Practical Tips for the Practicing Oncologist, 3rd Edition

2005 Supplement

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Chapter 1
2005 Medicare Changes

MEDICARE MODERNIZATION ACT (MMA)
PROVISIONS OF MMA
2005 MEDICARE PHYSICIAN FEE SCHEDULE

This chapter provides a brief overview of the Medicare Modernization Act of 2003. The information focuses on the law as it relates to oncology services.

MEDICARE MODERNIZATION ACT (MMA)

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, commonly known as the Medicare Modernization Act (MMA), was enacted in December 2003. The primary purpose of the MMA was to provide a prescription drug benefit under the Medicare program and to revise the Medicare Advantage program.

Many other provisions were included in the law, including expansions of coverage of preventive services, and changes in payment rates for physician services and drugs administered in the physician's office. These provisions are discussed briefly below.

PROVISIONS OF MMA

Provisions of the MMA affecting cancer care include:

- **Welcome to Medicare exam.** Beginning in 2005, Medicare covers an initial physical exam for new Medicare beneficiaries. The initial exam includes adult immunizations, electrocardiogram, pap exam, mammogram, colorectal and prostate screening tests, and other services. Beneficiaries at risk for cardiovascular disease and diabetes can also obtain screening tests for those diseases.

- **Replacement Drug Demonstration.** For 2004-2005, MMA established a drug replacement demonstration program, which is discussed in Chapter 4.

- **Payments for Drugs and Drug Administration.** MMA revised the payments for drugs provided in the office setting and the payments for drug administration services. These issues will be discussed in detail in subsequent chapters.

2005 MEDICARE PHYSICIAN FEE SCHEDULE

The final rule for the 2005 Medicare Physician Fee Schedule was published in the *Federal Register* on November 15, 2004. The rule can be accessed at

http://www.access.gpo.gov/su_docs/fedreg/a041115c.html under the Centers for Medicare & Medicaid Services (CMS). The fee schedule contains the coverage status of each code, the 2005 relative values for each code and the 2005 conversion factor. The conversion factor for 2005 is $37.8975.

Your local Medicare carrier should have available the fee schedule with the payment rates for each code. The payment rates will be specific to your geographic area or locality. Local Medicare carriers typically have the fee schedule available on their web sites. (To find your local carrier's web site, visit www.asco.org/cac.) You can also find payment rates for your area or another area on the CMS web site at http://www.cms.hhs.gov/physicians/mpfsapp/default.asp.

In the final rule, CMS announced a series of new temporary codes that are effective January 1, 2005. The temporary codes are in the form of G-codes and represent various drug administration services (Appendix pp. 1 - 4). Details on the codes and the billing of these codes can be found in the following chapters.

CMS also released information specific to the payment of drugs under the new average sales price (ASP) methodology. Details on the payments for drugs can be found in Chapter 4.

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Chapter 2
Drug Administration – Billing and Coding

CHANGES IN DRUG ADMINISTRATION CODES
MEDICARE'S USE OF NEW DRUG ADMINISTRATION CODES
MEDICARE G CODES FOR DRUG ADMINISTRATION
USE OF THE G CODES
USE OF THE NEW DRUG ADMINISTRATION CODES BY PRIVATE INSURANCE AND MEDICAID
BILLING E&M VISITS ON THE SAME DAY AS DRUG ADMINISTRATION SERVICES

CHANGES IN DRUG ADMINISTRATION CODES

Review of existing codes
The Medicare Modernization Act (MMA) includes a provision that drug administration CPT codes be reviewed to accurately reflect the resources required to perform them. In 2004, an evaluation of the CPT drug administration codes was performed by the American Medical Association's (AMA) CPT Editorial Panel.

The CPT Editorial Panel created a workgroup to perform the evaluation of the existing codes. The workgroup was composed of representatives from a number of specialty societies, including ASCO, who reviewed the codes and submitted recommendations to the Editorial Panel. Based upon the recommendations, the Panel approved substantial revisions to the CPT codes.

Changes in 2005 and beyond
The Editorial Panel's approval of the codes was not completed before the publication of the 2005 CPT codes. Therefore, the new and revised CPT codes for drug administration services will not appear until the 2006 CPT book is published. However, CMS created a number of temporary G codes for use by Medicare in 2005 that correspond to the 2006 CPT codes.

The temporary codes distinguish infusions and other types of administrations for each drug administered and classify the administrations as hydration, therapeutic or diagnostic infusion or injection, or chemotherapy infusion or injection. The irrigation of an implanted venous access device will also be captured by a new G code. Table 2.1 contains a listing of the temporary codes, their descriptions, and a crosswalk to the 2005 CPT codes.

MEDICARE'S USE OF NEW DRUG ADMINISTRATION CODES

Office Setting
The MMA did not change the coverage of drug administration services provided in the office setting. The temporary codes are to be reported for drug administration services provided in the office setting.

Hospital Setting
The temporary drug administration codes created by CMS are **not** recognized in the hospital outpatient setting. Drug administrations provided in the hospital outpatient setting are to be reported using CPT codes.

MEDICARE G CODES FOR DRUG ADMINISTRATION

Hydration services (Codes G0345 and G0346)
Hydration services are intravenous infusions to administer pre-packaged fluid and/or electrolytes (pre-packaged or mixed). For example, administrations of normal saline, D5-1/2 normal saline +30mEq KC1 liter 12 and magnesium would be billed as hydration. Hydration provided at the same time as chemotherapy to facilitate drug delivery is not paid separately by Medicare and should not be reported using the hydration codes.

G0345 is used only if hydration is the "initial" service during the encounter (see discussion of "initial" services below). If the hydration is not considered the initial service, then G0346 must be used to report any hydration service. G0346 can be used in that situation to report each hour of hydration service (or partial hour greater than 30 minutes). In addition, if G0345 is used to report hydration as the initial service, G0346 is used to report each additional hour (or portion of an hour exceeding 30 minutes).

Therapeutic and diagnostic (Codes G0347 through G0354)
Infusions and injections of antiemetics, growth factors, or other non-chemotherapy drugs are captured under the therapeutic and diagnostic codes.

Chemotherapy administration (Codes G0355 through G0363)
Infusions and injections of antineoplastic agents, biological response modifiers, and monoclonal antibodies are reported under the chemotherapy administration codes. These codes can be reported for both cancer and non-cancer diagnoses.

The following drugs were listed by CMS as monoclonal antibodies:
- infliximab
- rituximab
- alemtuzumab
- gemtuzumab
- trastuzumab

The following drugs were listed by CMS as hormonal antineoplastics:
- leuprolide acetate
- goserelin acetate

These are not complete listings, and CMS does not intend to maintain or publish a complete listing of drugs that can be used under the chemotherapy administration codes. CMS will, however, rely on local Medicare carriers to provide additional guidance.

USE OF THE G CODES

Use of "initial" codes

One code in each category of drug administration codes has been designated as the "initial"service and represents the first drug or agent administered within that category. The initial codes are G0345 (for hydration), G0347 (for therapeutic and diagnostic infusions), G0353 (for therapeutic and diagnostic pushes), G0357 (for chemotherapy pushes) and G0359 (for chemotherapy infusions).

Only one initial code can be billed per patient encounter. The initial code that best describes the service being performed that day should be reported. The initial code does not have to correspond to the first service performed. For example, if you perform hydration and chemotherapy infusion on the same day and the chemotherapy infusion is the key service, the initial code for chemotherapy (G0359) should be billed even if the hydration was performed prior to the chemotherapy infusion (Appendix p. 5).

Use of "each additional hour" codes

Each category of drug administration codes has a designated code for "each additional hour." This code is used to report the additional hours of infusion, after the first hour, of an individual drug. For example, if a drug is administered for two hours, the "additional hour" code is used to identify the second hour of infusion of that drug. The codes for "each additional hour" are G0346 (for hydration), G0348 (for therapeutic and diagnostic infusions) and G0360 (for chemotherapy infusions).

In order to report an additional hour of infusion of a particular drug, the infusion time must last more than 30 minutes beyond the first hour. Infusions lasting 30 minutes or less (after the first hour) should be rounded down and not reported.

The additional hour code can be used to report infusions up to eight hours. The first hour of the infusion would be captured using either the "additional sequential drug" or "initial" codes and the remaining hours are reported under the additional hour codes. (The additional hour code can be reported up to seven times.)

Multiple infusions

The "additional sequential drug" codes are used to report the second and subsequent drugs administered during a patient encounter. These codes should be used to report **each** additional drug administered. G0349 is used to report additional infused therapeutic and diagnostic drugs, and G0362 is used to report additional infused drugs categorized under chemotherapy administrations.

Codes were also created for "additional sequential" intravenous pushed therapeutic and diagnostic drugs and chemotherapy drugs. These codes are discussed under the multiple pushes section below.

Concurrent infusions
A concurrent infusion is one in which two drugs are simultaneously infused. Medicare created a temporary code (G0350) to identify the simultaneous infusion of two non-chemotherapy drugs.

G0350 is an add-on code and must be reported with another infusion code. For example, if two non-chemotherapy agents are administered simultaneously, G0347 would be reported for the initial drug infused and G0350 for the concurrently infused drug.

Code G0350 can be reported once per patient encounter. If a concurrent infusion occurs during a separate patient encounter on the same date of service, the –59 modifier should be reported with G0350 (Appendix p. 13).

Multiple pushes
The G-codes for intravenous (IV) pushes that are considered the initial service in a patient encounter are G0353 (for therapeutic and diagnostic IV pushes) and G0357 (for chemotherapeutic IV pushes).

Two G-codes are used to report each additional drug administered by IV push after the initial drug administration service -- G0354 (for therapeutic and diagnostic drugs) and G0358 (for chemotherapy drugs). It is possible that an IV push of a therapeutic/diagnostic drug may follow a chemotherapy drug administration service (Appendix p. 4).

Use of modifiers for multiple infusions
CMS believes that the temporary G-code descriptions now provide clear definition of drug administration services and distinctions between the first and subsequent drugs administered. Therefore, the –59 modifier is not needed to report multiple infusions or injections.

However, the –59 modifier should still be used with the hydration codes to indicate that hydration was provided prior to or following chemotherapy. This interpretation stems from Medicare's policy that hydration must occur sequential to chemotherapy to be eligible for a separate payment.

