Uptake of the First US Biosimilar: Filgrastim-sndz Utilization Observed in a Medical Transcription Database of Patient Office Visits

Karen E. Smoyer, Bríain Ó Hartaigh

[1]Envision Pharma Group, Philadelphia, PA, USA; [2]Envision Pharma Group, Southport, CT, USA

Envision Market Access Solutions
ENVISION PHARMA GROUP
Together, turning vision into reality

Objectives

- To identify physicians' documentation of granulocyte colony-stimulating factor (G-CSF) utilization, with a focus on filgrastim-sndz.
- To compare mentions in physicians' patient notes of filgrastim-sndz with other available G-CSFs in the United States (US).

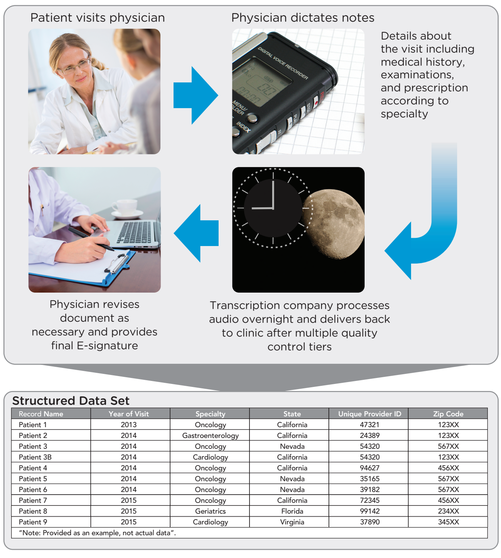
Background

- Filgrastim-sndz is the first biosimilar approved in the US.
- Available in the US since September 2015,[1] filgrastim-sndz has been approved for 5 of the 6 licensed indications for filgrastim, including prophylaxis for and treatment of febrile neutropenia in patients with cancer receiving myelosuppressive chemotherapy.[2]
- Tbo-filgrastim is approved for 1 of the 6 filgrastim indications and is not approved as a biosimilar in the US because the Food and Drug Administration (FDA) biosimilars regulatory pathway was not yet available when the product was submitted for review.[3]
- Filgrastim-sndz, along with other G-CSFs, is recognized by the American Society of Clinical Oncology for prevention of treatment-related febrile neutropenia in patients with a solid tumor or lymphoma undergoing chemotherapy[4] and is administered by subcutaneous injection or intravenous infusion, typically by a healthcare practitioner.[2]
- Currently, little information has been reported on US utilization of filgrastim-sndz compared with other available G-CSF agents.

Methods

- Mentions of a G-CSF were identified in physician records of patient consultations in RealHealthData (RHD), a US nationwide medical transcription database, for the period 1 January 2016 through 31 March 2017 (Figure 1).

Figure 1. Data Capture Process



Structured Data Set

Record Name	Year of Visit	Specialty	State	Unique Provider ID	Zip Code
Patient 1	2013	Oncology	California	47321	123XX
Patient 2	2014	Gastroenterology	California	24389	123XX
Patient 3	2014	Oncology	Nevada	54320	567XX
Patient 38	2014	Cardiology	California	54320	123XX
Patient 4	2014	Oncology	California	94627	456XX
Patient 5	2014	Oncology	Nevada	35165	567XX
Patient 6	2014	Oncology	Nevada	39182	567XX
Patient 7	2015	Oncology	California	72345	456XX
Patient 8	2015	Geriatrics	Florida	99142	234XX
Patient 9	2015	Cardiology	Virginia	37890	345XX

"Note: Provided as an example, not actual data".

