FDA APPROVED ONCOLOGY AGENTS NOT LISTED IN SEER BOOK 8

Adapted from: "Listing of Approved Oncology Drugs with Approved Indications," U.S. Food and Drug Administration Center for Drug Evaluation and Research; http://www.fda.gov/cder/cancer/druglistframe.htm. Information complete as of 5/17/02.

Drugs are listed in alphabetical order by **generic name**. **Brand names** are listed in the second column. **Category** refers to the correct cancer registry treatment data field. These drugs may be used for other indications; only FDA-approved uses are listed. ***Please notify the SEER Program of any other drugs not in SEER Book 8.***

Generic Drug Name	Drug Trade (Brand) Name	Category	Approved Use
alitretinoin	Panretin	Differentiation-inducing agent--DO NOT CODE	Topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma.
altretamine	Hexalen	Chemo	Single agent palliative treatment of patients with persistent or recurrent ovarian cancer following first-line therapy with a cisplatin and/or alkylating agent based combination.
alemtuzumab	Campath	Immunotherapy	Treatment of patients with B-cell chronic lymphocytic leukemia who have been treated with alkylating agents and have failed fludarabine therapy.
amifostine	Ethyol	Ancillary DO NOT CODE	To reduce the cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced ovarian cancer; Reduction of platinum toxicity in non-small cell lung cancer; To reduce post-radiation xerostomia for head and neck cancer where the radiation port includes a substantial portion of the parotid glands.
anastrozole	Arimidex	Hormone/anti-estrogen (aroma-tase inhibitor)	Treatment of advanced breast cancer in postmenopausal women with disease progression following tamoxifen therapy; For first-line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer.
arsenic trioxide	Trisenox	Chemo	Second line treatment of relapsed or refractory APL following ATRA plus an anthracycline.
BCG, live	Pacis	Immunotherapy	Treatment of carcinoma in situ (CIS) in the absence of associated invasive cancer of the bladder.
bexarotene	Targretin (LGD 1069)	Immunotherapy	Induces regression of hematopoietic and squamous tumor cell lines. For the treatment by oral capsule of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy; For the topical treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.
capecitabine	Xeloda	Chemo	Treatment of metastatic breast cancer resistant to both paclitaxel and an anthracycline containing chemotherapy regimen or resistant to paclitaxel and for whom further anthracycline therapy may be contraindicated, e.g., patients who have received cumulative doses of doxorubicin or doxorubicin equivalents; Initial therapy of patients with metastatic colorectal carcinoma when treatment with fluoropyrimidine therapy alone is preferred

carmustine with Polifepro-san 20 Implant	Gliadel Wafer	Chemo	For use in addition to surgery to prolong survival in patients with recurrent glioblastoma multiforme who qualify for surgery.
cytarabine liposomal	DepoCyt	Chemo	Intrathecal therapy of lymphomatous meningitis
daunorubicin liposomal	DaunoXome	Chemo	First line cytotoxic therapy for advanced, HIV related Kaposi's sarcoma.
denileukin diftitox	Ontak	Immunotherapy	Treatment of persistent or recurrent cutaneous T-cell lymphoma (CTCL)
doxorubicin liposomal	Doxil	Chemo	Treatment of AIDS-related Kaposi's sarcoma in patients with disease that has progressed on prior combination chemotherapy or in patients who are intolerant to such therapy; Treatment of metastatic carcinoma of the ovary in patient with disease that is refractory to both paclitaxel and platinum based regimens
epratuzumab	Avastin	Immunotherapy	Monoclonal antibody in clinical trials for enhancing treatment of relapsed and refractory non-Hodgkin lymphoma
epirubicin	Ellence	Chemo	A component of adjuvant therapy in patients with evidence of axillary node tumor involvement following resection of primary breast cancer.
etoposide phosphate	Etopophos	Chemo	Management of refractory testicular tumors, in combination with other approved chemotherapeutic agents; Management of small cell lung cancer, first-line, in combination with other approved chemotherapeutic agents; Management of refractory testicular tumors and small cell lung cancer.
exemestane	Aromasin	Hormone (aromatase inhibitor)	Treatment of advance breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy.
fulvestrant	Faslodex (Fulvestrant) 250mg/5ml Inj	Hormone (anti-estrogen)	Treatment of hormone receptor-positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy
gemcitabine	Gemzar	Chemo	Treatment of patients with locally advanced (nonresectable stage II or III) or metastatic (stage IV) adenocarcinoma of the pancreas. Indicated for first-line treatment and for patients previously treated with a 5-fluorouracil-containing regimen; For use in combination with cisplatin for the first-line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer.
gemtuzumab-ozogamicin	Mylotarg	Chemo	Treatment of CD33 positive acute myeloid leukemia in patients in first relapse who are 60 years of age or older and who are not considered candidates for cytotoxic chemotherapy. The antitumor agent is delivered by an antibody-targeted monoclonal antibody.

ibritumomab tiuxetan	Zevalin	RADIOISOTOPE (code as radiation)	Treatment of non-Hodgkin's lymphoma
imatinib mesylate	Gleevec	Chemo	Initial therapy of chronic myelogenous leukemia; metastatic or unresectable malignant gastrointestinal stromal tumors. The antitumor agent is delivered by an antibody-targeted monoclonal antibody.
imiquimod	Aldara	Immunotherapy	Not FDA approved but used off-label as a topical treatment for basal cell carcinoma, squamous cell carcinoma in situ, and high-grade intraepithelial neoplasia of anus and other sites
irinotecan	Camptosar	Chemo	Treatment of patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following 5-FU-based therapy; For first line treatment n combination with 5-FU/leucovorin of metastatic carcinoma of the colon or rectum.; Follow up of treatment of metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following 5-FU-based therapy.
letrozole	Femara	Hormone	Treatment of advanced breast cancer in postmenopausal women; First-line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer.
leuprolide acetate	Eligard	Hormone	Palliative treatment of advanced prostate cancer.
leuprolide acetate implant	Viadur	Hormone	Gonadotropin releasing hormone analog used for palliative treatment of advanced prostate cancer
levamisole	Ergamisol	Immunotherapy	Adjuvant treatment in combination with 5-fluorouracil after surgical resection in patients with Dukes' Stage C colon cancer.
nilutamide	Nilandron	Hormone	Used in combination with surgical castration for treatment of metastatic prostate cancer
oprelvekin	Neumega	Ancillary DO NOT CODE	Also called recombinant human interleukin-11. Prevents severe thrombocytopenia and reduces need for platelet transfusions following myelosuppressive chemotherapy in patients with nonmyeloid malignancies
oxaliplatin	Eloxatine	Chemo	Platinum-based antineoplastic for treatment of metastatic colorectal carcinoma when used in combination with 5-fluorouracil and leucovorin, as well as ovarian carcinoma, head/neck carcinoma, and malignant melanoma
paclitaxel	Paxene	Chemo	treatment of advanced AIDS-related Kaposi's sarcoma after failure of first line or subsequent systemic chemotherapy
pamidronate	Aredia	Ancillary DO NOT CODE	Treatment of osteolytic bone metastases of breast cancer in conjunction with standard antineoplastic therapy.
pegaspargase	Oncaspar	Immunotherapy	Treatment of acute lymphocytic leukemia

raltitrexed	Tomudex	Chemo	Used in Canada for treatment of advanced colorectal carcinoma
rituximab	Rituxan	Immunotherapy	Treatment of relapsed or refractory low-grade or follicular B-cell non-Hodgkin's lymphoma
taxotere	Docetaxel	Chemo	Treatment of breast cancer (mono- and combination therapy) and non-small cell lung cancer
temozolamide	Temodar, Temodol	Chemo	Treatment of adult patients with refractory anaplastic astrocytoma, i.e., patients at first relapse with disease progression on a nitrosourea and procarbazine containing regimen
topotecan	Hycamtin	Chemo	Treatment of patients with metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy; Treatment of small cell lung cancer sensitive disease after failure of first-line chemotherapy. In clinical studies submitted to support approval, sensitive disease was defined as disease responding to chemotherapy but subsequently progressing at least 60 days (in the phase 3 study) or at least 90 days (in the phase 2 studies) after chemotherapy
toremifene	Fareston	Hormone (anti-estrogen)	Treatment of advanced breast cancer in postmenopausal women.
trastuzumab	Herceptin	Immunotherapy	First line treatment for metastatic disease when used in combination with paclitaxel
tretinoin, ATRA	Vesanoid	Differentiation-inducing agent--DO NOT CODE	Induction of remission in patients with acute promyelocytic leukemia (APL) who are refractory to or unable to tolerate anthracycline based cytotoxic chemotherapeutic regimens.
triapine	Triapine	Chemo	Formerly 3-AP or OCX-191. Ribonucleotide reductase inhibitor in Phase II trials
triptorelin pamoate	Trelstar Depot	Hormone (LHRH agonist)	Palliative treatment of metastatic prostate, ovarian and pancreatic carcinoma.
valrubicin	Valstar	Chemo (anthracycline)	For intravesical therapy of BCG-refractory carcinoma in situ (CIS) of the urinary bladder in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality.
zoledronic acid	Zometa (Zoledronic Acid) Injection	Ancillary DO NOT CODE	Calcium regulator for hypercalcemia of malignancy. Treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy