ISPOR 19th Annual European Congress

Vienna, October 29th | November 2nd 2016

BUDGET IMPACT ANALYSIS OF VIACORAM FOR THE TREATMENT OF HYPERTENSION IN ITALY

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Introduction: Hypertension is a major risk factor for ischaemic and haemorrhagic stroke, myocardial infarction (MI), heart failure (HF), chronic kidney disease, cognitive decline and premature death. In 2008, approximately 40% of adults aged ≥25 years had been diagnosed with hypertension worldwide¹. According to the Italian Hypertension Society (SIIA), in Italy there are approximately 14 million of people who have elevated blood pressure (hypertension), but only 3 million receive appropriate therapy and just the 37% of these with controlled blood pressure. CVD is responsible for one-third of global deaths per year (approximately 17 million) and is a leading and increasing contributor to the global disease burden². The high prevalence of hypertension worldwide has significantly contributed to the present pandemic of CVD³.

Objectives: The objective of this study was to perform a Budget Impact Analysis (BIA) assessing the introduction of Viacoram for the treatment of hypertension into the Italian market. Viacoram is a single pill combination of an angiotensin-converting enzyme inhibitor (perindopril, arginine salt) and a calcium channel blocker (amlodipine, besilate salt) indicated for the treatment of essential hypertension in adult patients.

Methods: The BIA compares two different scenarios: one without a dual fixed combination therapy indicated as first line therapy for hypertension (Scenario 1) vs. another one with the introduction of Viacoram (Scenario 2). The study has been conducted considering the perspective of the Italian National Healthcare Service. Population data were obtained from a Local Project Database managed by Cegedim composed by 1.100.000 patients' records originated from software used by 900 Italian GPs. The time horizon considered was 3 years from the introduction of Viacoram. Total number of patients in each of the 3 years was the same for the two Scenarios, because the model assumes that each year new Patients with hypertension who would start the new therapy using the current dual therapy with the drug combinations currently on the market (23,7% of the patients in first line therapy for hypertension), Scenario 1, would actually be able to begin their treatment with the fixed dose of Viacoram, Scenario 2. According to the Cegedim database, there are about 128 thousand patients that in 2015 began therapies for hypertension, 30 thousands of whom treated with double first line therapy (Table 1). The reference market for Viacoram is composed by the patients in dual first line therapy.

In both scenarios, 51% of patients treated with traditional dual therapies and 44% of patients treated with Viacoram do not reach target blood pressure and, consequently, switch to dual or triple second line therapies (according to international hypertension guide line⁴, the 57% of patients not controlled switch to dual therapy and the 43% switch to the triple therapy).

| FIRST LINE THERAPY | | PATIENTS | | |
|----------------------------------|---|----------|---------|--|
| Patients in mono therapy | | 97.466 | | |
| Patients in dual therapy | | 30.275 | | |
| Patients in first line therapy | | | 127.741 | |
| S | Switch rate | | | |
| Traditional first line therapies | % patients who do not reach target blood pressure | | 51% | |
| First line therapy with Viacoram | % patients target k | 44% | | |
| Distribution of patients who do | % patients w | 57% | | |
| not reach target blood pressure | % patients v | 43% | | |
| Second line dual therapy | % patients target k | 30% | | |

Table 1. Upper panel: Patients in first line therapy Lower panel: Therapies efficacy and switch rate

| Ex factory prices | Price per day | Price per month |
|---|---------------|--------------------|
| Viacoram | € 0,28 | € 8,38 |
| Tripliam | € 0,34 | € 10,19 |
| Average price of first line dual therapy | € 0,37 | € 10,95 |
| Average price of second line dual therapy | € 0,27 | € 8,19 |

