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# Cancer Care

## REIMBURSEMENT

The Latest Reimbursement-Related Regulatory and Legislative News for Hematology/Oncology Healthcare Professionals

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## 2009 Outpatient Prospective Payment System Final Rule: Summary of Oncology Medications

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### Introduction

The Centers for Medicare & Medicaid Services (CMS) has released the 2009 Outpatient Prospective Payment System (OPPS) Final Rule.<sup>1</sup> After considering public comments regarding the Proposed Rule published in the Federal Register on July 18, 2008, CMS finalized revisions to the OPPS, including payment rates for hospital-based outpatient services. This article summarizes the key differences and similarities between the 2009 Proposed and Final Rules and categorizes oncology medications according to the 2009 OPPS payment classifications.

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 at the time of publication. 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/HospitalOutpatientPPS/HORD/>).

### Payment for Oncology Medications

The 2009 OPPS Final Rule provides the criteria required to assign pass-through status (ie, temporary, higher payment) to oncology drugs.<sup>2</sup> Moreover, drugs not qualifying for pass-through status

are paid by 1 of 2 methods: 1) drug costs are included in the packaged ambulatory payment classification (APC), or 2) drugs are paid separately (ie, specified covered outpatient drugs [SCODs]).<sup>1</sup> Payment rates are then established according to drug category.

### Drugs Without Pass-Through Status

#### Packaged APCs

After a review of public comments, CMS finalized the proposed packaging threshold, without modification, for 2009.<sup>1</sup> Oncology medications with a median cost per day of less than \$60, based on the average sales price (ASP) (submitted by the manufacturer in the first quarter of 2008) plus 4%, will be reimbursed as packaged APCs (ie, drug cost packaged with cost of associated service or procedure) (Table 1). Hospital-claims data were used to determine the daily cost for products without an ASP-based payment rate. Oral and injectable 5-HT<sub>3</sub> antiemetics will continue to be exempt from APC packaging. CMS recognizes the difficulty of chemotherapy and associated side effects and believes that the most effective antiemetic regimen should be determined by the treating physician and/or patient. Table 2 lists the separately payable drugs for 2009, including 5-HT<sub>3</sub> antiemetics.

The packaging status of some drugs changed between the publications of the Proposed and Final Rules.<sup>1</sup> For these products, CMS has enacted the following reimbursement rules for 2009: 1) drugs paid separately in 2008 and proposed for separate payment in 2009 with daily costs equal to or less than \$60, based on updated ASPs and hospital claims data, will continue to receive separate payment (this category includes no oncology drugs);

2) drugs packaged in 2008 but proposed for separate payment in 2009, with daily costs equal to or less than \$60, based on updated ASPs and hospital claims data, will remain packaged (oncology drug: oral busulfan); and 3) drugs proposed for packaged payment in 2009 with daily costs greater than \$60, based on updated ASPs and hospital claims data, will be paid separately (oncology drugs: plicamycin, mitomycin, and valrubicin).

## Specified Covered Outpatient Drugs

SCODs are covered outpatient drugs for which a separate APC has been established and for which pass-through payment was made on or before December 31, 2002.<sup>1</sup> These agents have a daily cost higher than the \$60 packaging threshold (Table 2). CMS is moving toward basing payment rates solely on hospital claims data, but in the interim are developing transitional rates, which are a blend of estimated hospital drug costs and past payment rates for SCODs. In both the Proposed and Final Rules, CMS reimburses SCODs at a transitional rate of ASP plus 4% in 2009, which is a combination of estimated hospital costs (ASP plus 2% for 2009) and 2008 drug costs (ASP plus 5%).<sup>1,2</sup> To improve the future distribution of pharmacy overhead costs, CMS also proposed adding 2 new cost centers in the revised Medicare hospital cost report form: “Drugs with High Overhead Cost Charged to Patients” and “Drugs with Low Overhead Cost Charged to Patients.”<sup>2</sup> CMS anticipated that these new cost centers would provide data in 2 to 3 years that would help to determine future OPSS drug cost estimates.<sup>1</sup> However, after a review of public comments citing increased hospital burden, CMS did not include these proposed cost centers in the Final Rule. Moreover, CMS has asked for public comment on the effect of the federal 340B drug pricing program on estimating hospital drug costs.

## Pass-Through Drugs

Newer oncology medications will continue to qualify for transitional pass-through payment (ie, temporary, higher payment) in 2009.<sup>1</sup> CMS has finalized its proposal to reimburse pass-through drugs at a rate of ASP plus 6%, a rate generally equivalent to the payment provided in a physician’s office.<sup>1,2</sup> Transitional pass-through status must be granted for at least 2 and no longer than 3 years.<sup>2</sup> Furthermore, CMS has finalized its proposal for anticancer medications with pass-through status expiring on December 31, 2008: in 2009, these products (decitabine, ibandronate, panitumumab) will be reimbursed as either a packaged APC or a separate payment, depending on the product’s median cost per day.<sup>1,2</sup> Moreover, bendamustine, ixabepilone, fosaprepitant, nelarabine, and temsirolimus are eligible for pass-through payment in 2009 (Table 3).

## Coding and Payment for Chemotherapy Administration

For 2009, the CMS has reduced the administration APCs from 6 to 5 levels based on a cost analysis and detailed clinical review (Table 4).<sup>1,2</sup> Hospitals must continue to report current procedural terminology codes for drug administration services.<sup>1</sup>

## Conclusions

After considering public comments regarding the 2009 Proposed Rule, CMS has finalized its payment policies and rates for 2009. The 2009 OPSS Final Rule, which includes updated payment rates for oncology medications administered in outpatient hospital clinics, will become effective on January 1, 2009.<sup>1</sup>

## References

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**Table 1. Oncology Drugs Without Separate APC Payments in 2009<sup>1</sup>**