- The data set comprises physicians' notes reporting on patients' office visits or care provided at healthcare facilities, available within 30 days of each encounter with a participating provider, reducing the likelihood of recall bias.
- Records were analyzed for mention of specific G-CSFs using the following terms:
  - Pegfilgrastim: "pegfilgrastim" or "Neulasta"
  - Filgrastim: "filgrastim" or "Neupogen"
  - Tbo-filgrastim: "tbo-filgrastim," "Granix," or "Neutroval"
  - Filgrastim-sndz: "filgrastim-sndz," "Zarxio," or "Zarzio."
- Data included either the physicians' intention-to-treat with a G-CSF at the time of consultation, G-CSF treatment history, or both.
- The name of the G-CSF agent and reported usage (as neutropenia treatment or prophylaxis) were identified and tabulated.
- Also recorded were the most common location (US state) and medical specialty of the provider who examined each patient.
- Presented are full-year data for 2016 and also for the first quarter of 2017, followed by differences in mentions among the filgrastim agents as well as treatment patterns for filgrastim-sndz.
- Provider notes for patients who received filgrastim-sndz in Q1 2017 were evaluated manually to classify mentions within 2 categories, prophylaxis or treatment, and to record whether the drug was prescribed or administered by the treating physician or documented in the patient's history.

Results

- In 2016, among 17,770 mentions of a G-CSF, 9990 were for pegfilgrastim (56%) and 5967 were for filgrastim (34%); <10% of mentions were for tbo-filgrastim and <1% were for filgrastim-sndz (Table 1).

Table 1. Counts of G-CSF Mentions and Number of Unique Patients and Providers, 1 January 2016 to 31 December 2016

G-CSF, n (%)	Mentions	Unique patients	Unique providers
All G-CSFs	17,770	9083	4774
Pegfilgrastim	9990 (56.2)	5202 (57.3)	1889 (39.6)
Filgrastim	5967 (33.6)	3217 (35.4)	2318 (48.6)
Tbo-filgrastim	1695 (9.5)	620 (6.8)	507 (10.6)
Filgrastim-sndz	118 (0.7)	44 (0.5)	60 (1.2)

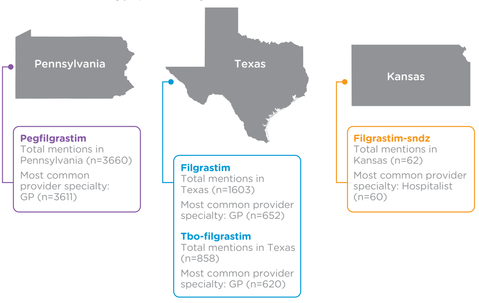
- During Q1 2017, although pegfilgrastim still had the most mentions, the share of both filgrastim and tbo-filgrastim G-CSF mentions increased when compared with 2016 data (Table 2).

Table 2. Counts of G-CSF Mentions and Number of Unique Patients and Providers, 1 January 2017 to 31 March 2017

G-CSF, n (%)	Mentions	Unique patients	Unique providers
All G-CSFs	3452	2259	1452
Pegfilgrastim	1621 (47.0)	1088 (48.2)	617 (42.5)
Filgrastim	1368 (39.6)	931 (41.2)	622 (42.8)
Tbo-filgrastim	441 (12.8)	226 (10.0)	195 (13.4)
Filgrastim-sndz	22 (0.6)	14 (0.6)	18 (1.3)

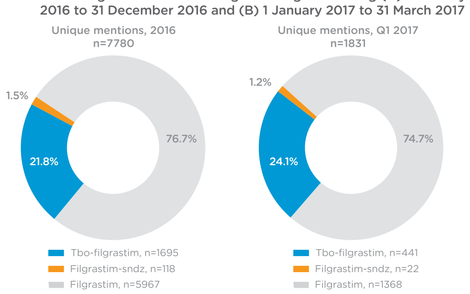
- The most frequent mentions of each G-CSF by provider location and specialty type for the full study period combined are presented in Figure 2.
- General practitioner (GP) was the most frequent provider type to mention pegfilgrastim, filgrastim, and tbo-filgrastim, whereas hospitalists mentioned tbo-filgrastim most often.
- Provider locations varied, with providers in Pennsylvania noting pegfilgrastim most often, Texas-based providers mentioning filgrastim as well as tbo-filgrastim most often, and providers in Kansas having the most mentions of filgrastim-sndz (Figure 2).

