

塩酸イリノテカン (カンプト ヤクルト: トボ テシン 第一)		CAMPTOSAR is also indicated for patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following initial fluorouracil-base therapy.	不能又は再発)、結腸・直腸癌(手術不能又は再発)、乳癌(手術不能又は再発)、有棘細胞癌、悪性リンパ腫(非ホジキンリンパ腫)
Letrozole FEMARA レトゾール	NOVARTIS	Femara (letrozole tablets) is indicated for the first-line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer. Femara is also indicated for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy.	国内未承認
Leucovorin injection	LEDERLE	<i>In combination with fluorouracil to prolong survival in the palliative treatment of patients with advanced colorectal cancer.</i> 術後補助療法の標準的治療に用いられているにもかかわらず、FDAの承認内容では補助化学療法での使用は認められていないことに注目！	国内未承認 (1-体のアイソポリは承認あり: レボホリナー ト・フルオロウラシル療法: 胃癌(手術不能又は再発)及び結腸・直腸癌に対するフルオロウラシルの抗腫瘍効果の増強が 効能・効果)
Levamisole ERGAMISOL tablets	JANSSEN	ERGAMISOL (levamisole hydrochloride) is only indicated as adjuvant treatment in combination with fluorouracil after surgical resection in patients with Duke's stage C colon cancer.	国内未承認
Leuprolide acetate for depot suspension Lupron Depot 7.5mg 酢酸リユープロレリン	TAP	LUPRON DEPOT 7.5 mg is indicated in the palliative treatment of advanced prostatic caeoner.	リユープリン(武田)の国内製剤は1.88mgと3.75mgであり、 癌関連の承認を持っているのは3.75mg 製剤 癌治療関連部分のみ抜粋 前立腺癌、閉経前乳癌
Lupron Depot 3 Month 22.5mg	TAP	3ヶ月製剤 11.25mg は子宮内膜症のみの効能・効果 LUPRON DEPOT-3 month 22.5mg is indicated in the palliative treatment of advanced prostatic cancer. It offers an alternative treatment of prostatic	前立腺癌 (平成14年7月5日国内承認: 薬価収載待ち)

			cancer when orchiectomy or estrogen administration are either not indicated or unacceptable to the patient. In clinical trials, the safety and efficacy of LUPRON DEPOT-3 Month 22.5mg were similar to that of the original daily subcutaneous injection and the monthly depot formulation.		
Lupron Depot 4 Month 30mg	TAP		LUPRON DEPOT 4-Month 30mg is indicated in the palliative treatment of advanced prostatic cancer.	国内未承認 (1ヶ月製剤および3ヶ月製剤は既承認)	
Levothyroxine sodium tablet LEVOTHROID	FOREST		癌治療関連部分の抜粋 In addition, Levothyroid, in conjunction with surgery and radioactive iodine therapy, is indicated as a pituitary TSH suppressant in the management of TSH-dependent well-differentiated papillary or follicular carcinoma of the thyroid.	当該効能・効果は国内未承認 錠剤 粘液水腫、クレチン病、甲状腺機能低下症(原発性及び下垂体性)、甲状腺腫	
レボチロキシンナトリウム チラージンス(帝國臓器)				散剤 乳児甲状腺機能低下症	
Levothyroxine sodium, USP SYNTHROID tablets & injection	ABBOT		癌治療関連部分のみ抜粋 and in conjunction with surgery and radioactive iodine therapy, is indicated as a pituitary TSH suppressant in the management of TSH-dependent well-differentiated papillary or follicular carcinoma of the thyroid.	国内未承認	
Levothyroxine sodium tablet, USP LEVOXYL	JONES		癌治療関連部分の抜粋 as adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer	当該効能・効果は国内未承認 錠剤 粘液水腫、クレチン病、甲状腺機能低下症(原発性及び下垂体性)、甲状腺腫	
Lomustine capsule CeeNU	BRISTOL-MYERES SQUIBB		CeeNU has been shown to be useful as a single agent in addition to other treatment modalities, or in established combination therapy with other approved chemotherapeutic agents in the following: Brain tumors: both primary and metastatic, in patients who have already received appropriate surgical and/or radiographic procedures.	国内未承認 (類薬(ACNU)は承認あり)	

Mechlorethamine HCl for injection MUSTAGEN	MERK	Hodgkin's disease: secondary therapy in combination with other approved drugs in patients who relapse while being treated with primary therapy, or who failed to respond to primary therapy. MUSTAGEN, administered intravenously, is indicated for the palliative treatment of Hodgkin's disease (Stage III and IV), lymphosarcoma, chronic myelocytic or chronic lymphocytic leukemia, polycythemia vera, mycosis fungoides, and broncogenic carcinoma. MUSTAGEN, administered intrapleurally, intraperitoneally, or intrapericardially, is indicated for the palliative treatment of metastatic carcinoma resulting in effusion.	国内未承認
Megestrol acetate tablets, USP MEGASE	Bristol-Myers Squibb	MEGASE (megestrol acetate tablets, USP) is indicated for the palliative treatment of advanced carcinoma of the breast or endometrium (i.e., recurrent, inoperable, or metastatic disease). It should not be used in lieu of currently accepted procedures such as surgery, radiation, or chemotherapy.	国内未承認 (類薬(ヒスロンH)は承認あり)
Melphalan ALKERAN for injection メルファラン アルケラン静注用(グラク ソ・スミスクライン)	GLAXO SMITH KLINE	ALKERAN for Injection is indicated for the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate.	以下の疾患における造血幹細胞移植時の前処置 白血病、悪性リンパ腫、多発性骨髄腫、小児固形腫瘍
Melphalan ALKERAN tablet メルファラン アルケラン錠(グラクソ・ス ミスクライン)	GLAXO SMITH KLINE	ALKERAN Tablets are indicated for the palliative treatment of multiple myeloma and for the palliation of no-resectable epithelial carcinoma of the ovary.	多発性骨髄腫の自覚的並びに他覚的症状の寛解
Mercaptopurine PURINETHOL 50-mg Scored Tablet メルカプトプリン ロイケリン(ワイズレダリー -武田)	Glaxo/Wellcome	PURINETHOL (mercaptopurine) is indicated for remission induction and maintenance therapy of acute lymphatic leukemia. The response to this agent depends upon the particular subclassification of acute lymphatic leukemia and the age of patient (pediatric or adult).	以下の疾患の自覚的並びに他覚的症状の寛解: 急性白血病、慢性骨髄性白血病
Mesna	ASTA MEDICA	MENEX has been shown to be effective as a prophylactic agent in reducing the incidence of ifosfamide-induced hemorrhagic cystitis.	イフォスファミド投与又はシクロホスファミド投与(造血幹細胞

