

Disclaimer

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview

Request Description FDA requested use of Modular Program #3 to investigate hemolysis events (see Appendix B) following new use of several Ig products (see Appendix A) with varying follow-up periods based on last date of exposure for each episode (exposure extension period). Users were excluded if evidence of use of another product listed in Appendix A was found in the 28 days before, the day of, or the 28 days after index use of the exposure of interest. In addition, the Charlson Comorbidity Index module was used. Two runs were executed to analyze two different age cohorts: one with all age groups, and a second with the 0-17 age group excluded. In total, 80 different scenarios (see Specifications - the 40 scenarios run twice with the different age groupings) were examined in this request with differing exposures and exposure extension periods. The time window for the request was January 1, 2006 to December 31, 2012. The package was distributed to 18 Data Partners on January 28, 2014. Please see the Specifications tab for more details on each scenario. This report provides results for the first run of the program, where the age groupings include 0-17, 18-44, 45-64, 65+ years.

Request ID to09y05_mpr_wp14_v03 - report 1 of 2

Specifications Program parameter inputs and scenarios

Glossary List of Terms found in this Report and their Definitions

Table 1 Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, New Episodes with Events, Number of Events, Years at Risk, Eligible Members, Member-Years, New Users per 100,000 Eligible Members, Dispensings per User, New Episodes with Events per 1,000 Years at Risk, and Number of Events per 1,000 Years at Risk by Drug Product and Episode Extension Period*

Table 2 Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, New Episodes with Events, Number of Events, Years at Risk, Eligible Members, Member-Years, New Users per 100,000 Eligible Members, Dispensings per User, New Episodes with Events per 1,000 Years at Risk, and Number of Events per 1,000 Years at Risk by Drug Product, Episode Extension Period and Age Group*

Table 3 Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, New Episodes with Events, Number of Events, Years at Risk, Eligible Members, Member-Years, New Users per 100,000 Eligible Members, Dispensings per User, New Episodes with Events per 1,000 Years at Risk, and Number of Events per 1,000 Years at Risk by Drug Product, Episode Extension Period and Sex*

Table 4 Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, New Episodes with Events, Number of Events, Years at Risk, Eligible Members, Member-Years, New Users per 100,000 Eligible Members, Dispensings per User, New Episodes with Events per 1,000 Years at Risk, and Number of Events per 1,000 Years at Risk by Drug Product, Episode Extension Period and Year*

Table 5 Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, New Episodes with Events, Number of Events, Years at Risk, Eligible Members, Member-Years, New Users per 100,000 Eligible Members, Dispensings per User, New Episodes with Events per 1,000 Years at Risk, and Number of Events per 1,000 Years at Risk by Drug Product, Episode Extension Period and Pre-Index Charlson Comorbidity Index (CCI) Score*

Appendix A List of exposure drug codes

Appendix B List of event diagnosis codes

Notes: * Dispensings = Days Supplied = Amount Supplied since the exposures are procedure codes. Therefore, Days Supplied, Amount Supplied, and associated rates are omitted from the tables.

Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document.

to09y05_mpr_wp14_v03 Specifications

Modular Program #3 was used to investigate hemolysis events (see Appendix B) following new use of several Ig products (see Appendix A) with varying follow-up periods based on last date of exposure for each episode (exposure extension period). Users were excluded if evidence of use of another product listed in Appendix A was found in the 28 days before, the day of, or the 28 days after index use of the exposure of interest. In addition, the Charlson Comorbidity Index module was used. Two runs were executed to analyze two different age cohorts: one with all age groups and the second excluding the 0-17 age group. In total, 80 different scenarios (the 40 below run twice with the different age groupings) were examined in this report with differing exposures and exposure extension periods. See below for a description of each of these scenarios.

Coverage Requirement	Drug and Medical Coverage
Query Period	January 1, 2006 to December 31, 2012
Enrollment Gap	45 Days
Enrollment Days	183
Age Stratifications	Run 1: 0-17, 18-44, 45-64, 65+ Run 2: 18-44, 45-64, 65+
Minimum Days Supplied and	0 Days

Scenario	Drug/Exposure						Exclusion Criteria	Event/Outcome						Charlson Comorbidity Index (CCI)						
	Incident exposure	Incident w/ respect to:	Episode Gap	Exposure Extension Period	Washout (days)	Cohort Definition		Inclusion/ Exclusion	Lookback Start	Lookback End	Care Setting PDX	Event/ Outcome	Incident w/ respect to:	Washout (days)	Event De- duplication	Care Setting PDX	Blackout Period	CCI Group Stratification	Number of Pre-Index Days	Number of Index Days
1	Flebogamma	Flebogamma	2	3	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
2	Gammagard Liquid	Gammagard Liquid	2	3	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
3	Gammaplex	Gammaplex	2	3	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
4	Gamunex	Gamunex	2	3	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
5	Octagam	Octagam	2	3	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
6	Privigen	Privigen	2	3	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
7	Lyophilized product IV	Lyophilized product IV	2	3	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
8	Non-lyophilized intramuscular route	Non-lyophilized intramuscular route	2	3	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
9	Non-lyophilized unspecified route	Non-lyophilized unspecified route	2	3	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
10	Other IVIg, brand not specified	Other IVIg, brand not specified	2	3	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
11	Flebogamma	Flebogamma	2	14	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
12	Gammagard Liquid	Gammagard Liquid	2	14	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
13	Gammaplex	Gammaplex	2	14	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
14	Gamunex	Gamunex	2	14	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
15	Octagam	Octagam	2	14	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
16	Privigen	Privigen	2	14	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
17	Lyophilized product IV	Lyophilized product IV	2	14	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
18	Non-lyophilized intramuscular route	Non-lyophilized intramuscular route	2	14	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
19	Non-lyophilized unspecified route	Non-lyophilized unspecified route	2	14	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
20	Other IVIg, brand not specified	Other IVIg, brand not specified	2	14	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
21	Flebogamma	Flebogamma	2	21	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
22	Gammagard Liquid	Gammagard Liquid	2	21	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0

Drug/Exposure							Exclusion Criteria				Event/Outcome						Charlson Comorbidity Index (CCI)				
Scenario	Incident exposure		Incident w/ respect to:	Exposure			Cohort Definition	Inclusion/ Exclusion	Lookback Start	Lookback End	Care Setting PDX	Event/ Outcome	Incident w/ respect to:	Washout (days)	Event De-duplication	Care Setting PDX	Blackout Period	CCI Group Stratification	Number of		
	Gap	Extension Period		Washout (days)	Episode	Period													Days	Pre-Index Days	Number of Index Days
23	Gammaplex	Gammaplex		2	21	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
24	Gamunex	Gamunex		2	21	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
25	Octagam	Octagam		2	21	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
26	Privigen	Privigen		2	21	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
27	Lyophilized product IV	Lyophilized product IV		2	21	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
28	Non-lyophilized intramuscular route	Non-lyophilized intramuscular route		2	21	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
29	Non-lyophilized unspecified route	Non-lyophilized unspecified route		2	21	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
30	Other IVIg, brand not specified	Other IVIg, brand not specified		2	21	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
31	Flebogamma	Flebogamma		2	28	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
32	Gammagard Liquid	Gammagard Liquid		2	28	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
33	Gammaplex	Gammaplex		2	28	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
34	Gamunex	Gamunex		2	28	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
35	Octagam	Octagam		2	28	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
36	Privigen	Privigen		2	28	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
37	Lyophilized product IV	Lyophilized product IV		2	28	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
38	Non-lyophilized intramuscular route	Non-lyophilized intramuscular route		2	28	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
39	Non-lyophilized unspecified route	Non-lyophilized unspecified route		2	28	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0
40	Other IVIg, brand not specified	Other IVIg, brand not specified		2	28	28	02	All specified Ig except exposure of interest	-28	28	IP, ED, OA, AV	Hemolysis	Hemolysis	90	2	IP*, ED*, OA*, AV*	0	0, 1, 2, 3-4, 5-6, 7+	365	0	0

All exposure, event, and pre-existing condition codes provided by FDA requester.

Glossary of Terms in Modular Program 3*

- Amount Supplied** - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing. This is equivalent to the "RxAmt"
- Blackout Period** - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.
- Care Setting** - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other
- Cohort Definition (drug/exposure)**- Indicates how the cohort will be defined: (1) 01: Cohort includes only the first valid incident treatment episode during the query period; (2) 02: Cohort includes all valid incident treatment episodes during the query period; (3) 03: Cohort includes all valid incident treatment episodes during the query period until an event occurs
- Days Supplied** - number of days supplied for all dispensings in qualifying treatment episodes.
- Years at Risk** - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.
- Eligible Members** - Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.
- Enrollment Gap** - number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled"
- Episode Gap** - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same
- Event Deduplication** - specifies how events are counted by the MP algorithm: A value of 0 counts all occurrences of an event group code of interest; a value of 1 de-duplicates occurrences of the same event code on the same day (i.e., de-duplicates at the exact match code level); and a value of 2 de-duplicates occurrences of the same event group code on the same day (e.g., de-duplicates at the GROUP level).
- Exposure Extension Period** - number of days post treatment period in which the outcomes/events are counted for a treatment episode.
- Lookback Period (pre-existing condition)** - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).
- Member-Years** - sum of all days of enrollment with medical and drug coverage** in the query period preceded by an exposure washout
- Minimum Days Supplied** - specifies a minimum number of days in length of the days supplied for the episode to be considered
- Minimum Episode Duration** - specifies a minimum number of days in length of the episode for it to be considered
- New Episodes** - new treatment episodes; length of episode is determined by days supplied in one dispensing (or consecutive dispensings
- New Episodes with Events** - number of unique episodes during which at least one incident event occurs. Each episode may only be counted
- New Users** - number of members with incident exposure during the query period. Member must have no evidence of exposure (s) of interest (defined by incidence criteria) in the prior washout period. A user may only be counted once in a query period.
- Number of Events** - total number of incident events. An individual or a treatment episode can have more than one incident event provided that the incident event meets the event incidence criteria.
- Principal Diagnosis (PDX)** - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. YES will only consider diagnoses flagged as Principal
- Query Period** - period in which the modular program looks for exposures and outcomes of interest.
- Treatment Episode Truncation Indicator** - indicates whether observation of the incident query code during follow-up requires truncation of valid treatment episodes. A value of Y indicates that the treatment episodes should be truncated at the first occurrence of an incident query code. A value of N indicates that the treatment episodes should not be truncated at the occurrence of the incident query code.
- Washout Period (drug/exposure)**** - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.
- Washout Period (event/outcome)**** - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

*all terms may not be used in this report

**incident treatment episodes must be incident to both the exposure and the event

Table 1. Summary of Incident Ig Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Ig Product and Episode Extension Period

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
Flebogamma													
<i>3 day episode extension</i>	2,008	6,525	8,104	8,104	76.2	9	11	86,110,508	193,410,324.3	2.33	4.04	118.04	144.27
<i>14 day episode extension</i>	2,008	6,525	8,104	8,104	269.5	14	16	86,110,508	193,410,324.3	2.33	4.04	51.96	59.38
<i>21 day episode extension</i>	2,008	6,525	8,104	8,104	389.6	16	18	86,110,508	193,410,324.3	2.33	4.04	41.06	46.20
<i>28 day episode extension</i>	2,008	6,525	8,104	8,104	498.7	21	24	86,110,508	193,410,324.3	2.33	4.04	42.11	48.12
Gammagard Liquid													
<i>3 day episode extension</i>	9,237	35,451	40,891	40,891	406.5	27	34	86,111,326	193,410,448.3	10.73	4.43	66.42	83.64
<i>14 day episode extension</i>	9,237	35,451	40,891	40,891	1,453.6	38	53	86,111,326	193,410,448.3	10.73	4.43	26.14	36.46
<i>21 day episode extension</i>	9,237	35,451	40,891	40,891	2,100.7	46	81	86,111,326	193,410,448.3	10.73	4.43	21.90	38.56
<i>28 day episode extension</i>	9,237	35,451	40,891	40,891	2,674.6	54	101	86,111,326	193,410,448.3	10.73	4.43	20.19	37.76
Gammaplex													
<i>3 day episode extension</i>	51	122	158	158	1.5	0	0	86,110,352	193,410,061.0	0.06	3.10	0.00	0.00
<i>14 day episode extension</i>	51	122	158	158	5.1	0	0	86,110,352	193,410,061.0	0.06	3.10	0.00	0.00
<i>21 day episode extension</i>	51	122	158	158	7.4	0	0	86,110,352	193,410,061.0	0.06	3.10	0.00	0.00
<i>28 day episode extension</i>	51	122	158	158	9.4	0	0	86,110,352	193,410,061.0	0.06	3.10	0.00	0.00
Gamunex													
<i>3 day episode extension</i>	6,655	25,651	29,983	29,983	294.9	12	12	86,111,023	193,409,772.9	7.73	4.51	40.69	40.69
<i>14 day episode extension</i>	6,655	25,651	29,983	29,983	1,052.3	21	28	86,111,023	193,409,772.9	7.73	4.51	19.96	26.61
<i>21 day episode extension</i>	6,655	25,651	29,983	29,983	1,518.0	32	46	86,111,023	193,409,772.9	7.73	4.51	21.08	30.30
<i>28 day episode extension</i>	6,655	25,651	29,983	29,983	1,929.3	36	62	86,111,023	193,409,772.9	7.73	4.51	18.66	32.14
Octagam													
<i>3 day episode extension</i>	2,133	7,183	8,294	8,294	82.6	9	17	86,110,666	193,410,412.6	2.48	3.89	108.91	205.73
<i>14 day episode extension</i>	2,133	7,183	8,294	8,294	295.3	13	32	86,110,666	193,410,412.6	2.48	3.89	44.02	108.35
<i>21 day episode extension</i>	2,133	7,183	8,294	8,294	427.5	15	41	86,110,666	193,410,412.6	2.48	3.89	35.09	95.92
<i>28 day episode extension</i>	2,133	7,183	8,294	8,294	546.5	15	46	86,110,666	193,410,412.6	2.48	3.89	27.45	84.18
Privigen													
<i>3 day episode extension</i>	3,182	10,279	12,339	12,339	119.0	12	16	86,110,640	193,409,882.7	3.70	3.88	100.80	134.41
<i>14 day episode extension</i>	3,182	10,279	12,339	12,339	422.9	17	27	86,110,640	193,409,882.7	3.70	3.88	40.19	63.84
<i>21 day episode extension</i>	3,182	10,279	12,339	12,339	610.9	17	34	86,110,640	193,409,882.7	3.70	3.88	27.83	55.65
<i>28 day episode extension</i>	3,182	10,279	12,339	12,339	778.3	20	42	86,110,640	193,409,882.7	3.70	3.88	25.70	53.96

