

# Oncology Reimbursement Connection

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## 2005 OUTPATIENT PROSPECTIVE PAYMENT SYSTEM PROPOSED RULE

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### Background

**W**hen Medicare was enacted by the US Congress in 1965, payment for hospital outpatient services was based on hospital-specific costs.<sup>1,2</sup> The Balanced Budget Act of 1997 replaced this cost-based payment system with a hospital outpatient prospective payment system (OPPS). Numerous acts since 1997 have revised the OPPS, the most recent being the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.<sup>2</sup>

Each year components of the OPPS are reviewed and revised to account for new services, changes in technology and/or medical practice, and the addition of new cost data.<sup>2</sup> In 2004, modifications to the OPPS reflected not only the annual changes instituted by the Centers for Medicare & Medicaid Services (CMS), but also changes mandated by MMA. These modifications provided the payment rates for drugs in 4 main categories: 1) specified covered outpatient drugs; 2) pass-through drugs; 3) nonpass-through drugs; and 4) drugs that become available before they are assigned Healthcare Common Procedure Coding System (HCPCS) codes.<sup>2,3</sup>

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 memorandums 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/default.asp>).

### 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; beginning in 2005, ASP will be used to determine reimbursement payment rates for drugs administered in a physician's office.

**Average wholesale price (AWP)**—suggested average price of a drug (ie, undiscounted price) based on a survey of wholesalers' listed price; used to determine reimbursement payment rates.

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

**Fiscal intermediary**—insurance company that has a private contract with the Centers for Medicare & Medicaid Services to administer the Medicare Part A program and some Medicare 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.

**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.

**Nonpass-through drug**—older drugs, including sole-source and innovator and non-innovator, multiple-source drugs, that do not qualify for pass-through payment.

**Outpatient code editor**—software package that reviews CPT/HCPCS codes and ICD-9-CM codes for validity and coverage. In addition to identifying coding errors, it also assigns APCs.

**Pass-through drug**—new drugs, biologics, or radiopharmaceuticals eligible for a higher reimbursement payment rate for the first 2–3 years of commercial availability.

**Single-source drug**—see sole-source drug.

**Sole-source drug**—brandname drug for which no FDA-approved generic alternative exists.

**Wholesale acquisition cost**—manufacturer's list price to wholesalers or direct purchasers, not including discounts, rebates, or other price reductions.

## 2005 Proposed Payments for Oncology Drugs

On August 16, 2004, the CMS released the proposed 2005 OPPS rule.<sup>1</sup> This article focuses on how this rule affects payment for oncology drugs, biologics, and radiopharmaceutical agents (for the remainder of this article “drugs, biologics, and radiopharmaceuticals” are referred to as “drugs”). The oncology drugs affected by this rule include: 1) drugs included in packaged ambulatory payment classifications (APCs), 2) specified covered outpatient drugs, 3) transitional pass-through drugs, and 4) orphan drugs. The rule also proposes changes to coding and payment for the administration of oncology-related drugs.

### Packaged Ambulatory Payment Classifications

Oncology drugs with nonpass-through status are reimbursed as either a packaged APC payment (ie, drug cost is included with the costs of the procedure or service provided) or a separate payment (ie, drug cost is based on the APC assigned to that oncology drug).<sup>2</sup> The proposed rule continues to establish individual APCs for oncology drugs that have a median cost per day that exceeds \$50.<sup>2</sup> Oncology drugs with a median cost per day of less than \$50 will be reimbursed as a packaged APC.<sup>2</sup> Median costs per day for oncology drugs were determined using claims data from January 1, 2003 to December 31, 2003 for agents that had an HCPCS code during that time and were paid within the OPPS.<sup>2</sup> Table 1 lists oncology drugs without separate APC payments in 2005.<sup>2,5,6</sup>

Generic Drug Name	Brand Name	Billing Code (Billing Unit)	Usual Administration Route(s)
Carmustine	BicNu <sup>®</sup>	J9050 (100 mg)	IV
Corticotropin	NA	J0800 (up to 40 U)	IV, IM, SC
Cyclophosphamide, oral <sup>†</sup>	Cytosan <sup>®</sup>	J8530 (25 mg, oral)	Oral
Cytarabine liposome <sup>§</sup>	Depocyt <sup>®</sup>	J9098 (10 mg)	IT
Dactinomycin	Cosmegen <sup>®</sup>	J9120 (0.5 mg)	IV
Dexamethasone acetate	Decaject <sup>®</sup> LA; others	J1094 (1 mg)	IM
Dexamethasone sodium phosphate	Decadron <sup>®</sup> Phosphate; others	J1100 (1 mg)	IM, IV
Estradiol cypionate	Depo-Estradiol <sup>®</sup>	J1000 (up to 5 mg)	IM
Estradiol valerate	Delestrogen <sup>®</sup>	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 <sup>®</sup>	J1436 (300 mg)	IV
Fluorouracil	Adrucil <sup>®</sup>	J9190 (500 mg)	IV
Hydrocortisone acetate	Hydrocortone <sup>®</sup> Acetate	J1700 (up to 25mg)	IV, IM, SC
Hydrocortisone sodium phosphate	Hydrocortone <sup>®</sup> Phosphate	J1710 (up to 50mg)	IV, IM, SC
Hydrocortisone succinate sodium	Solu-Cortef <sup>®</sup> ; A-hydroCort <sup>®</sup>	J1720 (up to 100 mg)	IV, IM, SC

**Table 1 (cont'd). Oncology Medications Without Separate APC Payments in 2005<sup>1,2,6</sup>**

Generic Drug Name	Brand Name	Billing Code (Billing Unit)	Usual Administration Route(s)
Leucovorin calcium	NA	J0640 (50 mg)	IM, IV
Mechlorethamine HCl	Mustargen <sup>®</sup>	J9230 (10 mg)	IV
Melphalan, oral <sup>  </sup>	Alkeran <sup>®</sup>	J8600 (2 mg)	Oral
Methotrexate	Trexall <sup>®</sup>	J9250 (5 mg) J8610 (2.5 mg oral)	IA, IM, IT, IV Oral
Methylprednisolone sodium succinate	Solu-Medrol <sup>®</sup> ; A-methaPred <sup>®</sup>	J2920 (up to 40 mg) J2930 (up to 125 mg)	IM, IV IM, IV
Nandrolone decanoate	Deca-Durabolin <sup>®</sup> ; Hybolin <sup>™</sup> Decanoate	J2320 (up to 50 mg) J2321 (up to 100 mg) J2322 (up to 200 mg)	IM IM IM
Pegaspargase	Oncaspar <sup>®</sup>	J9266 (single-dose vial)	IM, IV
Prednisone	Deltasone <sup>®</sup> ; others	J7506 (per 5 mg)	Oral
Streptozocin <sup>§</sup>	Zanosar <sup>®</sup>	J9320 (1 gm)	IV
Testosterone cypionate	Depo-Testosterone <sup>®</sup>	J1060 (1 mL) J1070 (100 mg) J1080 (200 mg)	IM IM IM
Testosterone enanthate	Delatestryl <sup>®</sup>	J3120 (up to 100 mg) J3130 (up to 200 mg)	IM IM
Testosterone propionate	NA	J3150 (up to 100 mg)	IM
Testosterone injectable suspension	NA	J3140 (up to 50 mg)	IM
Valrubicin <sup>§</sup>	Valstar <sup>®</sup>	J9357 (200 mg)	intravesical
Vinblastine sulfate	NA	J9360 (1 mg)	IV
Vincristine sulfate	Vincasar PFS <sup>®</sup>	J9370 (1 mg)	IV

\*Reimbursed by Medicare in 2005 through packaged APC.