Generic Name	Brand Name	Billing Code (Billing Unit)
Bleomycin sulfate	Blenoxane®	J9040 (15 U)
Carboplatin	Paraplatin®	J9045 (50 mg)
Chlorpromazine HCl	Thorazine®	Q0171 (10 mg)
Cisplatin	Platinol®-AQ	J9060 (10 mg) J9062 (50 mg)
Cyclophosphamide, oral	Cytosan®	J8530 (25 mg oral)
Cyclophosphamide, injection	Cytosan®	J9070 (100 mg) J9080 (200 mg) J9090 (500 mg) J9091 (1 g) J9092 (2 g)
Cyclophosphamide lyophilized	Cytosan® Lyophilized	J9093 (100 mg) J9094 (200 mg) J9095 (500 mg) J9096 (1 g) J9097 (2 g)
Cytarabine HCl	Cytosar-U®	J9100 (100 mg) J9110 (500 mg)
Dacarbazine	DTIC-Dome®	J9130 (100 mg) J9140 (200 mg)
Dexamethasone	Decadron®	J8540 (0.25 mg)
Dexamethasone acetate	Decaject® LA; others	J1094 (1 mg)

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**Table 1. Oncology Drugs Without Separate APC Payments in 2009<sup>1</sup>**  
(continued)

Generic Name	Brand Name	Billing Code (Billing Unit)
Dexamethasone sodium phosphate	Decadron® phosphate; others	J1100 (1 mg)
Doxorubicin	Adriamycin RDF®; Adriamycin PFS®	J9000 (10 mg)
Dronabinol	Marinol®	Q0167 (2.5 mg) Q0168 (5 mg)
Estradiol cypionate	Depo-Estradiol®	J1000 (up to 5 mg)
Estradiol valerate	Delestrogen®	J1380 (up to 10 mg) J1390 (up to 20 mg) J0970 (up to 40 mg)
Estrone	NA	J1435 (1 mg)
Etoposide	VePesid®	J9181 (10 mg) J9182 (100 mg)
Fluorouracil	Adrucil®	J9190 (500 mg)
Hydrocortisone acetate	Hydrocortone® Acetate	J1700 (up to 25 mg)
Hydrocortisone sodium phosphate	Hydrocortone® Phosphate	J1710 (up to 50 mg)
Hydrocortisone sodium succinate	Solu-Cortef®; A-HydroCort®	J1720 (up to 100 mg)
Leucovorin calcium	NA	J0640 (50 mg)
Mechlorethamine HCl	Mustargen®	J9230 (10 mg)
Medroxyprogesterone acetate	Depo-Provera®	J1051 (50 mg) J1055 (150 mg)
Melphalan, oral	Alkeran®	J8600 (2 mg)
Methotrexate sodium	NA Rheumatrex® Dose Pack	J9250 (5 mg) J9260 (50 mg) J8610 (2.5 mg oral)
Methylprednisolone sodium succinate	Solu-Medrol®; A-MethaPred®	J2920 (up to 40 mg) J2930 (up to 125 mg)
Methylprednisolone acetate	Depo-Medrol®	J1020 (20 mg) J1030 (40 mg) J1040 (80 mg)
Methylprednisolone	Medrol®	J7509 (4 mg)
Nandrolone decanoate	NA	J2320 (up to 50 mg) J2321 (up to 100 mg) J2322 (up to 200 mg)
Octreotide	Sandostatim® LAR®	J2354 (25 µg)
Prednisone	Deltasone®; others	J7506 (per 5 mg)
Prochlorperazine	Compazine®	Q0164 (5 mg) Q0165 (10 mg)
Promethazine HCl	Phenergan®	Q0169 (12.5 mg)
Testosterone cypionate	Depo-Testosterone®; Virilon® IM	J1060 (1 mL) J1070 (100 mg) J1080 (200 mg)
Testosterone enanthate	Delatestryl®	J3120 (up to 100 mg) J3130 (up to 200 mg)

**Table 1. Oncology Drugs Without Separate APC Payments in 2009<sup>1</sup>**  
(continued)

Generic Name	Brand Name	Billing Code (Billing Unit)
Testosterone propionate	NA	J3150 (up to 100 mg)
Testosterone suspension, injection	NA	J3140 (up to 50 mg)
Vinblastine sulfate	NA	J9360 (1 mg)
Vincristine sulfate	Vincasar PFS®	J9370 (1 mg) J9375 (2 mg) J9380 (5 mg)

Abbreviations: APC, ambulatory payment classification; HCl, hydrochloride; NA, not applicable.

**Table 2. 2009 Payment Rates for Separately Covered Outpatient Oncology Drugs<sup>a1</sup>**

Generic Name	Brand Name	Billing Code (Billing Unit)	APC	2009 Payment, \$
Abarelix	Plenaxis™ b	J0128 (10 mg)	9216	67.32
Amifostine	Ethyol®	J0207 (500 mg)	7000	416.03
Asparaginase	Elspar®	J9020 (10,000 U)	0814	56.97
Bacillus Calmette-Guérin, live	TheraCys®; Tice® BCG	J9031 (per vial)	0809	112.33
Bevacizumab	Avastin®	J9035 (10 mg)	9214	56.29
Bortezomib	Velcade®	J9041 (0.1 mg)	9207	34.68
Busulfan	Busulfex®	J0594 (6 mg)	1178	11.93
Busulfan, oral	Myleran®	J8510 (2 mg)	7015	2.74
Capecitabine, oral	Xeloda®	J8520 (150 mg) J8521 (500 mg)	7042 0934	4.82 16.04
Carmustine	BiCNU®	J9050 (100 mg)	0812	161.32
Cetuximab	Erbix®	J9055 (10 mg)	9215	48.82
Cladribine	Leustatin®	J9065 (1 mg)	0858	28.79
Corticotropin	NA	J0800 (up to 40 U)	1280	2,310.04
Darbepoetin alfa	Aranesp®	J0881 (1 µg)	1685	2.91
Daunorubicin HCl	Cerubidine®	J9150 (10 mg)	0820	16.58
Daunorubicin citrate liposome	DaunoXome®	J9151 (10 mg)	0821	55.04
Decitabine	Dacogen®	J0894 (1 mg)	9231	26.23
Dexrazoxane HCl	Zinecard®	J1190 (250 mg)	0726	263.77
Docetaxel	Taxotere®	J9170 (20 mg)	0823	328.32

