

## MEDICAL POLICY – 2.03.07

## Hyperthermic Intraperitoneal Chemotherapy (HIPEC) for Select Intra-Abdominal and Pelvic Malignancies

BCBSA Ref. Policy: 2.03.07

Effective Date: Jan. 1, 2021

Last Revised: Dec. 1, 2020


Replaces: N/A

RELATED MEDICAL POLICIES:

None

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## Introduction

Chemotherapy can be delivered directly into the abdominal cavity to treat certain types of cancer. However, chemotherapy has trouble penetrating large tumors. That's why surgery is done to remove as much cancer as possible before chemotherapy is directly given into the abdomen. Removing or reducing the size of the tumor—also called debulking—provides the chemotherapy drug the best chance to kill the remaining cancer cells. There are several different types of cancer in which this treatment has been tried. This policy describes when debulking surgery followed by direct application of chemotherapy may be considered medically necessary.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

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## Policy Coverage Criteria

**Note:** This policy addresses “perioperative” intraperitoneal chemotherapy; that is intraperitoneal chemotherapy which occurs at the same operative session as the cytoreductive or interval cytoreductive surgery. This policy does not address intraperitoneal chemotherapy which is delivered directly into the abdominal cavity through an indwelling catheter with an access port given post-operatively either in an inpatient or outpatient setting

Service	Medical Necessity
<p><b>Cytoreductive surgery plus hyperthermic intraperitoneal chemotherapy (HIPEC)</b></p>	<p><b>Cytoreductive surgery plus hyperthermic intraperitoneal chemotherapy (HIPEC) at the time of surgery may be considered medically necessary for the treatment of:</b></p> <ul style="list-style-type: none"> <li>• Pseudomyxoma peritonei (malignant tumor of the appendix)</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Diffuse malignant peritoneal mesothelioma</li> </ul> <p><b>The use of HIPEC may be considered medically necessary in newly diagnosed epithelial ovarian or fallopian tube cancer at the time of interval cytoreductive surgery when ALL of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• The patient has newly diagnosed stage III disease (see <a href="#">Related Information</a>)</li> <li>• The patient is not eligible for primary cytoreductive surgery or surgery has been performed but was incomplete and the patient received 3 cycles of cis-platinum and paclitaxel systemic neoadjuvant chemotherapy immediately prior to interval-debulking surgery (see <a href="#">Related Information</a>);</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Optimal cytoreduction (residual tumor nodules of &lt;10 mm is achieved at the time of the interval debulking surgery [see <a href="#">Related Information</a>])</li> <li>• The HIPEC agent used is cis-platinum</li> </ul> <p><b>The use of HIPEC in all other settings to treat ovarian cancer, including, but not limited to stage IIIC or IV ovarian cancer is considered investigational</b></p>



Service	Investigational
<b>Cytoreductive surgery plus hyperthermic intraperitoneal chemotherapy (HIPEC)</b>	<b>Cytoreductive surgery plus HIPEC is considered investigational for:</b> <ul style="list-style-type: none"> <li>• Peritoneal carcinomatosis from colorectal cancer, gastric cancer, or endometrial cancer</li> </ul> <b>AND</b> <ul style="list-style-type: none"> <li>• All other indications, including goblet cell tumors of the appendix</li> </ul>

Documentation Requirements
<p><b>The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:</b></p> <ul style="list-style-type: none"> <li>• For Cytoreductive surgery plus hyperthermic intraperitoneal chemotherapy (HIPEC) at the time of surgery: <ul style="list-style-type: none"> <li>○ Office visit notes that contain the relevant history and physical supporting any of the following diagnoses: <ul style="list-style-type: none"> <li>▪ Pseudomyxoma peritonei (malignant tumor of the appendix)</li> <li>▪ Diffuse malignant peritoneal mesothelioma</li> </ul> </li> </ul> </li> <li>• For HIPEC <ul style="list-style-type: none"> <li>○ Office visit notes that contain the relevant history and physical supporting: <ul style="list-style-type: none"> <li>▪ Newly diagnosed epithelial ovarian or fallopian tube cancer at the time of interval cytoreductive surgery and ALL of the following criteria: <ul style="list-style-type: none"> <li>▫ The patient has stage III disease</li> <li>▫ The patient is not eligible for primary cytoreductive surgery or surgery has been performed but was incomplete and the patient received 3 cycles of cis-platinum and paclitaxel systemic neoadjuvant chemotherapy immediately prior to interval-debulking surgery</li> <li>▫ Residual tumor nodules of &lt;10 mm is achieved at the time of the interval debulking surgery</li> </ul> </li> </ul> </li> </ul> </li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>▫ The HIPEC agent used is cis-platinum</li> </ul>

