Appendix to Pricing in the Market for Anticancer Drugs
Data Documentation

A.1 Drug identification

From the list of oncology drugs on the CenterWatch website, we identified drugs where:

1. the first FDA approval occurred between 1995 and 2013,
2. the initial indication was for cancer treatment, and
3. the drug is administered primarily to improve survival rather than alleviate symptoms.

We excluded drugs for which we could not identify an estimate of survival benefits. We also excluded drugs tested in randomized trials where the trials found that the drug was not associated with a benefit (for example, bosutinib). The drugs are listed in section A.5.

A.2 Survival benefits

For each drug, we examined the Clinical Studies section of the FDA-approved product label for randomized trial results. We examined the earliest label available on the FDA website (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/). We recorded median overall survival (when available) and median progression free survival (when available) for patients in the treatment and control arms. The gain in survival is equal to the difference in median survival times between the treatment and control arm. We converted days, weeks, and years to months assuming there are 30.5 days per month.

When the trial included three treatment arms (for example, the drug administered at a low dose, the drug administered at a high dose, and a control treatment), we focused on the results that were most favorable to the drug. When the label included results from two or more trials, we focused on results from the trial that included the most patients or the trial that addressed the indication with the largest market size (for example, first- versus second-line treatment) when the trials addressed different indications and both trials reported favorable results.

For drugs approved on the basis of single-arm trials, we searched Medline for randomized trials. We obtained results from these trials as long as the trial examined the same patient population as described in the drug's original product label. When we could not identify a randomized trial, we sought information on benefits from cost-effectiveness studies. These studies use data from trials and historical data to model the impact of a new drug in the absence of direct evidence about its long-term effectiveness When studies reported multiple comparisons, we used our judgment to determine which of the therapies was the next best treatment available at the time the drug was approved. Modeling studies typically state results in terms of mean survival times. We converted means to medians for the sale of consistency assuming that survival function is exponential (i.e., median survival = mean survival × ln[2]). Some modeling studies state the survival gain in quality-adjusted life years rather than life years. We converted quality-adjusted life years to life years using utility weights from the study. When studies reported multiple weights, we used our judgment to select the weight that best represents patients' utility from the point of treatment

initiation onward. Utility values are reported in the variables qaly_t and qaly_t (were t = treatment and c = control).

A.3 Treatment duration

We examined drug's product labels, published randomized trial results, and cost-effectiveness studies (in that order) for information on the median or mean duration of therapy. We converted days, weeks, and years to months assuming there are 30.5 days per month. In some cases product labels or published studies report the median number of cycles received rather than the median duration of therapy. For these drugs, we multiplied the median number of cycles by cycle length (as stated in drugs' product labels) to calculate the median duration of therapy. When we could not identify an estimate of treatment duration, we assumed that treatment duration equals median progression free survival. We recorded overall and progression free survival and treatment duration in months.

A.4 Variable list and sources

Below we list all of the variables in the dataset and their descriptions and sources.

`drug` Drug name. SOURCE: FDA label.

`brandname` Brand name of the drug. SOURCE: FDA label.

`manufacturer` Drug manufacturer. SOURCE: FDA label.

`approvalmonth` Month of FDA approval. SOURCE: Drugs@FDA.

`approvalyear` Year of FDA approval. SOURCE: Drugs@FDA.

`patentmonth` Month of patent expiration.

`patentyear` Year of patent expiration.

`disease` Primary indication. SOURCE: FDA label.

`deaths` Deaths attributable to tumor type. SOURCE: American Cancer Society. Cancer Facts & Figures 2013. Atlanta: American Cancer Society; 2013.

`incidence` Incidence of tumor type. SOURCE: American Cancer Society. Cancer Facts & Figures 2013. Atlanta: American Cancer Society; 2013.

`biologic` Whether the drug is a biologic product. SOURCE: FDA label.

`jcode` Billing code for IV drugs. SOURCE: CMS Medicare Part B Drug Average Sales Price Data.

`route` IV: injection, PO: oral. SOURCE: FDA label.

`line` Whether the drug was approved as a 1st or 2nd line therapy. SOURCE: FDA label.

`combregimen` whether the drug was approved as part of a combination regimen. SOURCE: FDA label.

`orphan` Orphan drug status. SOURCE: Drugs@FDA.

priority FDA priority status. SOURCE: Drugs@FDA.

rct Whether the drug was approved on the basis of a randomized controlled trial. SOURCE: FDA label.

gene Whether the drug was approved for use with a genetic test. SOURCE: FDA http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm.

competitors Number of drugs previously approved for the tumor site. SOURCE: NCI http://www.cancer.gov/cancertopics/druginfo/drug-page-index

comparator Treatment received by control group. SOURCE: FDA label.

trialsize Size of the treatment arm in the approval trial. SOURCE: FDA label.

meanormedian Survival times represent averages (1) or medians (0). SOURCE: See documentation.

qaly_t Quality of life weight for the treatment arm. Equals 1 if the trial/study reported unadjusted survival times. SOURCE: See documentation.

qaly_c Quality of life weight for the comparison arm. Equals 1 if the trial/study reported unadjusted survival times. SOURCE: See documentation.

os_t Overall survival in the treatment group, months. SOURCE: See documentation.

os_c Overall survival in the control group, months. SOURCE: See documentation.

pfs_t Progression free survival in the treatment group, months. SOURCE: See documentation.

pfs_c Progression free survival survival in the control group, months. SOURCE: See documentation.

cycles Median number of cycles received by patients in the trial. SOURCE: See documentation.

duration Median duration of therapy received by patients in the trial. SOURCE: See documentation.

cyclelength The duration of a cycle in days. SOURCE: FDA label.

monthlycostactual The nominal monthly cost of the drug. SOURCE: Bach, http://www.mskcc.org/research/health-policy-outcomes/cost-drugs.

monthlycostreal The real monthly cost of the drug. SOURCE: Bach, http://www.mskcc.org/research/health-policy-outcomes/cost-drugs.

diarrheat Rate of diarrhea-treatment group. SOURCE: FDA label.

diarrheac Rate of diarrhea-control group. SOURCE: FDA label.

vomitt Rate of vommiting-treatment group. SOURCE: FDA label.

vomitc Rate of vommiting-control group. SOURCE: FDA label.

nauseat Rate of nausea-treatment group. SOURCE: FDA label.

nauseac Rate of nausea-control group. SOURCE: FDA label.

neutropeniat Rate of neutropenia-treatment group. SOURCE: FDA label.

neutropeniac Rate of neutropenia-control group. SOURCE: FDA label.

anemiat Rate of anemia-treatment group. SOURCE: FDA label.

anemiac Rate of anemia-control group. SOURCE: FDA label.

diarrheat34 Rate of diarrhea-treatment group, grades 3 and 4. SOURCE: FDA label.

diarrheac34 Rate of diarrhea-control group, grades 3 and 4. SOURCE: FDA label.

vomitt34 Rate of vommiting-treatment group, grades 3 and 4. SOURCE: FDA label.

vomitc34 Rate of vommiting-control group, grades 3 and 4. SOURCE: FDA label.

nauseat34 Rate of nausea-treatment group, grades 3 and 4. SOURCE: FDA label.

nauseac34 Rate of nausea-control group, grades 3 and 4. SOURCE: FDA label.

neutropeniat34 Rate of neutropenia-treatment group, grades 3 and 4. SOURCE: FDA label.

neutropeniac34 Rate of neutropenia-control group, grades 3 and 4. SOURCE: FDA label.

anemiat34 Rate of anemia-treatment group, grades 3 and 4. SOURCE: FDA label.

anemiac34 Rate of anemia-control group, grades 3 and 4. SOURCE: FDA label.