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**Table 2. 2009 Payment Rates for Separately Covered Outpatient Oncology Drugs<sup>a1</sup> (continued)**

Generic Name	Brand Name	Billing Code (Billing Unit)	APC	2009 Payment, \$
Dolasetron mesylate	Anzemet®	J1260 (10 mg) Q0180 (100 mg oral)	0750 0763	4.52 56.00
Doxorubicin HCl liposomal	Doxil®	J9001 (10 mg)	7046	421.41
Epirubicin HCl	Ellence®	J9178 (2 mg)	1167	5.34
Epoetin alfa	Procrit®; Epogen®	J0885 (1,000 U)	1686	8.92
Etidronate disodium	Didronel®	J1436 (300 mg)	1436	70.06
Etoposide, oral	VePesid®	J8560 (50 mg)	0802	28.79
Filgrastim	Neupogen®	J1440 (300 µg) J1441 (480 µg)	0728 7049	196.54 301.43
Floxuridine	FUDR®	J9200 (500 mg)	0827	49.58
Fludarabine phosphate	Fludara®	J9185 (50 mg)	0842	217.03
Fulvestrant	Faslodex®	J9395 (25 mg)	9120	79.70
Gallium nitrate	Ganite™	J1457 (1 mg)	0878	1.56
Gemcitabine HCl	Gemzar®	J9201 (200 mg)	0828	132.54
Goserelin acetate implant	Zoladex®	J9202 (3.6 mg)	0810	185.87
Granisetron HCl	Kytril®	J1626 (100 µg) Q0166 (1 mg, oral)	0764 0765	4.25 17.54
Idarubicin HCl	Idamycin PFS®	J9211 (5 mg)	0832	230.09
Ifosfamide	Ifex®	J9208 (1 g)	0831	33.16
Interferon alfa-2a, recombinant	Roferon®-A	J9213 (3 million U)	0834	39.76
Interferon alfa-2b, recombinant	Intron®A	J9214 (1 million U)	0836	14.45
Irinotecan HCl	Camptosar®	J9206 (20 mg)	0830	36.30
Leuprolide acetate (for depot suspension)	Lupron Depot®	J1950 (3.75 mg) J9217 (7.5 mg)	0800 9217	435.72 169.68
Leuprolide acetate	Lupron®	J9218 (1 mg)	0861	6.56
Leuprolide acetate implant	Viadur®	J9219 (65 mg)	7051	1,661.45
Melphalan HCl	Alkeran®	J9245 (50 mg)	0840	1,593.94
Mesna	Mesnex®	J9209 (200 mg)	0732	6.83
Mitomycin	Mutamycin®	J9280 (5 mg) J9290 (20 mg) J9291 (40 mg)	1232 1233 1234	15.56 62.25 124.50
Mitoxantrone HCl	Novantrone®	J9293 (5 mg)	0864	85.55
Nabilone	Cesamet®	J8650 (1 mg)	1230	16.64

**Table 2. 2009 Payment Rates for Separately Covered Outpatient Oncology Drugs<sup>a1</sup> (continued)**

Generic Name	Brand Name	Billing Code (Billing Unit)	APC	2009 Payment, \$
Octreotide acetate depot	Sandostatin® LAR® Depot	J2353 (1 mg)	1207	101.89
Ondansetron HCl	Zofran® Zofran® ODT®	J2405 (1 mg) Q0179 (8 mg, oral)	0768 0769	0.19 3.86
Paclitaxel	Taxol®; Onxol™	J9265 (30 mg)	0863	10.83
Palonosetron	Aloxi®	J2469 (25 µg)	9210	16.13
Palifermin	Kepivance®	J2425 (50 µg)	1696	11.18
Pamidronate disodium	Aredia®	J2430 (30 mg)	0730	28.68
Panitumumab	Vectibix®	J9303 (10 mg)	9235	80.93
Pegaspargase	Oncaspar®	J9266 (single-dose vial)	0843	2,569.13
Pegfilgrastim	Neulasta®	J2505 (6 mg)	9119	2,155.11
Pemetrexed	Alimta®	J9305 (10 mg)	9213	46.40
Pentostatin	Nipent®	J9268 (10 mg)	0844	1,592.03
Plicamycin	Mithracin®	J9270 (2,500 µg)	1231	77.49
Porfimer sodium	Photofrin®	J9600 (75 mg)	0856	2,490.53
Rasburicase	Elitek®	J2783 (0.5 mg)	0738	152.34
Rituximab	Rituxan®	J9310 (100 mg)	0849	524.58
Sargramostim	Leukine®	J2820 (50 µg)	0731	25.76
Streptozocin	Zanosar®	J9320 (1 gm)	0850	193.00
Temozolomide, oral	Temodar®	J8700 (5 mg)	1086	8.09
Teniposide	Vumon®	Q2017 (50 mg)	7035	297.01
Thiotepa	NA	J9340 (15 mg)	0851	92.76
Topotecan HCl	Hycamtin®	J9350 (4 mg)	0852	913.11
Trastuzumab	Herceptin®	J9355 (10 mg)	1613	60.33
Triptorelin pamoate	Trelstar® Depot	J3315 (3.75 mg)	9122	149.61
Valrubicin	Valstar®	J9357 (200 mg)	1235	384.38
Vinorelbine tartrate	Navelbine®	J9390 (10 mg)	0855	16.26
Zoledronic acid	Zometa®	J3487 (1 mg)	9115	210.02

Abbreviations: APC, ambulatory payment classification; HCl, hydrochloride; NA, not applicable.

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

<sup>b</sup>Drug has been discontinued by manufacturer for economic reasons.

