

Supplementary Appendix

This appendix has been provided by the author to give readers additional information about his work.

Supplement to: Bach PB. Limits on Medicare's ability to control rising spending on cancer drugs. *N Engl J Med* 2009;360:626-33. DOI: 10.1056/NEJMp0807774.

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METHODS

All drugs approved by the US Food and Drug Administration for the treatment of cancer or myelodysplastic syndrome since 1965 were identified based on a search of lists obtained from the US Food and Drug Administration, the National Cancer Institute, the Association for Community Cancer Centers, and the National Comprehensive Cancer Network Compendium for Cancer. Drugs that were labeled only for the management of cancer related symptoms, management of cancer treatment side effects (e.g. anti-nausea agents), or para-neoplastic complications (e.g. octreotide acetate), and those labeled exclusively for the treatment of pediatric cancers (e.g. clofabrine) were not included.

The prices of drugs at the time of approval for their cancer indication are based on the allowable Medicare charge, or its equivalent, including payments derived from Medicare, patient and third party payor. So, for a Part B cancer drug, administered in the physician office, the listed price is 100% of the “allowed charge”, which is made up of Medicare’s portion (80% of the allowed charge), and the patient’s portion which is often covered by a third party payor (20% of the allowed charge). For oral drugs approved prior to 2006 and not covered under Medicare Part B, the price at the time of approval is based on the same formula used to reimburse Part B drugs during that year, even though some of these drugs were not covered by Medicare at the time. For cancer drugs covered in Part D from 2006 onward, the listed price is 100% of a representative prescription drug plan’s listed drug cost in 2008. Depending on the benefit structure, the actual cost of the drug can be borne entirely by the patient, entirely by the plan, or somewhere in-between.

The price listed is for a month of treatment determined by dividing a 12 week treatment course by 2.77 (the number of months in 12

weeks). The dosing regimen is for the first approved therapeutic cancer indication as listed on the FDA approved drug label for an adult weighing 70 kilograms, or with a body surface area of 1.7 meters squared. The use of a 12 week treatment period accommodated the reality that virtually all regimens are given in intervals that are factors of 12 (e.g. every other week, every third week).

There are a few drugs that are given for only a short period of time to reach the total dose. The price reported in these cases is the same as that for other drugs – the average over the 12 weeks, even if the total treatment duration is brief (e.g. gemtuzumab). The price reported is therefore much lower than the actual price during active treatment. When more than one dosing schedule was approved, the one that used a lower total amount of the drug was used for calculating the price.

Table 1. Medicare reimbursement rule used to determine drug price

Year of approval	Method for determining Medicare price
Part B physician administered and covered oral drugs	
Prior to 1997	100% of the Average Wholesale Price at the time of approval
1997 - 2003	95% of the Average Wholesale Price at the time of approval
2004	85% of the Average Wholesale Price at the time of approval
2005 - 2007	106% of the Average Sales Price at the time of approval
2008	Wholesale Acquisition Cost at the time of approval as reported by Manufacturer
Part D oral drugs	
prior to 2006	Follows method above for Part B drugs
2006 or later	"Full Cost of Drug" as reported in the PlanFinder for the Humana PDP Enhanced plan for year 2008, ZIP code 10021 (www.medicare.gov)

Table 2. Price at introduction for cancer drugs

Generic Drug Name	Drug Trade Name	Year of Approval	Monthly Medicare Price (USD, unadjusted, at time of approval)
vinblastine	Velban	1965	78
thioguanine, 6-TG	Thioguanine Tabloid	1966	17
hydroxyurea	Hydrea	1967	14
cytarabine	Cytosar-U, Tarabine PFS	1969	13
procarbazine	Matulane	1969	2
testolactone	Teslac	1969	179
mitotane	Lysodren	1970	134
plicamycin	Mithracin	1970	50
mitomycin C	Mutamycin	1974	4
dacarbazine	DTIC-Dome	1975	29
lomustine	CeeNU	1976	10
carmustine	BCNU, BiCNU	1977	33
tamoxifen citrate	Nolvadex	1977	44
cisplatin	Platinol	1978	125
estramustine	Emcyt	1981	420
streptozocin	Zanosar	1982	61
etoposide, VP-16	Vepesid	1983	181
interferon alfa 2a	Roferon A	1986	742
daunorubicin, daunomycin	Cerubidine	1987	533
doxorubicin hydrochloride for injection	Adriamycin	1987	521
mitoxantrone	Novantrone	1987	477
ifosfamide	IFEX	1988	1,667
flutamide	Eulexin	1989	213
altretamine	Hexalen	1990	341
idarubicin	Idamycin	1990	227
levamisole	Ergamisol	1990	105
carboplatin	Paraplatin	1991	860
fludarabine phosphate	Fludara	1991	662
pamidronate	Aredia	1991	507
pentostatin	Nipent	1991	1,767
aldesleukin	Proleukin	1992	13,503
melfhalan	Alkeran	1992	35
cladribine	Leustatin, 2-CdA	1993	764

