INNOVATIVE APPROACHES TO BROADEN ACCESS IN CHRONIC-HIGH PREVALENT DISEASES (OBESITY)

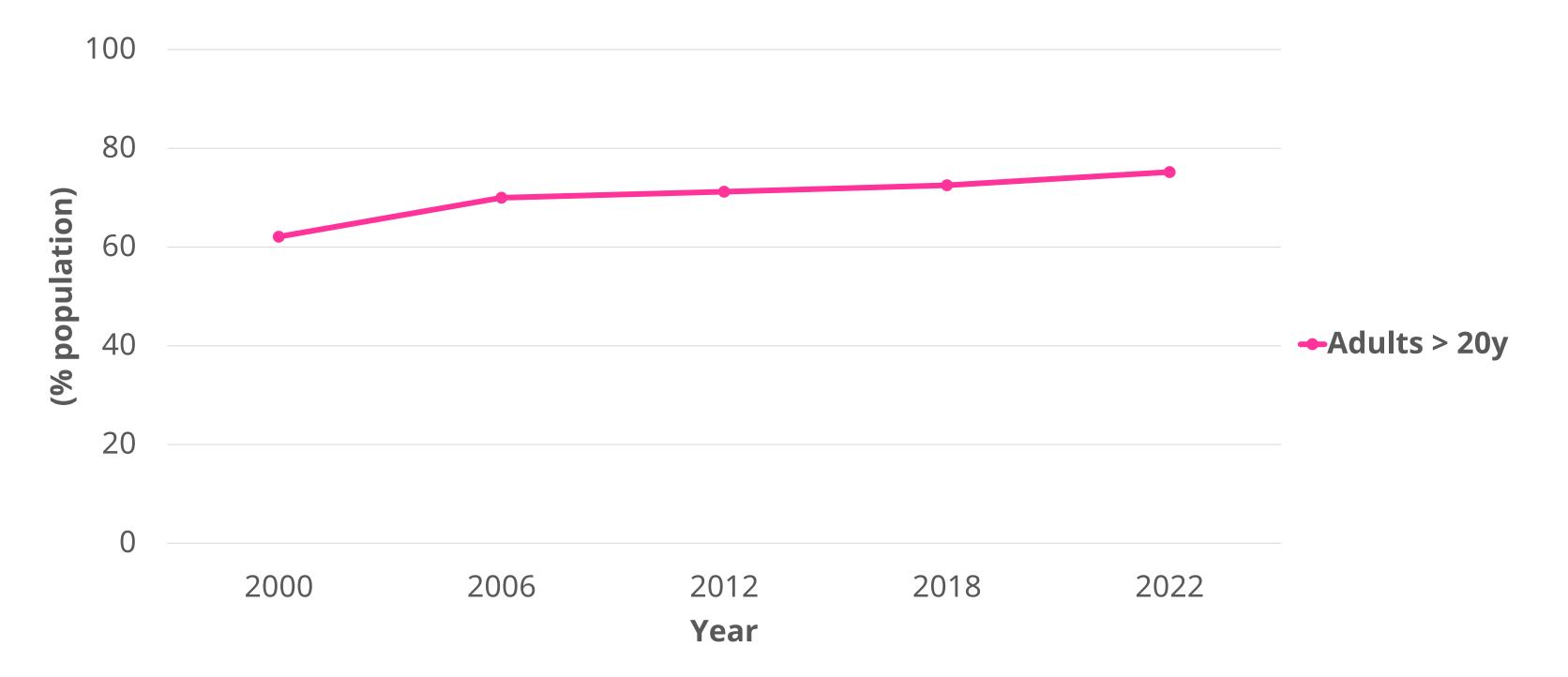
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INTRODUCTION

Obesity is a hot topic for most countries. Mexico has one of the highest and increasing prevalences in the world (32 million people). Since 20 years ago health authorities had pointed out the problem and face it with several policies such as health promotion for exercise and better nutrition or taxes for hypercaloric food and beverages. Even though, the prevalence is still growing. Actually, nearly 40% of Mexicans have obesity (1). **See Figure 1.**

In Mexico, the approval of medicines to be used in the Public Health Services (PHS) depends on a long and structured process. In average, access to the PHS were 4.5 years (2). Paradoxically, since 2018 the anti-Obesity Medicines (a-OM) were recommended by the Mexican Guidelines of Clinical Practice. Nevertheless, all previous attempts to add any a-OM into de National Formulary (NF) of the PHS had failed.

Fig 1. Prevalence of obesity in Mexican Adults since 2000 to 2022



OBJECTIVES

Describe the performed methodology to got public reimbursement for an anti-Obesity drug with an important financial risk but relevant health and economic results.