A.5 Drug selection and sources for survival benefit and treatment duration variables

The list of drugs below below is from the CenterWatch website's list of approved oncology products on June 23, 2014. The url is https://www.centerwatch.com/drug-information/fda-approved-drugs/therapeutic-area/12/oncology.

The drug list below was taken verbatim from the CenterWatch website. The spelling of drug names, approval dates, and indications are exactly as they appear on the website. The only modification we made was to add generic names for some drugs in parentheses.

DRUGS APPROVED IN 2013

Gazyva (obinutuzumab); Genentech; For the treatment of previously untreated chronic lymphocytic leukemia, Approved October of 2013

WAC: PriorityHealth, https://www.priorityhealth.com/~/~/media/documents/drug-auth-forms/gazyva-pa-commercial-medicaid-michild.pdf

DURATION and SURVIVAL: Product label.
The third paragraph of section 6.1 reports the median number of cycles (8). Table 5 reports progression free survival.

Gilotrif (afatinib); Boehringer Ingelheim; For the treatment of metastatic non-small cell lung cancer with EGFR mutations, Approved July 2013

DURATION and SURVIVAL: Product label.
The third paragraph of section 6.1 reports the median duration of treatment (11.0 months). Table 3 reports overall and progression free survival. Median overall survival was shorter among patients in the afatinib arm than among patients in the control arm (pemetrexed/cisplatin). According to the publication describing the trial (Sequist et al. 2013), overall survival was a secondary outcome. Therefore, we based survival figures on progression free survival.

Lecia V. Sequist, James Chih-Hsin Yang, Nobuyuki Yamamoto, Kenneth O'Byrne, Vera Hirsh, Tony Mok, Sarayut Lucien Geater, Sergey Orlov, Chun-Ming Tsai, Michael Boyer, Wu-Chou Su, Jaafar Bennouna, Terufumi Kato, Vera Gorbunova, Ki Hyeong Lee, Riyaz Shah, Dan Massey, Victoria Zazulina, Mehdi Shahidi, and Martin Schuler Phase III Study of Afatinib or Cisplatin Plus Pemetrexed in Patients With Metastatic Lung Adenocarcinoma With EGFR Mutations J Clin Oncol 31(27):3327-3334.

Imbruvica (ibrutinib); Pharmacyclics; For the treatment of mantle cell lymphoma, Approved November of 2013

Not included. We were unable to find data on effectiveness. Results from a trial testing ibrutinib in patients with chronic lymphocytic leukemia are forthcoming.

Kadcyla (ado-trastuzumab emtansine); Genentech; For the treatment of HER2-positive metastatic breast cancer, Approved February 2013

DURATION and SURVIVAL: Product label.
The third paragraph of section 6.1 reports the median duration of treatment (7.6 months). Table 8 reports progression free survival.

Mekinist (trametinib); GlaxoSmithKline; For the treatment of unresectable or metastatic melanoma with BRAF V600E or V600K mutations, Approved May of 2013

DURATION and SURVIVAL: Product label.
The third paragraph of section 6.1 reports the median duration of treatment (4.3 months). Table 4 reports progression free survival.

Pomalyst (pomalidomide); Celgene; For the treatment of relapsed and refractory multiple myeloma, Approved February 2013

DURATION and SURVIVAL: Jesus San Miguel, Katja Weisel, Philippe Moreau, Martha Lacy, Kevin Song, Michel Delforge, Lionel Karlin, Hartmut Goldschmidt, Anne Banos, Albert Oriol, Adrian Alegre, Christine Chen, Michele Cavo, Laurent Garderet, Valentina Ivanova, Joaquin Martinez-Lopez, Andrew Belch, Antonio Palumbo, Stephen Schey, Pieter Sonneveld, Xin Yu, Lars Sternas, Christian Jacques, Mohamed Zaki, Meletios Dimopoulos Pomalidomide plus low-dose dexamethasone versus high-dose dexamethasone alone for patients with relapsed and refractory multiple myeloma (MM-003): a randomised, open-label, phase 3 trial Lancet Oncol 2013; 14: 1055–66.

Note: The Results section reports overall and progression free survival. We assumed treatment duration equals progression free survival. The drug was approved on the basis of a single-arm study.

Revlimid (lenalidomide); Celgene; For the treatment of mantle cell lymphoma, Approved June 2013

Not included. The drug was originally approved for a non-oncologic indication.

Stivarga (regorafenib); Bayer; For the treatment of gastrointestinal stromal tumor, Approved February 2013

The drug was approved previously for another indication.

Tafinlar (dabrafenib); GlaxoSmithKline; For the treatment of unresectable or metastatic melanoma with BRAF V600E mutation, Approved May 2013

DURATION and SURVIVAL: Product label.
The third paragraph of section 6.1 reports the median duration of treatment (4.9 months). Table 5 reports progression free survival.

Valchlor (mechlorethamine) gel; Ceptaris Therapeutics; For the treatment of Stage IA/IB mycosisfungoides-type cutaneous T-cell lymphoma, Approved August 2013

Not included. We were unable to find data on effectiveness. Valchlor is a new formulation of an older drug (mechlorethamine).

Xgeva (denosumab); Amgen; For the treatment of giant cell tumor of bone, Approved June 2013

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Xofigo (radium Ra 223 dichloride); Bayer Healthcare Pharmaceuticals; For the treatment of prostate cancer with bone metastases, Approved May 2013

DURATION and SURVIVAL: Product label.
The second paragraph of section 6.1 reports the median number of cycles (6). Table 5 reports overall survival.

DRUGS APPROVED IN 2012

Abraxane (paclitaxel protein-bound particles for injectable suspension); Celgene; For the treatment of non-small cell lung cancer, Approved October 2012

The drug was approved previously for another indication.

Afinitor (everolimus); Novartis; For the treatment of renal angiomyolipoma associated with tuberous sclerosis complex, Approved April 2012

The drug was approved previously for another indication.

Afinitor (everolimus); Novartis; For the treatment of hormone receptor-positive, HER2-negative breast cancer, Approved July 2012

The drug was approved previously for another indication.

Bosulif (bosutinib); Pfizer; For the treatment of Ph+ chronic myelogenous leukemia, Approved September 2012

Not included. We were unable to find information on survival benefits for this drug. A recently published randomized trial (Cortes et al. 2012) found that bosutinib and imatinib were associated with similar complete cytogenetic response rates.

Cortes, Jorge E. Kim, Dong-Wook. Kantarjian, Hagop M. Brummendorf, Tim H. Dyagil, Irina. Griskevicius, Laimonas. Malhotra, Hemant. Powell, Christine. Gogat, Karin. Countouriotis, Athena M. Gambacorti-Passerini, Carlo. Bosutinib versus imatinib in newly diagnosed chronic-phase chronic myeloid leukemia: results from the BELA trial. Journal of Clinical Oncology. 30(28):3486-92, 2012 Oct 1.