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
Lyophilized product IV													
<i>3 day episode extension</i>	5,690	20,834	24,727	24,727	240.5	24	27	86,110,990	193,410,870.2	6.61	4.35	99.80	112.27
<i>14 day episode extension</i>	5,690	20,834	24,727	24,727	856.9	34	40	86,110,990	193,410,870.2	6.61	4.35	39.68	46.68
<i>21 day episode extension</i>	5,690	20,834	24,727	24,727	1,238.6	36	46	86,110,990	193,410,870.2	6.61	4.35	29.06	37.14
<i>28 day episode extension</i>	5,690	20,834	24,727	24,727	1,579.4	41	54	86,110,990	193,410,870.2	6.61	4.35	25.96	34.19
Non-lyophilized intramuscular route													
<i>3 day episode extension</i>	7,178	10,176	10,255	10,255	111.8	1	1	86,111,550	193,429,639.8	8.34	1.43	8.94	8.94
<i>14 day episode extension</i>	7,178	10,176	10,255	10,255	414.1	2	2	86,111,550	193,429,639.8	8.34	1.43	4.83	4.83
<i>21 day episode extension</i>	7,178	10,176	10,255	10,255	601.9	2	2	86,111,550	193,429,639.8	8.34	1.43	3.32	3.32
<i>28 day episode extension</i>	7,178	10,176	10,255	10,255	782.5	2	2	86,111,550	193,429,639.8	8.34	1.43	2.56	2.56
Non-lyophilized unspecified route													
<i>3 day episode extension</i>	11,397	15,009	15,240	15,240	163.8	181	209	86,111,977	193,428,891.1	13.24	1.34	1105.15	1276.12
<i>14 day episode extension</i>	11,397	15,009	15,240	15,240	605.7	200	331	86,111,977	193,428,891.1	13.24	1.34	330.17	546.44
<i>21 day episode extension</i>	11,397	15,009	15,240	15,240	879.9	213	406	86,111,977	193,428,891.1	13.24	1.34	242.06	461.40
<i>28 day episode extension</i>	11,397	15,009	15,240	15,240	1,147.4	222	468	86,111,977	193,428,891.1	13.24	1.34	193.49	407.89
Other IVig, brand not specified													
<i>3 day episode extension</i>	3,279	7,988	9,350	9,350	92.0	5	7	86,110,821	193,411,875.5	3.81	2.85	54.33	76.06
<i>14 day episode extension</i>	3,279	7,988	9,350	9,350	326.1	10	16	86,110,821	193,411,875.5	3.81	2.85	30.66	49.06
<i>21 day episode extension</i>	3,279	7,988	9,350	9,350	469.3	11	20	86,110,821	193,411,875.5	3.81	2.85	23.44	42.62
<i>28 day episode extension</i>	3,279	7,988	9,350	9,350	596.5	14	23	86,110,821	193,411,875.5	3.81	2.85	23.47	38.56

Table 2. Summary of Incident Ig Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Ig Product, Episode Extension Period, and Age Group

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
Flebogamma													
<i>3 day episode extension</i>													
0 to 17 Years	142	345	364	364	3.8	0	0	21,019,367	43,930,163.7	0.68	2.56	0.00	0.00
18 to 44 Years	385	1,103	1,422	1,422	13.1	1	1	38,897,900	70,364,592.9	0.99	3.69	76.40	76.40
45 to 64 Years	855	2,610	3,266	3,266	30.6	3	4	25,226,433	57,813,091.6	3.39	3.82	98.06	130.75
65+ Years	661	2,467	3,052	3,052	28.7	5	6	7,844,178	21,302,476.0	8.43	4.62	174.08	208.89
<i>14 day episode extension</i>													
0 to 17 Years	142	345	364	364	14.1	0	0	21,019,367	43,930,163.7	0.68	2.56	0.00	0.00
18 to 44 Years	385	1,103	1,422	1,422	45.5	2	2	38,897,900	70,364,592.9	0.99	3.69	43.96	43.96
45 to 64 Years	855	2,610	3,266	3,266	107.6	5	6	25,226,433	57,813,091.6	3.39	3.82	46.46	55.75
65+ Years	661	2,467	3,052	3,052	102.2	7	8	7,844,178	21,302,476.0	8.43	4.62	68.49	78.28
<i>21 day episode extension</i>													
0 to 17 Years	142	345	364	364	20.4	0	0	21,019,367	43,930,163.7	0.68	2.56	0.00	0.00
18 to 44 Years	385	1,103	1,422	1,422	65.4	3	3	38,897,900	70,364,592.9	0.99	3.69	45.89	45.89
45 to 64 Years	855	2,610	3,266	3,266	155.6	5	6	25,226,433	57,813,091.6	3.39	3.82	32.13	38.56
65+ Years	661	2,467	3,052	3,052	148.2	8	9	7,844,178	21,302,476.0	8.43	4.62	53.97	60.71
<i>28 day episode extension</i>													
0 to 17 Years	142	345	364	364	26.0	1	1	21,019,367	43,930,163.7	0.68	2.56	38.51	38.51
18 to 44 Years	385	1,103	1,422	1,422	82.7	3	4	38,897,900	70,364,592.9	0.99	3.69	36.28	48.38
45 to 64 Years	855	2,610	3,266	3,266	199.4	6	7	25,226,433	57,813,091.6	3.39	3.82	30.08	35.10
65+ Years	661	2,467	3,052	3,052	190.6	11	12	7,844,178	21,302,476.0	8.43	4.62	57.71	62.96
Gammagard Liquid													
<i>3 day episode extension</i>													
0 to 17 Years	987	3,275	3,676	3,676	37.0	3	3	21,019,459	43,930,137.8	4.70	3.72	80.99	80.99
18 to 44 Years	2,234	7,764	8,880	8,880	89.0	6	6	38,898,196	70,364,721.0	5.74	3.97	67.41	67.41
45 to 64 Years	4,153	16,370	18,900	18,900	187.9	8	14	25,226,865	57,813,143.6	16.46	4.55	42.58	74.52
65+ Years	2,091	8,042	9,435	9,435	92.6	10	11	7,844,330	21,302,445.8	26.66	4.51	108.00	118.81

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
14 day episode extension													
0 to 17 Years	987	3,275	3,676	3,676	134.3	3	3	21,019,459	43,930,137.8	4.70	3.72	22.34	22.34
18 to 44 Years	2,234	7,764	8,880	8,880	317.2	8	10	38,898,196	70,364,721.0	5.74	3.97	25.22	31.52
45 to 64 Years	4,153	16,370	18,900	18,900	670.5	14	25	25,226,865	57,813,143.6	16.46	4.55	20.88	37.29
65+ Years	2,091	8,042	9,435	9,435	331.6	13	15	7,844,330	21,302,445.8	26.66	4.51	39.21	45.24
21 day episode extension													
0 to 17 Years	987	3,275	3,676	3,676	194.2	3	3	21,019,459	43,930,137.8	4.70	3.72	15.45	15.45
18 to 44 Years	2,234	7,764	8,880	8,880	457.4	9	19	38,898,196	70,364,721.0	5.74	3.97	19.68	41.54
45 to 64 Years	4,153	16,370	18,900	18,900	968.5	17	36	25,226,865	57,813,143.6	16.46	4.55	17.55	37.17
65+ Years	2,091	8,042	9,435	9,435	480.7	17	23	7,844,330	21,302,445.8	26.66	4.51	35.37	47.85
28 day episode extension													
0 to 17 Years	987	3,275	3,676	3,676	245.8	3	3	21,019,459	43,930,137.8	4.70	3.72	12.21	12.21
18 to 44 Years	2,234	7,764	8,880	8,880	579.6	9	28	38,898,196	70,364,721.0	5.74	3.97	15.53	48.31
45 to 64 Years	4,153	16,370	18,900	18,900	1,233.3	19	39	25,226,865	57,813,143.6	16.46	4.55	15.41	31.62
65+ Years	2,091	8,042	9,435	9,435	615.9	23	31	7,844,330	21,302,445.8	26.66	4.51	37.34	50.33
Gammaplex													
3 day episode extension													
0 to 17 Years	1	2	2	2	0.0	0	0	21,019,351	43,930,136.8	0.00	2.00	0.00	0.00
18 to 44 Years	13	27	36	36	0.3	0	0	38,897,860	70,364,474.3	0.03	2.77	0.00	0.00
45 to 64 Years	25	63	88	88	0.8	0	0	25,226,347	57,813,016.3	0.10	3.52	0.00	0.00
65+ Years	13	30	32	32	0.3	0	0	7,844,125	21,302,433.5	0.17	2.46	0.00	0.00
14 day episode extension													
0 to 17 Years	1	2	2	2	0.1	0	0	21,019,351	43,930,136.8	0.00	2.00	0.00	0.00
18 to 44 Years	13	27	36	36	1.1	0	0	38,897,860	70,364,474.3	0.03	2.77	0.00	0.00
45 to 64 Years	25	63	88	88	2.6	0	0	25,226,347	57,813,016.3	0.10	3.52	0.00	0.00
65+ Years	13	30	32	32	1.2	0	0	7,844,125	21,302,433.5	0.17	2.46	0.00	0.00
21 day episode extension													
0 to 17 Years	1	2	2	2	0.1	0	0	21,019,351	43,930,136.8	0.00	2.00	0.00	0.00
18 to 44 Years	13	27	36	36	1.6	0	0	38,897,860	70,364,474.3	0.03	2.77	0.00	0.00
45 to 64 Years	25	63	88	88	3.8	0	0	25,226,347	57,813,016.3	0.10	3.52	0.00	0.00
65+ Years	13	30	32	32	1.8	0	0	7,844,125	21,302,433.5	0.17	2.46	0.00	0.00

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
28 day episode extension													
0 to 17 Years	1	2	2	2	0.2	0	0	21,019,351	43,930,136.8	0.00	2.00	0.00	0.00
18 to 44 Years	13	27	36	36	2.0	0	0	38,897,860	70,364,474.3	0.03	2.77	0.00	0.00
45 to 64 Years	25	63	88	88	4.9	0	0	25,226,347	57,813,016.3	0.10	3.52	0.00	0.00
65+ Years	13	30	32	32	2.4	0	0	7,844,125	21,302,433.5	0.17	2.46	0.00	0.00
Gamunex													
3 day episode extension													
0 to 17 Years	1,128	3,761	3,910	3,910	41.7	5	5	21,019,460	43,930,284.7	5.37	3.47	120.03	120.03
18 to 44 Years	1,496	5,299	6,246	6,246	61.1	1	1	38,898,068	70,364,494.3	3.85	4.18	16.36	16.36
45 to 64 Years	2,896	11,698	13,981	13,981	135.4	5	5	25,226,679	57,812,649.6	11.48	4.83	36.92	36.92
65+ Years	1,348	4,893	5,846	5,846	56.7	1	1	7,844,252	21,302,344.3	17.18	4.34	17.64	17.64
14 day episode extension													
0 to 17 Years	1,128	3,761	3,910	3,910	152.5	6	8	21,019,460	43,930,284.7	5.37	3.47	39.33	52.45
18 to 44 Years	1,496	5,299	6,246	6,246	216.9	5	6	38,898,068	70,364,494.3	3.85	4.18	23.06	27.67
45 to 64 Years	2,896	11,698	13,981	13,981	480.7	9	13	25,226,679	57,812,649.6	11.48	4.83	18.72	27.04
65+ Years	1,348	4,893	5,846	5,846	202.2	1	1	7,844,252	21,302,344.3	17.18	4.34	4.95	4.95
21 day episode extension													
0 to 17 Years	1,128	3,761	3,910	3,910	220.5	7	10	21,019,460	43,930,284.7	5.37	3.47	31.74	45.35
18 to 44 Years	1,496	5,299	6,246	6,246	312.1	8	9	38,898,068	70,364,494.3	3.85	4.18	25.63	28.84
45 to 64 Years	2,896	11,698	13,981	13,981	692.5	14	24	25,226,679	57,812,649.6	11.48	4.83	20.22	34.66
65+ Years	1,348	4,893	5,846	5,846	292.9	3	3	7,844,252	21,302,344.3	17.18	4.34	10.24	10.24
28 day episode extension													
0 to 17 Years	1,128	3,761	3,910	3,910	279.6	7	12	21,019,460	43,930,284.7	5.37	3.47	25.03	42.91
18 to 44 Years	1,496	5,299	6,246	6,246	395.0	9	13	38,898,068	70,364,494.3	3.85	4.18	22.78	32.91
45 to 64 Years	2,896	11,698	13,981	13,981	879.4	17	33	25,226,679	57,812,649.6	11.48	4.83	19.33	37.53
65+ Years	1,348	4,893	5,846	5,846	375.2	3	4	7,844,252	21,302,344.3	17.18	4.34	8.00	10.66
Octagam													
3 day episode extension													
0 to 17 Years	84	201	203	203	2.2	0	0	21,019,368	43,930,151.1	0.40	2.42	0.00	0.00
18 to 44 Years	478	1,623	1,952	1,952	19.1	3	4	38,897,929	70,364,572.2	1.23	4.08	157.37	209.82
45 to 64 Years	1,029	3,562	4,061	4,061	40.8	1	5	25,226,537	57,813,136.0	4.08	3.95	24.50	122.50
65+ Years	584	1,797	2,078	2,078	20.5	5	8	7,844,208	21,302,553.3	7.44	3.56	243.34	389.34

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
14 day episode extension													
0 to 17 Years	84	201	203	203	8.2	0	0	21,019,368	43,930,151.1	0.40	2.42	0.00	0.00
18 to 44 Years	478	1,623	1,952	1,952	66.6	4	16	38,897,929	70,364,572.2	1.23	4.08	60.09	240.35
45 to 64 Years	1,029	3,562	4,061	4,061	146.7	4	8	25,226,537	57,813,136.0	4.08	3.95	27.27	54.55
65+ Years	584	1,797	2,078	2,078	73.9	5	8	7,844,208	21,302,553.3	7.44	3.56	67.70	108.31
21 day episode extension													
0 to 17 Years	84	201	203	203	12.0	0	0	21,019,368	43,930,151.1	0.40	2.42	0.00	0.00
18 to 44 Years	478	1,623	1,952	1,952	95.8	5	23	38,897,929	70,364,572.2	1.23	4.08	52.18	240.01
45 to 64 Years	1,029	3,562	4,061	4,061	212.4	4	9	25,226,537	57,813,136.0	4.08	3.95	18.83	42.37
65+ Years	584	1,797	2,078	2,078	107.2	6	9	7,844,208	21,302,553.3	7.44	3.56	55.96	83.93
28 day episode extension													
0 to 17 Years	84	201	203	203	15.1	0	0	21,019,368	43,930,151.1	0.40	2.42	0.00	0.00
18 to 44 Years	478	1,623	1,952	1,952	122.1	5	27	38,897,929	70,364,572.2	1.23	4.08	40.95	221.12
45 to 64 Years	1,029	3,562	4,061	4,061	271.8	4	9	25,226,537	57,813,136.0	4.08	3.95	14.72	33.11
65+ Years	584	1,797	2,078	2,078	137.5	6	10	7,844,208	21,302,553.3	7.44	3.56	43.65	72.75
Priligyn													
3 day episode extension													
0 to 17 Years	273	785	806	806	8.6	2	2	21,019,376	43,930,134.3	1.30	2.95	231.24	231.24
18 to 44 Years	752	2,165	2,601	2,601	25.1	0	0	38,897,944	70,364,520.6	1.93	3.46	0.00	0.00
45 to 64 Years	1,386	4,520	5,518	5,518	52.6	5	5	25,226,498	57,812,945.2	5.49	3.98	95.07	95.07
65+ Years	831	2,809	3,414	3,414	32.7	5	9	7,844,187	21,302,282.6	10.59	4.11	153.11	275.59
14 day episode extension													
0 to 17 Years	273	785	806	806	32.0	3	4	21,019,376	43,930,134.3	1.30	2.95	93.75	125.00
18 to 44 Years	752	2,165	2,601	2,601	88.7	0	0	38,897,944	70,364,520.6	1.93	3.46	0.00	0.00
45 to 64 Years	1,386	4,520	5,518	5,518	186.2	8	12	25,226,498	57,812,945.2	5.49	3.98	42.96	64.45
65+ Years	831	2,809	3,414	3,414	116.1	6	11	7,844,187	21,302,282.6	10.59	4.11	51.70	94.79
21 day episode extension													
0 to 17 Years	273	785	806	806	46.4	3	6	21,019,376	43,930,134.3	1.30	2.95	64.71	129.43
18 to 44 Years	752	2,165	2,601	2,601	128.0	0	0	38,897,944	70,364,520.6	1.93	3.46	0.00	0.00
45 to 64 Years	1,386	4,520	5,518	5,518	268.8	8	17	25,226,498	57,812,945.2	5.49	3.98	29.77	63.25
65+ Years	831	2,809	3,414	3,414	167.8	6	11	7,844,187	21,302,282.6	10.59	4.11	35.75	65.54

