The Role of Biosimilars in the Oncology Care Model and the Value Based Care: Challenges, opportunities and strategies for the success of the uptake of biosimilars in therapeutic space

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Abstract

The US healthcare system is highly inefficient due to fragmented care and volume driven reimbursement. According to a WHO report in More Health for the Money, the main source of inefficiency in the healthcare system is the underuse of generic drugs and the higher price of name-brand medicines. Total national expenditures for cancer care in the U.S. are projected to increase from $124.57 billion in 2010 to $158-$173 billion by 2020. Drug costs are the fastest rising segment of healthcare spending. The trends in Medicare spending reveal an increase of 335% in biologic drugs relative to the total cost of care increase of 36% (Figure 1). CMS has developed VBC programs including OCM, APMs and the VBC to reward healthcare providers with incentives for improving the quality of care and reducing the overall cost of care, while also improving patient experience. As the costs of biologics are high, biosimilars offer the potential of greater choice and value, increased patient access to treatment, and the potential for improved outcomes. Biosimilars remain new to the U.S. market, particularly in the oncology space, but that is anticipated to change in upcoming years.

CBCCA was selected by CMS for an OCM pilot. We implemented several steps to succeed in OCM, one of the most critical of which was the usage of generics and biosimilars. We share the case study of our practice transformation into a PCCC. We also share three years of the results of savings that resulted from the switch to biosimilars, and project future savings that can be achieved in OCM, APMs and VBC via a complete conversion to biosimilars upon receipt of US approval.

Service Category	PPPY Cost Trends
Hospital Inpatient Admissions	22%
Cancer Surgeries (inpatient & outpatient)	0%
Sub-Acute Services	51%
Emergency Room	132%
Radiology – Other	24%
Radiation Oncology	204%
Other Outpatient Services	48%
Professional Services	40%
Biologic Chemotherapy	335%
Cytotoxic Chemotherapy	14%
Other Chemo and Cancer Drugs	-9%

Figure 1: Trends in Medicare Spending from 2004 to

Introduction

Biosimilars offer incredible health and economic opportunities in the United States, but unless substantial barriers are surmounted, these opportunities will not be fully realized. Significant challenges for biosimilars arise because all parties involved — patients, physicians, payers, and biosimilar manufacturers need to realize the potential of these products solving part B drug prices and improve access and affordability both at individual level and society as a whole. The last several years have seen the U.S. moving slowly toward a healthy biosimilars market, but there are more hurdles to address before biosimilars realize their full potential. This is true in particular with the introduction of the therapeutic class of biosimilars.

Significant knowledge gaps exist in the awareness of biosimilars, their approval process (totality of evidence) and special pathway 351 (k) created by the FDA under BPCIA of 2009 for biosimilars assessment and approval. This knowledge gap is primary reason to less than expected uptake of biosimilars in the US healthcare.

A survey of 376 US oncologists (part of a larger survey that included 1245 oncologists total from the United States, Europe, and Latin America) reported the lack of knowledge and understanding of the effects of biologics and biosimilars.[1] Earlier surveys also found significant knowledge gaps regarding all aspects of biosimilars (chemical structure, difference from reference product, approval process, availability of biosimilars in the United States, etc) among clinicians of various specialties.[2]

Figure 2: Barriers

Majority of oncologists simply continue to use the products they are most accustomed to. Adding to this are relatively low levels of knowledge about biosimilars among many providers. In a recent survey of physicians, less than half (45 percent) believed "that biosimilars would be safe and appropriate for use in both treatment-naive and existing patients," while more than one-third (36 percent) believed "that a biosimilar would be less safe than the reference biologic"[3].

Patients also lack awareness and education about biosimilars. According to a recent survey, 70 percent of U.S. respondents in the general population had never heard of biosimilars, compared to 57 percent who had never heard of biologics (Jacobs et al. 2015)[4]. Even among patients with breast, lung, or colorectal cancer; or non-Hodgkin's lymphoma, 54 percent had never heard of biosimilars, compared to 33 percent of people diagnosed with these illnesses who had never heard of biologics.

Gaining physician support for and confidence in biosimilars requires education of the evidence demonstrating that the biosimilar provides similar efficacy and safety to the reference product. Intensive education programs will definitely improve uptake of biosimilars amongst oncologists to include biosimilars in the treatment arena of solid tumors.

Figure 3: Lack of awareness amongst key stake holders in biosimilars

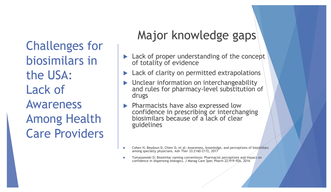

Figure 4: Major knowledge gaps in biosimilars

Figure 5: Summary of challenges for biosimilars in the USA

To assess safety and efficacy as well as establish non immunogenicity, some clinical trials have included product switching, although assessing immunogenicity often depends on the molecule and the indications studied.[5] An important issue affecting physician uptake of biosimilars is interchangeability and substitution. To receive interchangeability designation, the manufacturer must demonstrate not only that the biosimilar has similar efficacy and safety to the biologic, but also that there is no greater risk in switching between the biologic and biosimilar than remaining on the reference product.[6] The advantage to the manufacturer is some level of exclusivity.[7] The FDA announced a pathway to interchangeability in January 2017 and is expected to designate the first interchangeable products within the next 2 years.[8] An interchangeability designation allows the biosimilar to be substituted for the reference product at the pharmacy level similar to the way generic products are substituted for brand drugs today.