Cometriq (cabozantinib); Exelixis; For the treatment of metastatic medullary thyroid cancer, Approved November 2012

DURATION and SURVIVAL: Product label.
The second paragraph of section 6.1 reports the median duration of treatment (204 days). The third paragraph of the Clinical Studies section reports progression free survival.

Erivedge (vismodegib); Genentech; For the treatment of basal cell carcinoma, Approved January 2012

Not included. We were unable to find information on survival benefits for this drug.

Iclusig (ponatinib); Ariad Pharmaceuticals; For the treatment of chronic myeloid leukemia and Philadelphia chromosome positive acute lymphoblastic leukemia, Approved December 2012

Not included. We were unable to find information on survival benefits for this drug.

Inlyta (axitinib); Pfizer; For the treatment of advanced renal cell carcinoma, Approved January 2012

DURATION and SURVIVAL: Product label.

The first paragraph of section 6.1 reports the median duration of treatment (6.4 months). Table 3 reports overall and progression free survival.

Kyprolis (carfilzomib); Onyx Pharmaceuticals; For the treatment of multiple myeloma, Approved July 2012

Not included. We were unable to find data on survival benefits for this drug.

Marqibo (vinCRIStine sulfate LIPOSOME injection); Talon Therapeutics; For the treatment of Ph- acute lymphoblastic leukemia, Approved August 2012

Not included. We were unable to find data on survival benefits for this drug.

Neutroval (tbo-filgrastim); Teva Pharmaceutical; For the reduction in the duration of severe chemotherapy-induced neutropenia, Approved August 2012

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Perjeta (pertuzumab); Genentech; For the first-line treatment of HER2+ metastatic breast cancer, Approved June 2012

DURATION and SURVIVAL: Product label.
The second paragraph of the Clinical Studies section reports the median number of cycles (19.9). Table 2 reports progression free survival.

Picato (ingenol mebutate) gel; LEO Pharma; For the treatment of actinic keratosis, Approved January 2012

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Stivarga (regorafenib); Bayer HealthCare Pharmaceuticals; For the treatment of previously treated patients with metastatic colorectal cancer, Approved September 2012

DURATION and SURVIVAL: Product label.
The second paragraph of section 6.1 reports the median duration of treatment (12 weeks). Table 3 reports overall survival.

Subsys (fentanyl sublingual spray); Insys Therapeutics; For the treatment of breakthrough cancer pain, Approved January of 2012

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Synribo (omacetaxine mepesuccinate); Teva Pharmaceutical; For the treatment of chronic or accelerated phase chronic myeloid leukemia, Approved October 2012

Not included. We were unable to find data on survival benefits for this drug.

Votrient (pazopanib); GlaxoSmithKline; For the treatment of soft tissue sarcoma, Approved April 2012

The drug was approved previously for another indication.

Xtandi (enzalutamide); Medivation; For the treatment of metastatic castration-resistant prostate cancer, Approved August 2012

DURATION and SURVIVAL: Product label.
The second paragraph of section 6.1 reports the median duration of treatment (8.3 months). Table 2 reports overall survival.

Zaltrap (ziv-aflibercept); Sanofi-aventis; For the treatment of metastatic colorectal cancer, Approved August 2012

DURATION and SURVIVAL: Product label.
Note: The second paragraph of section 6.1 reports the median number of cycles (9). Table 2 reports overall and progression free survival.

DRUGS APPROVED IN 2011

Abstral (fentanyl sublingual tablets); ProStrakan; For the treatment of breakthrough cancer pain in opioid-tolerant patients, Approved January 2011

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Adcetris (brentuximab vedotin); Seattle Genetics; For the treatment of Hodgkin lymphoma and anaplastic large cell lymphoma, Approved August 2011

Not included. We were unable to find data on effectiveness. A Canadian review of an unpublished study by the manufacturer reported that the drug yields an estimated increase of about 1 QALY, but did not provide other details. See:
http://www.pcodr.ca/idc/groups/pcodr/documents/pcodrdocument/pcodr-adcetrishl-in-rec.pdf.

Afinitor (everolimus); Novartis; For the treatment of advanced pancreatic neuroendocrine tumors, Approved May 2011

The drug was approved previously for another indication.

Erwinaze (asparaginase Erwinia chrysanthemi); Eusa Pharma; For the treatment of acute lymphoblastic leukemia, Approved November of 2011

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Lazanda (fentanyl citrate) nasal spray; Archimedes; For the management of breakthrough cancer pain, Approved June 2011

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Sutent (sunitinib malate); Pfizer; For the treatment of pancreatic neuroendocrine tumors, Approved May 2011

The drug was approved previously for another indication.

Sylatron (peginterferon alfa-2b); Merck; For the treatment of melanoma, Approved April 2011

Not included. Peginterferon was originally approved for the treatment of hepatitis C.

Vandetanib (vandetanib); AstraZeneca; For the treatment of thyroid cancer, Approved April 2011

DURATION and SURVIAL: Samuel A. Wells Jr, Bruce G. Robinson, Robert F. Gagel, Henning Dralle, James A. Fagin, Massimo Santoro, Eric Baudin, Rossella Elisei, Barbara Jarzab, James R. Vasselli, Jessica Read, Peter Langmuir, Anderson J. Ryan, and Martin J. Schlumberger. Vandetanib in patients with locally advanced or metastatic medullary thyroid cancer: a randomized, double-blind phase III trial. J Clin Oncol 2012;30(2):134-141.
Note: The median progression free survival in the vandetanib arm was not reached at the time of approval. Wells et al. fit a Weibull model to project median progression free survival, as reported in the first paragraph of the Efficacy section. We assumed that treatment duration equals median progression free survival (30.5 months).

Xalkori (crizotinib); Pfizer; For the treatment of ALK+ non-small cell lung cancer, Approved August of 2011

DURATION and SURVIVAL: Shaw, Alice T. Kim, Dong-Wan. Nakagawa, Kazuhiko. Seto, Takashi. Crino, Lucio. Ahn, Myung-Ju. De Pas, Tommaso. Besse, Benjamin. Solomon, Benjamin J. Blackhall, Fiona. Wu, Yi-Long. Thomas, Michael. O'Byrne, Kenneth J. Moro-Sibilot, Denis. Camidge, D Ross. Mok, Tony. Hirsh, Vera. Riely, Gregory J. Iyer, Shrividya. Tassell, Vanessa. Polli, Anna. Wilner, Keith D. Janne, Pasi A. Crizotinib versus chemotherapy in advanced ALK-positive lung cancer. N Engl J Med 2013;368(25):2385-2394
Note: The drug was approved on the basis of single arm trials. The legend to Figure 1 reports progression free survival. The paper also reports median overall survival, but notes “This

analysis was immature, and it is likely that it was confounded by the high crossover rate among patients in the chemotherapy group." We use progression free survival to measure survival benefits. The first paragraph under the Safety and Adverse Events section reports median duration of therapy (31 weeks).

Yervoy (ipilimumab); Bristol-Myers Squibb; For the treatment of metastatic melanoma, Approved March 2011

DURATION and SURVIVAL: Product label.
Note: Table 3 reports overall survival. The second paragraph of section 6.1 reports the mean number of doses (4). The third paragraph in the Clinical Studies section reports that 61% of patients completed 4 doses.

Zelboraf (vemurafenib); Roche; For the treatment of BRAF + melanoma, Approved August of 2011

DURATION and SURVIVAL: Product label.
Note: Table 4 reports progression free survival. The third paragraph of section 6.1 reports median treatment duration (4.2 months).

