



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Stem-Cell Transplant for Epithelial Ovarian Cancer

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Genetic Testing for Susceptibility to Breast and Ovarian Cancer (BRCA1 and BRCA2)
Prophylactic Oophorectomy With or Without Hysterectomy

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Coverage Policy

CIGNA does not cover autologous or allogeneic hematopoietic stem-cell transplantation (HSCT) for the treatment of epithelial ovarian cancer because they are considered experimental, investigational or unproven.

General Background

According to the American Cancer Society ([ACS],2008), ovarian cancer is the eighth most common cancer among women, excluding non-melanoma skin cancers, and accounts for about 3% of all cancers in women in the United States. The risk of developing this cancer is one in 71 (ACS, 2008), with the risk slightly greater for Caucasian women compared to African-American women. Primarily a cancer that develops in older women, the incidence increases with age; about two-thirds of women who are diagnosed with ovarian cancer are >55 years (ACS, 2008). Approximately 5% to 10% of ovarian cancers are familial; three distinct hereditary patterns have been identified: ovarian cancer alone, ovarian and breast cancers, or ovarian and colon cancers (National Cancer Institute [NCI], 2008a). Most patients with ovarian cancer have widespread disease at presentation (NCI, 2008a; National Comprehensive Cancer Network [NCCN], 2008).

The three major types of ovarian tumors are epithelial tumors, germ cell tumors and stromal tumors. Epithelial tumors begin in the cells that cover the outer surface of the ovary and account for about 85% to 90% of ovarian cancer (ACS, 2008). Epithelial ovarian cancer is the leading cause of death from gynecologic cancer in the U.S.

and the fifth most frequent cause of cancer death in women. Fifty percent of all cases occur in women over the age of 65 years (NCCN, 2009; NCI, 2008a). The majority of ovarian masses in children are not neoplastic (NCI, 2008b).

Ovarian cancer usually spreads via local shedding into the peritoneal cavity followed by implantation on the peritoneum and via local invasion of bowel and bladder. According to the NCI, (2008a) factors indicative of a more favorable prognosis include younger age, good performance status, cell type other than mucinous and clear cell, lower stage, well-differentiated tumor, smaller disease volume prior to surgical debulking, absence of ascites, and smaller residual tumor following primary cytoreductive surgery.

In general, ovarian tumors are classified according to the kind of cells from which the tumor originated and whether the tumor is benign or cancerous. Identification of the type of cancer is important for treatment and prognosis.

Staging

The staging of cancer assists in determining prognosis and making treatment decisions. In the absence of extra-abdominal metastatic disease, definitive staging requires laparotomy. Prognosis is generally better for younger than for older patients. The Federation Internationale de Gynecologie et d'Obstetrique (FIGO) and the American Joint Committee on Cancer (AJCC) have developed a staging system used for ovarian cancer.

Treatment Options: Both the NCI (2008a; NCI, 2008b) and the NCCN (2009) document treatment options for epithelial ovarian cancer; treatment depends on the specific tumor type and stage. Generally, primary treatment for presumed ovarian cancer consists of appropriate surgical staging and cytoreduction, followed in many patients by systemic chemotherapy (NCCN, 2009). Intraperitoneal chemotherapy may also be appropriate for select patients with optimally cytoreduced stage III disease. Treatment of recurrent disease may include combination chemotherapy and cytoreductive surgery. For recurrent or persistent disease, care options include palliative measures. Patients with any stage of ovarian cancer are appropriate candidates for clinical trials (NCI, 2008a).

Stem-Cell Transplantation

Stem-cell transplantation refers to transplantation of hematopoietic stem cells (HSCs) from a donor into a patient. HSCs are immature cells that can develop into any of the three types of blood cells (red cells, white cells or platelets). Hematopoietic Stem-cell transplantation (HSCT) can be either autologous (i.e., using the patient's own stem cells) or allogeneic (i.e., using stem cells from a donor). Tandem HSCT involves performing multiple cycles of chemotherapy and stem-cell transplantation. This method theoretically allows an increase in the total dose of chemotherapy that can be given. Some patients are unable to tolerate the side effects of the chemotherapy cycle and transplantation process and are therefore unable to complete multiple cycles.

