Care (Aflibercept and Ranibizumab).
Time horizon	5 years.
Outcome	Budget Impact of the intervention mix utilisation.
Sensitivity Analysis	Probabilistic sensitivity analysis and scenario analyses were conducted to assess the study robustness.

Methodology

Study Framework and calculations



Yearly **DMO patient Total Cost =**

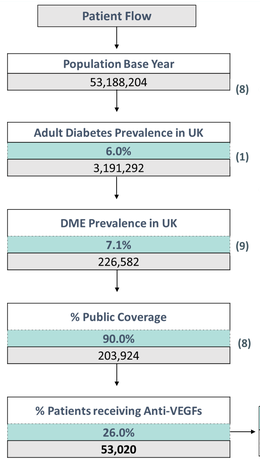
- **Yearly number of injection visits X** (drug acquisition cost + OCT cost + procedure administration cost that includes procedure setting and the consultation)

  +

- **Yearly number of monitoring visits X** (consultation cost + OCT cost).

Anti-VEGFs acquisition costs and resource utilisation costs were captured from the British National Formulary and NHS (6,7).

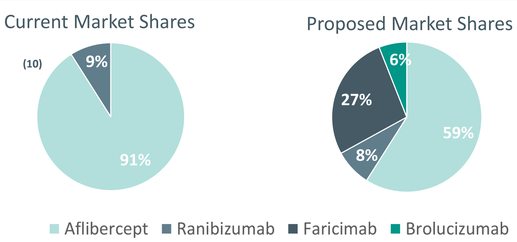
Study Population



Patients Flow	Year 1	Year 2	Year 3	Year 4	Year 5
# Eyes injected	60,052	60,262	60,459	60,642	60,809

- The study accounted for incidence rate, bilateral DMO incidence, and mortality rates for the following five years.
- For bilateral Patients with DMO, the study assumed that 50% of them will have a single injection visit for both eyes together and the expenditures were reduced accordingly.

Market Shares

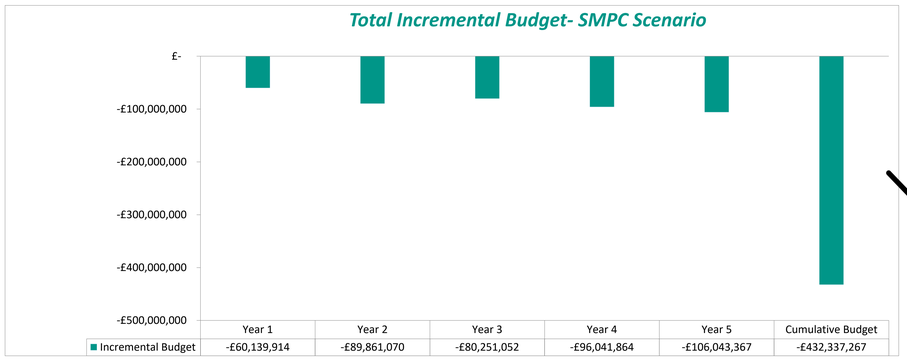


- Proposed Market Shares were assumed based on % of patients that switch their Aflibercept Injections due to treatment resistance in year 1 and 2 (11).
- This switch was favourable to Faricimab over Brolucizumab since Brolucizumab acquired more adverse events (12), (13).
- From year three onwards, market shares increased gradually, as assumed in NICE resource impact in TA790 (14).

Results and Discussion

Results presented the expenditures of the Injection visits and monitoring visits frequencies in two scenarios as follows:

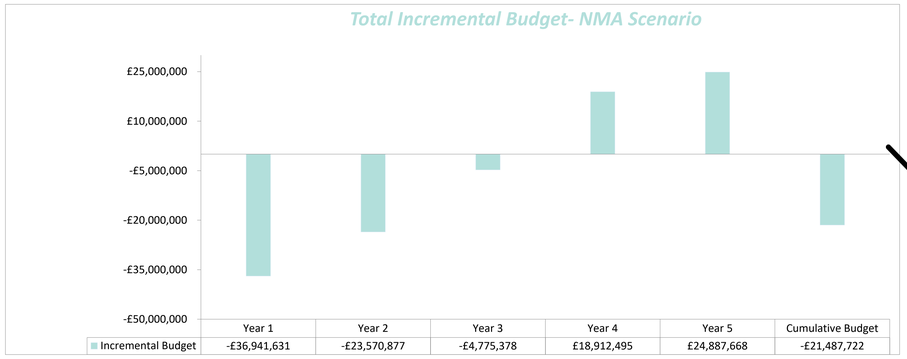
- ***Summary of product characteristics**, following NICE guidelines.*



	Year 1	Year 2	Year 3	Year 4	Year 5	Cumulative Budget
Incremental Budget	-£60,139,914	-£89,861,070	-£80,251,052	-£96,041,864	-£106,043,367	-£432,337,267

Cumulatively the UK healthcare system save the amount of **£ 8,154 Per Patient** treated across the **five years.**

- ***Network meta-analysis** conducted by NICE TA 790 (14) and TA 820 (15).*



	Year 1	Year 2	Year 3	Year 4	Year 5	Cumulative Budget
Incremental Budget	-£36,941,631	-£23,570,877	-£4,775,378	£18,912,495	£24,887,668	-£21,487,722

Cumulatively the UK healthcare system save the amount of **£ 405 Per Patient** treated across the **five years.**

- The findings of SMPC scenario stem from an ideal environment, simulating the environment of randomized controlled trials, which may potentially result in inflated cost estimates.
- Indirect evidence from the NMA presents a mixed treatment comparison; hence estimates are expected to be more precise and refined.
- In both scenarios, cost savings were averted as a consequence of :

1. **Fewer appointments** for injection for the novel interventions **(Faricimab and Brolucizumab)** in the initial year due to **lower number of loading doses** required.
2. **Lower frequency of injections** for the two novel Anti-VEGFs **(Faricimab and Brolucizumab) in the initial years.**
3. **Lower frequency of monitoring visits** due to the unique characteristics of the Faricimab intervention (16), which enable longer intervals between injections.

Conclusion

While literature suggests the four anti-VEGFs have equivalent efficacy, Brolucizumab and Faricimab, requiring fewer injections, resulted in savings of £21,487,722 over five years (£405 per patient annually) in NMA scenario and £432,337,267 over five years (£8,154 per patient annually) in the SMPC scenario. By assessing the potential cost savings that can be achieved by adopting novel anti-VEGFs, resource allocation can be optimized, and opportunity costs are identified throughout the decision-making process of the UK healthcare-system achieving the optimum financial efficiency.

Study Limitation

Commercial agreements remain confidential and are a true factor that can reverse the results in the budget impact analysis specifically the acquisition cost of the Aflibercept.

Disclosure

This work was completed in partial fulfilment of an MSc in Health Economics by FM under the supervision of SR. SR is an honorary lecturer at the University of South Wales and has no affiliation with the manufacturer of drugs included in this analysis.

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