

Title	Users of Pegfilgrastim Less Than or Equal to 13 Years of Age
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Joint PASS	Yes
Research Question and Objectives	Describe the first-time pegfilgrastim users between 01 January 2013 and 31 December 2018 stratified by calendar year and by place of service for administration of pegfilgrastim for populations ≤ 13 and < 2 years of age
Country of Study	United States
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1. ABSTRACT

- **Title**

Users of Pegfilgrastim Less Than or Equal to 13 Years of Age

- **Keywords**

myelosuppressive chemotherapy; on-label; pediatric; pegfilgrastim; place of service

- **Rationale and Background**

Neulasta® (pegfilgrastim) was approved in the United States in 2002 in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. On 08 November 2018, Amgen received a Food and Drug Administration (FDA) Information Request regarding medication errors associated with doses < 0.6 mL (6 mg) in pediatric patients weighing < 45 kg. Amgen submitted real-world data (included in observational research study report 20180440) that described the trends and use of pegfilgrastim injection in pediatric patients weighing < 45 kg from 2013 to 2017 in the United States. On 10 October 2019, the FDA issued an Order Letter that established postmarketing requirement (PMR) 3731-1, requesting Amgen to develop a presentation to directly and accurately administer Neulasta to pediatric patients < 45 kg, and conduct human factors studies to evaluate the ability of healthcare providers and/or caregivers to measure the appropriate doses.

To respond to this request, Study 20200114 was planned to understand the utilization frequency of and the setting for the first pegfilgrastim administration in patients < 2 years of age (a surrogate for weight < 10 kg) and various age ranges up to and including 13 years of age (a surrogate for weight < 45 kg). The results from this analysis will support Amgen's response to the FDA PMR.

- **Research Question and Objectives**

Describe the first-time pegfilgrastim users and the place of service for pegfilgrastim administration, stratified by calendar year, for populations ≤ 13 and < 2 years of age.

- **Study Design**

Retrospective real-world data analysis

- **Setting**

IBM® MarketScan® Commercial Claims and Encounters (CCAE) and Medicare Supplemental and Coordination of Benefits (Medicare) database, which is a large, nationally represented, US commercial health plan database.

- **Subjects and Study Size, Including Dropouts**

Commercially insured patients in the MarketScan database from 01 January 2013 to 31 December 2018.

- **Variables and Data Sources**

Data source: IBM MarketScan Database.

Variables: age and place of service for the first pegfilgrastim administration, health plan enrollment dates.

- **Results**

Overall results are summarized for 6 calendar years from 2013 to 2018.

Parameter	≤ 13 Years of Age	< 2 Years of Age
first-time users	762 of 126 150, 0.60%	75 of 126 150, 0.06%
Clinical setting	611 of 762, 80.2%	59 of 75, 78.7%
On-label use	729 of 762, 95.7%	70 of 75, 93.3%

Note: On-label and off-label exposures were assessed according to the Neulasta United States Prescribing Information (v25, dated January 2020).

- **Discussion**

The proportion of first-time pegfilgrastim users ≤ 13 years of age was low (0.60%; range 0.40% to 0.90%), and even lower (0.06%; range 0.03% to 0.10%) for patients < 2 years of age (from 2013 to 2018). Most patients ≤ 13 years and < 2 years of age received pegfilgrastim in clinical settings and for on-label use (on-label and off-label exposures were assessed according to the Neulasta United States Prescribing Information [v25, dated January 2020]). The MarketScan database does not include traditional Medicare or Medicare Advantage plans. Because the total number of pegfilgrastim users is likely under-represented in these databases, the proportion of first-time pegfilgrastim users ≤ 13 years of age is probably overestimated in this analysis.

- **Marketing Authorization Holder**

Amgen Inc.

- **Names and Affiliations of Principal Investigators**

A list of all collaborating institutions and investigators will be made available on request.

2. LIST OF ABBREVIATIONS

Abbreviation or Term	Definition/Explanation
FDA	Food and Drug Administration
HCP	healthcare provider
HF	human factors
PMR	postmarketing requirement
US	United States
USPI	United States Prescribing Information
Clinical setting	Inpatient hospital, outpatient hospital, emergency room hospital, ambulatory surgical center, physician office, and dispenses in pharmacy
Off-label use	If no occurrence of nonmyeloid cancer diagnosis before the first pegfilgrastim exposure (on-label and off-label exposures were assessed according to the Neulasta USPI [v25, dated January 2020])
On-label use	If a patient had evidence of a nonmyeloid cancer diagnosis occurring any time before the first pegfilgrastim exposure (on-label and off-label exposures were assessed according to the Neulasta USPI [v25, dated January 2020])
Other setting	Other place of service or dispensed through mail order

3. INVESTIGATORS

A list of all collaborating institutions and investigators will be made available on request.

4. OTHER RESPONSIBLE PARTIES

Covance Scientific Services & Solutions Pvt. Ltd. was responsible for authoring and publishing the observational research study report.

5. MILESTONES

The dates for cohort construction, data collection, study registration, analysis, and final report are provided in [Table 5-1](#).

Table 5-1. Study Milestones

Milestone	Planned Date	Actual Date
Cohort construction	03 March 2020	03 March 2020
End of data collection	16 March 2020	16 March 2020
Registration in the EU Postauthorization Safety Study	17 March 2020	17 March 2020
Analysis	09 April 2020	09 April 2020
Final report of study results	07 July 2020	07 July 2020

6. RATIONALE AND BACKGROUND

Neulasta® (pegfilgrastim) was approved in the United States (US) in 2002 to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

On 08 November 2018, Amgen received a Food and Drug Administration (FDA) Information Request regarding pegfilgrastim injection medication errors associated with doses < 0.6 mL (6 mg) in pediatric patients weighing < 45 kg. Amgen's response, submitted on 20 December 2018, provided real-world data (included in observational research study report 20180440) to describe the trends and use of pegfilgrastim injection in pediatric patients weighing < 45 kg from 2013 to 2017 in the United States.

Amgen received a Complete Response Letter and Order Letter from the FDA on 10 October 2019. To address the concerns raised in its review of pediatric dosing errors, the FDA Order Letter established the following postmarketing requirement (PMR):

PMR 3731-1: Submit pediatric assessments for Neulasta (pegfilgrastim) as described in section 505B(a)(2)(A) of the FD&C Act, including development of an "appropriate formulation" (presentation) that can be used to directly and accurately administer Neulasta (pegfilgrastim) to pediatric patients who weigh less than 45 kg and require doses that are less than 0.6 mL (6 mg), and conducting any necessary human factors studies to evaluate the ability of healthcare providers and/or caregivers to measure the appropriate doses.

On 08 January 2020, Amgen submitted a response to the FDA Order Letter, which included a proposal to address PMR 3731-1. Amgen's proposal consisted of a single-use, disposable vial intended for administering a variable, weight-based dose through a 0.01 mL graduated syringe in pediatric patients by a caregiver or healthcare provider (HCP). On 10 February 2020, the FDA provided a response to Amgen's proposal. The FDA was concerned that users may not be able to navigate the use of this vial and syringe in the real-world setting. The FDA recommended Amgen to submit the human factors (HF) validation study protocol for feedback from the FDA before commencing the study.

To inform Amgen's proposal for the intended users of the proposed pediatric presentation and design of the corresponding HF study, Study 20200114 was planned to understand the utilization frequency of pegfilgrastim, and to understand in what setting pegfilgrastim was being administered in patients < 2 years of age (a surrogate for weight < 10 kg) ([Centers for Disease Control and Prevention Growth Chart, 2009](#)) as well as various age ranges (up to and including 13 years of age) that corresponded to weight < 45 kg. The results from this analysis will support Amgen's response to the FDA PMR.

7. RESEARCH QUESTION AND OBJECTIVES

The primary objective of this study was to describe the pegfilgrastim users between 01 January 2013 and 31 December 2018, stratified by calendar year and by place of service for administration of pegfilgrastim, for the following age populations:

- patients ≤ 13 years of age
- subset of patients < 2 years of age
- patients by individual ages (< 1 , 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13 years of age)
- patients 0 to < 2 , 2 to 5, 6 to 10, and 11 to 13 years of age

8. AMENDMENTS AND UPDATES

None.

9. RESEARCH METHODS

9.1 Study Design

This was a descriptive, retrospective analysis of a nationally represented US commercial health plan database.

9.2 Setting

The study was conducted using both the databases from IBM® MarketScan® ([Cappell et al, 2014](#)): Commercial Claims and Encounters (CCAE) (Commercial) database and Medicare Supplemental and Coordination of Benefits (Medicare) database.

9.3 Subjects

Among the patients enrolled in the IBM MarketScan database, patients who received their first, incident, administration of pegfilgrastim from 01 January 2013 to 31 December 2018 were considered for analysis.

9.4 Variables

Primary variables included in the analysis were number of first-time pegfilgrastim users:

- ≤ 13 years of age with subset population < 2 years of age
- by individual ages (< 1 , 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13 years of age)
- in the age range 0 to < 2 , 2 to 5, 6 to 10, and 11 to 13 years

Data were stratified by place of service where the users received their first pegfilgrastim dose: whether at home, in the clinic, or in any other setting. Clinical setting included inpatient hospital, outpatient hospital, emergency room hospital, ambulatory surgical center, office, and prescriptions dispensed in the pharmacy; other setting included prescriptions dispensed through mail order or other places of service; and home setting was defined as the place of service for first pegfilgrastim administration at patient's home.

9.5 Data Sources and Measurement

The IBM MarketScan database, which captured person-specific clinical utilization, expenditures, and enrollment across inpatient, outpatient, prescription drug, and carve-out services from a selection of large employers, health plans, and government and public organizations, was the data source used. The database contains the inpatient, outpatient, and outpatient prescription drug experience of employees and their dependents, covered under a variety of fee-for-service, and managed care health plans,

including exclusive provider organizations, preferred provider organizations, point-of-service plans, indemnity plans, and health maintenance organizations.

9.6 Bias

The proportion of users of pegfilgrastim ≤ 13 years of age and the subset of patients < 2 years of age may be an overestimation of the national proportion of pegfilgrastim users in the corresponding age groups, as the IBM MarketScan database includes patients enrolled in Medicare Supplemental but it does not include traditional Medicare enrollees. In addition, patients enrolled in Medicaid are not included in the IBM MarketScan database, and because a substantial proportion of Medicaid enrollees in the United States are ≤ 18 years of age, this analysis may underestimate the proportion of pegfilgrastim users in ≤ 13 years of age. However, as a higher frequency of cancer diagnoses is generally observed in older patients (ie, Medicare aged patients) and thus most pegfilgrastim users are older, we can assume that the overestimation bias is more likely to occur than the underestimation bias.

9.7 Study Size

This was an observational study of a large representative sample of the US commercially insured population. The study was descriptive and no hypothesis was tested. Thus, no sample size was calculated for this analysis. The study population was extracted from the IBM MarketScan database, and all first-time pegfilgrastim users in the appropriate age ranges were included.

9.8 Data Transformation

The FDA requested a HF validation study to evaluate the ability of HCPs and/or caregivers to measure the appropriate doses of pegfilgrastim for pediatric patients weighing < 45 kg. As suggested by the FDA, patients ≤ 13 years of age were chosen as a surrogate for patients weighing < 45 kg. Patients < 2 years of age were chosen by Amgen as a surrogate for patients weighing < 10 kg ([Centers for Disease Control and Prevention Growth Chart, 2009](#)).

9.9 Statistical Methods

9.9.1 Main Summary Measures

The main summary measure was proportion of first-time pegfilgrastim users by calendar year. Data were stratified by individual age and place of service for the first administration of pegfilgrastim.

9.9.2 Main Statistical Methods

No statistical methods were used in this analysis.

9.9.3 Missing Values

Not applicable: no pegfilgrastim users ≤ 13 years of age had missing information.

9.9.4 Sensitivity Analyses

A sensitivity analysis was conducted to assess the number and proportion of pediatric patients who used pegfilgrastim on-label as compared with off-label use in age groups < 2 and ≤ 13 years, stratified by calendar year. On-label and off-label exposures were assessed according to the Neulasta United States Prescribing Information (USPI) (v25, dated January 2020) ([Neulasta® United States Prescribing Information, 2020](#)).

Among all patients ≤ 13 years of age identified as pegfilgrastim users, if a patient had evidence of a nonmyeloid cancer diagnosis occurring any time before the first pegfilgrastim exposure, the patient was considered “on-label” exposed; however, if no occurrence of nonmyeloid cancer diagnosis was found, the exposure was considered as “off-label.”

