# MAKING SENSE OF *the Conundrum*

## Medicare reimbursement for new FDA-approved drugs and biologics

*by Denise K. Pierce*

You know the scenario…The FDA has approved a new oncology drug or biologic, and patients are quickly identified who could ideally benefit from the treatment. Sounds like an easy process—just order the new drug and treat the patient, right? If only the situation were so simple. In this evolving reimbursement environment and with the increasing cost of newer drugs and biologics, cancer programs must confirm the three important components of reimbursement: coverage, coding, and payment—particularly with Medicare patients. This article will help community cancer centers answer three key questions surrounding Medicare drug reimbursement:

- Will Medicare cover the new drug or biologic?
- What documentation is required to identify the new drug or biologic to support claims payment?
- When and how will a Medicare contractor (MAC, FI, or Carrier) pay for a new drug or biologic?

### Coverage of New Drugs and Biologics

In the absence of a national policy from the Centers for Medicare & Medicaid Services (CMS), local Medicare contractors have the discretion to establish their own coverage position for a new FDA-approved drug or biologic. However, because Medicare reimburses for most FDA-approved cancer drugs, coverage tends not to be the issue. The real challenge for community cancer centers is to ensure that the drug or biologic is correctly identified through coding or some unique documentation to allow for claims payment.

Conventionally, when a new oncology drug or biologic enters the market, the manufacturer will send a drug announcement to payers, including Medicare Carriers, Fiscal Intermediaries (FIs), and Medicare Administrative Contractors (MACs). These mailings include key information such as the FDA approval letter, pivotal clinical trial documents, and the product package insert. This information is also sent to the Medicare medical directors and many policy analysts to help them develop an awareness and understanding of the new oncology agent.

Although most manufacturers have processes in place to work with payers on development of coverage, coding, and payment of the new drug or biologic, community cancer centers can take proactive steps to help ensure that their respective Medicare contractors are covering the new drug or biologic. Most important, the contractors' medical policy decision makers want to know that there is demand for the new agent, with that information coming from providers, rather than manufacturers.

**Step 1:** ***Call the drug manufacturer's reimbursement hotline.*** Many times, the hotline will already have information that confirms the coverage status and documentation requirements for a new oncology agent. Community cancer centers can often find information about drug replacement or patient assistance programs through these hotlines as well. Cancer centers can proactively work with their patients to enroll in these programs. Upon demonstration of payer denial these support programs will become effective. Keep in mind, however, that each program has different eligibility requirements.

**Step 2:** ***Contact your state medical oncology society and request support.*** Many state oncology societies establish a committee or individual to communicate directly with Medicare and other payers on the availability of new drugs and biologics. If this committee or individual does not already have the clinical and FDA approval information for the new agent, the drug manufacturer can usually deliver information to the society leadership to help with any Medicare communications.

**Step 3:** ***Contact your respective Medicare Contractor Advisory Committee (CAC) Representative.*** Your oncology CAC representative is invaluable in holding direct conversations with the medical director of your Medicare contractor. So, for example, this individual can deliver a review of what the ideal patient profile may be for the agent, and work with the medical director to identify the best way to process claims.

As you attempt to find out the reimbursement status of a new drug or biologic, keep the following factors in mind. First, Medicare contractors may not post information about a new FDA-approved drug or biologic on their website. Second, Medicare contractors may never publish a formal local coverage determination (LCD), or they may integrate the new drug or biologic into a current, broader LCD for drugs and biologics—a process that may not occur for several months. And because LCDs are generally developed based on concerns that a certain drug may be over-utilized, do not consider the lack of an LCD to be a negative sign. Remember, most Medicare contractors will inherently cover the agent as per the FDA-approved indications. Third, when you call provider relations representatives, understand that they may not be aware of the new drug or biologic. Why? Because new drugs or biologics are billed using a miscellaneous J-code that are not represented in their (i.e., the provider relations representatives') claims processing screens. Most important, the lack of an LCD or the absence of the new drug in your provider relations computer programs does *not* mean that the new drug or biologic will be denied payment. It simply means that CMS 1500 (for practices) or UB 04 (for hospitals) claims for new FDA-approved drugs and biologics require additional detail and will be suspended for manual review in order to confirm coverage, coding, and calculate payment.