Figure 2. Most Frequently Recorded Mentions of G-CSFs by US State and Provider Type, 1 January 2016 to 31 March 2017



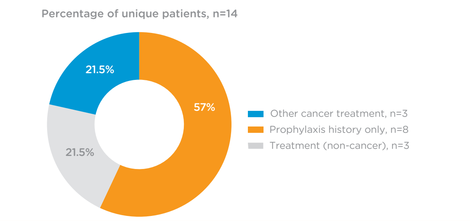
- Comparison of the share of mentions for filgrastim agents (excluding pegfilgrastim) between Q1 2017 and all of 2016 shows values did not differ appreciably (Figure 3).
  - However, a modest increase in the share of tbo-filgrastim was seen during Q1 2017 at the expense of filgrastim and filgrastim-sndz.

Figure 3. Percentage of Mentions of Filgrastim Agents During (A) 1 January 2016 to 31 December 2016 and (B) 1 January 2017 to 31 March 2017



- Figure 4 displays filgrastim-sndz treatment patterns during Q1 2017 among 14 patients with a G-CSF noted in their records; duplicate records for 6 hospitalized patients were combined and reported only once.
- A history of prophylaxis with filgrastim-sndz was mentioned most often, appearing in records for 8 patients (57%).
- The remaining 6 unique patients with mentions of filgrastim-sndz were subset evenly into (1) treatment for chemotherapy-induced neutropenia and (2) treatment for neutropenia without mention of cancer or chemotherapy in the patients' record (21.5% for each category).

Figure 4. Filgrastim-sndz Treatment Patterns, 1 January 2017 to 31 March 2017



Limitations

- This study provides only a proxy of utilization by G-CSF agent for distinct time periods rather than documented treatment patterns or trends in patients receiving G-CSFs, for the following reasons:
  - The study was based on mentions of G-CSFs in provider records, including G-CSF history; in some cases, G-CSF use as prophylaxis versus treatment was inferred based on reported information
  - Provider notes may have been repeated in cases of multi-day hospitalizations and thus G-CSF mentions could include duplicates; however, unique counts of patients for 2016 and Q1 2017 were provided to address this
  - Patient counts for 2016 and Q1 2017 could not be combined because unique patients were not identified across the 2 years
  - G-CSF data for 2017 were collected during Q1 only; it is unknown whether mentions of G-CSFs in providers' chart notes may have changed since this time.
- The small number of mentions of filgrastim-sndz during Q1 2017 and the disparity in collection periods impedes comparison over the 2 time periods; however, the proportion of mentions was similar.
- Not all states were included in the medical transcription database, so study findings are not nationally representative.

Conclusions

- Among 21,222 records reporting a G-CSF in this medical transcription database, only 140 mentions (0.7%) of filgrastim-sndz were documented in the 18 months since its entry into the US marketplace, with no observable increase in mentions between Q1 2017 and 2016.
- Observed differences in filgrastim-sndz from other G-CSFs in provider type and geographic patterns may reflect regional differences in formulary listings and clinical treatment patterns.
- Raising awareness and understanding of biosimilars among US clinicians and payers is likely required for filgrastim-sndz to be used more widely in clinical practice.
- Analyses over a longer time period, capturing longitudinal patient-level G-CSF utilization, will help to clarify the impact of biosimilar G-CSFs on US practice patterns.

References

1. https://www.novartis.com/news/media-releases/sandoz-launches-zarxiotm-filgrastim-sndz-first-biosimilar-united-states; accessed May 8, 2017.
2. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=fe707775-a0ae-41b5-a744-28c41889fce8&type=display; accessed May 8, 2017.
3. http://www.granixhcp.com/Pdf/prescribing-information.pdf; accessed May 8, 2017.
4. Smith TJ, et al. *J Clin Oncol* 2015. 33(28):3199-3212.

Disclosures

The authors are employees and stock shareholders of Envision Pharma Group and developed the data extraction criteria. RealHealthData provided the data for this study at the authors' request and without compensation.

karen.smoyer@envisionpharmagroup.com
briain.ohartaigh@envisionpharmagroup.com

Acknowledgements

The authors would like to thank Philip Howell of RealHealthData for his assistance in providing the patient counts and Envision Pharma Group's Creative and Editorial departments for their assistance in poster production. This study was funded by Envision Market Access Solutions, part of the Envision Pharma Group.

Presented at the 22nd Annual International Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), 20-24 May, 2017, Boston, MA, USA