Ovarian cancer demonstrates a high response rate to standard-dose chemotherapy. Outcomes of retrospective studies have identified a relationship between dose intensity and response. The use of high-dose chemotherapy with autologous stem-cell support in the treatment of solid organ cancer is based on the hypothesis that major dose escalations within the myeloablative range are needed to overcome tumor cell resistance and produce a meaningful clinical improvement. High-dose chemotherapy and autologous HSCT for epithelial ovarian cancer remains controversial (Papadimitriou, 2007). To date the role of this therapy has not been established as a standard treatment for patients with advanced ovarian cancer; however, it remains an area of active clinical investigation. There are several Phase I/II clinical trials in progress investigating the use of dose escalation as treatment for ovarian cancer. Previous Phase III trials in the U.S. and Europe have failed to accrue sufficient patients.

Theoretically, the graft-versus-tumor effect from allogeneic HSCT may cause regression of disease in patients with solid organ cancers. However, this modality of treatment has not yet been supported by solid clinical evidence that demonstrates its efficacy in the treatment of epithelial ovarian cancer. At this time the role of allogeneic HSCT for the treatment of epithelial ovarian cancer has not been established.

Literature Review

HDC with Autologous Stem-Cell Transplant:

In a randomized controlled trial, Papadimitriou et al. (2007) compared the efficacy and tolerability of high-dose chemotherapy as a consolidation approach in women with chemosensitive advanced epithelial ovarian cancer.

Eighty patients who achieved their first complete remission after six cycles of standard dose chemotherapy were randomly assigned to receive high-dose melphalan or other treatment. Patients not assigned to the high-dose arm were considered the control arm. Of the 37 patients assigned to receive the high-dose therapy, eleven patients (29%) did not receive high-dose therapy. In an intent-to-treat analysis, there were no significant differences between the two arms in time to progression ($p=0.59$) or overall survival ($p=0.38$). In this trial, high-dose chemotherapy failed to yield a statistically significant improvement in outcome. These results should be treated with caution given the small study population and that patients in the control arm were not treated with conventional dose consolidation chemotherapy.

Two hundred-eighteen patients were registered with the European Bone Marrow Transplant Solid Tumour Registry (EBMT) with a diagnosis of epithelial ovarian cancer in first complete remission treated with high-dose chemotherapy and autologous HSCT. To better define the subset of patients who might benefit from high-dose chemotherapy, Bengala et al. (2005) sent questionnaires to the treating physicians. Seventeen variables were analyzed, including performance status, stage at presentation, residual disease after cytoreductive surgery, histology, histological grade, type of induction chemotherapy, response to induction, high-dose regimen, schedule, source of cells, year of transplant, number of cells transplanted, and use of growth factor support. Data were received on 91 (40%) of patients, and a retrospective analysis was performed. Analysis of the recognized prognostic parameters failed to identify subgroups that significantly benefited from high-dose consolidation; however, median survival of patients with no residual disease has not been reached. This retrospective analysis did not use a comparison group and suffered from a low-response rate (40%).

Stiff (2004) conducted a randomized controlled trial of 58 women with stage III or stage IV persistent or recurrent ovarian cancer. Participants were assigned to receive high-dose carboplatin, mitoxantrone and cyclophosphamide (CMC) or high-dose cisplatin, thiotepa and cyclophosphamide (CTC); both chemotherapy regimens were followed by autologous HSCT. Progression-free survival rates were 13 months and eight months for CMC and CTC, respectively. Overall survival rates were 29 months and 22 months for CMC and CTC, respectively.

Donato et al. (2004) analyzed the results of 96 patients with epithelial ovarian cancer who received high-dose chemotherapy with peripheral blood stem-cell transplantation. Various chemotherapy regimens were utilized in the studies. The six-year overall survival was 38%. For the 41 patients who received transplant for remission consolidation, the six-year overall survival was 53%, with progression-free survival of 29%. The availability of only Phase II data makes it difficult to conclude that one treatment regimen is superior over the other. Since there is no standard or clearly superior treatment of patients in clinical remission, continued participation in clinical trials is recommended by the study authors.

High-dose chemotherapy followed by autologous HSCT was given to patients with advanced ovarian cancer who had undergone surgical treatment but had not had previous chemotherapy to treat their disease. Complete response rates were low (12.5%); 11 of 45 cycles of the protocol therapy resulted in hospitalizations. The researchers noted that the high treatment-related morbidity and low efficacy of the therapy did not support continuing, and the study was closed early (Schilder, 2003).

