Filgrastim originator use decreased and filgrastim biosimilar use increased over time. Pegfilgrastim biosimilar uptake is occurring.

CHANGES IN G-CSF BIOSIMILAR AND ORIGINATOR USE OVER TIME

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INTRODUCTION

- Since 2015, several filgrastim biosimilars have been introduced to the US market and pegfilgrastim biosimilars began entering the market in 2018
- The FDA created a biosimilar approval pathway to support the safety and availability of these medications
- Increased biosimilar availability can increase patient access and decrease the financial burden on patients and health care systems
- It is unknown how biosimilar availability influences prescribing patterns
- The Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) was established in 2015 to fill the public health gap of monitoring biosimilar effectiveness and safety relative to their reference biologics
- The BBCIC's Distributed Research Network (DRN) is uniquely positioned to support pharmacoepidemiologic studies of biologics and biosimilars
- The BBCIC G-CSF study team has previously demonstrated febrile neutropenia (FN) and G-CSF reference product adverse event rates identified in the BBCIC's DRN are consistent with reported outcomes
- Our objective was to summarize existing real-world data and observational studies of G-CSF products used for the prevention of chemotherapy-induced neutropenia (CIN)

RESEARCH QUESTION

- Has G-CSF product use and switching between products changed with biosimilar availability?

METHODS

- Retrospective descriptive analysis of administrative claims at participating BBCIC DRN sites: CVS Health Clinical Trial Services, an Aetna affiliate, Harvard Pilgrim Health Care Institute (HPHCI), HealthCore Inc., (Elevance Health), and HealthPartners Institute (HPI)
- Patients 20 years and older receiving any G-CSF originator or biosimilar for FN prophylaxis from 2015-2019 during first cycle chemotherapy for newly diagnosed cancers were included
- CIN was determined using National Comprehensive Cancer Network (NCCN) guidelines
- Chemotherapy drug codes were identified from Healthcare Common Procedure Coding System (HCPCS) J-codes, National Drug Codes (NDC), and Current Procedural Terminology (CPT) Level II codes
- Claims containing non-discriminate J-codes for new chemotherapy or G-CSF products not yet assigned a specific J-code were excluded
- FN and safety events including acute respiratory distress syndrome, capillary leak syndrome, cutaneous vasculitis, glomerulonephritis, leukocytosis, serious allergic reaction, splenic rupture, and thrombocytopenia are described
- HPHCI obtained an independent IRB review and the remaining Research Partners ceded IRB authority to HPI

RESULTS

- 17,006 patients received G-CSF prophylaxis: 15,496 (91%) pegfilgrastim, 858 (5%) pegfilgrastim biosimilars, 303 (2%) filgrastim, 296 (1%) filgrastim biosimilars, and 53 (<1%) combinations as described in Table 1
- G-CSF prophylaxis was highest among patients 50-64 years and females (Table 2)
- Combined Comorbidity scores were similar across products (Table 2)
- G-CSF prophylaxis administration to those at high FN risk was <100% and use was identified among those at low FN risk
- Filgrastim originator use decreased while filgrastim biosimilar use increased from 2016 to 2019 and in 2019, pegfilgrastim originator use decreased to 74% (Table 3)
- Of those receiving first cycle filgrastim product, 56 (9%) did not receive a second chemotherapy cycle, while those who received a 2nd cycle, 125 (20%) received a pegfilgrastim product (Table 4)
- Of those receiving first cycle pegfilgrastim product, 795 (5%) did not receive a second chemotherapy cycle, while those who received a 2nd cycle, 15,466 (99%) received a pegfilgrastim product (Table 4)

CONCLUSIONS

- Pegfilgrastim use is markedly higher than filgrastim use overall
- We identified G-CSF administration among patients receiving chemotherapy associated with low FN risk
- Filgrastim biosimilar use increased over time and pegfilgrastim biosimilar use is identified
- Switching G-CSF products from first to second cycle was more common in patients initially receiving filgrastim