<sup>†</sup>Injectable drugs, unless otherwise specified.

<sup>‡</sup>Intravenous formulation has its own APC (see Table 4).

<sup>§</sup>Assigned drug-specific APC status in 2004.

<sup>||</sup>Intravenous formulation has its own APC (see Table 3).

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

The 2005 rule provides exception, however, to the reimbursement of injectable and oral 5-hydroxytryptamine type 3 (5-HT<sub>3</sub>) receptor antagonist antiemetics (Table 2).<sup>2,5</sup> In 2004, 1 injectable product is

**Table 2. Proposed 2005 APC Payments for Oral and Injectable Antiemetics<sup>2,5</sup>**

Generic Drug Name	Brand Name	Billing Code (Billing Unit)	APC	2005 Proposed Payment, \$
Dolasetron mesylate, injection	Anzemet <sup>®</sup>	J1260 (10 mg)	0750	14.38
Dolasetron mesylate, oral	Anzemet <sup>®</sup>	Q0180 (100 mg)	0763	63.28
Granisetron HCl, injection	Kytril <sup>®</sup>	J1626 (100 µg)	0764	16.20
Granisetron HCl, oral	Kytril <sup>®</sup>	Q0166 (1 mg)	0765	39.04
Ondansetron HCl, injection	Zofran <sup>®</sup>	J2405 (1 mg)	0768	5.54
Ondansetron HCl, oral	Zofran <sup>®</sup>	Q0179 (8 mg)	0769	26.12

APC=ambulatory payment classification; HCl=hydrochloride.

paid separately, whereas 2 injectable products are packaged; 2 oral products are paid separately, whereas 1 oral product is packaged.<sup>2</sup> To ensure patient access to these antiemetics, the CMS proposes separate payment for all of these injectable and oral 5-HT<sub>3</sub> antiemetic agents in 2005.<sup>2</sup>

## Specified Covered Outpatient Drugs

### *Sole-Source, Innovator, and Noninnovator Multiple-Source Drugs*

A specified covered outpatient drug is a drug assigned a separate, drug-specific APC and for which payment was based on the payment for a pass-through drug on or before December 31, 2002.<sup>3</sup> Payment for specified covered outpatient drugs is based on the reference average wholesale price (AWP) in the CMS single drug pricer that uses prices published in the *Red Book* on May 1, 2003.<sup>2</sup> These drugs are classified according to 1 of 3 payment categories: sole-source drugs; innovator, multiple-source drugs; and noninnovator, multiple-source drugs.<sup>2</sup>

Sole-source, or single-source, drugs are brandname drugs for which there is no Food and Drug Administration (FDA)–approved generic product available.<sup>3</sup> Hence, these drugs are available from one manufacturer only. In 2004, sole-source drugs have been reimbursed at rates between 88% and 95% of the reference AWP.<sup>3</sup> In 2005, the proposed reimbursement for a sole-source drug is between 83% and 95% of the reference

Generic Drug Name	Brand Name	Billing Code (Billing Unit)	APC	2005 Proposed Payment, \$
Alemtuzumab	Campath®	J9010 (10 mg)	9110	510.70
Amifostine	Ethyo®	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	27.87
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 <sup>†</sup>	Aranesp®	Q0137 (1 µg)	0734	4.14
Daurorubicin citrate liposome	DaunoXome®	J9151 (10 mg)	0821	64.60
Docetaxel	Taxotere®	J9170 (20 mg)	0823	312.69
Doxorubicin HCl liposome	Doxil®	J9001(10 mg)	7046	343.78
Epirubicin	Ellence®	J9178 (2 mg)	1167	24.14
Epoetin alfa <sup>†</sup>	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

Generic Drug Name	Brand Name	Billing Code (Billing Unit)	APC	2005 Proposed Payment, \$
Fulvestrant <sup>‡</sup>	Faslodex®	J9395 (25 mg)	9120	79.65
Gemcitabine HCl	Gemzar®	J9201 (200 mg)	0828	105.73
Goserelin acetate implant	Zoladex®	J9202 (3.6 mg)	0810	390.09
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	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 <sup>§</sup>	Alkeran®	J9245 (50 mg)	0840	367.03
Mitoxantrone HCl	Novantrone®	J9293 (5 mg)	0864	313.96
Octreotide acetate	Sandostatin®	J2354 (25 µg)	7031	3.72
Octreotide acetate depot	Sandostatin LAR®	J2353 (1 mg)	1207	71.66
Pegfilgrastim <sup>‡</sup>	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 <sup>  </sup>	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	Herceptin®	J9350 (4 mg)	0852	697.76
Trastuzumab	Hycamtin®	J9355 (10 mg)	1613	50.79
Triptorelin pamoate <sup>‡</sup>	Trelstar® Depot	J3315 (3.75 mg)	9122	362.78
Vinorelbine tartrate	Navelbine®	J9390 (10 mg)	0855	95.23
Zoledronic acid <sup>‡</sup>	Zometa®	J3487 (1 mg)	9115	197.87

\*Injectable drugs, unless otherwise specified.

<sup>†</sup>For non-end stage renal disease.

<sup>‡</sup>Assigned for pass-through payment status in 2004.

<sup>§</sup>Oral formulation reimbursed through packaged APC (see Table 1).

<sup>||</sup>For cancer-related treatment only.

APC=ambulatory payment classification; HCl=hydrochloride.

AWP.<sup>2</sup> Table 3 lists oncology sole-source drugs and their new payment rates.<sup>2-6</sup>

Innovator, multiple-source drugs were originally sole-source drugs for which one or more generic alternatives was later approved by the FDA.<sup>3</sup> In 2004, these drugs have been reimbursed at no more than 68% of the reference AWP.<sup>3</sup> Noninnovator, multiple-source drugs are generic drugs approved by the FDA.<sup>3</sup> In 2004, these drugs have been reimbursed at no more than 46% of

the reference AWP.<sup>3</sup> The proposed rule for 2005 maintains the 2004 reimbursement rates for both drug categories.<sup>2</sup> Table 4 lists oncology innovator and noninnovator, multiple-source drugs and their proposed payments.<sup>2,5-7</sup>

### New Oncology Drugs

Recently approved oncology drugs often lack accompanying billing and reimbursement information. For example, the assignment of HCPCS codes to newly approved drugs may not be immediate. If a newly approved drug has been assigned a HCPCS code, but the reference AWP or pass-through payment status approval do not exist, this will prevent the use of hospital claims data in establishing an accurate payment rate for these drugs.<sup>2</sup> Pass-through payment is a special APC group that temporarily reimburses newly approved drugs at a higher rate.<sup>2</sup> The 2005 OPSS rule proposes payment rates for newly approved drugs with and without HCPCS codes until appropriate hospital claims data are available.