## Coding



The coding for this overall procedure would likely involve codes for the surgery, the intraperitoneal chemotherapy, and the hyperthermia.

Code	Description
<b>CPT</b>	
96446	Chemotherapy administration into the peritoneal cavity via indwelling port or catheter
96549	Unlisted chemotherapy procedure

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Cytoreduction

There is no specific CPT code for the surgical component of this complex procedure. It is likely that a series of CPT codes would be used describing exploratory laparotomies of various components of the abdominal cavity, in addition to specific codes for resection of visceral organs, depending on the extent of the carcinomatosis.

## Intraperitoneal Chemotherapy

When performed using a temporary catheter or performed intraoperatively, the unlisted code 96549 (unlisted chemotherapy procedure) would be reported.

## Hyperthermia

This procedure does not refer to external application of heat as described by CPT code 77605. There are no codes for the heating of the chemotherapy.

## Related Information

Ovarian cancer staging is as follows:



**Stage I:** The cancer is confined to the ovary or fallopian tube.

**Stage II:** The cancer involves one or both ovaries with pelvic extension.

**Stage III:** The cancer has spread within the abdomen.

**Stage IV:** The cancer is widely spread throughout the body.

Eligibility for neoadjuvant chemotherapy and interval debulking surgery is based on a high perioperative risk profile (ie, the patient is a poor candidate to withstand an aggressive initial cytoreductive procedure) or a low likelihood of achieving cytoreduction to less than 1 cm (ie, the patient has extensive disease that precludes upfront optimal cytoreduction) or surgery has been performed but was incomplete (ie, after surgery, one or more residual tumors measuring >1 cm in diameter were present).

Complete cytoreduction is defined as no visible disease and optimal cytoreduction as one or more residual tumors measuring 10 mm or less in diameter remaining.

## Evidence Review

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### Description

Cytoreductive surgery (CRS) includes peritonectomy (ie, peritoneal stripping) procedures and multivisceral resections, depending on the extent of intra-abdominal tumor dissemination. CRS may be followed intraoperatively by infusion of intraperitoneal chemotherapy with or without heating, which is intended to improve the tissue penetration of the chemotherapy. When heated, this is referred to as hyperthermic intraperitoneal chemotherapy (HIPEC). CRS and HIPEC have been proposed for a number of intra-abdominal and pelvic malignancies such as pseudomyxoma peritonei and peritoneal carcinomatosis from colorectal, gastric, or endometrial cancer.

### Background

#### Pseudomyxoma Peritonei

Pseudomyxoma peritonei is a clinicopathologic disease characterized by the production of mucinous ascites and mostly originates from epithelial neoplasms of the appendix. Appendix



cancer is diagnosed in fewer than 1000 Americans each year; less than half are epithelial neoplasms.<sup>1</sup> The incidence of pseudomyxoma peritonei is estimated at two cases per 1 million individuals.<sup>2</sup> As mucin-producing cells of the tumor proliferate, the narrow lumen of the appendix becomes obstructed and subsequently leads to appendiceal perforation. Neoplastic cells progressively colonize the peritoneal cavity and produce copious mucin, which collects in the peritoneal cavity. Pseudomyxoma peritonei ranges from benign (disseminated peritoneal adenomucinosis) to malignant (peritoneal mucinous carcinomatosis), with some intermediate pathologic grades. Clinically, this syndrome ranges from early pseudomyxoma peritonei, usually discovered on imaging or during a laparotomy performed for another reason, to advanced cases with a distended abdomen, bowel obstruction, and starvation.