Zytiga (abiraterone acetate); Centocor Ortho Biotech; For the treatment of prostate cancer, Approved May 2011

DURATION and SURVIVAL: Product label.
Note: The second paragraph of section 6.1 reports median treatment duration (8 months). Table 3 reports overall survival.

DRUGS APPROVED IN 2010

Halaven (eribulin mesylate); Eisai; For the treatment of metastatic breast cancer, Approved November 2010

DURATION and SURVIVAL: Product label.
Note: The first paragraph of the Clinical Studies section reports the median number of cycles (5). Table 3 reports overall survival.

Herceptin (trastuzumab); Genentech; For the treatment of gastric cancer, Approved October 2010

The drug was approved previously for another indication.

Jevtana (cabazitaxel); sanofi aventis; For the treatment of prostate cancer, Approved June 2010

DURATION and SURVIAL: Product label.
Note: Table 2 reports the median number of cycles (6). Table 3 reports overall survival.

Provenge (sipuleucel-T); Dendreon; For the treatment of hormone refractory prostate cancer, Approved May 2010

DURATION and SURVIVAL: Product label.
Note: We assumed patients receive all three treatments. Table 2 reports overall survival.

Xgeva (denosumab); Amgen; For the prevention of skeletal-related events in patients with bone metastases from solid tumors, Approved November 2010

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Zuplenz (ondansetron oral soluble film); Strativa Pharmaceuticals; For the prevention of post-operative, chemotherapy and radiotherapy induced nausea and vomiting, Approved July 2010

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

DRUGS APPROVED IN 2009

Afinitor (everolimus); Novartis; For the treatment of renal cell carcinoma, Approved March 2009

DURATION and SURVIVAL: Product label.
Note. The second paragraph of section 6.1 reports the median duration of treatment (141 days). Table 3 reports progression free survival.

Arzerra (ofatumumab); GlaxoSmithKline; For the treatment of chronic lymphocytic leukemia, Approved October 2009

DURATION and SURVIVAL. GlaxoSmithKlinOfatumumab (Arzerra®) for the treatment of chronic lymphocytic leukaemia in patients who are refractory to fludarabine and alemtuzumab. . 2010 http://www.nice.org.uk/guidance/ta202/resources/chronic-lymphocytic-leukaemia-ofatumumab-manufacturers-submission2
Note: Table 6.22 reports overall and progression free survival. We assumed that treatment duration equals median progression free survival (0.525 years).

Avastin (bevacizumab); Genentech; For the treatment of renal cell carcinoma, Approved July 2009

The drug was approved previously for another indication.

Cervarix [Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant; GlaxoSmithKline; For the prevention of cervical cancer and cervical intraepithelial neoplasia caused by HPV types 16 and 18, Approved October 2009

Not included. The drug is a vaccine.

Elitek (rasburicase); sanofi-aventis; For the management of plasma uric acid levels in adults with malignancies, Approved October 2009

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Folotyn (pralatrexate injection); Allos Therapeutics; For the treatment of peripheral T-cell lymphoma, Approved September 2009

Not included. We were unable to find data on effectiveness.

Istodax (romidepsin); Gloucester Pharmaceuticals; For the treatment of cutaneous T-cell lymphoma, Approved November 2009

Not included. We were unable to find data on effectiveness.

Onsolis (fentanyl buccal); BioDelivery Sciences; For the management of breakthrough cancer pain, Approved July 2009

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Votrient (pazopanib); GlaxoSmithKline; For the treatment of renal cell carcinoma, Approved October of 2009

DURATION and SURVIAL: Product label.
Note: The Adverse Reactions section reports the median treatment duration (7.4 months). Table 3 reports progression free survival.

DRUGS APPROVED IN 2008

Degarelix (degarelix for injection); Ferring Pharmaceuticals; For the treatment of prostate cancer, Approved December of 2008

No included. The drug has a minimal impact on survival. (Lu, Jaime Peters, Chris Roome, Ken Stein Cost-effectiveness analysis of degarelix for advanced hormone-dependent prostate cancer BJU Int. 2012 Apr;109(8):1183-92.)

Fusilev (levoleucovorin); Spectrum Pharmaceuticals; For rescue after high-dose methotrexate therapy in osteosarcoma and to reduce the toxicity of methotrexate, Approved March of 2008

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Mozobil (plerixafor injection); Genzyme; For the treatment of non-Hodgkin's lymphoma and multiple myeloma, Approved December 2008

Not included. The drug is used to mobilize stem cells for autologous stem cell transplantation.

Sancuso (granisetron); ProStrakan; For the treatment of chemotherapy-induced nausea and vomiting, Approved September 2008

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Treanda (bendamustine hydrochloride); Cephalon; For the treatment of Chronic lymphocytic leukemia and B-cell non-Hodgkin's lymphoma, Approved October 2008

DURATION: Wolfgang U. Knauf, Toshko Lissichkov, Ali Aldaoud, Anna Liberati, Javier Loscertales, Raoul Herbrecht,Gunnar Juliusson, Gerhard Postner, Liana Gercheva, Stefan Goranov, Martin Becker, Hans-Joerg Fricke, Francoise Huguet, Ilaria Del Giudice, Peter Klein, Lothar Tremmel, Karlheinz Merkle, and Marco Montillo Phase III randomized study of bendamustine compared with chlorambucil in previously untreated patients with chronic lymphocytic leukemia. Journal of Clinical Oncology. 27(26):4378-84, 2009
Note: The Efficacy section reports the median number of cycles (6).

SURVIVAL: Product label.
Note: Table 3 reports progression free survival.

DRUGS APPROVED IN 2007

Evista (raloxifene hydrochloride); Eli Lilly; For the treatment/prevention of osteoporosis and reduction of breast cancer risk in postmenopausal women, Approved September 2007

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Hycamtin (topotecan hydrochloride); GlaxoSmithKline; For the treatment of small cell lung cancer, Approved October 2007

The drug was approved previously for another indication.

Ixempra (ixabepilone); Bristol-Myers Squibb; For the treatment of breast cancer, Approved October 2007

DURATION and SURVIVAL: Product Label.
Note: The Clinical Studies section reports the median number of cycles (5). Table 7 reports progression free survival

Tasigna (nilotinib hydrochloride monohydrate); Novartis; For the treatment of chronic myelogenous leukemia, Approved October 2007

DURATION and SURVIVAL: Martin Hoyle, MA, MSc, PhD1,*, Gabriel Rogers, BA1, Tiffany Moxham, MSc1, Zulian Liu, BA1, Ken Stein Cost-effectiveness of dasatinib and nilotinib for imatinib-resistant or -intolerant chronic phase chronic myeloid leukemia. Value Health. 2011 Dec;14(8):1057-67.
Note: Table 5 reports life expectancy. Treatment duration, 6.8 years, is reported in the second-to-last paragraph of the Results section, page 1065.

Torisel (temsirolimus); Wyeth; For the treatment of renal cell carcinoma, Approved May 2007

DURATION and SURVIVAL: Product label.
Note: The Clinical Studies section, page 5, reports the median duration of treatment (17 weeks). Table 3 reports overall and progression free survival.

Tykerb (lapatinib); GlaxoSmithKline; For the treatment of breast cancer, Approved March 2007

DURATION and SURVIVAL: See Product Label.
Note: Table 3 reports progression free survival. We assumed treatment duration equals progression free survival (27.1 weeks).

