

FACT SHEET: Patient Access to Oral Oncolytics

The Community Oncology Alliance (COA), in cooperation with Avalere Health, has engaged in research surrounding the barriers to access of oral oncolytics. A three-year, three-part study has clearly evidenced the fact that high cost-sharing and higher concurrent prescription activity are key factors related to the abandonment of these medications; so impactful in fact, that one in ten cancer patients abandoned their oral anti-cancer drugs in the COA study.

The NCI in Bethesda, Maryland recently estimated that the number of cancer survivors will continue to increase over the next ten years from 14 to 18 million. It is likely that the percentage of cancer patients unable to access their cancer therapies due to cost will correspondingly increase as well. Thanks to improving survival, changing practice patterns and an aging and growing population, the total cost of cancer care in the United States may surpass \$200 billion by 2020, according to the new projections from the National Cancer Institute. That is 66% higher than total cancer costs today.

Clearly, these findings and predictions warrant a thorough investigation of not only the barriers to accessing oral oncolytics, but also the need to develop alternative solutions to doing without these life-saving medications, as is currently becoming the case.

Approximately half of all U.S. cancer patients are Medicare patients. This subset of the population had higher rates of drug abandonment according to the COA/Avalere study.

A notable statistic revealed in the orals research was the fact that patients with Medicare coverage and lower incomes had higher rates of abandonment of oral oncolytics. Medicare beneficiaries abandoned their oral prescriptions almost twice as frequently as commercially insured beneficiaries. Based on the sample of claims analyzed, 46% of Medicare patients had costs shares in excess of \$500 versus 11% of commercially insured patients.

The number of Medicare patients with cancer is dramatically increasing, both due to an increase in cancer prevalence and an aging U.S. population.^{1 2 3} The latest census shows that fifty percent of America's population is over the age of 50.

Oral anti-cancer medications comprise 25% to 35% of the oncology pipeline.

Targeted therapies that are delivered more conveniently in an oral form are attractive to many. Oral medications are reported to account for up to 35 percent of the current oncology pipeline.⁴

¹ American Cancer Society, *Cancer Facts and Figures*, 2010

² National Cancer Institute, *Cancer Trends Progress Report: 2009 / 2010 Update*, April 2010.

³ Tangka et al, *Cancer treatment cost in the United States: Has the burden shifted over time?*, Cancer, May 10, 2010

⁴ Mosely WG, Nystrom JS. *Dispensing oral medications: why now and how,* Community Oncology. 2009; 6:358-61

While their use is increasingly common, cancer patients frequently face even more barriers to accessing oral drugs compared to those delivered intravenously in oncology practice settings. Additionally, oncologists have noticed a troubling rate of patient abandonment and/or noncompliance with oral anti-cancer medications.⁵

The study found that the abandonment rate increased with cost-sharing amounts.

- A rising rate of abandonment corresponding to an increasing patient cost share was observed. And, while abandonment was noted at all out-of-pocket ranges, the likelihood increased four fold when the cost share exceeded \$500.
- The Patient Advocate Foundation (PAF) in its recent 2010 Patient Analysis Report finds, "78.69% of patients reporting issues related to financial burden had some form of health insurance."⁶
- Patients with 2-5 prescription claims and patients with more than 5 claims in the previous month had a 26% and 50% higher likelihood of abandoning the oral oncolytic agent (respectively) versus patients without concurrent prescription activity.

Medicare coverage and lower income were also related to higher rates of abandonment when each was compared individually.

- Patients with income lower than \$40,000 were 20% more likely to abandon versus patients with incomes of more than \$75,000.
- Based upon an assessment of cost-sharing distributions, a larger proportion of Medicare patients experienced higher cost-sharing than commercially-insured patients.
- Patients with Medicare coverage also had higher rates of abandonment (16%) versus commercial patients (9%).
- From the previously sited PAF Report, "despite having Part D coverage, Medicare patients were especially affected by issues related to access to pharmaceuticals."

The number of concurrent prescriptions also had an impact on abandonment of an oncolytic.