**Table 3. Oncology Drugs With Pass-Through Payment Status in 2009<sup>1</sup>**

Generic Name	Brand Name	Billing Code	APC	2009 Payment, \$
Bendamustine	Treanda®	J9033	9243	18.70
Ixabepilone	Ixemptra™	J9207	9240	65.15
Fosaprepitant	Emend®	J1453	9242	1.57
Nelarabine	Arranon®	J9261	0825	96.09
Temsirolimus	Torisel™	J9330	1168	47.90

Abbreviations: APC, ambulatory payment classification.

**Table 4. 2009 Chemotherapy Administration APCs<sup>1</sup>**

APC	2009 APC Median Cost, \$	Description	HCPCS Code
0436	24.00	Chemotherapy procedure, unlisted	96549
0437	35.00	SQ or IM chemotherapy administration, nonhormonal antineoplastic	96401
		SQ or IM chemotherapy administration, hormonal antineoplastic	96402
		Intralesional chemotherapy administration, ≤ 7 lesions	96405
		Chemotherapy administration, IV infusion technique; each additional hr	96415
0438	72.00	Intralesional chemotherapy administration, > 7 lesions	96406
		IV push chemotherapy administration, each additional substance/drug	96411
		IV infusion chemotherapy administration, ≤ 1 hr, each additional sequential infusion (different substance/drug)	96417
		IA infusion chemotherapy administration, each additional hr	96423
0439	126.00	IV push chemotherapy administration, single or initial substance/drug	96409
		IA push chemotherapy administration	96420
		Subarachnoid or intraventricular chemotherapy administration through SQ reservoir	96542
0440	184.00	IV infusion chemotherapy administration < 1 hr, single or initial substance/drug	96413
		IV infusion chemotherapy administration, initiation of > 8 hr infusion requiring use of portable or implantable pump	96416
		IA infusion chemotherapy administration, ≤ 1 hr	96422
		IA infusion chemotherapy administration, initiation of > 8-hr infusion requiring the use of portable or implantable pump	96425
		Intrapleural chemotherapy administration, requiring and including thoracentesis	96440
		Intraperitoneal chemotherapy administration, requiring and including peritoneocentesis	96445
		Central nervous system chemotherapy administration, requiring and including spinal puncture	96450
		IV infusion therapy for therapy or diagnosis, initiation of infusion > 8 hr requiring use of portable or implantable pump	C8957

Abbreviations: APC, ambulatory payment classification; HCPCS, Healthcare Common Procedure Coding System; IA, intraarterial; IM, intramuscular; IV, intravenous; SQ, subcutaneous.

## Networking Column

### Expansion of Centers for Medicare & Medicaid Services Compendia for Off-Label Use of Anticancer Agents

Kristin Hennenfent, PharmD, MBA, BCPS and Phil Johnson, MS, RPh, FASHP

The increasing complexities of treating cancer patients have led oncologists to prescribe anticancer medications for uses other than those referenced in the United States Food and Drug Administration (FDA)-approved label (ie, off-label). The FDA has recognized the potential benefits of unapproved uses, noting that, “In certain circumstances, off-label uses of approved products are appropriate, rational, and accepted medical practice.”<sup>1</sup> Today, 50% to 75% of all medications used in cancer care are off-label according to estimates by the National Comprehensive Cancer Network (NCCN).<sup>2</sup> For many types of cancers, the use of off-label drugs or biologic agents is the standard of care, and denial of insurance coverage for these agents may prohibit patients with cancer from receiving optimal treatment.<sup>3</sup>

Concerns about patient accessibility to high-quality cancer care prompted Congress to enact legislative provisions requiring federal healthcare programs to cover medically appropriate off-label indications of cancer therapies.<sup>3</sup> The Omnibus Reconciliation Act of 1993 (OBRA 93) mandated Medicare payment for indications approved by the FDA and for unapproved uses of approved cancer drugs included in medical compendia (defined as a comprehensive listing of FDA-approved medications, indexed by drug or biologic, with a summary of dosage information and recommended therapeutic uses).<sup>2-4</sup>

In the past, accepted indications of anticancer medications used off label were justified to the Centers for Medicare & Medicaid Services (CMS) by using 1 of 3 authoritative drug information references listed in the Social Security Act (ie, American Medical Association’s *Drug Evaluations [AMA-DE]*, *United States Pharmacopoeia-Drug Information [USP-DI]* or its successor publication, and American Society of Health-System Pharmacists’ *American Hospital Formulary Service-Drug Information [AHFS-DI]*).<sup>5</sup> Clinicians have also been able to appeal to local fiscal intermediaries to modify existing local coverage determinations.<sup>6</sup> However, because of changes in the pharmaceutical reference industry,

*AHFS-DI* is the only originally named compendia currently in publication, which prompted stakeholders to ask that CMS amend the compendia listings.<sup>7</sup> As a result, the final rule published in the CY 2008 Physician Fee Schedule established an annual process for evaluating requests for the addition and/or deletion of compendia.<sup>5</sup> Furthermore, the Medicare Evidence Development and Coverage Advisory Committee (MedCAC), previously known as the Medicare Coverage Advisory Committee (MCAC), has established the desirable characteristics for compendia being considered for use in the determination of medically accepted indications of drugs and biologics in anticancer therapy.<sup>4-5</sup>

Recently, CMS formally reviewed requests for the addition of Gold Standard’s *Clinical Pharmacology*, Thomson’s *Micromedex DrugPoints* and *DRUGDEX*, and the *National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium*.<sup>8-11</sup> After a period of public comment, *Clinical Pharmacology*, *DRUGDEX*, and the *NCCN Drugs & Biologics Compendium*, all of which possess each of the desirable characteristics recognized by MedCAC, were added to the CMS-approved list of compendia references. Thomson’s *DrugPoints* was not included because it did not meet the requirements set by MedCAC.<sup>10</sup> Furthermore, the accepted list of peer-reviewed journals used by CMS to determine payment of off-label indications has been expanded.<sup>12</sup> Although inclusion in

**Table 1. NCCN Drugs & Biologics Compendium and DRUGDEX Categories of Evidence and Consensus of Clinical Recommendations<sup>13,14</sup>**

