



BACKGROUND INFORMATION

Oral Oncolytics

Context – Access Challenges for Oral Oncolytics

There are a number of issues unique to oral oncolytics (chemotherapy drugs administered orally rather than by intravenous infusion) that influence prescribing decisions. These challenges ultimately may lead to a discrepancy in access to oral versus intravenous (IV) oncolytics. These issues are becoming increasingly pronounced as the role of oral drugs in the treatment of cancer continues to evolve.

With oral oncolytics currently encompassing 35 percent of the oncology pipeline, many different stakeholders are developing strategies to address the specific challenges related to the problem as outlined below. Community oncology practices face these challenges in delivering high-quality care to their patients.

Clinical

Treatment decisions related to oral oncolytics are complex and often directly influenced by non-clinical factors. IV and oral oncolytics are not always interchangeable. A variety of factors, both clinical and non-clinical, influence treatment decisions. Providers must determine patient eligibility for oral oncolytics; however, the standard protocols for determining appropriateness are not consistently employed. Oral oncolytics add an additional level of complexity related to patient safety. While clinicians oversee IV administration, they cannot guarantee integrity of oral oncolytics when these are delivered outside the clinic, such as when patients must manage their own dosing schedules.

Administrative

There are many components in delivering oncology care that require a significant investment of time and resources. Oncology practices are structured to manage and administer IV oncolytics, but oral oncolytics do not fit within this structure. Oral medications require additional staff to process insurance (verify eligibility, complete prior authorization requirements, etc.) prior to prescribing. Oral oncolytics are often distributed via specialty pharmacies, each of which has different policies and procedures for patients as they attempt to obtain the prescribed drugs. Most oncology practices lack tools such as software for documentation and tracking of the use of oral oncolytics.

Reimbursement

The existing reimbursement system creates different incentives for prescribing oral versus IV therapies. Under the current reimbursement system, treatment planning, patient education,

compliance management, and many other necessary services are often not reimbursed for oral oncolytics. Differing benefit packages and limits in benefits may affect prescribing behaviors and cause patient confusion regarding oral oncolytics. In some instances, stringent payer policies may limit patient access to orals. Coverage of oral oncolytics under the pharmacy benefit typically results in increased a higher, sometimes prohibitive, cost to the patient.

Compliance

The complexity of tracking and ensuring adherence to treatment regimen is both time- and resource-intensive. Issues unique to oral oncolytics exist related to compliance with treatment, side effect management and treatment modification; for oral oncolytics to be both safe and effective, a complex outreach and documentation system to ensure compliance will be needed. This system does not currently exist.

There are differing levels of complexity between oral and IV oncolytics based on variations in medication regimens, such as dosing or refill frequency. Limited data exists to indicate the amount of time and extent of services that will be needed to appropriately manage patients taking oral oncolytics. Oncology practices may be unable to consistently offer their full suite of compliance management services, as these services are largely uncompensated for oral oncolytics.

Patient Experience

Oral oncolytics provide patients with greater flexibility, but more responsibility as well. Patient and family members become part of the cancer care team. Additional burdens exist for patients taking oral oncolytics regarding:

- Managing dosing and administration
- Monitoring side effects
- Following safety protocols
- Scheduling refills

The added convenience oral oncolytics offer to patients may be offset by higher cost. Additional challenges exist for patients using combination oncolytics (multiple orals, oral/IV) in navigating medical and pharmacy benefit as well as the coordinated delivery of all medications.