<p>MESNEX ウロミテキサン(塩野義) Methotrexate injection メトトレキサート メソトレキセート 錠・注 (ワイズレダリー・武田)</p>	<p>Bedford Laboratories</p>	<p>Neoplastic diseases: Methotrexate in the treatment of gestational choriocarcinoma, chorioadenoma destruens and hydatidiform mole. In acute lymphocytic leukemia methotrexate is indicated in the prophylaxis of meningeal leukemia and is used in maintenance therapy in combination with other chemotherapeutic agents. Methotrexate is also indicated in the treatment of meningeal leukemia. Methotrexate is used alone or in combination with other anticancer agents in the treatment of breast cancer, epidermoid cancers of the head and neck, advanced mycosis fungoides, and lung cancer, particularly squamous cell and small cell types. Methotrexate is also used in combination with other chemotherapeutic agents in the treatment of advanced stage non-Hodgkin's lymphomas. Methotrexate in high doses followed by leucovorin rescue in combination with other chemotherapeutic agents is effective in prolonging relapse-free survival in patients with non-metastatic osteosarcoma who have undergone surgical resection or amputation to the primary tumor.</p>	<p>移植の前治療)に伴う泌尿器系障害(出血性膀胱炎、排尿障害等)の発現抑制</p>
<p>Methoxsalen UVADEX</p>	<p>Therakos</p>	<p>UVADEX (methoxsalen) Sterile Solution is indicated for extracorporeal administration with the UVAR Photopheresis System in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTLC) that is unresponsive to other forms of treatment.</p>	<p>国内未承認</p>
<p>Methylprednisolone acetate injectable suspension, USP DEPO-MEDROL</p>	<p>PHARMACIA UPJOHN</p>	<p>癌治療関連 10. Neoplastic Disease For palliative management of: Leukemias and lymphoma in adults Acute leukemia of childhood</p>	<p>国内未承認</p>
<p>Methylprednisolone sodium succinate for injection, USP</p>	<p>PHARMACIA & UPJOHN</p>	<p>癌治療関連 10. Neoplastic Disease For palliative management of: Leukemias and lymphoma in adults</p>	<p>癌関連の効能・効果は国内未承認</p>

<p>SOLU-MEDROL コハク酸メチルプレドニゾロンナトリウム ソル・メドロール(ファルマシア)</p>		<p>Acute leukemia of childhood</p>	
<p>Methyltestosterone Capsules, USP TESTRED メチルテストステロン エナルモン(帝国臓器)</p>	<p>ICN</p>	<p>2. Females Androgen may be used secondarily in women with advanced inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or antiestrogen therapy. This treatment has also been used in premenopausal women with breast cancer who have been benefited from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.</p>	<p>癌治療関連部分のみ抜粋 末期女性性器癌の頭痛緩和、手術不能の乳癌</p>
<p>Methyltestosterone Casules, USP ANDROID メチルテストステロン エナルモン(帝国臓器)</p>	<p>ICN</p>	<p>癌治療関連部分のみ抜粋 2. Females Androgen may be used secondarily in women with advanced inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or antiestrogen therapy. This treatment has also been used in premenopausal women with breast cancer who have been benefited from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.</p>	<p>癌治療関連部分のみ抜粋 末期女性性器癌の頭痛緩和、手術不能の乳癌</p>
<p>Mitomycin C MUTAMYCIN マイトマイシンC マイトマイシン(協和発酵)</p>	<p>BRISTOL-MYERS SQUIBB ONC</p>	<p>MUTAMYCIN is not recommended as single agent, primary therapy. It has been shown to be useful in the therapy of disseminated adenocarcinoma of the stomach or pancreas if proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed. MUTAMYCIN is not recommended to replace appropriate surgery and/or radiotherapy.</p>	<p>以下の疾患の自覚的並びに他覚的症状の寛解： 慢性リンパ性白血病、慢性骨髄性白血病、胃癌、結腸・直腸癌、肺癌、肝癌、子宮頸癌、子宮体癌、乳癌、頭頸部腫瘍、膀胱腫瘍</p>
<p>Mitotane LYSODREN</p>	<p>BRISTOL-MYERS SQUIBB ONC</p>	<p>LYSODREN is indicated in the treatment of inoperable adrenal cortical carcinoma of both functioning and nonfunctioning types.</p>	<p>国内未承認</p>