**Table 1. Current Oncology Drugs and Biologics Billed with a Miscellaneous J-Code***

| Generic Name | Code Designation | Brand Name | Billing Unit of Use | Medicare Allowable per Unit of Use |
|---|---|---|---|---|
| Bendamustine HCl | J9999 | Treanda | 1 mg | $19.08 |
| Ixabepilone | J9999 | Ixempra | 1 mg | $63.74 |
| Temsirolimus | J9999 | Torisel | Per 25 mg kit | $1,194.04 |

Source: Centers for Medicare & Medicaid Services (CMS). Payment allowance limits for Medicare Part B Not Otherwise Classified (NOC) Drugs. Effective July 1, 2008 through September 30, 2008.
*Physician practices only

**Table 2. Current Oncology Drugs and Biologics Billed with a Miscellaneous or Temporary C-Code+**

| Generic Name | Code Designation | Brand Name | Billing Unit of Use | Medicare Allowable per Unit of Use |
|---|---|---|---|---|
| Bendamustine HCl | C9399 | Treanda | 1 mg | 95% of AWP |
| Ixabepilone | C9240 | Ixempra | 1 mg | ASP+5% |
| Temsirolimus | C9239 | Torisel | 1 mg | ASP+5% |

Sources: Centers for Medicare & Medicaid Services (CMS). HCPCS Quarterly Update, January, 2008. CMS Manual System. Pub. 100-04 Medicare Claims Processing Transmittal 188. 5/28/2004; CHANGE REQUEST 3287.
+Hospital outpatient setting only

## Claims Documentation Requirements

New drugs and biologics are billed using one of four miscellaneous codes: J3490, J3590, and J9999 for practices and C9399 for hospital outpatient services. At any given time, numerous drugs are billed under these miscellaneous codes. In the CMS 2008 Quarter Three Pricing List for Not Otherwise Classified (NOC) Drugs, 74 Part B drugs were billed with a miscellaneous code.

For oncology practices, if a drug is classified as a chemotherapy agent, use code J9999. If the drug is a biologic, it can be billed using J3590 or J9999. The decision for which code to use will be at the discretion of your Medicare contractor. Table 1 lists the current oncology drugs that physician practices should bill using a miscellaneous code.

For hospital-based outpatient cancer centers, all new FDA-approved drugs are billed using the miscellaneous code C9399 until a drug-specific C-code is established. (C-codes are generally assigned three months after the drug is used by providers, which may be more than three months after FDA approval.) C9399 is an all-encompassing C-code, and is not differentiated by biological or chemotherapy agent. Table 2 lists the current oncology drugs that hospitals should bill using a miscellaneous or temporary C-code.

Because of the miscellaneous code billing process, Medicare contractors require documentation on a CMS 1500 claim form to help physician practices distinguish the different drugs and biologics. And while the claim will be suspended for manual pricing and payment, the claim will be matched up more quickly with drug information available at the Medicare contractor, such as the product package insert, or the NOC pricing list. Perhaps most important: each Medicare contractor may have different documentation requirements on the 1500 claim form. In most cases, if any information required by a particular contractor is *not* included, the claim will likely be denied. (Table 3 demonstrates this variation in Medicare contractor requirements for a new FDA-approved drug.)

While documentation requirements can also vary from contractor to contractor in the hospital outpatient setting, most UB-04 claims require the following information:

- Designation of revenue code 0636
- Name of the drug (brand and generic) in remarks section
- NDC code listed in remarks section
- Quantity of drug administered in remarks section
- Specific date(s) that the drug is administered in remarks section.

On the date of service line, the unit of use for billing is most commonly 1 vial until CMS assigns the drug a specific C-code. Generally, if any of the information above is missing or omitted, the claims form will be denied or returned to the provider with a reason code identifying lack of information.

