



Oncology Reimbursement Connection

A Newsletter for Oncology Pharmacists, Nurses, Social Workers, and Office Managers

VOLUME 2 NUMBER 4

WINTER, 2005

2005 OUTPATIENT PROSPECTIVE PAYMENT SYSTEM FINAL RULE: SUMMARY OF ONCOLOGY MEDICATIONS

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Introduction

Each year the Centers for Medicare & Medicaid Services (CMS) proposes revisions to the Outpatient Prospective Payment System (OPPS), including revisions of payment rates for hospital-based outpatient services, and considers comments from the public before implementing the revisions.¹ The proposed revisions are detailed in the OPPS Proposed Rule, which is published in the Federal Register, usually in late summer; the 2005 OPPS Proposed Rule was published on August 16, 2004.² For a complete summary of the 2005 OPPS Proposed Rule, August 16, 2004, please see the feature article entitled "2005 Outpatient Prospective Payment System Proposed Rule" in the 2004 Fall issue (volume 2, number 3) of the *Oncology Reimbursement Connection*.^{2,3} After the public-comment period, CMS reviews and addresses comments and any new recommendations from advisory panels, publishing the Final Rule that becomes effective for the next calendar year in late fall. On November

Medicare reimbursement regulations and policies related to the hospital Outpatient Prospective Payment System (OPPS) undergo revisions continually. Although we strive for currency in each issue of this newsletter, some information may not be current when you read it. For the most recent federal regulations and notices, program memoranda providing quarterly updates, and other OPPS information, please refer to the Centers for Medicare & Medicaid Services Web site (<http://www.cms.hhs.gov/providers/hopps/>).

Medicare Reimbursement Definitions

ambulatory payment classification (APC)—basic unit of payment in the Outpatient Prospective Payment system for outpatient services or procedures. APCs are based on patient diagnosis, type of treatment, and amount of resources required to provide a service.

average sales price (ASP)—manufacturer's average price, including discounts, of a drug; used to determine reimbursement payment rates for drugs administered in a physician's office and for some drugs administered in outpatient hospital clinics.

average wholesale price (AWC)—suggested average price of a drug (ie, undiscounted price) based on a survey of wholesalers' listed price; used to determine reimbursement payment rates for some drugs administered in outpatient hospital clinics.

Current Procedural Terminology (CPT)—list of descriptive terms and corresponding numeric codes used to identify healthcare services and procedures performed or supervised by physicians.

fiscal intermediary—insurance company that has a private contract with the Centers for Medicare & Medicaid Services (CMS) to administer the Medicare Part A program and some Part B program services.

Healthcare Common Procedure Coding System (HCPCS)—list of descriptive terms and corresponding numeric codes used to identify healthcare services, procedures, and supplies provided by hospital outpatient and physician office healthcare providers. The 3 levels of HCPCS codes are as follows: Level I—physician services (also known as CPT codes); Level II—national codes for physician-administered drugs, medical supplies, and durable medical equipment; and Level III—local codes, created for services and products not included in Levels I and II by carriers or fiscal intermediaries.

innovator, multiple-source drug—brand-name drug that also has a Food and Drug Administration (FDA)-approved generic alternative.

noninnovator, multiple-source drug—generic drug approved by the FDA

outpatient code editor—software package that reviews CPT/HCPCS codes and *International Classification of Diseases, 9th version, Clinical Modification (ICD-9-CM)* codes for validity and coverage. In addition to identifying coding errors, it also assigns APCs.

orphan drug—drug that is generally expensive and used for rare diseases or conditions and has been granted orphan drug status by the FDA.

pass-through drug—certain new drugs, biologics, or radiopharmaceuticals eligible for a higher reimbursement payment rate for the first 2–3 years of commercial availability (eg, cancer-treatment drugs).

reference AWP—AWP established by the CMS *Single Drug Pricer*, and index that establishes drug payment rates based on the price list printed in the *Red Book*, May 1, 2003.

single-source drug—see sole-source drug.

sole-source drug—brand-name drug for which no FDA-approved generic alternative exists.

specified covered outpatient drug—drugs for which a separate, drug-specific APC exists and payment was made on a pass-through payment basis on or before December 31, 2002. Exceptions include 1) a drug or biologic for which a temporary HCPCS code has not been assigned and 2) a drug assigned orphan status in 2004 or 2005.

wholesale acquisition cost (WAC)—manufacturer's list price to wholesalers or direct purchasers, not including discounts, rebates, or other price reductions.

Table 1. Oncology Drugs Without Separate APC Payments in 20051-7**

Generic Name	Brand Name	Billing Code (Billing Unit)	Usual Administration Route(s)
Corticotropin	NA	J0800 (up to 40 U)	IV, IM, SC
Cyclophosphamide, oral [‡]	Cytoxan [®]	J8530 (25 mg, oral)	Oral
Cytarabine liposome [§]	Depocyt [®]	J9098 (10 mg)	IT
Dactinomycin	Cosmegen [®]	J9120 (0.5 mg)	IV
Dexamethasone acetate	Decaject [®] LA; others	J1094 (1 mg)	IM
Dexamethasone sodium phosphate	Decadron [®] Phosphate; others	J1100 (1 mg)	IM, IV
Estradiol cypionate	Depo-Estradiol [®]	J1000 (up to 5 mg)	IM
Estradiol valerate	Delestrogen [®]	J1380 (up to 10 mg) J1390 (up to 20 mg) J0970 (up to 40 mg)	IM IM IM
Estrone	NA	J1435 (1 mg)	IM
Etidronate disodium	Didronel [®]	J1436 (300 mg)	IV
Fluorouracil	Adrucil [®]	J9190 (500 mg)	IV
Hydrocortisone acetate	Hydrocortone [®] Acetate	J1700 (up to 25 mg)	IV, IM, SC
Hydrocortisone sodium phosphate	Hydrocortone [®] Phosphate	J1710 (up to 50 mg)	IV, IM, SC
Hydrocortisone sodium succinate	Solu-Cortef [®] ; A-hydroCort [®]	J1720 (up to 100 mg)	IV, IM, SC
Leucovorin calcium	NA	J0640 (50 mg)	IM, IV
Mechlorethamine HCl	Mustargen [®]	J9230 (10 mg)	IV
Melphalan, oral ¹¹	Alkeran [®]	J8600 (2 mg)	Oral
Methotrexate sodium	NA Rheumatrex [®] Dose Pack	J9250 (5 mg) J8610 (2.5 mg oral)	IA, IM, IT, IV Oral
Methylprednisolone sodium succinate	Solu-Medrol [®] ; A-methaPred [®]	J2920 (up to 40 mg) J2930 (up to 125 mg)	IM, IV
Nandrolone decanoate	NA	J2320 (up to 50 mg) J2321 (up to 100 mg) J2322 (up to 200 mg)	IM IM IM
Prednisone	Deltason [®] ; others	J7506 (per 5 mg)	Oral
Streptozocin [§]	Zanosar [®]	J9320 (1 gm)	IV
Testosterone cypionate	Depo-Testosterone [®] ; Virilon [®] IM	J1060 (1 mL) J1070 (100 mg) J1080 (200 mg)	IM IM IM
Testosterone enanthate	Delatestryl [®]	J3120 (up to 100 mg) J3130 (up to 200 mg)	IM IM

Table 1. (cont'd) Oncology Drugs Without Separate APC Payments in 20051-7**

Generic Name	Brand Name	Billing Code (Billing Unit)	Usual Administration Route(s)
Testosterone propionate	NA	J3150 (up to 100 mg)	IM
Testosterone injectable suspension	NA	J3140 (up to 50 mg)	IM
Valrubicin [§]	Valstar [®]	J9357 (200 mg)	Intravesical
Vinblastine sulfate	NA	J9360 (1 mg)	IV
Vincristine sulfate	Vincasar PFS [®]	J9370 (1 mg)	IV

*Reimbursed by Medicare in 2005 as packaged APC.