Opportunities for biosimilars: The role that biosimilars can play in addressing part B drug prices

Cancer care costs in the U.S. are projected to increase from $124.57 billion in 2010 to $158-$173 billion by 2020.[9] The increase in new cancer therapeutics as well as the projected rise in the number of people living with a history of cancer from 14.5 million in 2014 to 18.1 million in 2020 will be major cost drivers in oncology care[10]. High-quality oncology care can be very expensive, and often entails resource-intensive therapy given over prolonged periods of time. In the US, net spending on pharmaceuticals has increased 42 percent since 2006, with more than two-thirds of that growth occurring since 2013[11]. Prescription drug spending is now the fastest growing share of health spending, and is projected to remain so. Currently, pharmaceuticals account for 16.7 percent of total expenditures[4]. This creates challenges for individual patients with very high out-of-pocket costs. American taxpayers and businesses end up indirectly paying the cost for these drugs through taxes and insurance premiums.

The cost of drugs and biologics are the fastest rising cost component of cancer care. A study of the 2004-2014 PPPY Medicare cost trends of the various segments of oncology care demonstrated the highest increase was in biologic chemotherapeutic drugs which rose by 335% relative to the overall PPPY cost rose by 36%. (figure 1)[12] According to a World Health Organization report in More Health for the Money, the number one source of inefficiency in the healthcare system is the underuse of generic drugs and the higher than necessary price of name-brand medicines.[13] Under the guidelines of the 2010 Affordable Care Act, the Centers for Medicare & Medicaid Services (CMS) established the Center for Medicare & Medicaid Innovation (CMMI) to pilot new and innovative payment models to incorporate the value element in the delivery of healthcare. CMMI is tasked with piloting different payment models to fulfil the triple aims of healthcare delivery.

In response to rising cancer treatment costs, in June 2016, the CMS launched a new, voluntary program the Oncology Care Model (OCM) as part of its broader initiative to improve the effectiveness and efficiency of specialty care; the OCM program aims to provide higher quality, more coordinated oncology care at the same or lower cost to Medicare than traditional FFS payments[14,15]

In order for us to establish the role of biosimilars we have created case study of a practice that can provide a model for financial projections. This practice saw an opportunity in additional savings by declining ASP of biosimilar (Figure 5) GCSF.

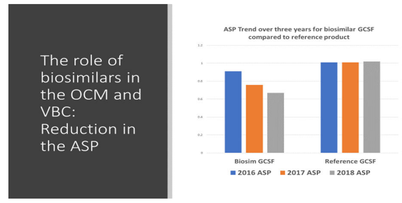

Figure 6

Figure 7: The OCM practice that we followed as a case study achieved significant savings by switching to biosimilar GCSF.

With the implementation of steps aimed at the goals of OCM, practice in the case study achieved savings from biosimilars in addition to other interventions. These savings came from the progressive decline in the ASP of biosimilar GCSF. Based on our experience and projections, we calculated projected savings in the OCM when additional biosimilars come into the market (therapeutic included are available for treatment). Additional savings of up to $1 million for is possible for this practice by 2021 (Figure 7).

Figure 8

Conclusions

In summary three years in the OCM several practices have fulfilled (close to third of all enrolled in the OCM program) the triple aim to improve the quality of care, while containing costs and improve patient experience. Biosimilars may provide an additional tool for providers participating in value-based care initiatives such as the MSSP and OCM as well as VBC, resulting in cost savings and efficiencies in the delivery of high-value care through expanded use of biologic treatment and supportive care agents during episodes of care. These savings may then be realized through the MSSP, OCM, or other incentive programs, with benefits passed on to health care providers, payers, and patients alike.Biosimilars might support broader access to equitable, high-quality oncology care. Patient access has become an important consideration when it comes to balancing high-quality care and cost. Within the context of this balance, biosimilars are being developed as alternative options with potentially lower costs and greater access. By 2020, a range of biosimilars for biologic agents used in oncology treatment are expected to receive US FDA approval and become available in the US market, providing increased treatment options and thus competition, with the potential for pricing reductions.

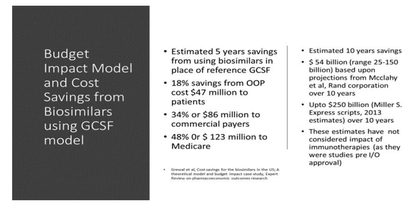

Figure 9: Biosimilars role at national level

However many challenges remain for full integration of biosimilars across all providers and all states and specialties. Defining the role of biosimilars in achieving goal of value, biosimilars definitely have place in today's value based healthcare.

Figure 10: Solutions using provider education at national, regional and local levels: