Reimbursement and Patient Assistance Programs for Oral Chemotherapy Agents

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The increased use of oral chemotherapy agents, rising cost of health care, and increasing numbers of under- and uninsured patients have resulted in oncology nurses being asked about reimbursement for these agents. As patient advocates, nurses need to be informed about Medicare reimbursement guidelines and medication assistance programs available to patients. In many small clinic and office settings, case managers and social workers are not available, and oncology nurses must fill this role.

This article reviews information about Medicare reimbursement for oral chemotherapy agents and medication assistance programs for patients who are receiving these drugs. Case studies with questions are presented at the beginning of each section, and the answers are listed at the end.

Medicare Coverage

Case study 1: B.H. is a 68-year-old man with an anaplastic astrocytoma that has progressed despite chemotherapy and radiation therapy. The oncologist would like to start B.H. on temozolomide. B.H. asks you about the cost of the medication and whether Medicare covers this drug. What is your response?

Medicare is the federal health insurance program available to people aged 65 and older, some people with disabilities under age 65, and people with end-stage renal disease (ESRD) with permanent kidney failure requiring dialysis or a kidney transplant. Medicare has two components: Part A is hospital insurance, and Part B is medical insurance. Part A coverage does not charge premiums for people who are aged 65 and older and have paid or have a spouse who paid Medicare taxes for at least 10 years. If patients or spouses did not pay Medicare taxes, they are still eligible to obtain Part A’s free premiums if they have been entitled to disability benefits for 24 months or have ESRD and receive dialysis or have received a kidney transplant. A premium is charged to people who have less than 30 quarters (7.5 years) of Medicare-covered employment. For 2003, the premium is $316 per month. People with 30–39 quarters (7.5–9.75 years) of Medicare-covered employment pay a premium of $174 per month (Centers for Medicare & Medicaid Services [CMS], 2003).

Part B Medicare coverage is medical insurance with a monthly premium in 2003 of $58.70 per month. Enrolling in Part B is optional, and enrollees may sign up anytime in a seven-month period beginning three months prior to their 65th birthday. If they do not enroll during this period, they still may enroll but premiums increase by 10% for every year that they were eligible to enroll but did not. Medicare Part B coverage has a $100 annual deductible. Medicare Parts A and B cover different costs and areas of health care (CMS, 2003). For instance, Medicare Part A covers the hospital portion of a facility fee. Medicare Part B helps to cover the following, with conditions:

- Hospital care
- Skilled nursing facility care
- Home health care
- Hospice care
- Blood and blood products
- Medical services and durable medical equipment
- Clinical laboratory services
- Home health care
- Outpatient hospital services
- Blood and blood products

People receiving Medicare benefits are responsible for 20% of their healthcare costs, and Medicare covers the remainder. When a facility or Medicare service provider agrees to take what is termed “Medicare assignment,” they accept the payment that Medicare will reimburse for a particular service or medication.

Choice plans or Medigap plans provide people receiving Medicare benefits with extra purchaseable coverage. Some choice plans are managed-care plans and cover extra costs not covered by Medicare, such as prescription drugs, eye examinations, hearing aids, and routine physical examinations. Medicare recipients with a secondary managed-care plan usually must see a physician or specialist associated with the plan. Another type of secondary insurance plan is a private fee-for-service plan. Medicare recipients with this type of secondary coverage generally have a wider choice of healthcare providers and are eligible for additional benefits. However, the cost may be high for this type of supplemental Medicare coverage. Detailed information

Key Words: healthcare costs; prescriptions, drug; drug costs

Oncology nurses increasingly are being asked about medication insurance coverage for oral chemotherapy agents and other medications. In small clinic and office settings, nurses often are key providers of this information. Nurses need to be informed about Medicare’s medication reimbursement guidelines and able to identify resources for patients. Resources may include pharmaceutical manufacturers, patient medication assistance programs, and medication discount programs. This article reviews these resources and provides tips to use them optimally in busy oncology practices.

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about these programs is available on the Medicare Web site (www.medicare.gov). Nurses need to be aware that these plans may have limited enrollment periods. For instance, in many Medigap plans, people may enroll only during the six-month period after the first day of the month in which they turn age 65 or older and enroll in Medicare Part B (CMS, 2003).

The dilemma this creates for some people with cancer is that if they defer enrolling in choice plans or Medigap plans and attempt to enroll after they have been diagnosed with cancer, additional coverage options are very limited or may be unavailable because many plans will not cover preexisting diseases. However, in this situation, these patients still are eligible for Medicare Part A and B benefits. Considering that half of all cancers occur in people aged 65 or older (Jemal et al., 2003), this often is a significant issue for patients cared for by oncology nurses.

