Modular Program Report

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 <u>not</u> 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	The FDA requested execution of Modular Program #6 (MP6), version 5.0.1, to investigate use of several immunoglobulin (Ig) product groups (subcutaneous Ig, other branded intravenous immunoglobulin (IVIg), other IVIg, and intramuscular Ig) and diagnosis of hemolysis events (see Appendix A for exposure and event codes) on the same day as (1 day risk window) and within 10 days (10 day risk window) of Ig injection. The query was run against the Mini-Sentinel Distributed Database (MSDD) for the time period of January 1, 2006 through December 31, 2012. The request was distributed to 18 Data Partners.
	This report presents results for incidence counts of new Ig users, new lookup periods, total lookup period duration (days), number of users with an event, eligible members, and member-years only. Results for prevalence are presented in a separate report (MSY4_MPR48_V1 - Report 2).
Request ID	msy4_mpr48_v1 - Report 1 of 2
Specifications	Program parameter inputs and scenarios
Glossary	List of terms found in this report and their definitions
Table 1	Table of Summary of Incident Ig use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product and Risk Window
Table 2	Table of Summary of Incident Ig use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Age Group
Table 3	Table of Summary of Incident Ig use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Sex
Table 4	Table of Summary of Incident Ig use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Year
Appendix A	List of Ig Exposure and Hemolysis Event Codes
Notes:	Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document.

Modular Program Specifications MSY4_MPR48_V1

Modular Program #6, version 5.0.1, was used to investigate use of Ig products and hemolysis. The query period was from January 1, 2006 to December 31, 2012, and the enrollment gap was set at 45 days. Age groups were split as follows: 0-17, 18-44, 45-64, and 65+ years. Enrollment gap was set at 45 days, the program considers Ig injections in all care settings, and minimum lookup period duration was set to zero. In total, 28 unique scenarios were examined in this request with differing exposures of interest and lookup period duration. See below for a description of each of these scenarios. An episode was excluded if the user switches to one of the listed products within 21 days of the index date of use of the product of interest (exclusion criteria).

	Exposure Criteria (Event file in MP6)					Exclusion Criteria					Outcome (Post-event treatment file in MP6)				
Scenario	Incident exposure	Incident w/ respect to:	Incidence Type	Washout Period (days)	Lookup Period Duration*	Exclusion Treatment	Lookback Period Start	Lookback Period End	Exclusion Treatment Care Setting	Exclusion Treatment Principal Dx	Event/ Outcome	Incident w/ respect to:	Incidence Type	Washout Period (days)	Care Setting PDx
1	Lyophilized Codes	Lyophilized Codes	MULTIPLE	21	1	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
2	Non-lyophilized intramuscular codes	Non-lyophilized intramuscular codes	MULTIPLE	21	1	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
3	Non-lyophilized intravenous codes	Non-lyophilized intravenous codes	MULTIPLE	21	1	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
4	Non-lyophilized unspecified route codes	Non-lyophilized unspecified route codes	MULTIPLE	21	1	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
5	Non-lyophilized subcutaneous codes	Non-lyophilized subcutaneous codes	MULTIPLE	21	1	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
6	Flebogamma	Flebogamma	MULTIPLE	21	1	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
7	Gammagard	Gammagard	MULTIPLE	21	1	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
8	Gammaplex	Gammaplex	MULTIPLE	21	1	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
9	Gamunex/Gamunex-C/Gammaked	Gamunex/Gamunex-C/Gammaked	MULTIPLE	21	1	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
10	Hizentra	Hizentra	MULTIPLE	21	1	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
11	Octagam	Octagam	MULTIPLE	21	1	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
12	Privigen	Privigen	MULTIPLE	21	1	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
13	Vivaglobin	Vivaglobin	MULTIPLE	21	1	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
14	All Ig Codes	All Ig Codes	MULTIPLE	21	1	None	NA	NA	NA	NA	Hemolysis	Hemolysis	MULTIPLE	90	All

15	Lyophilized Codes	Lyophilized Codes	MULTIPLE	21	10	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
16	Non-lyophilized intramuscular codes	Non-lyophilized intramuscular codes	MULTIPLE	21	10	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
17	Non-lyophilized intravenous codes	Non-lyophilized intravenous codes	MULTIPLE	21	10	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
18	Non-lyophilized unspecified route codes	Non-lyophilized unspecified route codes	MULTIPLE	21	10	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
19	Non-lyophilized subcutaneous codes	Non-lyophilized subcutaneous codes	MULTIPLE	21	10	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
20	Flebogamma	Flebogamma	MULTIPLE	21	10	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
21	Gammagard	Gammagard	MULTIPLE	21	10	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
22	Gammaplex	Gammaplex	MULTIPLE	21	10	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
23	Gamunex/Gamunex-C/Gammaked	Gamunex/Gamunex-C/Gammaked	MULTIPLE	21	10	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
24	Hizentra	Hizentra	MULTIPLE	21	10	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
25	Octagam	Octagam	MULTIPLE	21	10	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
26	Privigen	Privigen	MULTIPLE	21	10	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
27	Vivaglobin	Vivaglobin	MULTIPLE	21	10	All listed exposures except exposure of interest	-21	21	ALL	NO	Hemolysis	Hemolysis	MULTIPLE	90	All
28	All Ig Codes	All Ig Codes	MULTIPLE	21	10	None	NA	NA	NA	NA	Hemolysis	Hemolysis	MULTIPLE	90	All

* Lookup period duration of 1 day considers same day Ig and hemolysis only.