METHODS

We developed a four-step approach to fulfill the Mexican health requirements for the PHS reimbursement. It included building several realistic scenarios with their recently public raw data. These data was well known and validated by the authorities but, not for these purposes.

RESULTS

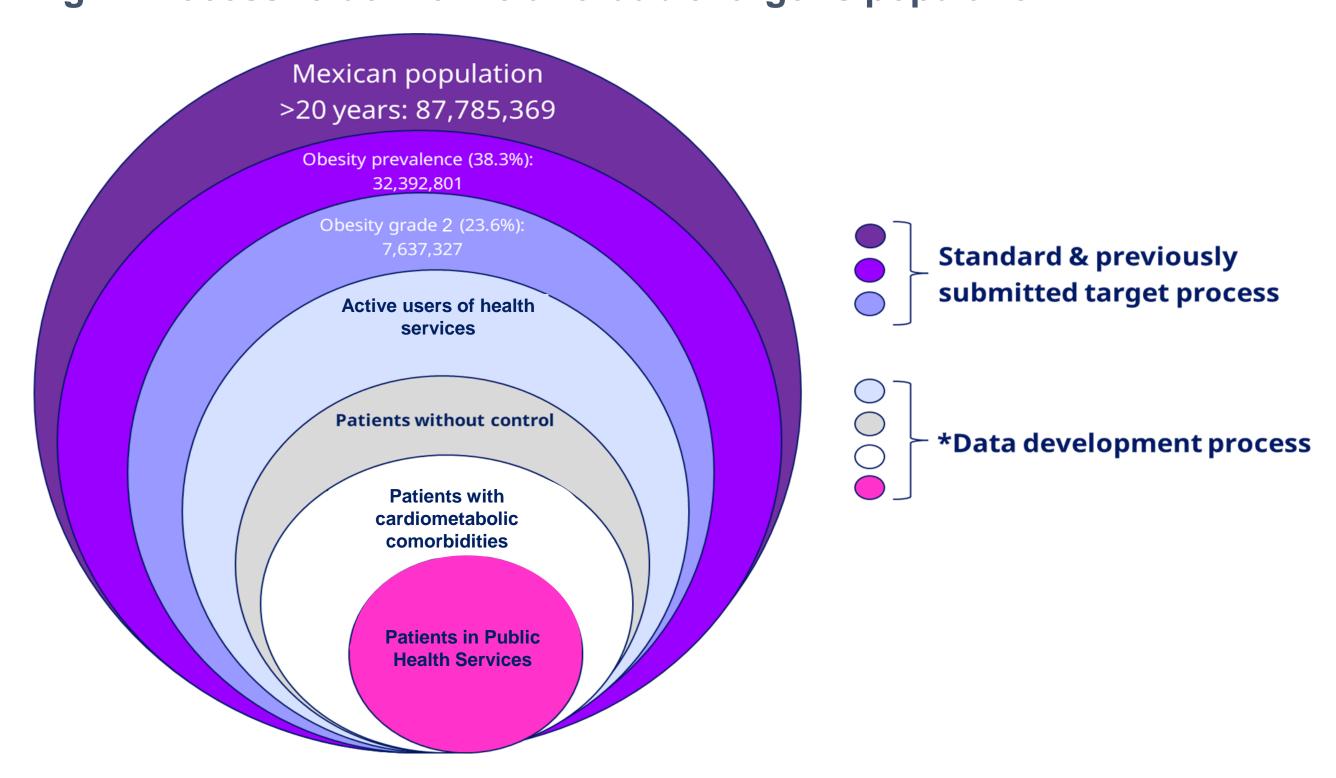
After 2 rejections, we got the approval of our a-OM (Liragutide / Saxenda®) into the NF with a mixed-strategy generating new evidence and building innovative pathways. In order to fulfilled the PHS's requirements we performed a 4 step strategy to got the faster approval process for any a-OM in 5 weeks (3).

First step: identify relevant causes of rejections validating NF "official response" with Therapeutic Area Leaders. Authorities recognized our a-OM as valuable and necessary but, "unaffordable". Three main drivers were identified: large-treated population (37% of adults); budget impact and; the absence of strategies to guarantee a rational use of a-OM.

Second step: find a specific population which benefits the most and would be "affordable". We found it in obesity grade 2 with cardiometabolic comorbidities; unfortunately, there were no official data to support it.