9.9.5 Amendments to the Statistical Analysis Plan

The protocol included the statistical analysis, and was not amended.

9.10 Quality Control

Amgen Inc. managed data quality, including both production and quality control programming. A primary programmer constructed the analytic data file, and an independent programmer verified it. Once completed, the primary statistical analysis programmer conducted the analysis.

10. RESULTS

10.1 Participants

Among the 126 150 first-time pegfilgrastim users, a total of 762 users ≤ 13 years of age and 75 users < 2 years of age were included in the analysis ([Table 10-1](#)).

10.2 Descriptive Data

Descriptive data included the number of first-time pegfilgrastim users by calendar year from 01 January 2013 to 31 December 2018.

10.3 Outcome Data

Outcome data included the number of first-time pegfilgrastim users ≤ 13 years of age, and place of service for the first-time administration of pegfilgrastim.

10.4 Main Results

10.4.1 Participants

Among the 126 150 first-time pegfilgrastim users from 01 January 2013 to 31 December 2018 in the IBM MarketScan database, 762 users (0.60%) were ≤ 13 years of age and 75 users (0.06%) were < 2 years of age ([Table 10-1](#)).

Table 10-1. Number of Users of Pegfilgrastim at First Administration

12-Month Intervals (Calendar Year)	All Ages	Age ≤ 13 Years n (%)	Age < 2 Years n (%)
2013	29 842	148 (0.50)	9 (0.03)
2014	31 190	133 (0.43)	18 (0.06)
2015	17 951	115 (0.64)	11 (0.06)
2016	17 437	112 (0.64)	10 (0.06)
2017	15 012	123 (0.82)	12 (0.08)
2018	14 718	131 (0.89)	15 (0.10)
Total	126 150	762 (0.60)	75 (0.06)

Note: Percentage of patients is calculated out of all patients.

Source: [Table 1](#) and [Table 2](#)

10.4.2 Frequency of Use

Of the 762 first-time pegfilgrastim users up to and including 13 years of age, proportion of users by individual age ranged from approximately 2% (< 1 year of age) to 11% (13 years of age) ([Table 10-2](#)).

Table 10-2. First-time Pegfilgrastim Users Stratified by Individual Age at First Administration

Age (years)	12-Month Intervals (Calendar Year), n (%)						Total N (%)
	2013	2014	2015	2016	2017	2018	
< 1	0 (0.0)	3 (2.3)	4 (3.5)	3 (2.7)	2 (1.6)	5 (3.8)	17 (2.2)
1	9 (6.1)	15 (11.3)	7 (6.1)	7 (6.3)	10 (8.1)	10 (7.6)	58 (7.6)
2	7 (4.7)	7 (5.3)	13 (11.3)	8 (7.1)	12 (9.8)	13 (9.9)	60 (7.9)
3	13 (8.8)	10 (7.5)	5 (4.3)	7 (6.3)	9 (7.3)	10 (7.6)	54 (7.1)
4	10 (6.8)	14 (10.5)	5 (4.3)	7 (6.3)	17 (13.8)	10 (7.6)	63 (8.3)
5	14 (9.5)	6 (4.5)	10 (8.7)	7 (6.3)	8 (6.5)	9 (6.9)	54 (7.1)
6	10 (6.8)	12 (9.0)	12 (10.4)	6 (5.4)	7 (5.7)	9 (6.9)	56 (7.3)
7	11 (7.4)	6 (4.5)	5 (4.3)	4 (3.6)	5 (4.1)	6 (4.6)	37 (4.9)
8	9 (6.1)	19 (14.3)	8 (7.0)	7 (6.3)	10 (8.1)	9 (6.9)	62 (8.1)
9	9 (6.1)	4 (3.0)	10 (8.7)	9 (8.0)	7 (5.7)	7 (5.3)	46 (6.0)
10	11 (7.4)	6 (4.5)	10 (8.7)	6 (5.4)	9 (7.3)	8 (6.1)	50 (6.6)
11	9 (6.1)	10 (7.5)	6 (5.2)	8 (7.1)	8 (6.5)	11 (8.4)	52 (6.8)
12	17 (11.5)	11 (8.3)	5 (4.3)	17 (15.2)	10 (8.1)	12 (9.2)	72 (9.4)
13	19 (12.8)	10 (7.5)	15 (13.0)	16 (14.3)	9 (7.3)	12 (9.2)	81 (10.6)
Total	148 (100.0)	133 (100.0)	115 (100.0)	112 (100.0)	123 (100.0)	131 (100.0)	762 (100.0)

Source: [Table 3](#)

Overall, most first-time pegfilgrastim users ≤ 13 years of age were between 6 and 10 years of age (251 of 762 patients, 32.9%) ([Table 10-3](#)).

Table 10-3. First-time Pegfilgrastim Users Stratified by Age Range at First Administration

12-Month Intervals (Calendar Year)	< 2 Years n (%)	2 - 5 Years n (%)	6 - 10 Years n (%)	11 - 13 Years n (%)	All Patients ≤ 13 Years N
2013	9 (6.1)	44 (29.7)	50 (33.8)	45 (30.4)	148
2014	18 (13.5)	37 (27.8)	47 (35.3)	31 (23.3)	133
2015	11 (9.6)	33 (28.7)	45 (39.1)	26 (22.6)	115
2016	10 (8.9)	29 (25.9)	32 (28.6)	41 (36.6)	112
2017	12 (9.8)	46 (37.4)	38 (30.9)	27 (22.0)	123
2018	15 (11.5)	42 (32.1)	39 (29.8)	35 (26.7)	131
Total	75 (9.8)	231 (30.3)	251 (32.9)	205 (26.9)	762

Note: Percentage of patients is calculated out of all patients ≤ 13 years of age.

Source: [Table 4](#)

10.4.3 Place of Service

Overall, most first-time users ≤ 13 years of age (611 of 762 patients, 80.2%) and < 2 years of age (59 of 75 patients, 78.7%) received pegfilgrastim in clinical settings (Table 10-4).

Table 10-4. Place of Service for First-time Administration of Pegfilgrastim (Age)

12-Month Intervals (Calendar Year)	Ages < 2 Years (N = 75) n (%)				Ages ≤ 13 Years (N = 762) n (%)			
	Home	Clinical ^a	Other ^b	Total N	Home	Clinical ^a	Other ^b	Total N
2013	1 (11.1)	8 (88.9)	0 (0.0)	9	19 (12.8)	123 (83.1)	6 (4.1)	148
2014	0 (0.0)	17 (94.4)	1 (5.6)	18	15 (11.3)	108 (81.2)	10 (7.5)	133
2015	0 (0.0)	11 (100.0)	0 (0.0)	11	10 (8.7)	97 (84.3)	8 (7.0)	115
2016	3 (30.0)	7 (70.0)	0 (0.0)	10	13 (11.6)	90 (80.4)	9 (8.0)	112
2017	1 (8.3)	8 (66.7)	3 (25.0)	12	12 (9.8)	96 (78.0)	15 (12.2)	123
2018	1 (6.7)	8 (53.3)	6 (40.0)	15	6 (4.6)	97 (74.0)	28 (21.4)	131
Total	6 (8.0)	59 (78.7)	10 (13.3)	75	75 (9.8)	611 (80.2)	76 (10.0)	762

^a Clinical was defined as inpatient hospital, outpatient hospital, emergency room hospital, ambulatory surgical center, physician office, and dispenses in pharmacy.

^b Other was defined as other place of service or dispensed through mail order.

Source: Table 5

The proportion of patients receiving pegfilgrastim in clinical settings by individual age-year (< 1 to 13 years) ranged from 75.8% to 87.5% (Table 10-5) and $> 75\%$ in all age categories (Table 10-6).

Place of service for administration of pegfilgrastim by age category is provided in Table 10-6. Overall, 78.8% of patients in the 2 to 5 years age group received pegfilgrastim in clinical settings. Similarly, 80.5% of patients in the 6 to 10 years age group and 82.0% of patients in the 11 to 13 years age group received pegfilgrastim in clinical settings.

**Table 10-5. Place of Service for First-time Administration of Pegfilgrastim
(Individual Age-year)**

Age (years)	All Years (2013 - 2018), n (%)			Total N
	Home	Clinical ^a	Other ^b	
< 1	1 (5.9)	14 (82.4)	2 (11.8)	17
1	5 (8.6)	45 (77.6)	8 (13.8)	58
2	5 (8.3)	49 (81.7)	6 (10.0)	60
3	9 (16.7)	43 (79.6)	2 (3.7)	54
4	9 (14.3)	48 (76.2)	6 (9.5)	63
5	4 (7.4)	42 (77.8)	8 (14.8)	54
6	4 (7.1)	49 (87.5)	3 (5.4)	56
7	3 (8.1)	32 (86.5)	2 (5.4)	37
8	10 (16.1)	47 (75.8)	5 (8.1)	62
9	6 (13.0)	35 (76.1)	5 (10.9)	46
10	5 (10.0)	39 (78.0)	6 (12.0)	50
11	4 (7.7)	41 (78.9)	7 (13.5)	52
12	8 (11.1)	58 (80.6)	6 (8.3)	72
13	2 (2.5)	69 (85.2)	10 (12.4)	81

^a Clinical was defined as inpatient hospital, outpatient hospital, emergency room hospital, ambulatory surgical center, physician office, and dispenses in pharmacy.

^b Other was defined as other place of service and dispensed through mail order.

Source: [Table 6](#)

**Table 10-6. Place of Service for First-time Administration of Pegfilgrastim
(Age Category)**

Age Range (years)	Setting	Calendar Year, n (%)						Total N (%)
		2013	2014	2015	2016	2017	2018	
< 2	Home	1 (11.1)	0 (0.0)	0 (0.0)	3 (30.0)	1 (8.3)	1 (6.7)	6 (8.0)
	Clinical ^a	8 (88.9)	17 (94.4)	11 (100.0)	7 (70.0)	8 (66.7)	8 (53.3)	59 (78.7)
	Other ^b	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	3 (25.0)	6 (40.0)	10 (13.3)
2 - 5	Home	8 (18.2)	8 (21.6)	2 (6.1)	5 (17.2)	3 (6.5)	1 (2.4)	27 (11.7)
	Clinical ^a	33 (75.0)	27 (73.0)	29 (87.9)	24 (82.8)	37 (80.4)	32 (76.2)	182 (78.8)
	Other ^b	3 (6.8)	2 (5.4)	2 (6.1)	0 (0.0)	6 (13.0)	9 (21.4)	22 (9.5)
6 - 10	Home	4 (8.0)	7 (14.9)	6 (13.3)	2 (6.3)	5 (13.2)	4 (10.3)	28 (11.2)
	Clinical ^a	44 (88.0)	37 (78.7)	38 (84.4)	26 (81.3)	30 (78.9)	27 (69.2)	202 (80.5)
	Other ^b	2 (4.0)	3 (6.4)	1 (2.2)	4 (12.5)	3 (7.9)	8 (20.5)	21 (8.4)
11 - 13	Home	6 (13.3)	0 (0.0)	2 (7.7)	3 (7.3)	3 (11.1)	0 (0.0)	14 (6.8)
	Clinical ^a	38 (84.4)	27 (87.1)	19 (73.1)	33 (80.5)	21 (77.8)	30 (85.7)	168 (82.0)
	Other ^b	1 (2.2)	4 (12.9)	5 (19.2)	5 (12.2)	3 (11.1)	5 (14.3)	23 (11.2)

Note: Total number of first-time pegfilgrastim users stratified by age range at first administration by calendar year are provided in [Table 10-3](#).

^a Clinical was defined as inpatient hospital, outpatient hospital, emergency room hospital, ambulatory surgical center, physician office, and dispenses in pharmacy.

^b Other was defined as other place of service or dispensed through mail order.

Source: [Table 7](#)

10.5 Sensitivity Analyses

Overall, on-label use of pegfilgrastim at first administration was reported for most users < 2 years of age (70 of 75 patients, 93.3%) and ≤ 13 years of age (729 of 762 patients, 95.7%) (Table 10-7). The on-label use of pegfilgrastim at first administration ranged from 81.8% to 100.0% in < 2 years age group and 93.8% to 97.6% in ≤ 13 years age group from 2013 to 2018. On-label and off-label exposures were assessed according to the Neulasta USPI (v25, dated January 2020).