[‡]Injectable drugs, unless otherwise specified.

[§]IV formulation has its own APC (see Table 3).

[§]Assigned drug-specific APC status in 2004.

¹¹IV formulation has its own APC (see Table 2).

APC=ambulatory payment classification; HCl=hydrochloride; IA=intraarterial; IM=intramuscular; IT=intrathecal; IV=intravenous; NA=not applicable; SC=subcutaneous.

15, 2004, the 2005 OPPS Final Rule was released.¹ This article summarizes the key differences between the 2005 OPPS Proposed and Final Rules and categorizes oncology medications according to 2005 OPPS payment classifications.

Payment for Oncology Medications

In 2005, OPPS classifies oncology drugs, biologics, and radiopharmaceuticals (for the remainder of this article, “drugs, biologics, and radiopharmaceuticals” are referred to as “drugs”) according to 5 basic categories: 1) drugs included in packaged ambulatory payment classifications (APCs); 2) specified covered outpatient drugs; 3) transitional pass-through drugs; 4) orphan drugs; and 5) new oncology drugs that do not fit into the other categories.¹ Payment rates differ based on these categories.

Packaged APCs

Oncology drugs with a median cost per day of less than \$50 (based on hospital claims data used to determine the 2005 OPPS Final Rule) that were reimbursed as packaged APCs (ie, drug cost included within the costs of the procedure or service provided) in 2004 continue to be reimbursed as packaged APCs in 2005 (Table 1).¹⁻⁷ Carmustine and pegaspargase, considered as packaged APCs in the 2005 OPPS Proposed Rule, are now categorized as a multiple-source drug and sole-source drug, respectively, in the Final Rule based on a recalculation of median costs (ie, > \$50/d) (Tables 2 and 3).^{1,2,4-6,8,9}

An exception to the packaged APC category is 5-hydroxytryptamine type 3 (5-HT₃) antiemetics. Because the costs of these antiemetics vary (ie, ≤ \$50/d vs > \$50/d), the current classification system reimburses some 5-HT₃ antiemetics as packaged APCs, whereas other 5-HT₃ antiemetics are reimbursed separately; this cost difference might influence a healthcare provider's choice of drug, ultimately impeding the patient's access to the

Table 2. 2005 Payment Rates for Sole-Source Oncology Drugs*1,2,4-6

Generic Name	Brand Name	Billing Code (Billing Unit)	APC	2005 Payment, \$
Amifostine	Ethyo1®	J0207 (500 mg)	7000	395.75
Asparaginase	Elspar®	J9020 (10,000 U)	0814	54.71
Bacillus Calmette-Guérin, live	TheraCys®; Tice® BCG	J9031 (per vial)	0809	139.90
Busulfan	Busulfex®	C1178 (6 mg)	1178	24.35†
Busulfan, oral	Myleran®	J8510 (2 mg)	7015	2.08
Capecitabine, oral	Xeloda®	J8520 (150 mg)	7042	2.96
Carboplatin	Paraplatin®	J9045 (50 mg)	0811	129.96
Darbepoetin alfa‡§	Aranesp®	Q0137 (1 µg)	0734	3.66†
Daunorubicin citrate liposome	DaunoXome®	J9151 (10 mg)	0821	56.44†
Docetaxel	Taxotere®	J9170 (20 mg)	0823	312.69
Dolasetron mesylate	Anzemet®	J1260 (10 mg) Q0180 (100 mg, oral)	0750 0763	14.38 63.28
Doxorubicin HCl liposomal	Doxil®	J9001(10 mg)	7046	343.78
Epirubicin HCl	Ellence®	J9178 (2 mg)	1167	24.14
Epoetin alfa†	Procrit®; Epogen®	Q0136 (1,000 U)	0733	11.09
Filgrastim	Neupogen®	J1440 (300 µg) J1441 (480 µg)	0728 7049	162.41 274.40
Fludarabine phosphate	Fludara®	J9185 (50 mg)	0842	311.09
Fulvestrant§	Faslodex®	J9395 (25 mg)	9120	79.65
Gallium nitrate	Ganite™	J1457 (1 mg)	1085	.23
Gemcitabine HCl	Gemzar®	J9201 (200 mg)	0828	105.73
Goserelin acetate implant	Zoladex®	J9202 (3.6 mg)	0810	390.09
Granisetron HCl	Kytril®	J1626 (100 µg) Q0166 (1 mg, oral)	0764 0765	16.20 39.04
Interferon alfa-2a, recombinant	Roferon®-A	J9213 (3 million U)	0834	30.48
Interferon alfa-2b, recombinant	Intron®A	J9214 (1 million U)	0836	13.00
Irinotecan HCl	Camptosar®	J9206 (20 mg)	0830	127.33
Leuprolide acetate (for depot suspension)	Lupron Depot®	J1950 (3.75 mg) J9217 (7.5 mg)	0800 9217	451.98 543.72
Leuprolide acetate implant	Viadur®	J9219 (65 mg)	7051	4,717.72
Melphalan HCl¶	Alkeran®	J9245 (50 mg)	0840	367.03

Table 2. (cont'd) 2005 Payment Rates for Sole-Source Oncology Drugs*1,2,4-6

Generic Name	Brand Name	Billing Code (Billing Unit)	APC	2005 Payment, \$
Mitoxantrone HCl	Novantrone®	J9293 (5 mg)	0864	313.96
Octreotide acetate	Sandostatin®	J2354 (25 µg)	7031	3.72
Octreotide acetate depot	Sandostatin LAR® Depot	J2353 (1 mg)	1207	69.44†
Ondansetron HCl	Zofran® Zofran ODT®	J2405 (1 mg) Q0179 (8 mg, oral)	0768 0769	5.54 26.12
Pegaspargase†	Oncaspar®	J9266 (single-dose vial)	0843	1,247.08
Pegfilgrastim§	Neulasta®	J2505 (6 mg)	9119	2,448.50
Pentostatin	Nipent®	J9268 (10 mg)	0844	1,683.24
Plicamycin	Mithracin®	J9270 (2,500 µg)	0860	93.80
Porfimer sodium	Photofrin®	J9600 (75 mg)	0856	2,274.78
Rituximab**	Rituxan®	J9310 (100 mg)	0849	437.83
Sargramostim	Leukine®	J2820 (50 µg)	0731	25.39
Temozolomide, oral	Temodar®	J8700 (5 mg)	1086	6.42
Teniposide	Vumon®	Q2017 (50 mg)	7035	224.94
Topotecan HCl	Hycamtin®	J9350 (4 mg)	0852	697.76
Trastuzumab	Herceptin®	J9355 (10 mg)	1613	50.79
Triptorelin pamoate§	Trelstar® Depot	J3315 (3.75 mg)	9122	362.78
Vinorelbine tartrate	Navelbine®	J9390 (10 mg)	0855	95.23
Zoledronic acid§	Zometa®	J3487 (1 mg)	9115	197.87

†Injectable drugs, unless otherwise specified.

‡Payment decreased in 2005 Final Rule compared with Proposed Rule.

§For non-end-stage renal disease.