Clarifying precisely what the Medicare contractor requires is extremely important, as it can mean the difference between an approved and denied claim. Here are two practical tips for community cancer centers to consider:

- Contact the manufacturer's reimbursement hotline. As reimbursement hotlines and manufacturer's field personnel identify Medicare requirements, they often will share this information with providers.
- Contact your respective Medicare contractor's medical director or policy analyst to clarify requirements. Provider Relations representatives do not have the level of knowledge necessary to inform you of claim submission

requirements for new drugs and biologics. Instead, contact—either individually, or through your state oncology society or CAC representative—your Medicare contractor medical director or policy analyst to confirm accurate documentation requirements for claim submissions. Then inform the Medicare carrier that claims are being submitted for the new drug or biologic.

## How will Medicare Pay for New Drugs?

Under current law, electronic claims are not to be paid any sooner than 14 days (29 days for paper claims) and not later than the 30th day after they are submitted (otherwise, CMS must pay interest on those claims). With a new FDA-approved drug, individual Medicare contractors may take the full 30 days to provide a response on the claim. In some cases, if the claim is considered in error (perhaps the appropriate documentation is not supplied or the coding doesn't match their systems) or if additional medical necessity information is required, the contractor will suspend the claim, request more information, and start the review time clock all over again.

According to the *2008 Medicare Claims Processing Manual*[1]:

> *The payment allowance limits for new drugs and biologics that are produced or distributed under a new drug application (or other new application) approved by the Food and Drug Administration, and that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, are based on 106 percent of the WAC, or invoice pricing if the WAC is not published, except under OPPS where the payment allowance limit is 95 percent of the published AWP. This policy applies only to new drugs that were first sold on or after January 1, 2005. At the contractors' discretion, contractors may contact CMS to obtain payment limits for new drugs not included in the quarterly ASP or NOC files or otherwise made available by CMS on the CMS web site. If the payment limit is available from CMS, contractors will substitute CMS-provided payment limits for pricing based on WAC or invoice pricing. CMS will provide the payment limits either directly to the requesting contractor or via posting an MS Excel file on the CMS Web site.*

In other words, this regulation states that claims submitted from the physician office setting will be paid at WAC (wholesale acquisition cost) + 6 percent, as long as there is documentation of published WAC. The WAC + 6 percent pricing will remain in effect until CMS has enough data to calculate an ASP for the new drug or biologic. In the hospital outpatient setting, new drugs and biologics are paid at 95 percent of the drug's AWP (average wholesale price) until CMS can establish an ASP (average sales price) payment rate.

This information is reviewed in a *Medicare Learning Network Matters* article, published on May 23, 2008. The article, entitled "Average Sales Price (ASP) Updates," can be accessed online at: *http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5798.pdf*.

Based on this regulation, some Medicare contractors may suspend a new drug claim and request submission of an invoice for the drug because the pricing databases that they subscribe to (e.g., Redbook) may only be received on a quarterly basis. In this scenario, if a drug is FDA approved in the next quarter's time period, Medicare contractors would not receive the WAC (wholesale acquisition cost) pricing for almost six months. In these cases, contact the drug manufacturer, who likely has WAC pricing information that can be submitted to the Medicare contractor. This proactive step can negate the need to submit drug invoices.

## NOC Pricing File

For oncology practices, the NOC Drug Pricing File details drugs that currently are billed using a miscellaneous code, such as J3490, J3590, or J9999. This list is different than the ASP drug list, which reflects allowables for drugs and biologics that have been assigned unique J- or Q-codes. Medicare contractors, prior to listing on the NOC Drug Pricing File, may require that a new drug be billed using a contractor-specific unit of use methodology. This is often one vial = one unit of use.

The NOC Drug Pricing File is updated each quarter. Once a new drug or biologic is added to the NOC drug pricing list, the contractor's unique unit of use billing will convert to the unit of use billing outlined in the NOC drug pricing list. For instance, the one unit of use of one vial may transition to a one unit of use of 1 mg. Oncology practices must reference the NOC drug pricing list to ensure that they do not under-bill the amount of drug administered to the patient. The payment methodology basis might also change once a new drug or biologic is added to the NOC drug pricing list. In some cases, CMS may have enough information from the drug's manufacturer to establish ASP pricing for the NOC drug pricing list. If not, the pricing reflected in the NOC drug pricing list will most commonly be WAC+6 percent.

You can access the NOC Drug Pricing File online at: *http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01a_2008aspfiles.asp#TopOfPage*.

