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 2017 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 US are projected to increase from $124.57 billion in 2010 to $158.32 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 50% (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 significant savings to Medicare. 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 genetics and biosimilars. We share the case study of our practice transformation into a PCCU. We also discuss three 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 complex conversion to biosimilars upon receipt of US approval.

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 parties involved—patients, physicians, payers, and biosimilar manufacturers—need to realize the potential of these products with part B drug prices and improve access and affordability both at the individual level and society as a whole. The last several years have seen the US moving toward a healthy biosimilar market, but there are more hurdles to address before biosimilars realize their full potential. This is in particular with the introduction of the therapeutic class of biologic agents. 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. 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.

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. An important issue affecting physician practice 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. The advantage to the manufacturer is some level of exclusivity. The FDA announced a pathway in interchangeability in January 2017 and is expected to designate the first interchangeable products within the next 2 years. 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.

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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 might 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 biosimimic and supportive care agents during episodes of care. These savings may be then realigned through the MSSP, OCM, or other in- centive 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.

Opportunities for biosimilars: The role that biosimilars can play in addressing part B drug prices Cancer care costs in the US are projected to increase from $124.57 billion in 2010 to $158.32 billion by 2020. The increase in new cancer therapeutics as well as the projected rise in the number of people living with a history of cancer from 14.3 million in 2014 to 18.1 million in 2020 will be major cost drivers in oncology care. High-quality oncology care can be very expensive, and often entails resources-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 2011. Prescription drug spending is now the fastest growing share of health spending, and is projected to remain so. Currently, pharmacists account for 16.7 percent of total expenditures. This creates challenges for individuals 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 PIPP Medicare cost trends of the various segments of oncology care demonstrated the highest increase was in biologic chemotherapy drugs which rose by 335% relative to the overall PIPP cost from 36% (figures 17). 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 generics and the higher than necessary price of name-brand medicines. In 2013, the HHS proposed the 2015 Affordable Care Act, the Centers for Medicare & Medicaid Services (CMS) established a new provider payment model to incorporate the value element in the delivery of healthcare. CMS is tasked with piloting different payment models to fulfill 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.

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 ASAP of biosimilar (Figure 5) GCSF.

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

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 ASAP 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 the practice by 2021 (Figure 7).