¶Assigned pass-through payment status in 2004.

||Equitable payment adjustment made because CMS considers epoetin alfa and darbepoetin alfa functionally equivalent for payment purposes.

¶Oral formulation reimbursed through packaged APC (see Table 1).

*Assigned packaged APC status in 2005 Proposed Rule.

**For cancer-related treatment only.

APC=ambulatory payment classification; HCl=hydrochloride.

most effective antiemetic therapy.¹ Therefore, CMS stipulates that all oral and intravenous (IV) 5-HT3 antiemetics be paid separately as sole-source drugs in 2005. Table 2 lists the 2005 payment rates for sole-source drugs, including 5-HT3 antiemetics. Although CMS provides payment rates for both oral and IV 5-HT3 antiemetics, these antiemetics may not be covered in all instances. For example, Medicare covers oral antiemetics administered in connection with chemotherapy only if they replace IV antiemetics and are initiated within 2 hours of chemotherapy administration, and their use does not extend beyond 48 hours

Table 3. 2005 Payment Rates for Innovator and Noninnovator, Multiple-Source Oncology Drugs^{*†1,2,4-6,8,9}

Generic Name	Brand Name	Billing Code (Billing Unit)	APC	2005 Payment, \$
Bleomycin sulfate	Blenoxane [®]	C9417 (15 U)	9417	130.56
		J9040 [‡] (15 U)	0857	88.32
Carmustine [§]	BiCNU [®]	C9437 (100 mg)	9437	79.42
		J9050 [‡] (100 mg)	0812	65.94
Cisplatin	Platinol [®] -AQ	C9418 (10 mg)	9418	11.42
		J9060 [‡] (10 mg)	0813	7.73
Cladribine	Leustatin [®]	C9419 (1 mg)	9419	36.72
		J9065 [‡] (1 mg)	0858	24.84
Cyclophosphamide ¹¹	Neosar [®]	C9420 (100 mg)	9420	4.10
		J9070 [‡] (100 mg)	0815	2.77
Cyclophosphamide, lyophilized	Cytosan [®] Lyophilized	C9421 (100 mg)	9421	3.50
		J9093 [‡] (100 mg)	0816	2.36
Cytarabine	Cytosar-U [®]	C9422 (100 mg)	9422	2.28
		J9100 [‡] (100 mg)	0817	1.55
Dacarbazine	DTIC-Dome [®]	C9423 (100 mg)	9423	8.15 [¶]
		J9130 [‡] (100 mg)	0819	6.14
Daunorubicin HCl	Cerubidine [®]	C9424 (10 mg)	9424	53.14
		J9150 [‡] (10 mg)	0820	35.94
Dexrazoxane HCl	Zinecard [®]	C9410 (250 mg)	9410	123.93 [¶]
		J1190 [‡] (250 mg)	0726	113.28
Doxorubicin HCl	Adriamycin RDF [®] ; others	C9415 (10 mg)	9415	6.94
		J9000 [‡] (10 mg)	0847	4.69
Etoposide	Toposar [®] ; VePesid [®]	C9425 (10 mg)	9425	1.22
		J9181 [‡] (10 mg)	0824	0.83
Etoposide, oral	VePesid [®]	C9414 (50 mg)	9414	25.71 [¶]
		J8560 [‡] (50 mg)	0802	21.91
Floxuridine	FUDR [®]	C9426 (500 mg)	9426	97.92
		J9200 [‡] (500 mg)	0827	66.24
Idarubicin HCl	Idamycin PFS [®]	C9429 (5 mg)	9429	66.58 [¶]
		J9211 [‡] (5 mg)	0832	66.58 [¶]
Ifosfamide	Ifex [®]	C9427 (1 g)	9427	90.80 [¶]
		J9208 [‡] (1 g)	0831	72.81
Leuprolide acetate	Lupron [®]	C9430 (1 mg)	9430	21.41
		J9218 [‡] (1 mg)	0861	14.48
Mesna	Mesnex [®]	C9428 (200 mg)	9428	23.79 [¶]
		J9209 [‡] (200 mg)	0732	17.66
Mitomycin	Mutamycin [®]	C9432 (5 mg)	9432	45.70
		J9280 [‡] (5 mg)	0862	30.91

of their initiation.¹⁰ Because some exceptions and/or additional limitations to this coverage rule exist, review of national and local coverage rules is recommended before administering these drugs to facilitate timely and appropriate reimbursement.^{10,11}

Table 3. (cont'd) 2005 Payment Rates for Innovator and Noninnovator, Multiple-Source Oncology Drugs^{*†1,2,4-6,8,9}

Generic Name	Brand Name	Billing Code (Billing Unit)	APC	2005 Payment, \$
Paclitaxel	Taxol [®] ; Onxol [™]	C9431 (30 mg)	9431	93.50 [¶]
		J9265 [‡] (30 mg)	0863	79.04
Pamidronate disodium	Aredia [®]	C9411 (30 mg)	9411	160.65 [¶]
		J2430 [‡] (30 mg)	0730	128.74
Thiotepa	NA ^{**}	C9433 (15 mg)	9433	66.98
		J9340 [‡] (15 mg)	0851	45.31

^{*}Injectable drugs, unless otherwise specified.

[†]Brand name drugs, unless otherwise specified.

[‡]Generic drugs.

[§]Assigned packaged APC status in 2005 proposed rule.

¹¹Oral formulation reimbursed through packaged APC (see Table 1).

[¶]Payment decreased in 2005 Final Rule compared with Proposed Rule.

^{**}Payment increased in 2005 Final Rule compared with Proposed Rule.

^{**}Brand name drug no longer commercially available.

APC=ambulatory payment classification; HCl=hydrochloride; NA=not applicable.

Drugs that were paid separately in 2004 (eg, specified covered outpatient drugs) but have a median cost per day of less than \$50 (based on the hospital claims data used to determine the 2005 OPSS Final Rule) continue to be paid separately in 2005. This category contains only 2 oncology drugs: oral busulfan and daunorubicin citrate liposome (see Table 2).¹

Specified Covered Outpatient Drugs

Specified covered outpatient drugs, drugs for which a separate, drug-specific APC exists and payment was made on a pass-through payment basis on or before December 31, 2002, are further classified according to 3 categories: 1) sole-source drugs, 2) innovator, multiple-source drugs, and 3) noninnovator, multiple-source drugs.¹ Payment rates for these categories are determined by comparing reference average wholesale price (AWP) values with adjusted median hospital costs.

Sole-Source Drugs

In 2005, sole-source drugs are paid at 83% to 95% of the reference AWP.^{1,12} Table 2 lists the 2005 payment rates for sole-source drugs. Final Rule payment rates for IV busulfan, darbepoetin alfa, daunorubicin citrate liposome, and octreotide acetate depot in 2005 are lower than the Proposed Rule payment rates; all other payment rates are the same (see Table 2).^{1,2}

Innovator, Multiple-Source Drugs

Innovator, multiple-source drugs—originally sole-source drugs that now have Food and Drug Administration (FDA)—approved generic alternatives—are paid at the lower of 2 costs: 1) the payment rate calculated according to adjusted median hospital cost or 2) 68% of the reference AWP.^{1,7} Table 3 lists the 2005 payment rates for innovator, multiple-source drugs. Final payment rates for dacarbazine, dexrazoxane, oral etoposide, ifosfamide, mesna, paclitaxel, and pamidronate disodium reflect

a decrease compared with the 2005 proposed payment rates, whereas the final payment rate for idarubicin increased; all other oncology drug payment rates remained the same (see Table 3).^{1,2}