If two separate intravenous sites are required by protocol and/or a patient comes back the same day for a separately identifiable service, the –59 modifier should be used (on the second/separately identifiable procedure) (Appendix p. 14).

Irrigation of implanted venous access device
A G code has been established to recognize the flushing of a port – G0363. Medicare will pay for this code if it is the only service provided to the patient. If this is reported

with any other service, it will be considered bundled into the payment for the other service and Medicare will not make a separate payment for the port flush.

Some local Medicare carriers have published local coverage policies and/or articles specifically addressing whether or not the drug used to flush a port is covered. Physicians should verify the local carrier's coverage policy before billing.

Related services for which no separate payment is made

Medicare does not pay separately for certain services that accompany drug administration services, including starting an intravenous line, accessing an intravenous line, any local anesthesia, or the flushing of a line. These procedures are considered integral to the drug administration service. Supplies such as syringes, tubing and bandages are not separately billable. These supplies are considered by Medicare to be incorporated into the practice expense amounts for each code.

Billing for the administration of Leucovorin

Leucovorin is used in some chemotherapy regimens as it enhances the antineoplastic effect of 5FU; however, the drug itself is not classified as an antineoplastic agent. CMS has stated that local carriers have discretion to determine whether the administration of Leucovorin is considered as non-chemotherapy or chemotherapy.

Short infusions

An intravenous or intra-arterial push is defined as, "an injection in which the healthcare professional who administers the substance or drug is continuously present to administer the injection and observe the patient; or an infusion of 15 minutes or less." This definition will be adopted by CPT in 2006; however, Medicare has applied the definition to the drug administration G codes as of March 15, 2005.

Therefore, when billing Medicare, infusions of 15 minutes or less are to be reported using the appropriate code for pushes (Appendix pp. 12 –13).

Examples of coding for chemotherapy and related services

Below, you will find two coding scenarios utilizing the new drug administration G codes.

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Coding Example #1			
Service	**Time**	**Codes**	**Explanation**
Hydration (saline)	9:00 to 9:35 (35 minutes)	G0346-59	The hydration service is reported using "each additional" hydration code. *The initial hour of hydration is not used because hydration does not accurately describe the key service performed.* The –59 modifier is used to indicate that hydration is performed prior to the chemotherapy infusion (if performed concurrently, then it would not be separately billable).
Antiemetic	9:35 to 10:15 (40 minutes)	G0349	A first antiemetic is infused prior to the chemotherapy; since it is not considered the "initial" (key) service, it is reported using an "additional sequential" therapeutic/diagnostic code.
Chemotherapy (first drug)	10:15 to 11:15 (1 hour)	G0359	Chemotherapy infusion best describes the key service performed; therefore, the first drug is reported using the code for the initial infused drug (first hour of service).
Chemotherapy (second drug)	11:15 to 12:50 (1 hr & 35 minutes)	G0362 & G0360	The second chemotherapy drug is reported as an "additional sequential" infusion. An additional hour of chemotherapy infusion is also used to report the remaining 35-minute infusion of the same drug.
Antiemetic	12:50 to 1:05 (15 minutes)	G0354	The second antiemetic was infused for 15 minutes; therefore, it is reported using the push/short-infusion code. The "additional sequentially pushed" therapeutic/diagnostic code is reported.

Coding Example #2			
Service	**Time**	**Codes**	**Explanation**
Antiemetic	9:30 to 9:50 (20 minutes)	G0349	A first antiemetic is infused prior to the chemotherapy; since it is not the "initial" (key) service, it is reported using an "additional sequential" therapeutic/diagnostic code.
Antiemetic	9:50 to 10:35 (45 minutes)	G0349 (2)	The second antiemetic was infused sequentially after the first antiemetic; therefore, it is reported as another sequential therapeutic/diagnostic infusion.
Chemotherapy (first drug)	10:35 to 11:05 (30 minutes)	G0359	Chemotherapy infusion best describes the key service performed; therefore, the first drug is reported as the initial hour of service.
Chemotherapy (second drug)	11:05 to 12:05 (1 hour)	G0362	The second chemotherapy drug is reported as an "additional sequential" infusion.

USE OF THE NEW DRUG ADMINISTRATION CODES BY PRIVATE INSURANCE AND MEDICAID

Private payors may implement some or all of these coding changes; however, some may continue to use CPT codes. It is important to communicate with your insurers to verify how they will cover and pay for drug administration services in 2005.

Many cancer patients are dually eligible under Medicare and Medicaid. Therefore, it is also important to communicate with your state Medicaid agency about whether the new codes will be recognized.

BILLING E&M VISITS ON THE SAME DAY AS DRUG ADMINISTRATION SERVICES

Medicare does not cover a level one office visit (99211) if it is billed on the same day as a drug administration service. A higher level visit may be billed if evaluation and management services separate from management of the drug administration services were furnished. Medicare continues to require the attachment of the –25 modifier to codes for evaluation and management services provided on the same day as drug administration services to indicate that a significant, separately identifiable evaluation and management service was furnished. Appropriate documentation should support the level of service billed.

(Documentation guidelines are outlined in the 1995 and 1997 E&M guidelines, which are available on CMS's web site at http://www.cms.hhs.gov/medlearn/emdoc.asp. More information can also be found in Chapter 11 of the 3rd Edition of *Practical Tips for the Practicing Oncologist*.)

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TABLE 2.1 - Medicare's Temporary G-codes for Drug Administration and Crosswalk to the 2005 CPT Drug Administration Codes

2005 Medicare Temporary Codes	2005 Medicare Temporary Code Description	2005 CPT Codes	2005 CPT Code Description
HYDRATION (APPLY TO PRE-PACKAGED FLUID AND ELECTROLYTES--MIXED OR UNMIXED)			
G0345	Intravenous infusion, hydration; initial, up to 1 hour	90780	Intravenous infusion for therapy/diagnosis, administered by physician or under direct supervision of physician: up to 1 hour
G0346	Each additional hour, up to 8 hours (list separately in addition to code for primary procedure)	90781	each additional hour, up to 8 hours (list separately in addition to code for primary procedure)
THERAPEUTIC/DIAGNOSTIC DRUG ADMINISTRATION (APPLY TO NON-CHEMOTHERAPY AGENTS)			
G0347	Intravenous infusion, for therapeutic/diagnostic (specify substance or drug): initial, up to 1 hour	90780	Intravenous infusion for therapy/diagnosis, administered by physician or under direct supervision of physician: up to 1 hour
G0348	Each additional hour, up to 8 hours (list separately in addition to code for primary procedure and report in conjunction with G0347)	90781	each additional hour, up to 8 hours (list separately in addition to code for primary procedure)
G0349	Additional sequential infusion, up to 1 hour (list separately in addition to code for primary procedure)	N/A	N/A
G0350	Concurrent infusion (list separately in addition to code for primary procedure) report only once per substance/drug regardless of duration, report G0350 in conjunction with G0345	N/A	N/A
G0351	Therapeutic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	90782	Therapeutic, prophylactic or diagnostic injection; subcutaneous or intramuscular
G0353	Intravenous push, single or initial substance/drug	90784	intravenous
G0354	Each additional sequential intravenous push (list separately in addition to code for primary procedure)	N/A	N/A
CHEMOTHERAPY DRUG ADMINISTRATION CODES (APPLY TO NON-RADIONUCLIDE ANTI-NEOPLASTIC AGENTS, MONOCLONAL ANTIBODIES, AND BIOLOGIC RESPONSE MODIFIERS)			
G0355	Chemotherapy administration, subcutaneous or intramuscular non-hormonal antineoplastic	96400	Chemotherapy administration, subcutaneous or intramuscular, with or without local anesthesia
G0356	Hormonal antineoplastic	96400	Chemotherapy administration, subcutaneous or intramuscular, with or without local anesthesia
G0357	Intravenous, push technique, single or initial substance/drug	96408	Chemotherapy administration, intravenous; push technique
G0358	Intravenous, push technique, each additional substance/drug (list separately in addition to code for primary procedure)	96408	Chemotherapy administration, intravenous; push technique
G0359	Chemotherapy administration, intravenous	96410	infusion technique, up to one hour

	infusion technique; up to 1 hour, single or initial substance/drug		
G0360	Each additional hour, one to 8 hours (list separately in addition to code for primary procedure) use G0360 in conjunction with G0359	96412	infusion technique, one to 8 hours, each additional hour
G0361	Initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump	96414	infusion technique, initiation of prolonged infusion (more than 8 hours), requiring the use of a portable or implantable pump
G0362	Each additional sequential infusion (different substance/drug), up to 1 hour (use with G0359)	N/A	N/A
G0363	Irrigation of implanted venous access device for drug delivery systems (do not report G0363 if an injection or infusion is provided on the same day)	N/A	N/A

Notes:

- Certain drug administration codes do not appear in this table because the codes remain the same. Those codes include 90783, 90788, 96520 and 96530. Code descriptions for these particular codes can be found in the 2005 CPT book.
- CMS has stated that codes for the infusion of "additional sequential" drugs (G0349 and G0362) crosswalk to the old codes for "each additional hour" of infusion (90781 and 96412, respectively).

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Chapter 3
Demonstration Project Related to Chemotherapy Administration

DEMONSTRATION PROJECT RELATED TO CHEMOTHERAPY ADMINISTRATION

Effective January 1, 2005, CMS is implementing a demonstration project that pays physicians who collect and report data to Medicare on side effects related to chemotherapy treatment. The project is designed to gather data on quality of life indicators for cancer patients and to offset the reduced payments for chemotherapy administration services.

This demonstration is a one year project scheduled to end December 31, 2005.

Demonstration project administration
Medicare has identified three areas of frequent patient concern for reporting purposes: nausea and vomiting, pain management, and fatigue. CMS has established a scale with four levels of assessment for each of the three indicators, based on the Rotterdam symptom checklist, a tool developed to assess quality of life in patients living with cancer. The levels are: **not at all**, **a little**, **quite a bit** or **very much**.

To qualify for payment, patients being seen for a chemotherapy visit must be asked if they are experiencing any nausea/vomiting, pain or fatigue and at what level they are experiencing the side effects. A chemotherapy visit is defined by Medicare as an encounter that involves chemotherapy administration by intravenous infusion or intravenous push to a patient with cancer.