**Prescription Medication Costs**

Medicare beneficiaries tend to have chronic health problems and often require multiple prescription medications. Data from the 1997 Medicare Current Beneficiary Survey of Cost and Use indicated that Medicare beneficiaries spent approximately 10% of their incomes on prescription medications (Sambamoorthi, Shea, & Crystal, 2003). Even when Medicare beneficiaries have private medication coverage, they still pay copayments or coinsurance amounts with each filled prescription (ranging from $5–$20), which contribute to out-of-pocket medical expenses (Mott & Schommer, 2002).

Prescription medication access and reimbursement are not problems isolated to Medicare recipients; patients with Medicaid and even private insurance coverage may experience financial concerns related to medication costs. For instance, a study conducted by the Center for Health System Change found that one in four Medicaid recipients aged 18–64 was not able to afford at least one prescribed medication in 2001 (Cunningham, 2002).

Limited medication insurance coverage combined with out-of-pocket medical expenses have the potential to cause patients with cancer to “pick and choose” which prescriptions they have filled or may cause them to attempt to reduce other costs of living, such as reducing food costs by buying less nutritious food, so they can afford their medications. Some costs of cancer care, such as oral chemotherapy, may cause financial distress because few of these drugs currently are covered by Medicare.

**Oral Chemotherapy Coverage**

Medicare does not cover most prescription drugs at this time. Oral chemotherapy agents are covered if the same drug is available in an injectable form. The agents that, as of July 2003, are covered by Medicare are (CMS, 2003)

- Busulfan
- Capsaicin
- Cyclophosphamide
- Etoposide
- Melphalan
- Methotrexate
- Temozolomide.

Medicare also funds oral antiemetics for patients receiving a Medicare-covered oral chemotherapy agent if the antiemetic completely replaces an IV antiemetic for a 24–48 hour period of that chemotherapy regimen cycle (CMS).

Patients obtain Medicare-covered oral chemotherapy agents by taking the prescription to a pharmacy or medication supplier that is enrolled in the Medicare program. The list of approved providers is available on the Medicare Web site. If the provider is Medicare approved and takes assignment, patients are responsible for 20% of the medication costs and the provider submits a charge to Medicare for the remaining 80% (CMS). If the pharmacy or medication supplier does not take Medicare assignment, it may ask that patients pay in full when their prescriptions are filled. The pharmacy then submits the claim to Medicare. Medicare reimburses patients for their share of the bill. If a claim is not filed, Medicare will not pay. The time limit on submitting claims ranges from 15–27 months, depending on local Medicare carriers (CMS, 2003).

All of the suppliers and pharmacies that dispense oral chemotherapy agents or oral antiemetics must have a Durable Medical Equipment Regional Carrier number to bill Medicare. When submitting the charges, they also must submit the J code for the oral chemotherapy agent and a Q code for the oral antiemetic. These codes are numbers that the Medicare system uses to identify the medication. The International Classification of Diseases (ICD)-9 code for the patients’ diagnoses also must be identified on the submitted document (CMS, 2003).

Among the challenges of reimbursement for oral chemotherapy is the lack of reimbursement for patient education. Oncology nurses can provide one-on-one teaching to educate patients about the prescribed oral chemotherapy agent, dosing, schedule of administration, side effects, symptom management, safety issues, and follow-up monitoring, which require lengthy teaching sessions. The majority of third-party payors and Medicare do not reimburse for these services.

**Case study 1 answers:** Your response should be: “Temozolomide is covered under Medicare Part B. You will be responsible for 20% of the cost of the drug in addition to your deductible if you have not met the $100 deductible amount. I will check to see if the pharmacy you routinely use is a Medicare provider and takes assignment. If your pharmacy does not take assignment, your cost will be more than the 20% you would pay under Medicare Part B coverage.”

As healthcare advocates, oncology nurses may want to visit the Medicare Web site and download information about Medicare providers in their communities and note whether they take Medicare assignment. Pharmacies commonly do not take assignment. For example, in one community, only one pharmacy takes Medicare assignment although 26 others are considered providers.