Mitoxantrone NOVANTRONE 塩酸ミトキサントロン ノバントロン(ワイスレダリ ---武田)	IMMUNEX	癌治療関連部分のみ抜粋 NOVANTRONE in combination with corticosteroids is indicated as initial chemotherapy for the treatment of patients with pain related to advanced hormone-refractory prostate cancer. NOVANTRONE in combination with other approved drug(s) is indicated in the initial therapy of acute nonlymphocytic leukemia (ANLL) in adults. This category includes myelogenous, promyelogenous, monocytic, and erythroid acute leukemias. ?(タンパク同化ステロイド:米国承認 1959年10月30日)	急性白血病(慢性骨髄性白血病の急性転化を含む)、悪性リンパ腫、乳癌、肝細胞癌
Nandrolone phenpropionate DURABOLIN-50	Organon		国内未承認
Nilotamide NILANDRON	AVENTIS	Metastatic Prostate Cancer NILANDRON tablets are indicated for use in combination with surgical castration for the treatment of metastatic prostate cancer (stage D2). For maximum benefit, NILANDRON treatment must begin on the same day as or on the day after surgical castration.	国内未承認
Nofetumomab VERLUMA	Boehringer Pharma KG	?	国内未承認
octeroid acetate SADOSTATIN 酢酸オクトレオチド サンドスタチン(チバガイギ ---ノバルティス)	NOVARTIS	Acromegaly 詳細略 Carcinoid Tumors Sandostation (octeroid acetate) is indicated for the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease. Sandostation (octeroid acetate) studies were not designed to show an effect on the size, rate of growth or development of metastases. Vasoactive Intestinal Peptide Tumors (VIPomas) Sandostation (octeroid acetate) is indicated for the treatment of the profuse watery diarrhea associated with VIP secreting tumors. Sandostation (octeroid acetate) studies were not designed to show an effect on the size, rate of growth or development of metastases.	1)以下の疾患に伴う諸症状の改善: 消化管ホルモン産生腫瘍(VIP産生腫瘍、カルチノイド症候群)の特徴を示すカルチノイド腫瘍、ガストリン産生腫瘍) 2)以下の疾患における成長ホルモン、ソマトメジン-C分泌過剰状態及び諸症状の改善: 末端肥大、下垂体性巨人症(外科的処置、他剤による治療で効果が不十分な場合又は施行が困難な場合)
Ondansetron hydrochloride ZOFFRAN	GLAXO SMITH KLINE	静注製剤 1. Prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high dose cisplatin. Efficacy of the 32-mg single dose beyond 24 hours in these patients has not been established.	抗悪性腫瘍剤(シスプラチン等)投与に伴う消化器症状(悪心、嘔吐)

<p>塩酸オンダンセトロン ゾフラン(GSK-三共)</p>		<p>2. Prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided postoperatively, ZOFTRAN Injection is recommended even where the incidence of postoperative nausea and/or vomiting is low. For patients who do not receive prophylactic ZOFTRAN Injection and experience nausea and/or vomiting postoperatively, ZOFTRAN Injection may be given to prevent further episodes (see CLINICAL TRIALS).</p> <p>錠剤</p> <ol style="list-style-type: none"> 1. Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin >50mg/m² 2. Prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy. 3. Prevention of nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen. 4. Prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided postoperatively, ZOFTRAN Tablets, ZOFTRAN ODT Orally Disintegrating Tablets, and ZOFTRAN Oral Solution are recommended even where the incidence of postoperative nausea and/or vomiting is low
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<p>Oprelvekin NEUMEGA IL-11</p>	<p>GENETICS</p>	<p>Neumega is indicated for the prevention of severe thrombocytopenia and the reduction of the need for platelet transfusion following myelosuppressive chemotherapy in patients with nonmyeloid malignancies who are at high risk of severe thrombocytopenia. Efficacy was demonstrated in patients who had experienced severe thrombocytopenia following the previous chemotherapy cycle. Neumega is not indicated following myeloablative chemotherapy.</p>	<p>国内未承認</p>
<p>Oxaliplatin ELOXATIN オキザリプラチン</p>	<p>SANOFI-SYNTHELABO</p>	<p>ELOXATIN, used in combination with infusional 5FU/LV, is indicated for the treatment of patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed during or within 6 months of completion of first-line therapy with the combination of bolus 5-FU/LV and irinotecan.</p> <p>The approval of ELOXATIN is based on response rate and an interim analysis showing improved time to radiographic progression. No results are available at this time that demonstrate a clinical benefit, such as improvement of disease-related symptoms or increased survival.</p>	<p>国内未承認 (現在ヤクルトが治験中)</p>
<p>Paclitaxel パクリタキセル (タキソール ブリストル製薬)</p>	<p>BRISTOL-MYERS SQUIBB ONC</p>	<p>TAXOL is indicated as first-line and subsequent therapy for the treatment of advanced carcinoma of the ovary. As first line therapy, TAXOL is indicated in combination with cisplatin.</p> <p>TAXOL is indicated for the adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy. In the clinical trial, there was an overall favorable effect on disease-free and overall survival in the total population of patients with receptor-positive and receptor-negative tumors, but the benefit has been specially demonstrated by available data (median follow-up 30 months) only in the patients with estrogen and progesterone receptor-negative tumors.</p> <p>TAXOL, in combination with cisplatin, is indicated for the first-line treatment of non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy.</p> <p>TAXOL is indicated for the second-line treatment of AIDS-related Kaposi's sarcoma.</p>	<p>卵巣癌、非小細胞肺癌、乳癌、胃癌</p>

