

## Corporate Medical Policy

### Hyperthermic Intraperitoneal Chemotherapy

<b>File Name:</b>	hyperthermic_intraperitoneal_chemotherapy
<b>Origination:</b>	5/19/2005
<b>Last CAP Review:</b>	3/2012
<b>Next CAP Review:</b>	3/2013
<b>Last Review:</b>	3/2012

#### Description of Procedure or Service

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Peritoneal carcinomatosis from nonovarian malignancies has long been regarded as a terminal disease with limited survival. In an attempt to prolong survival, aggressive locoregional therapy, such as combining cytoreductive surgery with perioperative intraperitoneal chemotherapy, has been used. Pseudomyxoma peritonei is a clinicopathologic entity characterized by the production of mucinous ascites and mostly originates from epithelial neoplasms of the appendix. As the tumor grows, the narrow lumen of the appendix becomes obstructed and subsequently leads to appendiceal perforation. The neoplastic cells progressively colonize the peritoneal cavity and copious mucin production builds up in the peritoneal cavity. Appendix tumors causing pseudomyxoma peritonei range from a benign pathologic appearance (disseminated peritoneal adenomucinosis) to malignant pathologic findings (peritoneal mucinous carcinomatosis), with some intermediate pathologic grades. Clinically, this syndrome ranges from early pseudomyxoma peritonei, fortuitously discovered on imaging or during a laparotomy performed for another reason, to advanced cases with a distended abdomen, bowel obstruction, and starvation. The conventional treatment of pseudomyxoma peritonei is surgical debulking repeated as necessary to alleviate pressure effects. However, repeated debulking surgeries become ever more difficult due to progressively thickened intra-abdominal adhesions, and this treatment is palliative, leaving visible or occult disease in the peritoneal cavity. Peritoneal dissemination develops in approximately 10–15% of patients with colon cancer, and despite the use of increasingly effective regimens of chemotherapy and biologic agents in the treatment of advanced disease, peritoneal metastases are associated with a median survival of 6 to 7 months.

#### Mesothelioma

Malignant mesothelioma is a relatively uncommon malignancy that may arise from the mesothelial cells lining the pleura, peritoneum, pericardium, and tunica vaginalis testis. In the U.S., 200-400 new cases of diffuse malignant peritoneal mesothelioma (DMPM) are registered every year, accounting for 10-30% of all-type mesothelioma. DMPM has traditionally been considered as a rapidly lethal malignancy with limited and ineffective therapeutic options. The disease is usually diagnosed at an advanced stage and is characterized by multiple variably sized nodules throughout the abdominal cavity. As the disease progresses, the nodules become confluent to form plaques, masses, or uniformly cover peritoneal surfaces. In most patients, death eventually occurs as a result of locoregional progression within the abdominal cavity. In historical case series, treatment by palliative surgery, systemic/intraperitoneal chemotherapy, and abdominal irradiation results in a median survival of approximately 12 months.

Surgical cytoreduction in conjunction with hyperthermic intraperitoneal chemotherapy is designed to remove visible tumor deposits with intraperitoneal chemotherapy to address remaining microscopic disease. By delivering chemotherapy intraperitoneally, drug exposure to the peritoneal

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surface is increased some 20-fold compared to systemic exposure. In addition, prior animal and in vitro studies have suggested that the cytotoxicity of mitomycin C is enhanced at temperatures greater than 39 degrees Celsius.

Cytoreductive surgery (CRS) consists of peritonectomy procedures and multivisceral resections, depending on the extent of intra-abdominal tumor dissemination. The surgical procedure may be followed intraoperatively by the infusion of hyperthermic chemotherapy, most commonly mitomycin C. Inflow and outflow catheters are placed in the abdominal cavity, along with temperature probes to monitor the temperature. The skin is then temporarily closed during the chemotherapy perfusion, which typically runs for 1 to 2 hours. This procedure is referred to as hyperthermic intraperitoneal chemotherapy (HIPEC). Other methods of intraperitoneal chemotherapy include early postoperative intraperitoneal chemotherapy (EPIC).

## **Related policies:**

Hyperthermia Therapy

***\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

## **Policy**

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**BCBSNC will provide coverage for hyperthermic intraperitoneal chemotherapy when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

**Some patients may be eligible for coverage under Clinical Trials. Refer to the policy on Clinical Trial Services for Life-Threatening Conditions.**

## **Benefits Application**

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## **When Intraperitoneal Hyperthermic Chemotherapy is covered**

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Cytoreductive surgery and perioperative intraperitoneal chemotherapy for the treatment of pseudomyxoma peritonei may be considered medically necessary.

Cytoreductive surgery and perioperative intraperitoneal chemotherapy for the treatment of diffuse malignant peritoneal mesothelioma may be considered medically necessary.

