

09-J0000-93

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## Subject: Carboplatin (Paraplatin®) Injection

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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### DESCRIPTION:

Carboplatin (Paraplatin) was approved by the US Food and Drug Administration (FDA) in 1989 for the treatment of ovarian cancer. The efficacy and safety of carboplatin has been studied in a variety of other cancers and its use in treatment of other cancers is supported by referenced compendia.

Carboplatin is platinum compound related to cisplatin; however, carboplatin has a more favorable adverse effect profile, which has led to the investigation of the replacement of cisplatin with carboplatin in many regimens. The two agents share a similar mechanism of action and exert their cytotoxic activity by binding with DNA to form intrastrand crosslinks and adducts. This process changes the conformation of DNA and affects DNA replication and ultimately results in cell cycle arrest in the G2-phase and then programmed cell death, or apoptosis.

### POSITION STATEMENT:

Carboplatin (Paraplatin®) IV **meets the definition of medical necessity** when administered for any of the following indications and the dosage does not exceed 360 mg/meter squared or alternately, dose derived from formula dosing (Total dose (mg) = (target AUC) × (GFR + 25):

- Advanced ovarian carcinoma
- Bladder cancer (including renal pelvis and ureter)
- Bone cancer
- Breast cancer
- Cervical cancer
- CNS cancers
- Esophageal cancer
- Gastric cancer

- Head and neck cancers
- Hodgkin's lymphoma
- Kidney cancer
- Malignant pleural mesothelioma
- Neuroendocrine tumors
- Non melanoma skin cancers
- Non small cell lung cancer
- Non-Hodgkin's lymphoma
- Occult primary
- Penile cancer
- Prostate cancer
- Rhabdomyosarcoma
- Small cell lung cancer
- Testicular cancer
- Thymomas and Thymic carcinomas
- Uterine neoplasms/endometrial carcinomas

## **DOSAGE/ADMINISTRATION:**

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

**FDA-approved:** carboplatin is indicated for initial treatment of advanced ovarian carcinoma and secondary treatment of advanced ovarian carcinoma. In addition, its use is supported by referenced compendium for several other off-label indications.

### **Single-Agent Therapy**

Carboplatin, as a single agent, has been shown to be effective in individuals with recurrent ovarian cancer at a dosage of 360 mg/m<sup>2</sup> IV on day 1 every 4 weeks. **Combination Therapy with Cyclophosphamide**

- Effective combination therapy for the treatment of advanced ovarian cancer includes
- Carboplatin – 300 mg/m<sup>2</sup> IV on day 1 every 4 weeks for 6 cycles.
- Cyclophosphamide – 600 mg/m<sup>2</sup> on day 1 every 4 weeks for 6 cycles

Intermittent courses of carboplatin, either as a single-agent or in combination with cyclophosphamide should not be repeated until the neutrophil count is at least 2,000 and the platelet count is at least 100,000.

### **Dose Adjustments**

- **Renal Impairment**
  - Baseline creatinine clearance (CrCl) 41-59 ml/min – 250 mg/m<sup>2</sup> on day 1
  - Baseline CrCl 16-40 ml/min – 200 mg/m<sup>2</sup> on day 1
  - Dosing recommendations apply to the initial course of treatment; subsequent dosages should be adjusted according to the person's tolerance based on the degree of bone marrow suppression.
  - Recommendations for dosing in persons with severe renal impairment (CrCl less than 15 ml/min) are unavailable.
- **Bone marrow suppression**

**Table 1**

<b>Table 1: Dose modifications for bone marrow suppression</b>
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Platelet Count (cells/mm3)	Neutrophils ((cells/mm3)	Adjusted Dose† (From prior course)
Greater than 100,000	Greater than 2,000	125%
50-100,000	500 to 2,000	No adjustment
Less than 50,000	Less than 500	75%
† Percentages apply to carboplatin injection as a single agent or to both carboplatin and cyclophosphamide in combination.		