30% of patients in second line dual therapy do not reach target blood pressure and switch to the triple therapy (Table 1). The model assumed that the percentage of patients who switch to Viacoram is 30%, 42% and 49% the first, second and third year respectively. The prices used in the model are ex-factory prices (Table 2) as published in AIFA web site after price cuts. The price of the first line dual therapy has been calculated using the average price of the dual therapies that showed a positive trend in the last years (Table 3). The price of the second line dual therapy has been calculated using the average price of the dual therapies weighted by volumes reported in the CEGEDIM database. (Table 3). The price of the triple therapy, instead, has been calculated using the price of Tripliam, triple fixed combination currently in the market.

| Class | Trend % |
|--------------------------------|---------|
| C09B3 ACE-INIB+C-ANTAGONISTI | 44 |
| C09D3 ANT ANGIOT+C-ANTAGONISTI | 31 |
| C09B3 ACE-INIB+C-ANTAGONISTI | 19 |
| C09B3 ACE-INIB+C-ANTAGONISTI | 15 |
| C09D1 ANT ANGIOT+A-IPERT/DIUR | 5 |
| C09B1 ACE-INIB+A-IPER/DIURET. | 1 |

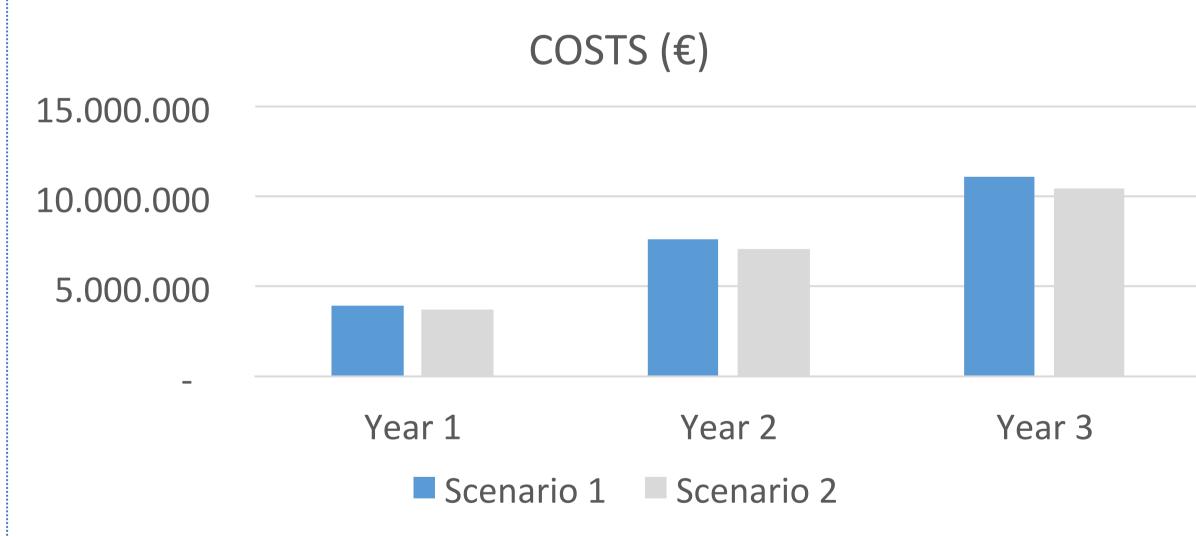
| DUAL THERAPY | VOLUMES (CEGEDIM) | % | PRICE PER MONTH | MONTHLY WEIGHTED PRICE |
|------------------------|----------------------|-------|-----------------------|------------------------------|
| Perindopril+Indapamide | 3.786 | 1,2% | 6,2 | 0,1 |
| Perindopril+Amlodipine | 24.714 | 7,7% | 6,7 | 0,5 |
| Indapamide+Amlodipine | 6.573 | 2,0% | 5,4 | 0,1 |
| Perindopril/Indapamide | 119.523 | 37,1% | 7,1 | 2,6 |
| Perindopril/Amlodipine | 167.690 | 52,0% | 9,4 | 4,9 |
| Total | 322.286 | 100% | | 8,2 |

Table 3. Left panel: First line dual therapies trend

Right panel: Second line dual therapies – Volumes and prices

Table 2. Ex-factory prices (AIFA)

Results: With a cost of 8,47 €/month, the introduction of Viacoram generates savings for the Italian NHS equal to 270.807, 516.494 and 707.090 € respectively in year 1, 2 and 3 over the total expenditure of 3.9, 7.6 and 11.1 €/millions related to the year 1, 2 and 3 in the first scenario. (Figure 1).



