

**Title** Hyperthermic Intraperitoneal Chemotherapy (HIPEC) associated or not with prior cytoreductive surgery

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**Reference** ISBN number: 978-2-11-162651-5, link to full report: [https://www.has-sante.fr/jcms/p\\_3168690/fr/chimiohyperthermie-intraperitoneale-chip-associee-ou-non-a-une-chirurgie-de-cytoreduction-prealable](https://www.has-sante.fr/jcms/p_3168690/fr/chimiohyperthermie-intraperitoneale-chip-associee-ou-non-a-une-chirurgie-de-cytoreduction-prealable).

## Aim

Hyperthermic Intraperitoneal Chemotherapy (HIPEC) consists, after prior cytoreductive surgery (curative indications, peritoneal carcinomatosis) or not (preventive indications, for the said carcinomatosis), in delivering a heated chemotherapy treatment to the abdominal cavity.

The two objectives of this report were:

- question 1: to assess the efficacy and safety of the HIPEC procedure associated or not with prior cytoreductive surgery in order to define which indications are approved/non-approved;
- question 2: to define the conditions in which the HIPEC procedure is carried out associated or not with prior cytoreductive surgery, and of the ensuing hospitalisation; along with the preoperative preparation required and methods of post-hospitalisation follow-up.

## Conclusions and results

The HAS's conclusions are the following:

**Concerning assessment of the efficacy and safety of HIPEC associated or not with prior cytoreductive surgery, and with the definition of its approved indications and non-approved indications, the HAS first of all considers that the currently approved indications for HIPEC are:**

- curative treatment of peritoneal carcinomatosis in patients with FIGO stage III epithelial ovarian cancer, non initially resectable after interval cytoreductive surgery (population in the OVHIPEC study);
  - with the following HIPEC protocol: cisplatin 100 mg/m<sup>2</sup> distributed according to the protocol in the OVHIPEC study at 50 mg/m<sup>2</sup> at the start of the perfusion, 25 mg/m<sup>2</sup> after 30 minutes and 25 mg/m<sup>2</sup> after 60 minutes, for a total perfusion duration of 90 minutes at 40°C, systematically associated with nephroprotection by IV hydration and sodium thiosulfate;
- curative treatment of primary peritoneal carcinomatosis/rare cancers (mesothelioma and pseudomyxoma peritonei);

- for peritoneal mesothelioma with HIPEC protocols containing cisplatin, doxorubicin and mitomycin used in combination or with cisplatin and mitomycin alone;
- for pseudomyxoma with HIPEC protocols containing mitomycin alone or oxaliplatin alone.

In effect, for these indications, data analysed from the literature of good methodological quality (despite limitations) and/or with hindsight of several years, are in favour of HIPEC (in terms of overall survival and/or progression-free survival), and also in a consensual manner, such is the position of experts from the work group and the point of view of stakeholders. It is however noted that except for ovarian cancer, no data on quality-of-life are available.

**The HAS then considers that the other indications studied to date are not approved and are subject to clinical research; they are:**

- curative treatment of peritoneal carcinomatosis of colorectal origin (first cancer and relapse);
- preventive treatment of peritoneal carcinomatosis of colorectal origin (first cancer and relapse);
- curative treatment of peritoneal carcinomatosis secondary to recurrent ovarian cancer;
- initial curative treatment of peritoneal carcinomatosis secondary to ovarian cancer;
- curative treatment of peritoneal carcinomatosis secondary to gastric cancer (first cancer and relapse).

In effect, for these indications, the data in the literature analysed are not in favour of using HIPEC, nor are most of the experts from the work group and stakeholders. The HAS recommends that clinical research continue in these indications.

**The report also defines the optimal conditions necessary for performing HIPEC procedures, from patient pre-hospitalisation preparation, through hospitalisation, to post-hospitalisation follow-up in a care structure or at home: preparation phase, surgery phase: HIPEC and cytoreductive surgery, and post-operative phase.**

The main points described in the report are the expertise of centres, choice of treatment, HIPEC administration sites, material resources required, team members and training, steps of HIPEC with or without cytoreductive surgery, hospital stay and patient management from the preoperative to the postoperative phase.

### **Recommendations**

The HAS recommends HIPEC reimbursement by the French national Health Insurance in certain indications with the defined optimal conditions.

### **Method**

The assessment method used in this report is based on:

- critical analysis of data from the literature identified after a systematic literature search and selected on the basis of explicit criteria;
- consultation of a group of experts of several healthcare professionals (six visceral and digestive surgeons, two gynaecologist-obstetricians, two anaesthetist and resuscitation specialists, a pathologist, a radiologist, a psychiatrist, a pharmacist, three nurses) and patients (three), brought together to collect their substantiated individual positions with regard to the data identified from the literature, based on their knowledge, their experience and their practices;
- consultation of professional bodies, patients' associations and public health institutions concerned by the subject, questioned as stakeholders in order to collect their collective points of view on a draft version of the report containing the elements collected previously and the conclusions that could be drawn from them;
- examination of the report by the National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) then its approval by the HAS College.

### **Further research/reviews required**

The HAS recommends that clinical research continue in the non-approved indications.

### **Written by**

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