



## MEDICAL POLICY STATEMENT

### Ohio Medicaid

| Policy Name & Number                                     | Date Effective        |
|--|-----------------------|
| Hyperthermic Intraperitoneal Chemotherapy-OH MCD-MM-1340 | 02/01/2024-12/31/2024 |
| Policy Type  |                       |
| MEDICAL  |                       |

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A. Subject

**Hyperthermic Intraperitoneal Chemotherapy**

B. Background

Patients with digestive system or ovary cancer have an increased risk of developing peritoneal metastases (PM). Hyperthermic intraperitoneal chemotherapy (HIPEC) is part of a multimodal treatment plan for PM. It is employed within the peritoneal cavity following cytoreductive surgery (CRS) of the abdominal cavity through a traditional open or laparoscopic approach. The hyperthermic agents are heated to 40 – 42 degrees Celsius. Hyperthermia is selectively lethal for malignant cells and the effects of heat can be synergistic with those of other anticancer treatments such as chemotherapy. This infusion facilitates the spread of the chemotherapeutic solution throughout the entire peritoneal cavity, avoiding compartmentalized spread that would be likely following post-operative adhesion formation.

Cytotoxic drugs most frequently used in HIPEC include mitomycin, doxorubicin, cisplatin, oxaliplatin and paclitaxel. These drugs are combined with a carrier solution of isotonic saline solutions or dextrose-based peritoneal dialysis solutions. Approximately 3 to 5 liters are infused into the peritoneum during the procedure.

The extent of tumor load is estimated through imaging methods, usually by computed tomography (CT) and magnetic resonance imaging (MRI) or preoperative laparoscopy. To describe peritoneal carcinomatosis with a universally accepted reference standard, the Peritoneal Cancer Index (PCI) was introduced initially for carcinomatosis of colorectal cancer and mesothelioma. PCI is calculated as the sum of scores in thirteen abdominal regions. Each region receives a score of 0-3 based on the largest tumor size. Scores range from 0 to 39, with higher scores indicating more widespread and/or larger tumors in the peritoneal cavity. In colorectal cancer, PCI is the most important prognostic factor, showing a linear relationship with overall survival. A consensus on a cutoff value for treatment has not been clearly established. However, surgery is not recommended for patients who have colorectal carcinomatosis with a PCI higher than 20. In ovarian cancer, assessment of PCI is not a standard of care in clinical practice or in surgical studies. However, van Driel et al (2018) conducted a Phase III study to investigate whether the addition of HIPEC to interval CRS would improve outcomes among patients who were receiving neoadjuvant chemotherapy for stage III epithelial ovarian cancer. The median recurrence free survival was 10.7 months in the surgery group and 14.2 months in the surgery plus-HIPEC group. Seventy-six patients (62%) in the surgery group and 61 patients (50%) in the surgery-plus-HIPEC group had died at a median follow-up of 4.7 years (hazard ratio, 0.67; 95% CI, 0.48 to 0.94; P=0.02). The median overall survival was 33.9 months in the surgery group and 45.7 months in the surgery-plus-HIPEC group.

HIPEC is completed with an open or closed abdominal technique. The open abdominal technique occurs at the end of CRS and peritoneal catheters are placed through the abdominal wall. The skin edges are suspended through use of a self-retaining retractor

to maintain the open space in the abdominal cavity. The temperature probes are attached to the skin edge for intraperitoneal temperature monitoring. To prevent leakage of the chemotherapy solution, a plastic sheet is placed. The surgeon continuously manipulates the perfusion to allow the uniform exposure of all anatomical structures to heat and chemotherapy. An external pump recirculates the chemotherapy infusion through inflow and outflow catheters.

In a closed HIPEC procedure (which is more commonly used), the peritoneal catheters and probes are placed in the same way, but the laparotomy incision and skin edges are closed to permit perfusion through a closed circuit. The surgeon manually shakes the abdominal wall during the infusion for uniform heat distribution. Greater perfusate is used in this technique to establish the circuit and generate higher abdominal pressure, which facilitates tissue penetration. After infusion, the abdomen is reopened to remove the perfusate, catheters, and to complete any additional surgical procedures needed (e.g., anastomosis).

### C. Definitions

- **Abdominal Cavity** - A cavity within the abdomen and continuous with the pelvic cavity and containing the stomach with lower portion of the esophagus, small and large intestines, liver, gallbladder, spleen, pancreas, kidney and ureter.
- **Carcinomatosis** - The condition of having widespread dissemination of carcinoma in the body.
- **Cytoreductive Surgery (CRS)** - The removal of all sites of cancer within the abdominal cavity.
- **Debulking Surgery** - The surgical removal of as much of a tumor as possible. Debulking may increase the chance that chemotherapy or radiation therapy will kill all the tumor cells. It may also be done to relieve symptoms or help the patient live longer. Also called tumor debulking.
- **Hyperthermic Perfusion** - A procedure in which a warmed solution containing anticancer drugs is used to bathe, or is passed through the blood vessels of, the tissue or organ containing the tumor.
- **Mesothelioma** - A cancer that affects tissue called the mesothelium, a lining that covers and protects many internal organs. Pleural and peritoneal mesothelioma account for most of the 2,000 to 3,000 new cases of the disease diagnosed in the United States each year. The most common cause of mesothelioma is exposure to asbestos.
- **Peritoneum** - The serous membrane lining the abdominal cavity and covering the abdominal organs.
- **Peritoneal Metastasis** - A late-stage manifestation of intra-abdominal malignancies.
- **Pseudomyxoma Peritonei (PMP)** - A build-up of mucus in the peritoneal cavity. The mucus may come from ruptured ovarian cysts, from the appendix, or from other abdominal tissues. Mucus secreting cells may attach to the peritoneal lining and continue to secrete mucus.

#### D. Policy

- I. CareSource considers HIPEC in combination with CRS medically necessary for ANY of the following indications:
  - A. Pseudomyxoma peritonei (PMP)
  - B. Appendiceal neoplasms with PMP/mucinous ascites
  - C. Diffuse malignant peritoneal mesothelioma (DPM) with metastasis limited to the abdominal cavity
  - D. Select patients with metastatic colorectal cancer with peritoneal involvement, with a PCI <20, no extra-abdominal metastasis, and in conjunction with planned or prior systemic therapy
  - E. Stage III epithelial ovarian cancer or fallopian tube carcinoma at the time of interval debulking surgery with stable disease after neoadjuvant chemotherapy
- II. HIPEC is considered experimental and investigational for indications not listed above due to insufficient evidence in the peer-reviewed literature. There is insufficient evidence to recommend HIPEC with CRS for the prevention of or for the treatment of gastric carcinoma and other malignancies outside of a clinical trial.

#### E. Conditions of Coverage

NA

#### F. Related Policies/Rules

Experimental and Investigational Item or Service

#### G. Review/Revision History

| DATE                  |            | ACTION  |
|-----------------------|------------|---|
| <b>Date Issued</b>    | 10/12/2023 | New policy, approved at Committee.  |
| <b>Date Revised</b>   | 10/11/2023 | Annual review; Approved at Committee  |
| <b>Date Effective</b> | 02/01/2024 |   |
| <b>Date Archived</b>  | 12/31/2024 | This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy. |

#### H. References

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The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

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This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

*Independent medical review – 09/30/2022*

Approved by ODM 10/26/2023

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.