DRUGS APPROVED IN 2006

Gardasil (quadrivalent human papillomavirus (types 6, 11, 16, 18) recombinant vaccine); Merck; For the prevention of cervical cancer associated with human papillomavirus, Approved June 2006

Not included. The drug is a vaccine.

Sprycel (dasatinib); Bristol-Myers Squibb; For the treatment of imatinib-resistant chronic myeloid leukemia, Approved June 2006

DURATION and SURVIVAL: Martin Hoyle, MA, MSc, PhD1,*, Gabriel Rogers, BA1, Tiffany Moxham, MSc1, Zulian Liu, BA1, Ken Stein Cost-effectiveness of dasatinib and nilotinib for imatinib-resistant or -intolerant chronic phase chronic myeloid leukemia. Value Health. 2011 Dec;14(8):1057-67.

Note: Table 4 reports average life expectancy. Treatment duration, 6.5 years, is reported in the first paragraph of the Results section. The paper notes there is a high degree of uncertainty around this figure.

Sutent (sunitinib); Pfizer; For the treatment of kidney cancer and gastrointestinal stromal tumors, Approved January 2006

Note: We focused on results for kidney cancer, the indication with the largest market size.

DURATION and SURVIVAL: Thompson Coon, J., Hoyle, M., Green, C., Liu, Z., Welch, K., Moxham, T. and Stein, K. Bevacizumab, sorafenib tosylate, sunitinib and temsirolimus for renal cell carcinoma: a systematic review and economic evaluation. Health Technol Assess 2010;14:1-184, iii-iv.
Note: Table 44 describes average survival and time on treatment (17.9 months).

Vectibix (panitumumab); Amgen; For the treatment of colorectal cancer, Approved September 2006

DURATION and SURVIVAL: Product label.
Notes: The third paragraph of the Clinical Studies section reports progression free survival. We assumed that treatment duration is equal to median progression free survival (90 days).

DRUGS APPROVED IN 2005

Arranon (nelarabine); GlaxoSmithKline; For the treatment of T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma, Approved October 2005

DURATION: Product label.
Note: The Clinical Studies section reports the median duration of therapy (56 days).

SURVIVAL: All Wales Medicines Strategy Group. Nelarabine (Atriance®) for the treatment of T-cell acute lymphoblastic leukaemia and T-cell lymphoblastic lymphoma. Final Appraisal Report. April 2009. http://www.awmsg.org/awmsgonline/app/appraisalinfo/216
Note: Section 8.9.1.2 reports that QALYs for nelarabine and best supportive care (0.58 versus 0.21). Section 8.6.3 reports utility weight assumptions (0.78 and 0.64 for treatment and control).

Nexavar (sorafenib); Bayer/Onyx; For the Treatment of Renal Cell Carcinoma, Approved December 2005

DURATION: Escudier, Bernard. Eisen, Tim. Stadler, Walter M. Szczylik, Cezary. Oudard, Stephane. Siebels, Michael. Negrier, Sylvie. Chevreau, Christine. Solska, Ewa. Desai, Apurva A. Rolland, Frederic. Demkow, Tomasz. Hutson, Thomas E. Gore, Martin. Freeman, Scott. Schwartz, Brian. Shan, Minghua. Simantov, Ronit. Bukowski, Ronald M. TARGET Study Group. Sorafenib in advanced clear-cell renal-cell carcinoma. New England Journal of Medicine. 356(2):125-34, 2007 Jan 11.
Note: The Adverse Events section reports the median time on treatment (23 weeks).

SURVIVAL: Product label.
Notes: Figure 1 reports progression free survival.

DRUGS APPROVED IN 2004

Alimta (pemetrexed for injection); Eli Lilly; For the treatment of malignant pleural mesothelioma, Approved February 2004
DURATION and SURVIVAL: Product label.
Note: The last paragraph in the Clinical Studies section reports the median number of cycles (6). Table 2 reports for survival.

Avastin (bevacizumab); Genentech; For the treatment of metastatic carcinoma of the colon or rectum, Approved February 2004

DURATION and SURVIVAL: Product label.
Note: The Adverse Events, top of page 19, section reports the median duration of treatment (8 months). Table 1 reports overall and progression free survival.

Clolar (clofarabine); Genzyme; For the treatment of acute lymphoblastic leukemia in pediatric patients, Approved December, 2004

Not included. We were unable to find data on effectiveness.

Erbitux (cetuximab); Imclone, Bristol-Myers Squibb; For the treatment of EGFR-expressing, metastatic colorectal cancer, Approved February 2004

DURATION: Derek J. Jonker, M.D., Chris J. O'Callaghan, Ph.D., Christos S. Karapetis, M.D., John R. Zalcberg, M.D., Dongsheng Tu, Ph.D., Heather-Jane Au, M.D., Scott R. Berry, M.D., Marianne Krahn, M.D., Timothy Price, M.D., R. John Simes, M.D., Niall C. Tebbutt, M.D., Guy van Hazel, M.D., Rafal Wierzbicki, M.D., Christiane Langer, M.D., and Malcolm J. Moore, M.D.. Cetuximab for the treatment of colorectal cancer. N Engl J Med 2007;357(20):2040-2048.
Note: The Treatment section reports that the median duration of treatment (8.1 weeks).

SURVIVAL: Starling, N., Tilden, D., White, J. and Cunningham, D. Cost-effectiveness analysis of cetuximab/irinotecan vs active/best supportive care for the treatment of metastatic colorectal cancer patients who have failed previous chemotherapy treatment. Br J Cancer 2007; 96(2)::206-212.
Note: Table 2 reports mean overall survival.

Sensipar (cinacalcet); Amgen; For the treatment of secondary hyperparathyroidism and hypercalcemia in parathyroid carcinoma patients, Approved March 2004

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Tarceva (erlotinib, OSI 774); Genentech, OSI Pharmaceuticals; For the treatment of advanced refractory metastatic non-small cell lung cancer, Approved November, 2004

DURATION and SURVIVAL: Product label.
Note: Table 2 reports overall and progression free survival. We assumed treatment duration equals median progression free survival (9.9 weeks).

DRUGS APPROVED IN 2003

Aloxi (palonosetron); MGI Pharma, Helsinn Healthcare; For the prevention of nausea and vomiting associated with emetogenic cancer chemotherapy, Approved August 2003

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Bexxar (Tositumomab); Corixa; For the treatment of patients with CD20 positive, follicular, non-Hodgkin's lymphoma following chemotherapy relapse, Approved June 2003

DURATION: Product label.
Note: Tositumomab is administered as a single course of therapy.

SURVIVAL: Flowers CR, S. J., Briggs A, Osenenko K, Wang H, Dalal MR. Cost-effectiveness of tositumomab and iodine I-131 tositumomab (Bexxar therapeutic regimen (BTR)), in treatment of non- Hodgkin lymphoma (NHL). Journal of Clinical Oncology Vol 25, No 18S (June 20 Supplement), 2007: 8089
Note: See Table. We used survival estimates for 3rd line treatment, Bexxar therapeutic regimen versus rituximab maintenance.

