

ECONOMIC EVALUATION AND BUDGET IMPACT FOR A REGIONAL HEALTH SERVICE ASSOCIATED WITH THE INCLUSION OF THE FLUOCINOLONE ACETONIDE INTRAVITREAL IMPLANT IN A REGIONAL PHARMACOTHERAPEUTIC GUIDELINE



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Background and importance

Due to the **high cost** of the **implant of fluocinolone acetonide (FAC) 190 µg**, it is especially important realize an economic evaluation and budget impact analysis before inclusion in the pharmacotherapeutic guide of any health institution.



Aim and objectives

Realize an **economic evaluation** and a **budget impact analysis** to assess its **inclusion** in our **regional pharmacotherapeutic guide**, maintaining the financing conditions of our National Health System (NHS).

Material and methods

PubMed and reports from independent evaluators were consulted: National Institute of Health Care Excellence (NICE) and Scottish Medicines Consortium (SMC) among others.

Results

- According to the product information, an implant releases FAC for a maximum of 36 months, and an additional implant can be placed after 12 months if vision decreases or retinal thickness increases. Pivotal studies and the IRISS observational study concluded in the need to use 1,3 implants/eye and 1,13 implants/eye affected during the first 3 years respectively, this last value being the one considered by ERG(Evidence Review Group). Taking this last reference, **the cost of treatment/affected eye**: € 1.558,84/eye/year or € 4.676,53/eye/3 years 
- To estimate the target population, we used the criteria of the SMC evaluation report in which they considered a total of 179 patients with pseudophakic chronic DME eligible for treatment in the first year, increasing to 186 in the fifth year. Unlike the SMC, our NHS restricts its funding to third-line, after antiangiogenic agents and in patients with a suboptimal response to various intravitreal dexamethasone implants or pseudophakic patients. Making a parallelism with the Scottish population, would be **candidates to receive FAC in our region**:
33,5 patients/1st year – 34,8 patients/5th year
- NICE and ERG found that in clinical practice 35% of patients would require bilateral treatment. Thus 12 patients/year would need treatment in both eyes in our population. 
- The **ECONOMIC IMPACT IN OUR REGION** would range between:
€ 53.000,56/year if it were inserted in only one eye and € 71.706,64/year in both eyes



Conclusion and relevance

- ✓ The **financing conditions of our NHS** position the drug in the **third-line**, which in a certain way **contains the budget impact**.
- ✓ Since SMC restricting the conditions of use more than our NHS, the **budget impact could be underestimated**.