A BUDGET IMPACT ANALYSIS OF ADALIMUMAB BIOSIMILARS; THE ALBANIAN CONTEXT

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ABSTRACT

Adalimumab is used to treat various autoimmune conditions, such as rheumatoid arthritis, ankylosing spondylitis, psoriasis, psoriatic arthritis, Crohn’s disease, and ulcerative colitis. Adalimumab is a tumor necrosis factor (TNF) inhibitor. Adalimumab biosimilars have the potential to reduce costs for the healthcare system. The aim of the study is to develop a drug budget impact analysis to assess the potential financial impact of the availability of the biosimilar adalimumab-aacf in terms of cost savings due to its lower price compared to adalimumab-adaz. Methods: This is a budget impact analysis and cost calculator model in Microsoft Excel based on FDSKSH’s data for 2023. Results: Adalimumab biosimilars accounted for approximately 25% of biologic drug prescriptions in 2023. The reimbursement cost of biologic drugs for autoimmune diseases was ALL 186,523,409 in 2023 (1 ALL = 0.01 USD). Of that cost, 15.21% accounted for treatment with adalimumab biosimilars. Adalimumab-aacf was available at a 15.82% lower price than adalimumab-adaz. The analysis indicated that the replacement of the biosimilar adalimumab-adaz with the biosimilar adalimumab-aacf could have resulted in cost savings of ALL 968,138, and the reimbursement cost of biologic drugs for autoimmune diseases could have been 3% lower. With the potential cost savings, two more patients could have had access to biologic drugs in 2023. Conclusions: The Drug Budget Impact Analysis estimated that the availability of adalimumab-aacf would be more profitable in terms of cost savings compared to adalimumab-adaz. The scenario could result in increased treatment access for patients.

KEYWORDS

Adalimumab, autoimmune conditions, biosimilars, budget impact analysis, cost savings

1. INTRODUCTION

BIOLOGICAL drugs (commonly referred to as ‘biologics’ or ‘biopharmaceuticals’) are drugs produced through biological processes. They currently target diseases which, hitherto, had very limited or no available treatment options – including several types of cancer, autoimmune diseases and other non-communicable diseases [1]. This category includes drugs such as Adalimumab, Etanercept, Infliximab, Golimumab etc. Biologics work by disrupting the inflammation process that leads to joint pain and destruction [2]. A biosimilar, sometimes referred to as a follow-on biologic, is a therapeutic drug that is highly similar but not structurally identical to a brand-name biologic, also referred to as the innovator or reference product [3].
Biologics are significant drivers of globally escalating healthcare costs. Biosimilars have the potential to offer cost-savings with comparable efficacy and safety to innovator products [4]. Adalimumab was approved by the US Food and Drug Administration (FDA) in 2002, quickly becoming the highest-selling biologic in the global pharmaceutical market by 2018 [5].

Healthcare providers are feeling the burden of rising costs. It’s important to identify opportunities for cost savings. Budget impact analysis (BIA) is one technique often used to complement other forms of economic evaluation. While some methods of economic evaluation consider the efficiency of healthcare resource allocation, BIA considers its affordability [6]. Since the 1990s, many countries have incorporated BIA into formulary listing or reimbursement decision-making [7].

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) described the benefits and uses of BIA: “BIA addresses the expected changes in the expenditure of a health care system after the adoption of a new intervention…. A BIA can also be used for budget or resource planning. A BIA can be freestanding or part of a comprehensive economic assessment along with a CEA [cost-effectiveness analysis]” [7].

To assess the affordability of health technologies, such as biosimilars, payers use BIAs to support decision-making at national, regional, and local levels. Moreover, reimbursement authorities increasingly require these models as part of a formulary listing request or reimbursement submission [8].

The object of this study is to assess through a budget impact analysis the potential financial impact of the availability of the biosimilar adalimumab-aacf compared to adalimumab-adaz in the Albanian pharmaceutical market in 2023 [9-14].

2. MATERIALS AND METHODS

This is a budget impact analysis and cost calculator model in Microsoft Excel based on FDSKSH’s data for the period between January 1, 2023 and December 31, 2023. The study period was determined to maximize the quality of the results, and the data was published on the official website of FDSKSH [15].

In this study, we propose conducting a scenario analysis to demonstrate the economic impact of the availability of the biosimilar adalimumab-aacf compared to adalimumab-adaz in terms of cost savings. The data about adalimumab biosimilars, such as the number of current and new autoimmune patients and the consumption, were retrieved from the website of FDSKSH. The reimbursement cost was calculated at list price for 2023. We will take into consideration only the reimbursement cost of adalimumab because other costs such as administration costs, costs of laboratory examinations, monitoring costs, and other medical costs will not be affected during this scenario analysis.