Table 10-7. Number of On-label and Off-label Users of Pegfilgrastim at First Administration (Sensitivity Analyses)

12-Month Intervals (Calendar Year)	Age < 2 Years			Age ≤ 13 Years		
	On-label n (%)	Off-label n (%)	Total N (%)	On-label n (%)	Off-label n (%)	Total N (%)
2013	8 (88.9)	1 (11.1)	9 (100.0)	143 (96.6)	5 (3.4)	148 (100.0)
2014	16 (88.9)	2 (11.1)	18 (100.0)	126 (94.7)	7 (5.3)	133 (100.0)
2015	9 (81.8)	2 (18.2)	11 (100.0)	109 (94.8)	6 (5.2)	115 (100.0)
2016	10 (100.0)	0 (0.0)	10 (100.0)	105 (93.8)	7 (6.3)	112 (100.0)
2017	12 (100.0)	0 (0.0)	12 (100.0)	120 (97.6)	3 (2.4)	123 (100.0)
2018	15 (100.0)	0 (0.0)	15 (100.0)	126 (96.2)	5 (3.8)	131 (100.0)
Total	70 (93.3)	5 (6.7)	75 (100.0)	729 (95.7)	33 (4.3)	762 (100.0)

Note: On-label and off-label exposures were assessed according to the Neulasta United States Prescribing Information (v25, dated January 2020).

Source: Table 8

Overall, among first-time pegfilgrastim users ≤ 13 years of age, the frequency of on-label use was evenly distributed in the users in the 2 and 5 years age group (221 of 762 patients, 30.3%), 6 and 10 years age group (239 of 762 patients, 32.8%), and 11 and 13 years age group (199 of 762 patients, 27.3%) (Table 10-8). Sensitivity analyses stratified by individual age and place of service are provided in Table 9 and Table 11, respectively.

Table 10-8. Proportion of On-label and Off-label Users of Pegfilgrastim at First Administration (Age Category) (Sensitivity Analyses)

12-Month Intervals (Calendar Year)	< 2 Years n (%)		2 - 5 Years n (%)		6 - 10 Years n (%)		11 - 13 Years n (%)		Total N (%)	
	On-label	Off-label	On-label	Off-label	On-label	Off-label	On-label	Off-label	On-label	Off-label
2013	8 (5.6)	1 (20.0)	44 (30.8)	0 (0.0)	46 (32.2)	4 (80.0)	45 (31.5)	0 (0.0)	143 (100.0)	5 (100.0)
2014	16 (12.7)	2 (28.6)	36 (28.6)	1 (14.3)	44 (34.9)	3 (42.9)	30 (23.8)	1 (14.3)	126 (100.0)	7 (100.0)
2015	9 (8.3)	2 (33.3)	32 (29.4)	1 (16.7)	43 (39.4)	2 (33.3)	25 (22.9)	1 (16.7)	109 (100.0)	6 (100.0)
2016	10 (9.5)	0 (0.0)	26 (24.8)	3 (42.9)	30 (28.6)	2 (28.6)	39 (37.1)	2 (28.6)	105 (100.0)	7 (100.0)
2017	12 (10.0)	0 (0.0)	45 (37.5)	1 (33.3)	37 (30.8)	1 (33.3)	26 (21.7)	1 (33.3)	120 (100.0)	3 (100.0)
2018	15 (11.9)	0 (0.0)	38 (30.2)	4 (80.0)	39 (31.0)	0 (0.0)	34 (27.0)	1 (20.0)	126 (100.0)	5 (100.0)
Total	70 (9.6)	5 (15.2)	221 (30.3)	10 (30.3)	239 (32.8)	12 (36.4)	199 (27.3)	6 (18.2)	729 (100.0)	33 (100.0)

Note: On-label and off-label exposures were assessed according to the Neulasta United States Prescribing Information (v25, dated January 2020).

Percentage of patients is calculated out of all patients ≤ 13 years of age.

Source: [Table 10](#)

10.6 Adverse Events/Adverse Reactions

This was a retrospective analysis of first-time pegfilgrastim user data. Adverse events or reactions were not recorded.

11. DISCUSSION

11.1 Key Results

Between 2013 and 2018 collectively, and by individual calendar year, the proportion of patients ≤ 13 years of age exposed to pegfilgrastim was low (762 of 126 150 patients, 0.60%; range 0.40% to 0.90%), and even lower for the subset of patients < 2 years of age (75 of 126 150 patients, 0.06%; range 0.03% to 0.10%), when assessed out of the total population of pegfilgrastim users captured in the IBM MarketScan database.

Overall, the proportion of first-time pegfilgrastim users was the highest in the 6 to 10 years age group (251 of 762 patients, 32.9%).

Overall, from 2013 to 2018, most patients (611 of 762 patients, 80.2% of those ≤ 13 years of age and 59 of 75 patients, 78.7% of those < 2 years of age) received pegfilgrastim in clinical settings. Patients across all age categories received pegfilgrastim more frequently in the clinical settings rather than at home or other place of service.

Overall, on-label use of pegfilgrastim at first administration was reported for most users ≤ 13 years of age (729 of 762 patients, 95.7%; range 93.8% to 97.6%) and < 2 years of age (70 of 75 patients, 93.3%; range 81.8% to 100.0%) (on-label and off-label exposures were assessed according to the Neulasta USPI [v25, dated January 2020]).

11.2 Limitations

Patients enrolled in Medicaid are not included in the IBM MarketScan database, and as a substantial proportion of the Medicaid enrollees in the United States are ≤ 18 years of age, this analysis may result in the underestimation of the proportion of users of pegfilgrastim in ≤ 13 years of age.

However, cancer diagnosis and thus use of pegfilgrastim is generally observed in older adults. According to Surveillance, Epidemiology, and End Results Program data for 2013 to 2017, patients ≥ 65 years of age account for 54.4% of new cases of cancer of any site ([National Cancer Institute, 2020](#)). Given that the IBM MarketScan database does not include traditional Medicare or Medicare Advantage plans, the total number of pegfilgrastim users captured in the IBM MarketScan is likely under-represented as a higher frequency of cancer diagnosis is generally observed in older patients.

Therefore, as most pegfilgrastim users are older, we can assume that an overestimation of the proportion of pegfilgrastim users ≤ 13 years of age is more likely to occur than an underestimation bias.

11.3 Interpretation

These results likely present an overestimation of the proportion of pegfilgrastim users who were ≤ 13 years of age.

11.4 Generalizability

These results are generalizable to the US commercially insured population of cancer patients who undergo myelosuppressive chemotherapy treatment. However, they are likely not generalizable to the cancer population at large in the United States who would receive myelosuppressive chemotherapy and would be eligible for pegfilgrastim treatment as the IBM MarketScan database represents a younger population.

12. OTHER INFORMATION

None.

13. CONCLUSION

Among all 126 150 pegfilgrastim users across the 6 calendar years (2013 to 2018), the number (%) of first-time pegfilgrastim users ≤ 13 years of age was 762 (0.60%) and the number of first-time pegfilgrastim users < 2 years of age was 75 (0.06%). Pegfilgrastim was administered in the clinical settings in most users ≤ 13 years of age (611 [80.2%]) and also in users < 2 years of age (59 [78.7%]). On-label use of pegfilgrastim at first administration was reported for most users ≤ 13 years of age (729 [95.7%]) and < 2 years of age (70 [93.3%]) (on-label and off-label exposures were assessed according to the Neulasta USPI [v25, dated January 2020]).

14. REFERENCES

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15. SUMMARY TABLES, FIGURES, AND LISTINGS

Table 1. Number of Users of Pegfilgrastim - All Ages

12-month intervals	ALL AGES
1 Jan 2013 - 31 Dec 2013	29,842
1 Jan 2014 - 31 Dec 2014	31,190
1 Jan 2015 - 31 Dec 2015	17,951
1 Jan 2016 - 31 Dec 2016	17,437
1 Jan 2017 - 31 Dec 2017	15,012
1 Jan 2018 - 31 Dec 2018	14,718
Total	126,150

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Table 2. Number of Users of Pegfilgrastim Stratified by Age ≤ 13 and Age < 2 at First Administration

12-month intervals	Age < 2 yr	Age ≤ 13 yr
1 Jan 2013 - 31 Dec 2013	9 (6.1)	148 (100.0)
1 Jan 2014 - 31 Dec 2014	18 (13.5)	133 (100.0)
1 Jan 2015 - 31 Dec 2015	11 (9.6)	115 (100.0)
1 Jan 2016 - 31 Dec 2016	10 (8.9)	112 (100.0)
1 Jan 2017 - 31 Dec 2017	12 (9.8)	123 (100.0)
1 Jan 2018 - 31 Dec 2018	15 (11.5)	131 (100.0)
Total	75 (9.8)	762 (100.0)

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Table 3. Number of Users of Pegfilgrastim Stratified by Individual Age at First Administration

12-month intervals	Age < 1 yr	Age 1 yr	Age 2 yr	Age 3 yr	Age 4 yr
1 Jan 2013 - 31 Dec 2013	0 (0.0)	9 (6.1)	7 (4.7)	13 (8.8)	10 (6.8)
1 Jan 2014 - 31 Dec 2014	3 (2.3)	15 (11.3)	7 (5.3)	10 (7.5)	14 (10.5)
1 Jan 2015 - 31 Dec 2015	4 (3.5)	7 (6.1)	13 (11.3)	5 (4.3)	5 (4.3)
1 Jan 2016 - 31 Dec 2016	3 (2.7)	7 (6.3)	8 (7.1)	7 (6.3)	7 (6.3)
1 Jan 2017 - 31 Dec 2017	2 (1.6)	10 (8.1)	12 (9.8)	9 (7.3)	17 (13.8)
1 Jan 2018 - 31 Dec 2018	5 (3.8)	10 (7.6)	13 (9.9)	10 (7.6)	10 (7.6)
Total	17 (2.2)	58 (7.6)	60 (7.9)	54 (7.1)	63 (8.3)

12-month intervals	Age 5 yr	Age 6 yr	Age 7 yr	Age 8 yr	Age 9 yr
1 Jan 2013 - 31 Dec 2013	14 (9.5)	10 (6.8)	11 (7.4)	9 (6.1)	9 (6.1)
1 Jan 2014 - 31 Dec 2014	6 (4.5)	12 (9.0)	6 (4.5)	19 (14.3)	4 (3.0)
1 Jan 2015 - 31 Dec 2015	10 (8.7)	12 (10.4)	5 (4.3)	8 (7.0)	10 (8.7)
1 Jan 2016 - 31 Dec 2016	7 (6.3)	6 (5.4)	4 (3.6)	7 (6.3)	9 (8.0)
1 Jan 2017 - 31 Dec 2017	8 (6.5)	7 (5.7)	5 (4.1)	10 (8.1)	7 (5.7)
1 Jan 2018 - 31 Dec 2018	9 (6.9)	9 (6.9)	6 (4.6)	9 (6.9)	7 (5.3)
Total	54 (7.1)	56 (7.3)	37 (4.9)	62 (8.1)	46 (6.0)

12-month intervals	Age 10 yr	Age 11 yr	Age 12 yr	Age 13 yr	TOTAL
1 Jan 2013 - 31 Dec 2013	11 (7.4)	9 (6.1)	17 (11.5)	19 (12.8)	148 (100.0)
1 Jan 2014 - 31 Dec 2014	6 (4.5)	10 (7.5)	11 (8.3)	10 (7.5)	133 (100.0)
1 Jan 2015 - 31 Dec 2015	10 (8.7)	6 (5.2)	5 (4.3)	15 (13.0)	115 (100.0)
1 Jan 2016 - 31 Dec 2016	6 (5.4)	8 (7.1)	17 (15.2)	16 (14.3)	112 (100.0)
1 Jan 2017 - 31 Dec 2017	9 (7.3)	8 (6.5)	10 (8.1)	9 (7.3)	123 (100.0)
1 Jan 2018 - 31 Dec 2018	8 (6.1)	11 (8.4)	12 (9.2)	12 (9.2)	131 (100.0)
Total	50 (6.6)	52 (6.8)	72 (9.4)	81 (10.6)	762 (100.0)

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Table 4. Number of Users of Pegfilgrastim Stratified by Age-Categories at First Administration