<p>Pamidronate disodium for injection Aredia</p> <p>パミドロン酸ナトリウム (アレディア チバガイギ ー 日本化薬)</p>	<p>NOVARTIS</p>	<p>Hypercalcemia of malignancy 略 Paget's disease 略</p> <p>Osteolytic Bone Metastases of Breast Cancer and Osteolytic Lesions of Multiple Myeloma</p> <p>Aredia is indicated in conjunction with standard antineoplastic therapy, for the treatment of osteolytic bone metastases of breast cancer and osteolytic lesions of multiple myeloma. The Aredia treatment effect appeared to be smaller in the study of breast cancer patients receiving hormonal therapy. Overall evidence of clinical benefit has been demonstrated (see CLINICAL PHARMACOLOGY, Osteolytic Bone Metastases of Breast Cancer and Osteolytic lesions of Multiple Myeloma, Clinical Trials section).</p>	<p>悪性腫瘍による高カルシウム血症 (用法・用量: 30~45mg を4時間以上かけて単回点滴静注) 当該効能・効果ならびに用法・用量は国内未承認 (ノバルティスは、次世代製品である Zometa に関連資源を集中しており、本邦で乳癌 & 多発性骨髄腫の溶骨性骨転移の効能の開発を実施する予定はない。しかし赤字の効能・効果はASCOガイドラインでも推奨されている。)</p>
<p>pegasparase ONCASPAR</p>	<p>AVENTIS</p>	<p>ONCASPAR is indicated for patients with acute lymphoblastic leukemia who require L-asparaginase in their treatment regimen, but have developed hypersensitivity to the native forms of L-asparaginase (see CLINICAL PHARMACOLOGY). ONCASPAR, like native L-asparaginase, is generally used in combination with other chemotherapeutic agents, such as vincristine, methotrexate, cytarabine, daunorubicin, and doxorubicin. Use of ONCASPAR as a single agent should only be undertaken when multi-agent chemotherapy is judged to be inappropriate for the patient.</p>	<p>国内未承認</p>
<p>Pegfilgrastim NEULASTA</p>	<p>AMGEN</p>	<p>Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.</p>	<p>国内未承認</p>
<p>Pentostatin injection NIPENT</p> <p>ペントスタチン コホリン(化血研)</p>	<p>SUPERGEN</p>	<p>NIPENT is indicated as single-agent treatment for both untreated and alpha-interferon-refractory hairy cell leukemia patients with active disease as defined by clinically significant anemia, neutropenia, thrombocytopenia, or disease-related symptoms.</p>	<p>以下の疾患の自覚的並びに他覚的症状の寛解: 成人T細胞性白血病リンパ腫、ヘアリーセル白血病</p>

<p>Pilocarpine hydrochloride SALAGEN TABLETS 塩酸ピロカルピン (眼軟膏、サンピロ、ピロリナ点眼液は国内承認あり)</p>	<p>MGJ</p>	<p>SALAGEN Tablets are indicated for 1) the treatment of symptoms of dry mouth from salivary gland dysfunction caused by radiotherapy for cancer of the head and neck; and 2) the treatment of symptoms of dry mouth in patients with Sjogren's syndrome.</p>	<p>国内未承認 塩酸ピロカルピン (眼軟膏、サンピロ、ピロリナ点眼液は国内承認あり)</p>
<p>Plicamycin MITHRACIN</p>	<p>BAYER</p>	<p>MITHRACIN is a potent antineoplastic agent which has been shown to be useful in the treatment of carefully selected hospitalized patients with malignant tumors of the testis in whom successful treatment by surgery and/or radiation is impossible. Also, on the basis of limited clinical experience to date, it may be considered in the treatment of certain symptomatic patients with hypercalcemia and hypercalcuria associated with a variety of advanced neoplasms. The use of Mithracin in other types of neoplastic disease is not recommended at the present time.</p>	<p>国内未承認</p>
<p>Polfeprosan 20 with carmustine implant GLIADEL Wafer</p>	<p>GULFORD</p>	<p>GLIADEL is indicated for use as an adjunct to surgery to prolong survival in patients with recurrent glioblastoma multiforme for whom surgical resection is indicated.</p>	<p>国内未承認</p>
<p>Porfimer sodium PHOTOFRIN for injection ポルフィマーナトリウム (フォトフリン ワイスレダリ —武田)</p>	<p>AXCAN SCANDIPHARM</p>	<p>手術等の他の根治的治療が不可能な場合、あるいは、肺又は子宮頸部の機能温存が必要な患者に他の治療法がしやうできない場合で、かつ内視鏡的に病巣全容が観察でき、レーザー照射が可能以下の患者 1) 早期肺癌(病期0期又は病期I期肺癌) 2) 表在性早期胃癌 3) 表在性食道癌 4) 子宮頸部初期癌及び異形成</p>	<p>国内未承認</p>