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
28 day episode extension													
0 to 17 Years	273	785	806	806	58.7	3	7	21,019,376	43,930,134.3	1.30	2.95	51.14	119.33
18 to 44 Years	752	2,165	2,601	2,601	162.8	1	1	38,897,944	70,364,520.6	1.93	3.46	6.14	6.14
45 to 64 Years	1,386	4,520	5,518	5,518	342.5	9	22	25,226,498	57,812,945.2	5.49	3.98	26.27	64.23
65+ Years	831	2,809	3,414	3,414	214.4	7	12	7,844,187	21,302,282.6	10.59	4.11	32.66	55.98
Lyophilized product IV													
3 day episode extension													
0 to 17 Years	543	1,606	1,669	1,669	17.8	1	2	21,019,406	43,930,227.4	2.58	3.07	56.16	112.32
18 to 44 Years	1,333	4,549	5,430	5,430	52.7	3	3	38,898,064	70,364,508.5	3.43	4.07	56.91	56.91
45 to 64 Years	2,488	9,271	11,267	11,267	107.9	7	7	25,226,696	57,813,233.7	9.86	4.53	64.90	64.90
65+ Years	1,473	5,408	6,361	6,361	62.1	13	15	7,844,308	21,302,900.6	18.78	4.32	209.31	241.51
14 day episode extension													
0 to 17 Years	543	1,606	1,669	1,669	65.4	3	5	21,019,406	43,930,227.4	2.58	3.07	45.84	76.40
18 to 44 Years	1,333	4,549	5,430	5,430	187.0	5	5	38,898,064	70,364,508.5	3.43	4.07	26.74	26.74
45 to 64 Years	2,488	9,271	11,267	11,267	382.3	8	8	25,226,696	57,813,233.7	9.86	4.53	20.93	20.93
65+ Years	1,473	5,408	6,361	6,361	222.3	18	22	7,844,308	21,302,900.6	18.78	4.32	80.99	98.99
21 day episode extension													
0 to 17 Years	543	1,606	1,669	1,669	94.8	3	5	21,019,406	43,930,227.4	2.58	3.07	31.65	52.75
18 to 44 Years	1,333	4,549	5,430	5,430	269.7	5	5	38,898,064	70,364,508.5	3.43	4.07	18.54	18.54
45 to 64 Years	2,488	9,271	11,267	11,267	552.4	9	12	25,226,696	57,813,233.7	9.86	4.53	16.29	21.72
65+ Years	1,473	5,408	6,361	6,361	321.8	19	24	7,844,308	21,302,900.6	18.78	4.32	59.05	74.59
28 day episode extension													
0 to 17 Years	543	1,606	1,669	1,669	119.8	4	6	21,019,406	43,930,227.4	2.58	3.07	33.40	50.09
18 to 44 Years	1,333	4,549	5,430	5,430	342.6	6	6	38,898,064	70,364,508.5	3.43	4.07	17.51	17.51
45 to 64 Years	2,488	9,271	11,267	11,267	704.3	9	13	25,226,696	57,813,233.7	9.86	4.53	12.78	18.46
65+ Years	1,473	5,408	6,361	6,361	412.8	22	29	7,844,308	21,302,900.6	18.78	4.32	53.29	70.25
Non-lyophilized intramuscular route													
3 day episode extension													
0 to 17 Years	1,343	1,527	1,531	1,531	16.7	0	0	21,019,905	43,933,557.2	6.39	1.14	0.00	0.00
18 to 44 Years	2,395	3,066	3,083	3,083	33.7	1	1	38,898,362	70,370,241.7	6.16	1.29	29.71	29.71
45 to 64 Years	2,752	4,299	4,325	4,325	47.2	0	0	25,226,959	57,820,908.5	10.91	1.57	0.00	0.00
65+ Years	737	1,284	1,316	1,316	14.2	0	0	7,844,490	21,304,932.5	9.40	1.79	0.00	0.00

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
14 day episode extension													
0 to 17 Years	1,343	1,527	1,531	1,531	62.5	1	1	21,019,905	43,933,557.2	6.39	1.14	16.00	16.00
18 to 44 Years	2,395	3,066	3,083	3,083	124.8	1	1	38,898,362	70,370,241.7	6.16	1.29	8.01	8.01
45 to 64 Years	2,752	4,299	4,325	4,325	174.3	0	0	25,226,959	57,820,908.5	10.91	1.57	0.00	0.00
65+ Years	737	1,284	1,316	1,316	52.5	0	0	7,844,490	21,304,932.5	9.40	1.79	0.00	0.00
21 day episode extension													
0 to 17 Years	1,343	1,527	1,531	1,531	91.3	1	1	21,019,905	43,933,557.2	6.39	1.14	10.95	10.95
18 to 44 Years	2,395	3,066	3,083	3,083	181.6	1	1	38,898,362	70,370,241.7	6.16	1.29	5.51	5.51
45 to 64 Years	2,752	4,299	4,325	4,325	252.6	0	0	25,226,959	57,820,908.5	10.91	1.57	0.00	0.00
65+ Years	737	1,284	1,316	1,316	76.4	0	0	7,844,490	21,304,932.5	9.40	1.79	0.00	0.00
28 day episode extension													
0 to 17 Years	1,343	1,527	1,531	1,531	119.6	1	1	21,019,905	43,933,557.2	6.39	1.14	8.36	8.36
18 to 44 Years	2,395	3,066	3,083	3,083	236.5	1	1	38,898,362	70,370,241.7	6.16	1.29	4.23	4.23
45 to 64 Years	2,752	4,299	4,325	4,325	327.1	0	0	25,226,959	57,820,908.5	10.91	1.57	0.00	0.00
65+ Years	737	1,284	1,316	1,316	99.4	0	0	7,844,490	21,304,932.5	9.40	1.79	0.00	0.00
Non-lyophilized unspecified route													
3 day episode extension													
0 to 17 Years	3,519	4,794	4,857	4,857	52.4	43	46	21,020,041	43,936,542.2	16.74	1.38	820.49	877.73
18 to 44 Years	2,951	3,672	3,738	3,738	40.1	42	55	38,898,570	70,369,154.1	7.59	1.27	1047.06	1371.15
45 to 64 Years	3,055	4,026	4,112	4,112	44.0	52	58	25,226,880	57,817,483.2	12.11	1.35	1182.41	1318.84
65+ Years	1,918	2,517	2,533	2,533	27.3	44	50	7,844,451	21,305,711.5	24.45	1.32	1612.91	1832.85
14 day episode extension													
0 to 17 Years	3,519	4,794	4,857	4,857	194.0	48	79	21,020,041	43,936,542.2	16.74	1.38	247.44	407.25
18 to 44 Years	2,951	3,672	3,738	3,738	148.2	46	78	38,898,570	70,369,154.1	7.59	1.27	310.37	526.28
45 to 64 Years	3,055	4,026	4,112	4,112	162.2	58	102	25,226,880	57,817,483.2	12.11	1.35	357.59	628.87
65+ Years	1,918	2,517	2,533	2,533	101.3	48	72	7,844,451	21,305,711.5	24.45	1.32	473.61	710.41
21 day episode extension													
0 to 17 Years	3,519	4,794	4,857	4,857	281.9	51	101	21,020,041	43,936,542.2	16.74	1.38	180.93	358.30
18 to 44 Years	2,951	3,672	3,738	3,738	215.5	50	94	38,898,570	70,369,154.1	7.59	1.27	231.97	436.10
45 to 64 Years	3,055	4,026	4,112	4,112	235.5	62	125	25,226,880	57,817,483.2	12.11	1.35	263.31	530.87
65+ Years	1,918	2,517	2,533	2,533	147.0	50	86	7,844,451	21,305,711.5	24.45	1.32	340.03	584.85

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
28 day episode extension													
0 to 17 Years	3,519	4,794	4,857	4,857	367.8	54	117	21,020,041	43,936,542.2	16.74	1.38	146.83	318.14
18 to 44 Years	2,951	3,672	3,738	3,738	281.9	51	101	38,898,570	70,369,154.1	7.59	1.27	180.89	358.23
45 to 64 Years	3,055	4,026	4,112	4,112	306.8	65	145	25,226,880	57,817,483.2	12.11	1.35	211.85	472.59
65+ Years	1,918	2,517	2,533	2,533	190.8	52	105	7,844,451	21,305,711.5	24.45	1.32	272.48	550.19
Other IVIg, brand not specified													
3 day episode extension													
0 to 17 Years	441	1,073	1,110	1,110	11.9	1	1	21,019,404	43,930,302.1	2.10	2.52	84.16	84.16
18 to 44 Years	870	1,970	2,289	2,289	22.7	2	2	38,898,031	70,365,108.1	2.24	2.63	88.13	88.13
45 to 64 Years	1,387	3,486	4,227	4,227	40.6	2	4	25,226,600	57,813,690.4	5.50	3.05	49.27	98.55
65+ Years	624	1,459	1,724	1,724	16.9	0	0	7,844,233	21,302,774.9	7.95	2.76	0.00	0.00
14 day episode extension													
0 to 17 Years	441	1,073	1,110	1,110	43.8	1	1	21,019,404	43,930,302.1	2.10	2.52	22.83	22.83
18 to 44 Years	870	1,970	2,289	2,289	80.2	3	4	38,898,031	70,365,108.1	2.24	2.63	37.39	49.86
45 to 64 Years	1,387	3,486	4,227	4,227	142.3	4	9	25,226,600	57,813,690.4	5.50	3.05	28.11	63.25
65+ Years	624	1,459	1,724	1,724	59.8	2	2	7,844,233	21,302,774.9	7.95	2.76	33.45	33.45
21 day episode extension													
0 to 17 Years	441	1,073	1,110	1,110	63.2	1	1	21,019,404	43,930,302.1	2.10	2.52	15.82	15.82
18 to 44 Years	870	1,970	2,289	2,289	115.3	3	5	38,898,031	70,365,108.1	2.24	2.63	26.01	43.35
45 to 64 Years	1,387	3,486	4,227	4,227	204.4	4	10	25,226,600	57,813,690.4	5.50	3.05	19.57	48.92
65+ Years	624	1,459	1,724	1,724	86.3	3	4	7,844,233	21,302,774.9	7.95	2.76	34.78	46.38
28 day episode extension													
0 to 17 Years	441	1,073	1,110	1,110	79.7	1	1	21,019,404	43,930,302.1	2.10	2.52	12.55	12.55
18 to 44 Years	870	1,970	2,289	2,289	146.1	3	5	38,898,031	70,365,108.1	2.24	2.63	20.54	34.23
45 to 64 Years	1,387	3,486	4,227	4,227	260.2	4	10	25,226,600	57,813,690.4	5.50	3.05	15.37	38.43
65+ Years	624	1,459	1,724	1,724	110.5	6	7	7,844,233	21,302,774.9	7.95	2.76	54.28	63.33

Table 3. Summary of Incident Ig Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Ig Product, Episode Extension Period, and Sex

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
Flebogamma													
3 day episode extension													
Female	1,016	3,327	4,047	4,047	38.6	6	7	43,823,368	99,621,691.9	2.32	3.98	155.47	181.38
Male	992	3,198	4,057	4,057	37.7	3	4	42,267,472	93,755,168.0	2.35	4.09	79.68	106.24
Unknown	0	0	0	0	0.0	0	0	19,668	33,464.4	0.00	---	---	---
14 day episode extension													
Female	1,016	3,327	4,047	4,047	137.1	8	9	43,823,368	99,621,691.9	2.32	3.98	58.34	65.63
Male	992	3,198	4,057	4,057	132.3	6	7	42,267,472	93,755,168.0	2.35	4.09	45.34	52.90
Unknown	0	0	0	0	0.0	0	0	19,668	33,464.4	0.00	---	---	---
21 day episode extension													
Female	1,016	3,327	4,047	4,047	198.3	10	11	43,823,368	99,621,691.9	2.32	3.98	50.43	55.47
Male	992	3,198	4,057	4,057	191.3	6	7	42,267,472	93,755,168.0	2.35	4.09	31.36	36.59
Unknown	0	0	0	0	0.0	0	0	19,668	33,464.4	0.00	---	---	---
28 day episode extension													
Female	1,016	3,327	4,047	4,047	253.4	12	14	43,823,368	99,621,691.9	2.32	3.98	47.35	55.24
Male	992	3,198	4,057	4,057	245.3	9	10	42,267,472	93,755,168.0	2.35	4.09	36.69	40.77
Unknown	0	0	0	0	0.0	0	0	19,668	33,464.4	0.00	---	---	---
Gammagard Liquid													
3 day episode extension													
Female	5,142	20,171	23,130	23,130	231.1	14	16	43,823,852	99,621,746.6	11.73	4.50	60.59	69.24
Male	4,094	15,268	17,749	17,749	175.3	13	18	42,267,806	93,755,238.2	9.69	4.34	74.15	102.67
Unknown	1	12	12	12	0.1	0	0	19,668	33,463.4	5.08	12.00	0.00	0.00
14 day episode extension													
Female	5,142	20,171	23,130	23,130	827.1	19	24	43,823,852	99,621,746.6	11.73	4.50	22.97	29.02
Male	4,094	15,268	17,749	17,749	626.0	19	29	42,267,806	93,755,238.2	9.69	4.34	30.35	46.32
Unknown	1	12	12	12	0.5	0	0	19,668	33,463.4	5.08	12.00	0.00	0.00
21 day episode extension													
Female	5,142	20,171	23,130	23,130	1,195.6	22	36	43,823,852	99,621,746.6	11.73	4.50	18.40	30.11
Male	4,094	15,268	17,749	17,749	904.4	24	45	42,267,806	93,755,238.2	9.69	4.34	26.54	49.76
Unknown	1	12	12	12	0.7	0	0	19,668	33,463.4	5.08	12.00	0.00	0.00