Noninnovator, Multiple-Source Drugs

Noninnovator, multiple-source drugs, or FDA-approved generics, are paid at the lower of 2 costs: 1) the payment rate calculated according to adjusted median hospital cost or 2) 46% of the reference AWP (see Table 3).^{1,7} The final payment rate for idarubicin increased compared with the 2005 proposed payment rate; all other noninnovator, multiple-source drug payment rates remained the same (see Table 3).^{1,2}

Pass-Through Drugs

Payment for pass-through drugs (ie, a temporary, higher payment) for certain newly approved drugs continues in 2005; however, the payment rate is not a percentage of the AWP as in previous years, but is equivalent to the payment for these drugs in a physician's office (ie, 106% of average sales price [ASP] or 106% of wholesale acquisition cost [WAC], whichever is less).^{1,13} With this payment method, no additional pass-through payment is included; payment rates will be updated based on quarterly ASP updates.¹ Table 4 lists the 9 oncology drugs with pass-through payment status for 2005.^{1,2} Final payment rates for abarelix, bortezomib, pemetrexed, and rasburicase increased compared with 2005 proposed payment rates, whereas final payment rates decreased for cetuximab, oxaliplatin, and palonosetron (see Table 4).^{1,2} Additionally, billing codes and/or units were revised for abarelix, bevacizumab, bortezomib, cetuximab, palonosetron, and pemetrexed.^{1,2}

Pass-through payment for 5 oncology drugs expired on December 31, 2004: darbepoetin alfa, fulvestrant, pegfilgrastim, triptorelin pamoate, and zoledronic acid.¹ Darbepoetin alfa, pegfilgrastim,

and zoledronic acid qualified as pass-through drugs before December 31, 2002; therefore, as mentioned previously, these drugs are now reimbursed as sole-source drugs according to the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (see Table 2). Although darbepoetin alfa is classified as a sole-source drug in 2005, CMS made an equitable adjustment to the payment rate because darbepoetin alfa is considered functionally equivalent to epoetin alfa for payment purposes; a conversion factor was applied to the payment rate of epoetin alfa to determine the 2005 payment rate for darbepoetin alfa. Fulvestrant and triptorelin pamoate were assigned pass-through payment status after January 1, 2003, and thus are ineligible to be reimbursed as sole-source drugs according to the MMA. However, CMS has determined payment rates for fulvestrant and triptorelin pamoate based on rates for sole-source drugs (see Table 2).

Orphan Drugs

Payment rates for orphan drugs in 2005 are 88% of AWP or 106% of ASP, whichever is higher, but do not include an upper limit as outlined in the Proposed Rule.¹ Additionally, CMS will review AWP and ASP data quarterly and update payment rates accordingly. Any changes in payment rates will be announced in the quarterly program instructions and posted on the CMS Web site, http://www.cms.hhs.gov/providers/hopps/hopps_trans.asp. After review of public comments following the proposed rule, CMS added 2 oncology drugs, alemtuzumab and azacitidine, to the orphan drug list. Azacitidine was assigned pass-through payment status in October 2004, and, in the 2005 Final Rule, this drug is listed as both a pass-through drug and an orphan drug; further clarification of this drug's payment status is likely in the next quarterly update of OPPS.¹ Table 5 lists the 2005 payment rates for oncology orphan drugs.^{1,2,4-7}

Table 4. Oncology Drugs With Pass-Through Payment Status in 2005^{1,2}

Generic Name	Brand Name	Billing Code (Billing Unit)	APC	2005 Payment, \$
Abarelix	Plenaxis TM	J0128 (10 mg) [†]	9216	67.62 [‡]
Azacitidine [§]	Vidaza TM	C9218 (1 mg)	9218	3.81
Bevacizumab	Avastin TM	J9035 (10 mg) [†]	9214	57.13
Bortezomib	Velcade [®]	J9041 (0.1 mg) ^{††}	9207	27.53 [‡]
Cetuximab	Erbitux TM	J9055 (10 mg) [†]	9215	49.87 [¶]
Oxaliplatin	Eloxatin TM	C9205 (5 mg)	9205	81.61 [¶]
Palonosetron HCl	Aloxi TM	J2469 (25 µg) [‡]	9210	18.25 [¶]
Pemetrexed	Alimta [®]	J9305 (10 mg) [†]	9213	40.54 [‡]
Rasburicase	Elitek [®]	J2783 (0.5 mg)	0738	106.04 [‡]

^{*}Injectable drugs; all drugs had pass-through payment status for at least part of 2004, unless otherwise specified.

[†]Billing code revised in 2005 Final Rule compared with Proposed Rule.

[‡]Payment increased in 2005 Final Rule compared with Proposed Rule.

[§]Approved for pass-through payment beginning on or after October 1, 2004.

^{††}Billing unit revised in 2005 Final Rule compared with Proposed Rule.

[¶]Payment decreased in 2005 Final Rule compared with Proposed Rule.

APC=ambulatory payment classification; HCl=hydrochloride.

New Oncology Drugs

Appropriate reimbursement and billing information, such as a drug's reference AWP and an assigned Healthcare Common Procedure Coding System (HCPCS) code, is required by CMS to create payment rates and reimburse for drugs. This information is often lacking for new drugs; therefore, CMS has developed a method to ensure payment for these drugs.¹ Understanding this method will facilitate appropriate and timely reimbursement of new oncology drugs.

New Drugs With HCPCS Codes

All new drugs with HCPCS codes but without both pass-through payment status and a reference AWP in 2005 are paid separately rather than packaged into a procedural or service APC; these drugs are paid at 106% of ASP.¹ In the absence of ASP data, the WAC is used to determine payment; in the absence of both ASP and WAC, the payment is 95% of the AWP reported in the *Red Book*, May 1, 2003, or the first-reported AWP for drugs without an AWP in the May 1, 2003, *Red Book*. Currently, gallium nitrate is the only oncology drug in this category.

Table 5. 2005 Payment Rates for Orphan Drugs^{1,2,4-7}

Generic Name	Brand Name	Billing Code (Billing Unit)	APC	2005 Payment, \$
Aldesleukin	Proleukin®	J9015 (single vial)	0807	680.35
Alemtuzumab ^{†*}	Campath®	J9010 (10 mg)	9110	541.45 [§]
Arsenic trioxide [†]	Trisenox®	J9017 (1 mg)	9012	34.10
Azacitidine [¶]	Vidaza™	C9218 (per 1 mg)	9218	3.81
Denileukin diftitox	Ontak®	J9160 (300 µg)	1084	1,232.88
Gemtuzumab ozogamicin	Mylotarg®	J9300 (5 mg)	9004	2,183.81
Oprelvekin	Neumega®	J2355 (5 mg)	7011	248.16

*Injectable drugs.

[†]Assigned sole-source drug status in 2004.

[‡]Assigned sole-source drug status in 2005 Proposed Rule.

[§]Payment increased in 2005 Final Rule compared Proposed Rule.

^{||}Payment decreased in 2005 Final Rule compared with Proposed Rule.

[¶]Recently approved drug not included in 2005 Proposed Rule.

APC=ambulatory payment classification.

