



HAWAII SOCIETY OF CLINICAL ONCOLOGY

*A Chapter Member of the Association of Community Cancer Centers
and An Affiliate of the American Society of Clinical Oncology*

SUMMER 2004

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Go to www.hsco-hawaii.com
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and coding questions.

President's Corner

By Charles F. Miller, MD, FACP

As we pass through summer, it is a good time to reflect back on some of the changes and events of the past year. A number of HSCO members attended the Annual ASCO Meeting in New Orleans in early June. There were many new advances reported and surprisingly very positive trial results in two of the most common cancers that we treat – lung and colon. The approval of two new targeted therapies for colon cancer provides oncologists around the world with powerful tools that can be synergistic with chemotherapy to offer significant improvement in both quality of life and length of survival for patients with recurrent or advanced colonic cancer. The surprising positive results of a number of adjuvant trials treating early stage lung cancer also have great potential to improve the survival for this large group of patients.

In addition to attending the ASCO Annual Meeting, I had the privilege of serving on a committee bringing together health care providers from Kaiser, the National Council of Quality Assurance (NCQA) and Intermountain Health Consortium. The purpose of this meeting was to develop and evaluate quality of care measurements for cancer patients. Eventually these measures would be used by NCQA, organized health care systems and other quality improvement organizations to measure the quality of health care provided in a given plan, region, city or state. This is a very ambitious project, but one that I think has great promise to improve the quality of care we provide to all our patients.

Dr. Reginald Ho and I attended the Annual ASCO Carrier Advisory Committee Meeting in July. This was my first meeting and a very enlightening one. It is clear that many oncologists around the country are having major problems with coding and reimbursement from Medicare. Dr Ho sent out a letter to all members reviewing many of the issues discussed at the meeting. In addition, there are plans to invite the Medical Director for the Hawaii Regional Medicare Carrier to meet with HSCO members in the near future to discuss how coding for cancer care might be improved. You will be notified of this event when it is finalized.

The HSCO Board of Directors met late in July and discussed a number of pertinent issues. Our major focus was on finalizing the plans for the Annual HSCO Meeting, which is scheduled for November 20, 2004. We have scheduled speakers on Palliative Care as well as Improving Patient/Physician Communication. In addition, Dr Joseph Bailes, Past President of ASCO will give us an update on current legislative and administrative issues at the national level.

The Board also supported the planning of an Oncology Journal Club to be held on a monthly basis. All HSCO members will be invited and two current articles will be discussed at each meeting. Further details will be forthcoming when plans are finalized.

Once again, I want to thank the Board for all of their time and effort in helping to make the Hawaii Society of Clinical Oncology an even better organization. Our continuing goal is to provide the best support possible to our members and meet their needs in caring for cancer patients.

HSCO MEMBERSHIP

There are 74 members in the HSCO: 59 physician members, 12 associate members and 3 affiliate members.

WELCOME NEW MEMBERS

Mary W. MacMillan, Pharm B
Tripler Army Medical Center
Honolulu

Stephanie A. Marshall, RN, MSN
Tripler Army Medical Center
Honolulu

John W. McBroom, MD
Tripler Army Medical Center
Kailua

Michelle H. Miyashiro, MD
Oncare Hawaii, Inc.
Honolulu

Richard S. Weeder, MD
Straub Clinic and Hospital
Honolulu

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The Society gratefully acknowledges the following companies who have contributed to the advancement of our Society. We would like to recognize and thank them for their help and support.

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Medical Carrier Advisory Committee (MCAC) Report

By Laeton J. Pang, M.D., M.P.H.

The MCAC last met May 28, 2004. Dr. Richard Whitten, Noridian Administrative Services (NAS) Carrier Medical Director for Hawaii, Alaska and Washington State was present.

Dr. Whitten announced that about 30% of claims are being initially denied, many of them due to forms being incomplete at time of submission. Common errors discussed include:

Block 32	Place where service rendered must be indicated.
Block 11	Check "none," if Medicare is not secondary.
ICD-9-CM	Codes must support medical necessity. Listing the cancer diagnosis may not be adequate. For example, serum magnesium testing is supported by use of V58.1 (chemotherapy) or V 58.69 long-term use of furosemide.