<p>Procarbazine hydrochloride MATULANE 塩酸プロカルバジン ナツラン(ロシュ)</p>	<p>SIGMA-TAU</p>	<p>Matulane is indicated for use in combination with other anticancer drugs for the treatment of stage III and IV Hodgkin's disease. Matulane is used as part of the MOPP(nitrogen mustard, vincristine, procarbazine, prednisone) regimen.</p>	<p>悪性リンパ腫(ホジキン病、細網肉腫、リンパ肉腫)</p>
<p>Rasburicase ELITEK</p>	<p>Sanofi-syntelabo, Inc</p>	<p>ELITEK is indicated for the initial management of plasma uric acid levels in pediatric patients with leukemia, lymphoma, and solid tumor malignancies who are receiving anti-cancer therapy expected to result in tumor lysis and subsequent elevation of plasma uric acid.</p>	<p>国内未承認</p>
<p>Rituximab Rituxan リツキシマブ(遺伝子組み換え) (リツキサン、全薬-ロシユ)</p>	<p>IDEC GENENTEC</p>	<p>RITUXAN is indicated for the treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma.</p>	<p>CD20 陽性のB細胞性非ホジキンリンパ腫、</p>

<p>Sargramostim LEUKINE Rhu-GM-CSF</p>	<p>IMMUNEX</p>	<p>Use Following Induction chemotherapy in Acute Myelogenous Leukemia 詳細略</p> <p>Use in Mobilization and Following Transplantation of Autologous Peripheral Blood Progenitor Cells 詳細略</p> <p>Use in Myeloid Reconstitution After Autologous Bone marrow Transplantation 詳細略</p> <p>Use in Myeloid Reconstitution After Allogenic Bone marrow Transplantation 詳細略</p> <p>Use in Bone Marrow Transplantation Failure or Engraftment Delay 詳細略</p>	<p>国内未承認</p>
<p>Streptozocin ZANOSAR</p>	<p>Pharmaci & Upjohn</p>	<p>ZANOSAR is indicated in the treatment of metastatic islet cell carcinoma of the pancreas. Response have been obtained with both functional and nonfunctional carcinoma. Because of its inherent renal toxicity, therapy with this drug should be limited to patients with symptomatic or progressive metastatic disease.</p>	<p>国内未承認</p>
<p>Talc SCLEOSOL</p>	<p>Bryan</p>	<p>Sclerosol Intrapleural Aerosol, administered by aerosol during thoracoscopy or open thoracotomy, is indicated to prevent recurrence of malignant pleural effusions in symptomatic patients.</p>	<p>国内未承認</p>
<p>Temozolomide TEMODAR capsules</p>	<p>SCHERING</p>	<p>TEMODAR (temozolomide) capsules are indicated for the treatment of adult patients with refractory anaplastic astrocytoma, ie, patients at first relapse who have experienced disease progression on a drug regimen containing a nitrosurea and procarbazine. This indication is based on the response rate in the indicated population. No results are available from randomized controlled trials in recurrent anaplastic astrocytoma that demonstrate a clinical benefit resulting from treatment, such as improvement in disease-related symptoms, delayed disease progression, or improved survival.</p>	<p>国内未承認</p>
<p>Teniposide VUMON</p>	<p>BRISTOL-MYERS SQUIBB ONC</p>	<p>VUMON, in combination with other approved anticancer agents, is indicated for induction therapy in patients with refractory childhood acute lymphoblastic leukemia.</p>	<p>国内未承認</p>

<p>Tamoxifen citrate クエン酸タモキシフェン ノルバデックス 他</p>	<p>ASTRAZENEKA</p>	<p>乳癌</p> <p>Metastatic Breast Cancer: NOLVADEX is effective in the treatment of metastatic breast cancer in women and men. In premenopausal women with metastatic breast cancer, NOLVADEX is an alternative to oophorectomy or ovarian irradiation. Available evidence indicates that patients whose tumors are estrogen receptor positive are more likely to benefit from NOLVADEX therapy.</p> <p>Adjuvant Treatment of Breast Cancer: NOLVADEX is indicated for the treatment of node-positive breast cancer in postmenopausal women following total mastectomy or segmental mastectomy, axillary dissection, and breast irradiation. In some NOLVADEX adjuvant studies, most of the benefit to date has been in the subgroup with four or more positive axillary nodes.</p> <p>NOLVADEX is indicated for the treatment of axillary node-negative breast cancer in women following mastectomy or segmental mastectomy, axillary dissection, and breast irradiation.</p> <p>The estrogen and progesterone receptor value may help to predict whether adjuvant NOLVADEX therapy is likely to be beneficial.</p> <p>NOLVADEX reduces the occurrence of contralateral breast cancer in patients receiving adjuvant NOLVADEX therapy for breast cancer.</p> <p>Ductal carcinoma in Situ (DCIS): In women with DCIS, following breast surgery, and radiation, NOLVADEX is indicated to reduce the risk of invasive breast cancer. The decision regarding therapy with NOLVADEX for the reduction in breast cancer incidence should be based upon an individual assessment of the benefits and risks of NOLVADEX therapy.</p> <p>Current data from clinical trials support five years of adjuvant NOLVADEX therapy for patients with breast cancer.</p> <p>Reduction in Breast Cancer Incidence in High Risk Women: NOLVADEX is indicated to reduce the incidence of breast cancer in women with at high risk for breast cancer. This effect was shown in a study of 5years planned duration with a median follow-up of 4.2 years. Twenty-five percent of the participants received drug for 5 years. The long-term effects are not known. In this study, there was no impact of tamoxifen on overall, or breast cancer-related mortality. NOLVADEX is indicated only for high-risk women. "High risk" us defined at least 35 years of age with a 5-year predicted risk of breast cancer > 1.67%, as calculated by the Gail Model.</p> <p>以下省略</p>
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<p>Thioguanine TABLOID tablets</p>	<p>GLAXO SMITH KLINE (国内未承認)</p>	<p>a) Acute Nonlymphocytic Leukemia: TABLOID brand Thioguanine is indicated for remission induction, remission consolidation, and maintenance therapy of acute nonlymphocytic leukemias. The response to this agent depends upon the age of the patient (younger patients faring better than older) and whether thioguanine is used in previously treated or previously untreated patients. Reliance upon thioguanine alone is seldom justified for initial remission induction of acute nonlymphocytic leukemia because combination chemotherapy including thioguanine results in more frequent remission induction and longer duration of remission than thioguanine alone.</p> <p>b) Other Neoplasms: TABLOID brand thioguanine is not effective in chronic lymphocytic leukemia, Hodgkin's lymphoma, multiple myeloma, or solid tumors. Although thioguanine is one of several agents with activity in the treatment of the chronic phase of chronic myelogenous leukemia, more objective response are observed with MYERAN (busulfan), and therefore busulfan is usually regarded as the preferred drug.</p>	<p>国内未承認</p>
<p>Thiotepa THIOPLEX</p>	<p>IMMUNEX</p>	<p>Thiotepa has been tried with varying results in the palliation of a wide variety of neoplastic diseases. However, the most consistent results have been seen in the following tumors:</p> <ol style="list-style-type: none"> 1. Adenocarcinoma of the breast 2. Adenocarcinoma of the ovary 3. For controlling intracavitary effusions secondary to diffuse or localized neoplastic diseases of various serosal cavities. 4. For the treatment of superficial papillary carcinoma of the urinary bladder <p>While now largely superseded by other treatments, thiotepa has been effective against, other lymphomas, such as lymphosarcoma and Hodgkin's disease.</p>	<p>国内未承認</p>
<p>Topotecan トポテカン (ハイカムチン グラクソ・スミスクライン)</p>	<p>GLAXO/SMITHKLINE</p>	<p>Hycamtin is indicated for the treatment of</p> <ul style="list-style-type: none"> • metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy • 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 (See Clinical Studies Section) 	<p>小細胞肺癌</p>
<p>Toremifen citrate FARESTON クエン酸トレミフェン フェアストン(日本化薬)</p>	<p>SHIRE US</p>	<p>FARESTON is indicated for the treatment of metastatic breast cancer in postmenopausal women with estrogen-receptor positive or unknown tumors.</p>	<p>閉経後乳癌</p>