Stiff (2000) analyzed data from the Autologous Blood and Marrow Transplant Registry (ABMTR) on 421 women who received high-dose chemotherapy followed by autologous HSCT. Eighty percent of the women had stage III or stage IV disease, and most of the women had received previous chemotherapy. Two-year progression-free survival and overall survival rates were 12% and 35%, respectively. Treatment-related mortality was 11%. Prognostic factors associated with better outcomes were the same for patients receiving standard-dose chemotherapy.

Sequential High-Dose Chemotherapy and Autologous HSCT:

Several case series have reported on the use of tandem cycles of high-dose chemotherapy with autologous HSCT in patients with stage III to stage IV ovarian cancer. Mobus et al. (2007) reported the results of a randomized controlled trial comparing sequential high-dose chemotherapy (i.e. five cycles) with HSCT support with standard dose chemotherapy. Ninety percent of the patients received at least three cycles of high-dose chemotherapy. After a median follow-up of 38 months, there was no significant difference in progression-free survival or overall survival between the two groups. High-dose chemotherapy does not appear to be superior to conventional dose chemotherapy.

Goncalves (2006) reported the results of a clinical trial investigating the feasibility, toxicity and efficacy of postoperative front-line sequential high-dose chemotherapy with autologous HSCT in 34 patients with advanced ovarian cancer. The observed pathological complete response was 37%, and the initial endpoint was not reached. The observed does not support a clear advantage over conventional therapy.

Twenty-one women with advanced or relapsed ovarian cancer were treated with up to three cycles of high-dose chemotherapy (Boiko, 2001). The overall response rate was 72%; 48% had a complete response and 24% had a partial response. The mean time-to-progression was seven months, with mean overall survival of 32 months. Similar results were found in other small-case series of women with either advanced or recurrent ovarian cancer treated with a variety of high-dose protocols followed by autologous HSCT (Prince, et al., 2001; Schilder, 2001; Viret, et al., 2002; Ikeba, et al., 2004).

Allogeneic Stem-Cell Transplant:

Studies evaluating allogeneic stem-cell transplantation for ovarian cancer have been designed to use the graft-versus-tumor effect to eliminate malignant host cells. These studies have been limited to individual cases and small-case series. Patient selection has primarily targeted patients with advanced refractory disease who have exhausted all other options, including treatment with high-dose chemotherapy with autologous HSCT. Reported outcomes include slow disease regression followed by disease relapse in a majority of patients (Donato, 2004; Hanel, 2003; Bay, 2002).

Professional Societies/Organizations

The National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology for Ovarian Cancer (2009) note that regarding epithelial ovarian cancer panel members discussed the issue of dose intensification utilizing high-dose chemotherapy with peripheral blood stem cell transplantation in selected patients with previously untreated ovarian cancer, or as a consolidation strategy after induction therapy with standard drug doses. The Guidelines note that “The consensus of the panel is that this approach remains investigational and should not be performed outside of an approved clinical trial.”

Summary

There is insufficient evidence in the published, peer-reviewed medical literature to support the use of autologous or allogeneic hematopoietic stem-cell transplantation (HSCT) for the treatment of epithelial ovarian cancer.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT[®]* Codes	Description
38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage
38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing
38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing
38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, T-cell depletion
38211	Transplant preparation of hematopoietic progenitor cells; tumor cell depletion
38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal
38213	Transplant preparation of hematopoietic progenitor cells; platelet depletion
38214	Transplant preparation of hematopoietic progenitor cells; plasma (volume)

	depletion
38215	Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer
38230	Bone marrow harvesting for transplantation
38240	Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic
38241	Bone marrow or blood-derived peripheral stem cell transplantation; autologous
38242	Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic donor lymphocyte infusions

HCPCS Codes	Description
S2140	Cord blood harvesting for transplantation, allogeneic
S2142	Cord blood-derived stem cell transplantation, allogeneic
S2150	Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including pheresis and cell preparation/storage; marrow ablative therapy; drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days or pre-and post-transplant care in the global definition

ICD-9-CM Diagnosis Codes	Description
183.0	Malignant neoplasm of ovary and other uterine adnexa; ovary
198.6	Secondary malignant neoplasm of other specified sites; ovary

*Current Procedural Terminology (CPT®) © 2008 American Medical Association: Chicago, IL.