Claims that are not HIPAA compliant will be processed and paid like paper claims (27 days).

Reviews now have 60 days to be processed. Effective 2005, deductibles increase to \$110.

The Centers for Medicare and Medicaid Services (CMS) has selected Advanced Med to request medical records to audit proper payment by NAS. If information is not returned as requested, the claim will be flagged as an overpayment and a refund will be requested.

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Legislative and Regulatory Round-up

By Deborah Walter, Senior Director, Policy and Government Affairs
Association of Community Cancer Centers

Proposed Physician Rule Includes Information on ASP: Reductions in Medicare Reimbursement for Drugs Could Impact Entire Continuum of Cancer Care

On July 27, 2004, the Centers for Medicare & Medicaid Services (CMS) issued its notice of proposed rulemaking (NPRM) on the 2005 physician fee schedule. Provisions included in the proposed rule relate to the implementation of the Average Sales Price (ASP) provisions addressed in the Medicare Modernization Act (MMA), issues affecting durable medical equipment, end-stage renal disease (ESRD) and other Part B provisions. The Association of Community Cancer Centers (ACCC) is concerned that changes in drug and biological reimbursement introduced by the proposed rule could have a profound effect on the continuum of cancer care and adversely impact beneficiaries, practitioners, and other healthcare stakeholders.

WHAT IS CMS PROPOSING?

The MMA fundamentally changed the manner in which physicians and other providers are reimbursed for drugs and biologics. Beginning in January 2005, reimbursement for most physician-administered drugs and biologics will change from the current average wholesale price (AWP) methodology to one based on "Average Selling Price (ASP)." The proposed rule includes a partial list of high-volume cancer drugs and the potential effect that an ASP-based reimbursement methodology could have on those drugs and physician practices. The rates listed in the proposed rule were taken from manufacturers' first quarter 2004 drug submissions. Accordingly, it is likely that some of these rates may

change between now and the final rule because third quarter 2004 manufacturer data will be used to set actual 2005 reimbursement rates for drugs. And it remains to be seen what the reimbursement rate will be for other cancer drugs that CMS chose not to publish in the proposed rule.

Comparison of Final 2004 and Proposed 2005 Physician Office Payment Rates

Commercial name / Chemical name	HCPCS	HCPCS Units	Average Dose	FINAL 2004 Rate [1]	PROPOSED 2005 Rate [2]	Change 2004-2005	
						\$	%
Anzemet / dolasetron mesylate (oral)	J1260	10 mg	100 mg	\$13.85			
Aranesp / darbepoetin alfa	J0880	5 mcg	153 mcg	\$21.20	\$18.10	-\$3.10	-14.62%
Campptosar / irinotecan injection	J9206	20mg	225mg (125mg/m2)	\$130.24	\$123.86	-\$6.38	-4.90%
Doxil / doxorubicin hcl liposome inj	J9001	10 mg		\$352.06			
Ethyol / amifostine	J0207	500 mg	1638 mg (910mg/m2)	\$405.29			
Gemzar / gemcitabine HCl	J9201	200 mg		\$111.33	\$107.46	-\$3.87	-3.48%
Herceptin / trastuzumab	J9355	10 mg	273 mg or 28 (4mg per kg)	\$52.01	\$50.84	-\$1.17	-2.25%
Kytril / granisetron HCl injection	J1626	100 mcg	682 (10 mcg/kg)	\$15.62			
Neulasta / pegfilgrastim	J2505	6 mg	6 mg	\$2,507.50	\$2,260.77	-\$246.73	-9.84%
Neupogen / filgrastim injection	J1440	300 mcg	300 mcg (132 lb)	\$158.50			
Procrit / non-esrd epoetin apha inj	Q0136	1000 units	40,000 units	\$11.62	\$10.37	-\$1.25	-10.76%
Rituxan / rituximab	J9310	100 mg	675 mg (375mg/m2)	\$427.28	\$438.38	\$11.10	2.60%
Taxol / paclitaxel	J9265	30 mg	243mg (135mg/m2)	\$138.28	\$25.84	-\$112.44	-81.31%
Taxotere / docetaxel	J9170	20 mg	100 mg	\$301.40	\$287.59	-\$13.81	-4.58%
Hycamtin / topotecan	J9350	4 mg	1.5 mg per kilometer squared	\$706.17	\$731.46	\$25.29	3.58%
Zofran / ondansetron	Q0179	8 mg	32 mg	\$27.22			