<p>Tositumomab BEXXAR</p>	<p>Corixa Corporation</p>	<p>June 27, 2003 approved The BEXXAR therapeutic regimen (Tositumomab and Iodine I 131 Tositumomab) is indicated for the treatment of patients with CD20 positive, follicular, non-Hodgkin's lymphoma, with and without transformation, whose disease is refractory to Rituximab and has relapsed following chemotherapy. The BEXXAR therapeutic regimen is not indicated for the initial treatment of patients with CD20 positive non-Hodgkin's lymphoma. The BEXXAR therapeutic regimen is intended as a single course of treatment. The safety of multiple courses of the BEXXAR therapeutic regimen, or combination of this regimen with other forms of irradiation or chemotherapy, has not been evaluated.</p>	<p>国内未承認</p>
<p>Trastuzumab HERCEPTIN トラスツズマブ ハーセプチン(ロシュ)</p>	<p>GENENTEC</p>	<p>HERCEPTIN as a single agent is indicated for the treatment of patients with metastatic breast cancer whose tumors overexpress the HER2 protein and who have received one or more chemotherapy regimens for their metastatic disease. HERCEPTIN in combination with paclitaxel is indicated for treatment of patients with metastatic breast cancer whose tumor overexpress the HER2 protein and who have not received chemotherapy for their metastatic disease. HERCEPTIN should only be used in patients whose tumors have HER2 protein overexpression. (See CLINICAL STUDIES: HER2 protein overexpression for information regarding HER2 protein testing and the relationship between the degree of overexpression and the treatment effect.)</p>	<p>HER2過剰発現が確認された転移性乳癌</p>
<p>tretinoin VESANOID CAPSULES トレチノイン (ベサノイド ロシュ)</p>	<p>ROCHE</p>	<p>VESANOID (tretinoin) capsules are indicated for the induction of remission in patients with acute promyelocytic leukemia (APL), French-American-British (FAB) classification M3 (including the M3 variant), characterized by the presence of the t(15;17) translocation and/or the presence of the PML/RARα gene who are refractory to, or who have relapsed from, anthracycline chemotherapy, or for whom anthracycline-based chemotherapy is contraindicated. VESANOID is for the induction of remission only. The optimal consolidation or maintenance regimens have not been defined, but all patients should receive an accepted form of remission consolidation and/or maintenance therapy for APL after completion of induction therapy with VESANOID.</p>	<p>急性前骨髄性白血病</p>

Valrubicin VALSTAR [®] Sterile solution for intravesical instillation (semisynthetic analog of the anthracycline doxorubicin)	CELLTECH	国内未承認
Vincristine 硫酸ビンクリスチン (オンコビン イーライリリ ー・塩野薬)	ELI LILLY	白血病(急性白血病、慢性白血病の急性転化時を含む)、 悪性リンパ腫(細網肉腫、リンパ肉腫、ホジキン病)、 小児腫瘍(神経芽腫、ウイルムス腫瘍、横紋筋肉腫、精巣胎 児癌、血管肉腫等)
Vinblastine 硫酸ビンブラスチン (エクザール イーライリリ ー・塩野薬)	ELI LILLY	以下の疾患の自覚的ならびに他覚的症状の寛解： 悪性リンパ腫(ホジキン病、リンパ肉腫、細網肉腫)、 絨毛性疾患(絨毛癌、破壊性胎状奇胎、胎状奇胎)

VALSTAR is indicated 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.