Compendium	Category/Class of Evidence	Definition
<i>NCCN Drugs &amp; Biologics Compendium</i>	Category 1	High-quality evidence (ie, high-powered randomized clinical trials or meta-analyses); uniform consensus
	Category 2A	Lower level of evidence (ie, phase 2 studies, large cohort studies, case series, or individual-practitioner experience); uniform consensus
	Category 2B	Lower level of evidence; nonuniform consensus
	Category 3	Any quality of evidence; major disagreement among NCCN panel members
<i>DRUGDEX</i>	Class I	Recommended; treatment proven useful
	Class IIa	Recommended in most cases; treatment generally considered useful
	Class IIb	Recommended in some cases; treatment may be useful and indicated in some but not most cases
	Class III	Treatment is not useful; should be avoided

Abbreviation: NCCN, National Comprehensive Cancer Network.

the CMS-approved compendia does not guarantee Medicare payment, these references can be used as admissible evidence to support a claim for the off-label use of drugs and biologics in cancer therapy.

Local fiscal intermediaries who determine Local Coverage Determinations are ultimately responsible for coverage policy and decisions, but they are required to consider approved compendia. For clinical recommendations deemed “equivocal” or “inconclusive” by the compendia sources, fiscal intermediaries have been instructed to consult peer-reviewed medical literature.<sup>8,11</sup> However, compendia references rating the quality of evidence reported in the medical literature (eg, NCCN level 1–3) have caused confusion (Table 1).<sup>13,14</sup>

<b>Medically Accepted Indication</b>	<i>NCCN Drugs and Biologics Compendium Category 1 or 2A</i>
	<i>DRUGDEX Class I, IIa, or IIb recommendation</i>
	<i>Supported by text of AHFS-DI or Clinical Pharmacology</i>
<b>Not Medically Accepted Indication</b>	<i>NCCN Drugs and Biologics Compendium Category 3</i>
	<i>DRUGDEX Class III recommendation</i>
	<i>Not supported by text of AHFS-DI or Clinical Pharmacology</i>

Abbreviations: *AHFS-DI*, American Hospital Formulary Service-Drug Information; CMS, Centers for Medicare & Medicaid; NCCN, National Comprehensive Cancer Network.

<sup>a</sup>CMS does not address NCCN Category 2B listings; therefore, these indications are left to the judgment of the local fiscal intermediary.

To provide clarity, CMS recently requested local Medicare intermediaries, when considering unapproved uses of drug therapy, to accept indications that are 1) favorably listed in one or more of the approved compendia, or 2) deemed by the intermediary to be a medically accepted indication based on peer-reviewed medical literature (unless CMS or another approved compendia reference has listed an indication as not medically accepted).<sup>15</sup> Table 2 lists the medically and not medically-accepted indications.

Oncology practitioners must stay informed about CMS rule changes to maximize Medicare coverage of off-label uses of drugs and biologics used in anticancer regimens. Compendia sources can be integrated into the drug-ordering process (eg, on computer screens, standardized drug order forms, or clinical notes), to document the justification for off-label indications that may potentially be challenged by CMS.<sup>6</sup> However, practitioners must understand

that local Medicare fiscal intermediaries ultimately decide whether to reimburse for unapproved uses of anticancer drugs or biologics; thus, healthcare professionals caring for Medicare cancer patients should contact local fiscal intermediaries when necessary to clarify support for off-label uses.

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## In the News

### Food and Drug Administration Approvals

#### *Final Approvals: New Agents and Supplemental Approvals*

*July 31, 2008:* **Pathwork® Tissue of Origin** (Pathwork Diagnostics, Inc), a test using microarray technology to compare the gene activity of a patient's tumor with the genetic expression patterns of 15 common tumor types (eg, bladder, breast, colorectal cancers), has been cleared by the Food and Drug Administration (FDA) to help health care professionals identify cancer cell types present in a hard-to-identify malignant tumor.

*August 21, 2008:* The FDA-approved package labeling of **Vidaza® (azacitidine)**, Celgene Corporation) was expanded to include survival data from the AZA-001 study. Vidaza is the only agent that has demonstrated improvement in overall survival in patients with myelodysplastic syndrome.

*August 22, 2008:* **Nplate™ (romiplostim)**, Amgen, Inc.) was the first thrombopoietin receptor agonist approved by the FDA for the treatment of patients with chronic immune thrombocytopenic purpura (ITP) whose clinical response to corticosteroids, immunoglobulins, and splenectomy was inadequate. This approval was based on the results of two phase 3 studies in which Nplate increased platelet counts in patients with or without splenectomy; platelet counts were sustained throughout these 6-month studies. As a requirement for approval, the FDA ordered Amgen to implement a Risk Evaluation and Mitigation Strategy (REMS), a program designed to assess the postmarketing risks and benefits of the drug. Amgen will launch the Nplate™ NEXUS (Network of Experts Understanding and Supporting Nplate and Patients) program to facilitate appropriate drug use, patient education and support, and the collection of long-term safety information.

*August 22, 2008:* The **Aloxi® (palonosetron hydrochloride)**, Eisai Inc. and Helsinn Healthcare SA) oral capsule 0.5 mg, a 5-HT<sub>3</sub> receptor antagonist, was approved for the prevention of chemotherapy-induced nausea and vomiting (CINV) after initial and repeated courses of moderately emetogenic chemotherapy. Aloxi capsules are administered approximately 1 hour before the start of chemotherapy. Aloxi injection was previously approved for the prevention of acute and delayed CINV after initial and repeat courses of moderately emetogenic chemotherapy, and for the prevention of acute CINV associated with initial and repeat courses of highly emetogenic chemotherapy.