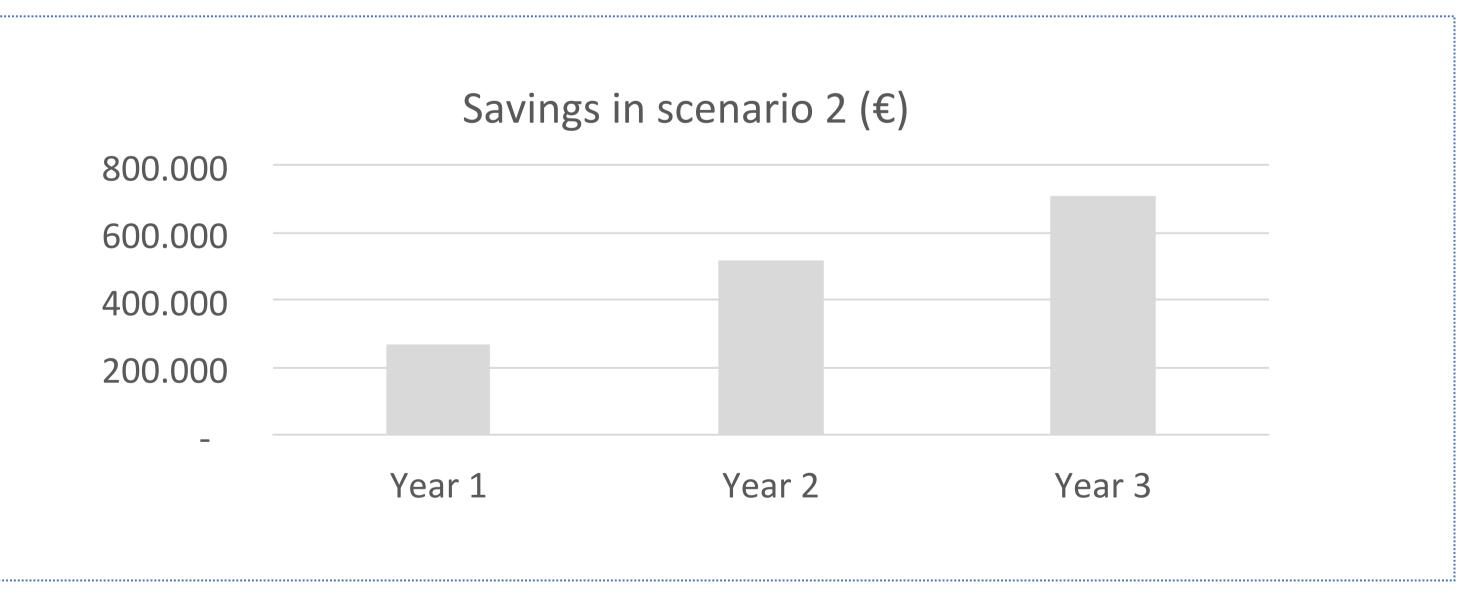


Figure 1

Conclusions: The present study indicates that the introduction of Viacoram has two important effects:

- 1. It does not imply additional treatment costs; from the first year, actually, it generates a saving for the NHS.
- 2. The introduction of Viacoram represents a benefit for the patients, especially for the elderly, because it improves the adherence to the therapy, thanks to the reduction in the number of pills taken. Better adherence is also linked to a reduction in the number of hospitalizations caused by therapy interruption and, consequently, permits to avoid the related costs.
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