New Drugs Without HCPCS Codes

New drugs that have not yet been assigned an HCPCS code are now reimbursable, if the drug is covered by Medicare and the following information is included on the CMS claim form.^{1,14}

Hospitals bill for a new drug without a HCPCS code by reporting HCPCS code C9399 (unclassified drug or biologic) and the National Drug Code (NDC) for the product, the quantity of drug administered, and the administration date in the “Remarks” section of the CMS claim form.¹⁴ An outpatient code editor suspends all C9399 claims and passes them to a fiscal intermediary, who manually prices the claim at 95% of AWP and processes the claim for payment.¹ Failure to provide the required information for new drugs without a HCPCS code delays timely reimbursement. When a HCPCS code is assigned to the new drug, hospitals use the new code (rather than C9399 and the NDC) on all claims.¹

Coding and Payment for Chemotherapy Administration

To pay more accurately for chemotherapy administration over the next few years, CMS has revised the coding for chemotherapy administration and is collecting cost data for these services.¹ Because future reimbursement decisions by CMS are likely to be based on 2005 cost data, healthcare providers should thoroughly understand this new coding and payment system.

In 2005, CMS bases chemotherapy administration payment on Current Procedural Terminology (CPT) codes rather than the previously used HCPCS codes.¹ These CPT codes are then matched with new APCs. For example, a hospital reports the service provided using the appropriate CPT code and shows the charges they assign to the CPT code on the claim. An outpatient editor then matches the CPT code to an APC; payment is based on the HCPCS code that would have been used. The CPT codes and APCs are being matched to collect cost data that will be used to determine future

Table 6. 2005 CPT Codes for Chemotherapy Administration^{1,15}

CPT Code	Description	APC	HCPCS Code
96400	Subcutaneous or intramuscular chemotherapy administration, with or without anesthesia	116	Q0083
96405	Intralesional chemotherapy administration, ≤ 7 lesions	116	Q0083
96406	Intralesional chemotherapy administration, > 7 lesions	116	Q0083
96408	Intravenous push chemotherapy administration	116	Q0083
96410	Intravenous infusion chemotherapy administration, < 1 hr	117	Q0084
96414	Intravenous infusion chemotherapy administration, initiation of > 8-hr infusion requiring the use of a portable or implantable pump	117	Q0084
96420	Intraarterial push chemotherapy administration	116	Q0083
96422	Intraarterial infusion chemotherapy administration, < 1 hr	117	Q0084
96425	Intraarterial infusion chemotherapy administration, initiation of > 8-hr infusion requiring the use of a portable or implantable pump	117	Q0084
96440	Intrapleural chemotherapy administration, requiring and including thoracentesis	116	Q0083
96445	Intraperitoneal chemotherapy administration, requiring and including peritoneocentesis	116	Q0083
96450	Central nervous system chemotherapy administration, requiring and including spinal puncture	116	Q0083
96542	Subarachnoid or intraventricular chemotherapy administration via subcutaneous reservoir, single or multiple agents	116	Q0083
96549	Chemotherapy administration, unspecified	116	Q0083
90780	Intravenous infusion therapy for therapy or diagnosis, administered by a physician or under direct supervision of a physician, < 1 hr	120	Q0081

To pay more accurately for chemotherapy administration, Medicare has revised the codes used to bill for these services. In 2005, CPT codes are used rather than HCPCS codes; in the future, APC codes will be used rather than CPT or HCPCS codes. APC=ambulatory payment classification; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System.

APC payment rates; use of APCs only for the payment of chemotherapy administration is anticipated in 2007. Table 6 lists the CPT codes to be used for chemotherapy administration in 2005 and their corresponding HCPCS codes and APCs.^{1,15}

CPT codes 96412 (IV infusion chemotherapy administration, each additional hr up to 8 hr), 96423 (intraarterial infusion chemotherapy administration, each additional hr up to 8 hr),

96545 (provision of chemotherapy agent), and 90781 (IV infusion for therapy or diagnosis administered by a physician or under direct supervision of a physician, each additional hr up to 8 hr) are paid as packaged APCs rather than separate payments; however, if the cost data collected in 2005 suggest that these APCs correspond to inadequate payment, CMS has indicated that the payment for these chemotherapy administration codes may be revised.^{1,15} Therefore, hospitals are strongly encouraged to bill charges for these codes in 2005 so that payment data can be collected and used to develop appropriate APC categories and payments for future use.¹

To obtain payment for multiple visits and services on the same day, hospitals must use the coding modifier 59 (distinct procedure) with the appropriate CPT code(s) when billing for additional services furnished after the initial visit on the same day.¹ With coding modifier 59, CMS reimburses up to 2 APC units for all chemotherapy CPT codes except 90780 (IV infusion for therapy or diagnosis, administered by a physician or under direct supervision of a physician, ≤ 1 hr); CPT 90780 is reimbursed up to 4 APC units.^{1,15}

Conclusions

The 2005 OPPS Final Rule, which became effective on January 1, 2005, updates payment rates for drugs and services provided in outpatient hospital clinics, providing approximately a 4% increase in payments in 2005. CMS accepted public comment about the rule until January 14, 2005.¹ The Final Rule will be updated quarterly, in April, July, and October. Keeping abreast of these changes can ensure maximum reimbursement. To view quarterly updates and other information regarding OPPS, log on to <http://www.cms.hhs.gov/providers/hopps>.

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NETWORKING COLUMN

2005 Medicare Physician Fee Schedule Final Rule: Summary of Oncology-Related Provisions

Stephanie Butler, PharmD

Syntaxx Communications, Inc.

The Centers for Medicare & Medicaid Services (CMS) has released the Physician Fee Schedule Final Rule for 2005. In response to public comment, this Final Rule includes several revisions to the Proposed Rule published on August 5, 2004, in the Federal Register.^{1,2} According to the American Society of Clinical Oncology's initial assessment of the Final Rule, assuming drug, biologic, and radiopharmaceutical (for the remainder of this article, "drugs, biologics, and radiopharmaceuticals" are referred to as "drugs") use does not change from year to year, Medicare revenue to oncologists will decrease from 2004 to 2005 by \$200 million (the decrease would have been \$500 million if the Proposed Rule had been implemented).² However, considering historical trends, CMS assumes drug use will increase approximately 20% from 2004 to 2005, which increases Medicare payments to oncologists by 8%.^{1,2}

The components of the Final Rule that are most pertinent to oncology practices include the implementation of 1) new drug administration codes; 2) drug payment based on average sales price (ASP); and 3) payment for the management of adverse drug reactions related to chemotherapy administration.¹ Additionally, Medicare has implemented a 1-year quality of care demonstration program that provides additional payment to participating oncologists.¹

New Drug Administration Codes

CMS adopted 18 new drug administration codes recently established by the American Medical Association's Current Procedural Terminology (CPT) Editorial Panel.¹ Because the new CPT codes will not be included in the CPT code book until 2006, CMS instituted temporary corresponding Healthcare Common Procedure Coding System (HCPCS) G codes that providers can use to bill for drug administration services provided in 2005.¹ Table 1 lists the new G codes to be used for coding chemotherapy administration, the corresponding previously used CPT codes, and 2004

for services provided after an initial administration reflect the use of incremental resources in providing these additional services.¹ If a patient receives multiple services (ie, chemotherapy administration, IV hydration, and/or nonchemotherapy drug administration) during a single encounter, providers can bill for 1 initial service only; providers should bill for the service that best describes the key service received by the patient irrespective of the order in which the services are provided.¹ Becoming familiar with the new drug codes and coding policies is essential to ensure proper coding for drug administration services. Additional information and examples showing how to use the new drug administration codes are available at http://www.asco.org/ac/1,1003,_12-002891-00_18-0036740-00_19-0036741-00_20-001,00.asp.⁴

Table 1. New 2005 Chemotherapy Administration Codes^{1,3}

Previously Used CPT Code	2005 HCPCS Code	Description	2004 Payment Rate, \$*	2005 Payment Rate, \$ [†]	% Change
96400	G0355	SC or IM chemotherapy administration; nonhormonal antineoplastic	NA	53.09	NA
96400	G0356	SC or IM chemotherapy administration; hormonal antineoplastic	64.07	36.69	-43%
96408	G0357	IV push chemotherapy administration, initial drug	154.76	125.69 255.69 [‡]	-19% 65% [‡]
96408	G0358	IV push chemotherapy administration, each additional drug	154.76	72.99	-53%
96410	G0359	IV infusion chemotherapy administration, single or initial drug (≤ 1 hr)	217.35	177.61 307.61 [‡]	-18% 42% [‡]
96412	G0360	IV infusion chemotherapy administration, each additional hour (> 1 to ≤ 8 hr)	48.30	40.21	-17%
96414	G0361	IV infusion chemotherapy administration, initiation of prolonged (> 8 hr) infusion	NA	190.88	NA
96412	G0362	IV infusion chemotherapy administration, each additional sequential infusion (≤ 1 hr)	48.30	86.66	79%

*Includes a 32% transitional adjustment required by the MMA for 2004.