Billing and coding
Medicare established 12 new G codes specifically for this demonstration project. The codes are broken into three categories (nausea/vomiting, pain and fatigue) and then by the assessment level. The G codes are listed in Table 3.1.

Table 3.1. G-codes Established for the Demonstration Project

CATEGORY OF PATIENT ASSESSMENT	G CODE	DESCRIPTION / LEVEL OF ASSESSMENT
Nausea and/or Vomiting	G9021	Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration assessment **level one: not at all**
	G9022	Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration assessment **level two: a little**
	G9023	Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration assessment **level three: quite a bit**

	G9024	Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration assessment **level four: very much**
Pain	G9025	Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration assessment **level one: not at all**
	G9026	Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration assessment **level two: a little**
	G9027	Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration assessment **level three: quite a bit**
	G9028	Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration assessment **level four: very much**
Lack of Energy (Fatigue)	G9029	Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration assessment **level one: not at all**
	G9030	Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration assessment **level two: a little**
	G9031	Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration assessment **level three: quite a bit**
	G9032	Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration assessment **level four: very much**

Physicians who report to Medicare on the level of nausea/vomiting, pain and fatigue experienced by their patients will be eligible for a $130 payment. To be eligible for the demonstration payment, one code from each category (nausea/vomiting, pain and fatigue) must be reported. Partial payment will not be made when reporting on only one or two categories.

The demonstration project payment of $130 will be paid only once per patient per day. Medicare will reimburse 80% of the project payment and the patient is responsible for a 20% co-pay.

For billing purposes, Medicare assigned individual payment amounts for each assessment category which will total the $130 demonstration project payment. The payment amounts for each category are as follows:

G9021-G9024 (report one code) $43.34

G9025-G9028 (report one code) $43.33

G9029-G9032 (report one code) $43.33

Participation
Provider participation in this demonstration project is voluntary. Physicians self-enroll in the project when they report the G codes established for this project.

A nurse practitioner or other non-physician staff may conduct the assessment of side effects and record the results of the assessment in the context of providing an incident-to service. The principal requirement for an incident-to service is that the physician must be present in the office suite. The physician should follow incident-to guidelines for reviewing and signing off on the assessment. CMS expects the practitioner to review the data as part of the patient's assessment.

Services performed by a nurse practitioner or other non-physician staff must adhere to the State laws defining their scope of practice.

Instead of responding to questions from the physician or office staff, the patient may be given the demonstration project questions to read and the patient can respond orally or in writing. ASCO created a document that contains the questions and a place for patients to write their responses (Appendix p. 18).

Documentation
Physicians participating in the demonstration project do not have to provide additional documentation beyond the G codes when submitting claims. Providers should document interventions related to these assessments but such documentation will not be considered as part of the qualifying criteria for the demonstration project payment. A CMS program memorandum describing the demonstration project states that, "we also expect that the patient's responses will be recorded and included as part of the patient's medical records."

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Chapter 4
Medicare Replacement Drug Demonstration Project

This chapter highlights changes in Medicare's coverage for drugs since the enactment of MMA in 2003.

MEDICARE REPLACEMENT DRUG DEMONSTRATION PROJECT

Demonstration description
CMS has implemented a Medicare Replacement Drug Demonstration to provide limited coverage for certain oral and other self-administered drugs until the Medicare prescription drug benefit becomes available in 2006. The benefit provided by this project is separate from the standard benefits a beneficiary receives under the Medicare program.

This demonstration project provides coverage for self-administered drugs that would be a "replacement" for drugs administered in the physician's office. Under this project, cancer patients may be eligible to receive coverage for some self-administered (oral) drugs. For example, the cancer drug imatinib mesylate (Gleevec®) is covered under the project as a "replacement" to an existing Medicare-covered drug the patient is or has taken for the treatment of his/her condition.

This project allows 50,000 Medicare beneficiaries to participate, and its limit for benefits is $500 million. The original enrollment deadline was September 30, 2004. However, CMS extended the deadline to December 31, 2005. After December 31, 2005, the demonstration project will be terminated.

The cancer drugs available under the project are listed in Table 4.1. Drugs covered for other diagnoses can be found on CMS's web site at http://www.cms.hhs.gov/researchers/demos/drugcoveragedemo.asp.

Table 4.1: Cancer Drugs Covered Under the Drug Replacement Demonstration Project

Covered Diagnosis or Indication	Drug Name
Cutaneous T-cell Lymphoma	Bexarotene (Targretin®)
Non-small cell lung cancer	Gefitinib (Iressa®) Erlotinib HCl (Tarceva®)
Epithelial ovarian cancer	Altretamine (Hexalen®)
Chronic Myelogenous Luekemia	Imatinib mesylate (Gleevec®)
GI Stromal Tumor	Imatinib mesylate (Gleevec®)
Multiple Myeloma	Thalidomide (Thalomid®)
Breast Cancer Stages 2-4 only	Hormonal therapy Anastrozole (Arimidex®)

	Exemestane (Aromasin®) Letrozole (Femara®) Tamoxifen (Nolvadex®) Toremifene (Fareston®)
Prophylactic agent to reduce ifosfamide-induced hemorrhagic cystitis	Mesna (Mesnex®)

Program administration

Enrollment and eligibility
Enrollment in the Medicare Replacement Drug Demonstration project is voluntary. The enrollment application for the project can be found on CMS's web site at http://www.cms.hhs.gov/forms/cms10113.pdf.

To be eligible for participation, a beneficiary must 1) be enrolled in Medicare Part A and Part B, 2) have Medicare as the primary insurer, 3) live in one of the 50 states or the District of Columbia, 4) have physician certification that the beneficiary needs one of the drugs covered under the project and 5) not have any other insurance that provides comprehensive drug coverage.

Physicians are required to fill out the physician certification portion of the application (Part II).

Beneficiary cost
Beneficiaries enrolled and participating in the demonstration project are required to pay an annual deductible and must incur some out-of-pocket expenses. Because the demonstration project started in the middle of 2004, the deductible and out-of-pocket expenses are higher in 2005 than 2004.

For those beneficiaries with limited resources, Medicare provides some financial assistance. You can find detailed information regarding the out-of-pocket expenses and the financial assistance available at CMS's web site at http://www.cms.hhs.gov/researchers/demos/drugcoveragedemo.asp.

Obtaining the drugs
Once a beneficiary is accepted in the demonstration project, a special pharmacy card will be sent to him or her. The card should be presented at the pharmacy (must be a Caremark participating pharmacy) whenever the beneficiary is obtaining the covered drug.

If providers or beneficiaries have questions on this project or need assistance with the application, contact TrailBlazer Health Enterprises, LLC. The contact information is provided below.

> Medicare Replacement Drug Program
> c/o TrailBlazer Health Enterprises, LLC
> P.O. Box 5136

Timonium, MD 21094
1-866-563-5386
Fax: 410-683-2933

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Chapter 5
Medicare Payment for Drugs

PAYMENT AMOUNTS FOR 2005 AND LATER YEARS

Medicare changed the reimbursement methodology for drugs. This chapter provides a brief overview of Medicare's reimbursement methodology and changes enacted by MMA.

PAYMENT AMOUNTS FOR 2005 AND LATER YEARS

Beginning in 2005, the Medicare allowed amount for drugs administered in the office is 106% of the manufacturer's average sales price (ASP). Manufacturers will report ASP data to CMS for each calendar quarter, and that data will be used to set the Medicare payment rates two quarters later. In the case of multiple-source drugs, the ASP data for each manufacturer will be weighted by sales volume to determine the ASP used to set the Medicare payment rate.

Payment amounts will be revised each quarter. However, Medicare may occasionally publish price corrections. If corrections are published, previously paid claims must be resubmitted to your local Medicare carrier to obtain any higher payment amounts.

CMS publishes the ASP payment amounts on their web site and can be found at: http://www.cms.hhs.gov/providers/drugs/asp.asp.

Beginning in 2006, CMS is authorized to begin offering an optional method by which physicians can elect to obtain all physician-administered drugs from a contractor. This program is referred to as the Competitive Acquisition Program (CAP). CMS is in the process of developing the framework for the implementation of the CAP.

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Chapter 6
Medicare Payment For Prolonged and Critical Care Services

PAYMENT FOR PROLONGED SERVICES
PAYMENT FOR CRITICAL CARE SERVICES

Physician services that require an intense level of physician work, such as services furnished to a patient who has a severe drug reaction, may be reported using the prolonged service codes or the critical care codes. This chapter provides a description of those codes and Medicare's payment policies for those codes.

PAYMENT FOR PROLONGED SERVICES

Description of codes

Codes 99354-99359 are used to identify prolonged physician services and are based on time. These codes are billed in addition to the appropriate visit code when the time involved exceeds the typical time of the visit code as defined in the CPT. Medicare covers the use of prolonged service codes only when the services are provided directly to the patient.

For example, the time associated with a level four office visit is 25 minutes. If a physician spent a total of 60 minutes with a patient, the prolonged service codes could be used to reflect time spent with the patient beyond the first 25 minutes.

Billing for prolonged services

Codes 99354 and 99355 are used to report face-to-face prolonged services provided in the **outpatient setting**. Code 99354 is used to capture the first hour and 99355 is used to report each additional 30 minutes.

Codes 99356 and 99357 are used to report face-to-face prolonged services provided in the **inpatient setting**. Code 99356 is used to capture the first hour and 99357 is used to report each additional 30 minutes.

To bill these codes, time with the patient does not have to be continuous and can be rounded up or down. In order to bill for the first hour of prolonged service (99354 or 99356), the physician must have spent at least 30 minutes of additional face-to-face time with the patient beyond the threshold time of the visit code.

Anything less than 30 minutes is rounded down and not reported. Services for 30 minutes or more are rounded up to one hour. An example of the use of the prolonged codes is provided in Table 6.1.

Subsequent services performed after the first hour are reported in increments of 30 minutes or more using codes 99355 and 99357. Services for 14 minutes or less are not reported and services lasting 15 minutes or more are rounded up to 30 minutes.

