



Academy of  
Managed Care  
Pharmacy®

## **Practice Advisory on Drug Coverage Parity across Medical and Pharmacy Benefits**

### **Introduction**

Oncology medications have historically been administered intravenously in a physician's office, infusion center or hospital. Over the past decade, the emergence of orally-administered agents has increased treatment options and changed the way in which many patients are treated. These new treatment options present the need for important considerations for health care decision-makers, both those prescribing and ordering medications and those making coverage decisions.

The Academy of Managed Care Pharmacy realizes that medical and pharmacy benefit design influences decisions that prescribers and patients make about medication therapy. This paper presents issues that arise when contemplating benefit design drug coverage parity issues. Although this paper looks at issues related to oral oncology medications, similar considerations are applicable to medications for rheumatoid arthritis, multiple sclerosis and other disease states in the future.

Policymakers are currently debating legislative proposals that would mandate coverage for oral oncology treatments in the same manner as intravenously administered oncology agents. The legislative proposals and policy debates focus almost entirely on the cost-burden imposed for the various methods of medication delivery. This practice advisory addresses not only those cost issues but also patient care considerations that are important when analyzing the relative merits of oral versus intravenously administered medications.

### **Discussion**

Traditionally benefit designs for coverage of intravenous and oral medications have determined that costs for intravenous medications be paid through the medical benefit, and costs for oral medications be paid through the pharmacy benefit. This practice advisory focuses on oncology medications, which have historically been administered intravenously in a physician's office, infusion center or hospital.

During the past decade, there has been a significant increase in the number of oral oncology agents in development. Oral oncology agents are seen as a potential therapeutic advancement by freeing patients of the need to make regular visits to physician offices, infusion centers, or hospitals for lengthy intravenous infusions. According to a March 2008 National Comprehensive Cancer Network (NCCN) Task Force report, an estimated

one quarter of the 400 antineoplastic oncology agents currently in the pipeline are oral agents.<sup>1</sup>

With the introduction of high-cost oral oncology agents paid under the pharmacy benefit, the situation has arisen where patients receiving oral oncology drugs are faced with significant cost burdens, often well in excess of the expenses a patient would be expected to bear for an intravenous oncology agent. Intravenously administered oncology regimens typically require modest office visit copayments with a maximum out-of-pocket expenditure for the patient. Conversely, medications covered under the pharmacy benefit are often covered under copayment or coinsurance benefit designs with no maximum out-of-pocket patient expenditures. Given the cost of some oncology agents and coinsurance ranging from 10% to 25%, the out-of-pocket expenditures for medications under the pharmacy benefit can be high.

The NCCN Task Force report notes that the annual cost of an oral oncology agent used in the treatment of multiple myeloma is \$74,000. Another oral agent used to treat chronic myelogenous leukemia ranges in cost from \$29,000 to \$57,000 annually, depending on dosage, and accounts for the largest percentage of spending on oral oncology agents. Although oral oncology agents still constitute only a small proportion of total pharmacy-benefit costs, spending on these agents as a proportion of total drug benefits costs more than doubled between 2002 and 2006, from 0.3% to 0.7%.<sup>2</sup>

This disparity in patient cost burden has spurred legislative activity in various states to require comparable levels of coverage (“coverage parity”) for oral and intravenous oncology medications. Many state legislatures have adopted or are considering legislation that requires health plans to provide coverage for orally administered oncology medications comparable to the coverage they provide for oncology medications administered intravenously.

- Since 2007, coverage parity for oncology medication legislation has been enacted in eight states (Connecticut, Colorado, Hawaii, Indiana, Iowa, Minnesota, Oregon, & Vermont) as well as the District of Columbia. Three other states (Louisiana, New Hampshire, & New Mexico) have enacted study bills.
- Additionally, in 2009-2010, 26 other state legislatures have had bills introduced on this subject.

Legislation has varied in language, with two main themes developing:

- Requirements that oral oncology drugs be covered at costs no less favorable to a patient than intravenously administered chemotherapy agents; or,
- Requirements that all oral oncology drugs be covered under the medical benefit.

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<sup>1</sup> SN Weingart et al, NCCN Task Force Report: Oral chemotherapy, *J Natl Compr Canc Netw*. 2008;6[Suppl 3]:S1-S14 <http://www.ncbi.nlm.nih.gov/pubmed/18377852> (accessed May 25, 2010).

<sup>2</sup> Curtiss FR. Pharmacy benefit spending on oral chemotherapy drugs. *J Managed Care Pharm* 2006; 12: 570-777. <http://www.amcp.org/data/jmcp/Sept06Journal4.pdf> (accessed August 10, 2010)

According to a 2010 client report prepared by Milliman, Inc. and commissioned by GlaxoSmithKline, oral oncology benefit parity will cost under \$0.50 per member per month (pmpm) for most benefit plans. However, there are a wide variety of benefit design variations which can affect parity costs. Parity costs for plan designs with very high cost sharing for oral specialty drugs and low cost sharing for medical benefits could cost about \$1.00 pmpm.<sup>3</sup>

## **Patient Care Considerations**

Aside from financial issues, there are many patient care considerations that should be considered when analyzing the relative merits of oral versus intravenously administered oncology agents. Evidence based treatment guidelines, including those issued by NCCN, recommend various oncology protocols targeted to a particular cancer and stage. These recommendations are made without regard to the route of administration. Protocols may recommend an oral agent, an infused agent, or a combination of agents, but the protocols rarely offer a choice of either infused or oral.<sup>4</sup> For some types of cancer, like chronic myelogenous leukemia (CML), the best treatment option may be an oral oncology agent. For other situations, oral and infused treatments may present therapeutic options that are roughly equivalent clinically.