[1] Final 2004 payment rate data taken from CMS Program Transmittal 75, Pub. 100-04, Medicare Claims Processing, Change Request 3105 (Jan. 30, 2004), as modified by Program Transmittal 119, Pub. 100-04, Medicare Claims Processing, Change Request 3161 (March 15, 2002) and Program Transmittal 90, Pub. 100-20, One-Time Notification, Change Request 3312 (June 25, 2004).

[2] Proposed 2005 payment rate data taken from Proposed Physician Fee Schedule for 2005, Table 28, available at <http://www.cms.hhs.gov/regulations/pfs/2005/1429p.asp>.

Data not available

The proposed rule also fails to provide additional guidance regarding how ASP should be calculated and reported—despite continued requests from ACCC—and the industry. However, ACCC understands that information in a number of “gray areas” may be forthcoming in the form of another guidance document in the upcoming months.

WHAT IS THE POTENTIAL IMPACT?

According to CMS estimates, oncology/hematology physicians derive 70 percent of their total Medicare revenue from drugs. As such, CMS claims that the effect of the introduction of the ASP methodology on physicians’ Medicare drug revenues in 2005 would translate into an 8 percent decrease in revenue primarily due to reimbursement changes between 2004 and 2005 in the following drugs: Q0136 (EPO; Procrit)—the highest utilized drug, will decline approximately 11 percent—and J9310 (Rituxan)—the second highest utilized drug, will rise by only about 3 percent. CMS attributes 5 percent of the projected 8 percent decline in drug revenue to the fact that three drugs will be coming off patent: J9265 (Onxol Taxol); J2430 (Pamidronate Disodium), and J9390 (Navelbine).

In keeping with the MMA’s effort to address concerns that the relative value unit-based system for reimbursing the administration of drugs does not adequately compensate practitioners for the costs associated with those services, the proposed rule addresses a variety of issues related to those services. Although it eliminates the one-year “payment bump” of 32 percent mandated by the MMA for administration services performed in 2004, a combination of factors has provided what CMS contends is still a substantial level of support for administration services. Administration service rate changes reflect the 3 percent special 2005 adjustment for these services, the 1.5 percent increase mandated by the MMA to the conversion factor, certain practice expense component refinements, increases in reimbursements related to the removal of some services from the zero work pool, and other factors. Additionally, CMS highlights rate increases in administration services from 2002 to 2005. Most notable, however, is that the rate decreases for these services occurring in 2005 when compared to the 2004 rates, which reflected the MMA mandated “payment bump” of 32 percent.

WHAT ARE ACCC'S CONCERNS?

Physicians and others within the cancer community are just beginning to assess the impact of proposed 2005 reductions on their practices. ACCC is concerned that the reductions in Medicare payment rates for drugs could force physicians to alter their treatment protocols and adversely impact the delivery of healthcare provided to cancer patients. This is particularly true if the reductions are implemented without the much needed increases in payment rates for drug administration and other related services. The Medicare cuts for 2005 could threaten the viability of many oncology practices—for example, for practices currently operating on the margin, it is conceivable that physicians may simply close their doors. Such significant reductions in Medicare payments for cancer therapies could influence physician behavior, impacting the entire continuum of cancer care. If Medicare does not reimburse adequately for cancer-related drugs and services, oncologists may no longer be able to provide high-quality care to their patients. Faced with inadequate reimbursement in the physician office, patients—especially those with more complex and costly conditions—could be required to travel greater distances to seek treatment at hospitals, thereby losing their right to choose the site of care that best meets their needs. And for those patients directly affected, this situation is untenable.

Also important to note is that some already stretched outpatient departments may not have the capacity to absorb a large volume of patients that are currently being treated in doctors' offices. In some areas, hospitals have closed their infusion centers because Medicare reimbursement does not accurately reflect the totality of costs included in administering cancer therapies to patients.