Table 6.1. Examples of use of Prolonged Service Codes

Basic Service	Typical Time for Service in CPT Book	Actual Time Spent with Patient	Codes Billed	Explanation
Level 4 outpatient visit	25 min.	50 min.	99214	No prolonged service code because less than 30 minutes of prolonged service
Level 4 outpatient visit	25 min.	60 min.	99214 and 99354	35 minutes of prolonged services rounds up to 1 hour
Level 4 outpatient visit	25 min.	1 hour and 40 min.	99214 and 99354 and 99355	1 hour and 15 minutes of prolonged services rounds up to 1 hour and 30 minutes

PAYMENT FOR CRITICAL CARE SERVICES

Description of codes
The codes 99291 and 99292 may be used to report physician time spent with a critically ill or injured patient in the office. A critical illness or injury is described as one that "acutely impairs one or more vital organ systems such that there is a high probability of imminent or life threatening deterioration in the patient's condition."

According to CPT, critical care services are usually provided in a critical care area like an emergency care facility or an intensive care unit. Medicare, however, covers these services if they meet the description above regardless of the location in which they are furnished. Medicare will cover and pay for critical care services provided in the office setting when the reporting criteria are met.

These services require the physician's sole attention (the physician should not provide any other services to another patient during the same time). The codes reflect the physician's services directly related to the patient's care whether those services were face-to-face with the patient or non-face-to-face, e.g., reviewing test results or images.

Billing for critical care services
As in the case of the prolonged service codes, time spent performing critical care services does not have to be continuous and can be rounded up or down. The first 30 to 74 minutes of critical care services performed should be reported using code 99291. Each additional 30 minutes of service beyond the first 74 minutes is reported using code 99292.

Documentation should include the time spent with the patient, a description of the critical care services performed, and a description of the patient's treatment during the critical care service.

If a physician provides less than 30 minutes of critical care services, only a visit may be billed.

AMERICAN SOCIETY OF CLINICAL ONCOLOGY

Chapter 7
Other Oncology/Hematology Changes

BONE MARROW ASPIRATION AND BONE MARROW BIOPSY
ROUTINE VENIPUNCTURE

This chapter contains a brief overview of Medicare changes affecting other oncology/hematology services.

BONE MARROW ASPIRATION AND BONE MARROW BIOPSY

Beginning January 1, 2005, Medicare uses a new G-code (G0364) to report a bone marrow aspiration performed on the same date through the same incision as a bone marrow biopsy. G0364 is to be reported with the bone marrow biopsy code, 38221. Therefore, physicians would bill both 38221 and G0364 when reporting that both procedures were performed during the same encounter (Appendix p. 9).

If the biopsy and aspiration are performed through different incisions or in different patient encounters on the same day, then Medicare will make separate payments for each procedure. When billing for both the bone marrow aspiration (38220) and bone marrow biopsy (38221) codes on the same date of service under these circumstances, the –59 modifier is required.

In this case, however, Medicare will reimburse for the procedures under the multiple procedure rule (Appendix p. 9), and Medicare reimburses the second procedure at fifty percent of the normal payment amount. If the two procedures are reported with the modifier, proper documentation should support the claim.

ROUTINE VENIPUNCTURE

As of January 1, 2005, code G0001 for routine venipunctures for the collection of specimen(s) was deleted. Medicare will now recognize CPT code 36415 (collection of venous blood by venipuncture); however, Medicare will not recognize 36416 (collection of capillary blood specimen).

Appendix Material

facilities rather than base the 2005 payment amounts solely on the acquisition costs of the other facilities.

In response to the commenters who requested clarification of the payment basis for separately billable ESRD drugs other than EPO billed by hospital-based ESRD facilities, we did not propose changes to the reasonable cost payment basis for these drugs. The OIG did not study separately billable ESRD drugs other than EPO billed by hospital-based ESRD facilities and accordingly, we did not propose to change the payment basis for these drugs.

e. Payment for Infusion Drugs Furnished Through an Item of DME

In 2005, section 1841(o)(1)(D)(i) of the Act requires that an infusion drug furnished through an item of DME covered under section 1861(n) of the Act be paid 95 percent of the average wholesale price for that drug in effect on October 1, 2003. No commenters objected.

2. Drug Administration Payment Policy and Coding Effective in 2005

Section 1848(c)(2)(J) of the Act (as added by section 303(a) of the MMA) requires the Secretary to promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for those services, taking into account levels of complexity of the administration and resource consumption. According to section 1848(c)(2)(B)(iv) of the Act (as amended by section 303(a) of the MMA), any changes in expenditures in 2005 or 2006 resulting from this review are exempt from the budget neutrality requirement of section 1848(c)(2)(B)(ii) of the Act. The statute further indicates that the Secretary shall use existing processes for the consideration of coding changes and, to the extent changes are made, shall use those processes to establish relative values for those services. The Secretary is also required to consult with physician specialties affected by the provisions that change Medicare payments for drugs and drug administration.

The AMA's CPT Editorial Panel established a workgroup, with representatives from affected specialties that met earlier this year to develop recommendations to the CPT Editorial Panel in August. Based on these recommendations, that panel adopted several new drug administration codes and revised several existing codes. Subsequently, the AMA's Relative Value Update Committee (RUC) met at the end of September to make recommendations to us on the practice expense resource inputs and work relative values for the new and revised drug administration codes.

We indicated in the proposed rule that we would consider whether it is necessary for us to make coding changes effective January 1, 2005 through the use of G-codes (because the 2005 CPT book will have already been published), and we requested public comment. As described in detail below, we are establishing new G-codes for 2005 that correspond with the new CPT codes that will become active in 2006. These new G-codes are interim until 2006.

The new CPT codes can be categorized into the following three categories of drug administration services: infusion for hydration; nonchemotherapy therapeutic/diagnostic injections and infusions other than hydration; and chemotherapy administration (other than hydration) which includes infusions/injections. There are some important changes in the new codes relative to current drug administration coding. The infusion of substances such as monoclonal antibody agents or other biologic response modifiers is reported under the chemotherapy codes, instead of the nonchemotherapy infusion codes, as is currently the case. There are also new codes in both the chemotherapy and nonchemotherapy sections for reporting the additional sequential infusion of different substances or drugs.

As we stated in the proposed rule, we plan to analyze any shift or change in utilization patterns once the payment changes for drugs and drug administration required by MMA go into effect. While we do not believe the changes will result in access problems, we plan to continue studying this issue. We also note that the MMA requires the Medicare Payment Advisory Commission (MedPAC) to study how the changes in payments for drugs and drug administration affect other specialties.

We received many comments on various aspects of coding and payment for drug administration services in response to the proposed rule. We are also responding below to comments we received on the January 7, 2004 interim final rule with comment period that announced the provisions of section 303 of the MMA affecting drug administration services that took effect in 2004 (69 FR 1094). Specifically, section 303 of the MMA required the following changes in 2004: a transitional adjustment that increases payments for specific drug administration services by 32 percent in 2004 (and 3 percent in 2005); establishing work RVUs for certain drug administration services equal to the work RVUs for a level 1 office medical visit for an established patient; the incorporation of supplemental survey data in the calculation of the practice expense RVUs for drug administration codes; and allowing oncologists to bill for multiple drug administrations by the "push" technique on a single day.

Comment: Many commenters supported the efforts to promptly evaluate existing drug administration codes to ensure accurate reporting and billing for services. They support our proposal to use G-codes until the new CPT codes are active. They asked us to adopt the recommendations of the CPT Editorial Panel for new drug administration codes.

Response: We appreciate the support of the commenters of all of the efforts to expeditiously review and update these codes. We also would like to specifically recognize the efforts of the CPT Editorial Panel's Drug Administration Workgroup to develop the new CPT codes, the Editorial Panel for its consideration and approval of the new codes, and the RUC for its similar efforts to develop recommendations for the inputs for the new codes.

We have reviewed the recommendations of the CPT Editorial Panel and, with one exception noted below, agree with their new and revised codes for drug administration for 2005. Because the new CPT codes will not be included in the 2005 CPT, we have decided to establish G-codes, where applicable. At this time, we anticipate these new G-codes will be temporary until the new CPT codes become active January 1, 2006.

A listing of the old CPT codes and their corresponding G-codes are in the table below. Some of the old CPT codes will correspond to more than one G-code, and there are codes that will allow physicians to bill for services that previously did not have a code or were bundled into other services.

The drug administration codes are divided into three categories: infusion codes for hydration; codes for therapeutic/diagnostic injections; and chemotherapy administration codes. The descriptions of the codes below are taken primarily from the AMA CPT Editorial Panel. We are including these specific descriptions here in order to provide as much information as possible about the new G-codes prior to their implementation on January 1, 2005. However, we anticipate that we will issue further instructions regarding the appropriate use of these G-codes, including clarifications, interpretations, and other modifications to the following guidance (apart from the G-codes

themselves) as part of any instructions issued through a subregulatory process.

The codes for hydration (G0345 and G0346 in the table below) are for reporting hydration intravenous (IV) infusions consisting of a prepackaged fluid and electrolytes. These codes are not used to report infusion of drugs or other substances. The codes for chemotherapy administration are to be used for reporting the administration of non-radionuclide anti-neoplastic drugs, and anti-neoplastic agents provided for treatment of noncancer diagnoses, or substances such as monoclonal antibody agents and other biologic response modifiers. The remaining codes are for reporting injections and infusions for all drug administrations that were previously reported using CPT codes 90780–90788, 96400, and 96408–96414 (other than those described above as hydration or chemotherapy).