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
28 day episode extension													
Female	5,142	20,171	23,130	23,130	1,521.4	25	44	43,823,852	99,621,746.6	11.73	4.50	16.43	28.92
Male	4,094	15,268	17,749	17,749	1,152.2	29	57	42,267,806	93,755,238.2	9.69	4.34	25.17	49.47
Unknown	1	12	12	12	1.0	0	0	19,668	33,463.4	5.08	12.00	0.00	0.00
Gammaplex													
3 day episode extension													
Female	36	82	106	106	1.0	0	0	43,823,281	99,621,592.8	0.08	2.94	0.00	0.00
Male	15	40	52	52	0.5	0	0	42,267,403	93,755,003.8	0.04	3.47	0.00	0.00
Unknown	0	0	0	0	0.0	0	0	19,668	33,464.4	0.00	---	---	---
14 day episode extension													
Female	36	82	106	106	3.4	0	0	43,823,281	99,621,592.8	0.08	2.94	0.00	0.00
Male	15	40	52	52	1.7	0	0	42,267,403	93,755,003.8	0.04	3.47	0.00	0.00
Unknown	0	0	0	0	0.0	0	0	19,668	33,464.4	0.00	---	---	---
21 day episode extension													
Female	36	82	106	106	4.9	0	0	43,823,281	99,621,592.8	0.08	2.94	0.00	0.00
Male	15	40	52	52	2.4	0	0	42,267,403	93,755,003.8	0.04	3.47	0.00	0.00
Unknown	0	0	0	0	0.0	0	0	19,668	33,464.4	0.00	---	---	---
28 day episode extension													
Female	36	82	106	106	6.3	0	0	43,823,281	99,621,592.8	0.08	2.94	0.00	0.00
Male	15	40	52	52	3.1	0	0	42,267,403	93,755,003.8	0.04	3.47	0.00	0.00
Unknown	0	0	0	0	0.0	0	0	19,668	33,464.4	0.00	---	---	---
Gamunex													
3 day episode extension													
Female	3,477	14,010	16,339	16,339	161.1	6	6	43,823,651	99,621,315.9	7.93	4.70	37.25	37.25
Male	3,175	11,607	13,609	13,609	133.5	6	6	42,267,703	93,754,996.0	7.51	4.29	44.96	44.96
Unknown	3	34	35	35	0.4	0	0	19,669	33,461.0	15.25	11.67	0.00	0.00
14 day episode extension													
Female	3,477	14,010	16,339	16,339	574.4	9	9	43,823,651	99,621,315.9	7.93	4.70	15.67	15.67
Male	3,175	11,607	13,609	13,609	476.5	12	19	42,267,703	93,754,996.0	7.51	4.29	25.18	39.87
Unknown	3	34	35	35	1.4	0	0	19,669	33,461.0	15.25	11.67	0.00	0.00

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
21 day episode extension													
Female	3,477	14,010	16,339	16,339	828.5	13	14	43,823,651	99,621,315.9	7.93	4.70	15.69	16.90
Male	3,175	11,607	13,609	13,609	687.4	19	32	42,267,703	93,754,996.0	7.51	4.29	27.64	46.55
Unknown	3	34	35	35	2.1	0	0	19,669	33,461.0	15.25	11.67	0.00	0.00
28 day episode extension													
Female	3,477	14,010	16,339	16,339	1,053.6	15	18	43,823,651	99,621,315.9	7.93	4.70	14.24	17.08
Male	3,175	11,607	13,609	13,609	873.0	21	44	42,267,703	93,754,996.0	7.51	4.29	24.06	50.40
Unknown	3	34	35	35	2.7	0	0	19,669	33,461.0	15.25	11.67	0.00	0.00
Octagam													
3 day episode extension													
Female	1,234	4,349	5,034	5,034	50.1	5	11	43,823,477	99,621,768.1	2.82	4.08	99.78	219.53
Male	899	2,834	3,260	3,260	32.5	4	6	42,267,521	93,755,180.1	2.13	3.63	122.98	184.47
Unknown	0	0	0	0	0.0	0	0	19,668	33,464.4	0.00	---	---	---
14 day episode extension													
Female	1,234	4,349	5,034	5,034	178.9	5	22	43,823,477	99,621,768.1	2.82	4.08	27.95	122.97
Male	899	2,834	3,260	3,260	116.4	8	10	42,267,521	93,755,180.1	2.13	3.63	68.72	85.90
Unknown	0	0	0	0	0.0	0	0	19,668	33,464.4	0.00	---	---	---
21 day episode extension													
Female	1,234	4,349	5,034	5,034	258.9	7	30	43,823,477	99,621,768.1	2.82	4.08	27.04	115.90
Male	899	2,834	3,260	3,260	168.6	8	11	42,267,521	93,755,180.1	2.13	3.63	47.45	65.24
Unknown	0	0	0	0	0.0	0	0	19,668	33,464.4	0.00	---	---	---
28 day episode extension													
Female	1,234	4,349	5,034	5,034	330.5	7	35	43,823,477	99,621,768.1	2.82	4.08	21.18	105.90
Male	899	2,834	3,260	3,260	216.0	8	11	42,267,521	93,755,180.1	2.13	3.63	37.04	50.93
Unknown	0	0	0	0	0.0	0	0	19,668	33,464.4	0.00	---	---	---
Privigen													
3 day episode extension													
Female	1,762	5,667	6,637	6,637	65.1	5	9	43,823,436	99,621,532.5	4.02	3.77	76.75	138.14
Male	1,419	4,610	5,700	5,700	53.9	7	7	42,267,536	93,754,886.2	3.36	4.02	129.94	129.94
Unknown	1	2	2	2	0.0	0	0	19,668	33,463.9	5.08	2.00	0.00	0.00

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
14 day episode extension													
Female	1,762	5,667	6,637	6,637	232.9	8	14	43,823,436	99,621,532.5	4.02	3.77	34.35	60.11
Male	1,419	4,610	5,700	5,700	190.0	9	13	42,267,536	93,754,886.2	3.36	4.02	47.38	68.44
Unknown	1	2	2	2	0.1	0	0	19,668	33,463.9	5.08	2.00	0.00	0.00
21 day episode extension													
Female	1,762	5,667	6,637	6,637	336.7	8	18	43,823,436	99,621,532.5	4.02	3.77	23.76	53.46
Male	1,419	4,610	5,700	5,700	274.1	9	16	42,267,536	93,754,886.2	3.36	4.02	32.83	58.37
Unknown	1	2	2	2	0.1	0	0	19,668	33,463.9	5.08	2.00	0.00	0.00
28 day episode extension													
Female	1,762	5,667	6,637	6,637	428.2	8	21	43,823,436	99,621,532.5	4.02	3.77	18.68	49.04
Male	1,419	4,610	5,700	5,700	349.9	12	21	42,267,536	93,754,886.2	3.36	4.02	34.29	60.01
Unknown	1	2	2	2	0.2	0	0	19,668	33,463.9	5.08	2.00	0.00	0.00
Lyophilized product IV													
3 day episode extension													
Female	3,099	11,521	13,574	13,574	132.7	9	11	43,823,640	99,621,929.1	7.07	4.38	67.81	82.88
Male	2,589	9,270	11,110	11,110	107.3	15	16	42,267,682	93,755,479.9	6.13	4.29	139.79	149.11
Unknown	2	43	43	43	0.5	0	0	19,668	33,461.2	10.17	21.50	0.00	0.00
14 day episode extension													
Female	3,099	11,521	13,574	13,574	473.9	13	17	43,823,640	99,621,929.1	7.07	4.38	27.43	35.87
Male	2,589	9,270	11,110	11,110	381.3	21	23	42,267,682	93,755,479.9	6.13	4.29	55.08	60.33
Unknown	2	43	43	43	1.8	0	0	19,668	33,461.2	10.17	21.50	0.00	0.00
21 day episode extension													
Female	3,099	11,521	13,574	13,574	685.0	15	19	43,823,640	99,621,929.1	7.07	4.38	21.90	27.74
Male	2,589	9,270	11,110	11,110	551.0	21	27	42,267,682	93,755,479.9	6.13	4.29	38.11	49.00
Unknown	2	43	43	43	2.6	0	0	19,668	33,461.2	10.17	21.50	0.00	0.00
28 day episode extension													
Female	3,099	11,521	13,574	13,574	872.4	19	24	43,823,640	99,621,929.1	7.07	4.38	21.78	27.51
Male	2,589	9,270	11,110	11,110	703.7	22	30	42,267,682	93,755,479.9	6.13	4.29	31.26	42.63
Unknown	2	43	43	43	3.4	0	0	19,668	33,461.2	10.17	21.50	0.00	0.00

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
Non-lyophilized intramuscular route													
<i>3 day episode extension</i>													
Female	4,113	6,198	6,240	6,240	68.1	1	1	43,823,960	99,632,442.5	9.39	1.52	14.69	14.69
Male	3,065	3,978	4,015	4,015	43.8	0	0	42,267,921	93,763,732.6	7.25	1.31	0.00	0.00
Unknown	0	0	0	0	0.0	0	0	19,669	33,464.8	0.00	---	---	---
<i>14 day episode extension</i>													
Female	4,113	6,198	6,240	6,240	251.6	1	1	43,823,960	99,632,442.5	9.39	1.52	3.97	3.97
Male	3,065	3,978	4,015	4,015	162.5	1	1	42,267,921	93,763,732.6	7.25	1.31	6.16	6.16
Unknown	0	0	0	0	0.0	0	0	19,669	33,464.8	0.00	---	---	---
<i>21 day episode extension</i>													
Female	4,113	6,198	6,240	6,240	365.1	1	1	43,823,960	99,632,442.5	9.39	1.52	2.74	2.74
Male	3,065	3,978	4,015	4,015	236.8	1	1	42,267,921	93,763,732.6	7.25	1.31	4.22	4.22
Unknown	0	0	0	0	0.0	0	0	19,669	33,464.8	0.00	---	---	---
<i>28 day episode extension</i>													
Female	4,113	6,198	6,240	6,240	473.8	1	1	43,823,960	99,632,442.5	9.39	1.52	2.11	2.11
Male	3,065	3,978	4,015	4,015	308.7	1	1	42,267,921	93,763,732.6	7.25	1.31	3.24	3.24
Unknown	0	0	0	0	0.0	0	0	19,669	33,464.8	0.00	---	---	---
Non-lyophilized unspecified route													
<i>3 day episode extension</i>													
Female	6,090	8,024	8,139	8,139	87.5	105	123	43,824,142	99,631,577.3	13.90	1.34	1200.50	1406.30
Male	5,305	6,983	7,099	7,099	76.3	76	86	42,268,167	93,763,845.4	12.55	1.34	996.16	1127.23
Unknown	2	2	2	2	0.0	0	0	19,668	33,468.4	10.17	1.00	0.00	0.00
<i>14 day episode extension</i>													
Female	6,090	8,024	8,139	8,139	323.6	114	200	43,824,142	99,631,577.3	13.90	1.34	352.24	617.96
Male	5,305	6,983	7,099	7,099	282.0	86	131	42,268,167	93,763,845.4	12.55	1.34	304.94	464.50
Unknown	2	2	2	2	0.1	0	0	19,668	33,468.4	10.17	1.00	0.00	0.00
<i>21 day episode extension</i>													
Female	6,090	8,024	8,139	8,139	470.3	119	247	43,824,142	99,631,577.3	13.90	1.34	253.01	525.16
Male	5,305	6,983	7,099	7,099	409.5	94	159	42,268,167	93,763,845.4	12.55	1.34	229.54	388.26
Unknown	2	2	2	2	0.1	0	0	19,668	33,468.4	10.17	1.00	0.00	0.00

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
28 day episode extension													
Female	6,090	8,024	8,139	8,139	613.3	122	282	43,824,142	99,631,577.3	13.90	1.34	198.91	459.78
Male	5,305	6,983	7,099	7,099	533.9	100	186	42,268,167	93,763,845.4	12.55	1.34	187.29	348.37
Unknown	2	2	2	2	0.1	0	0	19,668	33,468.4	10.17	1.00	0.00	0.00
Other IVIg, brand not specified													
3 day episode extension													
Female	1,798	4,300	5,036	5,036	49.5	4	6	43,823,549	99,622,667.2	4.10	2.80	80.73	121.09
Male	1,480	3,674	4,300	4,300	42.3	1	1	42,267,604	93,755,746.5	3.50	2.91	23.63	23.63
Unknown	1	14	14	14	0.2	0	0	19,668	33,461.9	5.08	14.00	0.00	0.00
14 day episode extension													
Female	1,798	4,300	5,036	5,036	175.2	8	14	43,823,549	99,622,667.2	4.10	2.80	45.67	79.93
Male	1,480	3,674	4,300	4,300	150.4	2	2	42,267,604	93,755,746.5	3.50	2.91	13.30	13.30
Unknown	1	14	14	14	0.6	0	0	19,668	33,461.9	5.08	14.00	0.00	0.00
21 day episode extension													
Female	1,798	4,300	5,036	5,036	251.9	8	16	43,823,549	99,622,667.2	4.10	2.80	31.76	63.52
Male	1,480	3,674	4,300	4,300	216.5	3	4	42,267,604	93,755,746.5	3.50	2.91	13.86	18.47
Unknown	1	14	14	14	0.8	0	0	19,668	33,461.9	5.08	14.00	0.00	0.00
28 day episode extension													
Female	1,798	4,300	5,036	5,036	320.0	10	18	43,823,549	99,622,667.2	4.10	2.80	31.25	56.25
Male	1,480	3,674	4,300	4,300	275.4	4	5	42,267,604	93,755,746.5	3.50	2.91	14.53	18.16
Unknown	1	14	14	14	1.1	0	0	19,668	33,461.9	5.08	14.00	0.00	0.00

Table 4. Summary of Incident Ig Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Ig Product, Episode Extension Period, and Year

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
Flebogamma													
<i>3 day episode extension</i>													
2006	0	0	0	0	0.0	0	0	19,584,410	11,873,771.3	0.00	---	---	---
2007	129	203	236	236	2.3	0	0	23,386,989	16,908,861.3	0.55	1.83	0.00	0.00
2008	391	857	1,002	1,002	9.8	3	4	44,518,108	27,769,435.4	0.88	2.56	305.82	407.76
2009	583	1,300	1,645	1,645	15.4	0	0	46,291,972	35,651,592.4	1.26	2.82	0.00	0.00
2010	613	1,357	1,712	1,712	15.9	0	0	44,552,880	34,499,862.8	1.38	2.79	0.00	0.00
2011	666	1,536	1,915	1,915	18.0	4	5	43,444,832	33,990,748.1	1.53	2.88	222.78	278.48
2012	571	1,272	1,594	1,594	14.9	2	2	42,322,815	32,716,053.0	1.35	2.79	134.46	134.46
<i>14 day episode extension</i>													
2006	0	0	0	0	0.0	0	0	19,584,410	11,873,771.3	0.00	---	---	---
2007	129	203	236	236	8.4	0	0	23,386,989	16,908,861.3	0.55	1.83	0.00	0.00
2008	391	857	1,002	1,002	35.2	3	4	44,518,108	27,769,435.4	0.88	2.56	85.13	113.50
2009	583	1,300	1,645	1,645	53.8	3	3	46,291,972	35,651,592.4	1.26	2.82	55.77	55.77
2010	613	1,357	1,712	1,712	56.2	1	1	44,552,880	34,499,862.8	1.38	2.79	17.78	17.78
2011	666	1,536	1,915	1,915	63.4	5	6	43,444,832	33,990,748.1	1.53	2.88	78.88	94.65
2012	571	1,272	1,594	1,594	52.4	2	2	42,322,815	32,716,053.0	1.35	2.79	38.15	38.15
<i>21 day episode extension</i>													
2006	0	0	0	0	0.0	0	0	19,584,410	11,873,771.3	0.00	---	---	---
2007	129	203	236	236	12.1	0	0	23,386,989	16,908,861.3	0.55	1.83	0.00	0.00
2008	391	857	1,002	1,002	51.2	3	4	44,518,108	27,769,435.4	0.88	2.56	58.62	78.16
2009	583	1,300	1,645	1,645	77.7	3	3	46,291,972	35,651,592.4	1.26	2.82	38.62	38.62
2010	613	1,357	1,712	1,712	81.4	2	2	44,552,880	34,499,862.8	1.38	2.79	24.57	24.57
2011	666	1,536	1,915	1,915	91.6	6	7	43,444,832	33,990,748.1	1.53	2.88	65.50	76.41
2012	571	1,272	1,594	1,594	75.6	2	2	42,322,815	32,716,053.0	1.35	2.79	26.44	26.44