Characteristic	Age < 2	Age 2 - 5	Age 6 - 10	Age 11 - 13	TOTAL
1 Jan 2013 - 31 Dec 2013	9 (6.1)	44 (29.7)	50 (33.8)	45 (30.4)	148 (100.0)
1 Jan 2014 - 31 Dec 2014	18 (13.5)	37 (27.8)	47 (35.3)	31 (23.3)	133 (100.0)
1 Jan 2015 - 31 Dec 2015	11 (9.6)	33 (28.7)	45 (39.1)	26 (22.6)	115 (100.0)
1 Jan 2016 - 31 Dec 2016	10 (8.9)	29 (25.9)	32 (28.6)	41 (36.6)	112 (100.0)
1 Jan 2017 - 31 Dec 2017	12 (9.8)	46 (37.4)	38 (30.9)	27 (22.0)	123 (100.0)
1 Jan 2018 - 31 Dec 2018	15 (11.5)	42 (32.1)	39 (29.8)	35 (26.7)	131 (100.0)
Total	75 (9.8)	231 (30.3)	251 (32.9)	205 (26.9)	762 (100.0)

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Table 5. Place of Service for Administration of Neulasta Stratified by Age <= 13 and Age < 2 at First Administration

	Age < 2 yr						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	1 (11.1)	0 (0.0)	6 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)
1 Jan 2014 - 31 Dec 2014	0 (0.0)	1 (5.6)	12 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	7 (63.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)
1 Jan 2016 - 31 Dec 2016	3 (30.0)	0 (0.0)	3 (30.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2017 - 31 Dec 2017	1 (8.3)	0 (0.0)	5 (41.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2018 - 31 Dec 2018	1 (6.7)	0 (0.0)	5 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	6 (8.0)	1 (1.3)	38 (50.7)	0 (0.0)	0 (0.0)	0 (0.0)	3 (4.0)

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Table 5. Place of Service for Administration of Neulasta Stratified by Age ≤ 13 and Age < 2 at First Administration

12-month intervals	Age < 2 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	1 (11.1)	0 (0.0)	9 (100.0)
1 Jan 2014 - 31 Dec 2014	3 (16.7)	1 (5.6)	18 (100.0)
1 Jan 2015 - 31 Dec 2015	3 (27.3)	0 (0.0)	11 (100.0)
1 Jan 2016 - 31 Dec 2016	4 (40.0)	0 (0.0)	10 (100.0)
1 Jan 2017 - 31 Dec 2017	3 (25.0)	3 (25.0)	12 (100.0)
1 Jan 2018 - 31 Dec 2018	3 (20.0)	6 (40.0)	15 (100.0)
Total	17 (22.7)	10 (13.3)	75 (100.0)

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Table 5. Place of Service for Administration of Neulasta Stratified by Age ≤ 13 and Age < 2 at First Administration

	Age ≤ 13 yr						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	19 (12.8)	1 (0.7)	67 (45.3)	0 (0.0)	2 (1.4)	0 (0.0)	7 (4.7)
1 Jan 2014 - 31 Dec 2014	15 (11.3)	1 (0.8)	63 (47.4)	1 (0.8)	1 (0.8)	0 (0.0)	7 (5.3)
1 Jan 2015 - 31 Dec 2015	10 (8.7)	1 (0.9)	52 (45.2)	0 (0.0)	0 (0.0)	1 (0.9)	6 (5.2)
1 Jan 2016 - 31 Dec 2016	13 (11.6)	0 (0.0)	38 (33.9)	0 (0.0)	0 (0.0)	0 (0.0)	6 (5.4)
1 Jan 2017 - 31 Dec 2017	12 (9.8)	0 (0.0)	53 (43.1)	0 (0.0)	1 (0.8)	0 (0.0)	3 (2.4)
1 Jan 2018 - 31 Dec 2018	6 (4.6)	1 (0.8)	51 (38.9)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.3)
Total	75 (9.8)	4 (0.5)	324 (42.5)	1 (0.1)	4 (0.5)	1 (0.1)	32 (4.2)

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Table 5. Place of Service for Administration of Neulasta Stratified by Age <= 13 and Age < 2 at First Administration

12-month intervals	Age <= 13 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	46 (31.1)	6 (4.1)	148 (100.0)
1 Jan 2014 - 31 Dec 2014	36 (27.1)	9 (6.8)	133 (100.0)
1 Jan 2015 - 31 Dec 2015	37 (32.2)	8 (7.0)	115 (100.0)
1 Jan 2016 - 31 Dec 2016	46 (41.1)	9 (8.0)	112 (100.0)
1 Jan 2017 - 31 Dec 2017	39 (31.7)	15 (12.2)	123 (100.0)
1 Jan 2018 - 31 Dec 2018	42 (32.1)	28 (21.4)	131 (100.0)
Total	246 (32.3)	75 (9.8)	762 (100.0)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

	Age < 1 yr						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2014 - 31 Dec 2014	0 (0.0)	1 (33.3)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2016 - 31 Dec 2016	1 (33.3)	0 (0.0)	2 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2017 - 31 Dec 2017	0 (0.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2018 - 31 Dec 2018	0 (0.0)	0 (0.0)	3 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	1 (5.9)	1 (5.9)	11 (64.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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 jaramilr: t02_table2_v3_rtf.sas
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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age < 1 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2014 - 31 Dec 2014	1 (33.3)	0 (0.0)	3 (100.0)
1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	4 (100.0)
1 Jan 2016 - 31 Dec 2016	0 (0.0)	0 (0.0)	3 (100.0)
1 Jan 2017 - 31 Dec 2017	0 (0.0)	1 (50.0)	2 (100.0)
1 Jan 2018 - 31 Dec 2018	1 (20.0)	1 (20.0)	5 (100.0)
Total	2 (11.8)	2 (11.8)	17 (100.0)

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 jaramilr: t02_table2_v3_rtf.sas
 Database: rwd_msccae_mdcr_20181231
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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

	Age 1 yr						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	1 (11.1)	0 (0.0)	6 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)
1 Jan 2014 - 31 Dec 2014	0 (0.0)	0 (0.0)	11 (73.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.7)
1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	3 (42.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)
1 Jan 2016 - 31 Dec 2016	2 (28.6)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2017 - 31 Dec 2017	1 (10.0)	0 (0.0)	4 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2018 - 31 Dec 2018	1 (10.0)	0 (0.0)	2 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	5 (8.6)	0 (0.0)	27 (46.6)	0 (0.0)	0 (0.0)	0 (0.0)	3 (5.2)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age 1 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	1 (11.1)	0 (0.0)	9 (100.0)
1 Jan 2014 - 31 Dec 2014	2 (13.3)	1 (6.7)	15 (100.0)
1 Jan 2015 - 31 Dec 2015	3 (42.9)	0 (0.0)	7 (100.0)
1 Jan 2016 - 31 Dec 2016	4 (57.1)	0 (0.0)	7 (100.0)
1 Jan 2017 - 31 Dec 2017	3 (30.0)	2 (20.0)	10 (100.0)
1 Jan 2018 - 31 Dec 2018	2 (20.0)	5 (50.0)	10 (100.0)
Total	15 (25.9)	8 (13.8)	58 (100.0)

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Project: PRISM 20-00460 / p20_onc_039
 jaramilr: t02_table2_v3_rtf.sas
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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

	Age 2 yr						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	0 (0.0)	0 (0.0)	7 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2014 - 31 Dec 2014	1 (14.3)	0 (0.0)	5 (71.4)	1 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2015 - 31 Dec 2015	0 (0.0)	1 (7.7)	6 (46.2)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)
1 Jan 2016 - 31 Dec 2016	3 (37.5)	0 (0.0)	2 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2017 - 31 Dec 2017	1 (8.3)	0 (0.0)	4 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
1 Jan 2018 - 31 Dec 2018	0 (0.0)	0 (0.0)	3 (23.1)	0 (0.0)	0 (0.0)	0 (0.0)	2 (15.4)
Total	5 (8.3)	1 (1.7)	27 (45.0)	1 (1.7)	0 (0.0)	1 (1.7)	3 (5.0)

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Project: PRISM 20-00460 / p20_onc_039
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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age 2 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	0 (0.0)	0 (0.0)	7 (100.0)
1 Jan 2014 - 31 Dec 2014	0 (0.0)	0 (0.0)	7 (100.0)
1 Jan 2015 - 31 Dec 2015	4 (30.8)	1 (7.7)	13 (100.0)
1 Jan 2016 - 31 Dec 2016	3 (37.5)	0 (0.0)	8 (100.0)
1 Jan 2017 - 31 Dec 2017	5 (41.7)	1 (8.3)	12 (100.0)
1 Jan 2018 - 31 Dec 2018	5 (38.5)	3 (23.1)	13 (100.0)
Total	17 (28.3)	5 (8.3)	60 (100.0)

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Project: PRISM 20-00460 / p20_onc_039
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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

	Age 3 yr						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	2 (15.4)	1 (7.7)	2 (15.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)
1 Jan 2014 - 31 Dec 2014	4 (40.0)	0 (0.0)	4 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
1 Jan 2016 - 31 Dec 2016	2 (28.6)	0 (0.0)	2 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2017 - 31 Dec 2017	0 (0.0)	0 (0.0)	6 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2018 - 31 Dec 2018	1 (10.0)	0 (0.0)	6 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	9 (16.7)	1 (1.9)	22 (40.7)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.7)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age 3 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	6 (46.2)	1 (7.7)	13 (100.0)
1 Jan 2014 - 31 Dec 2014	2 (20.0)	0 (0.0)	10 (100.0)
1 Jan 2015 - 31 Dec 2015	2 (40.0)	0 (0.0)	5 (100.0)
1 Jan 2016 - 31 Dec 2016	3 (42.9)	0 (0.0)	7 (100.0)
1 Jan 2017 - 31 Dec 2017	3 (33.3)	0 (0.0)	9 (100.0)
1 Jan 2018 - 31 Dec 2018	2 (20.0)	1 (10.0)	10 (100.0)
Total	18 (33.3)	2 (3.7)	54 (100.0)

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Project: PRISM 20-00460 / p20_onc_039
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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

	Age 4 yr						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	4 (40.0)	0 (0.0)	4 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2014 - 31 Dec 2014	3 (21.4)	0 (0.0)	6 (42.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2015 - 31 Dec 2015	1 (20.0)	0 (0.0)	3 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
1 Jan 2016 - 31 Dec 2016	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)
1 Jan 2017 - 31 Dec 2017	1 (5.9)	0 (0.0)	5 (29.4)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)
1 Jan 2018 - 31 Dec 2018	0 (0.0)	0 (0.0)	4 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	9 (14.3)	0 (0.0)	22 (34.9)	0 (0.0)	1 (1.6)	0 (0.0)	2 (3.2)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age 4 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	2 (20.0)	0 (0.0)	10 (100.0)
1 Jan 2014 - 31 Dec 2014	4 (28.6)	1 (7.1)	14 (100.0)
1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	5 (100.0)
1 Jan 2016 - 31 Dec 2016	6 (85.7)	0 (0.0)	7 (100.0)
1 Jan 2017 - 31 Dec 2017	8 (47.1)	2 (11.8)	17 (100.0)
1 Jan 2018 - 31 Dec 2018	3 (30.0)	3 (30.0)	10 (100.0)
Total	23 (36.5)	6 (9.5)	63 (100.0)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age 5 yr						
	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	2 (14.3)	0 (0.0)	6 (42.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2014 - 31 Dec 2014	0 (0.0)	0 (0.0)	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
1 Jan 2015 - 31 Dec 2015	1 (10.0)	0 (0.0)	5 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2016 - 31 Dec 2016	0 (0.0)	0 (0.0)	2 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)
1 Jan 2017 - 31 Dec 2017	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2018 - 31 Dec 2018	0 (0.0)	0 (0.0)	4 (44.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	4 (7.4)	0 (0.0)	19 (35.2)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.7)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age 5 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	4 (28.6)	2 (14.3)	14 (100.0)
1 Jan 2014 - 31 Dec 2014	3 (50.0)	0 (0.0)	6 (100.0)
1 Jan 2015 - 31 Dec 2015	3 (30.0)	1 (10.0)	10 (100.0)
1 Jan 2016 - 31 Dec 2016	4 (57.1)	0 (0.0)	7 (100.0)
1 Jan 2017 - 31 Dec 2017	4 (50.0)	3 (37.5)	8 (100.0)
1 Jan 2018 - 31 Dec 2018	3 (33.3)	2 (22.2)	9 (100.0)
Total	21 (38.9)	8 (14.8)	54 (100.0)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age 6 yr						
	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	1 (10.0)	0 (0.0)	4 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)
1 Jan 2014 - 31 Dec 2014	1 (8.3)	0 (0.0)	6 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
1 Jan 2015 - 31 Dec 2015	1 (8.3)	0 (0.0)	7 (58.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (16.7)
1 Jan 2016 - 31 Dec 2016	0 (0.0)	0 (0.0)	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2017 - 31 Dec 2017	0 (0.0)	0 (0.0)	4 (57.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2018 - 31 Dec 2018	1 (11.1)	0 (0.0)	4 (44.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	4 (7.1)	0 (0.0)	27 (48.2)	0 (0.0)	0 (0.0)	0 (0.0)	4 (7.1)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age 6 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	4 (40.0)	0 (0.0)	10 (100.0)
1 Jan 2014 - 31 Dec 2014	4 (33.3)	0 (0.0)	12 (100.0)
1 Jan 2015 - 31 Dec 2015	2 (16.7)	0 (0.0)	12 (100.0)
1 Jan 2016 - 31 Dec 2016	3 (50.0)	1 (16.7)	6 (100.0)
1 Jan 2017 - 31 Dec 2017	3 (42.9)	0 (0.0)	7 (100.0)
1 Jan 2018 - 31 Dec 2018	2 (22.2)	2 (22.2)	9 (100.0)
Total	18 (32.1)	3 (5.4)	56 (100.0)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