TABLE 8: Comparison of old CPT codes to G codes

Hydration

Old CPT	G Code	Descriptor
90780	G0345	Intravenous infusion, hydration; initial, up to one hour
90781	G0346	each additional hour, up to eight (8) hours

Injections and Infusions (Non-Chemotherapy, other than hydration)

Old CPT	G Code	Descriptor
90780	G0347	Intravenous infusion, for therapy/diagnosis, initial, up to one hour
90781	G0349	additional sequential infusion, up to one hour
90781	G0348	each additional hour, up to eight (8) hours
N/A	G0350	Concurrent infusion

Old CPT	G Code	Descriptor
90782	G0351	Therapeutic or diagnostic injection
90783	N/A	intra-arterial
90784	G0353	intravenous push, single or initial substance/drug
N/A	G0354	each additional sequential intravenous push
90788	N/A	Intramuscular injection of antibiotic
90799	N/A	Unlisted injection or infusion

Chemotherapy Administration

Old CPT	G Code	Descriptor
96400	G0355	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96400	G0356	hormonal anti-neoplastic
96405	N/A	Chemotherapy administration; intralesional, up to and including 7 lesions
96406	N/A	intralesional, more than 7 lesions
96408	G0357	intravenous, push technique, single or initial substance/drug
96408	G0358	intravenous, push technique, each additional substance/drug
96410	G0359	Chemotherapy administration, intravenous infusion technique; Up to one hour, single or initial substance/drug
96412	G0360	each additional hour, one to eight (8) hours
96414	G0361	initiation of prolonged chemotherapy infusion
96412	G0362	each additional sequential infusion, up to one hour
96420	N/A	Chemotherapy administration, intra-arterial; push technique
96422	N/A	infusion technique, up to one hour
96423	N/A	infusion technique, each additional hour, one to eight hours

96425	N/A	infusion technique, initiation of prolonged infusion (more than eight hours)
96440	N/A	Chemotherapy administration into pleural cavity
96445	N/A	Chemotherapy administration into peritoneal cavity
96450	N/A	Chemotherapy administration into CNS
96520	N/A	Refilling and maintenance of portable pump
N/A	G0363	Irrigation of implanted venous access device for drug delivery systems
96530	N/A	Refilling and maintenance of implantable pump
96542	N/A	Chemotherapy injection, subarachnoid or intraventricular via subcutaneous reservoir, single or multiple agents

The following coding guidance is based on the CPT Editorial Panel's explanatory language for the new CPT codes. As noted above, we plan to issue further guidance as needed.

Infusions that were previously reported under CPT code 90780 (non-chemotherapy infusion, 1st hour) will be billed under one of three G-codes beginning January 1, 2005. The first hour of a hydration infusion will be billed under G0345. The first hour of infusion of a nonchemotherapy drug other than hydration will be billed under G0347. The first hour of infusion of anti-neoplastic agents provided for treatment of noncancer diagnoses or substances such as monoclonal antibody agents and other biologic response modifiers is billed under G0359.

Similarly, services that were previously reported under CPT code 90781 (non-chemotherapy infusion, each additional hour) will be billed under one of four G-codes beginning January 1, 2005. Each additional hour of a hydration infusion will be billed under G0346. Each additional hour of a nonchemotherapy infusion will be billed under G0348. Currently, if a second (or other subsequent) nonchemotherapy drug is administered sequentially, the physician would bill code 90781 for the additional hour of infusion. Under the new G-codes, the physician will bill G0349, the sequential administration of a second or subsequent nonchemotherapy drug. In addition, each additional hour of the infusion of anti-neoplastic agents for the treatment of noncancer diagnoses or substances such as monoclonal antibodies and other biological modifiers is billed under G0360.

Injections that were previously billed under CPT code 90782 will now be billed under HCPCS code G0351. Physicians should use HCPCS code G0352 for injections previously billed under CPT code 90783. Nonchemotherapy drugs administered by IV push (currently using CPT code 90784) should now be billed under HCPCS code G0353. The CPT book does not currently contain a code for physicians to bill a second (or other subsequent) nonchemotherapy drug administered by IV push. The CPT Editorial Panel created a new code for each additional nonchemotherapy drug administered by IV push. For 2005, the physician should bill HCPCS code G0354.

The CPT coding system will be deleting code 90788 (Intramuscular injection of antibiotic) in 2006. We are maintaining CPT code 90788 as an active code until it is changed in the CPT coding system and instructions are provided on the code to bill in its place beginning January 1, 2006.

Chemotherapy injections, previously billed under the CPT code 96400, will now be billed using one of two new G-codes. For injection of nonhormonal anti-neoplastic drugs, the physician should bill HCPCS code G0355. For injection of hormonal anti-neoplastic drugs, the physician should bill HCPCS code G0356. CPT is not recommending any changes to CPT codes 96405 (Chemotherapy administration; intralesional, up to and including 7 lesions) and 96406 (more than 7 lesions), and these codes will remain active for Medicare in 2005.

Chemotherapy drugs administered by IV push (currently billed under CPT code 96408, or, if the drug meets the expanded definition of chemotherapy including monoclonal antibodies or other biologic response modifiers, currently billed under CPT code 90784) should be billed using G0357 for the initial drug administered. In 2004, Medicare paid for the second (or other subsequent) chemotherapy drug administered by IV push under CPT code 96408. CPT will be establishing a code that recognizes the resource inputs associated with each additional chemotherapy drug administered by IV push. For 2005, the analogous code to bill the second (or other subsequent) chemotherapy drug administered by IV push is G0358.

The first hour of chemotherapy administration, previously billed under CPT code 96410, should now be billed under CPT code G0359. Each additional hour of chemotherapy (previously billed under CPT code 96412) should now be billed under CPT code G0360. CPT is also recommending a new code for the first hour of a different chemotherapy drug administered sequentially by infusion. If a second chemotherapy drug is administered sequentially, the physician should bill for HCPCS G0362 for the first hour of infusion of the second drug. All additional hours (up to eight total hours) of chemotherapy infusion should be billed using HCPCS code G0360. Prolonged chemotherapy infusions (8 hours or more, previously billed under code 96414) should be billed in 2005 using HCPCS code G0361.

For three codes (G0350, G0354, G0363), the table above has an "N/A" listed in the "Old CPT" column, meaning there were no CPT codes that existed explicitly for these services. These services will now be billable under the new coding system. For instance, CPT will be establishing a code for a "concurrent infusion." A concurrent infusion refers to the simultaneous infusion of two nonchemotherapy drugs. We are using temporary code G0350 for this service. Code G0350 is an add-on code. It must be reported as an "add-on" or with another code and our payment reflects the incremental resources associated with infusing the second drug. For example, if two nonchemotherapy drugs are infused concurrently, the physician bills G0347 for the initial drug infused and G0350 as an add-on.

As indicated above, HCPCS code G0354 is a new code for each additional sequentialnonchemotherapy drug administered by IV push. HCPCS code G0354 is also an add-on code. In general, G0354 will be an add-on to G0353. However, it is possible that a nonchemotherapy drug administered by IV push may follow the administration of a chemotherapy drug administered by IV push, and HCPCS code G0354 would then be an add-on to HCPCS code G0357.

HCPCS code G0363 is a new code for irrigation of an implanted venous access device. There is currently no code to describe this service. Medicare will pay for G0363 if it is the only service provided that day. If there is a visit or other drug administration service provided on the same day, payment for this service is bundled into payment for the other service.

We are creating the following new add-on G-codes: G0346, G0348, G0349, G0350, G0354, G0358, G0360 and G0362. As indicated above, add-on codes must be billed with other codes, and our payment reflects the incremental resources associated with providing the additional service. The initial codes that these add-on codes could potentially be billed with include: G0345, G0347, G0353, G0357 and G0359. If a combination of chemotherapy, nonchemotherapy drugs, and/or hydration is administered by infusion sequentially, the initial code that best describes the service should always be billed irrespective of the order in which the infusions occur.

Comment: In the January 7, 2004 interim final rule with comment, we revised our payment policy for pushes of chemotherapy drugs to allow for payment of multiple pushes of different chemotherapy agents in one day. A commenter asked that we revise our policy for multiple pushes of nonchemotherapy agents, to allow multiple billings on a single day.

Response: The CPT/RUC recommendations address this comment. New codes have been created to account for the resources associated with multiple chemotherapy and nonchemotherapy drugs administered by IV push. HCPCS code G0353 is used for the initial IV push of a nonchemotherapy drug, while HCPCS code G0354 is used for each additional push of a nonchemotherapy drug. For chemotherapy drugs administered by IV push, HCPCS code G0357 is used for the first drug administered, while HCPCS code G0358 is used for each additional drug.

We also note that existing CPT codes 90782–90788 (Therapeutic, prophylactic or diagnostic injections) currently have a status indicator of "T", which means that payment for the service is bundled unless it is the only service billed by the physician for the patient that day. However, based on the RUC recommendations and the resulting values for the injection services, we are making the status indicator on HCPCS codes G0351—G0354 an "A", which will allow them to be separately paid even if another physician fee schedule service is billed for the same patient that day.

Comment: A commenter stated that, given the increased work and practice expense RVUs for drug administration codes, it follows that both the work and practice expense RVUs for the immunization administration codes (90471, 90472, 90473, and 90474) should also be increased. The commenter argued that the service involved in administering vaccines is more intense/complex than the service involved in the drug infusion codes.

Response: We agree with the commenter that the physician work and practice expenses associated with administering injections are similar to immunizations. In addition, we would point out that we currently pay for vaccine administrations (G0008–G0010) based on crosswalking the RVUs to CPT code 90471. Therefore, any changes to the physician work and practice expense RVUs for code 90471 would also affect payments for vaccine administrations.

Because we agree these services should be similar in the amount of physician work involved, we are assigning the physician work value recommended by the RUC for code 90782 (G-code G0351) to code 90471 and HCPCS G-codes G0008–G0010. We are combining the utilization data for all of these codes to determine a single practice expense RVU that will be applied to each of these codes.

We are also assigning a work RVU of 0.15 to code 90472. Codes 90473 (Immunization administration by intranasal or oral route; one vaccine (single or combination vaccine/toxoid)) and 90474 (Each additional vaccine (single or combination vaccine/toxoid)) are currently not covered. We are changing the status of these codes to "R", or restricted, meaning they are payable under some circumstances after carrier review. These codes will be carrier priced.

Comment: If a patient receives chemotherapy infusions, CPT code 96410 is used to report the infusion of the first drug up to one hour. Chemotherapy drugs are usually administered sequentially. Thus, if a patient receives the administration of a second chemotherapy drug at the same treatment session, CPT code 96412 is used to report the infusion of the second drug for each additional hour of infusion. In 2004, the national payment, including the transitional payment adjustment of 32 percent, for CPT code 96410 is $217. The comparable payment for CPT code 96412 is $48.

Commenters pointed out that this policy does not take into account the levels of complexity of administration and resource consumption. The administration of multiple drugs requires additional preparation time, supplies, and patient education, not currently accounted for in CPT code 96412.