Here are two tips for ensuring appropriate payment of new drugs and biologics.

First, because Medicare regulations cite that Medicare contractors should pay based on invoice *only if* they do not have WAC pricing available for new drugs and biologics, oncology practices should always contact manufacturers to request an invoice that will establish pricing for the drug or biologic. By receiving the WAC information and submitting it to the Medicare contractor, your practice can ensure appropriate payment on claims for new drugs and biologics.

Second, check your Medicare contractor website for updates to the quarterly NOC Drug Pricing File. At the beginning of each quarter (January, April, July, and October), Medicare contractors publish on their websites, updates to the NOC Drug Pricing File, as per the CMS changes. Oncology practices must remain educated on any changes in unit of use billing, and allowable rate (whether WAC- or ASP-based), so they can ensure the most accurate billing for drug(s) administered.

## HCPCS Release Code Set

For hospitals, CMS publishes a quarterly update to all HCPCS codes, with one of the files specific to new C-codes for use in the hospital outpatient setting. Once

**Table 3. Examples of CMS 1500 Physician Office Claims Documentation for New FDA-Approved Drugs and Biologics**

| Contractor | Drug Name | Dose Administered | Form of Administration | NDC Code | JW Modifier (Required to denote drug wastage) | Unit of Use (Until drug is listed on NOC Drug Pricing File) |
|---|---|---|---|---|---|---|
| **First Coast** | Yes. Generic name in Field 19/remarks. | Yes. In Field 19/remarks. | No | Yes. In Field 19/ remarks. | No | 1 unit = 1 vial |
| **NGS Medicare** | Yes. Brand and generic name in Field 19/remarks. | Yes. In Field 19/remarks. | No | Yes. In Field 19/ remarks. | No | 1 unit = 1 vial |
| **Noridian MAC** | Yes. Brand and generic name in Field 19/remarks. | Yes. In Field 19/remarks. | No | No. | No | Manually calculated from dosing in Field 19/ remarks |
| **Palmetto GBA** | Yes. Include brand and generic names. | Yes. In Field 19/remarks. | No | No | No | 1 unit = 1 vial |
| **Trailblazer** | Yes. Include brand and generic names. | Yes. In Field 19/remarks. | Yes. In Field 19/ remarks. | Not required, but information is helpful. | Yes. In general claim lines. | 1 unit = 1 vial |
| **WPS (Wisconsin Physician Services)** | Yes. Include brand and generic in Field 19/ remarks. | Yes. In Field 19/remarks. | N/A | N/A | N/A | Only 1 unit can be billed no matter how much drug is delivered. |

the new FDA-approved drug or biologic is listed in this HCPCS Release Code Set update, the contractor's unique unit of use billing will convert to the unit of use billing outlined in the C-code update. For example, a one unit of use may convert from one vial to 1 mg. In order to ensure that they are not under-billing for drug administration, hospitals must ensure that their coders and billers reference this list. The payment methodology basis can also change once a new drug or biologic is listed in this update. In some cases, for example, CMS may have enough data from the manufacturer to establish ASP pricing for the drug or biologic. If so, the payment allowable will now be ASP+5 percent.

You can access the HCPCS Release Code Set updates online at: *http://www.cms.hhs.gov/HCPCSReleaseCodeSets/02_HCPCS_Quarterly_Update.asp*. To ensure appropriate billing and adequate reimbursement, hospital-based outpatient cancer centers should monitor updates to the HCPCS Release Code Set. At the beginning of each quarter (January, April, July, and October), Medicare contractors publish updates to the files on their websites, per the CMS changes.

By taking a proactive approach with manufacturers, state oncology societies, CAC representatives, and Medicare contractor policy decision makers, oncology practices and hospital-based outpatient cancer centers may be able to minimize obstacles for patient access to new, novel therapies that can make a difference in treatment outcomes.

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## References

[1]Centers for Medicare & Medicaid Services. *Medicare Claims Processing Manual*. Chapter 1: Drugs and Biologics. 20.1.3: Exceptions to Average Sales Price (ASP) Payment Methodology. (Rev. 1513; Issued: 05-23-08; Effective/Implementation Date: 06-23-08).