**Oral Chemotherapy Prescribed for Noncovered Indications**

Case study 2: A 68-year-old woman with multiple myeloma is scheduled to begin treatment with thalidomide. Her husband asks if Medicare covers the medication. You inform the couple that thalidomide is not covered by Medicare and ask if the patient has other prescription drug coverage. She does, and her husband agrees to contact their insurance company to discuss coverage of thalidomide to treat multiple myeloma. A day later, the husband calls to inform you that an insurance company representative says that thalidomide is not approved under their plan for treatment of multiple myeloma. What is your next step?

Very often, oncology nurses coordinate or assist in coordinating the process and paperwork to appeal a denied insurance claim or provide the information necessary to request consideration of coverage. When contacting an insurance company, obtain the name and title of the representative and retain this information for future use if needed. Request names and addresses to send appeal letters as this may be different than the address used to submit claims. Usually, these letters are addressed to physicians or other medical professionals at the insurance company who have the responsibility of reviewing these types of requests (Bedell, Hartigan, Wilkinson, & Halpern, 2002).
Appeal letters need to include several elements. First, the patients’ diagnoses and past treatment histories should be described. Next, the proposed treatment plan should be stated, including specific information about the chemotherapy agent, dose, route, frequency, and anticipated duration of therapy. Reference to clinical trial data or inclusion of journal articles or professional society abstracts (e.g., American Society of Clinical Oncology, American Society of Hematology) provides supporting documentation. A valuable resource to nurses is the pharmaceutical company that manufactures the chemotherapy agent. Quite often, pharmaceutical companies can provide supporting documentation and guidance for pursuing consideration of coverage by the insurance companies.

The patients’ treating physicians usually draft letters to insurance companies, but in many settings, this is done by or with oncology nurses or other staff. Request that the insurance company notify patients regarding a time frame for making a determination about providing or not providing coverage for the medication, and advise patients to keep records of all correspondence with insurance companies.

**Case study 2 answers:** Following verbal denial of insurance coverage for an oral chemotherapy agent, a letter to the insurance company to advocate on the patient’s behalf is usually the next step. Figure 1 is an example of this type of letter.

### Medication Assistance Programs

**Case study 3: G.O. is a 65-year-old woman with stage II breast cancer that is estrogen and progesterone receptor positive.** She has completed adjuvant chemotherapy, and her physician would like her to begin tamoxifen 10 mg twice daily for five years. G.O. has no retirement income aside from Social Security and has no supplemental insurance other than Medicare Parts A and B. The physician has asked you to identify medication assistance programs for which this patient may be eligible. What is your plan of action?

Most pharmaceutical companies have programs to assist under- and uninsured patients as part of their commitment to charitable efforts. Eligibility criteria and enrollment procedures vary. For instance, many companies base eligibility on income level and other considerations, such as household size, self-paid expenses, inability to participate in government programs covering pharmaceuticals, and other financial criteria. Some organizations base eligibility on a specific household income (e.g., less than $25,000 per year), and others base eligibility on multiples of the federal poverty level adjusted for household size. Some also require that a copy of patients’ income tax returns be included with the application (Viale & Mister, 2001).

Information about medication reimbursement and medication assistance programs is available on pharmaceutical manufacturers’ Web sites (see Figure 2). Facts on reimbursement and payment assistance also are available on government, organization, and other informational Web sites and by telephone (the name of the company that manufactures the medication can be found in the package insert or by consulting resources, such as the Physicians’ Desk Reference or Facts and Comparisons). The following are examples of Web sites that contain information about medication assistance programs for patients.

- [www.medicare.gov/Prescription/Home.asp](http://www.medicare.gov/Prescription/Home.asp)
- [www.cms.hhs.gov/medicaid](http://www.cms.hhs.gov/medicaid)
- [www.ta.nodeyeds.com](http://www.ta.nodeyeds.com)
- [www.va.gov](http://www.va.gov)

The Veteran’s Administration Web site and office (877-222-VETS) have information about medication assistance for active and retired military personnel and their families. The National Mail-Order Pharmacy Program (www.tricare.osd.mil) is available to veterans and their families.

Figure 1. Sample Insurance Appeal Letter

[Date]
[Name and address of insurance company]

Dear [Name of person to direct letter to]:

A.S. is a 68-year-old woman with stage II multiple myeloma whose disease has progressed following prior treatment with melphalan and prednisone chemotherapy, and, most recently, treatment consisting of vincristine, carmustine, doxorubicin, and prednisone. I have recommended to her that she be treated with thalidomide 200 mg per day and dexamethasone 40 mg every week. Recent clinical trial data have shown that this regimen is active in the treatment of patients with multiple myeloma who have had extensive prior treatment and require further treatment. A three-month trial of thalidomide is proposed and has about a 30% chance of controlling her disease. Because of A.S.’s extensive prior treatment, she has developed progressive pancytopenia; therefore, treatment with thalidomide is an attractive option for her. Please review the attached supporting journal articles enclosed along with this request. Because I would like to initiate treatment as soon as possible, I would appreciate a prompt response to this request and ask that you inform the patient approximately how long the review process will take for you to consider this request.

