REPORT 120

Imatinib mesylate for the treatment of Hypereosinophilic Syndrome

Ordinance n° 39/2014 published on 10/08/2014
EXECUTIVE SUMMARY

Technology: Imatinib Mesylate.

Indication: Hypereosinophilic Syndrome.

Applicant: Secretaria de Atenção à Saúde of the Ministry of Health – SAS/MS.

Context: Hypereosinophilic Syndrome (HES) is a heterogeneous group of rare diseases defined by a variety of clinical manifestations, such as: persistent presence of peripheral blood eosinophilia (≥ 1.5 x 10^9/L) for at least 6 months; absence of a secondary cause; and evidence of target organ injury induced by the release of cytokines and humoral factors of eosinophilic granules. The mostly found genetic mutation is the FIP1L1/PDGFRα fusion. The incidence rate of HES is approximately 0.035 per 100,000 person-years, while the incidence of the FIP1L1/PDGFRα fusion is around 10-20% among patients with idiopathic hypereosinophilia.

Question: Is the use of Imatinib Mesylate effective and safe in patients with Hypereosinophilic Syndrome?

Scientific evidence: The evidence currently available on the efficacy and safety of imatinib mesylate for the treatment of HES is based on a Phase II experimental study, two case series and one case report. The Phase II study, with the best level of evidence, was conducted with 16 patients carrying the FIP1L1/PDGFRα mutation at an initial daily dose of 100 mg. At the end of the study, there was complete hematologic response in 100% of cases at a median time of 0.8 months (0.2-3.3) and complete molecular response in 75% of patients (n = 12) at 6 months. The study demonstrated hematologic toxicity in 31% of patients, occurring during the first 4-6 weeks.

Budget Impact Assessment: Imatinib mesylate is made available by SUS for other indications, and is purchased by the Ministry of Health with the value of BRL 17.51 for the 100-mg tablet. The drug will be provided to patients with HES (approximately 71 patients) and to those responding to treatment at 4 weeks (estimated at 36 patients), who will keep using the drug on an ongoing basis. Thus, it is considered that the budget impact for the treatment of HES with Imatinib Mesylate 100 mg used on an ongoing basis in the next 5 years will be approximately BRL 3,451,221.00.

Recommendation made by CONITEC: CONITEC, at its 22nd ordinary meeting held on February 5 and 6, 2014, recommended incorporating into SUS Imatinib Mesylate 100 mg for Hypereosinophilic Syndrome. It also recommended preparing the protocol for the use of this drug for HES.

Public Consultation: The public consultation was conducted between the period from 03/26/2014 to 04/17/2014. No contributions have been received on the topic.
**Final Deliberation:** CONITEC members attending the 24th plenary session meeting on 04/10/2014 unanimously deliberated in favor of recommending Imatinib Mesylate 100 mg incorporation for Hypereosinophilic Syndrome, as per protocol of the Ministry of Health.