Conitec

Recomendation report

DRUGS

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Orlistat for weight loss in overweight or obese patients

Brasília – DF
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Technology: Orlistat.

Indication: Overweight or obese patients.

Applicant: Secretariat of Science, Technology and Strategic Inputs (SCTIE/Ministry of Health of Brazil).

Background: The purpose of this report is to analyze the scientific evidence on the use of orlistat for weight loss in overweight or obese patients.

Question: Is orlistat effective and safe in weight loss?

Scientific evidence: Through the search strategies on two databases, Medline (via Pubmed) and Embase, 15 systematic reviews (SRs) were retrieved, which included a total of 88 randomized controlled trials (RCTs), and additional six RCTs, which were not included in the SRs. The evidence showed that orlistat produced mean weight loss of 2-3 kg over a period of at least six months, compared with placebo or minimal-care/advice. This magnitude of effect was statistically significant in most of the studies. However, after the follow-up period, weight loss was less than 5-10%, which is defined as the clinically significant weight loss threshold. Moreover, there was a statistically significant increase in gastrointestinal side effects, and also high drop-out rates. The evidence with the highest quality reported that orlistat achieved 5-10 kg of weight loss when combined with behavioral intervention, suggesting that pharmacological treatment should not be used alone without non-pharmacological interventions.

Cost-effectiveness analysis: The use of orlistat associated with diet and exercise, compared with non-pharmacological interventions alone (without pharmacological intervention or placebo associated with diet and exercise), resulted in an incremental cost of BRL 1,512.00, and incremental effectiveness of 0.18 per patient (18% more likely to achieve a weight loss of 10% of baseline weight in the group receiving orlistat). Thus, the Incremental Cost-Effectiveness Ratio (ICER) was BRL 8,400.00 for each additional patient with weight loss ≥ 10%.

Budget impact analysis: Considering the high prevalence of overweight and obesity, the incorporation of orlistat would have a major budget impact, so it was necessary to develop different scenarios. Initially, four scenarios were created, over a five-year period: Scenario 1 – 100% of patients receive orlistat (120 mg, three times a day), budget impact of BRL 660,229,935,815.52; Scenario 2 – 30 to 50% of patients receive orlistat, budget impact of BRL 264,789,501,395.83; Scenarios 3 and 4, based on a population of patients with obesity-associated cardiovascular diseases and diabetes– 30 to 50% (Scenario 3) and 100% (Scenario 4) of patients receive orlistat, budget impact of BRL 69,260,107,248.44 and BRL 172,694,143,544.81, respectively. Then, two other scenarios were developed, Scenario 5, population of overweight or obese patients, and Scenario 6, population of overweight or obese patients with diabetes and cardiovascular diseases, based on the following variables: 100% eligible patients receive orlistat; the lowest price of orlistat in public sector purchases; patients who achieve the percentage of effectiveness (significant weight loss, i.e. > 10% of body weight), and adherence (persistence rate of 6% per year) – budget impact of BRL 128,219,321,588.43 and BRL 32,611,780,932.25, respectively, over a five-year period.

Considerations: The scientific evidence showed that orlistat produced mean weight loss of 2-3 kg over a period of at least six months, compared with placebo or minimal-care/advice (which cannot be considered as clinically relevant weight loss). On the other hand, there was a statistically significant increase in gastrointestinal side effects, and also high drop-out rates. Considering the high prevalence of overweight and obesity, the incorporation of orlistat would have a major budget impact on the Brazilian Public Health System (SUS), even when using a restricted population as well as the best results of treatment effectiveness and adherence. Initial analysis showed that orlistat could be used as an adjuvant in the treatment of patients who do not respond to weight loss interventions based on lifestyle modifications, considering the effectiveness results and the high budget impact.

Public consultation: Thirty-nine contributions were received, 12 of which were technical-scientific contributions, and 27 were experience or opinion contributions. The majority disagreed with Conitec's recommendation, mainly pointing out the absence of pharmacological treatment in SUS, the effectiveness and safety of orlistat, and its clinical benefit in comorbidities such as hypertension and diabetes.

Final Recommendation: The Conitec's members present at the 86th Ordinary Meeting, after analyzing the contributions received, decided not to recommend the incorporation of orlistat for weight loss in overweight or obese patients. It was taken into consideration low effectiveness, adverse events, and high budget impact. The Deliberation Record No. 514/2020 was signed.

Decision: Not to incorporate orlistat for weight loss in overweight or obese patients, within the scope of SUS, according to Ordinance No. 14, published in the Official Gazette of the Federal Executive No. 78, Section 1, page 221, on April 24th, 2020.