### **Treatment**

The conventional treatment of pseudomyxoma peritonei is surgical debulking, repeated as necessary to alleviate pressure effects. However, repeated debulking surgeries become more difficult due to progressively thickened intra-abdominal adhesions, and this treatment is palliative, leaving visible or occult disease in the peritoneal cavity.<sup>3</sup>

## **Peritoneal Carcinomatosis of Colorectal Origin**

Peritoneal dissemination develops in 10% to 15% of patients with colon cancer.

### **Treatment**

Despite the use of increasingly effective regimens of chemotherapy and biologic agents to treat advanced disease, peritoneal metastases are associated with a median survival of six to seven months.

## **Peritoneal Carcinomatosis of Gastric Origin**

Peritoneal carcinomatosis is detected in more than 30% of patients with advanced gastric cancer and is a poor prognostic indicator. The median survival is three months, and five-year survival is less than 1%.<sup>4</sup> Sixty percent of deaths from gastric cancer are attributed to peritoneal carcinomatosis.<sup>5</sup>



## **Treatment**

Current chemotherapy regimens are nonstandard, and peritoneal seeding is considered unresectable for cure.<sup>6</sup>

## **Peritoneal 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 United States, 200 to 400 new cases of diffuse malignant peritoneal mesothelioma (DMPM) are registered every year, accounting for 10% to 30% of all-type mesothelioma.<sup>7</sup> DMPM has traditionally been considered a rapidly lethal malignancy with limited and ineffective therapeutic options.<sup>7</sup> 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 results from locoregional progression within the abdominal cavity. In historical case series, treatment by palliative surgery, systemic or intraperitoneal chemotherapy, and abdominal irradiation resulted in a median survival of 12 months.<sup>7</sup>

## **Treatment**

Surgical cytoreduction (resection of visible disease) in conjunction with hyperthermic intraperitoneal chemotherapy (HIPEC) is designed to remove visible tumor deposits and residual microscopic disease. By delivering chemotherapy intraperitoneally, drug exposure to the peritoneal surface is increased some 20-fold compared with systemic exposure. In addition, previous animal and in vitro studies have suggested that the cytotoxicity of mitomycin C is enhanced at temperatures greater than 39°C (102.2°F).

## **Ovarian Cancer**

Several different types of malignancies can arise in the ovaries; epithelial carcinoma is the most common, accounting for 90% of malignant ovarian tumors. Epithelial ovarian cancer is the fifth most common cause of cancer death in women in the United States. Most ovarian cancer



patients (>70%) present with widespread disease, and annual mortality is approximately 65% of the incidence rate.

## **Treatment**

Current management of advanced epithelial ovarian cancer is cytoreductive surgery (CRS) followed by combination chemotherapy. Tumor recurrences are common, and the prognosis for recurrent disease is poor.

CRS plus HIPEC in combination with systemic chemotherapy is being studied for primary and recurrent disease. Because HIPEC is administered at the time of surgery, treatment-related morbidity may be reduced compared with intraperitoneal chemotherapy administered postoperatively.

## **Summary of Evidence**

For individuals who have pseudomyxoma peritonei who receive cytoreductive surgery (CRS) plus HIPEC, the evidence includes cohort studies and a systematic review. The relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related mortality and morbidity. Retrospective cohort studies and systematic reviews have reported median survival ranging from 47 to 156 months and 5-year overall survival ranging from 41% to 96% for patients with primary treatment for pseudomyxoma peritonei treated with CRS plus HIPEC. Two retrospective studies reported results of CRS plus HIPEC for recurrence with 5-year overall survival rates of 34% to 79%. Although no direct comparisons between CRS plus HIPEC and other interventions have been published, traditional surgical debulking is not curative, and complete CRS alone (without HIPEC) has been associated with a 5-year OS of approximately 50%, along with high recurrence rates (91%, with a median disease-free survival of 24 months). Median progression-free survival with CRS plus HIPEC as primary treatment has been reported as 40 to 78 months, with 5-year progression-free survival rates of 38% to 80%. Procedure-related morbidity and mortality have generally decreased over time. Because the prevalence of pseudomyxoma peritonei is very low, conducting comparative trials is difficult. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have peritoneal carcinomatosis of colorectal origin who receive CRS plus HIPEC, the evidence includes a randomized controlled trial (RCT), systematic reviews, and a large number of observational studies. The relevant outcomes are overall survival, disease-specific





