Utilization Patterns of the First US Biosimilar, Filgrastim-Sndz, Observed Between 2015 and 2017 in a Medical Transcription Database

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Objectives
- To identify utilization of short-acting granulocyte colony-stimulating factor (G-CSF) as documented by physicians during patients’ healthcare encounters, with a focus on filgrastim-end
- To compare annual utilization between 2015 and 2017 of filgrastim-end relative to other G-CSFs available in the United States (US)

Background
- Filgrastim-end, the first biosimilar approved in the US, has been available since September 2015.
- Like G-CSFs, filgrastim-end is typically administered by a healthcare provider.
- US expenditures on biologic drugs have continued to grow, from an estimated $20 billion in 2016 to $23 billion in 2019; however, competition from the benefit of biosimilars available in the US represents less than 1% of the total biologic drug expenditure.
- Research has shown the use of biosimilars over time does not vary from year to year.
- In the case of filgrastim-end, this may be due to variable or modest price discounting (~15-20%) compared with a reference agent, filgrastim.
- Filgrastim-end is not a short-acting G-CSF. It has been approved for 5 of the 6 known indications for filgrastim, including prophylaxis and treatment of febrile neutropenia in patients with cancer receiving chemotherapy.
- Another short-acting G-CSF, tbo-filgrastim, is approved for only 1 of the filgrastim indications.
- Tbo-filgrastim is not approved as a biosimilar in the US, as the Food and Drug Administration (FDA) considers regulatory pathway was not available at the time of its regulatory submission.
- The American Society of Clinical Oncology includes filgrastim-end among the G-CSFs recommended for prevention of treatment-related neutropenia in patients with solid tumors receiving chemotherapy.

Methods
- Mentions of G-CSF were identified in physician records of patients consulted in the Revenue Health Database (RHD), the US’s largest observational medical transcription database, for the period January 1, 2015 through December 31, 2017.

Results
- The RHD database consists of unredacted data, reflecting clinicians’ transcription notes (i.e., the patient record), patient’s outpatient, emergency room, or inpatient encounters.
- G-CSF utilization was identified from patient records, queried for mention of the following:
  - Short-acting G-CSFs: Filgrastim, Neupogen; Tbo-filgrastim, Granix; Neulasta, Zarxio
  - Long-acting G-CSFs: Pegfilgrastim, Neulasta
- Data included either the physician’s intention to treat with a G-CSF at the time of consultation or upon discharge. G-CSF treatment history is not included.
- Abbreviated examples of the unredacted data are shown in Figure 2
- Structured data were generated from patient records to provide the annual percentage share of G-CSFs received by unique patients, which was compared annually over the study period.

Conclusions
- Among 38,355 records reporting a G-CSF in the RHD medical transcription database, only 295 mentions (0.8%) of filgrastim-end among 214 patients (1.0%) were documented in the same 2 years, leading to entry into the US marketplace, with almost no observable increase in mentions between 2015 and 2017.
- Despite coverage from all states in the RHD database, mentions did not result in direct substitution (i.e., patients were not switched). 
- Results were based on mentions of G-CSFs in provider records, including G-CSF history (such as noted on a patient’s visit and hospitalization, and therefore may not be reflective of prescribing patterns in clinical practice.
- In 2016-2017, administrative claims data of filgrastim-end versus filgrastim utilization in commercial and advantage health plans identified 47% filament filgrastim and 0.3% filgrastim utilization among 3,642 patients.
- Inclusion of higher utilization of filgrastim-end than filgrastim observed in the current study.
- These limitations are not unique to the RHD database, as observational databases, including those from administrative claims or electronic health records, are limited in their representation of clinical treatment patterns, characteristics of the type of data.

References
- Another short-acting G-CSF, tbo-filgrastim, is approved for only 1 of the filgrastim indications.
- Tbo-filgrastim is not approved as a biosimilar in the US, as the Food and Drug Administration (FDA) considers regulatory pathway was not available at the time of its regulatory submission.
- The American Society of Clinical Oncology includes filgrastim-end among the G-CSFs recommended for prevention of treatment-related neutropenia in patients with solid tumors receiving chemotherapy.
- This study provides an update of previous research to assess whether filgrastim-sndz utilization has increased as of 2017.
- Pegfilgrastim is not approved as a biosimilar in the US, as the Food and Drug Administration (FDA) considers regulatory pathway was not available at the time of its regulatory submission.
- The American Society of Clinical Oncology includes filgrastim-end among the G-CSFs recommended for prevention of treatment-related neutropenia in patients with solid tumors receiving chemotherapy.
- This study provides only a proxy for utilization of G-CSF agents, over 3 distinct time periods, as identified in a medical transcription database.
- Provider notes may have been repeated in cases of multi-day hospitalizations, resulting in potential duplication of G-CSF mentions; however, counts of unique patients were reported to address this.
- The data presented here may not be representative of US treatment patterns and substitution.
- It is not clear why the share of mentions of pegfilgrastim decreased and the percentage of short-acting G-CSFs increased over time, particularly between 2015 and 2016.
- Despite coverage from all states in the RHD database, mentions did not result in direct substitution (i.e., patients were not switched).
- Results were based on mentions of G-CSFs in provider records, including G-CSF history (such as noted on a patient’s visit and hospitalization, and therefore may not be reflective of prescribing patterns in clinical practice.
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Table 1: Annual mentions of short-acting G-CSFs, percentages by type of agent, 2015–2017

G-CSF (%) | Mentions | Patients
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All G-CSFs | 14,382 (100.0) | 3,784 (100.0)
Filgrastim | 5,172 (36.0) | 1,719 (45.4)
Pegfilgrastim | 7,662 (53.3) | 1,658 (43.8)

Table 2: Annual mentions of short-acting G-CSFs, percentages by type of agent, 2015–2017

Analysis of the short-acting G-CSFs confirms growth in use of filgrastim alternatives after 2015, led by tbo-filgrastim (Figure 2).
- Between 2015 and 2017, mentions increased slightly more for tbo-filgrastim compared to filgrastim.
- Approximately 69% of all short-acting G-CSF mentions in 2015 were attributable to filgrastim.
- The percentage of filgrastim mentions decreased 7% during 2016, while the percentage increased for tbo-filgrastim (21.4%) and filgrastim-sndz (1.6%).
- In 2017, the percentage of filgrastim mentions increased slightly (3.4%), mainly at the expense of tbo-filgrastim (17.8%) and filgrastim-sndz (15.8%).