### New Drugs With HCPCS Codes

Under the proposed rule, oncology drugs that have been assigned HCPCS codes but have no reference AWP or pass-through payment status approval will be paid at a rate 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).<sup>2,8</sup> This payment method is the same method that will be used to calculate pass-through payments in 2005.

Generic Drug Name	Brand Name	Billing Code (Billing Unit)	APC	2005 Proposed Payment, \$
Bleomycin sulfate	Blenoxane®	C9417 (15 U)	9417	130.56
		J9040 <sup>‡</sup> (15 U)	0857	88.32
Cisplatin	Platinol-AQ®	C9418 (10 mg)	9418	11.42
		J9060 <sup>‡</sup> (10 mg)	0813	7.73
Cladribine	Leustatin®	C9419 (1 mg)	9419	36.72
		J9065 <sup>‡</sup> (1 mg)	0858	24.84
Cyclophosphamide	Neosar®	C9420 (100 mg)	9420	4.10
		J9070 <sup>‡</sup> (100 mg)	0815	2.77
Cyclophosphamide, lyophilized	Cytosan® Lyophilized	C9421 (100 mg)	9421	3.50
		J9093 <sup>‡</sup> (100 mg)	0816	2.36
Cytarabine HCl	Cytosar-U®	C9422 (100 mg)	9422	2.28
		J9100 <sup>‡</sup> (100 mg)	0817	1.55
Dacarbazine	DTIC-Dome®	C9423 (100 mg)	9423	8.24
		J9130 <sup>‡</sup> (100 mg)	0819	6.14
Daunorubicin HCl	Cerubidine®	C9424 (10 mg)	9424	53.14
		J9150 <sup>‡</sup> (10 mg)	0820	35.94
Dexrazoxane HCl	Zinecard®	C9410 (250 mg)	9410	125.24
		J1190 <sup>‡</sup> (250 mg)	0726	113.28
Doxorubicin HCl	Adriamycin RDF®; others	C9415 (10 mg)	9415	6.94
		J9000 <sup>‡</sup> (10 mg)	0847	4.69
Etoposide	Toposar®; VePesid®	C9425 (10 mg)	9425	1.22
		J9181 <sup>‡</sup> (10 mg)	0824	0.83
Etoposide, oral	VePesid®	C9414 (50 mg)	9414	27.72
		J8560 <sup>‡</sup> (50 mg)	0802	21.91

Generic Drug Name	Brand Name	Billing Code (Billing Unit)	APC	2005 Proposed Payment, \$
Floxuridine	FUDR®	C9426 (500 mg)	9426	97.92
		J9200 <sup>‡</sup> (500 mg)	0827	66.24
Idarubicin HCl	Idamycin® PFS	C9429 (5 mg)	9429	13.45
		J9211 <sup>‡</sup> (5 mg)	0832	13.46
Ifosfamide	Ifex®	C9427 (1 g)	9427	101.46
		J9208 <sup>‡</sup> (1 g)	0831	72.81
Leuprolide acetate	Lupron®	C9430 (1 mg)	9430	21.41
		J9218 <sup>‡</sup> (1 mg)	0861	14.48
Mesna	Mesnex®	C9428 (200 mg)	9428	25.07
		J9209 <sup>‡</sup> (200 mg)	0732	17.66
Mitomycin	Mutamycin®	C9432 (5 mg)	9432	45.70
		J9280 <sup>‡</sup> (5 mg)	0862	30.91
Paclitaxel	Taxol®; Onxol™	C9431 (30 mg)	9431	95.84
		J9265 <sup>‡</sup> (30 mg)	0863	79.04
Pamidronate disodium	Aredia®	C9411 (30 mg)	9411	162.66
		J2430 <sup>‡</sup> (30 mg)	0730	128.74
Thiotepa	NA <sup>§</sup>	C9433 (15 mg)	9433	66.98
		J9340 <sup>‡</sup> (15 mg)	0851	45.31

\*Injectable drugs, unless otherwise specified.

<sup>†</sup>Brand name drugs unless otherwise specified.

<sup>‡</sup>Generic drugs.

<sup>§</sup>Brand name drug no longer available commercially.

APC=ambulatory payment classification; HCl=hydrochloride.

### New Drugs Without HCPCS Codes

MMA required CMS to develop a payment method for newly approved drugs without HCPCS codes.<sup>2</sup> An interim approach, which allows hospitals to bill and receive payment for a new drug immediately after its FDA approval rather than waiting for assignment of a drug-specific HCPCS code was adopted on May 28, 2004, and will continue in 2005.<sup>2</sup> Hospitals will bill for a newly approved oncology drug by reporting both the National Drug Code for the product and the new HCPCS code C9399 (unclassified drug or biologic). When the code C9399 appears on a claim, the outpatient code editor suspends the claim for manual processing by the fiscal intermediary. The fiscal intermediary prices the claim at 95% of its AWP in the *Red Book* or another accepted compendium and processes the claim for payment. When a drug is assigned an HCPCS code, hospitals should bill using the HCPCS code, not C9399 and the National Drug Code.<sup>2</sup>

### Coding and Billing for Specified Covered Outpatient Drugs in 2005

In the 2004 OPSS interim final rule, created to implement MMA provisions, healthcare providers were instructed to use existing HCPCS codes (ie, J codes) for noninnovator, multiple-source drugs.<sup>2</sup> Hospitals were instructed to use existing HCPCS codes to bill for sole-source drugs.<sup>2</sup> However, existing HCPCS codes did not differentiate between innovator and noninnovator, multiple-source drugs. Thus, new HCPCS codes (ie, C codes) for innovator, multiple-source drugs were implemented on April 1, 2004.<sup>2,9</sup> The

descriptors for the new C codes include “brandname” to further distinguish these C codes from existing HCPCS codes.<sup>9</sup> The CMS proposes continuing the coding practice implemented on April 1, 2004 for sole-source, innovator, multiple-source, and noninnovator, multiple-source drugs in 2005.<sup>2</sup>

## Transitional Pass-Through Drugs

A pass-through drug is a drug eligible for temporary additional payments for the first 2 to 3 years that the drug is commercially available.<sup>2</sup> The oncology drugs for which pass-through payment status will expire on December 31, 2004, include pegfilgrastim, fulvestrant, triptorelin pamoate, zoledronic acid, and darbepoetin alfa.<sup>2</sup> Each drug will now be reimbursed as a sole-source drug at a rate between 83% and 95% of its reference AWP. Table 5 lists the proposed 2005 APC payments for these 5 drugs.<sup>2,4,5</sup> The CMS is soliciting comments regarding the need for an equitable adjustment to the price of darbepoetin alfa in 2005.<sup>2</sup>

