

Budget Impact Analysis for the use of Long Acting muscarinic antagonists (LAMA) in patients with Chronic Obstructive Pulmonary Disease (COPD)

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Authors have no relevant interests to declare.

Introduction

LAMAs such as tiotropium and glycopyrronium are the most widely recommended and used treatments for COPD worldwide (GOLD 2016). They have been shown to improve lung function, quality of life, reduce exacerbations as well as hospitalisation and duration of hospital stay.

To support a decision surrounding the use of LAMAs in the public sector for the outlined indications, a budget impact analysis has been undertaken. This budget impact assessment is a freestanding economic assessment of the fiscal impact of the adoption of LAMAs in the public sector in the proposed indications for the management of COPD.

The indications for decision were in patients with Chronic Obstructive Pulmonary Disease (COPD) with following criteria:

- GOLD D patients: (FEV1<50% or frequently exacerbating) in combination with a Long-acting Beta-Adrenoceptor Agonists (LABA)/ Inhaled Corticosteroid (ICS)
- GOLD D patients: where the risks of Pneumonia from ICS are high in combination with a LABA
- GOLD B-D patients: as an alternative to LABA and where ICS are not justified (i.e. exacerbations ≤ 2 /year)

Methods

A Budget Impact Analysis (BIA) was undertaken for two specific groups of patients –**1) In addition to LABA** (Gold D patients, with or without ICS), and **2) as an alternative to LABA** (as monotherapy in Gold B-D patients).

Based on the current national procurement of salmeterol/fluticasone inhalers, it is estimated that 1.2% of the total COPD cases in South Africa are currently being treated with inhaler therapy in the public sector (approximately 5,750 patients).

Results

Estimated annual costs of LAMA adoption on the South African essential medicines list, looking across a range of patients accessing treatment and under a number of scenarios for price, are presented in table 1.

Table 1: Estimated annual budget impact of listing LAMAs on the EML

Total annual cost of listing tiotropium and glycopyrronium bromide on the National EML by assumed national tender price and % accessing treatment			
Assumed price of LAMAs	1.2% accessing treatment	5% accessing treatment	10% accessing treatment
80% of SEP	ZAR 29 885 272	ZAR 73 419 810	ZAR 129 528 693
60% of SEP	ZAR 21 552 350	ZAR 53 902 678	ZAR 95 596 947
40% of SEP	ZAR 13 219 429	ZAR 34 385 547	ZAR 61 665 202

Total 5 and 10 year budget impact estimates for introducing LAMAs in addition to LABAs on the EML were estimated across three scenarios depending on assumptions for expected uptake of LAMAs. The total estimated **5 year net present value (NPV)** of the introduction of LAMAs was estimated at between **ZAR 22.4 million – 41.6 million**, and the **10-year NPV was estimated at ZAR 88.6 million to 134.2 million**. Additional analysis showed that an increase in access to COPD inhaler therapy to 10% of those potentially eligible would result in a 10-year NPV of between ZAR 393 million – 595 million.

Provincial level split analysis for both analyses showed that the distribution of the budget impact by province was largest in Kwazulu-Natal (20%), Gauteng (20%) and the Western Cape (15%).

Decision

LAMAs are **not recommended** to be included on the Essential Medicines List for the maintenance treatment of COPD in the above outlined indication. Although there is benefit to this class of medicines, these agents cannot be considered until pricing is similar to that of LABA/ICS.