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
28 day episode extension													
2006	0	0	0	0	0.0	0	0	19,584,410	11,873,771.3	0.00	---	---	---
2007	129	203	236	236	15.5	0	0	23,386,989	16,908,861.3	0.55	1.83	0.00	0.00
2008	391	857	1,002	1,002	65.7	5	6	44,518,108	27,769,435.4	0.88	2.56	76.05	91.26
2009	583	1,300	1,645	1,645	99.4	4	4	46,291,972	35,651,592.4	1.26	2.82	40.24	40.24
2010	613	1,357	1,712	1,712	104.1	3	4	44,552,880	34,499,862.8	1.38	2.79	28.83	38.44
2011	666	1,536	1,915	1,915	117.2	7	8	43,444,832	33,990,748.1	1.53	2.88	59.75	68.28
2012	571	1,272	1,594	1,594	96.8	2	2	42,322,815	32,716,053.0	1.35	2.79	20.65	20.65
Gammagard Liquid													
3 day episode extension													
2006	6	16	38	38	0.2	0	0	19,584,382	11,873,752.1	0.03	6.33	0.00	0.00
2007	357	624	750	750	7.2	0	0	23,386,990	16,908,750.7	1.53	2.10	0.00	0.00
2008	2,138	4,670	5,448	5,448	54.0	2	3	44,518,481	27,769,149.9	4.80	2.55	37.05	55.57
2009	2,730	6,570	7,684	7,684	75.9	9	9	46,292,569	35,651,438.8	5.90	2.81	118.60	118.60
2010	2,838	7,004	7,979	7,979	79.9	7	10	44,553,678	34,499,870.4	6.37	2.81	87.60	125.15
2011	3,251	8,268	9,468	9,468	94.5	5	6	43,445,837	33,990,904.6	7.48	2.91	52.94	63.52
2012	3,202	8,299	9,524	9,524	94.8	4	6	42,324,215	32,716,581.6	7.57	2.97	42.19	63.29
14 day episode extension													
2006	6	16	38	38	0.7	0	0	19,584,382	11,873,752.1	0.03	6.33	0.00	0.00
2007	357	624	750	750	25.6	0	0	23,386,990	16,908,750.7	1.53	2.10	0.00	0.00
2008	2,138	4,670	5,448	5,448	191.7	3	6	44,518,481	27,769,149.9	4.80	2.55	15.65	31.30
2009	2,730	6,570	7,684	7,684	269.5	12	13	46,292,569	35,651,438.8	5.90	2.81	44.52	48.23
2010	2,838	7,004	7,979	7,979	287.1	10	16	44,553,678	34,499,870.4	6.37	2.81	34.83	55.72
2011	3,251	8,268	9,468	9,468	338.8	8	11	43,445,837	33,990,904.6	7.48	2.91	23.61	32.47
2012	3,202	8,299	9,524	9,524	340.1	5	7	42,324,215	32,716,581.6	7.57	2.97	14.70	20.58

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
21 day episode extension													
2006	6	16	38	38	1.0	0	0	19,584,382	11,873,752.1	0.03	6.33	0.00	0.00
2007	357	624	750	750	36.9	0	0	23,386,990	16,908,750.7	1.53	2.10	0.00	0.00
2008	2,138	4,670	5,448	5,448	276.9	3	10	44,518,481	27,769,149.9	4.80	2.55	10.84	36.12
2009	2,730	6,570	7,684	7,684	389.0	14	23	46,292,569	35,651,438.8	5.90	2.81	35.99	59.13
2010	2,838	7,004	7,979	7,979	415.3	11	18	44,553,678	34,499,870.4	6.37	2.81	26.49	43.35
2011	3,251	8,268	9,468	9,468	490.2	11	18	43,445,837	33,990,904.6	7.48	2.91	22.44	36.72
2012	3,202	8,299	9,524	9,524	491.5	7	12	42,324,215	32,716,581.6	7.57	2.97	14.24	24.41
28 day episode extension													
2006	6	16	38	38	1.3	0	0	19,584,382	11,873,752.1	0.03	6.33	0.00	0.00
2007	357	624	750	750	47.1	0	0	23,386,990	16,908,750.7	1.53	2.10	0.00	0.00
2008	2,138	4,670	5,448	5,448	352.1	3	10	44,518,481	27,769,149.9	4.80	2.55	8.52	28.40
2009	2,730	6,570	7,684	7,684	494.7	18	32	46,292,569	35,651,438.8	5.90	2.81	36.39	64.69
2010	2,838	7,004	7,979	7,979	528.9	13	20	44,553,678	34,499,870.4	6.37	2.81	24.58	37.82
2011	3,251	8,268	9,468	9,468	625.0	13	25	43,445,837	33,990,904.6	7.48	2.91	20.80	40.00
2012	3,202	8,299	9,524	9,524	625.6	7	14	42,324,215	32,716,581.6	7.57	2.97	11.19	22.38
Gammplex													
3 day episode extension													
2006	0	0	0	0	0.0	0	0	19,584,401	11,873,779.7	0.00	---	---	---
2007	0	0	0	0	0.0	0	0	23,386,959	16,908,894.6	0.00	---	---	---
2008	0	0	0	0	0.0	0	0	44,518,034	27,769,489.4	0.00	---	---	---
2009	0	0	0	0	0.0	0	0	46,291,823	35,651,601.7	0.00	---	---	---
2010	0	0	0	0	0.0	0	0	44,552,646	34,499,801.7	0.00	---	---	---
2011	5	5	5	5	0.1	0	0	43,444,539	33,990,653.3	0.01	1.00	0.00	0.00
2012	47	117	153	153	1.4	0	0	42,322,468	32,715,840.5	0.11	3.26	0.00	0.00
14 day episode extension													
2006	0	0	0	0	0.0	0	0	19,584,401	11,873,779.7	0.00	---	---	---
2007	0	0	0	0	0.0	0	0	23,386,959	16,908,894.6	0.00	---	---	---
2008	0	0	0	0	0.0	0	0	44,518,034	27,769,489.4	0.00	---	---	---
2009	0	0	0	0	0.0	0	0	46,291,823	35,651,601.7	0.00	---	---	---
2010	0	0	0	0	0.0	0	0	44,552,646	34,499,801.7	0.00	---	---	---
2011	5	5	5	5	0.2	0	0	43,444,539	33,990,653.3	0.01	1.00	0.00	0.00
2012	47	117	153	153	4.9	0	0	42,322,468	32,715,840.5	0.11	3.26	0.00	0.00

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
21 day episode extension													
2006	0	0	0	0	0.0	0	0	19,584,401	11,873,779.7	0.00	---	---	---
2007	0	0	0	0	0.0	0	0	23,386,959	16,908,894.6	0.00	---	---	---
2008	0	0	0	0	0.0	0	0	44,518,034	27,769,489.4	0.00	---	---	---
2009	0	0	0	0	0.0	0	0	46,291,823	35,651,601.7	0.00	---	---	---
2010	0	0	0	0	0.0	0	0	44,552,646	34,499,801.7	0.00	---	---	---
2011	5	5	5	5	0.3	0	0	43,444,539	33,990,653.3	0.01	1.00	0.00	0.00
2012	47	117	153	153	7.1	0	0	42,322,468	32,715,840.5	0.11	3.26	0.00	0.00
28 day episode extension													
2006	0	0	0	0	0.0	0	0	19,584,401	11,873,779.7	0.00	---	---	---
2007	0	0	0	0	0.0	0	0	23,386,959	16,908,894.6	0.00	---	---	---
2008	0	0	0	0	0.0	0	0	44,518,034	27,769,489.4	0.00	---	---	---
2009	0	0	0	0	0.0	0	0	46,291,823	35,651,601.7	0.00	---	---	---
2010	0	0	0	0	0.0	0	0	44,552,646	34,499,801.7	0.00	---	---	---
2011	5	5	5	5	0.4	0	0	43,444,539	33,990,653.3	0.01	1.00	0.00	0.00
2012	47	117	153	153	9.0	0	0	42,322,468	32,715,840.5	0.11	3.26	0.00	0.00
Gamunex													
3 day episode extension													
2006	1	1	1	1	0.0	0	0	19,584,371	11,873,736.9	0.01	1.00	0.00	0.00
2007	423	734	890	890	8.6	0	0	23,386,968	16,908,714.9	1.81	2.10	0.00	0.00
2008	1,641	3,771	4,341	4,341	43.1	3	3	44,518,280	27,769,131.9	3.69	2.65	69.53	69.53
2009	2,038	5,087	5,942	5,942	58.5	3	3	46,292,306	35,651,337.4	4.40	2.92	51.29	51.29
2010	2,137	5,194	6,079	6,079	59.7	2	2	44,553,334	34,499,771.2	4.80	2.84	33.48	33.48
2011	2,116	5,407	6,306	6,306	62.1	3	3	43,445,443	33,990,805.7	4.87	2.98	48.35	48.35
2012	2,181	5,457	6,424	6,424	62.9	1	1	42,323,566	32,716,274.9	5.15	2.95	15.91	15.91
14 day episode extension													
2006	1	1	1	1	0.0	0	0	19,584,371	11,873,736.9	0.01	1.00	0.00	0.00
2007	423	734	890	890	30.4	0	0	23,386,968	16,908,714.9	1.81	2.10	0.00	0.00
2008	1,641	3,771	4,341	4,341	154.7	5	6	44,518,280	27,769,131.9	3.69	2.65	32.31	38.77
2009	2,038	5,087	5,942	5,942	208.8	3	3	46,292,306	35,651,337.4	4.40	2.92	14.37	14.37
2010	2,137	5,194	6,079	6,079	213.1	5	5	44,553,334	34,499,771.2	4.80	2.84	23.47	23.47
2011	2,116	5,407	6,306	6,306	221.4	7	12	43,445,443	33,990,805.7	4.87	2.98	31.61	54.19
2012	2,181	5,457	6,424	6,424	223.8	1	2	42,323,566	32,716,274.9	5.15	2.95	4.47	8.94

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
21 day episode extension													
2006	1	1	1	1	0.1	0	0	19,584,371	11,873,736.9	0.01	1.00	0.00	0.00
2007	423	734	890	890	44.0	0	0	23,386,968	16,908,714.9	1.81	2.10	0.00	0.00
2008	1,641	3,771	4,341	4,341	223.5	7	10	44,518,280	27,769,131.9	3.69	2.65	31.32	44.74
2009	2,038	5,087	5,942	5,942	301.2	4	5	46,292,306	35,651,337.4	4.40	2.92	13.28	16.60
2010	2,137	5,194	6,079	6,079	307.5	5	5	44,553,334	34,499,771.2	4.80	2.84	16.26	16.26
2011	2,116	5,407	6,306	6,306	319.1	11	19	43,445,443	33,990,805.7	4.87	2.98	34.47	59.54
2012	2,181	5,457	6,424	6,424	322.6	5	7	42,323,566	32,716,274.9	5.15	2.95	15.50	21.70
28 day episode extension													
2006	1	1	1	1	0.1	0	0	19,584,371	11,873,736.9	0.01	1.00	0.00	0.00
2007	423	734	890	890	56.0	0	0	23,386,968	16,908,714.9	1.81	2.10	0.00	0.00
2008	1,641	3,771	4,341	4,341	284.0	7	12	44,518,280	27,769,131.9	3.69	2.65	24.65	42.26
2009	2,038	5,087	5,942	5,942	382.5	4	6	46,292,306	35,651,337.4	4.40	2.92	10.46	15.69
2010	2,137	5,194	6,079	6,079	391.2	7	8	44,553,334	34,499,771.2	4.80	2.84	17.89	20.45
2011	2,116	5,407	6,306	6,306	405.8	12	27	43,445,443	33,990,805.7	4.87	2.98	29.57	66.53
2012	2,181	5,457	6,424	6,424	409.7	6	9	42,323,566	32,716,274.9	5.15	2.95	14.65	21.97
Octagam													
3 day episode extension													
2006	0	0	0	0	0.0	0	0	19,584,415	11,873,790.5	0.00	---	---	---
2007	162	283	313	313	3.2	2	4	23,386,996	16,908,884.1	0.69	1.93	630.83	1261.66
2008	740	1,722	1,970	1,970	19.7	1	2	44,518,297	27,769,442.2	1.66	2.66	50.84	101.68
2009	840	2,391	2,798	2,798	27.9	3	8	46,292,199	35,651,640.2	1.81	3.33	107.71	287.23
2010	618	1,388	1,519	1,519	15.6	1	1	44,553,055	34,499,952.9	1.39	2.46	63.99	63.99
2011	68	135	147	147	1.5	0	0	43,444,788	33,990,825.6	0.16	2.16	0.00	0.00
2012	603	1,264	1,547	1,547	14.8	2	2	42,322,654	32,715,877.1	1.42	2.57	135.23	135.23
14 day episode extension													
2006	0	0	0	0	0.0	0	0	19,584,415	11,873,790.5	0.00	---	---	---
2007	162	283	313	313	11.5	2	4	23,386,996	16,908,884.1	0.69	1.93	173.56	347.11
2008	740	1,722	1,970	1,970	70.7	2	8	44,518,297	27,769,442.2	1.66	2.66	28.30	113.19
2009	840	2,391	2,798	2,798	98.5	5	10	46,292,199	35,651,640.2	1.81	3.33	50.76	101.52
2010	618	1,388	1,519	1,519	56.9	1	7	44,553,055	34,499,952.9	1.39	2.46	17.59	123.12
2011	68	135	147	147	5.5	0	0	43,444,788	33,990,825.6	0.16	2.16	0.00	0.00
2012	603	1,264	1,547	1,547	52.2	3	3	42,322,654	32,715,877.1	1.42	2.57	57.43	57.43

