# MEDICAL POLICY STATEMENT
# Georgia Medicaid

| Policy Name & Number | Date Effective |
|---|---|
| Hyperthermic Intraperitoneal Chemotherapy-GA MCD-MM-1342 | 04/01/2023-01/31/2024 |
| **Policy Type** | |
| **MEDICAL** | |

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.



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A. Subject

**Hyperthermic Intraperitoneal Chemotherapy**

B. Background

Patients with cancer of the digestive system, peritoneal lining or ovary are at heightened 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. Utilization of this HIPEC typically first involves surgical removal of all visible cancerous tumors followed by the infusion of heated chemotherapeutic agents directly into the peritoneal cavity. 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. The infusion of these agents facilitates 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. The most used carrier solutions chemotherapeutic agents are combined with for HIPEC are isotonic saline solutions or dextrose-based peritoneal dialysis solutions. Approximately 3 to 5 liters of carrier solution are infused 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 in that region. 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 hyperthermic 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.

The two methods for HIPEC are an open or a closed abdominal technique. Open abdomen technique occurs at the end of the surgical cytoreduction with the insertion of peritoneal catheters which are placed through the open 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 in a closed circuit. The abdominal wall is shaken manually by the surgeon during the infusion for uniform heat distribution. The volume of perfusate is greater in this technique to establish the circuit and higher abdominal pressure is obtained during the perfusion, which facilitates tissue penetration of the drug. After infusion, the abdomen is reopened to remove the perfusate. catheters, and to complete any additional surgical procedures needed (e.g. anastomosis). This technique allows maintenance of rapidly attained hyperthermia because there is minimal heat loss.

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 deposits within the abdominal cavity.
- **Debulking Surgery -** 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 -** Mesothelioma is 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 serious membrane reflected over the viscera and lining the abdominal cavity.
- **Peritoneal Metastasis -** A late-stage manifestation of intra-abdominal malignancies.
- **Pseudomyxoma Peritoneai (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 used in combination with CRS medically necessary for ANY of the following indications:
   A. Pseudomyxoma peritoneai (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

NA

G. Review/Revision History

| | DATE | ACTION |
|---|---|---|
| **Date Issued** | Not Set | |
| **Date Revised** | | |
| **Date Effective** | 04/01/2023 | |
| **Date Archived** | 01/31/2024 | 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

1. Ahmed S, Stewart JH, Shen P, Votanopoulos KI, Levine EA. Outcomes with cytoreductive surgery and HIPEC for peritoneal metastasis. Journal of Surgical Oncology. 2014 Oct;110(5):575-84.
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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.

3. Auer RC, Sivajohanathan D, Biagi J, Conner J, Kennedy E, May T. Indications for hyperthermic intraperitoneal chemotherapy with cytoreductive surgery: A systematic review. European Journal of Cancer. 2020 Mar 1;127:76-95.
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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*

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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