Generic Drug Name	Drug Trade Name	Year of Approval	Monthly Medicare Price (USD, unadjusted, at time of approval)
asparaginase	Elspar	1994	694
paclitaxel	Taxol	1994	2,614
pegaspargase	Oncaspar	1994	3,006
vinorelbine	Navelbine	1994	1,035
anastrozole	Arimidex	1995	189
bicalutamide	Casodex	1995	311
doxorubicin hydrochloride liposome	Doxil, Dox-SL, Evacet, LipoDox	1995	1,488
goserelin acetate	Zoladex	1995	415
porfimer sodium	Photofrin	1995	520
tretinoin, ATRA	Vesanoid	1995	2,435
bleomycin	Blenoxane	1996	421
daunorubicin liposomal	DanuoXome	1996	847
etoposide phosphate	Etopophos	1996	685
gemcitabine	Gemzar	1996	2,129
irinotecan	Camptosar	1996	5,326
nilutamide	Nilandron	1996	320
topotecan	Hycamtin	1996	2,344
letrozole	Femara	1997	180
Rituximab	Rituxan	1997	3,475
toremifene	Fareston	1997	93
BCG Live	TICE BCG	1998	53
capecitabine	Xeloda	1998	1,045
leuprolide; leuprolide acetate	Eligard, Lupron, Lupron Depot	1998	206
trastuzumab	Herceptin	1998	3,208
valrubicin	Valstar	1998	3,209
bexarotene	Targretin	1999	2,361
busulfan	Busulfex	1999	1,427
cytarabine liposomal	DepoCyt	1999	3,351
denileukin	Ontak	1999	14,291
docetaxel	Taxotere	1999	2,610
epirubicin hydrochloride	Ellence	1999	2,295
exemestane	Aromasin	1999	205
methoxsalen	Uvadex	1999	80
temozolomide	Temodar	1999	1,574
arsenic trioxide	Trisenox	2000	5,400

Generic Drug Name	Drug Trade Name	Year of Approval	Monthly Medicare Price (USD, unadjusted, at time of approval)
gemtuzumab ozogamicin	Mylotarg	2000	4,262
triptorelin pamoate	Trelstar Depot	2000	450
alemtuzumab	Campath	2001	19,925
imatinib mesylate	Gleevec	2001	3,401
fulvestrant	Faslodex	2002	948
ibritumomab tiuxetan	Zevalin	2002	1,000
oxaliplatin	Eloxatin	2002	5,911
zoledronic acid	Zometa	2002	881
abarelix	Plenaxis depot	2003	2,607
bortezomib	Velcade	2003	3,392
gefitinib	Iressa	2003	1,608
Tositumomab	Bexxar	2003	1,449
azacitidine	Vidaza	2004	3,909
bevacuzimab	Avastin	2004	4,430
cetuximab	Erbitux	2004	9,465
erlotinib	Tarceva	2004	4,174
pemetrexed disodium	Alimta	2004	5,086
lenalidomide	Revlimid	2005	7,989
nelarabine	Arranon	2005	19,425
paclitaxel albumin-stabilized nanoparticle formulation	Abraxane, Nanoparticle Paclitaxel	2005	5,640
sorafenib	Nexavar	2005	5,097
dasatinib	Sprycel	2006	4,529
decitabine	Dacogen	2006	4,652
panitumumab	Vectibix	2006	7,991
sunitinib maleate	Sutent	2006	4,590
thalidomide	Thalomid	2006	5,613
vorinostat	Zolinza	2006	8,134
ixabepilone	Ixempra	2007	6,781
Lapatinib ditosylate	Tykerb	2007	3,124
nilotinib	Tasigna	2007	6,140
temsirolimus	Torisel	2007	5,497
Bendamustine hydrochloride	Treanda	2008	7,023