Table 6 lists the 8 oncology drugs with pass-through payment status for 2005.<sup>2,3,6,7</sup> These drugs will be reimbursed at a rate equivalent to the payment for these drugs in a physician’s office (ie, 106% of ASP or 106% of WAC, whichever is less).<sup>2,8</sup> Previously, payment for pass-through drugs included the APC payment plus the additional pass-through payment to offset some of the expense of the new drug. However, in the proposed 2005 rule, the additional pass-through payment amount equals zero.<sup>2</sup>

## Orphan Drugs

Orphan drugs are medications that are generally expensive and used for rare orphan conditions (ie, diseases or conditions that affect less than 200,000 people in the United States).<sup>2</sup> If more than 200,000 persons are affected and the cost of manufacturing and marketing a drug to treat the condition would not be recovered from sales in the United States, the condition is still considered an orphan condition.<sup>10</sup> If the cost of these drugs were to be packaged into the payment for an associated procedure or healthcare visit, the payment received by a hospital may be insufficient to reimburse the high cost of these drugs.<sup>2</sup> Therefore, the 2005 rule continues to permit separate payments for orphan drugs at a rate of 88% of AWP or 106% of the ASP, whichever is higher.<sup>2</sup> However, payment will be capped at 95% of the AWP for drugs if 106% of the ASP exceeds 95% of the AWP, the upper limit allowed for sole-source drugs.<sup>2</sup> Table 7 lists the oncology orphan drugs and their respective payments.<sup>2,6</sup>

## Coding and Payment for Drug Administration

Under the OPPTS, the following HCPCS codes have been used for administration of chemotherapy: Q0081, infusion therapy other than chemotherapy, per visit; Q0083, administration of chemotherapy by any route other than infusion, per visit; Q0084, administration of chemotherapy by infusion only, per visit; and Q0085, administration of chemotherapy by both infusion and another route, per visit.<sup>2</sup> In 2004, the use of code Q0085 was

**Table 5. Proposed 2005 APC Payment for Oncology Medications With Pass-Through Payment Status Expiring in 2004<sup>2,4,5</sup>**

Generic Drug Name	Brand Name	Billing Code (Billing Unit)	APC	2005 Proposed Payment, \$
Darbepoetin alfa	Aranesp®	Q0137 (1 µg)	0734	4.14
Fulvestrant	Faslodex®	J9395 (25 mg)	9120	79.65
Pegfilgrastim	Neulasta®	J2505 (6 mg)	9119	2,448.50
Triptorelin pamoate	Trelstar® Depot	J3315 (3.75 mg)	9122	362.78
Zoledronic acid	Zometa®	J3487 (1 mg)	9115	197.87

\*Injectable drugs; pass-through payment status expires December 31, 2004. APC=ambulatory payment classification.

**Table 6. Oncology Medications With Pass-Through Payment Status in 2005<sup>2,3,5,6</sup>**

Generic Drug Name	Brand Name	Billing Code (Billing Unit)	APC	2005 Proposed Payment, \$
Abarelix	Plenaxis™	C9216 (10 mg)	9216	66.82
Bevacizumab	Avastin™	C9214 (10 mg)	9214	57.13
Bortezomib	Velcade®	C9207 (3.5 mg)	9207	946.57
Cetuximab	Erbitux™	C9215 (10 mg)	9215	51.98
Oxaliplatin	Eloxatin™	C9205 (5 mg)	9205	81.98
Palonosetron HCl	Aloxi™	C9210 (250 µg)	9210	194.91
Pemetrexed	Alimta®	C9213 (10 mg)	9213	40.02
Rasburicase	Elitek®	J2783 (0.5 mg)	0738	105.87

\*Injectable drugs; all drugs had pass-through payment status for at least part of 2004. APC=ambulatory payment classification; HCl=hydrochloride.

discontinued because codes Q0083 and Q0084 could be combined to include services described by Q0085.<sup>2</sup> In 2005, the CMS proposes to use current procedural terminology (CPT) codes for drug administration instead of the Q codes. The CPT codes would eventually be assigned APCs that will reflect how these services would have been paid under the Q codes. The CMS is also proposing a new, separate CPT code for an unlisted chemotherapy procedure (96549) instead of bundling that service into an APC.<sup>2</sup>

With this proposed conversion of Q codes to CPT codes, hospitals will report the CPT codes for the services they furnished and the charges they assign to the CPT codes on the claim.<sup>2</sup> The Medicare outpatient coding editor will assign the code to an APC, the payment for which will be based on the Q code that would have been used.<sup>2</sup> The current payment rate for the CPT codes will be based on the median costs from 2003 using data corresponding to the Q codes for drug administration.<sup>2</sup> Therefore, billing the charges for the packaged CPT codes for drug administration in 2005, even though no separate payment for them exists, is essential to ensure accurate payment in 2007 when claims data from 2005 were used to determine the median costs for each CPT code.<sup>2</sup>

## Experimentation in Cancer Care: Changes in Medicare Payments for Oncology Drugs

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The system for new drug approval in the United States may be the most rigorous in the world.<sup>1</sup> On average, it takes 12 years for an experimental drug to be developed and approved for use in humans.<sup>1</sup> For antineoplastic agents, this methodical, highly regulated process of drug development and delivery ensures that the benefits of a new cancer therapy outweigh the risks.

Conversely, the Centers for Medicare & Medicaid Services (CMS) does not require the same extensive investigation of the benefits and risks of reimbursement rules and regulations before their implementation, as evidenced by recent legislation (ie, the Medicare Prescription, Drug, Improvement, and Modernization Act [MMA] of 2003), now in process of being implemented by the CMS. Changes in reimbursement rules and regulations can negatively affect the financial viability of healthcare practices and ultimately the care of patients; in short, healthcare providers may limit or discontinue their practices or may choose to prescribe older, standard treatment regimens because state-of-the-art therapies are not adequately reimbursed and their patients cannot afford out-of-pocket expenses to cover the recommended cutting-edge therapy. The CMS does use several advisory panels that provide some measure of regulation: the Ambulatory Payment Classification (APC) Advisory Panel, for example, oversees proposed changes to the Hospital Outpatient Prospective Payment System; the Medicare Payment Advisory Commission (MedPAC), an independent federal body established by the Balanced Budget Act of 1997 to advise Congress on issues affecting the Medicare program, reviews and provides comments on CMS' proposed rules; the Practice Expense Advisory Committee of the American Medical Association's Specialty Society Relative Value Update Committee reviews proposed changes to the payment policies under the physician fee schedule.<sup>2,3,4</sup> These panels consist of representatives directly affected by proposed rulings. Despite the availability of these advisory panels, CMS will not evaluate the impact of the MMA on cancer care until 2 years after implementation, when the completion of 3 ongoing government-mandated studies is anticipated.<sup>5</sup>

Recent changes in cancer therapy reimbursement legislated by the MMA may reduce provider access and/or limit the ability of oncology healthcare providers to provide cutting-edge cancer therapies. Effective January 1, 2005, the reimbursement structure will fundamentally change for oncology drugs or services provided in physician offices, where more than 80% of cancer patients receive their care.<sup>6</sup> Hospital-based outpatient programs are not immune to the effects of this legislation, because similar changes

Table 7. Oncology Orphan Drugs\*<sup>2-6</sup>

Generic Drug Name	Brand Name	Billing Code (Billing Unit)	APC	2005 Proposed Payment, \$
Aldesleukin	Proleukin®	J9015 (single vial)	0807	680.35
Arsenic trioxide <sup>†</sup>	Trisenox®	J9017 (1 mg)	9012	34.32
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.