ONCOVIN is indicated in acute leukemia. Oncovin has also been shown to be useful in combination with other oncolytic agents in Hodgkin's disease, non-Hodgkin's malignant lymphomas (lymphocytic, mixed-cell, histiocytic, undifferentiated, nodular, and diffuse types), rhabdomyosarcoma, neuroblastoma, and Wilms' tumor.

Velban is indicated in the palliative treatment of the following:
 I. *Frequently Responsive Malignancies*-
 Generalized Hodgkin's disease (Stage III and IV, Ann Arbor modification of Rye staging system)
 Lymphocytic lymphoma (nodular and diffuse, poorly and well differentiated)
 Histiocytic lymphoma
 Mycosis fungoides (advanced stages)
 Advanced carcinoma of the testis
 Kaposi's sarcoma
 Lettere-Siwe disease (histiocytosis X)
 II. *Less Frequently Responsive Malignancies*-
 Choriocarcinoma resistant to other chemotherapeutic agents
 Carcinoma of the breast, unresponsive to appropriate endocrine surgery and hormonal therapy.
 Current principles of chemotherapy for many types of cancer include the concurrent administration of several antineoplastic agents. For enhanced therapeutic effect without additive toxicity, agents with different dose-limiting clinical toxicities and different mechanism of action are generally selected. Therefore, although Velban is effective as a single agent in the aforementioned indications, it is usually administered in combination with other antineoplastic drugs. Such combination therapy

		<p>produces a greater percentage of response than dose a single-agent regimen. These principles have been applied, for example, in the chemotherapy of Hodgkin's disease.</p> <p><i>Hodgkin's disease</i>- Velban has been shown to be one of the most effective single agents for the treatment of Hodgkin's disease. Advanced Hodgkin's disease has also been successfully treated with several multiple-drug regimens that included Velban. Patients who had relapsed after treatment with the MOPP program-mechlorethamine hydrochloride(nitrogen mustard), vincristine (Oncovin[vincristine Sulfate Injection]), predomison, and procarbazine-have likewise responded to combination-drug therapy that included Velban. A protocol using cyclophamide in place of nitrogen mustard and Velban instead of Oncovin is an alternative therapy for previously untreated patients with advanced Hodgkin's disease.</p> <p>Advanced testicular germinal-cell cancers (embryonal carcinoma, teratocarcinoma, and choriocarcinoma) are sensitive to Velban alone, but better clinical results are achieved when Velban is administered concomitantly with other antineoplastic agents. The effect of bleomycin is significantly enhanced if Velban is administered 6 to 8 hours prior to the administration of bleomycin; this schedule permits more cells to be arrested during metaphase, the stage of the cell cycle in which bleomycin is active</p>	
<p>Vinorelbine 酒石酸ビンレルビン (ナベルビン, 協和発酵)</p>	<p>GLAXO/SMITHKLINE</p>	<p>NAVELBINE is indicated as a single agent or in combination with cisplatin for the first-line treatment of ambulatory patients with unresectable, advanced nonsmall cell lung cancer (NSCLC). In patients with Stage IV NSCLC, NAVELBINE is indicated as a single agent or in combination with cisplatin. In Stage III NSCLC, NAVELBINE is indicated in combination with cisplatin.</p>	<p>非小細胞肺癌</p>

<p>Zoledronic acid for injection Zometa</p>	<p>NOVARTIS PHARMA</p>	<p>ZOMETETA (zoledronic acid for injection) is indicated for the treatment of hypercalcemia of malignancy. Vigorous saline hydration, an integral part of hypercalcemia therapy, should be initiated promptly and an attempt should be made to restore the urine output to about 2L/day throughout treatment. Mild or asymptomatic hypercalcemia may be treated with conservative measures (i.e., saline hydration, with or without loop diuretics). Patients should be hydrated adequately throughout the treatment, but overhydration, especially in those patients who have cardiac failure, must be avoided. Diuretics therapy should not be employed prior to correction of hypercalcemia. The safety and efficacy of Zometa in the treatment of hypercalcemia associated with hyperparathyroidism or with other non-tumor-related conditions has not been established.</p> <p>米国未承認</p>	<p>国内未承認 (治験中)</p>
<p>Vindesine 硫酸ビンデシン (注射用ファイルデシン 塩野義)</p>			<p>以下の疾患の自覚的並びに他覚的症状の寛解： 急性白血病(慢性骨髄性白血病の急性転化も含む)、悪性リンパ腫、肺癌、食道癌</p>

成人脳腫瘍

Adult Brain Tumors

Glioma, Meddulloblastoma, some Germ Cell Tumors には化学療法の延命効果あり(NCI-PDQ)

Adult noninfiltrating astrocytoma

手術

Adult Well-differentiated mildly and moderately anaplastic astrocytoma

手術

Adult anaplastic astrocytoma

一般名	商品名	NCI-PDQ(07/2002)	2002AHFS	FDA	厚生労働省
prolifeprosan 20 with ca	GLIADEL Wafer	○	○(glioblastoma multiforme)	○(glioblastoma multiforme)	未承認
temozolomide	TEMODAR	-	○(anaplastic astrocytoma)	○(anaplastic astrocytoma)	未承認
carmustine	BICNU 静注	-	○(malignant glioma)	○	未承認
lomustien	CeeNU 経口	-	○(astrocytic tumors, medullob)	○	未承認
塩酸ニムスチン	ニドラン	n.d.	n.d.	未承認	○(脳腫瘍)
ラニムスチン	注射用サイメリン	n.d.	n.d.	未承認	○(脳芽腫)
硫酸ビンクリスチン	オンコピン	-	○(brain tumors)	-	-
エトポシド	ベプシド、ラステット	-	○(other usesでbrain tumors)	-	-
シスプラチン	プリプラチン、ランダ	-	○(astrocytic tumors, medullob)	-	-
カルボプラチン	パラプラチン	-	○(astrocytic tumors, medullob)	-	-
塩酸プロカルバジン	ナツラン	-	○(brain tumors)	-	-