**Drug Availability:** carboplatin is supplied as 600 mg/60 mL multi-dose vial.

## PRECAUTIONS:

### Boxed Warning:

- Carboplatin should be administered under the supervision of a qualified physician experienced in the use of chemotherapeutic agents
- Bone marrow suppression is dose related and may be severe, resulting in infection and/or bleeding. Anemia may be cumulative and may require transfusion support. Vomiting is another frequent drug related side effect.
- Anaphylactic-like reactions to carboplatin have been reported and may occur within minutes of product administration. Epinephrine, corticosteroids, and antihistamines have been used to alleviate symptoms.

### Contraindications:

- Carboplatin is contraindicated in persons with a history of severe allergic reactions to cisplatin or other platinum-containing compounds.
- Carboplatin should not be used in persons with severe bone marrow suppression or significant bleeding.

### Warnings:

- **Bone marrow suppression:** leukopenia, neutropenia, and thrombocytopenia is dose dependent and is also a dose-limiting toxicity. Monitor complete blood counts (CBC).
- **Emesis:** incidence and intensity of emesis has been reduced by premedication with antiemetics.
- **Nephrotoxicity:** avoid concomitant use with other nephrotoxic agents (e.g., aminoglycosides)
- **Ototoxicity:** clinically significant hearing loss has been reported in pediatric persons when carboplatin was administered at a higher than recommended dose.
- **Peripheral neurotoxicity:** incidence is increased in persons over the age of 65 and in persons previously treated with cisplatin.
- **Pregnancy Category D:** there are no adequate and well-controlled studies in pregnant women. Women of childbearing age should be advised to avoid becoming pregnant.

## BILLING/CODING INFORMATION:

### HCPCS Coding:

J9045	Injection, carboplatin, 50mg
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### ICD-10 Diagnosis Codes That Support Medical Necessity:

C00.0 – C06.9	Malignant neoplasm of lip, base of tongue and other unspecified parts of the tongue, gum, floor of mouth, palate and other unspecified parts of mouth
C09.0	Malignant neoplasm of tonsillar fossa
C09.1	Malignant neoplasm of tonsillar pillar

C09.9	Malignant neoplasm of tonsil, unspecified
C10.3	Malignant neoplasm of posterior wall of oropharynx
C11.0 – C16.9	Malignant neoplasm of nasopharynx, pyriform sinus, hypopharynx, other and ill-defined sites in the lip, oral cavity and pharynx, esophagus and stomach
C31.0 – C31.1	Malignant neoplasm of maxillary sinus and ethmoidal sinus
C32.0 – C37	Malignant neoplasm of larynx, trachea, bronchus and lung and thymus
C38.4	Malignant neoplasm of pleura
C40.00 – C43.9	Malignant neoplasm of bone and articular cartilage of limbs, articular cartilage of other and unspecified sites, melanoma of skin, Merkel cell carcinoma and other malignant neoplasm of skin
C44.01	Basal cell carcinoma of skin of lip
C44.111	Basal cell carcinoma of skin of unspecified eyelid, including canthus
C44.211	Basal cell carcinoma of skin of unspecified ear and external auricular canal
C44.310	Basal cell carcinoma of skin of unspecified parts of face
C44.311	Basal cell carcinoma of skin of nose
C44.319	Basal cell carcinoma of skin of other parts of face
C44.41	Basal cell carcinoma of skin of scalp and neck
C44.510	Basal cell carcinoma of anal skin
C44.511	Basal cell carcinoma of skin of breast
C44.519	Basal cell carcinoma of skin of other part of trunk
C44.611	Basal cell carcinoma of skin of unspecified upper limb, including shoulder
C44.711	Basal cell carcinoma of skin of unspecified lower limb, including hip
C44.81	Basal cell carcinoma of overlapping sites of skin
C44.91	Basal cell carcinoma of skin, unspecified
C48.0 – C48.8	Malignant neoplasm of retroperitoneum and peritoneum
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C50.011 – C50.929	Malignant neoplasm of breast
C53.0 – C54.9	Malignant neoplasm of cervix uteri and corpus uteri
C56.0 – C57.4	Malignant neoplasm of fallopian tube, broad ligament, round ligament, parametrium and uterine adnexa, unspecified
C60.0	Malignant neoplasm of prepuce
C60.1	Malignant neoplasm of glans penis
C60.2	Malignant neoplasm of body of penis
C60.8	Malignant neoplasm of overlapping sites of penis
C60.9	Malignant neoplasm of penis, unspecified
C61 – C62.92	Malignant neoplasm of prostate and testis
C63.7	Malignant neoplasm of other specified male genital organs
C63.8	Malignant neoplasm of overlapping sites of male genital organs
C65.0 – C67.9	Malignant neoplasm of renal pelvis, ureter and bladder
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7B.1	Secondary Merkel cell carcinoma
C71.0 – C71.9	Malignant neoplasm of brain
C72.9	Malignant neoplasm of central nervous system, unspecified
C74.90 – C74.92	Malignant neoplasm of adrenal gland, unspecified
C7A.091	Malignant carcinoid tumor of the thymus
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7B.00	Secondary carcinoid tumors, unspecified site