survival, quality of life, and treatment-related mortality and morbidity. A meta-analysis of controlled studies found that CRS plus HIPEC, compared with traditional therapy without HIPEC, was associated with significantly higher survival rates, and was not associated with significantly higher treatment-related morbidity rates. The RCT, in which patients with peritoneal carcinomatosis due to colorectal cancer were followed for at least six years, demonstrated improved survival in patients who received CRS plus HIPEC and systemic chemotherapy compared with patients who received systemic chemotherapy alone. However, procedure-related morbidity and mortality were relatively high, and systemic chemotherapy regimens did not use currently available biologic agents. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have peritoneal carcinomatosis of gastric origin who receive CRS plus HIPEC, the evidence includes two small RCTs, observational studies, and a systematic review. The relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related mortality and morbidity. A 2017 meta-analysis identified 2 RCTs and 12 controlled nonrandomized studies comparing surgery plus HIPEC with standard surgical management in patients who had peritoneal carcinomatosis due to gastric cancer. The meta-analysis found significantly better survival in the surgery plus HIPEC group at one year but not at two or three years. One small (N=17) preliminary RCT showed improved survival in patients with peritoneal carcinomatosis due to gastric cancer who received CRS plus HIPEC compared with patients who received chemotherapy alone. Another (N=68) RCT showed improved survival in patients who received CRS plus HIPEC compared with CRS alone. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have peritoneal carcinomatosis of endometrial origin who receive CRS plus HIPEC, the evidence includes cohort studies. The relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related mortality and morbidity. Only uncontrolled retrospective cohort studies were available, with the largest including only 43 patients. Randomized trials that compare CRS plus HIPEC with standard treatment (eg, CRS alone or systemic chemotherapy alone) are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have peritoneal mesothelioma who receive CRS plus HIPEC, the evidence includes retrospective cohort studies and systematic reviews. The relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related mortality and morbidity. Retrospective cohort studies have shown median and 5-year overall survival ranging from 30 to 92 months and 33% to 68%, respectively, for patients with peritoneal mesothelioma treated with CRS plus HIPEC. Although no RCTs or comparative studies have been published, historical case series have reported a median survival of 12 months with treatment by palliative surgery,



systemic or intraperitoneal chemotherapy, and abdominal irradiation. Procedure-related morbidity and rates with CRS plus HIPEC have remained relatively steady over time, at approximately 35% and 5%, respectively.. Because the prevalence of peritoneal mesothelioma is very low, conducting comparative trials is difficult. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have newly diagnosed stage III ovarian cancer who receive CRS plus HIPEC, the evidence includes an RCT. The relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related mortality and morbidity. For patients with newly diagnosed stage III ovarian cancer who received neoadjuvant chemotherapy, HIPEC increased the time to disease recurrence and reduced mortality. HIPEC did not increase serious adverse events compared with surgery alone. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have recurrent stage IIIC or IV ovarian cancer who receive CRS plus HIPEC, the evidence includes an RCT and systematic reviews. The relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related mortality and morbidity. For recurrent stage IIIC or IV disease (second-line setting), evidence from an RCT indicated that CRS plus HIPEC improved survival compared with CRS without HIPEC. However, interpretation of this study is limited because treatment groups in this RCT were unbalanced at baseline (variation in the completeness of cytoreduction), which has been shown to be associated with survival. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have appendiceal goblet cell tumors who receive CRS plus HIPEC, the evidence includes retrospective cohort studies. The relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related mortality and morbidity. A propensity score-matched analysis found that CRS plus HIPEC was associated with improved median survival compared to surgery alone. However, this analysis was limited by the retrospective nature of the data and small sample size (N=44). Rates of complete cytoreduction were not reported or accounted for in this study, so between-group differences in this or other variables may have influenced the observed outcomes. Additional studies - preferably controlled and ideally, RCTs - are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

## Ongoing and Unpublished Clinical Trials

Some currently ongoing or unpublished trials that might influence this review are listed in [Table 1](#).