	Age 7 yr						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	1 (9.1)	0 (0.0)	6 (54.5)	0 (0.0)	1 (9.1)	0 (0.0)	2 (18.2)
1 Jan 2014 - 31 Dec 2014	1 (16.7)	0 (0.0)	3 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (33.3)
1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
1 Jan 2016 - 31 Dec 2016	0 (0.0)	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2017 - 31 Dec 2017	1 (20.0)	0 (0.0)	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2018 - 31 Dec 2018	0 (0.0)	0 (0.0)	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	3 (8.1)	0 (0.0)	15 (40.5)	0 (0.0)	1 (2.7)	0 (0.0)	5 (13.5)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age 7 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	1 (9.1)	0 (0.0)	11 (100.0)
1 Jan 2014 - 31 Dec 2014	0 (0.0)	0 (0.0)	6 (100.0)
1 Jan 2015 - 31 Dec 2015	2 (40.0)	1 (20.0)	5 (100.0)
1 Jan 2016 - 31 Dec 2016	3 (75.0)	0 (0.0)	4 (100.0)
1 Jan 2017 - 31 Dec 2017	2 (40.0)	0 (0.0)	5 (100.0)
1 Jan 2018 - 31 Dec 2018	3 (50.0)	1 (16.7)	6 (100.0)
Total	11 (29.7)	2 (5.4)	37 (100.0)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

	Age 8 yr						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	2 (22.2)	0 (0.0)	2 (22.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2014 - 31 Dec 2014	4 (21.1)	0 (0.0)	7 (36.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)
1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	5 (62.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2016 - 31 Dec 2016	1 (14.3)	0 (0.0)	4 (57.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2017 - 31 Dec 2017	2 (20.0)	0 (0.0)	6 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2018 - 31 Dec 2018	1 (11.1)	0 (0.0)	4 (44.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	10 (16.1)	0 (0.0)	28 (45.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)

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Project: PRISM 20-00460 / p20_onc_039
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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age 8 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	5 (55.6)	0 (0.0)	9 (100.0)
1 Jan 2014 - 31 Dec 2014	5 (26.3)	2 (10.5)	19 (100.0)
1 Jan 2015 - 31 Dec 2015	3 (37.5)	0 (0.0)	8 (100.0)
1 Jan 2016 - 31 Dec 2016	0 (0.0)	2 (28.6)	7 (100.0)
1 Jan 2017 - 31 Dec 2017	2 (20.0)	0 (0.0)	10 (100.0)
1 Jan 2018 - 31 Dec 2018	3 (33.3)	1 (11.1)	9 (100.0)
Total	18 (29.0)	5 (8.1)	62 (100.0)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

	Age 9 yr						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	0 (0.0)	0 (0.0)	4 (44.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2014 - 31 Dec 2014	1 (25.0)	0 (0.0)	3 (75.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2015 - 31 Dec 2015	3 (30.0)	0 (0.0)	3 (30.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2016 - 31 Dec 2016	0 (0.0)	0 (0.0)	6 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2017 - 31 Dec 2017	0 (0.0)	0 (0.0)	5 (71.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)
1 Jan 2018 - 31 Dec 2018	2 (28.6)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	6 (13.0)	0 (0.0)	22 (47.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age 9 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	4 (44.4)	1 (11.1)	9 (100.0)
1 Jan 2014 - 31 Dec 2014	0 (0.0)	0 (0.0)	4 (100.0)
1 Jan 2015 - 31 Dec 2015	4 (40.0)	0 (0.0)	10 (100.0)
1 Jan 2016 - 31 Dec 2016	2 (22.2)	1 (11.1)	9 (100.0)
1 Jan 2017 - 31 Dec 2017	0 (0.0)	1 (14.3)	7 (100.0)
1 Jan 2018 - 31 Dec 2018	2 (28.6)	2 (28.6)	7 (100.0)
Total	12 (26.1)	5 (10.9)	46 (100.0)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

	Age 10 yr						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	0 (0.0)	0 (0.0)	7 (63.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)
1 Jan 2014 - 31 Dec 2014	0 (0.0)	0 (0.0)	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2015 - 31 Dec 2015	2 (20.0)	0 (0.0)	4 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2016 - 31 Dec 2016	1 (16.7)	0 (0.0)	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2017 - 31 Dec 2017	2 (22.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2018 - 31 Dec 2018	0 (0.0)	1 (12.5)	4 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	5 (10.0)	1 (2.0)	19 (38.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age 10 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	2 (18.2)	1 (9.1)	11 (100.0)
1 Jan 2014 - 31 Dec 2014	3 (50.0)	1 (16.7)	6 (100.0)
1 Jan 2015 - 31 Dec 2015	4 (40.0)	0 (0.0)	10 (100.0)
1 Jan 2016 - 31 Dec 2016	3 (50.0)	0 (0.0)	6 (100.0)
1 Jan 2017 - 31 Dec 2017	5 (55.6)	2 (22.2)	9 (100.0)
1 Jan 2018 - 31 Dec 2018	1 (12.5)	2 (25.0)	8 (100.0)
Total	18 (36.0)	6 (12.0)	50 (100.0)

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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

	Age 11 yr						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	1 (11.1)	0 (0.0)	3 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2014 - 31 Dec 2014	0 (0.0)	0 (0.0)	2 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)
1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2016 - 31 Dec 2016	1 (12.5)	0 (0.0)	4 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2017 - 31 Dec 2017	2 (25.0)	0 (0.0)	4 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2018 - 31 Dec 2018	0 (0.0)	0 (0.0)	5 (45.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	4 (7.7)	0 (0.0)	20 (38.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)

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 jaramilr: t02_table2_v3_rtf.sas
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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age 11 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	5 (55.6)	0 (0.0)	9 (100.0)
1 Jan 2014 - 31 Dec 2014	5 (50.0)	2 (20.0)	10 (100.0)
1 Jan 2015 - 31 Dec 2015	3 (50.0)	1 (16.7)	6 (100.0)
1 Jan 2016 - 31 Dec 2016	2 (25.0)	1 (12.5)	8 (100.0)
1 Jan 2017 - 31 Dec 2017	1 (12.5)	1 (12.5)	8 (100.0)
1 Jan 2018 - 31 Dec 2018	4 (36.4)	2 (18.2)	11 (100.0)
Total	20 (38.5)	7 (13.5)	52 (100.0)

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Project: PRISM 20-00460 / p20_onc_039
 jaramilr: t02_table2_v3_rtf.sas
 Database: rwd_msccae_mdcr_20181231
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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

	Age 12 yr						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	3 (17.6)	0 (0.0)	8 (47.1)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)
1 Jan 2014 - 31 Dec 2014	0 (0.0)	0 (0.0)	8 (72.7)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
1 Jan 2015 - 31 Dec 2015	2 (40.0)	0 (0.0)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2016 - 31 Dec 2016	2 (11.8)	0 (0.0)	3 (17.6)	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)
1 Jan 2017 - 31 Dec 2017	1 (10.0)	0 (0.0)	6 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2018 - 31 Dec 2018	0 (0.0)	0 (0.0)	5 (41.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	8 (11.1)	0 (0.0)	31 (43.1)	0 (0.0)	2 (2.8)	0 (0.0)	2 (2.8)

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Project: PRISM 20-00460 / p20_onc_039
 jaramilr: t02_table2_v3_rtf.sas
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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age 12 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	5 (29.4)	0 (0.0)	17 (100.0)
1 Jan 2014 - 31 Dec 2014	2 (18.2)	0 (0.0)	11 (100.0)
1 Jan 2015 - 31 Dec 2015	2 (40.0)	0 (0.0)	5 (100.0)
1 Jan 2016 - 31 Dec 2016	6 (35.3)	4 (23.5)	17 (100.0)
1 Jan 2017 - 31 Dec 2017	2 (20.0)	1 (10.0)	10 (100.0)
1 Jan 2018 - 31 Dec 2018	6 (50.0)	1 (8.3)	12 (100.0)
Total	23 (31.9)	6 (8.3)	72 (100.0)

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Project: PRISM 20-00460 / p20_onc_039
 jaramilr: t02_table2_v3_rtf.sas
 Database: rwd_msccae_mdcr_20181231
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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

	Age 13 yr						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	2 (10.5)	0 (0.0)	8 (42.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)
1 Jan 2014 - 31 Dec 2014	0 (0.0)	0 (0.0)	3 (30.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	6 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2016 - 31 Dec 2016	0 (0.0)	0 (0.0)	7 (43.8)	0 (0.0)	0 (0.0)	0 (0.0)	2 (12.5)
1 Jan 2017 - 31 Dec 2017	0 (0.0)	0 (0.0)	6 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)
1 Jan 2018 - 31 Dec 2018	0 (0.0)	0 (0.0)	4 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
Total	2 (2.5)	0 (0.0)	34 (42.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (6.2)

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Project: PRISM 20-00460 / p20_onc_039
 jaramilr: t02_table2_v3_rtf.sas
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Table 6. Place of Service for Administration of Neulasta Stratified by Age at First Administration

12-month intervals	Age 13 yr		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	7 (36.8)	1 (5.3)	19 (100.0)
1 Jan 2014 - 31 Dec 2014	5 (50.0)	2 (20.0)	10 (100.0)
1 Jan 2015 - 31 Dec 2015	5 (33.3)	4 (26.7)	15 (100.0)
1 Jan 2016 - 31 Dec 2016	7 (43.8)	0 (0.0)	16 (100.0)
1 Jan 2017 - 31 Dec 2017	1 (11.1)	1 (11.1)	9 (100.0)
1 Jan 2018 - 31 Dec 2018	5 (41.7)	2 (16.7)	12 (100.0)
Total	30 (37.0)	10 (12.3)	81 (100.0)

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Project: PRISM 20-00460 / p20_onc_039
 jaramilr: t02_table2_v3_rtf.sas
 Database: rwd_msccae_mdcr_20181231
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Table 7. Place of Service for Administration of Neulasta Stratified by Age Categories at First Administration

	Age < 2						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	1 (11.1)	0 (0.0)	6 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)
1 Jan 2014 - 31 Dec 2014	0 (0.0)	1 (5.6)	12 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	7 (63.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)
1 Jan 2016 - 31 Dec 2016	3 (30.0)	0 (0.0)	3 (30.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2017 - 31 Dec 2017	1 (8.3)	0 (0.0)	5 (41.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2018 - 31 Dec 2018	1 (6.7)	0 (0.0)	5 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	6 (8.0)	1 (1.3)	38 (50.7)	0 (0.0)	0 (0.0)	0 (0.0)	3 (4.0)

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Project: PRISM 20-00460 / p20_onc_039
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 Database: rwd_msccae_mdcr_20181231
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Table 7. Place of Service for Administration of Neulasta Stratified by Age Categories at First Administration

12-month intervals	Age < 2		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	1 (11.1)	0 (0.0)	9 (100.0)
1 Jan 2014 - 31 Dec 2014	3 (16.7)	1 (5.6)	18 (100.0)
1 Jan 2015 - 31 Dec 2015	3 (27.3)	0 (0.0)	11 (100.0)
1 Jan 2016 - 31 Dec 2016	4 (40.0)	0 (0.0)	10 (100.0)
1 Jan 2017 - 31 Dec 2017	3 (25.0)	3 (25.0)	12 (100.0)
1 Jan 2018 - 31 Dec 2018	3 (20.0)	6 (40.0)	15 (100.0)
Total	17 (22.7)	10 (13.3)	75 (100.0)