- Virtually all of the new drugs released after the beginning of this decade cost hundreds to thousands of dollars per month, and the price tag for some is more than \$5000 dollars per month. The number of health insurance plans covering most or all of the costs of these drugs is shrinking dramatically. As a result, many patients now have co-pays of 25% to 50% of the retail drug cost. After factoring in the other expensive non-oncology drugs many patients also take, it is easy to see how quickly it can become impossible for patients to pay for treatment and still have enough left over for living expenses.
- Patients with more than five claims for non-cancer medicines in the previous month had an abandonment rate of 12% as compared to 9% for patients with no claims in the previous month.⁷

Oral anti-cancer medications are often placed in specialty drug tiers

Because of cost, oral cancer drugs are frequently placed in the highest price tier, where the patient's out of pocket cost can be as much as 25-50% of the total cost.⁸ Most drugs placed on specialty tiers are medications treating severely ill patients with debilitating diseases.

In Medicare, approximately 85% of plans place oral oncolytics on specialty tiers. Medicare defines a specialty tier as one which corresponds to a per-member, per-month cost in excess of \$600. According to the Kaiser Family Foundation's Annual Employer Health Benefit Survey, "thirteen percent of covered workers are in a plan that has four or more tiers of cost sharing for prescription drugs. For covered workers in plans with four cost-sharing tiers, 46% face a copayment for fourth-tier drugs and 24% face co-insurance."

⁵ Community Oncology Alliance, May 2011

⁶ Patient Advocate Foundation, *2010 Patient Analysis Report*, March 2010

⁷ Lee Schwartzberg, MD, *Casting Oral Cancer Drug Therapy in a Different Light,* Oncology Stat, April 28, 2009

⁸ Lee Schwartzberg, MD, *Casting Oral Cancer Drug Therapy in a Different Light,* Oncology Stat, April 28, 2009

Drug Name	% of Plans with Drug on Formulary	Primary Tier Placement	Primary Cost- Sharing Range	Highest Cost Sharing by Any Plan*	% of Plans with Drug on Specialty Tier
Xeloda	Part B Covered Product				
Gleevec	100%	4	25.01%-35%	\$100/35%	99%
Nexavar	100%	4	25.01%-35%	\$100/35%	99%
Revlimid	100%	4	25.01%-35%	\$100/50%	99%
Sutent	100%	4	25.01%-35%	\$100/35%	99%
Tarceva	100%	4	25.01%-35%	\$100/35%	100%**
Temodar	Part B Covered Product				
Tykerb	100%	4	25.01%-35%	\$100/50%	99%

The Part D analysis below reflects Part D drugs on specialty tiers 99–100% of the time:⁹

In the next 5 years, it is anticipated that specialty medications, encompassing all disease states, will account for approximately 25% of total pharmacy benefit costs, up from 15% of current costs.¹⁰

What Does This Mean for Patients with Cancer?

Regardless of income or type of insurance, cancer patients should have access to the most clinically appropriate care for their condition, including oral anti-cancer medications. In order for the use of these new medications to be successful, benefit design changes are needed. As is currently status quo with Medicare, all payers should view anti-neoplastic drugs as a protected class, thereby allowing cancer patients' access to the most appropriate therapy for their cancer condition, with a cost sharing that is achievable and unbiased.

Between 2010 and 2030, total projected cancer incidence will increase by approximately 45% from 1.6 million in 2010 to 2.3 million in 2030.¹¹ This is due to multiple factors, including the aging American population, rising cancer incidence, and recurrent but treatable cancers among cancer survivors.

COA believes it imperative that all stakeholders work together to resolve this growing issue. Failure to accomplish this restructuring of the cancer care delivery system will result in the actual impedance of effective cancer treatment by, in essence, preventing access to such care.

⁹ Avalere Health, Part D Specialty Tier Analysis, May 2011 ¹⁰ Journal of Managed Care Discussion, October 2000

¹⁰ Journal of Managed Care Pharmacy, October 2009

¹¹ American Association for Clinical Chemistry