**Table 1. Summary of Key Trials**

<b>NCT No.</b>	<b>Title</b>	<b>Enrollment</b>	<b>Completion Date</b>
<b>Ongoing</b>			
<b>Colorectal and appendiceal cancer</b>			
<b>NCT01815359</b>	ICARuS Post-operative Intraperitoneal Chemotherapy (EPIC) and Hyperthermic Intraperitoneal Chemotherapy (HIPEC) After Optimal Cytoreductive Surgery (CRS) for Neoplasms of the Appendix, Colon or Rectum With Isolated Peritoneal Metastasis	282	Sep 2021
<b>NCT02614534</b>	Multicentre, Randomized Clinical Trial to Evaluate Safety and Efficacy of Hyperthermic Intra-peritoneal Chemotherapy (HIPEC) With Mitomycin C Used During Surgery for Treatment of Locally Advanced Colorectal Carcinoma	200	Oct 2023
<b>NCT02231086</b>	Adjuvant Hyperthermic Intraperitoneal Chemotherapy in Patients With Colon Cancer at High Risk of Peritoneal Carcinomatosis	204	Apr 2022
<b>NCT04370925</b>	A Multicenter Prospective Randomized Controlled Clinical Trial of Hyperthermic Intraperitoneal Chemotherapy After Colectomy in Patients With Colorectal Cancer at High Risk of Peritoneal Carcinomatosis	688	Apr 2026
<b>Gastric cancer</b>			
<b>NCT02960061</b>	D2 Radical Resection After Neoadjuvant Chemotherapy Combined With HIPEC for Advanced Gastric Cancer: a Prospective Randomized Controlled Trial	640	Dec 2019 (unknown)
<b>NCT02158988</b>	Prospective Multicenter Phase III Trial Using CRS With / Without HIPEC After Preoperative Chemotherapy in Patients With Peritoneal Carcinomatosis of Gastric Cancer Incl. Adenocarcinoma of the Esophagogastric Junction	105	Sep 2021
<b>NCT01882933</b>	GASTRICHIP : D2 Resection and HIPEC (Hyperthermic Intraperitoneal Chemoperfusion) in Locally Advanced Gastric Carcinoma. A Randomized and Multicentric Phase III Study	367	May 2025
<b>Ovarian cancer</b>			
<b>NCT01767675</b>	A Phase II Randomized Study: Outcomes After Secondary Cytoreductive Surgery With or Without Carboplatin Hyperthermic Intraperitoneal Chemotherapy (HIPEC) Followed by Systemic Combination Chemotherapy for	99	Jan 2021