Adult glioblastoma multiforme

一般名	商品名	NCI-PDQ(07/2002)	2002AHFS	FDA	厚生労働省
prolifeprosan 20 with ca	GLIADEL Wafer	○	○(glioblastoma multiforme)	○(glioblastoma multiforme)	未承認
temozolomide	TEMODAR	○	△(anaplastic astrocytoma)	△(anaplastic astrocytoma)	未承認
carmustine	BICNU 静注	-	○(malignant glioma)	○	未承認
lomustien	CeeNU 経口	-	○(astrocytic tumors, medullob)	○	未承認
塩酸ニムスチン	ニドラン	n.d.	n.d.	未承認	○(脳腫瘍)
ラニムスチン	注射用サイメリン	n.d.	n.d.	未承認	○(脳芽腫)
硫酸ビンクリスチン	オンコピン	-	○(brain tumors)	-	-
エトポシド	ベプシド、ラステット	-	○(other usesでbrain tumors)	-	-
シスプラチン	プリプラチン、ランダ	-	○(astrocytic tumors, medullob)	-	-
カルボプラチン	パラプラチン	-	○(astrocytic tumors, medullob)	-	-
塩酸プロカルバジン	ナツラン	-	○(brain tumors)	-	-

Adult brain stem glioma

放射線治療

Adult well-differentiated ependymoma

手術+放射線治療

Adult malignant ependymoma (anaplastic ependymoma, ependymblastoma)

手術+放射線治療

Adult well-differentiated oligodendroglioma

手術+放射線治療

Adult anaplastic oligodendroglioma

手術+放射線治療 +/- 化療 (Ann Neurology 23:360-364, 1988)

一般名	商品名	NCI-PDQ(07/2002)	2002AHFS	FDA	厚生労働省
lomustien	CeeNU 経口	-	○(astrocytic tumors, medullob)	○	未承認
塩酸ニムスチン	ニドラン	n.d.	n.d.	未承認	○(脳腫瘍)
硫酸ビンクリスチン	オンコピン	-	○(brain tumors)	-	-
エトポシド	ベプシド、ラステット	-	○(other usesでbrain tumors)	-	-
シスプラチン	プリプラチン、ランダ	-	○(astrocytic tumors, medullob)	-	-
塩酸プロカルバジン	ナツラン	-	○(brain tumors)	-	-

Mixed glioma

手術+放射線治療+/-化療(化療のrefなし)

Adult medulloblastoma

手術+放射線治療

一般名	商品名	NCI-PDQ (07/2002)	2002AHFS	FDA	厚生労働省
Iomustien	CeeNU 経口	-	○ (astrocytic tumors, medullo)	○	未承認
塩酸ニムスチン	ニドラン	n.d.	n.d.	未承認	○ (脳腫瘍)
硫酸ビシクリスチン	オンコピン	-	○ (brain tumors)	-	-
エトボシド	ベブシド、ラステット	-	○ (other usesでbrain tumors)	-	-
シスプラチン	プリプラチン、ランダ	-	○ (astrocytic tumors, medullo)	-	-
カルボプラチン	パラプラチン	-	○ (astrocytic tumors, medullo)	-	-
塩酸プロカルバジン	ナツラン	-	○ (brain tumors)	-	-

Adult pineal parenchymal tumor (pineocytoma, pineoblastoma/pineal astrocytoma)

手術+放射線治療

Adult central nervous system germ cell tumor

組織型による

Adult craniopharyngioma

手術+/-放射線治療

Adult Meningioma

手術+/-放射線治療

Adult malignant meningioma

手術+放射線治療

再発脳腫瘍

一般名	商品名	NCI-PDQ (07/2002)	2002AHFS	FDA	厚生労働省
proliferosan 20 with carmustine implant	GLIADEL Wafer	○	○ (glioblastoma multiforme)	○ (glioblastoma multiforme)	未承認
temozolomide	TEMODAR	○	○ (anaplastic astrocytoma)	○ (anaplastic astrocytoma)	未承認
carmustine	BiCNU 静注	-	○ (malignant glioma)	○	未承認
Iomustien	CeeNU 経口	-	○ (astrocytic tumors, medullo)	○	未承認
塩酸ニムスチン	ニドラン	n.d.	n.d.	未承認	○ (脳腫瘍)
ラニムスチン	注射用サイメリン	n.d.	n.d.	未承認	○ (膠芽腫)
硫酸ビシクリスチン	オンコピン	-	○ (brain tumors)	-	-
プレオマイシン	プレオ	-	△ (other usesでintracranial g)	-	-
エトボシド	ベブシド、ラステット	-	○ (other usesでbrain)	-	-
シスプラチン	プリプラチン、ランダ	-	○ (astrocytic tumors, medullo)	-	-
カルボプラチン	パラプラチン	-	○ (astrocytic tumors, medullo)	-	-
塩酸プロカルバジン	ナツラン	-	○ (brain tumors)	-	-