Table 1. G-CSF receipt by cancer diagnosis and G-CSF product

Cancer Diagnosis	Filgrastim	tbo-filgrastim	Filgrastim-sndz	Filgrastim Combo	Pegfilgrastim	Pegfilgrastim-cbqv	Pegfilgrastim-jmdb	Pegfilgrastim / Filgrastim Combo
First Cycle Use n (%)	303 (1.8%)	87 (<1%)	209 (1.2%)	16 (<1%)	15,496 (91.1%)	507 (3.0%)	351 (2.1%)	37 (<1%)
Breast	156 (51.5%)	46 (52.9%)	118 (56.5%)	7 (43.8%)	10,895 (70.3%)	315 (62.1%)	225 (64.1%)	26 (70.3%)
Cervical	--	--	--	--	29 (0.2%)	--	--	--
Colorectal	11 (3.6%)	3 (3.4%)	7 (3.3%)	1 (6.3%)	274 (1.8%)	11 (2.2%)	6 (1.7%)	--
Lung	21 (6.9%)	9 (10.3%)	12 (5.7%)	2 (12.5%)	791 (5.1%)	41 (8.1%)	23 (6.6%)	2 (5.4%)
NHL	54 (17.8%)	16 (18.4%)	36 (17.2%)	3 (18.8%)	2,312 (14.9%)	83 (16.4%)	60 (17.1%)	7 (18.9%)
Ovarian	31 (10.2%)	6 (6.9%)	7 (3.3%)		379 (2.4%)	12 (2.4%)	12 (3.4%)	1 (2.7%)
Pancreatic	17 (5.6%)	5 (5.7%)	15 (7.2%)	2 (12.5%)	473 (3.1%)	38 (7.5%)	21 (6.0%)	--
Testicular	6 (2.0%)	--	7 (3.3%)	1 (6.3%)	135 (0.9%)	2 (0.4%)	1 (0.3%)	--
Uterine	7 (2.3%)	2 (2.3%)	7 (3.3%)	--	208 (1.3%)	5 (1.0%)	3 (0.9%)	1 (2.7%)

Table 2. Cycle 1 G-CSF receipt by patient age, sex, mean combined comorbidity score, chemotherapy risk of febrile neutropenia (FN), and antibiotic use

Cancer Diagnosis	Filgrastim	tbo-filgrastim	Filgrastim-sndz	Filgrastim Combo	Pegfilgrastim	Pegfilgrastim-cbqv	Pegfilgrastim-jmdb	Pegfilgrastim / Filgrastim Combo
First Cycle Use n (%)	303 (1.8%)	87 (<1%)	209 (1.2%)	16 (<1%)	15,496 (91.1%)	507 (3.0%)	351 (2.1%)	37 (<1%)
Age at index date								
20-49	77 (25.4%)	22 (25.3%)	72 (34.4%)	2 (12.5%)	4,614 (29.8%)	131 (25.8%)	88 (25.1%)	11 (29.7%)
50-64	142 (46.9%)	41 (47.1%)	85 (40.7%)	5 (31.3%)	7,049 (45.5%)	207 (40.8%)	147 (41.9%)	15 (40.5%)
65-79	70 (23.1%)	22 (25.3%)	46 (22.0%)	9 (56.3%)	3,309 (21.4%)	144 (28.4%)	97 (27.6%)	9 (24.3%)
80+	14 (4.6%)	2 (2.3%)	6 (2.9%)	--	524 (3.4%)	25 (4.9%)	19 (5.4%)	2 (5.4%)
Female Sex	239 (78.9%)	63 (72.4%)	161 (77.0%)	11 (68.8%)	13,151 (84.9%)	398 (78.5%)	293 (83.5%)	32 (86.5%)
Mean CC Score* (SD)	1.2 (1.9)	1.2 (1.8)	1.3 (2.0)	1.5 (2.1)	0.9 (1.6)	1.2 (1.8)	1.1 (1.9)	0.8 (1.6)
Cycle 1 FN risk								
High	160 (52.8%)	50 (57.5%)	126 (60.3%)	10 (62.5%)	12,609 (81.4%)	400 (78.9%)	267 (76.1%)	29 (78.4%)
Inter-mediate	124 (40.9%)	30 (34.5%)	75 (35.9%)	5 (31.3%)	2,549 (16.4%)	85 (16.8%)	76 (21.7%)	8 (21.6%)
Low	19 (6.3%)	7 (8.0%)	8 (3.8%)	1 (6.3%)	338 (2.2%)	22 (4.3%)	8 (2.3%)	--
Antibiotic use	35 (11.6%)	13 (14.9%)	30 (14.4%)	1 (6.3%)	1,243 (8.0%)	37 (7.3%)	26 (7.4%)	10 (27.0%)