A physician panel currently is evaluating coding changes for drug administration and related services to ensure that oncologists are reimbursed adequately for all the costs of providing high-quality cancer care. ACCC is hopeful that CMS will carefully consider these needed reforms in the final rule.

LINGERING CONCERNS?

One significant source of concern centers around the MMA provisions that require CMS to replace the ASP-based reimbursement methodology with either a widely available market price (WAMP) or an average manufacturer price (AMP). Under the MMA, ASP may be replaced by these alternative mechanisms if, in 2005, ASP exceeds either alternative by 5 percent or, in 2006 and subsequent years, by whatever percentage as may be selected by the Secretary of Health and Human Services. The ASP proposed rule does not discuss how these alternatives may be applied.

The MMA also directs CMS to determine if better coding is needed to allow for proper reimbursement for drug administration services. The proposed rule indicates that the CPT Editorial Panel is evaluating coding changes for drug administration and related services to ensure that oncologists are reimbursed adequately for all the costs of providing high-quality cancer care. ACCC is hopeful that CMS will carefully consider coding changes using G codes (because the 2005 CPT book already will be published) that will be effective January 1, 2005. According to the proposed rule, CMS will make the final determination of Medicare coding policy.

ACCC POLICY AND LEGISLATIVE ACTION PLAN.

ACCC is:

- Using practice level data to estimate the precise impact that these changes will have on physician office revenue, and using these data to educate Congress, CMS, and other stakeholders in the cancer community.
- Responding to local and national press inquiries regarding the potential impact of this proposed rule on physician practices and patients. ACCC's concerns for physicians and patients have been reported in approximately 100 local news articles throughout the United States, including the Chicago Sun Times, Los Angeles Times, and Boston Globe.
- Keeping membership informed through e-mail alerts and ACCC's web site.
- Submitting comments to CMS on the proposed rule. Comments are due by September 27, 2004, and can be submitted electronically to www.cms.hhs.gov/regulations/ecomments.
- Developing educational programs to educate ACCC members about the implications of these reimbursement changes on practices.
- Supporting the recommendations made by a physician panel that is currently evaluating coding changes for drug administration and related services.
- Addressing the impact of these important issues at ACCC's National Oncology Economics Conference in October and other ACCC meetings.

Reimbursement Issues and Coding Update

Mary Lou Bowers, Director

ACCC

Trends in Reimbursement: Summer Update

On July 27, the Centers for Medicare and Medicaid Services (CMS) issued the 2005 Proposed Physician Fee Schedule, which includes estimated payment rates for select chemotherapy drugs used to treat patients in physician offices. While the Association of Community Cancer Centers is analyzing the 400-plus-page document, every physician and practice manager should also be focusing on their private payers. More insurers are looking for ways to reduce their costs of delivering care for cancer patients by changing the way they pay for pharmaceutical treatments.

Many insurers are following Medicare drug payments and reducing drug payments *without* notice and *without* any increases in administration codes. If you haven't reviewed your existing contracts, please do so now!

During the past two months, several new reimbursement changes have arisen which have caught many practices unaware:

- SNF-consolidated payment by Medicare
- Payment slowdowns for new drugs without specific J-codes by all payers
- Nonpayment of off-labeled drug use by self-funded plans
- Reduction of all CPT code rates by insurers

SNF Consolidation

As part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), skilled nursing facilities/homes (SNFs) are responsible for all payments for services that occur outside their facilities effective January 1, 2004. This means if you see a patient who resides in a SNF for treatment, you must have a contract with the SNF and bill them, not Medicare, even though Medicare is the insurer.

Many practices weren't aware of this change and only found out by getting denials for payment from their Medicare Carrier. What should you do? Many times the practice isn't aware that a patient is a SNF resident, so the first thing you should consider is posting a requirement that patients must notify you if they are residing in a SNF. For SNF patients, use your pre-authorization form to identify the treatment request. Send the form to the SNF administration with request for signature as approval of your contract to treat. The SNF is responsible to pay you at the Medicare-allowable rate, less the patient's coinsurance responsibility, and bill Medicare. You might send a cover letter with your contract identifying your payment terms and other expectations. You would expect the SNF to give the patient any supportive care injectables.