[†]Includes a 3% transitional adjustment required by the MMA for 2005.

[‡]Includes an additional \$130 payment if practitioner is participating in the 1-yr quality of care demonstration project.

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; IM=intramuscular; IV=intravenous; MMA=Medicare Prescription Drug, Improvement, and Modernization Act of 2003; NA=not available; SC=subcutaneous.

and 2005 payment rates.^{1,3} Several previously used CPT codes covered multiple services (ie, 96400 referred to subcutaneous [SC] or intramuscular [IM] hormonal and nonhormonal chemotherapy administration). To further delineate these services, CMS assigned new G codes to each service previously billed under a single CPT code (ie, HCPCS codes G0355 and G0356 refer to SC or IM nonhormonal and hormonal chemotherapy administration, respectively).¹

An important distinction between the previously used CPT codes and the new codes is that the new codes differentiate between an "initial" drug administration (ie, first hour of an intravenous [IV] infusion or first IV push) and subsequent drug administrations (ie, each additional hour of an IV infusion, the first hour of sequential IV drug infusions, or additional drugs administered by IV push); the payment rates associated with these "add-on" codes

Additionally, physicians are authorized to bill for injections provided to a patient receiving other Medicare physician fee schedule services on the same day.¹ The CMS estimates this policy change will increase drug payments to oncologists by approximately 3% compared with 2004.¹

New Drug Payment System

Beginning January 1, 2005, Medicare began paying for most Medicare Part B-covered drugs according to the ASP pricing system as mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.¹ The ASP for a drug is the volume-weighted average of a manufacturer's ASP for all national drug codes assigned to the HCPCS code for that drug.¹ Medicare pays 106%

of the ASP for drugs included in the same HCPCS code.¹ Payment rates will be updated quarterly using pricing data that manufacturers are required to submit to CMS no later than 30 days after the end of each quarter (the payment rates for the first quarter of 2005 are based on the third quarter of 2004 and were available to the public before January 1, 2005 at <http://www.cms.hhs.gov/providers/drugs/asp.asp>).¹ New drugs are paid at wholesale acquisition cost or 95% of the average wholesale price until CMS obtains sufficient ASP data from the manufacturer for the first full quarter of sales.^{1,5} Additional information, including frequently asked questions regarding the ASP pricing system, is available at <http://www.cms.hhs.gov/providers/drugs/asp.asp>.⁶ Many patient advocates believe that patient-access problems may arise from the implementation of the new drug payment system; therefore, CMS will continually monitor for these potential problems.¹

Payment for Adverse Drug Reaction Management

Although not a new policy, the CMS 2005 Final Rule addresses the use of existing codes for physician office visits, including the provision of prolonged and higher-level physician visits and critical care services, when oncologists are involved in the management of serious adverse drug reactions that may occur during chemotherapy administration.¹

1-Year Demonstration Project

CMS has the authority to measure both economic and humanitarian outcomes of health services provided to Medicare beneficiaries.¹ For 2005, CMS has implemented a 1-year demonstration project to assess the quality of care that cancer patients receive in oncology clinics. Office-based oncologists or other practitioners who assess and report on the Medicare claims form the status of 3 symptoms—nausea/vomiting, fatigue, and pain—in patients receiving chemotherapy by IV push or infusion will receive an additional \$130 per patient per day.¹ CMS has established 12 new HCPCS codes (G codes) (Table 2) that describe 4 patient assessment levels (1=“not at all”; 2=“a little”; 3=“quite a bit”; 4=“very much”) based on the Rotterdam Symptom Checklist, a scale used to measure symptoms in cancer patients.^{1,7} To be eligible for payment, practitioners

Assessment Level*	Symptom, HCPCS Code		
	Nausea/Vomiting	Pain	Fatigue
1 (Not at all)	G9021	G9025	G9029
2 (A little)	G9022	G9026	G9030
3 (Quite a bit)	G9023	G9027	G9031
4 (Very much)	G9024	G9028	G9032

*All assessments must be performed at the time of chemotherapy administration; assessment levels are patient reported and based on the Rotterdam Symptom Checklist. HCPCS=Healthcare Common Procedure Coding System.

must report an assessment level for all 3 symptoms by including the appropriate G code on the Medicare claims form.¹ No other documentation is required.⁴ The demonstration project will significantly increase payment to physicians for certain drug administration services.¹ For example, physicians will receive \$255.69 for administering chemotherapy by IV push (\$125.69, code G0357 + \$130, payment for participating in the demonstration project), a 65% increase compared with the amount paid in 2004 for the comparable CPT code.¹

The regulations outlined in the 2005 Physician Fee Schedule Final Rule were effective January 1, 2005.¹ The Final Rule was published in the Federal Register on November 15, 2004, and is available at http://www.access.gpo.gov/su_docs/fedreg/a041115c.html.

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IN THE NEWS

FDA Approvals

Final Approvals

September 24, 2004: The US Food and Drug Administration (FDA) approved **Palladone™ (hydromorphone hydrochloride [HCl] extended-release**, Purdue Pharma L.P.) capsules for the treatment of moderate to severe persistent pain. With once-daily administration, Palladone is the first long-acting hydromorphone formulation available in the US. It will be available in 12-, 16-, 24-, and 32-mg dosage strengths. Availability of Palladone in retail pharmacies is anticipated in early 2005.

October 19, 2004: The FDA approved **Vantas™ (histrelin acetate**, Valera Pharmaceuticals) for the palliative treatment of advanced prostate cancer. Vantas is a synthetic nonapeptide agonist of luteinizing hormone-releasing hormone that has been formulated using Valera's Hydron Implant technology, allowing the drug to be administered every 12 months.

October 31, 2004: **Femara® (letrozole**, Novartis Pharmaceuticals), an aromatase inhibitor, was approved by the FDA for use in postmenopausal women with breast cancer completing 5 years of adjuvant tamoxifen. The use of letrozole in these patients reduces the risk of recurrence by approximately 38%. Femara is also approved as first-line treatment of locally advanced or metastatic, hormone-receptor–positive or unknown-receptor–status breast cancer in postmenopausal women and as treatment of advanced breast cancer in postmenopausal women experiencing disease progression after antiestrogen therapy.

November 5, 2004: **Eloxatin™ (oxaliplatin)**, Sanofi-Synthelabo, Inc.) in combination with infusional fluorouracil (5FU)-leucovorin was approved by the FDA for the adjuvant treatment of stage III colon cancer after surgical resection of the primary tumor. Before this approval, Eloxatin in combination with infusional 5FU-leucovorin was indicated only for the treatment of advanced cancer of the colon or rectum. This approval of adjuvant chemotherapy for colorectal cancer is the first in a decade.