<sup>†</sup>Assigned sole-source drug status in 2004.

APC=ambulatory payment classification.

### Final 2005 Rule

Written comments from the public on this proposed ruling were accepted until 5:00 PM on October 8, 2004.<sup>2</sup> The final 2005 OPPS rule, which will address pertinent public comments, will likely be published later this year in the Federal Register; this rule will become effective on January 1, 2005.<sup>2</sup> Medicare reimbursement for oncology-related services can be maximized by maintaining a current knowledge of the proposed and final revisions to the OPPS. For more information regarding the 2005 OPPS rule, view the Federal Register online at [http://www.access.gpo.gov/su\\_docs/fedreg/a040816c.html](http://www.access.gpo.gov/su_docs/fedreg/a040816c.html). Locate recent Medicare regulations at <http://www.cms.gov/providerupdate/newregs.asp>.

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to the reimbursement structure in hospital settings will be imposed on January 1, 2006.<sup>7</sup> While these changes impact reimbursement directly, their potentially negative impact on patient access to cancer care and treatment breakthroughs are particularly alarming and difficult to ignore.

The MMA contains several provisions related to the reimbursement of injectable drugs in outpatient departments. One of the key provisions is replacement of the average wholesale price (AWP) with the average sales price (ASP) as the basis for calculating reimbursement rates.<sup>8</sup> This change is based on results of several government studies in the 1990s, which concluded that the CMS paid more than other purchasers for Part B-covered drugs, primarily because the CMS used AWP as the basis for calculating reimbursement rates.<sup>8</sup> The CMS' proposed solution to prevent overpayment is to use the ASP as the basis for calculating reimbursement rates.<sup>2</sup> The proposed formula for calculating injectable drug reimbursement rates is ASP plus 6%.<sup>2</sup> In 2006, providers can choose to be reimbursed using this formula or a competitive bidding program.<sup>8</sup> All manufacturers must report their ASP, including all discounts (volume, prompt pay, cash), chargebacks, free goods that are contingent on any purchase requirement, and rebates (excluding rebates under the Medicaid drug rebate program) to the CMS on a quarterly basis.<sup>2,9</sup>

In the past, overpayment for medications using the AWP-based reimbursement method balanced the underpayment for chemotherapy-related services.<sup>5</sup> In fact, the CMS recognized this payment imbalance as a significant problem when it provided a 32% transitional add-on payment for practice expenses in 2004.<sup>2,5</sup> Nonetheless, effective January 1, 2005, this transitional add-on payment decreases to 3% and the proposed reduction in oncology drug reimbursement using the ASP-based formula will be implemented.<sup>2</sup>

Oncologists and other physicians caring for cancer patients have several objections to the impending implementation of the ASP model:

- ASP is a conceptual system—it has never been analyzed or tested in a practice environment. Furthermore, the CMS has no historical data justifying the superiority of the new ASP system.<sup>10</sup>
- By definition, the **average** sales price indicates that 50% of community oncologists will pay more than the drug's ASP and therefore be reimbursed at a level below their actual acquisition cost.
- The 6% add-on payment does not cover all direct drug costs (ie, pharmacy, storage, waste).<sup>11</sup> The cost of administering chemotherapy and providing cancer care is at least increasing by 4% per year, the general increase in medical services as measured by the Consumer Price Index for Medical Care, an index often used to measure healthcare inflation.<sup>11</sup> Unfortunately, oncology drugs costs are increasing at a higher rate than most other pharmaceuticals. The Community

Oncology Alliance (COA) has estimated that a 12% add-on payment over drug-acquisition costs is needed to cover all direct drug costs for administering oncology drugs.<sup>10</sup>

- ASP is not a market price available to all community cancer centers. Purchasing intermediaries buy large quantities of drugs at significantly discounted prices and resell these drugs to oncology practices at market price. Furthermore, because the purchasing patterns of these purchasing groups and their buying practices vary each quarter, the quarterly ASP is likely to vary significantly.<sup>11</sup>
- Price increases for oncology drugs will not be reflected promptly in reimbursement payments because there will be a 3- to 6-month lag period required to update the quarterly ASPs.<sup>11</sup>

The CMS estimates that Medicare payments in 2005 using ASP-based reimbursement rates will be reduced by approximately \$500 million, or approximately 8%.<sup>2,6,11</sup> However, a recent survey by the American Society of Clinical Oncology (ASCO) suggests a 15% reduction in reimbursement rates, and the COA estimates a 17.8% reduction.<sup>5,11</sup> Regardless of which figure is more accurate, the impact of the ASP-model implementation on an individual oncology practice is extremely difficult to estimate, primarily because of 2 key factors:

- The published list of drugs in the August 5, 2004, Federal Register for which ASP data is available does not include several commonly used oncology drugs.<sup>2</sup>
- Payments in this published list are based on ASP submissions from the first quarter of 2004. Payments for 2005 will be based on ASP submissions from the third quarter of 2004.<sup>2</sup>

Because the ASP rule has not been tested, ASCO advocates maintaining net 2004 reimbursement levels for 2005 and 2006 until the 3 previously mentioned government-mandated studies of MMA's effect are completed.<sup>5</sup> COA takes a similar view, advocating that there "should be a transition for a year...while a new ASP-based system is correctly defined and worked out." (Community Oncology Alliance [newsbriefs@communityoncology.org], e-mail, July 20, 2004). The likelihood of reopening the MMA legislation in a presidential election year, however, is thought to be remote. In a letter dated June 29th, 2004 to Dr. Mark McClellan, CMS Administrator, urging the release of ASP data as soon as possible, Senator Barbara Boxer (D-CA) noted that the "proposed reimbursement system is completely new and untested. Those who treat cancer patients have no way of estimating what the total reimbursement [for cancer-related drugs and services] will be for 2005." Unfortunately, even with the release of the preliminary ASP data, these statements still hold true today.

The real impact of these reimbursement changes on cancer patients remains unclear. For example, during the past few decades, patients' access to ambulatory therapy within their community and home has expanded greatly, enabling patients, caregivers, and family members to better cope with the disease and its treatment.

The implementation of the provisions mandated by the MMA, however, may increase difficulties in obtaining access to care, either because of a reduction in the number of providers or the relocation of physician office-based programs to hospital-based programs, the latter of which is less convenient for many patients.<sup>12</sup>

Community-based practices owned by hospitals that bill according to CMS 1500 processes may be able to convert to an alternate billing process (ie, hospital-based UB92 billing process) to temporarily avoid some of the impending decreases in reimbursement. However, based on the current legislation and regulations, such a change would be beneficial in 2005 only, because hospital-based programs will convert to the ASP model in 2006.<sup>7</sup> An assessment of the legality, practicality, required resources, and impact on all other patient charges and reimbursement rates for all payers is warranted to determine whether a temporary change in billing procedures is worthwhile.