C7B.1	Secondary Merkel cell carcinoma
C73	Malignant neoplasm of thyroid gland
C76.0	Malignant neoplasm of head, face and neck
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck
C78.00 – C78.02	Secondary malignant neoplasm of lung
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.70 – C79.72	Secondary malignant neoplasm of unspecified adrenal gland
C79.89	Secondary malignant neoplasm of other specified sites
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
C81.00 – C81.49	Hodgkin lymphoma
C81.90 – C81.99	Hodgkin lymphoma, unspecified
C82.90 – C82.99	Follicular lymphoma, unspecified
C83.10 – C83.39	Mantle cell lymphoma and diffuse large B-cell lymphoma
C83.70 – C83.79	Burkitt lymphoma
C83.80 – C84.09	Other follicular and non-follicular and mycosis fungoides
C84.40 – C84.79A	Peripheral T-cell lymphoma, not classified, Anaplastic large cell lymphoma, ALK-positive and anaplastic large cell lymphoma, ALK-negative
C85.80 – C85.89	Other specified types of non-Hodgkin lymphoma
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell in relapse
C91.90	Lymphoid leukemia, unspecified not having achieved remission
C91.92	Lymphoid leukemia, unspecified, in relapse
D03.0 – D03.9	Melanoma in situ
D09.9	Carcinoma in situ, unspecified
D15.0	Benign neoplasm of thymus
D37.01	Neoplasm of uncertain behavior of lip
D37.02	Neoplasm of uncertain behavior of tongue
D37.04	Neoplasm of uncertain behavior of the minor salivary glands
D37.05	Neoplasm of uncertain behavior of pharynx
D37.1	Neoplasm of uncertain behavior of stomach
D37.2	Neoplasm of uncertain behavior of small intestines
D37.4	Neoplasm of uncertain behavior of colon
D37.5	Neoplasm of uncertain behavior of rectum
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
D38.0	Neoplasm of uncertain behavior of larynx
D43.2	Neoplasm of uncertain behavior of brain, unspecified
D43.4	Neoplasm of uncertain behavior of spinal cord
G73.1	Lambert-Eaton syndrome
Z80.49	Family history of malignant neoplasm of other genital organs
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.020	Personal history of malignant carcinoid tumor of stomach
Z85.028	Personal history of other malignant neoplasm of stomach

Z85.030	Personal history of malignant carcinoid tumor of large intestine
Z85.040	Personal history of malignant carcinoid tumor of rectum
Z85.060	Personal history of malignant carcinoid tumor of small intestine
Z85.110	Personal history of malignant carcinoid tumor of bronchus and lung
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.230	Personal history of malignant carcinoid tumor of thymus
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary
Z85.46	Personal history of malignant neoplasm of prostate
Z85.47	Personal history of malignant neoplasm of testis
Z85.520	Personal history of malignant carcinoid tumor of kidney
Z85.71	Personal history of Hodgkin lymphoma
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues
Z85.821	Personal history of Merkel cell carcinoma
Z85.828	Personal history of other malignant neoplasm of skin
Z85.830	Personal history of malignant neoplasm of bone
Z85.841	Personal history of malignant neoplasm of brain
Z85.858	Personal history of malignant neoplasm of other endocrine glands

### **REIMBURSEMENT INFORMATION:**

Refer to section entitled [POSITION STATEMENT](#).