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
21 day episode extension													
2006	0	0	0	0	0.0	0	0	19,584,415	11,873,790.5	0.00	---	---	---
2007	162	283	313	313	16.8	3	5	23,386,996	16,908,884.1	0.69	1.93	178.72	297.87
2008	740	1,722	1,970	1,970	102.2	3	14	44,518,297	27,769,442.2	1.66	2.66	29.36	137.01
2009	840	2,391	2,798	2,798	142.5	5	11	46,292,199	35,651,640.2	1.81	3.33	35.09	77.20
2010	618	1,388	1,519	1,519	82.6	1	8	44,553,055	34,499,952.9	1.39	2.46	12.11	96.87
2011	68	135	147	147	8.0	0	0	43,444,788	33,990,825.6	0.16	2.16	0.00	0.00
2012	603	1,264	1,547	1,547	75.4	3	3	42,322,654	32,715,877.1	1.42	2.57	39.80	39.80
28 day episode extension													
2006	0	0	0	0	0.0	0	0	19,584,415	11,873,790.5	0.00	---	---	---
2007	162	283	313	313	21.5	3	5	23,386,996	16,908,884.1	0.69	1.93	139.25	232.08
2008	740	1,722	1,970	1,970	130.5	3	18	44,518,297	27,769,442.2	1.66	2.66	22.99	137.91
2009	840	2,391	2,798	2,798	182.2	5	12	46,292,199	35,651,640.2	1.81	3.33	27.45	65.87
2010	618	1,388	1,519	1,519	105.8	1	8	44,553,055	34,499,952.9	1.39	2.46	9.45	75.59
2011	68	135	147	147	10.3	0	0	43,444,788	33,990,825.6	0.16	2.16	0.00	0.00
2012	603	1,264	1,547	1,547	96.1	3	3	42,322,654	32,715,877.1	1.42	2.57	31.22	31.22
Privigen													
3 day episode extension													
2006	0	0	0	0	0.0	0	0	19,584,399	11,873,769.4	0.00	---	---	---
2007	1	1	1	1	0.0	0	0	23,386,948	16,908,873.5	0.00	1.00	0.00	0.00
2008	253	471	560	560	5.5	1	1	44,518,094	27,769,417.2	0.57	2.21	183.36	183.36
2009	531	1,189	1,428	1,428	13.8	0	0	46,291,926	35,651,504.6	1.15	2.69	0.00	0.00
2010	958	2,170	2,673	2,673	25.4	1	2	44,552,806	34,499,670.6	2.15	2.79	39.38	78.76
2011	1,285	2,984	3,587	3,587	34.6	5	5	43,444,860	33,990,610.5	2.96	2.79	144.64	144.64
2012	1,436	3,464	4,090	4,090	39.9	5	8	42,322,992	32,716,037.0	3.39	2.85	125.43	200.69
14 day episode extension													
2006	0	0	0	0	0.0	0	0	19,584,399	11,873,769.4	0.00	---	---	---
2007	1	1	1	1	0.0	0	0	23,386,948	16,908,873.5	0.00	1.00	0.00	0.00
2008	253	471	560	560	19.2	1	1	44,518,094	27,769,417.2	0.57	2.21	51.99	51.99
2009	531	1,189	1,428	1,428	48.8	0	0	46,291,926	35,651,504.6	1.15	2.69	0.00	0.00
2010	958	2,170	2,673	2,673	89.4	2	3	44,552,806	34,499,670.6	2.15	2.79	22.38	33.57
2011	1,285	2,984	3,587	3,587	122.8	7	12	43,444,860	33,990,610.5	2.96	2.79	57.00	97.72
2012	1,436	3,464	4,090	4,090	142.7	7	11	42,322,992	32,716,037.0	3.39	2.85	49.07	77.10

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
21 day episode extension													
2006	0	0	0	0	0.0	0	0	19,584,399	11,873,769.4	0.00	---	---	---
2007	1	1	1	1	0.1	0	0	23,386,948	16,908,873.5	0.00	1.00	0.00	0.00
2008	253	471	560	560	27.8	1	1	44,518,094	27,769,417.2	0.57	2.21	36.00	36.00
2009	531	1,189	1,428	1,428	70.5	0	0	46,291,926	35,651,504.6	1.15	2.69	0.00	0.00
2010	958	2,170	2,673	2,673	128.7	2	3	44,552,806	34,499,670.6	2.15	2.79	15.54	23.31
2011	1,285	2,984	3,587	3,587	177.5	7	17	43,444,860	33,990,610.5	2.96	2.79	39.45	95.80
2012	1,436	3,464	4,090	4,090	206.5	7	13	42,322,992	32,716,037.0	3.39	2.85	33.90	62.96
28 day episode extension													
2006	0	0	0	0	0.0	0	0	19,584,399	11,873,769.4	0.00	---	---	---
2007	1	1	1	1	0.1	0	0	23,386,948	16,908,873.5	0.00	1.00	0.00	0.00
2008	253	471	560	560	35.4	1	1	44,518,094	27,769,417.2	0.57	2.21	28.24	28.24
2009	531	1,189	1,428	1,428	89.2	1	1	46,291,926	35,651,504.6	1.15	2.69	11.21	11.21
2010	958	2,170	2,673	2,673	163.4	2	3	44,552,806	34,499,670.6	2.15	2.79	12.24	18.36
2011	1,285	2,984	3,587	3,587	226.4	8	22	43,444,860	33,990,610.5	2.96	2.79	35.34	97.18
2012	1,436	3,464	4,090	4,090	263.9	8	15	42,322,992	32,716,037.0	3.39	2.85	30.32	56.85
Lyophilized product IV													
3 day episode extension													
2006	1,022	1,983	2,399	2,399	23.1	1	1	19,584,618	11,873,629.6	5.22	2.35	43.33	43.33
2007	1,347	3,275	3,828	3,828	37.6	4	5	23,387,340	16,908,753.4	5.76	2.84	106.48	133.10
2008	1,969	4,448	5,191	5,191	51.2	5	6	44,518,763	27,769,462.6	4.42	2.64	97.65	117.18
2009	1,765	4,399	5,230	5,230	50.7	5	5	46,292,659	35,651,778.0	3.81	2.96	98.64	98.64
2010	1,153	2,722	3,265	3,265	31.5	6	6	44,553,474	34,500,121.8	2.59	2.83	190.61	190.61
2011	941	2,386	2,883	2,883	27.7	2	3	43,445,250	33,990,954.3	2.17	3.06	72.08	108.12
2012	697	1,621	1,931	1,931	18.7	1	1	42,323,145	32,716,170.5	1.65	2.77	53.41	53.41
14 day episode extension													
2006	1,022	1,983	2,399	2,399	81.6	3	3	19,584,618	11,873,629.6	5.22	2.35	36.77	36.77
2007	1,347	3,275	3,828	3,828	134.4	6	7	23,387,340	16,908,753.4	5.76	2.84	44.64	52.08
2008	1,969	4,448	5,191	5,191	182.5	6	7	44,518,763	27,769,462.6	4.42	2.64	32.88	38.36
2009	1,765	4,399	5,230	5,230	181.0	5	5	46,292,659	35,651,778.0	3.81	2.96	27.62	27.62
2010	1,153	2,722	3,265	3,265	112.1	8	10	44,553,474	34,500,121.8	2.59	2.83	71.34	89.17
2011	941	2,386	2,883	2,883	98.4	3	5	43,445,250	33,990,954.3	2.17	3.06	30.48	50.79
2012	697	1,621	1,931	1,931	66.9	3	3	42,323,145	32,716,170.5	1.65	2.77	44.87	44.87

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
21 day episode extension													
2006	1,022	1,983	2,399	2,399	117.6	3	3	19,584,618	11,873,629.6	5.22	2.35	25.52	25.52
2007	1,347	3,275	3,828	3,828	194.2	6	7	23,387,340	16,908,753.4	5.76	2.84	30.89	36.04
2008	1,969	4,448	5,191	5,191	263.7	7	8	44,518,763	27,769,462.6	4.42	2.64	26.55	30.34
2009	1,765	4,399	5,230	5,230	262.1	5	6	46,292,659	35,651,778.0	3.81	2.96	19.08	22.89
2010	1,153	2,722	3,265	3,265	162.1	8	13	44,553,474	34,500,121.8	2.59	2.83	49.36	80.21
2011	941	2,386	2,883	2,883	142.2	3	5	43,445,250	33,990,954.3	2.17	3.06	21.09	35.15
2012	697	1,621	1,931	1,931	96.7	4	4	42,323,145	32,716,170.5	1.65	2.77	41.36	41.36
28 day episode extension													
2006	1,022	1,983	2,399	2,399	149.3	4	4	19,584,618	11,873,629.6	5.22	2.35	26.79	26.79
2007	1,347	3,275	3,828	3,828	247.4	6	7	23,387,340	16,908,753.4	5.76	2.84	24.25	28.29
2008	1,969	4,448	5,191	5,191	337.0	7	9	44,518,763	27,769,462.6	4.42	2.64	20.77	26.71
2009	1,765	4,399	5,230	5,230	334.6	6	7	46,292,659	35,651,778.0	3.81	2.96	17.93	20.92
2010	1,153	2,722	3,265	3,265	206.2	9	16	44,553,474	34,500,121.8	2.59	2.83	43.65	77.60
2011	941	2,386	2,883	2,883	181.4	4	6	43,445,250	33,990,954.3	2.17	3.06	22.05	33.08
2012	697	1,621	1,931	1,931	123.6	5	5	42,323,145	32,716,170.5	1.65	2.77	40.46	40.46
Non-lyophilized intramuscular route													
3 day episode extension													
2006	1,214	1,475	1,479	1,479	16.2	0	0	19,584,663	11,874,183.3	6.20	1.22	0.00	0.00
2007	1,479	1,734	1,741	1,741	19.0	0	0	23,388,301	16,910,553.5	6.32	1.18	0.00	0.00
2008	1,440	1,851	1,857	1,857	20.3	0	0	44,520,703	27,772,071.4	3.23	1.29	0.00	0.00
2009	1,298	1,793	1,830	1,830	19.9	0	0	46,295,288	35,655,035.8	2.80	1.41	0.00	0.00
2010	1,195	1,586	1,599	1,599	17.4	0	0	44,556,497	34,503,566.3	2.68	1.34	0.00	0.00
2011	750	969	972	972	10.6	0	0	43,448,666	33,994,591.5	1.73	1.30	0.00	0.00
2012	569	768	777	777	8.4	1	1	42,326,510	32,719,638.0	1.34	1.37	118.59	118.59
14 day episode extension													
2006	1,214	1,475	1,479	1,479	60.3	0	0	19,584,663	11,874,183.3	6.20	1.22	0.00	0.00
2007	1,479	1,734	1,741	1,741	71.0	0	0	23,388,301	16,910,553.5	6.32	1.18	0.00	0.00
2008	1,440	1,851	1,857	1,857	75.1	1	1	44,520,703	27,772,071.4	3.23	1.29	13.31	13.31
2009	1,298	1,793	1,830	1,830	73.0	0	0	46,295,288	35,655,035.8	2.80	1.41	0.00	0.00
2010	1,195	1,586	1,599	1,599	64.3	0	0	44,556,497	34,503,566.3	2.68	1.34	0.00	0.00
2011	750	969	972	972	39.3	0	0	43,448,666	33,994,591.5	1.73	1.30	0.00	0.00
2012	569	768	777	777	31.1	1	1	42,326,510	32,719,638.0	1.34	1.37	32.19	32.19

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
21 day episode extension													
2006	1,214	1,475	1,479	1,479	88.2	0	0	19,584,663	11,874,183.3	6.20	1.22	0.00	0.00
2007	1,479	1,734	1,741	1,741	103.7	0	0	23,388,301	16,910,553.5	6.32	1.18	0.00	0.00
2008	1,440	1,851	1,857	1,857	109.2	1	1	44,520,703	27,772,071.4	3.23	1.29	9.15	9.15
2009	1,298	1,793	1,830	1,830	105.6	0	0	46,295,288	35,655,035.8	2.80	1.41	0.00	0.00
2010	1,195	1,586	1,599	1,599	93.2	0	0	44,556,497	34,503,566.3	2.68	1.34	0.00	0.00
2011	750	969	972	972	56.9	0	0	43,448,666	33,994,591.5	1.73	1.30	0.00	0.00
2012	569	768	777	777	45.0	1	1	42,326,510	32,719,638.0	1.34	1.37	22.22	22.22
28 day episode extension													
2006	1,214	1,475	1,479	1,479	115.5	0	0	19,584,663	11,874,183.3	6.20	1.22	0.00	0.00
2007	1,479	1,734	1,741	1,741	135.7	0	0	23,388,301	16,910,553.5	6.32	1.18	0.00	0.00
2008	1,440	1,851	1,857	1,857	142.2	1	1	44,520,703	27,772,071.4	3.23	1.29	7.03	7.03
2009	1,298	1,793	1,830	1,830	136.7	0	0	46,295,288	35,655,035.8	2.80	1.41	0.00	0.00
2010	1,195	1,586	1,599	1,599	120.7	0	0	44,556,497	34,503,566.3	2.68	1.34	0.00	0.00
2011	750	969	972	972	73.5	0	0	43,448,666	33,994,591.5	1.73	1.30	0.00	0.00
2012	569	768	777	777	58.2	1	1	42,326,510	32,719,638.0	1.34	1.37	17.18	17.18
Non-lyophilized unspecified route													
3 day episode extension													
2006	666	947	963	963	10.4	7	7	19,584,592	11,873,909.2	3.40	1.45	673.54	673.54
2007	904	1,217	1,236	1,236	13.3	15	17	23,387,642	16,909,527.5	3.87	1.37	1128.48	1278.94
2008	1,876	2,323	2,356	2,356	25.2	38	46	44,519,724	27,771,010.2	4.21	1.26	1505.21	1822.09
2009	2,308	2,894	2,955	2,955	31.7	22	25	46,294,562	35,654,376.3	4.99	1.28	693.61	788.20
2010	2,304	2,723	2,757	2,757	29.7	29	37	44,556,429	34,503,581.5	5.17	1.20	975.52	1244.64
2011	2,357	2,781	2,825	2,825	30.4	24	28	43,449,234	33,995,330.8	5.42	1.20	789.16	920.69
2012	1,996	2,124	2,148	2,148	23.0	46	49	42,327,934	32,721,155.6	4.72	1.08	2000.89	2131.39
14 day episode extension													
2006	666	947	963	963	38.3	7	9	19,584,592	11,873,909.2	3.40	1.45	182.53	234.69
2007	904	1,217	1,236	1,236	49.2	15	19	23,387,642	16,909,527.5	3.87	1.37	304.98	386.31
2008	1,876	2,323	2,356	2,356	93.5	38	68	44,519,724	27,771,010.2	4.21	1.26	406.63	727.65
2009	2,308	2,894	2,955	2,955	117.4	25	42	46,294,562	35,654,376.3	4.99	1.28	212.98	357.81
2010	2,304	2,723	2,757	2,757	109.8	33	64	44,556,429	34,503,581.5	5.17	1.20	300.46	582.71
2011	2,357	2,781	2,825	2,825	112.7	27	52	43,449,234	33,995,330.8	5.42	1.20	239.65	461.54
2012	1,996	2,124	2,148	2,148	84.9	55	77	42,327,934	32,721,155.6	4.72	1.08	647.96	907.15