References

1. American Cancer Society (ACS). Ovarian cancer. Updated 2008 Aug 29. Accessed Mar 3, 2009. Available at URL address: <http://documents.cancer.org/114.00/114.00.pdf>
2. Bay JO, Fleury J, Choufi B, Tournilhac O, Vincent C, Bailly C, et al. Allogeneic hematopoietic stem cell transplantation in ovarian carcinoma: results of five patients. *Bone Marrow Transplant.* 2002;30:95-102.
3. Bengala C, Guarneri V, Ledermann J, Rosti G, Wandt H, Lotz J-P, et al. High-dose chemotherapy with autologous haemopoietic support for advanced ovarian cancer in first complete remission: retrospective analysis from the solid tumour registry of the european group for blood and marrow transplantation (EBMT). *Bone Marrow Transplant.* 2004;36:25-31.
4. Bojko P, Scheulen ME, Hilger R, Oberhoff C, Schindler AE, Seeber S. High-dose chemotherapy with peripheral blood stem cell transplantation for patients with advanced ovarian cancer. *J Cancer Res Clin Oncol.* 2001;127:243-50.
5. Donato ML, Aleman A, Champlin RE, Saliba RM, Wharton JT, Burke TW, et al. Ovarian Cancer: analysis of 96 patients with advanced ovarian carcinoma treated with high-dose chemotherapy and autologous stem cell transplantation. *Bone Marrow Transplant.* 2004;33:1219-1224.
6. Donato ML, Levenback C, Gershenson DM, McMeekin S, Champlin RE. Matched unrelated donor bone marrow transplantation for the treatment of platinum refractory ovarian carcinoma: a case report. *Gynecol Oncol.* 2004;97:365-7.
7. ECRI Institute. High-dose chemotherapy with autologous bone marrow or peripheral stem cell transplant for epithelial ovarian cancer. Plymouth Meeting (PA): ECRI Institute Health Technology Assessment

Information Service; 2004 Dec. 57 p. (Evidence Report; no. 117). Available at URL address: www.ecri.org.