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Project: PRISM 20-00460 / p20_onc_039
 jaramilr: t02_table2_v3_rtf.sas
 Database: rwd_msccae_mdcr_20181231
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Table 7. Place of Service for Administration of Neulasta Stratified by Age Categories at First Administration

	Age 2 - 5						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	8 (18.2)	1 (2.3)	19 (43.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
1 Jan 2014 - 31 Dec 2014	8 (21.6)	0 (0.0)	17 (45.9)	1 (2.7)	0 (0.0)	0 (0.0)	1 (2.7)
1 Jan 2015 - 31 Dec 2015	2 (6.1)	1 (3.0)	16 (48.5)	0 (0.0)	0 (0.0)	1 (3.0)	2 (6.1)
1 Jan 2016 - 31 Dec 2016	5 (17.2)	0 (0.0)	6 (20.7)	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.9)
1 Jan 2017 - 31 Dec 2017	3 (6.5)	0 (0.0)	15 (32.6)	0 (0.0)	1 (2.2)	0 (0.0)	1 (2.2)
1 Jan 2018 - 31 Dec 2018	1 (2.4)	0 (0.0)	17 (40.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.8)
Total	27 (11.7)	2 (0.9)	90 (39.0)	1 (0.4)	1 (0.4)	1 (0.4)	9 (3.9)

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 jaramilr: t02_table2_v3_rtf.sas
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Table 7. Place of Service for Administration of Neulasta Stratified by Age Categories at First Administration

12-month intervals	Age 2 - 5		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	12 (27.3)	3 (6.8)	44 (100.0)
1 Jan 2014 - 31 Dec 2014	9 (24.3)	1 (2.7)	37 (100.0)
1 Jan 2015 - 31 Dec 2015	9 (27.3)	2 (6.1)	33 (100.0)
1 Jan 2016 - 31 Dec 2016	16 (55.2)	0 (0.0)	29 (100.0)
1 Jan 2017 - 31 Dec 2017	20 (43.5)	6 (13.0)	46 (100.0)
1 Jan 2018 - 31 Dec 2018	13 (31.0)	9 (21.4)	42 (100.0)
Total	79 (34.2)	21 (9.1)	231 (100.0)

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Project: PRISM 20-00460 / p20_onc_039
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Table 7. Place of Service for Administration of Neulasta Stratified by Age Categories at First Administration

	Age 6 - 10						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	4 (8.0)	0 (0.0)	23 (46.0)	0 (0.0)	1 (2.0)	0 (0.0)	4 (8.0)
1 Jan 2014 - 31 Dec 2014	7 (14.9)	0 (0.0)	21 (44.7)	0 (0.0)	0 (0.0)	0 (0.0)	4 (8.5)
1 Jan 2015 - 31 Dec 2015	6 (13.3)	0 (0.0)	20 (44.4)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.7)
1 Jan 2016 - 31 Dec 2016	2 (6.3)	0 (0.0)	15 (46.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2017 - 31 Dec 2017	5 (13.2)	0 (0.0)	17 (44.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)
1 Jan 2018 - 31 Dec 2018	4 (10.3)	1 (2.6)	15 (38.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	28 (11.2)	1 (0.4)	111 (44.2)	0 (0.0)	1 (0.4)	0 (0.0)	12 (4.8)

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 jaramilr: t02_table2_v3_rtf.sas
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Table 7. Place of Service for Administration of Neulasta Stratified by Age Categories at First Administration

12-month intervals	Age 6 - 10		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	16 (32.0)	2 (4.0)	50 (100.0)
1 Jan 2014 - 31 Dec 2014	12 (25.5)	3 (6.4)	47 (100.0)
1 Jan 2015 - 31 Dec 2015	15 (33.3)	1 (2.2)	45 (100.0)
1 Jan 2016 - 31 Dec 2016	11 (34.4)	4 (12.5)	32 (100.0)
1 Jan 2017 - 31 Dec 2017	12 (31.6)	3 (7.9)	38 (100.0)
1 Jan 2018 - 31 Dec 2018	11 (28.2)	8 (20.5)	39 (100.0)
Total	77 (30.7)	21 (8.4)	251 (100.0)

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Project: PRISM 20-00460 / p20_onc_039
 jaramilr: t02_table2_v3_rtf.sas
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Table 7. Place of Service for Administration of Neulasta Stratified by Age Categories at First Administration

	Age 11 - 13						
12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
1 Jan 2013 - 31 Dec 2013	6 (13.3)	0 (0.0)	19 (42.2)	0 (0.0)	1 (2.2)	0 (0.0)	1 (2.2)
1 Jan 2014 - 31 Dec 2014	0 (0.0)	0 (0.0)	13 (41.9)	0 (0.0)	1 (3.2)	0 (0.0)	1 (3.2)
1 Jan 2015 - 31 Dec 2015	2 (7.7)	0 (0.0)	9 (34.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1 Jan 2016 - 31 Dec 2016	3 (7.3)	0 (0.0)	14 (34.1)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.8)
1 Jan 2017 - 31 Dec 2017	3 (11.1)	0 (0.0)	16 (59.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.7)
1 Jan 2018 - 31 Dec 2018	0 (0.0)	0 (0.0)	14 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)
Total	14 (6.8)	0 (0.0)	85 (41.5)	0 (0.0)	2 (1.0)	0 (0.0)	8 (3.9)

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Project: PRISM 20-00460 / p20_onc_039
 jaramilr: t02_table2_v3_rtf.sas
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Table 7. Place of Service for Administration of Neulasta Stratified by Age Categories at First Administration

12-month intervals	Age 11 - 13		
	Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
1 Jan 2013 - 31 Dec 2013	17 (37.8)	1 (2.2)	45 (100.0)
1 Jan 2014 - 31 Dec 2014	12 (38.7)	4 (12.9)	31 (100.0)
1 Jan 2015 - 31 Dec 2015	10 (38.5)	5 (19.2)	26 (100.0)
1 Jan 2016 - 31 Dec 2016	15 (36.6)	5 (12.2)	41 (100.0)
1 Jan 2017 - 31 Dec 2017	4 (14.8)	3 (11.1)	27 (100.0)
1 Jan 2018 - 31 Dec 2018	15 (42.9)	5 (14.3)	35 (100.0)
Total	73 (35.6)	23 (11.2)	205 (100.0)

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Project: PRISM 20-00460 / p20_onc_039
 jaramilr: t02_table2_v3_rtf.sas
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Table 8. Sensitivity: Number of Users of Pegfilgrastim Stratified by Age <= 13 and Age < 2 at First Administration, On-Label or Off-Label

12-month intervals	Age < 2 yr			Age <= 13 yr		
	On Label	Off Label	TOTAL	On Label	Off Label	TOTAL
1 Jan 2013 - 31 Dec 2013	8 (88.9)	1 (11.1)	9 (100.0)	143 (96.6)	5 (3.4)	148 (100.0)
1 Jan 2014 - 31 Dec 2014	16 (88.9)	2 (11.1)	18 (100.0)	126 (94.7)	7 (5.3)	133 (100.0)
1 Jan 2015 - 31 Dec 2015	9 (81.8)	2 (18.2)	11 (100.0)	109 (94.8)	6 (5.2)	115 (100.0)
1 Jan 2016 - 31 Dec 2016	10 (100.0)	0 (0.0)	10 (100.0)	105 (93.8)	7 (6.3)	112 (100.0)
1 Jan 2017 - 31 Dec 2017	12 (100.0)	0 (0.0)	12 (100.0)	120 (97.6)	3 (2.4)	123 (100.0)
1 Jan 2018 - 31 Dec 2018	15 (100.0)	0 (0.0)	15 (100.0)	126 (96.2)	5 (3.8)	131 (100.0)
Total	70 (93.3)	5 (6.7)	75 (100.0)	729 (95.7)	33 (4.3)	762 (100.0)

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Project: PRISM 20-00460 / p20_onc_039
 jaramilr: t01_table1_v4_rtf.sas
 Database: rwd_msccae_mdcr_20181231
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Table 9. Sensitivity: Number of Users of Pegfilgrastim Stratified by Individual Age at First Administration, On-Label or Off-Label

Use	12-month intervals	Age < 1 yr	Age 1 yr	Age 2 yr	Age 3 yr	Age 4 yr
On Label	1 Jan 2013 - 31 Dec 2013	0 (0.0)	8 (5.6)	7 (4.9)	13 (9.1)	10 (7.0)
On Label	1 Jan 2014 - 31 Dec 2014	3 (2.4)	13 (10.3)	7 (5.6)	10 (7.9)	13 (10.3)
On Label	1 Jan 2015 - 31 Dec 2015	3 (2.8)	6 (5.5)	12 (11.0)	5 (4.6)	5 (4.6)
On Label	1 Jan 2016 - 31 Dec 2016	3 (2.9)	7 (6.7)	8 (7.6)	6 (5.7)	7 (6.7)
On Label	1 Jan 2017 - 31 Dec 2017	2 (1.7)	10 (8.3)	12 (10.0)	8 (6.7)	17 (14.2)
On Label	1 Jan 2018 - 31 Dec 2018	5 (4.0)	10 (7.9)	12 (9.5)	9 (7.1)	9 (7.1)
On Label	Total	16 (2.2)	54 (7.4)	58 (8.0)	51 (7.0)	61 (8.4)
Off Label	1 Jan 2013 - 31 Dec 2013	0 (0.0)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	1 Jan 2014 - 31 Dec 2014	0 (0.0)	2 (28.6)	0 (0.0)	0 (0.0)	1 (14.3)
Off Label	1 Jan 2015 - 31 Dec 2015	1 (16.7)	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)
Off Label	1 Jan 2016 - 31 Dec 2016	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)
Off Label	1 Jan 2017 - 31 Dec 2017	0 (0.0)	0 (0.0)	0 (0.0)	1 (33.3)	0 (0.0)
Off Label	1 Jan 2018 - 31 Dec 2018	0 (0.0)	0 (0.0)	1 (20.0)	1 (20.0)	1 (20.0)
Off Label	Total	1 (3.0)	4 (12.1)	2 (6.1)	3 (9.1)	2 (6.1)

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Project: PRISM 20-00460 / p20_onc_039
 jaramilr: t01_table1_v4_rtf.sas
 Database: rwd_msccae_mdcr_20181231
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Table 9. Sensitivity: Number of Users of Pegfilgrastim Stratified by Individual Age at First Administration, On-Label or Off-Label

Use	12-month intervals	Age 5 yr	Age 6 yr	Age 7 yr	Age 8 yr	Age 9 yr
On Label	1 Jan 2013 - 31 Dec 2013	14 (9.8)	10 (7.0)	8 (5.6)	9 (6.3)	9 (6.3)
On Label	1 Jan 2014 - 31 Dec 2014	6 (4.8)	12 (9.5)	6 (4.8)	16 (12.7)	4 (3.2)
On Label	1 Jan 2015 - 31 Dec 2015	10 (9.2)	12 (11.0)	5 (4.6)	7 (6.4)	10 (9.2)
On Label	1 Jan 2016 - 31 Dec 2016	5 (4.8)	6 (5.7)	4 (3.8)	7 (6.7)	9 (8.6)
On Label	1 Jan 2017 - 31 Dec 2017	8 (6.7)	6 (5.0)	5 (4.2)	10 (8.3)	7 (5.8)
On Label	1 Jan 2018 - 31 Dec 2018	8 (6.3)	9 (7.1)	6 (4.8)	9 (7.1)	7 (5.6)
On Label	Total	51 (7.0)	55 (7.5)	34 (4.7)	58 (8.0)	46 (6.3)
Off Label	1 Jan 2013 - 31 Dec 2013	0 (0.0)	0 (0.0)	3 (60.0)	0 (0.0)	0 (0.0)
Off Label	1 Jan 2014 - 31 Dec 2014	0 (0.0)	0 (0.0)	0 (0.0)	3 (42.9)	0 (0.0)
Off Label	1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)
Off Label	1 Jan 2016 - 31 Dec 2016	2 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	1 Jan 2017 - 31 Dec 2017	0 (0.0)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	1 Jan 2018 - 31 Dec 2018	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	Total	3 (9.1)	1 (3.0)	3 (9.1)	4 (12.1)	0 (0.0)

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 jaramilr: t01_table1_v4_rtf.sas
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Table 9. Sensitivity: Number of Users of Pegfilgrastim Stratified by Individual Age at First Administration, On-Label or Off-Label

