Longitudinal evaluation of characteristics, treatment patterns, and general outcomes among patients using granulocyte colony stimulating factors: a study by the Biologics and Biosimilars Collective Intelligence Consortium.

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INTRODUCTION

Active and systematic post-marketing evidence generation for biologics, including their corresponding biosimilar products, is a critical public health need. The Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) is a non-profit initiative created in 2015 under the auspices of the Academy of Managed Care Pharmacy (AMCP). The BBCIC is a collaboration between product manufacturers, payers, managed care organizations, integrated delivery networks, other non-profit organizations, and public representatives. The Consortium uses a distributed research network (DRN) approach that includes medical and pharmacy claims data on approximately 95 million patient lives to perform ongoing analyses of biosimilars and their innovator products.1,2

The BBCIC leverages the FDA Sentinel System data and analytic infrastructure, including the Sentinel Common Data Model for data standardization and Sentinel-based analytic tools for distributed analyses and examining medical product risk and benefit.1 The BBCIC DRN is used to monitor utilization of medications of interest and capture basic patient characteristics to inform BBCIC research priorities and future research projects.1

In 2015, a granulocyte colony stimulating factor (G-CSF) became the first biologic product to have an American Medical Association (AMA) code, allowing for better tracking of G-CSF use in providers’ electronic health records. This paper aims to describe the utilization patterns and patient characteristics of currently used G-CSFs and future research projects.

RESULTS

This retrospective, observational, descriptive study evaluated utilization patterns and patient characteristics using data from five BBCIC DRN Research Partners that contributed over 80 million patients-year of data for individuals currently covered by Commercial or Medicare-Advantage health insurance.

Study Population:

• Adults who received G-CSF treatment for any indication between January 1, 2012 and June 30, 2018
• Patients receiving chemotherapy regimen treatments other than high-neutropenic risk breast- or lung-cancer therapy were included to get a broader picture of the patients receiving G-CSFs in real clinical settings
• Patients were required to have medical and pharmacy claims data for at least 183 days before the episode exposure
• An enrollment gap of 45 days was permitted

Medications included:

• filgrastim (Neupogen®)
• filgrastim-sndz (Nivestym®)
• TBO-filgrastim (Treanda®)
• pegfilgrastim (Neulasta®)

Note: The biosimilars filgrastim-aafi (Nivestym®), pegfilgrastim-sndz (Injurysafe®), and pegfilgrastim-elosent (Elozet®) were approved too recently to appear in these results, but will be captured in future queries.

Data were analyzed for both incident (new) and prevalent patients treated with filgrastim products has varied over time, with declining relative utilization of filgrastim and increasing utilization of filgrastim-sndz (Figure 2). Utilization of TBO-filgrastim has remained constant since 2015.

METHODS

This study was supported by federal funding from the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) and National Institutes of Health (NIH). The National Institutes of Health, HealthPartners, and Boston Permanente Medicine, provided support for the research. Data were analyzed from the BBCIC Clinical Intelligence Database (CID), a longitudinal, administrative claims database comprising health care utilization for over 95 million patient lives. The study was approved by the BBCIC IRB.

The proportion of patients treated with any filgrastim compared to pegfilgrastim remained constant over time. (Figure 3)

REFERENCES

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CONCLUSIONS

This systematic, longitudinal surveillance on G-CSF utilization patterns in the US showed that new users of biosimilars increased over time while the overall number of new users remained flat.

- Tracking of a biosimilar from the reference product was observed in some patients, though the reason for switching is not available.

- This analysis suggests sufficient utilization of biosimilar G-CSFs to conduct a comparative safety and effectiveness study using the BBCIC DRN.

Figure 1. Longitudinal Utilization Trends Across Filgrastim Products

The proportion of patients treated with G-CSF products has varied over time, with declining relative utilization of filgrastim and increasing utilization of filgrastim-sndz (Figure 2). Utilization of TBO-filgrastim has remained constant since 2015.

Figure 3. Comparison of Utilization Across All Filgrastim Products

The proportion of patients treated with any filgrastim compared to pegfilgrastim remained constant over time. (Figure 3)