## **When Intraperitoneal Hyperthermic Chemotherapy is not covered**

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Cytoreductive surgery and perioperative intraperitoneal chemotherapy is considered investigational for peritoneal carcinomatosis from colorectal cancer.

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## Policy Guidelines

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### **Pseudomyxoma peritonei**

Several case studies and a systematic review on the use of cytoreductive surgery and hyperthermic intraperitoneal chemotherapy have been published. Although no randomized trials or comparative studies have been published, the data have shown consistent, long-term disease-free survival (DFS) and overall survival (OS) with the use of this technique as compared to historic controls.

### **Peritoneal carcinomatosis from colorectal cancer**

Numerous studies with different levels of evidence support the safety and feasibility of cytoreductive surgery and hyperthermic intraperitoneal chemotherapy, and existing data suggest a possible improvement in long-term survival of select patients. However, prospective randomized trials are needed to compare best available systemic therapy with and without cytoreductive surgery and hyperthermic intraperitoneal chemotherapy to determine the exact effects of each step, which are currently unknown. An ongoing Phase III trial (NCT00769405) addresses this question of how much of the survival benefit is derived from the cytoreduction and how much from hyperthermic intraperitoneal chemotherapy, as patients will be randomly assigned to hyperthermic intraperitoneal chemotherapy or no hyperthermic intraperitoneal chemotherapy after complete cytoreductive surgery.

### **Peritoneal mesothelioma**

The conventional treatment of peritoneal mesothelioma (diffuse malignant type) has resulted in a median survival of approximately 12 months. Although the data on the use of cytoreductive surgery and perioperative intraperitoneal chemotherapy consists of non-randomized case series without control groups, they have shown a significant prolongation of survival ranging from 29.5 to 92 months.

When the service requested does not meet the criteria and guidelines set forth in this policy, the service components related to Hyperthermic Intraperitoneal Chemotherapy are also considered investigational. These components would include the intraperitoneal chemotherapy, the externally generated hyperthermia (deep) and the placement and removal of catheters for the administration of the chemotherapy. Surgical procedures directly relating to the removal of the tumor will be reimbursed based on the member's benefit language.

The National Comprehensive Cancer Network (NCCN) does not recommend the use of this technology in the treatment of colon cancer guidelines outside the clinical trial setting.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 77605, 96446*

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BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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Medical Director – 12/2011

Specialty Matched Consultant Advisory Panel – 3/2012

## Policy Implementation/Update Information

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10/20/05 New policy. Specialty Matched Consultant Advisory Panel review 9/19/2005. Hyperthermic Intraperitoneal Chemotherapy is considered investigational.

9/24/07 Specialty Matched Consultant Advisory Panel review 8/23/2007. No changes to policy statement. Updated rationale in "Policy Guidelines" section. References added. (btw)

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- 10/12/09 Specialty Matched Consultant Advisory Panel review 8/28/09. "Description" section revised. No change to policy statement. Updated rationale in "Policy Guidelines" section. References added. (btw)
- 6/22/10 Policy Number(s) removed (amw)
- 1/4/11 Added new 2011 CPT code, 96446 to "Billing/Coding" section. Removed deleted code, 96445. Added "Related Policies: Hyperthermia Therapy" to "Description" section. (btw)
- 4/26/11 Specialty Matched Consultant Advisory Panel review March 30, 2011. "Description: revised. New indication for "When Covered" states the following: "Cytoreduction and hyperthermic intraperitoneal chemotherapy for the treatment of pseudomyxoma peritonei may be considered medically necessary." The "When Not Covered" section was revised to indicate; "Cytoreduction and hyperthermic intraperitoneal chemotherapy is considered investigational for peritoneal carcinomatosis from colorectal cancer." "Policy Guidelines" updated. References added. (btw)
- 5/24/11 Corrected policy to include information related to 1/4/11 code update. (btw)
- 1/24/12 "Description" section updated to include information related to Mesothelioma. The "When Covered" section updated to indicate; "Cytoreductive surgery and perioperative intraperitoneal chemotherapy for the treatment of pseudomyxoma peritonei may be considered medically necessary. Cytoreductive surgery and perioperative intraperitoneal chemotherapy for the treatment of diffuse malignant peritoneal mesothelioma may be considered medically necessary." The "When Not Covered" section updated to indicate; "Cytoreductive surgery and perioperative intraperitoneal chemotherapy is considered investigational for peritoneal carcinomatosis from colorectal cancer." "Policy Guidelines" updated. Medical Director review 12/24/11 References added. (btw)
- 4/17/12 Specialty Matched Consultant Advisory Panel review 3/21/2012. No change to policy intent. (btw)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.