NCT No.	Title	Enrollment	Completion Date
	Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer		
<a href="#">NCT02124421</a>	Phase II Randomized Study: Cytoreductive Surgery (CRS) With/Without Carboplatin Hyperthermic Intraperitoneal Chemotherapy (HIPEC) Followed by Adjuvant Chemotherapy as Initial Treatment of Ovarian, Fallopian Tube, & Primary Peritoneal Cancer	48	Apr 2020 (recruiting)
<a href="#">NCT01376752</a>	A Phase III Randomized Study Evaluating Hyperthermic Intra-Peritoneal Chemotherapy (HIPEC) in the Treatment of Relapse Ovarian Cancer	444	Apr 2025
<a href="#">NCT04473339</a>	A Randomized Prospective Trail of Hyperthermic Intraperitoneal Chemotherapy (HIPEC) in Recurrent Ovarian Cancer Patients With Mutations in Homologous Recombination Repair (HRR) Genes	280	Dec 2023
<a href="#">NCT03772028</a>	Phase III Randomized Clinical Trial for Stage III Epithelial Ovarian Cancer Randomizing Between Primary Cytoreductive Surgery With or Without Hyperthermic Intraperitoneal Chemotherapy	538	Apr 2025
<b>Unpublished</b>			
<b>Gastric cancer</b>			
<a href="#">NCT02240524</a>	A Phase III Study of Hyperthermic Intraperitoneal Chemotherapy in the Treatment of Locally Advanced Gastric Cancer After radical Gastrectomy With D2 Lymphadenectomy	582	July 2019 (unknown)
<b>Ovarian cancer</b>			
<a href="#">NCT01628380</a>	Stage IIIC Unresectable Epithelial Ovarian/Tubal Cancer With Partial or Complete Response After 1st Line Neoadjuvant Chemotherapy (3 Cycles CBDCA+Paclitaxel): a Phase 3 Prospective Randomized Study Comparing Cytoreductive Surgery + Hyperthermic Intraperitoneal Chemotherapy (CDDP+Paclitaxel) + 3 Cycles CBDCA+Paclitaxel vs Cytoreductive Surgery Alone + 3 Cycles CBDCA+Paclitaxel	94	Jul 2018
<a href="#">NCT01539785</a>	Surgery Plus Hyperthermic Intra-peritoneal Chemotherapy (HIPEC) Versus Surgery Alone in Patients With Platinum-sensitive First Recurrence of Ovarian Cancer: a Prospective Randomized Multicenter Trial	158	Sep 2018 (unknown)

NCT: National Clinical Trial



## Practice Guidelines and Position Statements

### National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) guidelines include the following relevant recommendations for colon cancer (v.4.2020): "The panel currently believes that complete cytoreductive surgery and/or intraperitoneal chemotherapy can be considered in experienced centers for selected patients with limited peritoneal metastases for whom R0 resection can be achieved. However, the significant morbidity and mortality associated with HIPEC, as well as the conflicting data on clinical efficacy, make this approach very controversial."<sup>42</sup>

The NCCN guidelines on gastric cancer (v.3.2020) and for uterine neoplasms (v.2.2020), and rectal cancer (v.6.2020) do not discuss cytoreductive surgery (CRS) plus hyperthermic intraperitoneal chemotherapy (HIPEC).<sup>6,43,44</sup>

The NCCN guidelines on ovarian cancer (v.1.2020) state that "patients with low volume residual disease after surgical debulking for stage II or II invasive epithelial ovarian or peritoneal cancer are candidates for intraperitoneal (IP) chemotherapy" and " HIPEC with cisplatin (1 00 mg/m<sup>2</sup>) can be considered at the time of interval debulking surgery for stage III disease."<sup>45</sup>

### American Society of Colon and Rectal Surgeons

In 2017, the practice guidelines on the treatment of colon cancer by the American Society of Colon and Rectal Surgeons stated that treatment of patients with isolated peritoneal carcinomatosis may include CRS in conjunction with perioperative intraperitoneal chemotherapy with or without hyperthermia.<sup>46</sup>

In 2019, the American Society of Colon and Rectal Surgeons guidelines on the management of appendiceal neoplasms state that "in selected patients with appendiceal epithelial neoplasms, intraperitoneal chemotherapy may offer additional benefit for reducing peritoneal disease recurrence compared with CRS alone." The guidelines mention that HIPEC performed concurrently with CRS is the most common method of delivering this intraperitoneal chemotherapy.<sup>47</sup>



## Society of Surgical Oncology

In 2007, the Society of Surgical Oncology issued a consensus statement on CRS and HIPEC in the management of peritoneal surface malignancies of colonic origin.<sup>48</sup> The Society recommended that patients with peritoneal carcinomatosis without distant disease, in whom complete cytoreduction is possible, undergo HIPEC before systemic therapy. As of August 2020, an updated statement has not been published.