Response: The CPT/RUC recommendations addressed this issue. We are implementing new code G0362, Chemotherapy administration, intravenous technique; each additional sequential infusion, up to one hour. This code will allow, effective January 1, 2005, physicians to begin to bill for the first hour of chemotherapy of the second chemotherapy drug administered.

Comment: Several commenters requested clarification that the changes to the drug administration codes resulting from the CPT changes and our G-codes would be exempted from budget neutrality by the provision at section 1848(c)(2)(B)(iv)(III), as added by MMA section 303(a)(1). This provision stipulates that the evaluation of the existing drug administration codes described above as leading to the interim G-codes and the new CPT codes for 2006, is to be exempt from budget neutrality.

Response: The commenters are correct that the additional expenditures that result from the interim G-code changes we are implementing in this rule are exempt from budget neutrality.

Comment: Several commenters asked that we continue payment for drug administration codes at the 2004 levels, which included the 32 percent transitional payment adjustment, instead of paying at the 3 percent transitional payment adjustment for 2005, or adopt other measures. For example, commenters suggested temporary codes to offset the large reductions that would otherwise go into effect in 2005.

Response: Section 303(a)(4) of the MMA is very specific on the application of the transitional payment adjustments in 2004 and 2005. We do not have the legal authority to continue payments based on the 2004 payment levels. In 2005, the transitional adjustment percentage for drug administration

decreases from 32 percent to 3 percent. No transitional percentage is applied in 2006 or subsequent years.

Comment: One commenter requested additional temporary G-codes to offset the payment reductions for oncologists that would otherwise go into effect in 2005. According to this commenter, the payment amount associated with each of these codes would be a percentage add-on amount sufficient to offset the reductions in drug margins and payments for drug administration services.

Response: We have worked extensively with the major associations representing oncologists and their patients to ensure that Medicare continues to pay appropriately for these extremely critical services. The payment changes we made for 2004, the new G-codes, and allowing additional payment for injections and additional infusions, either have already increased, or will increase, payments for drug administration services. The impacts of these changes are discussed extensively in the impact analysis section of this final rule.

In addition, as we indicated above, we plan to analyze any shift or change in utilization patterns once the payment changes for drugs and drug administration required by MMA go into effect. While we do not believe the changes will result in access problems, we plan to continue studying this issue.

Comment: One commenter expressed concern that the reductions in payments to oncologists described in the proposed rule could make it difficult, if not impossible, for many patients to continue to access cancer care in nonhospital community settings.

Response: As noted above, we have taken several steps to increase payments for drug administration services in this final rule. We recognize that oncology patients in the Medicare population undergoing chemotherapy face serious and unique issues and problems related to quality of care throughout the life cycle of their disease process; from the time of first diagnosis, through treatment, until the patient experiences an end to medical (including hospice) care. Patients, national cancer organizations, and medical providers have identified certain factors that they believe affect the comfort and ultimately the care for cancer patients in the physician office setting.

We believe that the goals and objectives of optimal treatment include reviewing and analyzing pain control management, minimization of nausea and vomiting, explaining treatment options, outlining existing chemotherapy regimens, assessing quality of life, assessing patient symptoms and complaints, supporting and educating caregivers, and avoidance of unnecessary Emergency Department visits and inpatient hospitalizations. Further, we believe that clinicians armed with appropriate assessments can proactively intervene with medical treatment and nonmedical assistance to help ameliorate some of the distressing and unpleasant, but frequent and predictable, events that may accompany certain cancers and chemotherapeutic regimens used to combat cancer.

The Secretary has been given the authority under sections 402(a)(1)(B) and 402(a)(2) of the Social Security Act Amendments of 1967 (Pub. L. 90–248), as amended, to develop and engage in experiments and demonstration projects to provide incentives for economy, while maintaining or improving quality in provision of health services. In order to identify and assess certain oncology services in an office-based oncology practice that positively affect outcomes in the Medicare population, we will initiate a one-year demonstration project for CY 2005. While we encourage optimal care in all facets of treatment, the focus of the demonstration project will be on three areas of concern often cited by patients: pain control management, the minimization of nausea and vomiting, and the reduction of fatigue.

Practitioners participating in the project must provide and document specified services related to pain control management and minimization of nausea and vomiting, and the reduction of fatigue. To facilitate the collection of this information, we have established 12 new G-codes to be reported by program participants.

G-Codes for Assessment of Nausea and/or Vomiting

G9021: Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level one: not at all (for use in a Medicare-approved demonstration project).

G9022: Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level two: a little (for use in a Medicare-approved demonstration project).

G9023: Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level three: quite a bit (for use in a Medicare-approved demonstration project).

G9024: Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level four: very much (for use in a Medicare-approved demonstration project).

G-Codes for Assessment for Pain

G9025: Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration, assessment level one: not at all (for use in a Medicare-approved demonstration project).

G9026: Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration, assessment level two: a little (for use in a Medicare-approved demonstration project).

G9027: Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration assessment level three: quite a bit (for use in a Medicare-approved demonstration project).

G9028: Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration, assessment level four: very much (for use in a Medicare-approved demonstration project).

G-Codes for Assessment for Lack of Energy (Fatigue)

G9029: Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level one: not at all (for use in a Medicare approved demonstration project).

G9030: Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level two: a little (for use in a Medicare approved demonstration project).

G9031: Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level three: quite a bit (for use in a Medicare approved demonstration project).

G9032: Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level four: very much (for use in a Medicare-approved demonstration project).

The codes correspond to four patient assessment levels (''not at all,'' ''a little,'' ''quite a bit,'' or ''very much'') for each of the following three patient status factors: nausea and/or vomiting;

pain; and lack of energy (fatigue). These levels, based on the Rotterdam scale, were chosen since they appear to be less burdensome for the practitioner and more easily understood by the patient. Participating practitioners must bill the applicable G-codes for each patient status factor (that is, one G-code each for patient comfort assessment factors: nausea and/or vomiting; pain; and fatigue) assessed during a chemotherapy encounter in order to receive payment under the demonstration. A G-code for each patient status factor must appear on the claim for payment to be made under the demonstration project. A patient chemotherapy encounter is defined as chemotherapy administered through intravenous infusion or push, limited to once per day. During the course of the demonstration, an additional payment of $130 per encounter will be paid to participating practitioners for submitting the patient assessment data as described above.

Any office-based physician or nonphysician practitioner operating within the State scope of practice laws who takes care of and administers chemotherapy to oncology patients in an office setting is eligible to participate in this demonstration project. By billing the designated G-codes, the practitioner self-enrolls in the project and agrees to all of the terms and conditions of the demonstration project.

This information will help us to work with those who care for cancer patients to determine ways to improve the quality of care and quality of life for patients as demonstrated by measuring objective parameters and the medical response to those standardized measurements. The evaluation of the project will be based on data reported to us by the practitioners and the use of our administrative claims data to examine Emergency Department visits and inpatient hospitalizations.

We anticipate that further information regarding this demonstration project will be forthcoming after publication of this final rule.

Comment: Commenters pointed out that, under the MMA, we added physician work RVUs to specified drug administration codes equivalent to a level 1 established office visit. They indicated that we should also have increased the practice expense inputs for the same drug administration codes to account for the practice expense inputs associated with a level 1 established office visit.

Response: Section 1848(c)(2)(H)(iii) of the Act (as added by 303(a)(1)(B) of the MMA) specified that we increase the work RVUs for drug administration services equal to the work RVUs for a level 1 established patient office visit (CPT code 99211). As indicated in the January 7, 2004 **Federal Register** (69 FR 1093), we established work RVUs of 0.17 for specific CPT codes that met the statutory definition of "drug administration services."

However, the legislation did not direct us to also increase the practice expense RVUs of the drug administration codes to include the clinical staff time associated with a level 1 office visit. The practice expense inputs of the existing CPT codes for drug administration were refined in 2002. We believe the recommendations from the PEAC included the typical clinical staff time associated with each drug administration service.

The CPT Editorial Panel approved new and revised codes for drug administration services for 2005. Depending upon the service, the RUC is recommending work RVUs for the new drug administration codes that may equal, exceed or be less than 0.17. Although section 1848(c)(2)(H)(iii) of the Act requires that the work RVUs for drug administration services shall equal those of a level 1 office medical visit, new subparagraph (J) requires the Secretary to "promptly evaluate existing drug administration codes for physicians' services". The statute further indicates that the "Secretary shall use existing processes for the consideration of coding changes and * * * in establishing relative values * * *"

Because we typically use the CPT and RUC processes to establish codes and relative values, we believe the statute gives us authority to establish work RVUs at a level other than those of a level 1 established patient office visit. Therefore, for 2005, we are accepting the RUC recommendations for the interim G-codes even though they result in work RVUs that are different than 0.17.

Comment: Several organizations and physicians commented that the Medicare payments for the chemotherapy codes do not include payment for many services provided by an oncology practice. These services include support services such as nutrition counseling, social work services, case management, psychosocial counseling, and educational services provided by an oncology nurse to the patient.

Response: Under certain circumstances, Medicare does make explicit payment for clinical social worker and medical nutrition therapy services. Medicare can pay separately for the services of clinical psychologists (CPs), clinical social workers (CSWs), and nurse practitioners (NPs), clinical nurse specialists (CNS) and physician assistants (PAs).

CPs can bill directly for services and supplies they are legally authorized by the State to perform that could also be furnished by a physician or incident to a physician's service. Payment for CP services is made at 100 percent of the physician fee schedule for services they are authorized to provide that are comparable to those of a physician.

CSWs can furnish services for the diagnosis and treatment of mental illnesses that they are legally authorized by the State to provide. Payment for CSW services is made at 75 percent of the CP fee schedule, which is 100 percent of the physician fee schedule.

NPs, CNSs and PAs can bill for mental health services consistent with their authority under law to furnish physician services. They may also bill for services furnished incident to their own professional services that fall under the State scopes of practice. Payment for these services is made at 85 percent of the physician fee schedule. Medicare will pay for medical nutrition therapy services provided by a registered dietitian or nutrition professional for a beneficiary with diabetes or renal disease. Based on a comment on our August 20, 2003 proposed rule (68 FR 50428), we understand that social worker services could involve different tasks ("helping patients with their health insurance, filling and refilling prescriptions") than those that are explicitly paid for by Medicare. However, we believe Medicare does pay for these services indirectly through the practice expense RVUs for drug administration services. If these services are typically provided to cancer patients, we believe the RUC could consider whether it is possible for resource inputs for these types of staff to be incorporated into the new drug administration codes. We also believe that the RUC could consider whether these types of staff activities are unique to physicians who provide drug administration or if they apply to other physicians' services as well.