November 18, 2004: **Tarceva™ (erlotinib)**, OSI Pharmaceuticals, Inc. and Genentech, Inc.) was approved by the FDA for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) in patients failing at least 1 prior chemotherapy regimen. Tarceva, an oral tablet administered once daily, blocks tumor cell growth by inhibiting the tyrosine kinase activity of the human epidermal growth factor receptor 1 (HER1) signaling pathway.

New Drug Applications

October 4, 2004: Impax Laboratories, Inc. announced FDA approval of its abbreviated new drug application (NDA) for generic **oxycodone HCl** controlled-release 80-mg tablets.

October 21, 2004: American Pharmaceutical Partners, Inc. received approval of their abbreviated NDA for generic **carboplatin injection** (liquid form). The company currently markets the lyophilized form of carboplatin injection.

October 22, 2004: Celgene Corporation received an approval letter from the FDA for its supplemental NDA for **Thalomid® (thalidomide)** for the treatment of multiple myeloma. Submission of data from a large, randomized Eastern Cooperative Oncology Group study (E1A100) comparing thalidomide plus dexamethasone with dexamethasone alone in untreated patients with multiple myeloma may result in accelerated approval of thalidomide as treatment of multiple myeloma.

November 15, 2004: Supergen, Inc. received approval of their abbreviated NDA for generic **paclitaxel**. Supergen, Inc. plans to complete a marketing and distribution licensing agreement for this product in the first half of 2005.

Fast-Track Status

September 29, 2004: **BLP25 Liposome Vaccine (L-BLP25)**, Biomira Inc. and Merck KGaA of Darmstadt, Germany), as treatment of NSCLC, was granted fast-track status. BLP25 is a synthetic mucin 1 (MUC1) vaccine encapsulated in a liposomal delivery system to improve drug delivery of the agent and enhance immune response to the cancer antigen.

ODAC Update

The **Oncology Drugs Advisory Committee (ODAC)** met on December 1, 2004. The committee reviewed **Marqibo™ (vincristine sulfate liposome injection, formerly Onco TCS)**, Inex Pharmaceuticals Corporation and Enzon Pharmaceuticals, Inc.) and **Clolar™ (clofarabine)**, ILEX Oncology, Inc.). The ODAC voted unanimously against recommending Marqibo, vincristine

encapsulated in a sphingosomal delivery system, for accelerated approval as treatment for patients with relapsed aggressive non-Hodgkin's lymphoma. Clolar, a purine nucleoside antimetabolite, was endorsed by the ODAC for the treatment of refractory or relapsed acute lymphoblastic leukemia. Additional studies investigating the use of Clolar in the treatment of acute myelogenous leukemia were recommended by the ODAC before recommending approval for this indication. The FDA's decision on the NDAs for Marqibo and Clolar were expected by January 15, 2005 and December 30, 2004, respectively.

Legislative and Regulatory News

Revised ASCO Position Statement Regarding Delivery of Antineoplastic Agents Now Available

October 4, 2004: *The Journal of Clinical Oncology Online* published an updated version of the American Society of Clinical Oncology (ASCO) position statement "Criteria for Facilities and Personnel for the Administration of Parenteral Systemic Antineoplastic Therapy" (see <http://www.jco.org/cgi/reprint/JCO.2004.05.077v1>). This revised statement includes updated regulatory references, a discussion of safe preparation and administration of antineoplastic medications, and precautions for oncology drugs obtained from or prepared by entities outside of the oncologist's office.

CMS Approves Additional Payment to Physicians Providing Office-Based Chemotherapy

November 1, 2004: As part of a 1-year demonstration project, the Centers for Medicare & Medicaid Services (CMS) will pay physicians an extra \$130 per patient on each day chemotherapy is administered. The purpose of the extra payment is to measure and improve the quality of care provided to Medicare patients receiving chemotherapy. To earn the extra payment, physicians are required to assess 3 patient status-factors (fatigue, pain, nausea/vomiting) and bill using a series of 12 new G codes (see <http://www.cms.hhs.gov/media/press/release.asp?Counter=1245>) that will supplement the current billing codes. The severity scale for each of these 3 factors has 4 levels, ranging from no impairment to severe impairment. The practitioner is automatically enrolled in the demonstration project by billing the designated codes with each chemotherapy encounter. CMS estimates a \$300 million increase in payments to oncologists in 2005.

CMS to Provide Coverage of Colorectal Cancer Drugs in Select Clinical Trials

November 1, 2004: The CMS has proposed Medicare coverage for chemotherapy agents used for the off-label treatment of colorectal cancer in 9 clinical trials sponsored in part by the National Cancer Institute (see <http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=90>). These agents include **Eloxatin™ (oxaliplatin)**, Sanofi-Synthelabo, Inc.), **Camptosar® (irinotecan)**, Pfizer & UpJohn Co.), **Avastin™ (bevacizumab)**, Genentech, Inc.), and **Erbix™ (cetuximab)**, Imclone Systems, Inc. and Bristol-Myers Squibb Company). The CMS extended

the due date for public comments on its draft decision until December 31, 2004. A final decision by the CMS is expected to be published by January 31, 2005.

CMS Issues Final Rule For Physician Payment For 2005

November 3, 2004: The CMS issued the final rule, effective on January 1, 2005, that updates 2005 payment rates for physicians. The final rule will implement the revised system of paying for drugs based on 106% of average sales price (ASP) as mandated by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. Additionally, the rule will 1) implement 18 new codes developed by the American Medical Association's Current Procedural Terminology Editorial Board to be used in billing for drug administration; 2) allow oncologists to be paid for injections provided on the same day as other Medicare services; and 3) allow oncologists to bill Medicare separately for the management of adverse drug reactions related to chemotherapy administration. For a summary of the final rule changes relevant to oncology drug reimbursement, see the Networking column (2005 Medicare Physician Fee Schedule Final Rule: Summary of Oncology-Related Provisions) in this issue.

CMS Issues Final Rule For Hospital Outpatient Services For 2005

November 3, 2004: The CMS released its final rule for the Outpatient Prospective Payment System (OPPS) for 2005. The rule will increase projected Medicare payments to hospitals by \$1.5 billion compared with 2004. An increase in Medicare payments for screening examinations, including 1) bone density studies, 2) pelvic and breast examinations for the detection of cervical and breast cancer, and 3) barium enema, flexible sigmoidoscopy, and screening colonoscopy for the detection of colorectal cancer, is included. Diagnostic mammograms will also be reimbursed at a higher rate. Additionally, payment rates for drugs have been updated. For a summary of the final rule changes relevant to oncology drug reimbursement, see the Feature article (2005 OPPS Final Rule: Summary of Oncology Medications) in this issue. The new rule will be effective on January 1, 2005.

