Conitec

Recomendation report

DRUGS

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Baricitinib (Olumiant®) for patients with moderate to severe Active Rheumatoid Arthritis

Brasília – DF
2020

Technology: Baricitinib (Olumiant®), 2 mg or 4 mg.

Indication: Treatment of adult patients with established moderate to severe rheumatoid arthritis (RA), who have responded inadequately to, or who are intolerant to one or more non-biological and biological disease-modifying antirheumatic drugs (DMARDs).

Applicant: Eli Lilly do Brasil LTDA.

Background: Rheumatoid Arthritis (RA) is an autoimmune chronic disease, for which there is currently no cure, with a higher prevalence in women. It is characterized by inflammation of the joints, especially the hands and feet, causing pain, swelling, difficulty moving and fatigue, and also an increased risk for cardiovascular diseases. The diagnosis is based on clinical and complementary tests. The RA Clinical Protocol and Therapeutic Guidelines (2019) includes non-steroidal anti-inflammatory drugs, glucocorticoids, immunosuppressants, synthetic disease-modifying antirheumatic drugs (DMARDs) (methotrexate, sulfasalazine, leflunomide, hydroxychloroquine, and chloroquine), a targeted synthetic DMARD (tofacitinib), anti-TNF biological DMARDs (adalimumab, certolizumab pegol, etanercept, infliximab, and golimumab), and non-anti-TNF biological DMARDs (abatacept , rituximab and tocilizumab).

Question: Do the use of baricitinib (Olumiant®) in adult patients with established moderate to severe RA, who have responded inadequately to, or who are intolerant to one or more non-biological and biological DMARDs, provide clinical benefit (efficacy and safety) comparable to biological DMARDs and tofacitinib?

Scientific evidence: Baricitinib was compared with adalimumab in a randomized controlled trial (RCT), and tofacitinib in a network meta-analysis. Compared with adalimumab, baricitinib demonstrated similarity in outcomes of ACR50 and fatigue, and superiority in the global assessment by the patient and decrease in pain, for up to 16 weeks of follow-up, and high-quality evidence. With respect to safety outcomes, no differences were identified between baricitinib and adalimumab in the outcomes of death and serious infections, with a 52-week follow-up, and low-quality evidence. Baricitinib demonstrated a higher frequency of serious adverse events compared with adalimumab, with a 52-week follow-up, and moderate-quality evidence. Compared with tofacitinib, baricitinib demonstrated similarity in outcomes of ACR20 and serious adverse events, with follow-up between three and six months, and moderate-quality evidence. No RCTs or observational studies that compared baricitinib with other drugs offered by the Brazilian Public Health System (SUS) at the same treatment stage were identified.

Economic evaluation: The applicant proposed the price of BRL 1,020.07 for 30 tablets of baricitinib 2mg or 4mg. Cost per responder was estimated comparing baricitinib with adalimumab, as well as cost-minimization comparing baricitinib with biological and non-biological DMARDs available in SUS. The time horizon was two years and the SUS perspective was adopted, including only direct medical costs for the purchase of medicines. Data on the number of doses and unit costs were updated by Conitec's Executive Secretariat. In the first two years of treatment, baricitinib would cost BRL 24,821.70. From

the second year of treatment, the annual cost of baricitinib would be higher than that of tofacitinib (BRL 11,071.67), which currently has the lowest treatment cost.

Budget impact analysis: The analysis presented by the applicant took into account the number of patients with RA being treated in SUS, with a linear growth projection for the following years. The proposed market share of baricitinib would be 2%, 6%, 10%, 12% and 15% in the five years after its incorporation, with patients changing from the drugs already incorporated homogeneously. Based on the cost data updated, the accumulated savings with the incorporation of baricitinib would be BRL 35,299,956 in five years. These values are potentially overestimated. The economic benefits of incorporating baricitinib may be less or absent.

International recommendations: Baricitinib is recommended in England, Scotland, Canada and Australia if treatment cost is equal to or less than the drugs already offered by these countries for the same indication.

Technology horizon scanning: It was found five drugs for the treatment of patients with moderate to severe active RA, who have responded inadequately to, or who are intolerant to one or more non-biological and biological DMARDs, in phase 3 of clinical development. Two of them have an oral route of administration (upadacitinib and filgotinib).

Competing interests: The authors declare that they have no competing interests in relation to the content of this report.

Initial Recommendation: Baricitinib did not demonstrate clinical or economic superiority over the available drugs that would justify its incorporation in the scope of SUS. Therefore, Conitec, on November 7th, 2019, did not recommend the incorporation of baricitinib (Olumiant®) in the scope of SUS, for the treatment of patients with established moderate to severe rheumatoid arthritis, who have responded inadequately to, or who are intolerant to one or more non-biological and biological disease-modifying antirheumatic drugs.

Public consultation: There were 143 technical-scientific contributions, and 748 experience or opinion contributions, including contributions from the applicant and a RA patient association (GrupAR / EncontrAR). The content of the contributions was mainly about: 1) patients who remain in a high disease activity, even after using the treatment options available in SUS; 2) the need to increase the number of therapies available; 3) both logistical and dosage convenience, with potential for increased adherence; and 4) a new price proposal for incorporation of BRL 30.33 per pill, and annual treatment cost of BRL 11,071.67, equivalent to that of tofacitinib, which currently has the lowest treatment cost. Additional discussions and references were added to the report. Conitec decided that there was sufficient reason to change the preliminary recommendation.

Final Recommendation: The Conitec's members, on February 5th, 2020, decided to recommend the incorporation of baricitinib (Olumiant®) in the scope of SUS, for the treatment of patients with established moderate to severe rheumatoid arthritis, who have responded inadequately to, or who are intolerant to one or more non-biological and biological disease-modifying antirheumatic drugs, subject to reassessment of the set of available drugs in the same treatment stages, based on economic evaluation. The Deliberation Record No. 501/2020 was signed.

Decision: To incorporate baricitinib for patients with moderate to severe active rheumatoid arthritis, in the scope of SUS, according to Ordinance No. 8, published in the Official Gazette of the Federal Executive No. 49, Section 1, page 187, on March 12th, 2020.