Comment: Current CPT code 96412 (infusion techniques, one to 8 hours, each additional hour) is an add-on code, billed in addition to the primary code, 96410 (the first hour of chemotherapy). There is no national coding policy that explains how this add-on code is to be reported if less than a full hour of chemotherapy infusion is provided. A commenter pointed out that the Medicare carriers have different policies for reporting this service. Some carriers require the infusion to extend at least 16 minutes into the subsequent hour before

an add-on code can be billed, and others impose a 31 minute requirement. The commenter asked that we establish a uniform policy for the carriers to follow.

Response: The CPT Editorial Panel addressed this issue as part of its review of the drug administration codes. Effective in 2006, the add-on code is to be used for "infusion intervals of greater than thirty minutes beyond one hour increments". We are adopting this policy for chemotherapy administration codes furnished on or after January 1, 2005.

Comment: The nonchemotherapy subcutaneous injection is currently reported and paid under CPT code 90782, while a chemotherapy subcutaneous injection is currently reported under CPT code 96400. Some commenters recommended that we permit billing for nonchemotherapy injections for cancer patients to be made under CPT code 96400. They believe this code more appropriately reflects the practice expenses related to supportive care for chemotherapy.

Response: The CPT Editorial Panel explicitly addressed this issue by creating separate drug administration codes for hydration, nonchemotherapy infusions and injections, and chemotherapy infusions and injections. It further expanded the definition of chemotherapy to include those drugs where the resource costs associated with the drug administration are similar to those administered as anti-neoplastics. Other drugs administered in support of chemotherapy, such as anti-emetics and drugs to prevent anemia, are billed using the injection code, G0351, which replaces CPT code 90782 (consistent with the CPT recommendations). We have reviewed the practice expense inputs for this code from the RUC and accepted their recommendation.

Comment: Some commenters asked that complex non-oncology infusions, such as Remicade, be paid at the same level as chemotherapy infusions. They indicate that these nonchemotherapy infusions have similar complexity and resource use as chemotherapy infusions.

Response: The CPT recommendations address this issue. The codes for chemotherapy administration are for reporting the administration of non-radionuclide, anti-neoplastic drugs, anti-neoplastic agents provided for treatment of noncancer diagnoses or substances such as monoclonal antibody agents, and other biologic response modifiers.

Comment: Some commenters inquired about the recognition of a severe drug reaction management code that could be used during the administration of high complexity biologic medications and less frequently during other drug administrations or chemotherapy services. While the CPT Drug Administration Workgroup supported the creation of a severe drug reaction management code, the CPT Editorial Panel did not approve this code.

Response: We recognize that considerable physician effort may be required to monitor and attend to patients who develop significant adverse reactions to chemotherapy drugs, or otherwise have complications in the course of chemotherapy treatment. Physicians may not be aware that these services can be billed using existing CPT codes. The following scenarios are examples where existing codes may be used in addition to the routine billing for the physician's care of a cancer patient:

- Bill for the Physician Visit. If a patient has a significant adverse reaction to drugs during a chemotherapy session and the physician intervenes, the physician could bill for a visit in addition to the chemotherapy administration services.
- Bill for the Higher-Level Physician Visit. If the patient had already seen the physician prior to a chemotherapy session for a problem that is unrelated to the supervision of the administration of chemotherapy drugs, the physician may bill a visit for a significant adverse drug reaction. The total time, resources, and complexity of the physician's interaction with the patient may justify a higher level of visit service.
- Bill for a Prolonged Service. If the patient had a physician visit prior to the chemotherapy session and experienced a significant adverse reaction to drugs on the same day, the physician can bill a prolonged service code in addition to the physician visit. There are several code combinations to use depending on the number of minutes involved. The physician must have a face-to-face encounter with the patient and must spend at least 30 minutes beyond the threshold or typical time for that level of visit for the physician to bill for the prolonged service code.
- Bill for Critical Care Service. If the patient had a physician visit prior to the chemotherapy session and experienced a life-threatening adverse reaction to the drugs, the physician could bill for a critical care service in addition to the visit if the physician's work involves at least 30 minutes of direct face-to-face involvement managing the patient's life-threatening condition. Examples of life-threatening conditions are: central nervous failure, circulatory failure, shock, renal, hepatic, metabolic, and/or respiratory failure.

These instructions are published here for informational purposes, and we anticipate that we will issue further instructions regarding the appropriate use of these G-codes including clarifications, interpretations and other modifications to the following guidance as part of any instructions issued through a subregulatory process.

Comment: The American Urological Association (AUA) commented in response to the January 7, 2004 interim final rule to ask us to include the following codes in the MMA-mandated evaluation of existing drug administration codes for physicians' services to ensure accurate reporting and billing for such services: CPT codes 11980, 11981, 11982, 11983, 51700, 51720, 54200, 54231, and 54235. The AUA asked that we consider applying the transitional adjustment payment to these codes for 2005.

Response: We presented these codes to the CPT Drug Administration Workgroup. After subsequent discussion with representatives of the AUA, the AUA withdrew these codes from consideration by the workgroup.

These codes are not subject to the "transitional adjustment payment provision" because they are not included in the definition of "drug administration codes."

Comment: Ophthalmologists frequently perform the procedure photodynamic therapy (CPT code 67221 and 67225) by infusing the drug Visudyne. While separate payment is allowed for the drug, the infusion is considered an integral part of the photodynamic therapy code. Thus, the physician is not allowed to bill a separate code for the infusion of the drug.

According to one commenter, Visudyne is also a drug used in cancer chemotherapy. The commenter pointed out that when Visudyne is provided for photodynamic therapy, ophthalmologists incur drug administration costs similar to oncologists who use infused drugs.

The AAO asked why we did not include CPT codes 67221 and 67225 among the drug administration codes that benefited under the MMA.

Response: In this instance, the infusion of the drug is an integral part of the surgical procedure and it was valued by the RUC and CMS that way. The code of which it is a part is not considered a drug administration code under section 303 of the MMA.

3. Blood Clotting Factor

For clotting factors furnished on or after January 1, 2005, we proposed to establish a separate payment of $0.05

basis, and we are requesting that the RUC or HCPAC consider this series of three G–codes at an upcoming meeting.

Because RTs cannot directly bill Medicare for their services, these G-codes can only be billed as incident to services in physician offices and outpatient hospital departments or as CORF services. When performed in the CORF setting, these services must be delivered by qualified personnel, that is, RTs and respiratory therapy technicians, as defined at § 485.70. The CORF benefit requires the physician to establish the respiratory therapy plan of care and mandates a 60-day recertification for therapy plans of care, including physical therapy (PT), occupational therapy (OT), speech language pathology (SLP), and respiratory therapy. As we stated in the December 31, 2002 final rule, we believe that specially trained professionals (that is, registered nurses, physical therapists and occupational therapists) can also provide these services.

These respiratory therapy G-codes were designed to provide more specific information about the medically necessary services being provided to improve respiratory function and to substitute for the physical medicine series of CPT codes 97000 through 97799, except when services are furnished and meet all the requirements for physical and occupational therapy services.

Comment: While three commenters voiced concerns about the significant undervaluing of these codes, one commenter noted that the practice expense RVUs fail to recognize the intensity of services and the cost of monitoring and other equipment associated with providing these services.

Response: We agree that the practice expenses, particularly the equipment, for G0237 and G0238 are not equivalent and that there are more resources required to provide the medically necessary services of G0238. The necessary monitoring equipment referenced by commenters were considered at the time G0327 was originally valued. The appropriate direct inputs will be added to the practice expense database. However, we identified the omission of therapeutic exercise equipment for G0238 and G0239 and we will also add this to the practice expense database.

Result of Evaluation of Comments

We are assigning practice expense and malpractice RVUs to G0238 and G0239 and will add the additional items to the practice expense database. These codes are being valued in the nonphysician work pool as proposed. We will also ask the RUC or HCPAC to consider these codes.

4. Bone Marrow Aspiration and Biopsy through the Same Incision on the Same Date of Service.

In the August 5, 2004 rule, we proposed a new add-on G-code, G0364 (proposed as G0XX1): Bone marrow aspiration performed with bone marrow biopsy through same incision on same date of service. The physician would use the CPT code for bone marrow biopsy (38221) and G0364 for the second procedure (bone marrow aspiration).

We believe that there is minimal incremental work associated with performing the second procedure through the same incision during a single encounter. We estimated that the time associated with this G-code is approximately 5 minutes based on a comparison to CPT code 38220 bone marrow aspiration which has 34 minutes of intraservice time and a work RVU of 1.08 work when performed on its own. We proposed 0.16 work RVUs for this new add-on G-code and malpractice RVUs of 0.04 (current malpractice RVUs assigned to CPT code 38220). For practice expense, we proposed the following practice expense inputs:

— Clinical staff time: Registered nurse—5 minutes Lab technician—2 minutes
— Equipment: Exam table

We also proposed a ZZZ global period (code related to another service and is always in the global period of the other service) for this add-on code since this code is related to another service and is included in the global period of the other service.

In the August 5, 2004 proposed rule, we also stated that if the two procedures, aspiration and biopsy, are performed at different sites (for example, contralateral iliac crests, sternum/iliac crest or two separate incisions on the same iliac crest), the −59 modifier, which denotes a distinct procedural service, is appropriate to use and Medicare's multiple procedure rule will apply. In this instance, the CPT codes for aspiration and biopsy are each being used.

Comment: Many commenters supported creation of this G-code; however, all commenters stated that the time for this procedure (5 minutes) was substantially underestimated. Commenters recommended increasing the added incremental time associated with the aspiration to 15 minutes. One commenter noted that this time is needed for the actual aspiration procedure, approving the quality of the aspiration, collecting flow cytometry and chromosome studies, preparing additional slides, ordering appropriate lab tests on the slides, and performing the added recordkeeping and documentation. Another commenter provided a detailed description of the activities involved in this procedure. Commenters also recommended that the practice expense input for the nurse assisting with the procedure should be increased to 15 minutes.

