Oncology management is coming into focus as a key strategy for payers within their specialty pharmacy management programs. Historically, oncology was unmanaged as a result of limited therapeutic options, and the majority of drugs were delivered to patients by infusion in the physician’s office or in the hospital setting. The approval of high-cost oral cancer agents in the past few years has increased the importance of oncology for payers, with managed care trend reports placing oncology as the third highest category of specialty drug spending, after rheumatoid arthritis and multiple sclerosis.1

More than 900 oncology drugs are currently in development, and more than 50% of these are oral agents.2 The 15 oral cancer drugs approved by the US Food and Drug Administration in the past 10 years are now targets for management by health plans. The utilization management (UM) programs that have been used for the traditional small molecules are now being expanded to cover specialty drugs, including oral and infusible oncology agents. Overall, health plans cover infused drugs under the medical benefit and oral drugs under the pharmacy benefit, which can pose management challenges, because the claim systems for each benefit typically do not communicate directly with one another. It requires manual systems and pharmacists or nurse case managers to implement these controls.

Specialty Pharmacy
Specialty pharmacies will play a key role in the management of oral cancer drugs for health plans. These pharmacies provide effective product distribution, promote compliance, reduce waste, offer nursing and pharmacist expertise by disease and by drug, and deliver the drugs at a lower reimbursement rate than traditional retail pharmacies. They can also develop, manage, and implement UM programs for health plans, or the health plan can develop UM programs and let the specialty pharmacy operate them.

Specific control strategies include prior authorizations, step-edits, quantity limits, pathways, guidelines, increased patient cost-sharing, diagnostic testing, and preferred formularies driven by drug cost differences and manufacturer contracts. A prior authorization is the most effective method for driving appropriate use in oncology as plans restrict access based on the approved labeling, with restrictions by indication, and additional access may be allowed if the drug is listed in compendia or in published guidelines from credible groups, such as the National Comprehensive Cancer Network or the American Society of Clinical Oncology.

Step-edits are most often used for ancillary medications, including antinauseants or blood cell growth factor agents, in which interchanges of agents are well received by prescribers. Step-edits are growing in importance for oncology-specific categories in which a number of agents have been approved for the same indication, including chronic myelogenous leukemia (CML), renal-cell carcinoma, and castration-resistant metastatic prostate cancer. The recent approval of generic drugs for cancer, including letrozole and aromatase inhibitors, has allowed health plans to require the use of generics for first-line therapy before brand-name drugs in an effort to control costs. The pending launch of generic imatinib has several plans focusing attention on CML, promoting imatinib for first-line use now in anticipation of the potential savings when the generic equivalent becomes available.

The challenge to using generic cancer agents may be similar to the situation with HIV drugs, with newer brand-name drugs often replacing older ones before the generics are being launched, resulting in the value of generics being severely limited, because the standard of care has shifted to the newer, more targeted agents, and the generic drug is no longer a viable first-line option for newly diagnosed patients.

Molecular Diagnostics
Genomic testing and molecular diagnostics provide additional guidance and support for the management of targeted cancer drugs, with health plans adding specific testing as part of the requirements for coverage of certain drugs. Certainly the use of molecular diagnostic assays or drug-specific diagnostics will enhance the appropriate use of agents and allow for the management of select therapies. This is an area of potential growth and significant value, but we have a long way to go before it is routinely part of the treatment paradigm for most cancers. For example, tumor classification is unknown or, at best, is uncertain in more than 33% of patients with metastatic disease.3
In general, health plans support diagnostic testing, provided that they affect care in a positive way either by directing a treatment approach or by changing an existing strategy for care. Perhaps the greatest potential for molecular diagnostics is the ability to avoid giving a patient a drug that will not work based on that patient’s genetic profile, and eliminate the potential side effects that would place the patient at risk for other medical complications and would also drive up costs.

Copay and Coinsurance

Standard quantity limits of 30-day supplies are routinely used as part of the specialty pharmacy distribution model. A typical oral cancer agent can cost ≥$6000 monthly, and plans want to avoid waste; in addition, side effects, lack of response, or change in the stage of cancer may make the continued use of an agent inappropriate.

Another common strategy is to use a short-fill or short-cycle dispensing program. In this case, the specialty pharmacy will ship a 1- or 2-week supply of a new medication and will communicate with the patient about his or her ability to tolerate the medication and allow for discontinuation of subsequent refills, as appropriate. The patient is charged a copay or coinsurance on the first fill, and subsequent refills adjust for any additional coinsurance as needed. Industry estimates suggest that a 25% savings in drug cost can be achieved with this type of program.

Increases in copays and coinsurance are occurring across all specialty drugs, as employers seek relief from high costs of drug benefits. Commercial plan members may have access to copay assistance programs, but Medicare patients are not allowed to participate in them.

A number of states have passed legislation to limit the out-of-pocket costs for consumers; in particular, the oral chemotherapy parity laws require the cost burden for patients to be equivalent for the medical benefit and the pharmacy benefit drugs. Recent trend surveys suggest that 50% of patients have a coinsurance in the medical benefit, which has been increasing steadily over the past 2 to 3 years. This will assist health plans in their efforts to manage pharmacy and medical benefit drugs used to treat the same cancer.

Formulary Management

Plans can also use formulary management strategies to increase the utilization of preferred treatments. Benefit designs may limit restrictions on preferred agents by tier, require out-of-pocket differences, and impose higher restrictions on nonpreferred agents. Medicare plans are challenged by oncology agents as being a protected class by statute; however, they can still use some level of UM if managed carefully. Another challenge in formulary management involves state laws that mandate off-label coverage for oncology agents provided that there is a compendia listing or published clinical evidence to support the off-label use. These laws have discouraged some health plans from using any restrictions, based on the belief that any therapy that is restricted will likely be approved on appeal. Recently, the pressure of the growth in cancer drugs has reduced this concern among payers, and all payers are now using some level of UM programs for oncology drugs.

Pathways

Pathway programs are an interesting new management approach designed to improve clinical and economic outcomes for specific cancer diagnoses by incorporating evidence-based information into treatment. To be successful, pathway programs need to include a formal treatment guideline; physician support (some experts suggest that an 80% concurrence rate is needed for success); robust information technology systems; and clinical support from pharmacists, nurse case managers, and care coordinators.

Pathways decrease variation in care, promote quality, improve care coordination and communication among the treatment team, and optimize overall resources. Pathways are physician-directed, require routine evaluation and evidence updates, empower patients, and may decrease litigation risk for providers, as a result of increased patient involvement in their treatment.

Expanding Oncology Management

It is evident that oncology management will continue to expand, and health plans will apply any reasonable UM strategies to promote appropriate use, improve clinical outcomes, and achieve cost-effectiveness. Several other types of therapy are also candidates for UM programs, including the use of palliative care, hospice care, pain management, and health and wellness programs, such as nutritional support and exercise. A coordinated care team will be needed to effectively manage patients with cancer throughout the course of their disease, from initial diagnosis to placement on an effective therapeutic regimen and any subsequent maintenance regimens. Health plans welcome this challenge, and look forward to improvements in technology, medication development, and diagnostics to achieve greater success in the management of patients with cancer.

References