### **PROGRAM EXCEPTIONS:**

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Advantage Products:** No National Coverage Determination (NCD) was found at the time of the last guideline revised date. The following Local Coverage Determination (LCD) was reviewed on the last guideline revised date: Carboplatin (Paraplatin, Paraplatin-AQ), (L33275) located at fcso.com.

### **DEFINITIONS:**

No guideline specific definitions apply.

### **RELATED GUIDELINES:**

[Rituximab \(Rituxan®\), 09-J0000-59](#)

[Off-Label Use of FDA Approved Drugs, 09-J0000-68](#)

[Azacitidine \(Vidaza®\) Injection, 09-J0000-84](#)

[Trastuzumab \(Herceptin®\) Injection, 09-J0000-86](#)

[Octreotide Acetate \(Sandostatin LAR® Depot\) Injection, 09-J0000-90](#)

[Doxorubicin HCl Liposome \(Doxil®\) IV, 09-J0000-91](#)

[Bortezomib \(Velcade®\) IV, 09-J0000-92](#)

[Docetaxel \(Taxotere®\) IV, 09-J0000-95](#)

[Gemcitabine \(Gemzar®\), 09-J0000-96](#)

[Irinotecan HCl \(Camptosar®\) IV, 09-J0000-99](#)

[Oxaliplatin \(Eloxatin®\) IV, 09-J1000-00](#)

[Pemetrexed \(Alimta®\) IV, 09-J1000-01](#)

[Topotecan HCl \(Hycamtin®\) IV, 09-J1000-02](#)

[Vinorelbine Tartrate \(Navelbine®\) IV, 09-J1000-03](#)

[Fulvestrant \(Faslodex®\) IM, 09-J1000-04](#)

### **OTHER:**

None applicable.

### **REFERENCES:**

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2. DRUGDEX®. Accessed 01/30/13.
3. Facts & Comparisons® E Answers. Accessed 02/02/12.
4. Ingenix, HCPCS Level II, Expert 2011.
5. Ingenix, ICD-9-CM for Physicians-Volumes 1 & 2, Expert, 2011.
6. NCCN Drugs & Biologics Compendium™. Accessed 01/30/13.
7. Paraplatin® Prescribing Information. Revised August 2012.

### **COMMITTEE APPROVAL:**

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 01/15/14.

### **GUIDELINE UPDATE INFORMATION:**

04/15/09	New Medical Coverage Guideline.
10/01/09	Revision; consisting of modifying maximum dosage.
10/15/09	Revision; consisting of adding 2 new indications and updating coding.
01/15/10	Revision; consisting of updating coding.
04/15/10	Review and revision; consisting of updating codes and references.
08/01/10	Revision; consisting of updating coding.
04/15/11	Review and revision to guideline; consisting of updating references.
04/15/12	Review and revision to guideline; consisting of updating precautions, coding and references.
10/15/12	Revision to guideline; consisting of removing melanoma indication and adding penile cancer indication.
12/15/12	Revision to guideline; consisting of updating coding.

04/15/13	Review and revision to guideline; consisting of revising position statement to include treatment of gastric cancer, kidney cancer, and thymomas and thymic cancers as medically necessary; revised and reformatted description, dosage/administration, and precautions section; updated coding and references.
12/15/13	Revision to guideline; consisting of adding new indication and updating coding.
02/15/14	Revision to guideline; consisting of adding and removing neuroendocrine tumor codes.
10/01/15	Revision consisting of update to Program Exceptions section.
10/01/21	ICD10 code update