*September 12, 2008:* **Gardasil® (human papillomavirus [HPV] quadrivalent [Types 6, 11, 16, and 18] vaccine, recombinant)**, Merck & Co., Inc.) was approved by the FDA for the prevention of vaginal and vulvar cancer caused by HPV types 16 and 18 in girls and women aged 9 to 26 years. The approval was based on the results of the 2-year follow-up of more than 15,000 patients from the initial cervical cancer studies: Gardasil was highly effective in preventing HPV-related precancerous vulvar and vaginal lesions in women who tested negative for HPV types 16 and 18 at the time of study enrollment. Gardasil was originally approved by the FDA in 2006 for the prevention of 1) cervical cancer caused by HPV types 16 and 18; 2) precancerous genital lesions caused by HPV types 6, 11, 16, and 18; and 3) genital warts caused by HPV types 6 and 11.

*September 15, 2008:* **Sancuso® (granisetron)**, ProStrakan, Inc.) transdermal system was approved by the FDA for the prevention of CINV in patients receiving moderately and/or highly emetogenic chemotherapy for up to 5 consecutive days. The approval was based on the results of a phase 3 study in which Sancuso eliminated CINV; Sancuso worked as well as once-daily oral granisetron.

*October 15, 2008:* **Ontak® (denileukin diftitox)**, Eisai Medical Research) was received full approval for the treatment of persistent or recurrent CD-25 positive cutaneous T-cell lymphoma. The FDA converted Ontak's approval status from accelerated to full after an improvement in progression-free survival and overall response rate was confirmed by a multinational placebo-controlled trial. Denileukin diftitox received accelerated FDA-approval in 1999 for this indication after an open-label study evaluating 2 different doses demonstrated durable, objective responses.

*October 19, 2008:* **Alimta® (pemetrexed)**, Eli Lilly and Company) received its third FDA-approved indication. The results of a phase 3 trial comparing Alimta plus cisplatin (AC) with gemcitabine plus cisplatin (GC) supported the use of Alimta, combined with cisplatin as first-line treatment of non-small cell lung cancer (NSCLC) patients with nonsquamous histology. AC improved the median overall survival (OS) time of patients with nonsquamous NSCLC, although the OS time in patients with squamous histology was diminished. Alimta received its previous approvals in 2004; first in combination with cisplatin for patients with malignant pleural mesothelioma who are either not surgical candidates or whose disease is unresectable, then later as a single agent for the second-line treatment of locally advanced or metastatic NSCLC patients failing prior chemotherapy. Based on the most recent data showing the impact of histology on OS time in NSCLC, the FDA revised its second-line indication: Alimta is now indicated as a single agent for patients with nonsquamous NSCLC failing prior chemotherapy and no longer approved for patients with squamous histology.

October 31, 2008: **Treanda® (bendamustine hydrochloride**, Cephalon, Inc.) received its second FDA-approved indication. Treanda is now approved for the treatment of indolent B-cell non-Hodgkin lymphoma that has progressed during or within 6 months of receiving rituximab or regimen that included rituximab based on a clinical study demonstrating durable clinical responses. Treanda was first FDA-approved in March 2008 for the treatment of chronic lymphocytic leukemia.

### Final Approvals: New Generic Approvals

August 11, 2008: The FDA approved Ebewe Pharma's generic formulation of **fluorouracil for injection** (500 mg/10 mL).

August 20, 2008: The FDA approved Barr Pharmaceutical, Inc.'s generic formulation of **pamidronate disodium injection**.

October 20, 2008: Teva Pharmaceutical USA announced the approval of its **fentanyl transdermal system**, a generic equivalent of Duragesic® (Ortho-McNeil™) chronic pain medication.

November 3, 2008: Barr Pharmaceutical Inc. announced the FDA-approval of its generic formulation of **irinotecan hydrochloride for injection**.

November 3, 2008: A generic formulation of **pamidronate disodium injection** 3 mg/mL and 9 mg/mL, developed by Akorn, Inc., has been granted FDA-approval.

### Fast-Track Status

August 22, 2008: OncoGenex Pharmaceuticals, Inc. announced that **OGX-011 (custirsén sodium)**, combined with docetaxel, received fast-track designation from the FDA for the treatment of hormone-refractory metastatic prostate cancer progressing on standard chemotherapy. Phase 2 studies of OGX-011 in prostate, lung, and breast cancers are underway.

August 27, 2008: Novartis was granted expedited FDA review of **Gleevec® (imatinib mesylate)**, as therapy after surgery to remove stomach and intestinal tumors.

### Orphan Drug Designations

October 20, 2008: The Cure Our Children Foundation announced that its antisense oligonucleotide in a nanotechnology formulation has been granted orphan drug status by the FDA for the treatment of children with Ewing's Sarcoma.

### Other FDA News

July 31, 2008: The FDA exercised its authority, granted in a 2007 amendment to the Federal Food, Drug, and Cosmetic Act, to order Amgen and Ortho Biotech, a Johnson & Johnson subsidiary, to make safety-related revisions to the approved labeling of their antianemia medications, **Procrit® (epoetin alfa**, Ortho Biotech Products, L.P.), **Epogen® (epoetin alfa**, Amgen, Inc.) and **Aranesp® (darbepoetin alfa**, Amgen, Inc.). With the amended labels, erythropoiesis stimulating agents are no longer indicated

for patients receiving myelosuppressive chemotherapy with curative intent, should not be initiated if a patient's hemoglobin level is  $\geq 10$  g/dL, and should target the lowest hemoglobin concentration necessary to avoid transfusions.

September 9, 2008: Johnson & Johnson requested that the FDA expand its approved labeling to include the use of **Doxil® (doxorubicin hydrochloride liposome injection**, Ortho Biotech Products, L.P.) in patients with advanced breast cancer in combination with docetaxel.

### Legislative and Regulatory News

#### CMS Announces Plans for National Coverage Determinations (NCDs)

July 31, 2008: The Centers for Medicare & Medicaid (CMS) released an online list of 19 drugs, medical devices, or procedures that Medicare patients may no longer be able to access if certain National Coverage Determinations (NCDs) are implemented. To maintain transparency, CMS announced the NCDs being considered; establishing a payment policy for antianemia drugs (eg, Aranesp®, Procrit®) leads the list. CMS will accept public comment regarding the list.