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
21 day episode extension													
2006	666	947	963	963	55.8	7	9	19,584,592	11,873,909.2	3.40	1.45	125.53	161.39
2007	904	1,217	1,236	1,236	71.6	15	25	23,387,642	16,909,527.5	3.87	1.37	209.57	349.28
2008	1,876	2,323	2,356	2,356	135.2	38	78	44,519,724	27,771,010.2	4.21	1.26	281.13	577.05
2009	2,308	2,894	2,955	2,955	170.7	26	53	46,294,562	35,654,376.3	4.99	1.28	152.34	310.53
2010	2,304	2,723	2,757	2,757	159.6	35	79	44,556,429	34,503,581.5	5.17	1.20	219.29	494.96
2011	2,357	2,781	2,825	2,825	163.6	33	70	43,449,234	33,995,330.8	5.42	1.20	201.71	427.87
2012	1,996	2,124	2,148	2,148	123.5	59	92	42,327,934	32,721,155.6	4.72	1.08	477.56	744.66
28 day episode extension													
2006	666	947	963	963	72.7	7	9	19,584,592	11,873,909.2	3.40	1.45	96.30	123.81
2007	904	1,217	1,236	1,236	93.6	15	29	23,387,642	16,909,527.5	3.87	1.37	160.28	309.88
2008	1,876	2,323	2,356	2,356	175.2	39	84	44,519,724	27,771,010.2	4.21	1.26	222.63	479.50
2009	2,308	2,894	2,955	2,955	222.7	28	60	46,294,562	35,654,376.3	4.99	1.28	125.74	269.45
2010	2,304	2,723	2,757	2,757	208.1	38	93	44,556,429	34,503,581.5	5.17	1.20	182.61	446.91
2011	2,357	2,781	2,825	2,825	213.4	36	85	43,449,234	33,995,330.8	5.42	1.20	168.70	398.33
2012	1,996	2,124	2,148	2,148	161.7	59	108	42,327,934	32,721,155.6	4.72	1.08	364.79	667.74
Other IVIg, brand not specified													
3 day episode extension													
2006	1,630	3,203	3,776	3,776	37.0	3	4	19,584,758	11,873,614.3	8.32	2.32	81.09	108.12
2007	1,788	3,734	4,334	4,334	42.9	2	3	23,387,678	16,908,964.6	7.65	2.42	46.65	69.97
2008	173	252	259	259	2.8	0	0	44,518,625	27,769,926.6	0.39	1.50	0.00	0.00
2009	170	248	291	291	2.9	0	0	46,292,307	35,652,038.9	0.37	1.71	0.00	0.00
2010	100	145	174	174	1.7	0	0	44,553,108	34,500,198.8	0.22	1.74	0.00	0.00
2011	187	281	367	367	3.4	0	0	43,444,933	33,990,988.6	0.43	1.96	0.00	0.00
2012	93	125	149	149	1.4	0	0	42,322,834	32,716,143.7	0.22	1.60	0.00	0.00

Table 5. Summary of Incident Ig Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Ig Product, Episode Extension

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
Flebogamma										
<i>3 day episode extension</i>										
0	447	1,379	1,905	1,905	16.7	3	5	4.26	180.18	300.30
1	283	842	1,058	1,058	9.9	0	0	3.74	0.00	0.00
2	473	1,168	1,375	1,375	13.4	5	5	2.91	373.41	373.41
3-4	540	1,478	1,722	1,722	16.9	0	0	3.19	0.00	0.00
5-6	226	547	634	634	6.3	0	0	2.81	0.00	0.00
7+	168	356	474	474	4.3	1	1	2.82	235.29	235.29
unable to classify	452	755	936	936	8.9	0	0	2.07	0.00	0.00
<i>14 day episode extension</i>										
0	447	1,379	1,905	1,905	57.4	4	6	4.26	69.75	104.62
1	283	842	1,058	1,058	34.9	0	0	3.74	0.00	0.00
2	473	1,168	1,375	1,375	47.7	6	6	2.91	125.81	125.81
3-4	540	1,478	1,722	1,722	60.8	2	2	3.19	32.88	32.88
5-6	226	547	634	634	22.6	1	1	2.81	44.25	44.25
7+	168	356	474	474	14.8	1	1	2.82	67.57	67.57
unable to classify	452	755	936	936	31.3	0	0	2.07	0.00	0.00
<i>21 day episode extension</i>										
0	447	1,379	1,905	1,905	82.7	4	6	4.26	48.37	72.55
1	283	842	1,058	1,058	50.5	0	0	3.74	0.00	0.00
2	473	1,168	1,375	1,375	69.0	7	7	2.91	101.41	101.41
3-4	540	1,478	1,722	1,722	88.2	2	2	3.19	22.69	22.69
5-6	226	547	634	634	32.8	2	2	2.81	60.92	60.92
7+	168	356	474	474	21.3	1	1	2.82	46.86	46.86
unable to classify	452	755	936	936	45.1	0	0	2.07	0.00	0.00
<i>28 day episode extension</i>										
0	447	1,379	1,905	1,905	105.3	4	6	4.26	37.99	56.99
1	283	842	1,058	1,058	64.3	0	0	3.74	0.00	0.00
2	473	1,168	1,375	1,375	88.7	8	9	2.91	90.16	101.43
3-4	540	1,478	1,722	1,722	113.4	4	4	3.19	35.27	35.27
5-6	226	547	634	634	42.2	2	2	2.81	47.37	47.37
7+	168	356	474	474	27.2	1	1	2.82	36.71	36.71
unable to classify	452	755	936	936	57.5	2	2	2.07	34.78	34.78
Gammagard Liquid										
<i>3 day episode extension</i>										
0	2,673	9,339	11,148	11,148	108.3	5	6	4.17	46.19	55.43
1	2,163	7,212	8,274	8,274	82.4	5	5	3.83	60.68	60.68
2	1,916	5,632	6,311	6,311	64.0	2	3	3.29	31.24	46.85
3-4	1,931	5,383	6,018	6,018	61.1	4	5	3.12	65.51	81.89
5-6	812	1,966	2,190	2,190	22.3	6	6	2.70	269.42	269.42
7+	479	1,153	1,290	1,290	13.1	0	0	2.69	0.00	0.00
unable to classify	2,608	4,766	5,660	5,660	55.4	5	9	2.17	90.19	162.34

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
14 day episode extension										
0	2,673	9,339	11,148	11,148	383.4	5	6	4.17	13.04	15.65
1	2,163	7,212	8,274	8,274	295.9	5	6	3.83	16.90	20.28
2	1,916	5,632	6,311	6,311	230.8	3	4	3.29	13.00	17.33
3-4	1,931	5,383	6,018	6,018	220.7	8	11	3.12	36.26	49.85
5-6	812	1,966	2,190	2,190	80.3	8	8	2.70	99.69	99.69
7+	479	1,153	1,290	1,290	46.9	1	1	2.69	21.33	21.33
unable to classify	2,608	4,766	5,660	5,660	195.7	8	17	2.17	40.87	86.85
21 day episode extension										
0	2,673	9,339	11,148	11,148	552.6	6	9	4.17	10.86	16.29
1	2,163	7,212	8,274	8,274	427.5	6	14	3.83	14.04	32.75
2	1,916	5,632	6,311	6,311	334.3	5	6	3.29	14.96	17.95
3-4	1,931	5,383	6,018	6,018	319.8	11	20	3.12	34.39	62.54
5-6	812	1,966	2,190	2,190	116.2	8	8	2.70	68.86	68.86
7+	479	1,153	1,290	1,290	67.8	2	3	2.69	29.50	44.25
unable to classify	2,608	4,766	5,660	5,660	282.6	8	21	2.17	28.30	74.30
28 day episode extension										
0	2,673	9,339	11,148	11,148	703.2	6	9	4.17	8.53	12.80
1	2,163	7,212	8,274	8,274	541.0	8	22	3.83	14.79	40.67
2	1,916	5,632	6,311	6,311	427.5	5	6	3.29	11.69	14.03
3-4	1,931	5,383	6,018	6,018	408.3	16	31	3.12	39.19	75.92
5-6	812	1,966	2,190	2,190	148.3	9	9	2.70	60.69	60.69
7+	479	1,153	1,290	1,290	86.6	2	3	2.69	23.09	34.64
unable to classify	2,608	4,766	5,660	5,660	359.7	8	21	2.17	22.24	58.39
Gammaplex										
3 day episode extension										
0	23	48	73	73	0.6	0	0	3.17	0.00	0.00
1	8	18	21	21	0.2	0	0	2.63	0.00	0.00
2	9	17	21	21	0.2	0	0	2.33	0.00	0.00
3-4	7	23	23	23	0.3	0	0	3.29	0.00	0.00
5-6	4	4	5	5	0.1	0	0	1.25	0.00	0.00
7+	2	4	7	7	0.1	0	0	3.50	0.00	0.00
unable to classify	4	8	8	8	0.1	0	0	2.00	0.00	0.00
14 day episode extension										
0	23	48	73	73	2.1	0	0	3.17	0.00	0.00
1	8	18	21	21	0.7	0	0	2.63	0.00	0.00
2	9	17	21	21	0.7	0	0	2.33	0.00	0.00
3-4	7	23	23	23	0.9	0	0	3.29	0.00	0.00
5-6	4	4	5	5	0.2	0	0	1.25	0.00	0.00
7+	2	4	7	7	0.2	0	0	3.50	0.00	0.00
unable to classify	4	8	8	8	0.3	0	0	2.00	0.00	0.00

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
21 day episode extension										
0	23	48	73	73	3.0	0	0	3.17	0.00	0.00
1	8	18	21	21	1.0	0	0	2.63	0.00	0.00
2	9	17	21	21	1.0	0	0	2.33	0.00	0.00
3-4	7	23	23	23	1.4	0	0	3.29	0.00	0.00
5-6	4	4	5	5	0.2	0	0	1.25	0.00	0.00
7+	2	4	7	7	0.3	0	0	3.50	0.00	0.00
unable to classify	4	8	8	8	0.5	0	0	2.00	0.00	0.00
28 day episode extension										
0	23	48	73	73	3.8	0	0	3.17	0.00	0.00
1	8	18	21	21	1.3	0	0	2.63	0.00	0.00
2	9	17	21	21	1.3	0	0	2.33	0.00	0.00
3-4	7	23	23	23	1.8	0	0	3.29	0.00	0.00
5-6	4	4	5	5	0.3	0	0	1.25	0.00	0.00
7+	2	4	7	7	0.3	0	0	3.50	0.00	0.00
unable to classify	4	8	8	8	0.6	0	0	2.00	0.00	0.00
Gamunex										
3 day episode extension										
0	1,923	7,339	8,969	8,969	85.6	3	3	4.66	35.06	35.06
1	1,458	5,031	5,843	5,843	57.7	3	3	4.01	52.00	52.00
2	1,451	4,100	4,700	4,700	46.9	2	2	3.24	42.63	42.63
3-4	1,358	3,641	4,078	4,078	41.2	3	3	3.00	72.74	72.74
5-6	552	1,250	1,422	1,422	14.3	0	0	2.58	0.00	0.00
7+	365	893	1,016	1,016	10.2	0	0	2.78	0.00	0.00
unable to classify	1,912	3,397	3,955	3,955	39.0	1	1	2.07	25.61	25.61
14 day episode extension										
0	1,923	7,339	8,969	8,969	302.6	6	9	4.66	19.83	29.75
1	1,458	5,031	5,843	5,843	206.1	3	3	4.01	14.55	14.55
2	1,451	4,100	4,700	4,700	168.2	3	3	3.24	17.84	17.84
3-4	1,358	3,641	4,078	4,078	148.8	6	6	3.00	40.33	40.33
5-6	552	1,250	1,422	1,422	51.0	1	2	2.58	19.59	39.18
7+	365	893	1,016	1,016	36.5	0	0	2.78	0.00	0.00
unable to classify	1,912	3,397	3,955	3,955	139.1	2	5	2.07	14.38	35.94
21 day episode extension										
0	1,923	7,339	8,969	8,969	436.2	7	12	4.66	16.05	27.51
1	1,458	5,031	5,843	5,843	297.2	6	6	4.01	20.19	20.19
2	1,451	4,100	4,700	4,700	243.0	6	7	3.24	24.69	28.80
3-4	1,358	3,641	4,078	4,078	214.8	8	8	3.00	37.25	37.25
5-6	552	1,250	1,422	1,422	73.8	2	3	2.58	27.10	40.64
7+	365	893	1,016	1,016	52.7	0	0	2.78	0.00	0.00
unable to classify	1,912	3,397	3,955	3,955	200.3	3	10	2.07	14.98	49.93

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
28 day episode extension										
0	1,923	7,339	8,969	8,969	554.2	7	14	4.66	12.63	25.26
1	1,458	5,031	5,843	5,843	375.7	7	7	4.01	18.63	18.63
2	1,451	4,100	4,700	4,700	309.9	6	9	3.24	19.36	29.04
3-4	1,358	3,641	4,078	4,078	274.1	10	11	3.00	36.48	40.13
5-6	552	1,250	1,422	1,422	94.5	3	6	2.58	31.76	63.51
7+	365	893	1,016	1,016	67.4	0	0	2.78	0.00	0.00
unable to classify	1,912	3,397	3,955	3,955	253.5	3	15	2.07	11.83	59.16
Octagam										
3 day episode extension										
0	517	1,593	1,863	1,863	18.4	1	1	3.60	54.23	54.23
1	411	1,207	1,407	1,407	13.9	0	0	3.42	0.00	0.00
2	419	1,200	1,365	1,365	13.7	1	2	3.26	72.94	145.88
3-4	424	1,139	1,293	1,293	13.1	2	6	3.05	153.02	459.07
5-6	206	436	482	482	4.9	1	1	2.34	202.43	202.43
7+	161	341	376	376	3.9	1	1	2.34	259.07	259.07
unable to classify	683	1,267	1,508	1,508	14.8	3	6	2.21	203.11	406.23
14 day episode extension										
0	517	1,593	1,863	1,863	65.4	2	2	3.60	30.58	30.58
1	411	1,207	1,407	1,407	49.8	1	1	3.42	20.08	20.08
2	419	1,200	1,365	1,365	49.4	2	3	3.26	40.47	60.70
3-4	424	1,139	1,293	1,293	47.0	2	6	3.05	42.53	127.58
5-6	206	436	482	482	17.8	2	2	2.34	112.61	112.61
7+	161	341	376	376	13.8	1	1	2.34	72.57	72.57
unable to classify	683	1,267	1,508	1,508	52.1	3	17	2.21	57.55	326.11
21 day episode extension										
0	517	1,593	1,863	1,863	94.5	2	2	3.60	21.16	21.16
1	411	1,207	1,407	1,407	72.1	1	1	3.42	13.86	13.86
2	419	1,200	1,365	1,365	71.7	2	3	3.26	27.90	41.85
3-4	424	1,139	1,293	1,293	68.3	3	7	3.05	43.94	102.53
5-6	206	436	482	482	25.7	2	3	2.34	77.79	116.69
7+	161	341	376	376	19.9	1	1	2.34	50.30	50.30
unable to classify	683	1,267	1,508	1,508	75.3	4	24	2.21	53.16	318.94
28 day episode extension										
0	517	1,593	1,863	1,863	120.8	2	2	3.60	16.55	16.55
1	411	1,207	1,407	1,407	91.8	1	1	3.42	10.89	10.89
2	419	1,200	1,365	1,365	92.0	2	4	3.26	21.73	43.46
3-4	424	1,139	1,293	1,293	87.3	3	7	3.05	34.35	80.15
5-6	206	436	482	482	32.8	2	3	2.34	60.94	91.41
7+	161	341	376	376	25.5	1	1	2.34	39.25	39.25
unable to classify	683	1,267	1,508	1,508	96.2	4	28	2.21	41.60	291.21