Use	12-month intervals	Age 10 yr	Age 11 yr	Age 12 yr	Age 13 yr	TOTAL
On Label	1 Jan 2013 - 31 Dec 2013	10 (7.0)	9 (6.3)	17 (11.9)	19 (13.3)	143 (100.0)
On Label	1 Jan 2014 - 31 Dec 2014	6 (4.8)	9 (7.1)	11 (8.7)	10 (7.9)	126 (100.0)
On Label	1 Jan 2015 - 31 Dec 2015	9 (8.3)	5 (4.6)	5 (4.6)	15 (13.8)	109 (100.0)
On Label	1 Jan 2016 - 31 Dec 2016	4 (3.8)	8 (7.6)	15 (14.3)	16 (15.2)	105 (100.0)
On Label	1 Jan 2017 - 31 Dec 2017	9 (7.5)	7 (5.8)	10 (8.3)	9 (7.5)	120 (100.0)
On Label	1 Jan 2018 - 31 Dec 2018	8 (6.3)	11 (8.7)	12 (9.5)	11 (8.7)	126 (100.0)
On Label	Total	46 (6.3)	49 (6.7)	70 (9.6)	80 (11.0)	729 (100.0)
Off Label	1 Jan 2013 - 31 Dec 2013	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
Off Label	1 Jan 2014 - 31 Dec 2014	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	7 (100.0)
Off Label	1 Jan 2015 - 31 Dec 2015	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)	6 (100.0)
Off Label	1 Jan 2016 - 31 Dec 2016	2 (28.6)	0 (0.0)	2 (28.6)	0 (0.0)	7 (100.0)
Off Label	1 Jan 2017 - 31 Dec 2017	0 (0.0)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)
Off Label	1 Jan 2018 - 31 Dec 2018	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)	5 (100.0)
Off Label	Total	4 (12.1)	3 (9.1)	2 (6.1)	1 (3.0)	33 (100.0)

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Project: PRISM 20-00460 / p20_onc_039
 jaramilr: t01_table1_v4_rtf.sas
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Table 10. Sensitivity: Number of Users of Pegfilgrastim Stratified by Age-Categories at First Administration, On-Label or Off-Label

Use	12-month intervals	Age < 2	Age 2 - 5	Age 6 - 10	Age 11 - 13	TOTAL
On Label	1 Jan 2013 - 31 Dec 2013	8 (5.6)	44 (30.8)	46 (32.2)	45 (31.5)	143 (100.0)
On Label	1 Jan 2014 - 31 Dec 2014	16 (12.7)	36 (28.6)	44 (34.9)	30 (23.8)	126 (100.0)
On Label	1 Jan 2015 - 31 Dec 2015	9 (8.3)	32 (29.4)	43 (39.4)	25 (22.9)	109 (100.0)
On Label	1 Jan 2016 - 31 Dec 2016	10 (9.5)	26 (24.8)	30 (28.6)	39 (37.1)	105 (100.0)
On Label	1 Jan 2017 - 31 Dec 2017	12 (10.0)	45 (37.5)	37 (30.8)	26 (21.7)	120 (100.0)
On Label	1 Jan 2018 - 31 Dec 2018	15 (11.9)	38 (30.2)	39 (31.0)	34 (27.0)	126 (100.0)
On Label	Total	70 (9.6)	221 (30.3)	239 (32.8)	199 (27.3)	729 (100.0)
Off Label	1 Jan 2013 - 31 Dec 2013	1 (20.0)	0 (0.0)	4 (80.0)	0 (0.0)	5 (100.0)
Off Label	1 Jan 2014 - 31 Dec 2014	2 (28.6)	1 (14.3)	3 (42.9)	1 (14.3)	7 (100.0)
Off Label	1 Jan 2015 - 31 Dec 2015	2 (33.3)	1 (16.7)	2 (33.3)	1 (16.7)	6 (100.0)
Off Label	1 Jan 2016 - 31 Dec 2016	0 (0.0)	3 (42.9)	2 (28.6)	2 (28.6)	7 (100.0)
Off Label	1 Jan 2017 - 31 Dec 2017	0 (0.0)	1 (33.3)	1 (33.3)	1 (33.3)	3 (100.0)
Off Label	1 Jan 2018 - 31 Dec 2018	0 (0.0)	4 (80.0)	0 (0.0)	1 (20.0)	5 (100.0)
Off Label	Total	5 (15.2)	10 (30.3)	12 (36.4)	6 (18.2)	33 (100.0)

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Table 11. Sensitivity: Place of Service for Administration of Neulasta Stratified by Age <= 13 and Age < 2 at First Administration, On-Label or Off-Label

Use	12-month intervals	Age < 2 yr						
		Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
On Label	1 Jan 2013 - 31 Dec 2013	1 (12.5)	0 (0.0)	5 (62.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)
On Label	1 Jan 2014 - 31 Dec 2014	0 (0.0)	1 (6.3)	10 (62.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)
On Label	1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	5 (55.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)
On Label	1 Jan 2016 - 31 Dec 2016	3 (30.0)	0 (0.0)	3 (30.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
On Label	1 Jan 2017 - 31 Dec 2017	1 (8.3)	0 (0.0)	5 (41.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
On Label	1 Jan 2018 - 31 Dec 2018	1 (6.7)	0 (0.0)	5 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
On Label	Total	6 (8.6)	1 (1.4)	33 (47.1)	0 (0.0)	0 (0.0)	0 (0.0)	3 (4.3)
Off Label	1 Jan 2013 - 31 Dec 2013	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	1 Jan 2014 - 31 Dec 2014	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	1 Jan 2016 - 31 Dec 2016	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	1 Jan 2017 - 31 Dec 2017	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	1 Jan 2018 - 31 Dec 2018	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	Total	0 (0.0)	0 (0.0)	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 11. Sensitivity: Place of Service for Administration of Neulasta Stratified by Age ≤ 13 and Age < 2 at First Administration, On-Label or Off-Label

Use	12-month intervals	Age < 2 yr		
		Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
On Label	1 Jan 2013 - 31 Dec 2013	1 (12.5)	0 (0.0)	8 (100.0)
On Label	1 Jan 2014 - 31 Dec 2014	3 (18.8)	1 (6.3)	16 (100.0)
On Label	1 Jan 2015 - 31 Dec 2015	3 (33.3)	0 (0.0)	9 (100.0)
On Label	1 Jan 2016 - 31 Dec 2016	4 (40.0)	0 (0.0)	10 (100.0)
On Label	1 Jan 2017 - 31 Dec 2017	3 (25.0)	3 (25.0)	12 (100.0)
On Label	1 Jan 2018 - 31 Dec 2018	3 (20.0)	6 (40.0)	15 (100.0)
On Label	Total	17 (24.3)	10 (14.3)	70 (100.0)
Off Label	1 Jan 2013 - 31 Dec 2013	0 (0.0)	0 (0.0)	1 (100.0)
Off Label	1 Jan 2014 - 31 Dec 2014	0 (0.0)	0 (0.0)	2 (100.0)
Off Label	1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	2 (100.0)
Off Label	1 Jan 2016 - 31 Dec 2016	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	1 Jan 2017 - 31 Dec 2017	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	1 Jan 2018 - 31 Dec 2018	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	Total	0 (0.0)	0 (0.0)	5 (100.0)

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Table 11. Sensitivity: Place of Service for Administration of Neulasta Stratified by Age <= 13 and Age < 2 at First Administration, On-Label or Off-Label

		Age <= 13 yr						
Use	12-month intervals	Home	Inpatient Hospital	Outpatient Hospital	Other Place of Service	Emergency Room - Hospital	Ambulatory Surgical Center	Office
On Label	1 Jan 2013 - 31 Dec 2013	19 (13.3)	1 (0.7)	64 (44.8)	0 (0.0)	1 (0.7)	0 (0.0)	6 (4.2)
On Label	1 Jan 2014 - 31 Dec 2014	14 (11.1)	1 (0.8)	59 (46.8)	1 (0.8)	1 (0.8)	0 (0.0)	6 (4.8)
On Label	1 Jan 2015 - 31 Dec 2015	10 (9.2)	1 (0.9)	48 (44.0)	0 (0.0)	0 (0.0)	1 (0.9)	6 (5.5)
On Label	1 Jan 2016 - 31 Dec 2016	13 (12.4)	0 (0.0)	36 (34.3)	0 (0.0)	0 (0.0)	0 (0.0)	6 (5.7)
On Label	1 Jan 2017 - 31 Dec 2017	12 (10.0)	0 (0.0)	52 (43.3)	0 (0.0)	1 (0.8)	0 (0.0)	3 (2.5)
On Label	1 Jan 2018 - 31 Dec 2018	6 (4.8)	1 (0.8)	49 (38.9)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)
On Label	Total	74 (10.2)	4 (0.5)	308 (42.2)	1 (0.1)	3 (0.4)	1 (0.1)	29 (4.0)
Off Label	1 Jan 2013 - 31 Dec 2013	0 (0.0)	0 (0.0)	3 (60.0)	0 (0.0)	1 (20.0)	0 (0.0)	1 (20.0)
Off Label	1 Jan 2014 - 31 Dec 2014	1 (14.3)	0 (0.0)	4 (57.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)
Off Label	1 Jan 2015 - 31 Dec 2015	0 (0.0)	0 (0.0)	4 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	1 Jan 2016 - 31 Dec 2016	0 (0.0)	0 (0.0)	2 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	1 Jan 2017 - 31 Dec 2017	0 (0.0)	0 (0.0)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Off Label	1 Jan 2018 - 31 Dec 2018	0 (0.0)	0 (0.0)	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Off Label	Total	1 (3.0)	0 (0.0)	16 (48.5)	0 (0.0)	1 (3.0)	0 (0.0)	3 (9.1)

Table 11. Sensitivity: Place of Service for Administration of Neulasta Stratified by Age <= 13 and Age < 2 at First Administration, On-Label or Off-Label

Use	12-month intervals	Age <= 13 yr		
		Prescription dispensed in pharmacy	Prescription dispensed through mail order	ALL LOCATIONS
On Label	1 Jan 2013 - 31 Dec 2013	46 (32.2)	6 (4.2)	143 (100.0)
On Label	1 Jan 2014 - 31 Dec 2014	35 (27.8)	9 (7.1)	126 (100.0)
On Label	1 Jan 2015 - 31 Dec 2015	36 (33.0)	7 (6.4)	109 (100.0)
On Label	1 Jan 2016 - 31 Dec 2016	42 (40.0)	8 (7.6)	105 (100.0)
On Label	1 Jan 2017 - 31 Dec 2017	38 (31.7)	14 (11.7)	120 (100.0)
On Label	1 Jan 2018 - 31 Dec 2018	40 (31.7)	28 (22.2)	126 (100.0)
On Label	Total	237 (32.5)	72 (9.9)	729 (100.0)
Off Label	1 Jan 2013 - 31 Dec 2013	0 (0.0)	0 (0.0)	5 (100.0)
Off Label	1 Jan 2014 - 31 Dec 2014	1 (14.3)	0 (0.0)	7 (100.0)
Off Label	1 Jan 2015 - 31 Dec 2015	1 (16.7)	1 (16.7)	6 (100.0)
Off Label	1 Jan 2016 - 31 Dec 2016	4 (57.1)	1 (14.3)	7 (100.0)
Off Label	1 Jan 2017 - 31 Dec 2017	1 (33.3)	1 (33.3)	3 (100.0)
Off Label	1 Jan 2018 - 31 Dec 2018	2 (40.0)	0 (0.0)	5 (100.0)
Off Label	Total	9 (27.3)	3 (9.1)	33 (100.0)

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16. ANNEXES

Annex 1. List of Stand-alone Documents

Not Applicable

Annex 2. Study Protocol and Amendments

Product: Neulasta
Abbreviated Retrospective Observational Research Protocol: 20200114
Date: 18 March 2020

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Title: *Users of pegfilgrastim less than or equal to 13 years of age*

Amgen Protocol Number: 20200114

Study Sponsor: Amgen, Inc.
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Thousand Oaks, CA
Tel: 805-447-1000

Department: Center for Observational Research

Therapeutic Area: Oncology

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Date: 18 March 2020
Version: 1.0

Approved

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Date: 18 March 2020

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1. BACKGROUND AND RATIONALE

On 08 November 2018, the FDA informed Amgen that they were evaluating pegfilgrastim Injection medication errors associated with doses less than 6 mg (0.6 mL) in pediatric patients weighing less than 45 kg.