Traditional oncology regimens usually involve a patient being treated under the supervision of a medical professional within a physician's office, an outpatient infusion center or a hospital setting.

Oral oncology regimens require a patient to take the medications exactly as prescribed, with an average regimen consisting of up to 10 to 20 tablets each day. Oral oncology treatment affords both flexibility and convenience to the patient. However, this mode of dosing does remove the patient from a setting with direct medical supervision.

The newer oral oncology medications can offer significant options for patients that were not previously available. Obviously, the oral route of administration offers several advantages over intravenously administered routes. These may include ease of administration, patient preference, and lower risk of complications. Other advantages and savings are lower cost of administration, (e.g., not incurring the direct costs in medical professional time, medical supplies, and intravenous pumps) and lower indirect costs associated with travel time to medical facilities and caregiver time. Oral agents may also have fewer side effects thus leading to improved tolerance and adherence to therapy.

Some concerns have been raised about whether patients prescribed oral oncology agents will always take the appropriate dose and whether side-effects may be missed. Research has been published indicating that some patients on oral oncology agents are not adherent

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<sup>3</sup> Milliman Inc., *Parity for Oral and Intravenous/Injected Cancer Drugs*. January 25, 2010, p. 1. <http://publications.milliman.com/research/health-rr/pdfs/parity-oral-intravenous-injected.pdf> (accessed August 11, 2010)

<sup>4</sup> Milliman Inc., *Parity for Oral and Intravenous/Injected Cancer Drugs*.

to their medication regimen as prescribed.<sup>5,6</sup> Adherence to parenteral therapy is far more straightforward because it is administered in a controlled environment. Conversely, compliance with oral therapy is a more complex and multifaceted issue. In a 2002 analysis, it was found that factors associated with nonadherence to oral oncology medication regimens — complex treatment protocols, inadequate supervision, dissatisfaction with care, inadequate social support — required substantial changes in behavior.<sup>7</sup> In addition, financial barriers related to the cost of oncology medications may discourage appropriate utilization. When selecting an oral medication, an emphasis on the importance of medication adherence must be explained to patients.

The unique requirements often necessary to handle and manage oral oncology agents obligate pharmacists to acquire special expertise. Since this expertise is not always available in community or mail service practices, health plans and other managed care organizations have developed alternative approaches to the delivery of these specialty pharmaceuticals. For example, some managed care organizations contract with specialty pharmacies. Specialty pharmacies are licensed entities providing services to meet the unique challenges of dispensing and monitoring the use of these complex regimen and treatment protocols.<sup>8</sup>

Several oral oncology agents now require a risk evaluation and mitigation strategy (REMS) program with limited distribution networks. Due to the expertise required in dispensing these medications, some oral oncology agents are distributed only through specialty pharmacy providers. This will require the patients to enroll in a program allowing them access to the services and the medication. Such programs provide identification of specialty pharmacies that distribute the medication, assistance with reimbursement and coverage questions, product information and support with medication adherence.

## Conclusion

New treatment options present the need for those prescribing medications and those making benefit design decisions to analyze current practices to ensure that decisions on the use of oral or intravenously administered medications are made based on what best meets the patient's treatment needs, rather than patient financial considerations resulting from coverage differences between oral and intravenously administered medications.

Health care practitioners managing medication coverage under medical and pharmacy benefits should take action when disparate patient burdens between the two benefit

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<sup>5</sup> W. Feng et al, Compliance and persistency with imatinib, *J Clin Oncol* (Meeting Abstracts) 2006 24: 6038. [http://meeting.ascopubs.org/cgi/content/abstract/24/18\\_suppl/6038](http://meeting.ascopubs.org/cgi/content/abstract/24/18_suppl/6038) (accessed May 25, 2010).

<sup>6</sup> AH Partridge et al, Adherence to Initial Adjuvant Anastrozole Therapy Among Women With Early-Stage Breast Cancer, *J Clin Oncol*, 2008; 24:556-62. <http://www.jco.ascopubs.org/cgi/content/abstract/26/4/556> (accessed May 25, 2010).

<sup>7</sup> AH Partridge et al, Adherence to Therapy With Oral Antineoplastic Agents, *J Natl Cancer Inst*. 2002;94:652-661

<sup>8</sup> Academy of Managed Care Pharmacy, *Concept Series Paper on Specialty Pharmaceuticals*, 2007. <http://www.amcp.org/amcp.ark?p=AAAC630C> (accessed on April 23, 2010).

structures might adversely impact therapeutic decisions. The introduction of high-cost oral agents serves as a reminder that historic medication coverage differences between medical and pharmacy benefits may not serve patients well today.

Health care practitioners in managed care organizations determining how oral oncology agents will be covered for members must be cognizant of the complex decision-making process that goes into the selection of the most appropriate oncology regimen for an individual patient. Benefit design should allow for the selection of oncology agents to be made by qualified health care practitioners using the best available evidence, rather than being dictated by patient financial burden. Legislative mandates may result when the selection of agents is influenced by patient cost factors that are based on the method or site of administration.

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