In conclusion, one thing is certain. We are about to undergo a fundamental change in the reimbursement of injectable drugs administered in the outpatient setting. Unfortunately, we are about to undergo this change without any of the benefits of the normal experimentation and research processes that are required of the physicians and other healthcare professionals who develop and prescribe these drugs.

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## IN THE NEWS

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### FDA Approvals

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#### Final Approvals

*July 12, 2004: ImageChecker® CT System* (R2 Technology, Inc.), an image analysis system used by radiologists to review computed tomography (CT) images of the chest, was approved by the Food and Drug Administration (FDA) as a system to identify lung nodules that a radiologist may have missed. After a radiologist reviews a case, the ImageChecker CT System detection software examines the CT images to highlight suspicious nodules.

*July 15, 2004: Aldara™ (imiquimod)*, 3M Pharmaceuticals), a topical cream initially approved as treatment of patients with actinic keratosis and external genital warts, was approved as treatment of patients with superficial basal cell carcinoma. The FDA recommends the use of Aldara in patients who are not good surgical candidates. Aldara is not approved for use on the face or for tumors larger than 2 cm.

*August 1, 2004: Sichel Technologies, Inc.* received FDA clearance to manufacture and market **OneDose™**, a disposable, surface dosimeter. The wireless, precalibrated, patient dosimetry system has a built-in memory to create a permanent record of the radiation dose received by the patient.

*August 19, 2004: Taxotere® (docetaxel)*, Aventis Pharmaceuticals, Inc.), combined with doxorubicin and cyclophosphamide (TAC), received approval as adjuvant treatment of patients with operable, node-positive breast cancer. Taxotere is also approved as treatment of patients with metastatic breast cancer, non-small cell lung cancer (NSCLC), and androgen-independent (hormone-refractory) metastatic prostate cancer.

*August 19, 2004: Alimta® (pemetrexed)*, Eli Lilly and Company) was granted accelerated approval for the treatment of locally advanced or metastatic NSCLC in previously treated patients. In February 2004, Alimta was approved in combination with cisplatin as treatment of patients with malignant pleural mesothelioma.

## ***Tentative Approvals***

*August 27, 2004:* Barr Pharmaceuticals, Inc. announced that Barr Laboratories, Inc. has received tentative approval for its generic version of **Zofran® (ondansetron)**, GlaxoSmithKline) Orally Disintegrating Tablets (ODT), 4 mg and 8 mg. GlaxoSmithKline's patent for Zofran ODT will expire June 24, 2006. After expiration of the patent, Barr Laboratories, Inc. anticipates receiving final approval of the generic version.

## ***New Drug Applications***

*May 10, 2004:* The New Drug Application (NDA) for **Abraxane™ (albumin nanoparticle paclitaxel)**, American Pharmaceutical Partners, Inc. and American BioScience) as treatment of metastatic breast cancer was accepted for filing with standard review by the FDA.

*August 2, 2004:* The NDA for **Tarceva™ (erlotinib HCl)**, OSI Pharmaceuticals, Inc. and Genentech, Inc.) as monotherapy for patients with advanced NCSLC that has not responded to previous chemotherapy has been granted pilot 1 status under the FDA's Pilot 1 Program for Continuous Marketing Applications. This new program applies to investigational therapies that have been given fast-track status and have demonstrated significant promise in clinical trials as an advance over available therapies.

## ***Orphan Drug Designations***

*May 4, 2004:* **PI-88** (Progen Industries Limited) was granted orphan drug status for the treatment of malignant melanoma. PI-88 inhibits the activity of angiogenesis factors (ie, vascular endothelial growth factor and fibroblast growth factors 1 and 2) and heparanase, an enzyme associated with tumor metastasis.

*June 9, 2004:* **MDX-010** (Medarex, Inc.), a fully human anticytotoxic T-lymphocyte-associated protein 4 (CTLA-4) antibody, was granted orphan drug status for the treatment of high-risk stage II, III, and IV melanoma. CTLA-4 is a molecule on T cells that is believed to be responsible for suppressing the immune response.

## ***ODAC Update***

*July 27, 2004:* The Oncology Drugs Advisory Committee (ODAC) met in July 2004 to discuss the NDA for Alimta as single-agent treatment of patients with locally advanced or metastatic NSCLC who have received prior chemotherapy. The committee voted unanimously to endorse Alimta for accelerated approval for second-line treatment of NSCLC. A transcript of the meeting is available at <http://www.fda.gov/ohrms/dockets/ac/04/transcripts/2004-4060T1.htm>.

## ***Legislative and Regulatory News***

### ***CMS Provides Information About Correction of Minor Errors and Omissions Without Appeals***

*April 30, 2004:* The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 required the establishment of a process that enables physicians, providers, and suppliers to correct minor errors and omissions in claims without initiating a formal appeal. In an article in *Medlearn Matters*, an online publication for Medicare providers, the Centers for Medicare & Medicaid Services (CMS) explains how to correct incomplete or invalid claims, correct mistakes in previously processed claims, reopen claims, and correct Health Insurance Portability and Accountability Act (HIPAA) of 1996 compliance issues. Find the article at <http://www.cms.hhs.gov/medlearn/matters/mmarticles/2004/SE0420.pdf>.

### ***New Oncology Office to be Established by the FDA***

*July 16, 2004:* The FDA is creating a new oncology office, the Office of Oncology Drug Products, to be housed within the Center for Drug Evaluation and Research. This new office will be responsible for the review of drugs and therapeutic biologics used to diagnose, treat, and prevent cancer, including agents used in medical imaging. Additionally, the Office of Oncology Drug Products will include an oncology program that will facilitate expert consultation from different FDA-based agencies, allow for collaboration between the FDA and various oncology professional societies, serve as a forum for the development and discussion of regulatory policies and standards, and coordinate training and educational activities.

### ***CMS Releases Proposed 2005 Physician Fee Schedule***

*July 27, 2004:* The CMS released its proposed physician fee schedule for 2005, which implements provisions of the MMA and provides reduced reimbursement rates for numerous chemotherapy drugs. Under the MMA, the standard payment rate for most Medicare Part B drugs will be set at 106% of the average sales price (ASP); preliminary data regarding ASP for 32 widely used Part B drugs are included in the proposed rule. Based on these preliminary ASP data and other proposed changes, the CMS projects a net reduction in total oncology Medicare revenues as a result of more accurate payment for drugs. The American Society of Clinical Oncology (ASCO) is conducting a full analysis of the CMS ruling and advocates maintaining 2004 net reimbursement levels for cancer treatment during 2005 and 2006 until completion of 3 government-mandated studies of the effect of the MMA on cancer care. The proposed rule was published in the August 5, 2004, Federal Register. The CMS plans to publish the final rule by November 1, 2004, with an effective date of January 1, 2005.