Thank you for your attention to this matter.

Sincerely,

[Physician name and signature]
The site also has information on poverty guidelines and medication discount cards. A written guide containing all of the applications and information available on the Web site can be purchased for $135, and updates for the year of purchase and supplements for future years are offered at discounted cost.  
- www.helpingpatients.org  
This site is sponsored by 48 pharmaceutical companies known as the Pharmaceutical and Research Manufacturers Association (PhRMA, 2003) and may be searched using the medication name or pharmaceutical company. Extensive information about covered medications, patient eligibility criteria, contacts, and downloadable applications is available at the site.  
- www.rxhope.com  
This site has information on medication assistance programs but requires registration in order to access the site. (Physicians or other healthcare providers must supply their Drug Enforcement Agency numbers as part of the registration process.) This site is supported by PhRMA and has a request-tracking mechanism and patient information-management section that can be used to store and track patient data related to medication assistance requests.  
- www.cancersupportivecare.com/drug_assistance.html  
This Web site has an extensive list of 29 pharmaceutical company medication assistance programs, provides contact information, and lists medications by trade and generic names.  
- www.RXAssist.org  
This site is supported by the Robert Wood Johnson Foundation and provides a free search for medications by trade or generic name, drug class, or manufacturing company. It also provides information about the program and application process with printable forms. For a fee, a software program can be used to set up a patient assistance program in a clinical, office, or another setting.  
- www.themedicineprogram.com  
This site assists patients with the enrollment process for a processing fee of $5 for each medication requested. (This fee is refunded if the patient is deemed ineligible for medication assistance.) The application is sent directly to the Medicine Program. All other programs are free of charge, and the applications are sent to the drug companies.

### Medication Discount Programs

Discount programs’ medication prices are to assist patients who do not have prescription medication coverage and do not qualify for state programs or pharmaceutical medication assistance programs because their income level is too high to meet the programs’ eligibility requirements. Eligibility requirements vary. For example, some of the pro-
programs are limited to Medicare beneficiaries who do not have prescription medication coverage, and others do not have age or income stipulations. Examples of discount programs are listed in Figure 3. Other pharmacy programs also are available, and patients should be encouraged to investigate their options. Organizations such as the American Association of Retired Persons (AARP) have group medication plans. AARP can be contacted by phone at 800-456-2277, or visit its Web site at www.aarppharmacy.com. Some have a fee or require membership. These programs also can assist with reducing the cost of many of the supportive medications that patients need, such as antiemetics, or routine medications, that include cardiac medications, diuretics, and anticoagulants.

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<th>FIGURE 3. DRUG DISCOUNT CARDS AND RELATED INFORMATIONa</th>
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<td>aFor patients who do not qualify for patient medication assistance programs but have limited financial resources</td>
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**Note.** Based on information retrieved July 4, 2003, from pharmaceutical company Web sites.

### Eli Lilly—Lilly Answers Card
877-RX-LILLY (795-4559); www.lillyanswers.com
- Offers all Lilly medications with the exception of controlled substances
- Eligibility: Medicare beneficiaries without prescription medication coverage with incomes less than $18,000 for individuals and less than $24,000 per household
- Cost of medication: $12 charge for each 30-day supply of medication; medications are obtained from participating pharmacies.

### GlaxoSmithKline—The Orange Card
888-ORANGE6 (672-6436)
- Offers all GlaxoSmithKline medications
- Eligibility: Medicare beneficiaries without prescription medication coverage with incomes less than $30,000 for individuals and less than $40,000 for couples
- Cost of medication: Varies; discount is approximately 30%. Medications can be obtained at participating pharmacies.
- Note: Patients can participate in either the Orange Card or Together Rx (see Together Rx Card) for GlaxoSmithKline medications; however, the Orange Card has higher income limits.

### Nonprofit Warehouse
770-541-7777; www.nonprofitwarehouse.com
- Offers wide variety of medications from various manufacturers
- Eligibility: No age or income limits
- Cost of medication: Varies depending on the medication, but discount is generally 25% or more at participating pharmacies.