## Chicago Consensus Working Group

In 2020, the Chicago Consensus Working Group for the Management of Peritoneal Surface Malignancies published a consensus statement on the management of ovarian neoplasms.<sup>49</sup> The consensus statement mentions HIPEC and includes it in its management pathway for patients with peritoneal metastasis from epithelial ovarian cancer. However, the authors also state that "level I evidence is lacking for HIPEC at the time of primary CRS or for stage IV disease" and "similarly, no level I evidence exists for HIPEC use in patients with rare ovarian histologies." Other consensus statements from this group on appendiceal neoplasms, peritoneal mesothelioma, gastric metastases, and colorectal metastases include CRS plus intraperitoneal chemotherapy or CRS +/- intraperitoneal chemotherapy in their management pathways; however, they do not specify whether this intraperitoneal chemotherapy should be HIPEC or another form of intraperitoneal chemotherapy.<sup>50,51,52,53</sup>

## Medicare National Coverage

There is no national coverage determination.

## Regulatory Status

Mitomycin, oxaliplatin, carboplatin, and other drugs used for HIPEC have not been approved by the U.S. Food and Drug Administration (FDA) for this indication.

Several peritoneal lavage systems (FDA product code: LGZ) have been cleared for marketing by FDA through the 510(k) process to provide "warmed, physiologically compatible sterile solution" (eg, Performer® HT perfusion system; RanD Srl). None has received marketing approval or clearance to administer chemotherapy. The FDA has issued warnings to manufacturers of



devices that are FDA-cleared for peritoneal lavage using sterile saline solutions when these devices are marketed for off-label use in HIPEC (eg, ThermaSolutions<sup>8</sup>; Belmont Instrument,<sup>9</sup>).

**Table 2. Hyperthermic Intraperitoneal Lavage Devices Cleared by the US Food and Drug Administration**

Device	Manufacturer	Date Cleared	510(k) No.	Indication
FluidSmart	THERMEDX LLC	9/5/2017	K172048	For irrigation, distention, fluid warming, and fluid volume/deficit measurements in endoscopic procedures within gynecology, urology, and orthopedic disciplines.
Hang&Go PAC	RanD S.r.l.	12/28/2016	K161613	To recirculate, filtrate and perfuse physiologically compatible sterile solution (ie saline solution) in the thoracic or abdominal cavity
The Belmont Hyperthermia Pump	BELMONT INSTRUMENT CORPORATION	9/2/2015	K152208	To raise the temperature of the thoracic or peritoneal cavity to the desired target temperature by continuously lavaging the cavity with circulating warmed sterile solution

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## History

Date	Comments
10/11/05	Add to Medicine section, Oncology subsection - New Policy



Date	Comments
06/23/06	Update Scope and Disclaimer - No other changes.
07/10/07	Replace policy - Policy updated with literature review; references added. No change in policy statement.
10/9/07	Cross References Updated - No other changes.
07/08/08	Replace policy - Policy updated with literature search; no change to the policy statement. References added.
08/11/09	Replace policy - Policy updated with literature search; no change to the policy statement References added.
12/14/10	Replace policy - Policy updated with literature search; Rationale and Background sections revised extensively. Policy statement added that cytoreduction and hyperthermic intraperitoneal chemotherapy for the treatment of pseudomyxoma peritonei may be considered medically necessary; investigational policy statement clarified to specify that the indication considered is peritoneal carcinomatosis from colorectal cancer. The term, "pseudomyxoma peritonei" was added to the policy title. References 1-8, 10-12, and 17 added; reference 18 updated.
11/08/11	Replace policy – Policy updated with literature search. References 2, 4 and 20 added; references renumbered. Title changed to include peritoneal mesothelioma. Policy statement added that cytoreductive surgery and perioperative intraperitoneal chemotherapy for the treatment of peritoneal mesothelioma, previously not addressed, may be considered medically necessary. Use of the term "hyperthermic" changed to "perioperative" in the title and policy statements to include early postoperative intraperitoneal chemotherapy. Use of the term "cytoreduction" changed to "cytoreductive surgery" to be more specific. CPT codes added.
01/03/12	Deleted code 96445 removed.
12/19/12	Replace policy. Policy updated with literature search. No references added. No change to policy statements. ICD-10 codes are now effective 10/01/2014.
12/09/13	Replace policy. Policy updated with literature search through August 2013, references 18-22, 27, and 28 added; reference 26 updated. No change to policy statements.
03/11/14	Coding Update. Code 99.85 was removed per ICD-10 mapping project; this code is not utilized for adjudication of policy.
12/17/14	Annual Review. Policy updated with literature search; policy statements unchanged. ICD-9 diagnosis and ICD-10 diagnosis and procedure codes removed; these are not utilized in adjudication of the policy.
03/10/15	Annual Review. Policy updated with literature review through January 2, 2015 references 4-8, 10-14, 18-19, 24, 26-35, 43, 51-61, 63-80, and 83-85 added; references 14 and 23-24 deleted. Investigational policy statement for ovarian cancer, peritoneal carcinomatosis due to gastric cancer or endometrial cancer, and for all other indications added. Medically necessary policy statement unchanged. Clarification note added to policy statement regarding perioperative Title changed to "Select Intra-