The FDA requested the following information from Amgen:

1. *"An analysis of your U.S. and foreign postmarket serious and non-serious medication error/adverse event cases and complaints associated with Pegfilgrastim Injection and suspected wrong dose errors (including but not limited to overdose, underdose, dose omission, and dose confusion) involving the preparation and administration of doses less than 6 mg (0.6 mL). You should limit your analysis to cases and complaints received in the last 5 years. Your analysis should include:*
2. *Describe the trends and use of Pegfilgrastim Injection in U.S. pediatric patients weighing less than 45 kg (using ≤ 13 years of age as a surrogate for weight) in the last 3 years.*
3. *A description of your plans to prevent wrong dose errors in patients requiring Pegfilgrastim doses less than 6 mg (0.6 mL). It would be helpful if you could include discussion on any recommendations or suggestions made by a reporter such as including a dosage form suitable for pediatric doses and addition of syringe markings to measure doses less than 6 mg (0.6 mL)."*

To address the above outlined summary, the study protocol (20180440) was executed and completed, including a CSR.

On 10 October 2019, Amgen received a Complete Response Letter and Order Letter from the FDA regarding the prior approval labeling supplement that was submitted in response to the FDA's concerns regarding pediatric dosing errors.

- The Agency concluded that the Pegfilgrastim pediatric dosing errors and their potential clinical consequences, cannot be appropriately and fully addressed through changes to Pegfilgrastim product labeling alone.
- Amgen is expected to develop a presentation that can be used to directly and accurately administer Pegfilgrastim (pegfilgrastim) to pediatric patients who weigh < 45 kg and require doses that are < 0.6 mL (6 mg).
- Amgen is required to conduct any necessary human factors studies to evaluate the ability of HCPs and/or caregivers to administer the appropriate doses.
- Amgen must submit a proposal to address the requirements set forth in the abovementioned letter within 90 days from the date of the letter.

In response, on 08 Jan 2020, Amgen submitted a response to the FDA Pediatric Assessment Required Letter which included a proposal to address FDA concerns. Amgen's proposal consisted of a presentation for pediatric administration of a

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single-use, disposable, vial intended for administering a variable, weight-based dose via a .01 mL graduated syringe in pediatric patients by a caregiver in the home setting or by the healthcare provider in a clinic setting.

On 10 Feb 2020, Amgen received FDA's feedback to the response submitted on 08 January 2020:

- The FDA remains concerned that Amgen's planned approach may not be adequate to accurately administer Pegfilgrastim to pediatric patients who weigh less than 45 kg and require doses that are less than 0.6 mL (6 mg).
- The FDA recommends development of a separate lower-concentration Pegfilgrastim vial presentation with appropriate clinical studies to evaluate safety/efficacy/PK of this formulation for pediatric patients.
- The FDA acknowledged Amgen's proposal of a vial intended for administration of a variable, weight-based dose via a 0.01mL graduated syringe in pediatric patients by a caregiver in the home setting or by the healthcare provider in a clinic setting. However, the Agency is concerned that users may not be able to navigate the use of this vial and syringe in the real-world setting. The FDA recommended Amgen to submit the HF validation study protocol for feedback from the Agency before commencing the study.

To support the design of the Human factor (HF) study Amgen would like to understand the utilization frequency of Pegfilgrastim and in what setting Pegfilgrastim is being administered, among patients ages < 2 years (a surrogate for weight < 10 kg), as well as various age ranges that correspond to weight < 45kg. The results from this analysis will help inform the Regulatory and Safety team in terms of how to respond to the FDA inquiry. The results may be used in a CSR that would accompany the follow-up correspondence with the FDA.

2. OBJECTIVES

The primary objectives of this study are:

Describe the users of pegfilgrastim between 01/01/2013 and 12/31/2018 stratified by calendar year and by place-of-service for administration of pegfilgrastim, for the following age populations:

- a. Patients aged ≤ 13 years;
- b. (Subset) Patients aged < 2 years;
- c. Patients by individual ages (< 1, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13 years)
- d. Patients aged 0 -< 2, 2 - 5, 6 – 10, 11-13 years

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3. STUDY POPULATION/SAMPLE SIZE/STATISTICAL ANALYSES PLANS

The Truven MarketScan® database¹ captures person-specific clinical utilization, expenditures, and enrollment across inpatient, outpatient, prescription drug, and carve-out services from a selection of large employers, health plans, and government and public organizations. The MarketScan® databases link paid claims and encounter data to detailed patient information across sites and types of providers, and over time. The annual medical databases include private sector health data from approximately 100 payers. Our study population was extracted from both “Commercial Claims and Encounters (Commercial) Database” and the “Medicare Supplemental and Coordination of Benefits (Medicare) Database”, which is what makes up the MarketScan Commercial Database. The MarketScan Commercial Database contains the inpatient, outpatient, and outpatient prescription drug experience of employees and their dependents, covered under a variety of fee-for-service and managed care health plans, including exclusive provider organizations, PPOs, POS plans, indemnity plans, and health maintenance organizations (HMOs).

Users of pegfilgrastim will be identified as patients who received their first administration of pegfilgrastim between 01 January 2013 and 31 December 2018 without any prior use of pegfilgrastim. Users of pegfilgrastim will be identified in the database as patients with at least one claim with HCPCS code (“J2505”, “C9119”, “S0135”) or at least one claim with an NDC code (“54868522900”, “55513019001”, “55513019201”) for pegfilgrastim. There will be no continuous enrollment required for users of pegfilgrastim. The age of users of pegfilgrastim will be defined as the difference between year of first pegfilgrastim administration and year of birth (date of birth is not available in the database).

The results will be stratified by age at first administration and reported by 12-month intervals (Table 1A-1C):

- Ages ≤ 13 years;
 - Subset population of ages < 2 years;
- By Individual Age for < 1 to 13 years;
- Age ranges: 0 - < 2, 2 - 5, 6 - 10, 11 – 13 years.

Stratify the above sets of results by Place-of-Service, in particular home vs hospital vs clinic vs other vs vs missing-data (Table 2A -2C).

To assess the number and frequency of pediatric patients that use pegfilgrastim on label as compared to off-label use, a sensitivity analysis will be conducted as follows: among

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all patients identified as pegfilgrastim users, if a patient has evidence of a non-myeloid cancer diagnosis occurring any time prior to the first pegfilgrastim exposure the patient will be considered “on-label” exposed, however if no occurrence of non-myeloid cancer diagnosis is found, the patient will be categorized as “off-label”. The definition of a non-myeloid cancer will be: 1 inpatient diagnostic claim or 2 outpatient diagnostic claims (at least 7 days apart) for the same non-myeloid cancer. The number and frequency of patients on label and off-label will be calculated for ages < 2 years and ages ≤ 13 years, stratified by calendar year (Table 1A-Sensitivity). Pending the available sample size, tables 1B, 1C, and possibly 2A will be replicated, stratifying by on-label and off-label results.

Table Shells

Table 1A. Number of Users of Pegfilgrastim Stratified by Age ≤ 13 and Age < 2 at First Administration

12-month intervals	Age < 2		Age ≤ 13 years	
	n	%	n	%
1 Jan 2013 - 31 Dec 2013	n	%	n	%
1 Jan 2014 - 31 Dec 2014	n	%	n	%
1 Jan 2015 - 31 Dec 2015	n	%	n	%
1 Jan 2016 - 31 Dec 2016	n	%	n	%
1 Jan 2017 - 31 Dec 2017	n	%	n	%
1 Jan 2018 – 31 Dec 2018	n	%	n	%
Total	n	%	n	%

Table 1A. Sensitivity: Number of Users of Pegfilgrastim Stratified by Age ≤ 13 and Age < 2 at First Administration

Label Use	Age < 2				Age ≤ 13 years			
	On-Label		Off-Label		On-Label		Off-Label	
12-month intervals	n	%	n	%	n	%	n	%
1 Jan 2013 - 31 Dec 2013	n	%	n	%	n	%	n	%
1 Jan 2014 - 31 Dec 2014	n	%	n	%	n	%	n	%
1 Jan 2015 - 31 Dec 2015	n	%	n	%	n	%	n	%
1 Jan 2016 - 31 Dec 2016	n	%	n	%	n	%	n	%
1 Jan 2017 - 31 Dec 2017	n	%	n	%	n	%	n	%
1 Jan 2018 – 31 Dec 2018	n	%	n	%	n	%	n	%
Total	n	%	n	%	n	%	n	%

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Table 1B. Number of Users of Pegfilgrastim Stratified by Individual Age at First Administration

12-month intervals	Ages (in Years)													
	< 1	1	2	3	4	5	6	7	8	9	10	11	12	13
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
1 Jan 2013 - 31 Dec 2013														
1 Jan 2014 - 31 Dec 2014														
1 Jan 2015 - 31 Dec 2015														
1 Jan 2016 - 31 Dec 2016														
1 Jan 2017 - 31 Dec 2017														
1 Jan 2018 – 31 Dec 2018														
Total														

Table 1C. Number of Users of Pegfilgrastim Stratified by Age-categories at First Administration

12-month intervals	Age 0 - < 2		Age 2- 5		Ages 6-10		Ages 11 - 13	
	n	%	n	%	n	%	n	%
1 Jan 2013 - 31 Dec 2013	n	%	n	%	n	%	n	%
1 Jan 2014 - 31 Dec 2014	n	%	n	%	n	%	n	%
1 Jan 2015 - 31 Dec 2015	n	%	n	%	n	%	n	%
1 Jan 2016 - 31 Dec 2016	n	%	n	%	n	%	n	%
1 Jan 2017 - 31 Dec 2017	n	%	n	%	n	%	n	%
1 Jan 2018 – 31 Dec 2018	n	%	n	%	n	%	n	%
Total	n	%	n	%	n	%	n	%

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Table 2A. Place of Service for Administration of Neulasta Stratified by Age

	Age < 2					Age ≤ 13 years				
	Home	Hospital	Clinic	Other	Missing	Home	Hospital	Clinic	Other	Missing
12-month intervals	N (%)	N (%)	N(%)	N(%)	N (%)	N (%)	N (%)	N (%)	N(%)	N (%)
1 Jan 13 - 31 Dec 13										
1 Jan 14 - 31 Dec 14										
1 Jan 15 - 31 Dec 15										
1 Jan 16 - 31 Dec 16										
1 Jan 17 - 31 Dec 17										
1 Jan 18 – 31 Dec 18										
Total										

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The [Table 2A](#) will be regenerated for each defined age category: by individual age (Table 2b) and by age-groups 0- < 2, 2-5, 6-10, 10-13 (Table 2c).

Although the Truven Marketscan database includes patients enrolled in Medicare Supplemental but, it does not include traditional Medicare enrollees. Thus, proportion of users of pegfilgrastim ≤ 13 years of age and the subset of patients < 2 years of age may be an overestimation of the national proportion of users of pegfilgrastim ≤ 13 years and < 2 years of age.

4. COLLECTION, RECORDING, AND REPORTING OF SAFETY INFORMATION AND PRODUCT COMPLAINTS

4.1 Safety Collection and Recording Requirements

This study is analyzing secondary data from Truven Marketscan commercial claims database and no safety data will be collected or reported.

5. SUBJECT CONFIDENTIALITY

This study will comply with all applicable laws regarding subject privacy. No direct subject contact or collection of additional subject data will occur. Study results will be in tabular form and aggregate analyses that omits subject identification. Any publications and reports will not include subject identifiers.

6. PUBLICATION INTENT

The results of this study will not be published separate from submission to relevant regulatory authorities.

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7. REFERENCES

1. Cappell KA, Shreay S, Cao Z, Varker HV, Paoli CJ, Gitlin M. Red blood cell (RBC) transfusion rates among US chronic dialysis patients during changes to Medicare end-stage renal disease (ESRD) reimbursement systems and erythropoiesis stimulating agent (ESA) labels. *BMC Nephrology*. 2014;15:116.

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Annex 3. Signature of Coordinating Investigator

Investigator Signature

STUDY NUMBER: 20200114

STUDY REPORT TITLE: Users of Pegfilgrastim Less Than or Equal to 13 Years of Age

I have read the above named Observational Research Study Report and signify my agreement with the overall conclusions.

Name of Coordinating Investigator:	Jennifer Schenfeld
Institution:	Amgen Inc., One Amgen Center Drive, Thousand Oaks, CA 91320 Phone: 805-313-9013 Email: jschenfe@amgen.com
Signature of Investigator:	<i>Jennifer Schenfeld</i>
Date:	16 June 2020