### ***CMS Proposes New Payment Rates and Policy Changes for Hospital Outpatient Services***

*August 9, 2004:* To increase the focus of Medicare on the prevention and early detection of diseases, CMS has proposed a rule that increases the payment rate for certain hospital outpatient services by 6.6% and updates other policies in the annual Outpatient Prospective Payment System (OPPS) rule. The rule proposes an increase in payment for screening examinations covered by Medicare, including 1) pelvic and breast examinations

for the detection of cervical and breast cancer, 2) barium enema, flexible sigmoidoscopy, and screening colonoscopy for the detection of colorectal cancer, and 3) bone density studies. The proposed rule also increases payment for diagnostic mammograms and allows hospitals to receive payment for new drugs and biologics that have received FDA approval but have not been assigned codes and payment rates. The payment for most drugs that cost more than \$50 per administration will continue to be reimbursed separately, rather than as part of a packaged ambulatory payment classification (APC). Small rural hospitals (fewer than 100 beds) and sole community hospitals in rural areas will continue to receive payments that are at least as much within the OPSS as they were according to the cost-based payment method used before August 2000. Finally, the rule proposes to reduce the maximum Medicare coinsurance rate in 2005 from 50% to 45% of the total payment to the hospital for any service. The proposed rule was published in the August 16, 2004, Federal Register. Comments were accepted until October 8, 2004, and the final rule will be published by November 1, 2004.

### ***New Edition of Practical Tips for the Practicing Oncologist Now Available***

*August 27, 2004: Practical Tips for the Practicing Oncologist*, 3rd edition, is now available. This book is a resource for oncology-related billing, coding, and reimbursement questions. The 3rd edition covers timely topics related to HIPAA, Medicare's coverage of clinical trials, and the effects of the MMA on oncology practice. The new edition of this text can be purchased through ASCO's online publications catalog ([www.asco.org](http://www.asco.org)) or by calling the ASCO customer service department at 888-273-3508 or 703-519-1430.

### ***Cancer Care Preservation Act of 2004 Introduced to House of Representatives***

*September 24, 2004:* The Cancer Care Preservation Act of 2004, introduced to the House of Representatives by Congressman Charlie Norwood (R-GA), is intended to limit the scheduled reductions in Medicare payments for oncology drugs and services administered in community physician practices until data are available from government-mandated studies analyzing the ASP reimbursement system. This bill requires CMS to create a billing and payment code that ensures reimbursement for oncology drugs is no less than 95% of 2004 payment amounts in 2005 and 95% of 2005 payment amounts in 2006. Additionally, rather than the significant reduction in transitional payment for practice expenses that is currently scheduled for implementation on January 1, 2005 (ie, 32% payment reduced to 3%), this bill sets the transitional payment for practice expenses at 30.4% in 2005 and 28.9% in 2006.

## **ORC NEWSLETTER FEATURE ARTICLE FEEDBACK**

The purpose of the *Oncology Reimbursement Connection (ORC)* newsletter is to inform readers of the latest oncology-related reimbursement information, including the opinions and practices of others in the cancer community. One way of sharing opinions is to provide our readers with a summary of the feedback received through surveys conducted using the *ORC* newsletter evaluation forms about previously published *ORC* feature articles. The results of the Fall 2003 feature article survey are provided here.

The title of the Fall 2003 *ORC* newsletter feature article was "*Darbepoetin Alfa (Aranesp®): Practical Issues in the Management of Chemotherapy-Related Anemia.*" Sixty-three evaluation forms were returned. The survey questions and responses are provided below.

### **1) Which erythropoietic agent(s) is/are primarily prescribed to treat chemotherapy-related anemia at your institution?**

Answers	Darbepoetin alfa	Epoetin alfa	Darbepoetin alfa > epoetin alfa	Epoetin alfa > darbepoetin alfa	Both agents are prescribed at comparable rates	No answer
<b>No. of responses(%)</b>	<b>7 (11)</b>	<b>24 (38)</b>	<b>5 (8)</b>	<b>10 (16)</b>	<b>5 (8)</b>	<b>12 (19)</b>

### **2) For treatment of chemotherapy-related anemia, what initial dosage of an erythropoietic agent is most commonly used?\***

Answers	Darbepoetin alfa 2.25 µg/kg/wk	Darbepoetin alfa 3 µg/kg every 2 weeks	Darbepoetin alfa 200 µg every 2 weeks	Epoetin alfa 40,000 U/wk	Other (please specify agent and dosage)	No answer
<b>No. of responses(%)</b>	<b>6 (8)</b>	<b>5 (7)</b>	<b>9 (12)</b>	<b>35 (49)</b>	<b>2 (3)</b>	<b>15 (21)</b>

\*More than 1 answer checked on some evaluation forms; total no. of responses=72.

### **3) What percentage of erythropoietic therapy administered in the outpatient setting is reimbursed by Medicare according to the Outpatient Prospective Payment System (OPPS) ruling?**

Answers	25%	26% - 50%	51% - 75%	> 75%	No answer
<b>No. of responses(%)</b>	<b>3 (5)</b>	<b>7 (11)</b>	<b>9 (14)</b>	<b>18 (29)</b>	<b>26 (41)</b>

### **4) How have changes in reimbursement for erythropoietic agents as mandated by the OPPS affected financial performance in the outpatient department of your institution?**

Answers	Significantly	Modestly	Minimally	Not at all	Do not know	No answer
<b>No. of responses(%)</b>	<b>5 (8)</b>	<b>12 (19)</b>	<b>8 (13)</b>	<b>0 (0)</b>	<b>18 (28)</b>	<b>20 (32)</b>

# REIMBURSEMENT HOTLINES & RESOURCES FOR ONCOLOGY DRUGS

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
3M Pharmaceuticals	Imiquimod (Aldara™)	Patient-Assistance Program; <a href="http://www.3m.com/us/healthcare/pharma/patient_assistance.jhtml">http://www.3m.com/us/healthcare/pharma/patient_assistance.jhtml</a>	800.328.0255	PAP
Aventis Pharmaceuticals Inc.	Docetaxel (Taxotere®)	Pact Plus; <a href="http://www.aventisoncology.com/reimbursement.htm">http://www.aventisoncology.com/reimbursement.htm</a>	800.996.6626	PRA; PAP
Eli Lilly and Company	Pemetrexed (Alimta®)	Lilly Oncology Reimbursement; <a href="http://www.lillyoncology.com/professionals/reimbursement.jsp?reqNavId=1.10">http://www.lillyoncology.com/professionals/reimbursement.jsp?reqNavId=1.10</a>	888.443.6927	PRA; PAP

PAP=patient-assistance program; PRA=provider-reimbursement assistance.

