

Oral Chemotherapy Issue Brief

Oral chemotherapy represents an important breakthrough in treatment options for people living with cancer. Since its rapid development over the past 10 years, oral chemotherapy has changed the landscape of treatment options for providers, as well as the quality of life for patients living with cancer. However, oral chemotherapies present new risks in health care delivery as patients take responsibility for their own treatment. Through any course of chemotherapy, and especially with new oral agents, the role of the oncology pharmacist is essential in ensuring patient safety. Also, much work remains to ensure equal access to oral chemotherapies to allow patients and their health care providers the ability to make the best decisions about the course of their cancer treatment.

Oncology Pharmacists and Oral Chemotherapy

Prior to the advent of oral agents, chemotherapy was primarily administered intravenously in clinic or hospital settings, requiring travel and multiple visits per month for most patients. Since oral agents are administered by the patient (or a caregiver) in their home, oncology pharmacists have an increasingly important role to play to ensure that patients understand and adhere to their treatment regimen and administer the medication safely.

- Oncology pharmacists monitor oral chemotherapy treatments to prevent medication and food interactions, adverse drug reactions, and medication errors.
- Patient education programs are important to help individuals understand the proper administration, handling, storage and disposal for oral chemotherapy.
- There is sometimes a false patient perception that oral chemotherapy agents are less dangerous than traditional intravenous (IV) chemotherapy, furthering supporting the important role of the pharmacist in educating the patients about the medication, its adverse effects, how to manage toxicities, and when to contact their health care team.

Patient Benefits of Oral Chemotherapy

Cancer treatment is a stressful time for patients and their families. The introduction of oral chemotherapy presents many benefits to both patients and the health care system. Oral medications have demonstrated similar efficacy to their IV counterparts, from preventing further tumor growth to totally killing a tumor, and they can be used throughout the disease spectrum, from induction to maintenance therapy.

- There have been over 30 oral chemotherapies approved by the FDA over the past 10 years.
- It is estimated that oral agents comprise more than 30 percent of the 900 chemotherapy treatments in the development pipeline.
- Oral chemotherapy requires fewer health care resources as patients can administer the medication at home, following the guidance of skilled health care professionals.
- Patients using oral chemotherapies have a greater sense of control over their treatment, experience less interference with daily work and social activities, and may not need to experience the pain and discomfort of an IV chemotherapy line.

Chemotherapy Reimbursement

In contrast to the rapidly evolving treatment options for cancer patients, medical and pharmacy benefits in the United States have remained relatively static. IV and oral chemotherapy medications have different dispensing sites, which often dictate which portion of a patient's health insurance provides coverage. Although treatment outcomes may be similar, a disparity exists in out-of-pocket payments required of patients with cancer.

- IV medication—administered in an outpatient infusion clinic—is usually covered through the medical benefit whereas oral medication is covered under the pharmacy benefit.
- Often, patients pay a much larger proportion of the overall cost under prescription benefits compared with IV agents covered under the medical benefit.
- Most insurance plans place orally administered chemotherapy into a “specialty tier” or “fourth or fifth specialty tier,” which may require a cost-sharing responsibility for the patient of anywhere from 25 to 33 percent of the cost of the drug, leading to copays which can be \$2000-\$7000 per month.

Impact on Patients

Financial disparity between oral and IV chemotherapy reimbursement can create serious barriers to care when orally administered chemotherapy is the most appropriate treatment option. Unfortunately, affordability of care is often the most significant factor affecting treatment success. Treatment is often delayed because of payer rules requiring prior authorization and manufacturer rules requiring patients to obtain their medication through a mail order, specialty pharmacy, rather than their regular pharmacy provider.

- While some patients qualify for copayment cards and assistance funds as a stop-gap to bridge the disparity in cost for oral medications, these funds cannot meet the needs of all patients and some payers prohibit their use. As a result, many patients remain ineligible for assistance based on the type of insurance, income requirements, or availability of copayment assistance program funding.
- The financial constraints imposed by out-of-pocket expenses may force patients to choose an alternative IV treatment (which may not be the most effective therapy for their specific type of cancer) or abandon their therapy all together.
- Requiring patients to receive their medication from a specialty pharmacy leads to a fragmented medication list, coordination of care issues, and poses significant patient safety concerns.

Oral Chemotherapy Parity Laws

To ensure selection of therapy is based on scientific evidence rather than route or administration location, it is critical to support legislation that will address the oral chemotherapy disparity. Thirty-five states including the District of Columbia have passed oral chemotherapy access legislation and an additional seven have legislation pending. To date no federal legislation has passed to ensure equal access to oral chemotherapy.

HOPA Recommendations

- Encourage appropriate training and patient education by a qualified practitioner to ensure patient safety during oral chemotherapy treatments.
- Support national legislation to amend the Employee Retirement Income Security Act of 1975 to require insurance plans to provide no less favorable coverage for orally administered chemotherapy than they do for IV chemotherapy.