Emend (aprepitant); Merck; For the treatment of nausea and vomiting associated with chemotherapy, Approved March 2003

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Iressa (gefitinib); AstraZeneca; For the second-line treatment of non-small-cell lung cancer, Approved May 2003

DURATION and SURVIVAL: Makoto Maemondo, Akira Inoue, Kunihiko Kobayashi, Shunichi Sugawara, Satoshi Oizumi, Hiroshi Isobe, Akihiko Gemma, Masao Harada, Hirohisa Yoshizawa, Ichiro Kinoshita, Yuka Fujita, Shoji Okinaga, Haruto Hirano, Kozo Yoshimori, Toshiyuki Harada, Takashi Ogura, Masahiro Ando, Hitoshi Miyazawa, Tomoaki Tanaka, Yasuo Saijo, Koichi HagiwaraSatoshi Morita, Toshihiro Nukiwa, for the North-East Japan Study Group Gefitinib or chemotherapy for non-small-cell lung cancer with mutated EGFR. N Engl J Med 2010;362(25):2380-2388.

Note: The Patient Characteristics section reports the median duration of treatment (308 days) days. The Efficacy section reports progression free survival. The drug was approved on the basis of a single-arm study.

Plenaxis (abarelix for injectable suspension); Praecis Pharmaceuticals; For treatment of advanced prostate cancer, Approved December 2003

Not included. We were unable to find data on effectiveness.

Premarin (conjugated estrogens); Wyeth; For the prevention of postmenopausal osteoporosis and treatment of vasomotor menopause symptoms, Approved July of 2003

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

UroXatral (alfuzosin HCl extended-release tablets); Sanofi-aventis; For the treatment of the signs and symptoms of benign prostatic hyperplasia, Approved June 2003

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Velcade (bortezomib); Millennium Pharmaceuticals; Injectable agent for the treatment of multiple myeloma patients who have received at least two prior therapies., Approved May 2003

DURATION and SURVIVAL: Richardson PG, Sonneveld P, Schuster MW, Irwin D, Stadtmauer EA, Facon T, Harousseau JL, Ben-Yehuda D, Lonial S, Goldschmidt H, Reece D, San-Miguel JF, Bladé J, Boccadoro M, Cavenagh J, Dalton WS, Boral AL, Esseltine DL, Porter JB, Schenkein D, Anderson KC; Assessment of Proteasome Inhibition for Extending Remissions (APEX) Investigators. Bortezomib or high-dose dexamethasone for relapsed multiple myeloma. N Engl J Med. 2005 Jun 16;352(24):2487-98.
Notes: The Drug Exposure section reports “56 percent of patients completed five three-week cycles of bortezomib”. Progression free survival results are reported in the Efficacy section. The drug was approved on the basis of a single-arm study.

DRUGS APPROVED IN 2002

Eligard (leuprolide acetate); Atrix Laboratories; For the palliative treatment of advanced prostate cancer, Approved January 2002

Not included. We were unable to find data on effectiveness. The drug is indicated for “palliative” treatment.

Eloxatin (oxaliplatin/5-fluorouracil/leucovorin); Sanofi-aventis; For the treatment of colon or rectum carcinomas, Approved August 2002

DURATION and SURVIVAL: Product label.
Note: Page 6 in the Clinical Studies section reports the median number of cycles (6). Table 4 reports time to progression.

Faslodex (fulvestrant); AstraZeneca; For the treatment of hormone receptor positive metastatic breast cancer, Approved April 2002

SURVIVAL: Product label.
Note: Table 3 reports progression free and overall survival. We used time to progression as a proxy for duration.

Gleevec (imatinib mesylate); Novartis; For the treatment of gastrointestinal stromal tumors (GISTs), Approved February 2002

The drug was approved previously for another indication.

Neulasta; Amgen; Treatment to decrease the chance of infection by febrile neutropenia in patients receiving chemotherapy, Approved January 2002

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

SecreFlo (secretin); Repligen; To aid in the diagnosis of pancreatic dysfunction and gastrinoma, Approved April 2002

Not included. SecreFlo is an imaging agent.

Zevalin (ibritumomab tiuxetan); Biogen IDEC; For the treatment of non-Hodgkin's lymphoma, Approved February 2002

DURATION and SURVIVAL: Product label.
Note: Time to progression is reported in Table 6. Patients receive only one dose of ibritumomab tiuxetan.

Zometa (zoledronic acid); Novartis; For the treatment of multiple myeloma and bone metastases from solid tumors, Approved February 2002

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

DRUGS APPROVED IN 2001

Campath (Alemtuzumab); Berlex Laboratories; Injectable treatment of B-cell chronic lymphocytic leukemia, Approved May 2001

DURATION and SURVIVAL: N. Mittmann, P. K. I., J.M. Connors, M. Rebeira, M.C. Cheung Economic Analysis of Alemtuzumab (MabCampath®) in Fludarabinerefractory Chronic Lymphocytic Leukemia. The Open Pharmacoeconomics & Health Economics Journal 2012;4:18-25.
Notes: Table 3 reports mean survival. The comparison is best supportive care. As described in the last paragraph in the Results section, patients received 12 cycles in the baseline analysis.

Femara (letrozole); Novartis; First-line treatment of postmenopausal women with locally advanced or metastatic breast cancer, Approved January 2001

The drug was approved previously for another indication.

Gleevec (imatinib mesylate); Novartis; Oral therapy for the treatment of chronic myeloid leukemia, Approved May 2001

DURATION and SURVIVAL: Shelby D. Reed, Kevin J. Anstrom, Jennifer A. Ludmer, G. Alastair Glendenning, M.Sc. Kevin A. Schulman, Reed, S. D., Anstrom, K. J., Ludmer, J. A., Glendenning, G. A. and Schulman, K. A. Cost-effectiveness of imatinib versus interferon-alpha plus low-dose cytarabine for patients with newly diagnosed chronic-phase chronic myeloid leukemia. Cancer 2004;101:2574-2583.
Notes: See Results section of the abstract for survival information. Reed et al. did not directly report treatment duration. Instead, we divided by the difference in costs ($241,800, see Table 2) by daily drug costs ($19.68 × 4) to estimate treatment duration (3,071 days). This calculation assumes that the entire difference in costs between treatment approaches is due to the direct costs of imatinib mesylate.

Kytril (granisetron) solution; Roche; For the prevention of nausea and vomiting associated with cancer therapy, Approved June 2001

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Trelstar LA (triptorelin pamoate); Debiopharm; Intramuscular injection for the treatment of advanced stage prostate cancer, Approved June 2001

Not included. We were unable to find data on effectiveness. The drug is indicated for "palliative" treatment.

Xeloda (Capecitabine); Roche; Oral chemotherapy for the treatment of metastatic colorectal cancer, Approved May 2001

The drug was approved previously for another indication.

Zometa (zoledronic acid); Novartis; For the treatment of hypercalcemia of malignancy, Approved August 2001

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

DRUGS APPROVED IN 2000

Mylotarg (gemtuzumab ozogamicin); Wyeth; For the treatment of CD33 positive acute myeloid leukemia (AML), Approved May 2000

Not included. The drug was approved on the basis of single arm trials, and post-approval randomized trials have failed to detect a benefit.

Trelstar Depot (triptorelin pamoate); Debio Rechereche Pharmaceutique, Target Research Associates; For the palliative treatment of advanced prostate cancer, Approved June 2000

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Trisenox (arsenic trioxide); Cell Therapeutics; For the induction of remission and consolidation in patients with acute promyelocytic leukemia (APL), Approved September 2000

Not included. We were unable to find data on effectiveness.