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
Privigen										
<i>3 day episode extension</i>										
0	773	2,314	2,955	2,955	27.4	2	5	3.82	73.10	182.75
1	663	1,967	2,317	2,317	22.7	0	0	3.49	0.00	0.00
2	643	1,728	2,052	2,052	19.9	3	3	3.19	150.45	150.45
3-4	728	1,881	2,227	2,227	21.6	1	1	3.06	46.21	46.21
5-6	310	735	808	808	8.3	2	2	2.61	240.96	240.96
7+	207	455	536	536	5.3	0	0	2.59	0.00	0.00
unable to classify	698	1,199	1,444	1,444	13.9	4	5	2.07	288.60	360.75
<i>14 day episode extension</i>										
0	773	2,314	2,955	2,955	95.7	3	7	3.82	31.35	73.15
1	663	1,967	2,317	2,317	81.0	2	2	3.49	24.69	24.69
2	643	1,728	2,052	2,052	71.0	5	9	3.19	70.45	126.81
3-4	728	1,881	2,227	2,227	77.6	1	1	3.06	12.88	12.88
5-6	310	735	808	808	30.1	2	3	2.61	66.53	99.80
7+	207	455	536	536	18.6	0	0	2.59	0.00	0.00
unable to classify	698	1,199	1,444	1,444	49.0	4	5	2.07	81.60	102.00
<i>21 day episode extension</i>										
0	773	2,314	2,955	2,955	137.9	3	9	3.82	21.75	65.25
1	663	1,967	2,317	2,317	117.1	2	2	3.49	17.08	17.08
2	643	1,728	2,052	2,052	102.6	5	14	3.19	48.73	136.44
3-4	728	1,881	2,227	2,227	112.4	1	1	3.06	8.89	8.89
5-6	310	735	808	808	43.6	2	3	2.61	45.92	68.89
7+	207	455	536	536	26.7	0	0	2.59	0.00	0.00
unable to classify	698	1,199	1,444	1,444	70.7	4	5	2.07	56.60	70.75
<i>28 day episode extension</i>										
0	773	2,314	2,955	2,955	175.5	3	10	3.82	17.09	56.98
1	663	1,967	2,317	2,317	148.5	3	3	3.49	20.21	20.21
2	643	1,728	2,052	2,052	131.1	5	18	3.19	38.15	137.34
3-4	728	1,881	2,227	2,227	143.8	3	3	3.06	20.86	20.86
5-6	310	735	808	808	55.8	2	3	2.61	35.87	53.81
7+	207	455	536	536	33.9	0	0	2.59	0.00	0.00
unable to classify	698	1,199	1,444	1,444	89.8	4	5	2.07	44.56	55.70
Lyophilized product IV										
<i>3 day episode extension</i>										
0	1,465	4,997	6,188	6,188	58.5	2	2	4.22	34.20	34.20
1	1,147	3,847	4,633	4,633	44.6	4	5	4.04	89.69	112.11
2	1,074	2,969	3,443	3,443	34.1	4	4	3.21	117.41	117.41
3-4	1,089	2,944	3,403	3,403	33.7	5	5	3.12	148.28	148.28
5-6	455	1,140	1,302	1,302	13.0	2	2	2.86	154.20	154.20
7+	342	870	966	966	9.8	4	4	2.82	409.00	409.00
unable to classify	2,264	4,067	4,792	4,792	46.9	3	5	2.12	64.02	106.70

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
14 day episode extension										
0	1,465	4,997	6,188	6,188	206.4	2	2	4.22	9.69	9.69
1	1,147	3,847	4,633	4,633	158.2	5	6	4.04	31.60	37.92
2	1,074	2,969	3,443	3,443	122.3	6	6	3.21	49.08	49.08
3-4	1,089	2,944	3,403	3,403	121.0	6	6	3.12	49.58	49.58
5-6	455	1,140	1,302	1,302	46.6	2	2	2.86	42.88	42.88
7+	342	870	966	966	35.3	6	9	2.82	170.12	255.17
unable to classify	2,264	4,067	4,792	4,792	167.1	7	9	2.12	41.89	53.85
21 day episode extension										
0	1,465	4,997	6,188	6,188	297.9	3	5	4.22	10.07	16.78
1	1,147	3,847	4,633	4,633	228.4	6	7	4.04	26.27	30.64
2	1,074	2,969	3,443	3,443	177.0	6	6	3.21	33.90	33.90
3-4	1,089	2,944	3,403	3,403	175.4	6	6	3.12	34.20	34.20
5-6	455	1,140	1,302	1,302	67.5	2	3	2.86	29.62	44.42
7+	342	870	966	966	51.0	6	10	2.82	117.62	196.04
unable to classify	2,264	4,067	4,792	4,792	241.3	7	9	2.12	29.01	37.30
28 day episode extension										
0	1,465	4,997	6,188	6,188	379.0	4	7	4.22	10.55	18.47
1	1,147	3,847	4,633	4,633	290.0	6	7	4.04	20.69	24.14
2	1,074	2,969	3,443	3,443	226.3	7	9	3.21	30.93	39.77
3-4	1,089	2,944	3,403	3,403	225.0	7	7	3.12	31.12	31.12
5-6	455	1,140	1,302	1,302	86.6	2	3	2.86	23.11	34.66
7+	342	870	966	966	65.2	7	11	2.82	107.31	168.63
unable to classify	2,264	4,067	4,792	4,792	307.4	8	10	2.12	26.03	32.53
Non-lyophilized intramuscular route										
3 day episode extension										
0	4,062	5,110	5,142	5,142	56.1	1	1	1.27	17.82	17.82
1	907	1,438	1,449	1,449	15.8	0	0	1.60	0.00	0.00
2	355	577	584	584	6.3	0	0	1.65	0.00	0.00
3-4	222	358	361	361	3.9	0	0	1.63	0.00	0.00
5-6	93	137	144	144	1.5	0	0	1.55	0.00	0.00
7+	62	102	110	110	1.2	0	0	1.77	0.00	0.00
unable to classify	1,980	2,454	2,465	2,465	26.9	0	0	1.24	0.00	0.00
14 day episode extension										
0	4,062	5,110	5,142	5,142	208.3	1	1	1.27	4.80	4.80
1	907	1,438	1,449	1,449	58.5	0	0	1.60	0.00	0.00
2	355	577	584	584	23.3	0	0	1.65	0.00	0.00
3-4	222	358	361	361	14.3	0	0	1.63	0.00	0.00
5-6	93	137	144	144	5.6	0	0	1.55	0.00	0.00
7+	62	102	110	110	4.2	0	0	1.77	0.00	0.00
unable to classify	1,980	2,454	2,465	2,465	99.9	1	1	1.24	10.01	10.01

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
21 day episode extension										
0	4,062	5,110	5,142	5,142	303.4	1	1	1.27	3.30	3.30
1	907	1,438	1,449	1,449	84.8	0	0	1.60	0.00	0.00
2	355	577	584	584	33.7	0	0	1.65	0.00	0.00
3-4	222	358	361	361	20.6	0	0	1.63	0.00	0.00
5-6	93	137	144	144	8.0	0	0	1.55	0.00	0.00
7+	62	102	110	110	6.1	0	0	1.77	0.00	0.00
unable to classify	1,980	2,454	2,465	2,465	145.3	1	1	1.24	6.88	6.88
28 day episode extension										
0	4,062	5,110	5,142	5,142	395.2	1	1	1.27	2.53	2.53
1	907	1,438	1,449	1,449	109.9	0	0	1.60	0.00	0.00
2	355	577	584	584	43.3	0	0	1.65	0.00	0.00
3-4	222	358	361	361	26.7	0	0	1.63	0.00	0.00
5-6	93	137	144	144	10.2	0	0	1.55	0.00	0.00
7+	62	102	110	110	7.8	0	0	1.77	0.00	0.00
unable to classify	1,980	2,454	2,465	2,465	189.3	1	1	1.24	5.28	5.28
Non-lyophilized unspecified route										
3 day episode extension										
0	4,693	6,037	6,111	6,111	65.9	58	69	1.30	879.59	1046.41
1	1,522	2,042	2,072	2,072	22.3	21	25	1.36	941.28	1120.57
2	1,201	1,457	1,495	1,495	15.9	26	29	1.24	1639.34	1828.50
3-4	1,132	1,363	1,394	1,394	14.8	29	33	1.23	1958.14	2228.22
5-6	582	664	672	672	7.2	12	12	1.15	1664.36	1664.36
7+	389	433	436	436	4.7	5	5	1.12	1061.57	1061.57
unable to classify	2,602	3,013	3,060	3,060	32.9	30	36	1.18	911.02	1093.23
14 day episode extension										
0	4,693	6,037	6,111	6,111	244.0	69	130	1.30	282.81	532.83
1	1,522	2,042	2,072	2,072	82.6	21	33	1.36	254.11	399.32
2	1,201	1,457	1,495	1,495	58.5	28	45	1.24	478.88	769.63
3-4	1,132	1,363	1,394	1,394	54.6	33	50	1.23	604.06	915.25
5-6	582	664	672	672	26.7	13	16	1.15	486.16	598.35
7+	389	433	436	436	17.5	6	10	1.12	342.47	570.78
unable to classify	2,602	3,013	3,060	3,060	121.8	30	47	1.18	246.37	385.97
21 day episode extension										
0	4,693	6,037	6,111	6,111	354.5	76	165	1.30	214.37	465.42
1	1,522	2,042	2,072	2,072	120.0	21	42	1.36	174.94	349.88
2	1,201	1,457	1,495	1,495	84.9	29	56	1.24	341.42	659.29
3-4	1,132	1,363	1,394	1,394	79.3	34	56	1.23	428.59	705.91
5-6	582	664	672	672	38.9	15	19	1.15	385.21	487.93
7+	389	433	436	436	25.5	6	13	1.12	234.93	509.01
unable to classify	2,602	3,013	3,060	3,060	176.6	32	55	1.18	181.17	311.39

	New Users	New Episodes	Dispensings	Days Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Dispensings / User	New Episodes w/ Events / 1K Years at Risk	Total Number of Events / 1K Years at Risk
28 day episode extension										
0	4,693	6,037	6,111	6,111	462.9	78	186	1.30	168.52	401.85
1	1,522	2,042	2,072	2,072	156.2	23	54	1.36	147.26	345.73
2	1,201	1,457	1,495	1,495	110.7	32	67	1.24	289.04	605.18
3-4	1,132	1,363	1,394	1,394	103.4	35	66	1.23	338.36	638.05
5-6	582	664	672	672	50.9	15	24	1.15	294.58	471.33
7+	389	433	436	436	33.5	6	14	1.12	179.27	418.29
unable to classify	2,602	3,013	3,060	3,060	229.8	33	57	1.18	143.61	248.05
Other IVIg, brand not specified										
3 day episode extension										
0	983	2,048	2,441	2,441	23.8	0	0	2.48	0.00	0.00
1	593	1,176	1,378	1,378	13.5	0	0	2.32	0.00	0.00
2	476	895	1,069	1,069	10.3	1	2	2.25	96.71	193.42
3-4	408	779	883	883	8.9	0	0	2.16	0.00	0.00
5-6	184	308	350	350	3.5	1	1	1.90	284.09	284.09
7+	109	197	213	213	2.2	0	0	1.95	0.00	0.00
unable to classify	1,468	2,585	3,016	3,016	29.7	3	4	2.05	100.87	134.50
14 day episode extension										
0	983	2,048	2,441	2,441	83.2	1	1	2.48	12.02	12.02
1	593	1,176	1,378	1,378	48.4	0	0	2.32	0.00	0.00
2	476	895	1,069	1,069	36.9	1	5	2.25	27.10	135.50
3-4	408	779	883	883	31.8	0	0	2.16	0.00	0.00
5-6	184	308	350	350	12.5	3	3	1.90	240.19	240.19
7+	109	197	213	213	7.9	0	0	1.95	0.00	0.00
unable to classify	1,468	2,585	3,016	3,016	105.4	5	7	2.05	47.43	66.40
21 day episode extension										
0	983	2,048	2,441	2,441	119.8	1	1	2.48	8.35	8.35
1	593	1,176	1,378	1,378	69.6	0	0	2.32	0.00	0.00
2	476	895	1,069	1,069	53.2	1	5	2.25	18.79	93.97
3-4	408	779	883	883	45.9	0	0	2.16	0.00	0.00
5-6	184	308	350	350	17.8	3	3	1.90	168.92	168.92
7+	109	197	213	213	11.2	0	0	1.95	0.00	0.00
unable to classify	1,468	2,585	3,016	3,016	151.8	6	11	2.05	39.53	72.47
28 day episode extension										
0	983	2,048	2,441	2,441	152.9	1	1	2.48	6.54	6.54
1	593	1,176	1,378	1,378	87.7	0	0	2.32	0.00	0.00
2	476	895	1,069	1,069	67.8	1	5	2.25	14.74	73.71
3-4	408	779	883	883	58.5	0	0	2.16	0.00	0.00
5-6	184	308	350	350	22.5	3	3	1.90	133.16	133.16
7+	109	197	213	213	14.2	1	1	1.95	70.37	70.37
unable to classify	1,468	2,585	3,016	3,016	192.8	8	13	2.05	41.49	67.43

Appendix A. Code List for Ig Products

IVIg Product	Code	Code Type
Gammaflex	J1557, C9270	HCPCS
Privigen	J1549, Q4097	HCPCS
Gamunex	J1561, Q4092	HCPCS
Octagam	J1568, Q4087	HCPCS
Gammagard Liquid	J1569, Q4088	HCPCS
Flebogamma	J1572, Q4091	HCPCS
Lyophilized product IV	J1566, Q9941, Q9942	HCPCS
Non-lyophilized intramuscular route	90281, J1460, J1470, J1480, J1490, J1500, J1510, J1520, J1530, J1540, J1550, J1560, P9014	CPT and HCPCS
Non-lyophilized unspecified route	90399, 99.14	CPT and ICD-9 Procedure
Other IVIg, brand not specified	J1563, J1564, J1567, J1599, Q9943, Q9944, S9545, 90283	HCPCS

Appendix B. Hemolysis Events

Description	Code	Code Type
Acquired hemolytic anemias	283*	ICD-9
ABO incompatibility reaction	999.6	ICD-9
Rh incompatibility reaction	999.7	ICD-9
Hemolytic transfusion reaction, incompatibility unspecified	999.83	ICD-9
Acute hemolytic transfusion reaction, incompatibility unspecified	999.84	ICD-9
Delayed hemolytic transfusion reaction, incompatibility unspecified	999.85	ICD-9