If you have already treated a patient and have outstanding liabilities, you should contact the SNF administrator immediately. Many national SNF chains will expect to pay you once you send them the appropriate information, so that they can bill Medicare. It seems local providers have created problems for practices. Remember, the SNF has a legal obligation to treat the patient and follow Medicare rules. Don't write off their obligation just because you weren't aware of the rule change. Use a committed reasonable approach to working together cooperatively to do what is "right" for the patient and both parties providing services. Most SNFs will respond positively to you.

Paper Claim Requirements and Payment Slowdowns

There are four drugs that many practices are using now that do not have J-codes, and while previously you were able to use electronic claims by completing box 19 correctly, today many practices are being asked to drop these claims to paper. This is being asked by Medicare Carriers and private insurers in many parts of the country. It feels like a payment slow-down and extends a 14-day turn-around into a nearly 60-day process in many cases. There is probably not much you can do except comply and complain to your Carrier through your CAC and the Medical Director.

Be certain that all of your information is complete and accurate in box 19. If your software is not HIPAA compliant, it may limit the number of characters that will print in this box. Also, check your clearinghouses' software. Sometimes the clearinghouse software is not HIPAA compliant. Finally, if you are getting denied, verify that the insurers' software is HIPAA compliant so that all characters appear in your electronic claim.

Self-funded Insurers

Many large employers have self-funded health insurance programs, which are administered by commercial insurers. You send the claim to Blue Cross or Aetna or Cigna or United, etc. You think the coverage rules required for those patients who are fully insured in your state are in force. You get denials. Self-funded plans are ERISA exempt, which means that neither federal nor state requirements are in effect for these patients.

The major issue we are seeing throughout the country deals with off-labeled use of drugs with compendia listing. Self-funded plans are not obligated to cover these uses even though your state has a law requiring coverage. It appears that many insurers have a dollar threshold that causes claims to be denied. This means inexpensive drugs used off-label for compendia-listed indications may be paid and expensive drugs may be denied. No appeal to the third-party administrator (insurer) will win.

However, you should try working with the patient to go to the benefits manager of his or her insurer. Retirees usually have an insurance commission or board that will hear their appeals. We must work to inform the employer what treatments are being denied to their employees. While the commercial insurers who administer these programs claim that employers are fully aware of the limitations of their plans, our experience shows that employers don't want their insured patients getting less than state-of-the-art cancer treatment. Employers can make the decision to cover individual patients and change their plans at any time. We have to make them aware of the problem and ask them to cover appropriate treatments.

Reduction of All CPT Code Rates by Insurers

Throughout the country many Blue Cross plans have initiated a new policy of tying their payments to Medicare Physician Rates. They are paying more than Medicare, but less than in the past. Previously, we have seen commercial plans paying in a range from 125 percent above Medicare to 360 percent above. Many physicians groups note that the new rates offer approximately an 18 to 36 percent reduction in reimbursement, reducing payments to the 120 percent range.

We cannot predict whether other national insurers will adopt this philosophy as they search for ways to reduce their medical expenses. Most of the national insurers watch the effectiveness of their competitor's actions. This plan appears easy to implement and if it reduces medical expenses, others will adopt it quickly. Also, Blue Cross plans often administer self-funded plans or smaller insurance company plans, and it would be wise to expect them to carry this policy to those plans.

In the next newsletter, we will do an analysis of the proposed Medicare changes and how we expect they will affect your practice.



Upcoming Event

2004 Fall Membership Meeting

November 20, 2004
Shriners' Hospital for Children
Honolulu, HI

Drugs in the News

Approved Drugs

■ **Vidaza**[™] (azacitidine for injectable suspension) (Pharmion Corp., Boulder, Colo.) has been approved for marketing by the Food and Drug Administration (FDA) for the treatment of all five myelodysplastic syndromes (MDS) subtypes: refractory anemia or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions); refractory anemia with excess blasts; refractory anemia with excess blasts in transformation; and chronic myelomonocytic leukemia.