COMPENDIA UPDATE

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Rationale for Deletion of ICD-9-CM Information from Compendia Update

Medicare and most private insurance companies require health-care providers to use codes from the *International Classification of Diseases*, 9th version, *Clinical Modification* (ICD-9-CM) when billing for medical services provided to a patient.¹ Proper coding is an important step in proving medical necessity of a provided service, preventing rejection of medical claims, and ensuring

Drugs and Indications Added to or Changed in Compendia in August and November 2004*

Generic Drug Name	Brand Name	Indication	Compendia Listing	Billing Code (Billing Unit) [†]
<i>New drugs</i>				
Abarelix	Plenaxis™	Prostate cancer	*	C9216 (10 mg)
Azacitidine	Vidaza™	Myelodysplastic syndromes	AHFS, USP DI	C9218 (1 mg) [§] J9999
Sorafenib	BAY 43-9006	Renal cell carcinoma	Orphan drug status**	NA
<i>New indications</i>				
Docetaxel	Taxotere®	Prostate cancer	AHFS, USP DI	J9170 (20 mg)
Gemcitabine HCl	Gemzar®	Breast cancer	AHFS, USP DI	J9201 (200 mg)
Pemetrexed	Alimta®	Non-small cell lung cancer	*	C9213 (10 mg)
Vinblastine	NA	Immune or idiopathic thrombocytopenic purpura	AHFS	J9360 (1 mg)
Vincristine	Vincasar PFS®	Chronic lymphocytic leukemia	AHFS, USP DI	J9370 (1 mg) J9375 (2 mg) J9380 (5 mg)
		Immune or idiopathic thrombocytopenic purpura	AHFS	

*From *Compendia-Based Drug Bulletin*. 2004:13.

†Codes and units for injectable formulations, unless otherwise indicated.

**Food and Drug Administration–approved indication, not yet in compendia.

§Code for Medicare patients treated as hospital outpatients.

||Miscellaneous temporary code suggested by manufacturer. Often used until final code assigned; results in no reimbursement. Manufacturer expects Medicare code (C code) to be available in 2004 or early 2005.

*Code for Medicare and nonMedicare patients treated in a physician's office and nonMedicare patients treated as hospital outpatients.

**Drug has orphan drug status and may not be reimbursed by local carrier.

AHFS=American Hospital Formulary Service Drug Information; HCl=hydrochloride; NA=not applicable; USP DI=United States Pharmacopeia Drug Information.

reimbursement for services rendered.^{1,2} Although the US Public Health Service and the Centers for Medicare and Medicaid Services (formally the Health Care Financing Administration) approve the nationwide use of ICD-9-CM extensions, interpretations, modifications, addenda, or errata, local Medicare contractors (ie, fiscal intermediaries [FIs] for Medicare Part A and some Part B programs and carriers for Medicare Part B) determine coding procedures for reimbursement of services provided in their coverage areas.^{3,4} FIs and carriers develop Local Medical Review Policies (LMRPs) that explain the coding for particular services or items and the circumstances warranting coverage of these services or items.^{4,5} These policies, which are effective only

ONCOLOGY REIMBURSEMENT CONNECTION NEWSLETTER EVALUATION FORM

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FEATURE ARTICLE FEEDBACK

1) How does your institution stay abreast of drug reimbursement policy changes made by the Center for Medicaid Services (CMS)? (tick all that apply)

- The *Oncology Reimbursement Connection* Newsletter
- The Internet, please specify Web site you find most helpful _____
- Mailouts/publications from your local Medicare carrier
- CMS/Medicare hotline
- Do not know
- Other, please specify _____

2) Do you (or your institution) provide comments to CMS during a comment period that often follows the release of a proposed rule such as the 2005 Outpatient Prospective Payment System (OPPS) Proposed Rule? (Please tick the box that best answers the following questions.)

- Always Sometimes Never Do not know

3) Do you feel your institution was prepared for the changes to the OPPS implemented on January 1, 2005 by CMS?

- Yes
 No
 Do not know

Using a scale of 1 to 5, with 1 indicating that you strongly disagree and 5 indicating that you strongly agree, please complete the following survey. N/A=not applicable.

NEWSLETTER EFFECTIVENESS ASSESSMENT

Disagree → Agree

(Please tick (✓) the rating that best represents your opinion)

How well was the information presented?	N/A	1	2	3	4	5
1) The newsletter provided information that was relevant to my practice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2) The newsletter's content was presented at an appropriate level of learning.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3) The newsletter was organized efficiently and effectively.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4) The length of the newsletter was appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please rate the overall value of the feature article and newsletter columns in this issue of the *Oncology Reimbursement Connection* newsletter using the following 5 point scale.

1=not valuable 2=slightly valuable 3=valuable 4=very valuable 5=extremely valuable

FEATURE ARTICLE / COLUMNS VALUE ASSESSMENT

(Please tick (✓) the rating that best represents your opinion)

How valuable were the following articles/columns to your practice?	N/A	1	2	3	4	5
1) Feature Article: 2005 Outpatient Prospective Payment System Final Rule: Summary Of Oncology Medications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2) "In the News"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3) Networking Column	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4) Compendia Update	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5) Hotlines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

AUDIENCE ASSESSMENT (Please tick (✓) the rating that best represents your opinion)

Yes No

1) Would you like to have ACPE-accredited continuing education credits awarded for the material in this newsletter?	<input type="checkbox"/>	<input type="checkbox"/>
2) Would you like to have ACCN-accredited continuing education credits awarded for the material in this newsletter?	<input type="checkbox"/>	<input type="checkbox"/>
3) Would you like to have ACCME-accredited continuing education credits awarded for the material in the newsletter?	<input type="checkbox"/>	<input type="checkbox"/>
4) Would you be interested in receiving this newsletter online (with printable text)?	<input type="checkbox"/>	<input type="checkbox"/>

If you answered "Disagree", "Not Valuable", or "No" to any of the questions, would you please explain: _____

What feature article topics or regular columns would you like to see in future issues? _____

What reimbursement questions would you like the editorial board to address in future newsletters? _____

Suggestions for improving the value of the newsletter: _____

in the jurisdiction of the FI or carrier, decentralize Medicare coding guidelines and may result in different coverage policies in different areas.⁵ Therefore, confirming the approved codes for medications and other services by reviewing a patient's Medicare contract is important to prevent claim denials.

Because each Medicare contractor may require different ICD-9-CM codes for coding and billing procedures, providing an accurate, comprehensive list of ICD-9 codes for proper billing and coding of each drug in the Compendia Update column is not feasible. Therefore, we will no longer include ICD-9-CM codes in the Compendia Update column of this newsletter. Coding information, LMRPs, and local coverage determinations for each Medicare contractor are available at <http://cms.hhs.gov/mcd/indexes.asp>. Changes in Medicare billing regulations are also published and made available to Medicare providers in the *Medicare Bulletin*, which is provided on the Web site of each local Medicare contractor.⁶

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REIMBURSEMENT HOTLINES

Reimbursement Hotlines for Oncology Drugs With Recent Initial or Expanded Approvals

Manufacturer	Generic Drug Name (Brand Name)	Program Name; Web Site	Phone Number	Information Available
OSI Pharmaceuticals, Inc. and Genentech, Inc.	Erlotinib (Tarceva™)	SPOC Online SM ; https://www.spoconline.com/spoconline/tarceva/professionals/welcome.jsp	888.249.4918	PAP; PRA
Valera Pharmaceuticals	Histrelin (Vantas™)	Patient-Assistance Program*	888.282.5372	PAP; PRA
Novartis Pharmaceuticals	Letrozole (Femara®)	Patient-Assistance Program; http://www.us.femara.com/hcp/page/patient-assistance	800.282.7630	PAP
Sanofi-Synthelabo, Inc.	Oxaliplatin (Eloxatin™)	Reimbursement Hotline; http://www.eloxatin.com/hcp/reimbursement.asp	877.435.6928	PAP; PRA
Celgene Corporation	Thalidomide (Thalomid®)	Patient-Assistance Program*	800.890.4619 ext 3905	PAP

*Web site information on reimbursement programs is currently not available. PAP=patient-assistance program; PRA=provider reimbursement assistance.

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