8. Goncalves A, Delva R, Fabbro M, Gladeiff L, Lotz JP, Ferrero JM, et al. Post-operative sequential high-dose chemotherapy with haematopoietic stem cell support as front-line treatment in advanced ovarian cancer: a phase II multicentre study.
9. Hanel M, Bornhauser M, Muller J, Thiede C, Ehninger G, Kroschinsky F. Evidence for a graft-versus-tumor effect in refractory ovarian cancer. *J Cancer Res Clin Oncol*. 2003;129:12-6.
10. Ikeba K, Okubo M, Takeda S, Kinoshita K, Maeda H. Five-year results of cyclic semi-high dose neoadjuvant chemotherapy supported by autologous peripheral blood stem-cell transplantation in patients with advanced ovarian cancer. *Int J Clin Oncol*. 2004;9:113-9.
11. Karlan BY, Markman MA, Eifel PJ. Ovarian Cancer, Peritoneal Carcinoma, and Fallopian Tube Carcinoma. In: DeVita, Jr. VT, Hellman S, Rosenberg SA, editors. *Cancer: Principles & Practice of Oncology*. Philadelphia: Lippincott Williams & Wilkins; 2005.
12. Markman M, Bookman MA. Second-line treatment of ovarian cancer. *Oncologist*. 2000;5(1):26-35.
13. Markman M, Walker JL. Intraperitoneal chemotherapy of ovarian cancer: a review, with a focus on practical aspects of treatment. *J Clin Oncol*. 2006 Feb 20;24(6):1-7.
14. Mobus V, Wandt H, Frickhofen N, Bengala C, Champion K, Kimmig R, et al. Phase III trial of high-dose sequential chemotherapy with peripheral blood stem cell support compared with standard dose chemotherapy for first-line treatment of advanced ovarian cancer: intergroup trial of the AGO-Ovar/AIO and EBMT. *J Clin Oncol*. 2007 Sep 20;25(27):4187-93. Epub 2007 Aug 13.
15. National Cancer Institute (NCI) (a) . Ovarian epithelial cancer (PDQ[®]): treatment [health professional version]. Updated 2008 Jul 18. Accessed Mar 3, 2009. Available at URL address: <http://www.cancer.gov/cancertopics/pdq/treatment/ovarianepithelial/healthprofessional>
16. National Cancer Institute (NCI) (b). Ovarian germ cell tumors: treatment [health professional version]. Updated 2008 May 22. Accessed Mar 3, 2009. Available at URL address: <http://www.cancer.gov/cancertopics/pdq/treatment/ovarian-germ-cell/healthprofessional>
17. National Cancer Institute (NCI). Unusual cancers of childhood: treatment [health professional version]. Updated 2009 Feb 26. Accessed Mar 3, 2009. Available at URL address: http://www.cancer.gov/cancer_information/doc.aspx?viewid=F442B3FF-3213-40D9-8D90-7F6CAA3AB10&version=1
18. National Comprehensive Cancer Network (NCCN). Ovarian cancer: clinical practice guidelines in oncology. V.1.2009. Updated 2009 Feb 2. Accessed Mar 3, 2009. Available at URL address: http://www.nccn.org/professionals/physician_gls/PDF/ovarian.pdf
19. Papadimitriou C, Dafni U, Anagnostopoulos A, Vlachos G, Voulgaris Z, Rodolakis A, et al. High-dose melphalan and autologous stem cell transplantation as consolidation treatment in patients with chemosensitive ovarian cancer: results of a single-institution randomized trial. *Bone Marrow Transplant*. 2007 Nov 19; [Epub ahead of print]
20. Prince HM, Rischin D, Quinn M, Allen D, Planner R, Neesham D, et al. Repetitive high-dose topotecan, carboplatin, and paclitaxel with peripheral blood progenitor cell support in previously untreated ovarian cancer: results of a phase I study. *Gynecol Oncol*. 2001;81:216-24.
21. Schilder RJ, Brady MF, Spriggs D, Shea T. Pilot evaluation of high-dose carboplatin and paclitaxel followed by high-dose melphalan supported by peripheral blood stem cells in previously untreated advanced ovarian cancer: a Gynecologic Oncology Group study. *Gynecol Oncol*. 2003;88:3-8.

22. Schilder RJ, Gallo JM, Millenson MM, Bookman MA, Weiner LM, Rogatko A, et al. Phase I trial of multiple cycles of high-dose carboplatin, paclitaxel, and topotecan with peripheral-blood stem-cell support as front-line therapy. *J Clin Oncol*. 2001 Feb 15;19(4):1183-94.
23. Stiff PJ, Shpall EJ, Liu PY, Wilczynski SP, Callander NS, Scudder SA, et al. Randomized phase II trial of two high-dose chemotherapy regimens with stem cell transplantation for the treatment of advanced ovarian cancer in first remission or chemosensitive relapse: a Southwest Oncology Group study. *Gynecol Oncol*. 2004;94:98-106.
24. Stiff PJ, Veum-Stone J, Lazarus HM, Ayash L, Edwards JR, Keating A, et al. High-dose chemotherapy and autologous stem-cell transplantation for ovarian cancer: an Autologous Blood and Marrow Transplant Registry report. *Ann Intern Med*. 2000;133:504-56.
25. Thigpen JT. Ovaries and Fallopian Tubes. In: Abeloff MD, Armitage JO, Lichte AS, Niederhuber JE, editors. *Clinical oncology*, 3rd ed. New York: Churchill Livingstone; 2004.
26. Viret F, Bertucci F, Genre D, Gravis G, Chabannon C, Conte M, et al. Intensive sequential dose dense chemotherapy with stem cell support as first-line treatment in advanced ovarian carcinoma: a phase II study. *Bone Marrow Transplant*. 2002;30:879-84.
27. Walker JL, Armstrong DK, Huang HQ, Fowler J, Webster K, Burger RA, et al. Intraperitoneal catheter outcomes in a phase III trial of intravenous versus intraperitoneal chemotherapy in optimal stage III ovarian and primary peritoneal cancer: a gynecologic oncology group study. *Gynecol Oncol* . 2006;100:27-32.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	4/15/2008	0321	Stem-Cell Transplant for Epithelial Ovarian Cancer

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