Viadur (leuprolide acetate implant); Alza; For pain relief in men with advanced prostate cancer, Approved March 2000

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

DRUGS APPROVED IN 1999

Aromasin Tablets; Pharmacia & Upjohn; Exemestane Tablets, 25 mg, October 21, 1999

DURATION: Kaufmann M. Bajetta E. Dirix LY. Fein LE. Jones SE. Zilembo N. Dugardyn JL. Nasurdi C. Mennel RG. Cervek J. Fowst C. Polli A. di Salle E. Arkhipov A. Piscitelli G. Miller LL. Massimini G. Exemestane is superior to megestrol acetate after tamoxifen failure in postmenopausal women with advanced breast cancer: results of a phase III randomized double-blind trial. The Exemestane Study Group. Journal of Clinical Oncology. 18(7):1399-411, 2000 Apr.
Note: Median treatment duration (17 weeks) is reported in the first section of the Results section.

SURVIVAL: Product label.
Note: Table 2 reports progression free survival.

Busulflex; Orphan Medical; For use in combination for the treatment of leukemia, Approved February 1999

Not included. The drug is used as a conditioning regimen in patients undergoing stem cell transplantation.

Doxil (doxorubicin HCl liposome injection); Alza; Treatment for ovarian cancer that is refractory to other first-line therapies, Approved June 1999

Not included. The drug was initially approved to treat AIDS-related Kaposi's sarcoma.

Ellence; Pharmacia & Upjohn; epirubicin hydrochloride, Approved September 1999

Not included. The drug is indicated for patients with early stage disease.

Ethyol (amifostine); US Bioscience, Alza; Treatment for xerostomia (dry mouth) due to radiation, Approved June 1999

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Temodar (Temozolomide); Schering-Plough; Treatment for refractory anaplastic astrocytoma, Approved August 1999

SURVIVAL and DURATION: Dinnes J, Cave C, Huang S, Major K, Milne R The effectiveness and cost-effectiveness of temozolomide for the treatment of recurrent malignant glioma: a rapid and systematic review Health Technology Assessment Volume: 2001. 5 Issue: 13
URL: http://www.journalslibrary.nihr.ac.uk/__data/assets/pdf_file/0007/65059/FullReport-hta5130.pdf
Note: See Table 8. We assumed that treatment duration equals progression free survival.

UVADEX Sterile Solution; Therakos; Treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL), Approved February 1999

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Zofran; GlaxoSmithKline; Treatment for the prevention of chemotherapy and radiation-induced nausea, Approved January 1999

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

DRUGS APPROVED IN 1998

Actiq; Anesta Corporation; Treatment for Cancer Pain, Approved November 1998

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Anzemet; Hoechst Marion Roussel; Treatment for the prevention of nausea and vomiting associated with chemotherapy and surgery, Approved February 1998

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Campostar; Pharmacia & Upjohn; Treatment for Colon or Rectal Cancer, Approved October 1998

The drug was approved previously for another indication.

Gemzar (gemcitabine HCL); Eli Lilly; Treatment for Lung Cancer, Approved August 1998

The drug was approved previously for another indication.

Herceptin (Trastuzumab); Genentech; Treatment for metastatic breast cancer, Approved October 1998

DURATION: Charles L. Vogel, Melody A. Cobleigh, Debu Tripathy, John C. Gutheil, Lyndsay N. Harris, Louis Fehrenbacher, Dennis J. Slamon, Maureen Murphy, William F. Novotny, Michael Burchmore, Steven Shak, Stanford J. Stewart, and Michael Press
Efficacy and safety of trastuzumab as a single agent in first-line treatment of HER2-overexpressing metastatic breast cancer. J Clin Oncol 2002;20(3):719-726.
Note: Duration is reported at the end of the Patients section in the Results.

SURVIAL: Product label.
Note: Table 1 reports progression free survival.

Inform HER-2/neu breast cancer test; Oncor; Treatment for breast cancer prediction, Approved January 1998

Not included. Inform HER-2 is a diagnostic test.

Neupogen; Amgen; Treatment for slow white blood cell recovery following chemotherapy, Approval April 1998

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Nolvadex; AstraZeneca; Treatment for Breast Cancer, Approved October 1998

Not included. The drug was first approved before 1995.

Photofrin; QLT; Treatment for early-stage, microinvasive endobronchial non-small cell lung cancer, Approved January 1998

Not included. The drug is indicated for early stage tumors.

Proleukin; Chiron; Treatment for metastatic melanoma, Approved January 1998

Not included. The drug was first approved before 1995.

Sclerosol Intrapleural Aerosol; Bryan Corporation; Treatment for malignant pleural effusions, Approved January 1998

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Valstar; Anthra Pharmaceuticals; Treatment for Bladder Cancer, Approved October 1998

Not included. The drug is indicated for treatment of patients with non-metastatic tumors.

Xeloda (Capecitabine); Roche; Treatment for advanced breast cancer tumors, Approved April 1998

DURATION and SURVIVAL: Joyce O'Shaughnessy, David Miles, Svetislava Vukelja, Vladimir Moiseyenko, Jean-Pierre Ayoub, Guadalupe Cervantes, Pierre Fumoleau, Stephen Jones, Wing-Yiu Lui, Louis Mauriac, Chris Twelves, Guy Van Hazel, Shailendra Verma, and Robert Leonard Superior survival with capecitabine plus docetaxel combination therapy in anthracycline-pretreated patients with advanced breast cancer: phase III trial results. J Clin Oncol. 2002 Jun 15;20(12):2812-23.
Note: Figures 1 and 2 report median progression free survival and overall survival. Duration is reported in the Safety section. The drug was approved on the basis of a single-arm study.

Zofran; GlaxoSmithKline; Treatment for postoperative vomiting and nausea in adults, Approved April 1998

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

DRUGS APPROVED IN 1997

Anzemet; Hoechst Marion Roussel; Treatment for emesis, Approved September 1997

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Bromfenac; Duract, Wyeth-Ayerst Laboratories; Management of acute pain, Approved July 1997

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Femara (letrozole); Novartis; Treatment for breast cancer, Approved July 1997

DURATION and SURVIVAL: Product label.
Notes: Treatment duration was based on the median time to progression. Table 6 reports overall and progression free survival.

Gliadel Wafer (polifeprosan 20 with carmustine implant); Rhone-Poulenc Rorer, Guilford Pharmaceuticals; Treatment for brain cancer, Approved February 1997

AWP: Paul C. McGovern,1,4,5 Ebbing Lautenbach,1,2,4,5 Patrick J. Brennan,1 Robert A. Lustig,3 and Neil O. Fishman1,5 Risk Factors for Postcraniotomy Surgical Site Infection after 1,3-Bis (2-Chloroethyl)-1-Nitrosourea (Gliadel) Wafer Placement Clinical Infectious Diseases 2003; 36:759–65

12,480 per box

DURATION: Product label.
Note: There is a single administration.

SURVIVAL: Brem, Henry., Steven Piantadosi., Peter C. Burger, Michael Walker, Robert Selker, Nicholas A. Vick, Keith Black, Michael Sisti, Steven Brem, Gerald Mohr, Paul Muller, Richard Morawetz, S. Clifford Schold, for the Polymer-Brain Tumor Treatmnt Group. Placebo-Controlled Trial of Safety and Efficacy of Intraoperative Controlled Delivery by Biodegradable Polymers of Chemotherapy for Recurrent Gliomas. Lancet 1995;345(8956):1008-1012.
Note: See Statistical Analysis section in the Results.