Reimbursement Resources		
Resource Name	Web Site and/or Phone Number	Description of Resource and/or Reimbursement Information Provided
<b>Government-based sites</b>		
CMS	<a href="http://www.cms.gov">www.cms.gov</a>	Official site of federal agency that runs Medicare and Medicaid programs; site provides <ul style="list-style-type: none"> <li>• Information about specific government insurance programs</li> <li>• Information about coverage laws and regulations</li> <li>• CMS-related news</li> <li>• Glossary of terms</li> </ul>
FDA	<a href="http://www.fda.gov">www.fda.gov</a>	Official site for FDA news and other related information; site provides <ul style="list-style-type: none"> <li>• Information about recent FDA product approvals</li> <li>• Information about recent ODAAC activities</li> </ul>
Medicare	<a href="http://www.medicare.com">www.medicare.com</a>	Official site of Medicare; site provides <ul style="list-style-type: none"> <li>• Online access to policy and coverage manuals</li> <li>• List of prescription drug-assistance programs and other assistance programs</li> </ul>
THOMAS	<a href="http://thomas.loc.gov">http://thomas.loc.gov</a>	Online access to federal legislative information, including <ul style="list-style-type: none"> <li>• Legislation and bill summaries</li> <li>• Congressional records</li> <li>• Committee records</li> </ul>
<b>National Organizations</b>		
American Society of Clinical Oncology	<a href="http://www.asco.org">www.asco.org</a>	Official site of largest professional organization representing physicians who treat patients with cancer; site provides <ul style="list-style-type: none"> <li>• Legislative and organizational news affecting reimbursement and clinical news</li> <li>• Online access to practice guidelines</li> </ul>
Association of Community Cancer Centers	<a href="http://www.accc-cancer.org">www.accc-cancer.org</a>	Organization charged with helping oncology professionals adapt to challenges of program management, cuts in reimbursement, hospital consolidation and mergers, and legislation and regulations that threaten delivery of high-quality cancer care; site provides <ul style="list-style-type: none"> <li>• Online access to <i>Compendia-Based Drug Bulletin</i> and <i>United States Pharmacopeia Oncology Drug Information</i></li> <li>• List of oncology drug reimbursement hotlines</li> <li>• Oncology-related news</li> </ul>
Pharmaceutical Research and Manufacturers of America	<a href="http://www.helpingpatients.org">www.helpingpatients.org</a>	Interactive Web site helps patients, healthcare providers, and/or family members/caregivers find information about PAPs; site provides <ul style="list-style-type: none"> <li>• List of available PAPs based on specific patient characteristics</li> <li>• List of pharmaceutical company-based PAPs</li> </ul>
<b>Other Resources</b>		
Copayment Assistance Program	800.272.9376	Program that provides copayment financial assistance to patients who meet objective financial eligibility criteria; administered by Patient Services Incorporated

Table continued on page 13.

# ONCOLOGY REIMBURSEMENT CONNECTION NEWSLETTER EVALUATION FORM

Name \_\_\_\_\_ Degree \_\_\_\_\_

Title \_\_\_\_\_

Institution/Practice Site \_\_\_\_\_

Street Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

E-mail Address \_\_\_\_\_

Please tick (✓) the box if you would like to be added to our mailing list and receive complimentary copies of future *Oncology Reimbursement Connection* newsletters.

## FEATURE ARTICLE FEEDBACK

1) How have the payment changes mandated by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 affected your practice setting's operations and/or practice patterns?

- Significantly       Not at all  
 Modestly           Do not know  
 Minimally

2) Do you feel the proposed changes in reimbursement for antiemetics under Medicare's 2005 OPSS proposed rule will affect prescribing patterns for these agents in your practice setting?

- No                       Yes, minimally  
 Yes, significantly     Do not know  
 Yes, modestly

3) How does your institution educate staff about changes in OPSS? (tick all that apply)

- Internal education programs       Referrals to CMS-based or other Web sites  
 External education programs       No education on OPSS has been conducted  
 Distribution or posting of reading material      in my institution

4) Have you noticed an increase in the number of patients previously treated in a physician's office now being treated in a hospital-based outpatient setting because of the effects on reimbursement mandated by the MMA?

- No                       Yes, 21%-30%  
 Yes, < 10%           Yes, >30%  
 Yes, 11%-20%

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 Proposed Rule	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2) Networking Column	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3) "In the News"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4) ORC Newsletter Feature Article Feedback	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5) Hotlines & Resources	<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: \_\_\_\_\_

Reimbursement Resources (cont'd)		
Resource Name	Web Site and/or Phone Number	Description of Resource and/or Reimbursement Information Provided
<i>Other Resources (cont'd)</i>		
NeedyMeds.com	www.needyMeds.com	<p>Regularly updated Web site that provides reimbursement and/or PAP information to patients and healthcare workers; site provides</p> <ul style="list-style-type: none"> <li>• List of reimbursement programs and PAPs accessible by drug or manufacturer name</li> <li>• Printed version of Web site information (available for \$100)</li> <li>• Downloads for PAP applications</li> <li>• Links to Medicaid sites</li> </ul>
Patient Advocate Foundation	www.patientadvocate.org	National nonprofit organization that serves as active liaison between the patient and insurer, employer, and/or creditors to resolve insurance, job-retention, and/or debt-crisis matters
ProCert	888.776.2378	Service provided by Bristol-Myers Squibb Oncology that conducts, on provider's behalf, appeals for Medicare denials for off-label use of ProCert-covered products; if appeal is not won, Bristol-Myers Squibb Oncology reimburses provider with enough drug needed to treat patient, including amount of drug already administered; drugs covered include bleomycin, carboplatin, carmustine, cisplatin, cyclophosphamide, etoposide, ifosfamide, mesna, mitomycin, paclitaxel, teniposide
PROCRIline	www.procritline.com	<p>Program that provides reimbursement assistance for Procrit®; site provides</p> <ul style="list-style-type: none"> <li>• Educational primer, "Oncology Coding and Reimbursement for Beginners"</li> <li>• Quick Reference to 2004 ICD-9-CM Diagnosis Codes</li> <li>• "Online Reimbursement &amp; Health Care Resources" (an extensive list of Web sites)</li> </ul>
Reimbursement Connection	www.reimbursementconnection.com; 800.272.9376	<p>Program that provides reimbursement assistance for Amgen's oncology products; site provides</p> <ul style="list-style-type: none"> <li>• Summaries of coverage and reimbursement policies for various insurers</li> <li>• Information about coding and claims processing, including sample forms and letters</li> <li>• Assistance with insurance verification</li> </ul>
RxAssist	www.rxassist.org	<p>Online service that provides healthcare providers with information about accessing various PAPs, including</p> <ul style="list-style-type: none"> <li>• Pharmaceutical company programs</li> <li>• Federal programs for military personnel or veterans</li> <li>• State Medicaid programs</li> <li>• State programs for elderly, disabled, or low-income patients</li> <li>• City, county, or community programs</li> <li>• Drug discount cards, some of which are for seniors</li> </ul>

CMS=Centers for Medicare & Medicaid Services; FDA=Food and Drug Administration; ICD-9-CM=International Classification of Diseases, 9th Revision, Clinical Modification; ODAC=Oncology Drug Advisory Committee; PAP=patient-assistance program.

# Oncology Reimbursement Connection

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