The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is required and must be obtained through Case Management.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

### Description
The use of hematopoietic stem-cell transplantation (HSCT) has been investigated for treatment of patients with epithelial ovarian cancer. Hematopoietic stem cells are infused to restore bone marrow function following cytotoxic doses of chemotherapeutic agents with or without whole-body radiation therapy.

### Background
**Hematopoietic Stem-Cell Transplantation**

Hematopoietic stem-cell transplantation (HSCT) refers to a procedure in which hematopoietic stem cells are infused to restore bone marrow function in cancer patients who receive bone-marrow-toxic doses of cytotoxic drugs with or without whole body radiation therapy. Bone marrow stem cells may be obtained from the transplant recipient (autologous HSCT) or from a donor (allogeneic HSCT). They can be harvested from bone marrow, peripheral blood, or umbilical cord blood and placenta shortly after delivery of neonates. Although cord blood is an allogeneic source, the stem cells in it are antigenically “naïve” and thus are associated with a lower incidence of rejection or graft-versus-host disease (GVHD).

HSCT is an established treatment for certain hematologic malignancies; however, its use in solid tumors in adults continues to be largely experimental. Initial enthusiasm for the use of autologous transplant with the use of high-dose chemotherapy and stem cells for solid tumors has waned with the realization that dose intensification often fails to improve survival, even in tumors with a linear-dose response to chemotherapy. With the advent of reduced-intensity conditioning (RIC) allogeneic transplant, interest has shifted to exploring the generation of alloreactivity to metastatic solid tumors via a graft-versus-tumor (GVT) effect of donor-derived T cells.

**Epithelial Ovarian Cancer**

Several different types of malignancies can arise in the ovary; epithelial carcinoma is the most common. Epithelial ovarian cancer is the fifth most common cause of cancer death in women. New cases and deaths from ovarian cancer in the United States in 2012 are estimated at 22,280 and 15,500, respectively. (1) Most ovarian cancer patients present with widespread disease, and yearly mortality is approximately 65% of the incidence rate.

Current management of advanced epithelial ovarian cancer is cytoreductive surgery followed by combination chemotherapy. (2) Approximately 75% of patients present with International Federation of Gynecology and Obstetrics (FIGO) stage III or IV ovarian cancer and are treated with the combination of paclitaxel and a platinum analog being the preferred regimen for newly diagnosed advanced disease. (3, 4) The use of platinum and taxanes has improved progression-free survival (PFS) and overall survival (OS) rates in advanced disease to 16–
21 months and 32–57 months, respectively. (3) However, most of these women develop recurrences and die of the disease as chemotherapy drug resistance leads to uncontrolled cancer growth. (4)

High-dose chemotherapy (HDC) has been investigated as a way to overcome drug resistance. However, limited data exist on this treatment approach; the ideal patient population and best regimen remain to be established. (4) HSCT has been studied in a variety of patient groups with ovarian cancer as follows:

- to consolidate remission after initial treatment
- to treat relapse after a durable response to platinum-based chemotherapy
- to treat tumors that relapsed after less than six months
- to treat refractory tumors

**Related Protocols**

Hematopoietic Stem-Cell Transplantation in the Treatment of Germ-Cell Tumors

Hematopoietic Stem-Cell Transplantation for Miscellaneous Solid Tumors in Adults

**Policy (Formerly Corporate Medical Guideline)**

Autologous or allogeneic hematopoietic stem-cell transplantation is considered **investigational** to treat epithelial ovarian cancer.

Stem-cell transplantation to treat germ cell tumors of the ovary is considered separately in Protocol Hematopoietic Stem-Cell Transplantation in the Treatment of Germ-Cell Tumors.

**Medicare Advantage**

If a transplant is needed, we arrange to have the transplant center review and decide whether the patient is an appropriate candidate for the transplant.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. **For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.**

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

**References**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


5. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). High-dose chemotherapy with autologous stem-cell support for epithelial ovarian cancer. TEC Assessments 1998; Volume 13, Tab 6.

6. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Salvage high-dose chemotherapy with allogeneic stem cell support for relapse following high-dose chemotherapy with autologous stem cell support for non-lymphoid solid tumors. TEC Assessments 1999; Volume 14, Tab 11.