Drugs in the Pipeline

■ The FDA has granted orphan drug designation to Medarex, Inc.'s (Princeton, N.J.) fully human anti-CTLA-4 antibody, **MDX-010**, for the treatment of high-risk Stage II, Stage III, and Stage IV melanoma. Pending approval of a Special Protocol Assessment (SPA) application that has been filed with the FDA, Medarex expects to initiate a pivotal study for MDX-010 in combination with a gp100 melanoma vaccine in the second half of 2004. Positive data from a Phase II trial with MDX-010 alone and in combination with dacarbazine for the treatment of metastatic melanoma has already been reported.

■ Allos Therapeutics, Inc. (Westminster, Colo.) has received an "approvable" letter from the FDA for its NDA for **RSR13** (efaproxiral) for the treatment of patients with brain metastases originating from breast cancer. In the letter, the FDA indicated that before the NDA may be approved, Allos needs to complete its ongoing Phase III clinical trial of RSR13 in patients with brain metastases originating from breast cancer and submit the results as an NDA amendment for the FDA's review.

■ Corixa Corp. (Seattle, Wash.) has filed a supplemental biologics license application with the FDA requesting accelerated approval for expanded use of the **Bexxar**[®] therapeutic regimen (Tositumomab and Iodine I 131 Tositumomab) in the treatment of patients with relapsed or refractory low-grade, follicular, or transformed CD20 positive non-Hodgkin's lymphoma (NHL), whose disease has relapsed following chemotherapy.

■ Novartis Oncology (Basel, Switzerland) announced that its supplementary New Drug Application (NDA) for **Femara**[®] (letrozole) has been granted priority review by the FDA for an indication in the extended adjuvant treatment of early breast cancer in postmenopausal women who have completed standard adjuvant (post-surgery) tamoxifen therapy. The priority review establishes an action date no less than six months after the filing date, which was at the end of April 2004.

■ Inex Pharmaceuticals Corp. and Enzon Pharmaceuticals Inc. (Vancouver, Canada) announced that the NDA for **Onco TCS** (vincristine sulfate liposomes injection) has been accepted by the FDA and has been granted a Standard Review designation. Based on this designation, the FDA has established a target date of January 15, 2005 for completion of review of the Onco TCS NDA.

The NDA is seeking marketing approval for Onco TCS as a single-agent treatment for patients with relapsed aggressive Non-Hodgkin's Lymphoma (NHL), previously treated with at least two combination chemotherapy regimens. Onco TCS is also being evaluated in several Phase II oncology clinical trials, including first-line NHL.

■ The FDA has accepted Bioenvision, Inc.'s (New York, N.Y.) filing of the NDA for **clofarabine** for the treatment of refractory or relapsed acute leukemia in children. The NDA has been granted a priority review by the FDA. Bioenvision is currently conducting two Phase II clinical trials for clofarabine in Europe to further evaluate the drug's efficacy and safety profile in children with acute lymphoblastic leukemia (ALL) and in adults with acute myeloid leukemia (AML).

■ OSI Pharmaceuticals, Inc. (Melville, N.Y.) announced that the NDA for **Tarceva**[™] (**erlotinib HCl**) has been accepted into the FDA's Pilot 1 Program for Continuous Marketing Applications (also known as Rolling NDAs). The Pilot 1 Program is designed for products that have been designated fast track status and have demonstrated significant promise in clinical trials as a therapeutic advance over available therapy for the disease or condition. Tarceva is designed to block tumor cell growth by inhibiting the tyrosine kinase activity of the HER1/EGFR receptor thereby blocking the HER1/EGFR signaling pathway inside the cell.

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■ Therion Biologics Corporation (Cambridge, Mass.) obtained agreement from the FDA to initiate a Phase III trial of its lead vaccine candidate, **PANVAC™-VF**, for the treatment of metastatic pancreatic cancer in patients who have failed treatment with gemcitabine. The study is targeted to begin this summer and will be conducted under a special protocol assessment (SPA) by the FDA. The SPA indicates that if the trial successfully meets its primary endpoint, the data will provide the basis for an efficacy claim in a marketing application to the FDA. The study's primary endpoint will be overall survival compared with best supportive care or palliative chemotherapy.

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