3. RESULTS

The number of patients who received treatment with adalimumab biosimilars in 2023 was 209. In 2023, in the reimbursement list of Albania, were reimbursed these adalimumab biosimilars: adalimumab-aacf approved by FDA in 2022, adalimumab-adaz approved in 2018 and adalimumab-fkjp approved in 2020. The consumption, the number of patients and the reimbursement costs in 2023 are illustrated in Table 1, respectively.
Table 1: Adalimumab biosimilars

<table>
<thead>
<tr>
<th>Reimbursement Code</th>
<th>Drug</th>
<th>Pharmaceutical form</th>
<th>Consumption</th>
<th>Reimbursement Cost</th>
<th>The no of prescriptions</th>
<th>The no of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>664/237</td>
<td>Adalimumab-adaz 40mg</td>
<td>pre-filled syringe</td>
<td>498</td>
<td>6,521,719</td>
<td>122</td>
<td>60</td>
</tr>
<tr>
<td>664/48</td>
<td>Adalimumab-aacf 40mg</td>
<td>pre-filled syringe</td>
<td>1,750</td>
<td>20,914,018</td>
<td>375</td>
<td>118</td>
</tr>
<tr>
<td>664/48a</td>
<td>Adalimumab-aacf 40mg</td>
<td>pre-filled pen.</td>
<td>84</td>
<td>936,749</td>
<td>31</td>
<td>31</td>
</tr>
</tbody>
</table>

We evaluated adalimumab biosimilars based on two factors. First, adalimumab biosimilars will account for approximately 25% of biologic drug prescriptions in 2023 (Chart 1). Secondly, in 2023, there was consumption of different reimbursement alternatives for adalimumab and infliximab in Albania. This allows us to estimate the economic impact of substituting expensive adalimumab with cheaper alternatives.

The reimbursement cost of biological drugs for autoimmune diseases in 2023 was ALL 186,523,409. Of that cost, 15.21% accounted for treatment with adalimumab biosimilars. Therefore, a possible reduction in their cost will be accompanied by a reduction in the reimbursement cost. To estimate cost savings, we compared the prices of adalimumab-adaz and adalimumab-aacf. To enable the comparison of the results, all prices were converted to 2023 euros (Chart 2). The price of adalimumab-aacf was 15.82% lower.
The reimbursement cost for adalimumab-adaz was ALL 6,521,719 in 2023. We will develop the scenario of total replacement of adalimumab-adaz with adalimumab-aacf, and the value of cost savings is ALL 968,138. The reimbursement cost of biological drugs for autoimmune diseases could have been 3% lower in 2023 (Chart 3).

In Table 2, we have estimated the annual cost per patient for treatment with adalimumab-aacf, and considering the cost savings of ALL 968,138, 2 more patients could have had access to biological drugs in 2023.
Table 2: The annual cost 2023/patient

<table>
<thead>
<tr>
<th>Biosimilar</th>
<th>Strength</th>
<th>Dosage form</th>
<th>Price (ALL)</th>
<th>Recommend ed dose</th>
<th>Average daily drug cost (ALL)</th>
<th>Annual drug cost (ALL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab-aacf</td>
<td>40 mg/0.8ml</td>
<td>Prefilled syringe or prefilled pen.</td>
<td>11151.77</td>
<td>40 mg once a week</td>
<td>1593.11</td>
<td>581,485,15</td>
</tr>
</tbody>
</table>

The analysis revealed that countries with adalimumab may achieve cost savings due to two factors. First, the availability of adalimumab biosimilars is associated with lower prices for adalimumab. Second, the drug-mix effect played a role in reducing adalimumab expenditure, by substituting expensive adalimumab with cheaper alternatives [16].

4. LIMITATIONS

We focused on only one biologic, adalimumab, and the study period was relatively short. So, assessing the potential impact of our findings on other biosimilars may be limited. Also, the number of patients who receive treatment with adalimumab biosimilars in Albania is small. As the use of biologics increases, future studies with larger patient samples will provide more valid and interpretable data.

5. CONCLUSIONS

Drug Budget Impact Analysis tries to evaluate whether and how profitable the biosimilar availability will be for the FDSKSH, in terms of cost savings. Our budget impact analysis demonstrated that the replacement of biosimilar adalimumab-adaz with adalimumab-aacf for the treatment of autoimmune disorders would lead to cost savings ALL 968,138 in the 2023 reimbursement budget. This scenario will be associated with considerable cost savings to the health system that could result in increased treatment access for patients. More patients could be treated with a biologic by managing financial resources more efficiently.

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REFERENCES

[1] Sushil S. Kore, Biosimilar the New Era of Theraptic Science, IJIRT | Volume 7 Issue 3 | ISSN: 2349-6002, 2020, pp.81


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