#### CMS Expands "No Pay" Policy for Hospital-Related Conditions

July 31, 2008: CMS has expanded its "no-pay" policy for hospital-acquired conditions. In August 2007, CMS announced that they would no longer provide payment to hospitals for 8 preventable hospital-related conditions. Now, they have added 3 more conditions to the list: pulmonary embolism following knee- or hip-replacement surgery, complications related to inadequate blood sugar control, and development of surgical-site infections after elective procedures. The expanded policy listing 11 total conditions went into effect on October 1, 2008.

#### CMS Considering Requiring Specialized Physician Training to Prescribe Narcotics

August 17, 2008: The FDA is considering requiring physicians to receive specific education to prescribe certain potent narcotics (eg, methadone, fentanyl). State medical boards have typically governed physician licensing and continuing education requirements; however, the FDA has become increasingly concerned with physician misprescribing, inadvertent patient misuse, and preventable patient deaths. Opponents of the FDA's consideration fear that this requirement may prevent patients in pain from receiving optimal care because fewer physicians will be able to prescribe pain medications.

#### CMS Prohibits Pharmacists From Initiating Clinical Protocols

September 18, 2008: The American Society of Health-System Pharmacists (ASHP) has expressed concern to CMS about their guidelines, prohibiting pharmacists from initiating clinical protocols. ASHP is encouraging CMS to clarify that pharmacists can initiate actions specified in Pharmacy & Therapeutics–approved protocols or standing orders and perform therapeutic interchanges when necessary.

## Medicare Part D Update

### Prior Authorization Process Used to Establish Medicare Payment

*July 18, 2008:* The Centers for Medicaid & Medicare Services (CMS) updated its Medicare Prescription Drug Benefit Manual to allow Medicare Part D prescription drug plans to use a prior-authorization process at any time to establish payment under Part B or Part D, even if the beneficiary is already taking the medication. Moreover, Part D sponsors must now evaluate drugs with long-acting formulations and calculate monthly drug cost using their full duration of action.

### Bonuses for Electronic Prescribing

*July 22, 2008:* Beginning January 1, 2009, physicians who prescribe electronically will receive bonuses from CMS. Electronic prescriptions will likely reduce drug errors (eg, improved legibility of prescriptions, ability to check for drug interactions) and decrease costs. Physicians opting to participate will receive a 2% incentive payment in 2009 and 2010, a 1% payment in 2011 and 2012, and a 0.5% payment in 2013. Moreover, qualifying physicians will receive total incentive payments of 5.1 percent in 2009; physicians reporting clinical measures receive an additional 2 percent under the Physician Quality Reporting Initiative and the Medicare Improvements for Patients and Providers Act of 2008 provides for a fee schedule increase of 1.1 percent. After 5 years,

bonuses for electronic prescribing will cease and practitioners not prescribing electronically will be reimbursed at lower rates. However, the Drug Enforcement Administration (DEA) may hinder adoption of electronic prescribing for some physicians because it prohibits electronic prescribing of controlled substances, which comprise 10% of all written prescriptions.

### Medicare Part D Drug Plan Premiums Increase

*August 15, 2008:* CMS has announced that Medicare Part D drug-plan premiums will increase in 2009. As a result of rising drug costs and higher cost estimates of catastrophic drug coverage, Medicare beneficiaries are likely to pay approximately 24% more per month than in 2008. Moreover, Medicare officials anticipate reduced coverage in the Part D benefit gap. Despite the increase in 2009, Medicare Part D premiums remain lower than those projected when the program was approved in 2003.

### Fewer Medicare Part D Drug-Plan Choices

*October 9, 2008:* In 2009, many low-income Medicare members will have fewer prescription drug-plan choices. Insurers must keep premiums below a government-established threshold to service low-income participants. However, many insurance companies have increased premiums and no longer qualify to provide low-income coverage. With fewer options (participating drug plans are expected to fall from more than 500 choices to approximately 300), some low-income Medicare patients may be forced to make changes in their prescription drugs or other therapies because of coverage changes.

**Reimbursement and Patient Assistance Hotlines for Recently Approved (or New Indication) Oncology Drugs**

Manufacturer	Generic Drug Name (Brand Name)	Program Name; Web Site	Phone Number	Information Available
Amgen Inc.	Romiplostim (Nplate™)	Amgen Reimbursement Connection® <a href="http://www.amgen.com/reimbursement_connection/nplate_romiplostim.html">http://www.amgen.com/reimbursement_connection/nplate_romiplostim.html</a>	800.272.9376	PRA
Cephalon, Inc.	Bendamustine hydrochloride (TREANDA®)	TREANDA Reimbursement Expertise Hotline <a href="http://www.treanda.com/">http://www.treanda.com/</a>	888.587.3263	PAP; PRA
Eisai Inc.	Palonosetron (Aloxi®)	Eisai Reimbursement Support <a href="http://www.aloxi.com/Reimbursement/default.aspx">www.aloxi.com/Reimbursement/default.aspx</a>	877.644.6270	PAP; PRA
Eli Lilly & Company	Pemetrexed (Alimta®)	PatientOne <a href="http://www.lillypatientone.com/index.jsp">http://www.lillypatientone.com/index.jsp</a>	866.472.8663	PAP; PRA
Merck & Co., Inc.	Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant (Gardasil®)	Reimbursement Codes <a href="https://www.merckvaccines.com/gardasilProductPage_frmst.html">https://www.merckvaccines.com/gardasilProductPage_frmst.html</a>	800.734.6282	PRA
		Dose Replacement Program <a href="http://www.drp4gardasil.com/Site/Home.aspx">http://www.drp4gardasil.com/Site/Home.aspx</a>	800.668.8414	PRA
Prostrakan, Inc.	Granisetron Transdermal System (Sancuso®)	Patient Assistance Program <sup>a</sup>	800.726.2876	PAP

<sup>a</sup>Web site information is currently unavailable.

Abbreviations: PAP, patient-assistance programs; PRA, provider reimbursement assistance.