Date	Comments
	Abdominal and Pelvic Malignancies” to include the additional indications. Clinical trials note added to Benefit Application.
10/01/16	Annual Review, approved September 13, 2016. Policy updated with literature review through June 10, 2016; references 73 and 86 added. Policy statements unchanged.
10/01/17	Annual Review, approved September 5, 2017. Policy updated with literature review through June 6, 2017; references 26 and 33 added. Policy statements unchanged.
10/01/18	Annual Review, approved September 20, 2018. Policy updated with literature review through August 2018; no references added. Policy statements unchanged. Removed CPT codes 77600, 77605, 77610, 77615, and 77620.
02/01/19	Interim Review, approved January 8, 2019. Policy updated with literature review through September 2018; reference 34 added; references 9-10 updated; some references removed. Hyperthermic intraperitoneal chemotherapy may be considered medically necessary for the treatment of newly diagnosed stage III ovarian cancer. Policy title changed from “Cytoreductive Surgery and Perioperative Intraperitoneal Chemotherapy for Select Intra-Abdominal and Pelvic Malignancies” to “Hyperthermic Intraperitoneal Chemotherapy for Select Intra-Abdominal and Pelvic Malignancies”.
01/01/20	Annual Review, approved December 10, 2019. Policy updated with literature review through August 2019; references added; references on NCCN updated. Policy statements unchanged.
01/01/21	Annual Review, approved December 1, 2020. Policy updated with literature review through August 17, 2020; references added. Policy statements unchanged.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2021 Premera All Rights Reserved.

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200 Independence Avenue SW, Room 509F, HHH Building  
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본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

**ລາວ (Lao):**

ແຈ້ງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາຮ້ອງສະໝັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈ້ງການນີ້. ທ່ານອາດຈະຈໍາເປັນຕ້ອງດໍາເນີນການຕາມກຳນົດ ເວລາສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວີ້ ຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄດ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

**ភាសាខ្មែរ (Khmer):**

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចការច្នៃផ្ទះធានា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងអនាគតរបស់អ្នក ឬប្រាក់ដុល្លារចេញថ្លៃ។ អ្នកមានសិទ្ធិទទួលបានព័ត៌មាននេះ និងដុល្លារនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

**ਪੰਜਾਬੀ (Punjabi):**

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

**فارسی (Farsi):**

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیر بران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

**Polskie (Polish):**

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

**Português (Portuguese):**

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

**Română (Romanian):**

Prezenta notificare conține informații importante. Această notificare poate conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

**Русский (Russian):**

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

**Fa'asamoa (Samoan):**

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

**Español (Spanish):**

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

**Tagalog (Tagalog):**

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

**ไทย (Thai):**

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือนี้ในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

**Український (Ukrainian):**

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

**Tiếng Việt (Vietnamese):**

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).