### Novartis—The Care Card
866-974-CARE (2273); http://novartiscareplan.com
- Offers select medications
- Eligibility: Medicare beneficiaries without prescription medication coverage with income less than 300% of poverty level ($28,000 for individuals and $38,000 for couples)
- Cost of medication: Discount up to 50% off regular retail price on generic medications and up to 15% on brand name medications at participating pharmacies.

### Pfizer—The Share Card
800-717-6005; www.pfizerforliving.com/sharecard
- Offers all Pfizer medications
- Eligibility: Medicare beneficiaries over age 65 without prescription coverage with income less than $18,000 for individuals and less than $24,000 for couples
- Cost of medication: $15 for each 30-day supply of medication at participating pharmacies.

### Together Rx Card
800-865-7211; www.together_rx.com
- Offers select medications from participating manufacturers (about 150 select medications manufactured by Abbott Laboratories, AstraZeneca, Aventis Pharmaceuticals, Bristol-Myers Squibb, GlaxoSmithKline, Janssen, Johnson & Johnson, and Novartis)
- Eligibility: Medicare beneficiaries without prescription coverage with income less than $28,000 for individuals and less than $38,000 for couples (Alaska and Hawaii residents have higher income limits.)
- Cost of medication: Varies depending on the company, and discounts range from 20%–40% at participating pharmacies.

### Case study 3 answers:
After determining that tamoxifen is manufactured by AstraZeneca, the nurse contacts the company’s patient assistance program. The nurse arranges for G.O. to complete and submit an application to AstraZeneca’s Patient Assistance Foundation. G.O. is informed that she qualifies for the program and will receive a monthly supply of tamoxifen for $5. She will need to reapply for the AstraZeneca program annually.

#### Legislative Action

The Access to Cancer Therapies Act bill, which would expand 1993 legislation and mandate Medicare coverage of all oral cancer agents, is being reintroduced in the House of Representatives (Froner, 2003). This legislation would increase the number of oral agents for cancer treatment covered by Medicare to all oral cancer medications approved by the U.S. Food and Drug Administration. The bill has more than 50 cosponsors and was supported by the National Coalition for Cancer Survivorship but failed to be passed in the 107th session of Congress. House Representative Deborah Pryce has reintroduced this legislation. Letters, e-mails, and phone calls to support this legislation may to be sent to congressional representatives. Contact information for local representatives is available online at http://thomas.loc.gov, www.senate.gov, and www.house.gov.

The Oncology Nursing Society Advocacy in Health Care tool kit contains an informative section titled, “Being Effective in the Health Policy Arena” (Gomez, 2002). The tool kit provides guidance on letter writing and e-mail communication with legislators. Other ideas to support legislative action include encouraging patients to write personal letters and share their stories with their congressional representatives, visit their representatives in person, and use other avenues of advocacy (e.g., newspaper and television interviews, writing letters to the editors of newspapers and magazines). The Oncology Nursing Society Legislative Action Center
Practical Tips for Managing Patient Assistance Programs in Your Practice

- Maintain and periodically update a list of medication assistance programs and resources. For frequently used medications, keep a stock of medication assistance applications available to avoid searching for the form online to print out for patients.
- If you have computer access, find the medication assistance search site that you are most comfortable with and bookmark it (mark it as a “favorite”) on your computer.
- Maintain a file on every patient who is applying for or enrolled in a medication assistance program. Keep copies of applications and all documents sent or faxed and the date they were sent.
- Keep a log of when you sent forms, contact information, and any course of action related to this program.
- Encourage patients or caregivers to participate in this process. Having patients or caregivers assume this responsibility helps to give them a sense of control and frees up valuable time for nurses.

Summary

As healthcare resources decline and increasing numbers of patients are under- or uninsured, oncology nurses will assume an even greater role in assisting patients with their financial concerns. Many resources are available to healthcare providers and patients, and all are accessible via telephone or the Internet. Nurses play an important role in locating appropriate resources for patients with no or limited prescription medication coverage but can optimize this role only when they are fully informed about these resources and familiar with accessing them.

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References


For more information on this topic, visit the following Web sites.

Association of Community Cancer Centers: Oral Chemotherapy, Cytostatic, and Supportive Care Agents: New Opportunities and Challenges
http://www.accc-cancer.org/pubs/march00/oral.htm

Toronto-Sunnybrook Regional Cancer Centre: Accessing Medication
http://www.tsrcc.on.ca/HotSpot/Vol4Iss3Sup.pdf

Links can be found at www.ons.org.