**For a complete listing of Reimbursement and Patient Assistance Hotlines for Oncology Drugs, please see <http://www.ccrnewsletterhotlines.com>.**



## Continuing Pharmacy Education Available

This continuing education course, released in December 2008, is best suited for oncology pharmacists. This program was supported through educational donations from Amgen, Inc. and Onyx Pharmaceuticals and is offered to oncology pharmacists free of charge. The newsletter discusses billing and reimbursement issues related to the Outpatient Prospective Payment System and changes to the Centers for Medicare & Medicaid Services-approved compendia. This newsletter may discuss uses of oncology-related drugs that have not been approved by the US Food and Drug Administration.

Syntaxx Communications, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Syntaxx Communications, Inc. designates this continuing education program for 1.0 contact hours (0.1 CEU). Partial credit will not be offered. This newsletter is eligible for credit through December 2009 (Universal Program Number: 299-999-08-298-H04-P).

### Learning Objectives

#### 2009 Outpatient Prospective Payment System (OPPS) Final Rule: Summary of Oncology Medications

After reading this article, the participant should be able to

1. State the OPPS 2009 drug packaging threshold.
2. Describe OPPS payment methods for drugs with and without pass-through status in 2009.
3. Recall the 2009 payment rates for packaged ambulatory payment classifications, specified covered outpatient drugs, and pass-through drugs.

#### Expansion of Centers for Medicare & Medicaid Services (CMS) Compendium for Off-Label Use of Anticancer Agents

After reading this column, the participant should be able to

1. Define medical compendia.
2. List the CMS-approved compendia resources for determining the Medicare payment for off-label uses of anticancer drugs or biologics.
3. State the CMS criteria for a "medically accepted" indication for the off-label use of an anticancer drug or biologic.

### Self-Assessment Questions

#### 2009 OPPS Final Rule: Summary of Oncology Medications

1. The OPPS drug packaging threshold (median daily cost) for 2009 is
  - a. \$50 per day.
  - b. \$55 per day.
  - c. \$60 per day.
  - d. \$65 per day.
2. Through which method are drugs with a median cost per day higher than the packaging threshold reimbursed?
  - a. Packaged Ambulatory Payment Classification
  - b. Separate payment
  - c. Transitional pass-through payment
  - d. Hospital claims-based payment

3. The OPPS Final Rule established which payment rate for pass-through drugs?
  - a. Average sales price (ASP) + 4%
  - b. Wholesale acquisition price (WAC) + 6%
  - c. ASP + 6%
  - d. WAC + 4%

#### Expansion of CMS Compendium for Off-Label Use of Anticancer Agents

4. A medical compendia is best defined as a
  - a. Comprehensive listing of Food and Drug Administration-approved medications, indexed by drug or biologic, with a summary of dosage information and recommended therapeutic uses.
  - b. Comprehensive listing of off-label uses of drugs and biologics incorporated into anticancer treatment regimens.
  - c. Comprehensive listing of reimbursement codes necessary to receive Medicare payment of off-label uses of drugs and biologics for treatment of cancer.
  - d. Summary of dosage information for off-label uses of cancer medications.
5. Which of the following drug information references is not currently used by local contractors to determine CMS payment for off-label indications of anticancer therapy?
  - a. Thomson's Micromedex *DRUGDEX*
  - b. Gold Standard's *Clinical Pharmacology*
  - c. *United States Pharmacopoeia-Drug Information*
  - d. *NCCN Drugs & Biologics Compendium*
6. Which of the following criteria has CMS deemed acceptable for determining a "not medically accepted" indication for the off-label use of an anticancer medication?
  - a. Favorably supported by peer-reviewed medical literature
  - b. *NCCN Drugs & Biologics Compendium Category 3* recommendation
  - c. Supported by text from the *American Hospital Formulary Service-Drug Information* or *Clinical Pharmacology*
  - d. *DRUGDEX* Class IIb recommendation

To obtain continuing education credit, participants will need to complete and return the course evaluation form to:

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# Course Evaluation Form

## Cancer Care Reimbursement: The Latest Reimbursement-Related Regulatory and Legislative News for Hematology/Oncology Healthcare Professionals *Fall 2008 Volume 1 Number 2*

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4) a b c d                      5) a b c d                      6) a b c d

### Feature Article Feedback (Please tick (✓) the appropriate answer.)

1) At your institution, the change in packaged drug payment for 2009 will, on average,

- adequately cover drug costs.  
 inadequately cover drug costs.  
 result in no change in drug costs.

3) At your institution, do you anticipate the change in basing payment rates solely on hospital claims data will result in

- improved reimbursement for these services.  
 inadequate reimbursement for these services.  
 no change in reimbursement for these services.

2) At your institution, the change in coding and payment for chemotherapy administration from 6 Ambulatory Payment Classifications (APCs) to 5 APCs has resulted in

- improved reimbursement for these services.  
 inadequate reimbursement for these services.  
 no change in reimbursement for these services.

### Newsletter Effectiveness Assessment (Please tick (✓) the rating that best represents your opinion.)

Disagree  → Agree

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. NA=not applicable.

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

### Feature Article/Columns Value Assessment (Please tick (✓) the rating that best represents your opinion.)

Please rate the overall value of the feature article and newsletter columns in this issue of the *Cancer Care Reimbursement* newsletter using the following 5 point scale. 1 = not valuable 2 = slightly valuable 3 = valuable 4 = very valuable 5 = extremely valuable

How valuable were the following articles/columns to your practice?	N/A	1	2	3	4	5
1) Feature Article: 2009 OPPI final rule: summary of oncology medications						
2) Networking Column: Expansion of CMS compendium for off-label use of anticancer agents						
3) In the News						
4) Medicare Part D Update						
5) Reimbursement and Patient Assistance Hotlines for Oncology Drugs						

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

\_\_\_\_\_

Suggestions for improving the value of the newsletter:

\_\_\_\_\_

\_\_\_\_\_

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# CancerCare REIMBURSEMENT

The Latest Reimbursement-Related Regulatory and Legislative News for Hematology/Oncology Healthcare Professionals

## Cancer Care Reimbursement Newsletter

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# Cancer Care

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