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

K Patel MD, A Gor MD, S Naidu MD, N Nathwani MD, V Rabara MD, D Mehta MS RDN, R Kodali BS, T Barnes BS, L Travis BS, R Fortner BS, T Lavender PA-C, M Patel MB MB

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 genuine drugs and the higher price of name-brand medicines. Total national expenditures for cancer care in the U.S. are projected to increase from $124.5 billion in 2010 to $188-$173 billion by 2020. Drug costs are the fastest rising segment of healthcare spending. The trends in Medicare spending reveal an increase of 33.5% in biologic drugs relative to the total cost of care increase of 30% (Figure 1). CMS has developed VBC programs including OCM, APMS, and the VRC 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 cost of healthcare is high, biosimilars offer the potential of greater price 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 as an OCM pilot. We implemented several steps to succeed in OCM, one of the most critical of which was the issue of education. We share the details of our practice transition into a PCCM. 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 VRC via a complete 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 arose because all patents issued to biologics— patents to physicians, patients, payers, and biosimilar manufacturers. Biosimilars must demonstrate interchangeability with the reference product, approval process, availability of biosimilars in the United States, etc) among clinicians of various specialties.

Significant knowledge gaps exist in the awareness of biosimilars, their approval process (totality of evidence) and special pathway 351 k) existed by the FDA under BPCIA of 2009 for biosimilar demonstration and approval. This knowledge gap is a 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, involved — patients, physicians, payers, and biosimilar manufacturers need to realize the potential of these products.

To assess safety and efficacy as well as 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 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. The advantage to the manufacturer is some level of exclusivity. The FDA announced a pathway to 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.

Figure 1: Problems of biosimilars in the US healthcare

Figure 2: Barriers to biosimilar adoption

Figure 3: Lack of awareness among key stakeholder holders in biosimilars

Figure 4: Major knowledge gaps in biosimilars

Figure 5: Summary of challenges for biosimilars in the USA

Figure 6: Conclusions

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

Figure 8: The Role of Oncology in Value Based Care

Figure 9: Biosimilars role at national level

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

Opportunities for biosimilars: The role that biosimilars can play in addressing biologic drug pricing

Cancer care costs in the U.S. are projected to increase from $124.5 billion in 2010 to $188-$173 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 14.5 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 resource-intensive therapy given over prolonged periods of time. In the US, net spending on pharmacotherapies has increased 42 percent since 2006, with more than two-thirds of that growth occurring since 2011. Prophylactic 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 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 is the single largest cost component of cancer care. A study of the 2004-2014 PEPY Medicare cost trends of the various segments of oncology care demonstrated the highest increase was in biologic chemotherapy drugs which rose by 33.5% relative to the overall PEPY cost rose by 30% (Figure 1). According to a World Health Organization report in More Health for the Money, the main source of inefficiency in the healthcare system is the underuse of generics drugs and the higher than necessary price of name-brand medicines. Under the guidelines of the 2010 Affordable Care Act, the Center for Medicare and Medicaid Innovation (CMMI) established the Center for Medicare & Medicaid Innovation (CMMI) to pilot new and innovative payment models to incentivize 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 ASP of biosimilar (Figure 2).

Figure 11: Definition of proposed Oncology Care Model

Figure 12: Proposed Oncology Care Model

Figure 13: The Oncology and Value-Based Care Provider

Figure 14: The role of Oncology in Value Based Care

Figure 15: The role of Oncology in Value Based Care

Figure 16: The role of Oncology in Value Based Care

Figure 17: The OCM practice that was selected as a case study achieved significant savings by switching to biosimilar GCSF.

Figure 18: The Role of Oncology in Value Based Care

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 program designed 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 (biosimilar included are available for treatment). Additional savings of up to $1 million is possible for this practice by 2021 (Figure 7).