Trends in the US biosimilar market : Insights from a real-world analysis using de-identified Market Clarity database

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Objectives

- Despite expected hurdles, the Food and Drug Administration (FDA) had approved the first biosimilar in 2015 in the US. Presently, 45 biosimilars are present in the US biotherapeutic landscape, with a compounded annual growth rate of 97% from 2015 to 2021.
- In view of the emerging biosimilar market, the aim of this study is to comparatively analyze the evolution of total cost and patient distribution for biosimilars and reference drugs in the oncology and rheumatology therapeutic areas in the US. Since ensuring patient safety, efficacy and cost-effectiveness is crucial for these drugs, understanding the pattern of utilization of biosimilar market in these therapeutic areas is essential and pertinent.

Methods

- A retrospective exploratory analysis was carried out, considering 10 reference drugs for the oncology and rheumatology therapeutic domain. All corresponding approved biosimilars for each of these drugs are included in the analysis.
- 5 reference drugs for each of the therapeutic areas were considered.
- Both pharmacy and medical claims were used from Optum® de-identified Market Clarity database spanning across 2016 (index date of the first biosimilar launch) until 2021.
- Standard costs were analyzed for biosimilar and reference drugs across time and line of business (LOB) (Commercial, Medicare, Medicaid).
- Evolution of patient distribution was also studied across time and LOB (Commercial, Medicare, Medicaid).

Results

Figure 1: Change in total cost and patients for both reference drugs and biosimilars in oncology and rheumatology

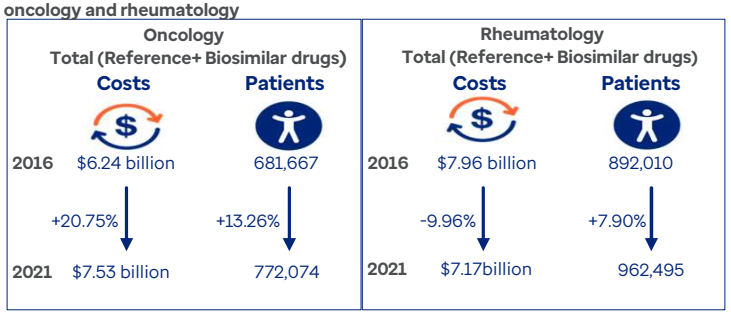


Figure 2: % Change in total cost, 2016-2021 (Reference + Biosimilar drugs)

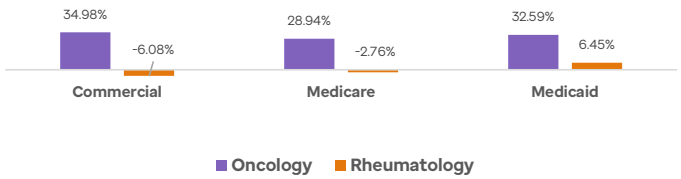
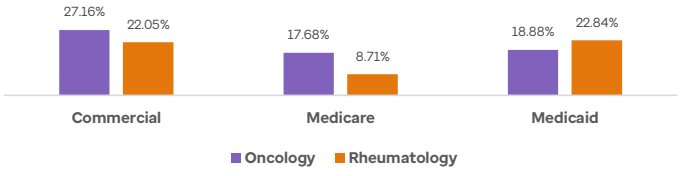


Figure 3: % Change in total patients, 2016-2021 (Reference + Biosimilar drugs)



- With the launch of biosimilar drugs in the US pharmaceutical market, total cost of reference and biosimilars had increased by 20.75% from 2016 to 2021 for oncology drugs. However, total cost had declined by 9.96% for rheumatology biologics during the same time span.
- Total patients using reference and biosimilar drugs in both the therapeutic areas had consistently increased within our study period. The rate of patient increase is higher in case of oncology drugs (13.26%) compared to rheumatology drugs (7.90%).
- Similar trends in the evolution of cost and patient distribution was seen in different LOB. For biologics in rheumatology, total cost decreased over time for Commercial (-6.08%) and Medicare (-2.76%), while an increase was seen for Medicaid (6.45%). But total cost for reference and biosimilar drugs had increased in oncology for Commercial (34.98%), Medicare (28.94%) and Medicaid (32.59%). Total patients had invariably increased across all LOB and for both therapeutic areas.

Conclusions

- With the introduction of biosimilars, the number of patients have increased from 2016 to 2021 for both oncology and rheumatology therapeutic areas. This reflects on the fact that increased access to biologic treatments has enabled more patients to utilize the treatment options, and with greater affordability.
- However, although total cost for biosimilar and reference drugs has decreased systematically for rheumatology drugs (except for Medicaid patients), the scenario is not the same for oncology drugs. Studies suggest that patent litigations of oncology drugs have limited the ability for biosimilar competition to drive down prices are quickly as other therapeutic areas.
- Nevertheless, lower price of biosimilars create an array of opportunities for different treatment options and thereby improve patient's quality of life. Hence, a greater rate of expansion of the biosimilar market can be anticipated for both therapeutic areas.
- Further analysis will be done on market share of biosimilars and reference drugs, which will be extrapolated at the national level.

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