*Combined Comorbidity Score

Table 3. Cycle 1 G-CSF administration by product and year

Year	Filgrastim n (%)	tbo-filgrastim n (%)	Filgrastim-sndz n (%)	Filgrastim Combo n (%)	Pegfilgrastim n (%)	Pegfilgrastim-cbqv n (%)	Pegfilgrastim-jmdb n (%)	Pegfilgrastim/ Filgrastim Combo n (%)
2015	102 (3.3%)	17 (<1%)	--	1 (<1%)	2,972 (95.8%)	--	--	10 (<1%)
2016	81 (2.3%)	16 (<1%)	26 (<1%)	1 (<1%)	3,332 (96.2%)	--	--	7 (<1%)
2017	54 (1.5%)	24 (<1%)	54 (1.5%)	3 (<1%)	3,387 (95.9%)	--	--	10 (<1%)
2018	43 (1.3%)	19 (<1%)	65 (1.9%)	3 (<1%)	3,197 (95.1%)	--	32 (<1%)	4 (<1%)
2019	23 (<1%)	11 (<1%)	64 (1.8%)	8 (<1%)	2,604 (73.6%)	503 (14.2%)	319 (9.0%)	6 (<1%)

Table 4. Cycle 1 and Cycle 2 G-CSF receipt by product

G-CSF Product	Filgrastim	tbo-filgrastim	Filgrastim-sndz	Filgrastim Combo	Pegfilgrastim	Pegfilgrastim-cbqv	Pegfilgrastim-jmdb	Pegfilgrastim/ Filgrastim Combo
First Cycle Use n (%)	303 (1.8%)	87 (<1%)	209 (1.2%)	16 (<1%)	15,496 (91.1%)	507 (3.0%)	351 (2.1%)	37 (<1%)
Second Cycle Use n(%)								
No receipt	26 (8.6%)	9 (10.3%)	20 (9.6%)	1 (6.3%)	704 (4.5%)	66 (13.0%)	25 (7.1%)	3 (8.1%)
Filgrastim	203 (67.0%)	2 (2.3%)	1 (0.5%)	5 (31.3%)	54 (0.3%)	--	--	4 (10.8%)
tbo-filgrastim	4 (1.3%)	61 (70.1%)	--	2 (12.5%)	13 (0.1%)	--	2 (0.6%)	--
Filgrastim-sndz	2 (0.7%)	--	142 (67.9%)	3 (18.8%)	20 (0.1%)	1 (0.2%)	--	--
Filgrastim combo	--	2 (2.3%)	2 (1.0%)	5 (31.3%)	3 (0.0%)	--	--	--
Pegfilgrastim	64 (21.1%)	11 (12.6%)	37 (17.7%)	--	14,639 (94.5%)	19 (3.7%)	19 (5.4%)	20 (54.1%)
Pegfilgrastim-cbqv	1 (0.3%)	2 (2.3%)	3 (1.4%)	--	18 (0.1%)	420 (82.8%)	11 (3.1%)	--
Pegfilgrastim-jmdb	--	--	2 (1.0%)	--	22 (0.1%)	--	294 (83.8%)	--
Pegfilgrastim/ Filgrastim combo	3 (1.0%)	--	2 (1.0%)	--	23 (0.1%)	1 (0.2%)	--	10 (27.0%)

COI & FINANCIAL SUPPORT

- This project was funded by the BBCIC
- Erick Moyneur is a consultant of HPHCI, Pfizer, IMV, and Endoceutics. Jaclyn Bosco is an employee at IQVIA. Djeneba Audrey Djibo, Elizabeth Engelhardt, Annemarie Kline, Cheryl McMahill-Walraven are employees at CVS Health. Aziza Jamal-Allial is an employee at HealthCore, Inc. (Elevance Health). Edward Li is an employee at Sandoz. Nancy Lin is an employee at Health Catalyst. Ali McBride is an employee at Bristol Myers Squibb.

HealthPartners Institute

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