Conitec

Recomendation report

DRUGS

Nº 518

April/2020

Cytoreductive surgery (peritonectomy) with Hyperthermic Intraperitoneal Chemotherapy (HIPEC)

Brasília – DF
2020

Indication: Treatment of Pseudomyxoma Peritonei.

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

Background: Pseudomyxoma peritonei (PMP) is a clinical condition characterized by mucinous ascites generally arising from a perforated appendiceal epithelial tumour. Nowadays, the most indicated treatment approach is a surgical and chemotherapeutical modality, which seems to win ground as standard treatment for peritoneal surface disease of all kinds of origin. In this treatment, the peritonectomy procedures aim at resection of peritoneal surfaces, thus making it easier to accomplish a macroscopic complete cytoreduction. In addition, for the purpose of eradicating any macroscopic or microscopic tumour residue to prevent recurrence, surgery is combined with hyperthermic intraperitoneal chemotherapy (HIPEC). This combined modality treatment is an approach with curative intent especially in PMP patients, due to its characteristic dissemination pattern and non-invasive character.

Question: Is treatment with cytoreductive surgery with hyperthermic chemotherapy more effective and cost-effective than systemic chemotherapy for survival of patients with pseudomyxoma peritonei?

Scientific evidence: Clinical trials on cytoreductive surgery with HIPEC specifically for patients with pseudomyxoma peritonei were not found. Fifteen observational studies were selected, the number of patients evaluated ranged from 29 to 636, and the data collection period ranged from 3 to 26 years. The overall 5-year survival rate ranged from 42% to 94%. The studies with the largest number of patients reported an overall 5-year survival rate ranging from 73% to 84%. For the two most recently published studies, the 5-year survival rates were 87% and 82%. Although studies with a comparison group were not found, observational studies on older treatment methods (surgery and/or systemic chemotherapy) reported lower overall survival, indirectly suggesting the superiority of the cytoreduction with HIPEC procedure.

Economic evaluation: Markov chain simulations were performed, with 24 patients, over a 7-year time horizon, from the perspective of the Brazilian Public Health System (SUS), using a discount rate of 5%. The incremental cost-effectiveness ratio (ICER) of the procedure was estimated at BRL 68,920.00/QALY (Quality Adjusted Life Years). In none of the simulations, ICER was estimated below 1 GDP per capita. When the value of the surgery was limited to BRL 21,393.00, ICER was equal to this threshold.

Budget impact analysis: The incremental value per health centre was assessed considering it would perform 24 procedures per year. A dynamic microsimulation model was developed, over a 5-year time horizon. According to the Brazilian Society of Surgical Oncology (SBCO in Portuguese), 120-200 cases per year in Brazil of pseudomyxoma peritonei and peritoneal mesothelioma would be eligible for the procedure. The average annual budget impact for the 24 patients was estimated to be BRL 1,692,864.36. For the entire population, the values per year ranged from BRL 8,661,117.15 to BRL 14,657,044.06.

Initial Recommendation: Conitec's plenary session, at the meeting on December 4th, 2019, considered that, despite the limited scientific evidence, the results indicated greater efficacy of the treatment with cytoreductive surgery with HIPEC in PMP patients. The economic evaluation estimated the incremental cost-effectiveness ratio with a value close to 2 GDP per capita, which was considered acceptable for rare clinical condition. Therefore, the preliminary recommendation was to incorporate Cytoreductive surgery (peritonectomy) with Hyperthermic Intraperitoneal Chemotherapy (HIPEC) into SUS, for the treatment of PMP. The incorporation should be implemented in health centres with professionals trained to perform this complex procedure.

Competing interests: The authors declare that they have no competing interests.

Public consultation: A total of 58 technical-scientific contributions and 8 experience or opinion contributions were received, most of which agreed with the favourable preliminary recommendation to the incorporation of cytoreductive surgery with HIPEC for the treatment of pseudomyxoma peritonei. Only one contribution disagreed. There was not sufficient reason to change the preliminary recommendation.

Final Recommendation: The Conitec's members present at the 86th Ordinary Meeting, on March 4th and 5th, 2020, unanimously decided to recommend the incorporation of cytoreductive surgery with HIPEC for the treatment of pseudomyxoma peritonei, in the scope of SUS, in accordance with a protocol to be developed by the Ministry of Health.

Decision: To incorporate cytoreductive surgery with Hyperthermic Intraperitoneal Chemotherapy for the treatment of pseudomyxoma peritonei, in the scope of SUS, as established by the Ministry of Health of Brazil, according to Ordinance No. 13, published in the Official Gazette of the Federal Executive No. 64, Section 1, page 91, on April 2nd, 2020.