Intron A (interferon alfa-2b, recombinant); Schering-Plough; Treatment for non-Hodgkin's lymphoma, Approved December 1997

Not included. The drug was first approved before 1995.

Kytril (granisetron) tablets; SmithKline Beecham; Prevention of nausea and vomiting associated with chemotherapy, Approved November 1997

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Lupron Depot (leuprolide acetate for depot suspension); TAP Pharmaceuticals; Treatment for prostate cancer, Approved July 1997

Not included. We were unable to find data on effectiveness.

Miraluma test; DuPont Merck Pharmaceutical Company; Test for breast cancer, Approved May 1997

Not included. The Miraluma test is a diagnostic test.

Neumega; Genetics Institute; Treatment for thrombocytopenia, Approved November 1997

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Quadramet (Samarium Sm 153 Lexidronam Injection); DuPont Merck Pharmaceutical Company; Treatment for pain associated with bone cancer, Approved March 1997

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Rituxan; Biogen IDEC, Genentech; Treatment for non-hodgkin's lymphoma, Approved November 1997

DURATION and SURVIVAL: Hornberger, J. C. and Best, J. H. Cost utility in the United States of rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisone for the treatment of elderly patients with diffuse large B-cell lymphoma. Cancer 2005;103:1644-1651.
Notes: See Tables 1 and 2.

Taxol; Bristol-Myers Squibb; Treatment for AIDS-related Kaposi's Sarcoma, Approved August 1997

Not included. The drug was first approved before 1995.

DRUGS APPROVED IN 1996

Anexsia; Mallinckrodt Group; Treatment for chronic pain, Approved August 1996

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Aredia (pamidronate disodium for injection); Chiron; Treatment for osteolytic bone metastases of breast cancer, Approved August 1996

Not included. The drug was first approved before 1995.

Arimidex (anastrozole); AstraZeneca; Treatment for advanced breast cancer in postmenopausal women, Approved January 1996
Note: According to the FDA website, approval was granted in December 1995.

DURATION and SURVIVAL: Product label.

Note. Table 3 reports overall and progression free survival. We assumed time on treatment equals progression free survival.

Campostar (Irinotecan); Pharmacia & Upjohn; Treatment for metastatic colorectal cancer, Approved June 1996

DURATION: and SURVIVAL Product label.
Note: See Table 3, Study 1, under Clinical Studies section. Figure 1 reports overall survival. Median treatment duration is 4.1 months.

CEA-Scan; Immunomedics; Diagnostic imaging product for colorectal cancer, Approved April 1996

Not included. The agent is used as a diagnostic aid.

Elliotts B Solution (buffered intrathecal electrolyte/dextrose injection); Orphan Medical; Treatment of meningeal leukemia or lymphocytic lymphoma, Approved October 1996

Not included. The product is a diluent.

Eulexin (flutamide); Schering-Plough; Treatment for prostate cancer, Approved June 1996

Not included. The drug was approved prior to 1995.

Feridex I.V.; Advanced Magnetics; Contrast agent for magnetic resonance imaging of liver lesions, Approved February 1996

Not included. The agent is used as a diagnostic aid.

GastroMARK; Advanced Magnetics; Contrast agent for magnetic resonance imaging of the gastrointestinal tract, Approved May 1996

Not included. The agent is used as a diagnostic aid.

Gemzar (gemcitabine HCL); Eli Lilly; Treatment for pancreatic cancer, Approved May 1996

DURATION: Mark D. Danese, Carolina Reyes, Kelly Northridge, Deborah Lubeck, Chin-Yu Lin, Paula O'Connor. Budget impact model of adding erlotinib to a regimen of gemcitabine for the treatment of locally advanced, nonresectable or metastatic pancreatic cancer. Clin Ther 2008;30(4):775-784.
Note: See Treatment Duration section of Methods.

SURVIVAL: Product label.
Note: Table 3 reports overall survival.

Hycamtin (topotecan hydrochloride); SmithKline Beecham; Treatment for metastatic ovarian cancer, Approved May 1996

DURATION and SURVIVAL: Product label.
Note: Table 1 in the Clinical Studies section reports the median response duration (25.9 weeks). The cycle length is 21 days. Table 1 reports overall and progression free survival.

Kadian; Purepac Pharmaceutical; Treatment for chronic moderate to severe pain, Approved July 1996

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Leukine (sargramostim); Immunex; Treatment for the replenishment of white blood cells, Approved November 1996

Not included. The product is used in conjunction with stem cell transplantation.

Lupron Depot (leuprolide acetate for depot suspension); Abbott Laboratories; Treatment for advanced prostate cancer, Approved January 1996

Not included. Lupron Depot was originally approved by the FDA in 1989.

Photodynamic Therapy; Sanofi-aventis; Photodynamic therapy device for the treatment of esophageal cancer, Approved January, 1996

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Taxotere (Docetaxel); Rhone Poulenc Rorer; Treatment for locally advanced or metastatic breast cancer, Approved May 1996

DURATION: Nabholtz, J. M., Senn, H. J., Bezwoda, W. R., Melnychuk, D., Deschenes, L., Douma, J., Vandenberg, T. A., Rapoport, B., Rosso, R., Trillet-Lenoir, V., Drbal, J., Molino, A., Nortier, J. W., Richel, D. J., Nagykalnai, T., Siedlecki, P., Wilking, N., Genot, J. Y., Hupperets, P. S., Pannuti, F., Skarlos, D., Tomiak, E. M., Murawsky, M., Alakl, M., Aapro, M. and et al. Prospective randomized trial of docetaxel versus mitomycin plus vinblastine in patients with metastatic breast cancer progressing despite previous anthracycline-containing chemotherapy. 304 Study Group. J Clin Oncol 1999;17(5):1413-1424.
Note: See Exposure to Study Medication section.

SURVIVAL: Product label
Note: The table on pages 4 and 5 reports overall and progression free survival.

UltraJect; Mallinckrodt Group; Treatment for chronic pain, Approved August 1996

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Visipaque (iodixanol); Nycomed; Diagnostic contrast agent, Approved April 1996

Not included. The agent is used as a diagnostic aid.

Zoladex (10.8 mg goserelin acetate implant); AstraZeneca; Treatment for advanced prostate cancer, Approved January 1996

Not include, The drug was originally approved before 1995.

DRUGS APPROVED IN 1995

Ethyol (amifostine); Alza; Treatment to reduce renal toxicity associated with chemotherapy in subjects with advanced ovarian cancer, Approved December 8, 1995

Not included. The drug is administered primarily to relieve symptoms rather than prolong survival.

Intron A (Interferon alfa-2b, recombinant); Schering-Plough; An adjuvant treatment to surgery in subjects at high risk for systemic recurrence of malignant melanoma, Approved December 1995.

Not included. The drug is an adjuvant treatment for patients undergoing surgery.

Leukine (sargramostim); Immunex; Treatment for mobilizing peripheral blood progenitor cells for use after transplantation., Approved on November 24, 1995

Not included. The product is used in conjunction with stem cell transplantation.

Self-examination breast pad; Inventive Products; Self-examination breast pad, Approved on December 22, 1995

Not included. The product is not a treatment for late stage cancer.