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Recomendation report

DRUGS

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Risankizumab for the treatment of adult patients with moderate to severe plaque psoriasis

Brasília – DF
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Technology: Risankizumab (SKYRIZI®).

Indication: Moderate to severe plaque psoriasis.

Applicant: ABBVIE Pharmaceutical Ltd. (Brazil).

Background: Psoriasis is a chronic immune-mediated inflammatory disease of the skin and joints, which manifests in different ways, characterized by hard erythematous lesions covered by silvery scales. Its worldwide prevalence is 0.5% to 11.4%, and in Brazil around 1.5%. The diagnosis is a clinical one, and psoriasis can be classified as mild or moderate-to-severe according to the Psoriasis Area Severity Index (PASI). The Clinical Protocol and Therapeutic Guidelines of the Ministry of Health of Brazil recently included biologic therapies for moderate to severe plaque psoriasis in adults with inadequate response, loss of response or intolerance to non-biologic systemic therapy (methotrexate, acitretin and ciclosporin).

Question: Is risankizumab effective, safe and cost-effective for the treatment of patients with moderate to severe psoriasis, who have had an inadequate response, loss of response or intolerance to non-biologic systemic therapy (methotrexate, acitretin and ciclosporin), compared with ustekinumab, from the perspective of the Brazilian Public Health System (SUS)?

Scientific evidence: Evidence about the efficacy and safety of risankizumab was based on meta-analysed data from three Randomized Controlled Trials (RCTs), comparing it to ustekinumab, with a moderate to high level of evidence. Their results were summarised and presented Risk Ratio (RR)=1.71 (95% Confidence Interval [CI]: 1.48-1.99) for the outcome PASI 90; for the outcome sPGA RR=1.38 (95% CI: 1.25-1.53); and for adverse events RR=0.55 (95% CI: 0.55-1.40).

Economic evaluation: The cost-effectiveness threshold analysis, using the efficiency-frontier approach, and the strategy of comparing all biologics showed that the treatment with risankizumab has an effectiveness similar to that of ixekizumab, but at a higher cost. Therefore, in order to maintain the same efficiency profile, it would be necessary to reduce the price of some biologics such as risankizumab (which is addressed in this Report), secukinumab and ixekizumab by at least 55.09%, 10.74%, and 9.08%, respectively.

Budget impact analysis: The budget impact of incorporating risankizumab, considering that it would be available to 60% of the patient population treated with adalimumab, was estimated to be BRL 740,154,472.67 in five years, with an incremental impact of more than BRL 260 million.

International recommendations: The international Health Technology Assessment (HTA) agencies in the United Kingdom and Canada recommend risankizumab as an option for treating moderate to severe psoriasis in some cases and with confidentiality agreements.

Technology horizon scanning: Seven potential drugs were identified for the first stage of the second-line treatment of moderate to severe psoriasis.

Considerations: The certainty of the evidence of efficacy was assessed as moderate to high for the outcomes of effectiveness (PASI 90) and safety for risankizumab. According to the results of the cost-effectiveness analysis, the biologics adalimumab and ustekinumab are the most cost-effective treatments currently available in SUS for the treatment of moderate to severe psoriasis. Therefore, in order to maintain the same efficiency profile compared with ixekizumab, it would be necessary to reduce the price of risankizumab by 55.09 %, since treatment with risankizumab was found to have an effectiveness similar to that of ixekizumab, but at a higher cost.

Initial Recommendation: CONITEC, at its 85th Ordinary Meeting, on February 4th, 2020, decided not to recommend the incorporation of risankizumab in the scope of SUS, for the treatment of adult patients with moderate to severe psoriasis, who have had a treatment failure, contraindication or intolerance to adalimumab. It was considered that, despite risankizumab is associated with incremental benefits in terms of effectiveness,

its efficiency (cost-effectiveness) is lower than that of the treatments available in SUS at the price proposed by the manufacturer.

Public consultation: A total of 386 contributions were received, of which 214 were technical-scientific contributions, and 172 were experience or opinion contributions from patients, relatives or caregivers of patients. The majority disagreed with CONITEC's preliminary recommendation. After analysing these contributions, received in the Public Consultation No. 08/2020, and addressing the main points raised, it was noted that the majority agreed with the evidence about the effectiveness of risankizumab, and also that it has a lower efficiency (cost-effectiveness) compared with the treatments available in SUS. CONITEC considered that, despite risankizumab is associated with incremental benefits in terms of effectiveness for treating moderate to severe psoriasis, there was no sufficient reason to change the preliminary recommendation, based on the price proposed by the manufacturer.

Final Recommendation: CONITEC, at its plenary session on August 6th, 2020, considered that the reduction in the price of risankizumab proposed by the manufacturer was consistent with the recommendation in CONITEC's preliminary report for a percentage reduction in the price initially offered. The new economic model based on the reduced price assessed six treatment strategies, and risankizumab was the dominant one (more effective and less costly). Treatment with risankizumab was considered to be both the most effective and the most cost-effective treatment among the comparators, with an incremental cost-effectiveness ratio (ICER) of BRL 164,692.90/QALY (Quality Adjusted Life Years) in relation to adalimumab (reference treatment). The budget impact was estimated to be BRL 496,667,529.48 in five years, with an incremental impact of more than BRL 18 million. Therefore, the CONITEC's members present at the 89th Ordinary Meeting, on August 6th, 2020, decided to recommend the incorporation of risankizumab for treating moderate to severe psoriasis in the scope of SUS, with the proposal for a re-negotiation of prices of technologies already incorporated into SUS for this treatment.

Decision: To incorporate risankizumab for the treatment of adult patients with moderate to severe plaque psoriasis, according to the Clinical Protocol and Therapeutic Guidelines of the Ministry of Health of Brazil, in the scope of SUS, according to Ordinance No. 40, published in the Official Gazette of the Federal Executive No. 181, Section 1, page 235, on September 21, 2020.