Response: We continue to believe that the proposed 5 minutes of physician time, 5 minutes of registered nurse time, and 2 minutes of lab technician time reflect the additional effort involved when a bone marrow aspiration is performed in conjunction with a bone marrow biopsy through the same incision during a single encounter. It is our understanding that some of the activities attributed to the additional 15 minutes of physician work generally are performed by ancillary staff, for example, preparing slides. While we appreciate the information provided, we believe that the majority of the effort and specific tasks discussed are accounted for in the CPT code for bone marrow biopsy (38221) which is the primary code being billed.

Comment: Two physician specialty societies, representing radiologists and interventional radiologists, questioned the need for the proposed code, because the multiple surgical discount rule that reduces payment for a subsequent lower valued service applies, thereby taking into account any savings in physician work. If we choose to proceed with the proposal, the commenter recommended the RVUs be consistent with those determined using the current values for CPT codes 38220 and 38221 and the multiple surgical discount rule.

Response: One of the primary reasons for our proposal for this G-code was that we believe that, even with the application of the multiple procedure reduction, we would be overpaying for these services when they are performed on the same day, at the same encounter and using the same incision.

Result Of Evaluation of Comments

We are finalizing our proposal and using new G-code G0364, Bone marrow aspiration performed with bone marrow biopsy through the same incision on the same date of service. Payment is based on the work and malpractice RVUs and practice expense inputs proposed and the global period for this service is "ZZZ".

CMS Manual System

Pub 100-20 One-Time Notification Transmittal Sheet

Transmittal 148

Department of Health & Human Services
Center for Medicare and & Medicaid Services
Date: APRIL 15, 2005
Change Request # 3818

SUBJECT: Revised Coding Guidelines for Drug Administration Codes

I. SUMMARY OF CHANGES: This one time notification incorporates revisions to the coding guidelines for drug administration services adopted by the Current Procedural Terminology (CPT) Editorial Panel in February 2005. These revisions pertain to the short duration infusion, the allowable number of concurrent infusions per patient per encounter, and clarification of the term "initial" service for drug administration services. We are also providing corrections to two issues presented in Transmittal 129, released on December 10, 2004, which addressed the 2005 drug administration coding revisions. These corrections relate to the use of modifier 59, instead of modifier 76, for the patient who has to come back for a separately identifiable service on the same day, or has 2 IV lines per protocol and that hydration services are billable only if they are performed sequentially, but not concurrently, to a drug infusion service.

NEW/REVISED MATERIAL :
EFFECTIVE DATE : March 15, 2005
IMPLEMENTATION DATE : May 16, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R = REVISED, N = NEW, D = DELETED – ***Only One Per Row.***

R/N/D	Chapter / Section / Subsection / Title

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

One-Time Notification

**Unless otherwise specified, the effective date is the date of service.*

Attachment – One-Time Notification

Pub. 100-04	Transmittal: 148	Date: April 15, 2005	Change Request 3818

SUBJECT: Revised Coding Guidelines for Drug Administration Codes

I. GENERAL INFORMATION

A. Background: CMS issued Transmittal 129 (2005 Drug Administration Coding Revisions) on December 10, 2004. This transmittal implemented the drug administration policy in the physician fee schedule final rule published in the **Federal Register** on November 15, 2004. In that final rule, we announced that we would adopt G codes for 2005 for drug administration services that correspond to the new CPT drug administration codes that will become effective in 2006. (The 2005 CPT had already been published prior to the adoption of the new and revised drug administration codes.)

In addition to adopting the G codes, we also adopted, in 2005, the CPT coding rules (which remain unpublished until the 2006 CPT book is published) for the new drug administration codes.

We have received a number of questions from our carriers and the oncology community since the issuance of Transmittal 129. When the CPT Editorial Panel met in February 2005, we asked them to consider revised drug administration coding guidelines to address these questions. The Panel approved revised drug administration coding guidelines at this meeting and communicated this information to CMS in a letter dated March 3, 2005.

We are adopting these guidelines now to make for an easier transition next year.

B. Policy: Transmittal 129 incorporates coding guidelines adopted by CPT in September 2004 for drug administration codes. One of these guidelines defines an intravenous or intra-arterial push as an injection/infusion of short duration (i.e., 30 minutes or less) in which the healthcare professional who administers the substance/drug is continuously present to administer the injection and observe the patient.

We have received a number of questions from the carriers and the oncology community on this guideline. The most notable question is whether the professional administering the infusion must be continuously present to administer the infusion and observe the patient or whether this requirement only applies to the push itself. Concerns have also been raised from the medical community that an infusion is not a push and should not be coded as such.

In February 2005, the CPT Editorial Panel met and discussed revisions to the coding guidelines for drug administration codes for 2006. The CPT sent a letter to CMS on March 3, 2005 noting that it would be desirable from the perspective of the American Medical Association and the CPT Editorial Panel to resolve implementation issues associated with the earlier drug administration guidelines. For the short duration infusion, the CPT Editorial Panel Meeting adopted the following coding guideline (which will appear in the 2006 book):

Intravenous or intra-arterial push is defined as: an injection in which the healthcare professional who administers the substance/drug is continuously present to administer the injection and observe the patient; or an infusion of 15 minutes or less.

<u>Concurrent Infusions</u>

For 2005, there is a new drug administration code for a concurrent infusion. The specific G code is: G0350 *Intravenous infusion, for therapy/diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for procedure)*

Transmittal 129 did not limit the billing of concurrent infusions.

At its February meeting, the CPT Editorial Panel Meeting adopted the coding guideline that the concurrent infusion code is reported only once per encounter.

We are adopting this guideline effective with the implementation date of this transmittal. The carrier shall allow payment for only one concurrent infusion per patient per encounter. The carrier shall not allow payment for G0350 if it is billed with modifier 59 unless this is provided during a second encounter on the same day with the patient and is accompanied by supporting medical documentation.

<u>Initial Code</u>

Transmittal 129 stated the initial code is "the code that best describes the service the patient is receiving and the additional codes are secondary to the initial code".

At its February 2005 meeting, the CPT clarified that the initial code best describes the key or primary reason for the encounter and should always be reported irrespective of the order in which the infusions or injections occur.

<u>Implementation of Revised Coding Guidelines</u>

We are adopting these guidelines in 2005 and not waiting to implement these guidelines until the 2006 CPT book is published. The carriers shall implement these revised guidelines effective with the implementation date of this transmittal. The carriers shall make no adjustments to claims that were processed and paid under the previous guidelines unless brought to their attention.

<u>Corrections</u>

Transmittal 129 stated the policy in section 30.5 C of Chapter 12 of Pub. 100-04 that permits separate payment of hydration therapy sequentially (but not concurrently) to the chemotherapy applies to services furnished in 2005. However, later in Transmittal 129, it incorrectly stated that: "Report G0346 to identify hydration furnished concurrent with G0359". To be consistent with section 30.5C, this statement should read, "Report G0346 to identify hydration **not** furnished concurrent with G0359" (emphasis added).

Transmittal 129 included the statement, “If the patient has to come back for a separately identifiable service on the same day, or has 2 IV lines per protocol, these services are separately payable and reported with modifier 76”. We understand that the use of modifier 59, instead of 76, is more appropriate for this arrangement. We are including a revised business requirement to reflect this revision.

II. BUSINESS REQUIREMENTS

“Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3818.1	Effective for dates of service on and after March 15, 2005, contractors shall use the revised CPT coding guidelines for drug administration codes listed above in section I., B., Policy, of this CR.			X						
3818.2	Effective for dates of service on and after March 15, 2005, contractors shall allow payment for only one concurrent infusion code per patient per encounter. The concurrent infusion code is G0350.			X						
3818.3	Effective for dates of service on and after March 15, 2005, if more than one concurrent infusion is billed per patient per encounter, contractors shall deny the second concurrent infusion code and generate the appropriate message(s), such as: MSN 15.1 (The information provided does not support the need for this many services or items.); Claims Adjustment Reason Code 151 (Payment adjusted because the payer deems the information submitted does not support this many services.); Remittance Advice Code N20 (Service not payable with other service rendered on the same date.).			X						
3818.4	The contractors shall not allow payment of G0350 if it is billed with modifier 59 unless this is a service provided for the same patient for a second encounter on the same day and is			X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		F I	R H H I	C a rr i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
	accompanied by medical documentation									
3818.5	If more than one "initial" service code is billed per day, contractors shall deny the second "initial" service code and generate MSN messages 18.16 and 16.45 and Remittance Advice remark code M86 (unless the patient has to come back for a separately identifiable service on the same day or has two IV lines per protocol). For these separately identifiable services, instruct the biller to report with modifier 59.			X						
3818.6	Contractors shall not reopen or adjust claims already processed unless brought to their attention.			X						

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		F I	R H H I	C a rr i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3818.7	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider			X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matter articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. Contractors shall educate the physician community via Medlearn Matters article about the new coding guidelines adopted by CMS.									

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A
D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: March 15, 2005 **Implementation Date:** May 16, 2005	**No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating**

Pre-Implementation Contact(s): James Menas, 410-786-4507 JMenas@cms.hhs.gov; Kathleen Kersell 410-786-2033, KKersell@cms.hhs.gov **Post-Implementation Contact(s):**	**budgets.**

***Unless otherwise specified, the effective date is the date of service.**

To our patients,

The Medicare program is collecting data to better understand cancer patients' symptoms during chemotherapy. Our practice is participating in this data collection effort.

Using the form below, please record your experiences of pain, fatigue and nausea. Your answers to these questions will help us care for your symptoms during your treatment.

Thank you,

____

(Practice)

Patient Name: ______________________________

Date: ___/___/_____

Patient Symptom Assessment

Please indicate the extent to which you have been bothered by each symptom, by circling the most appropriate answer.

During the past week, have you been bothered by:

Nausea and/or vomiting?

Not at all | A little | Quite a bit | Very Much

Pain?

Not at all | A little | Quite a bit | Very Much

Lack of energy (fatigue)?

Not at all | A little | Quite a bit | Very Much

____

(Provider Signature)