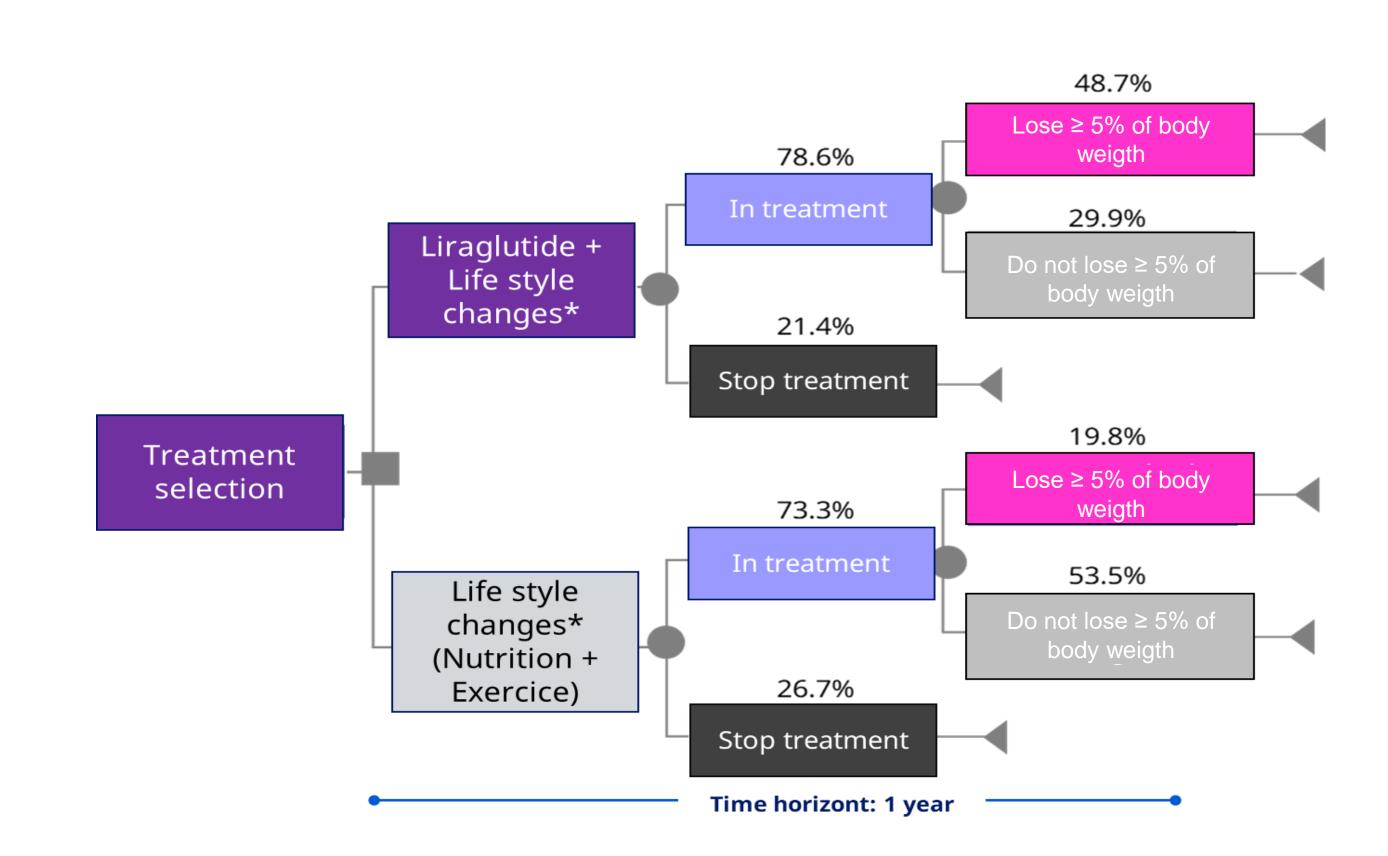
Third step: build new evidence from a raw dataset of the national nutrition survey to estimate target population. See Figure 2.

Fig 2. Process to define the affordable target's population



Fourth step: develop realistic and simple pharmacoenomic models. **See Figure 3**. So, we excluded patients who abandoned the treatment and measure costly-relevant outcomes (macro and micro-cardiovascular complications) in short and long-term (bariatric surgeries and avoided deaths). Also, we made explicit the hidden cost-effectiveness of diet and exercise.

Fig 3. Decision tree developed, excludes patients who dropped out or did not tolerate the treatment



Finally, to limit budget impact and rationalize the use of the medicine, only active users of health services were considered.

CONCLUSIONS

Access of medicines is not a linear process. Guidelines are important to fulfill technical requirements and new evidence, and realistic pathways are the root for success to expand access reimbursement into constricted and complex markets.

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