Glossary of Terms in Modular Program 6*

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 Ambulatory Visit (OA).

Eligible Members - Number of members eligible for an incident exposure/lookup period (defined by the 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" sequence.

Incidence Type (drug/exposure)- *Minimum Incidence type* will consider the first exposure/lookup period in the query period as long as it is the first exposure/lookup period in the user's entire available history. *Single* and *Multiple Incidence types* will use the washout period to establish incidence; however, *Single* will only consider the first exposure/lookup period whereas *Multiple* will consider all qualifying exposures/lookup periods.

Incidence Type (event/outcome)- *Minimum Incidence type* considers the first event in a valid episode as long as it is the first event in the user's entire available history. *Multiple Incidence type* uses the washout period to establish incidence and considers all qualifying incident exposures/lookup periods.

Inclusion/Exclusion Indicator - indicates whether condition(s) of interest are used for inclusion or exclusion criteria. A value of 1 instructs the program that members must have the condition of interest (inclusion criteria); a value of 0 instructs the program that members must not have the condition of interest (exclusion criteria).

Lookback Period Start and End - range of days relative to index that the program looks for inclusion/exclusion conditions of interest. For example, if the Inclusion/Exclusion Indicator =1, Lookback Period Start = -183 and Lookback Period End = 0, the cohort will only include members with the condition of interest present in the 183 days prior to and including the index date (the index date is day 0).

Lookup Period - fixed period of time following an incident exposure that the MP6 program searches for events of interest.

Member-Days - sum of all days a member is eligible for an incident exposure/lookup period (i.e., days that the member meets all inclusion criteria such a incidence, pre-existing condition, and enrollment requirements).

Minimum Lookup Period Duration - minimum number of enrollment days required after an incident exposure/lookup period start. For example, if the minimum duration =10, a member must have 10 or more days of continuous enrollment in drug and medical benefit coverage following the exposure/lookup period start in order for the lookup period to be included in output metrics.

New Users - number of members with incident exposure/lookup period during the query period. A user may only be counted once in a query period.

Principal Diagnosis - 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 evaluates exposures of interest.

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 exposure/lookup period.

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 exposure/lookup period.

*all terms may not be used in this report

Table 1. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product and Risk Window

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Lyophilized								
1 day risk window	7,623	48,204	48,204	26	92,475,217	210,057,193	8.24	0.34
10 day risk window	7,623	48,204	482,040	44	92,475,217	210,057,193	8.24	0.58
Non-lyophilized intramuscular								
1 day risk window	3,360	8,106	8,106	0	92,474,907	210,061,714	3.63	0.00
10 day risk window	3,360	8,106	81,060	0	92,474,907	210,061,714	3.63	0.00
Non-lyophilized intravenous								
1 day risk window	3,681	17,621	17,621	11	92,474,927	210,057,053	3.98	0.30
10 day risk window	3,681	17,621	176,210	21	92,474,927	210,057,053	3.98	0.57
Non-lyophilized unspecified route								
1 day risk window	13,127	18,363	18,363	189	92,475,385	210,074,259	14.20	1.44
10 day risk window	13,127	18,363	183,630	204	92,475,385	210,074,259	14.20	1.55
Non-lyophilized subcutaneous								
1 day risk window	0	0	0	0	92,474,675	210,056,304	0.00	---
10 day risk window	0	0	0	0	92,474,675	210,056,304	0.00	---
Flebogamma								
1 day risk window	2,456	12,699	12,699	13	92,474,789	210,056,617	2.66	0.53
10 day risk window	2,456	12,699	126,990	17	92,474,789	210,056,617	2.66	0.69
Gammagard								
1 day risk window	10,900	74,913	74,913	34	92,475,396	210,056,666	11.79	0.31
10 day risk window	10,900	74,913	749,130	54	92,475,396	210,056,666	11.79	0.50
Gammaplex								
1 day risk window	62	179	179	1	92,474,678	210,056,307	0.07	1.61
10 day risk window	62	179	1,790	1	92,474,678	210,056,307	0.07	1.61
Gamunex/Gamunex-C/Gammaked								
1 day risk window	7,921	54,359	54,359	14	92,475,170	210,056,026	8.57	0.18
10 day risk window	7,921	54,359	543,590	31	92,475,170	210,056,026	8.57	0.39

Table 1. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product and Risk Window

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Hizentra								
1 day risk window	1,321	8,888	8,888	1	92,474,767	210,055,501	1.43	0.08
10 day risk window	1,321	8,888	88,880	1	92,474,767	210,055,501	1.43	0.08
Octagam								
1 day risk window	2,643	15,634	15,634	11	92,474,873	210,056,668	2.86	0.42
10 day risk window	2,643	15,634	156,340	15	92,474,873	210,056,668	2.86	0.57
Privigen								
1 day risk window	3,733	20,767	20,767	15	92,474,854	210,056,168	4.04	0.40
10 day risk window	3,733	20,767	207,670	22	92,474,854	210,056,168	4.04	0.59
Vivaglobin								
1 day risk window	1,402	12,403	12,403	2	92,474,804	210,055,925	1.52	0.14
10 day risk window	1,402	12,403	124,030	6	92,474,804	210,055,925	1.52	0.43
All Ig								
1 day risk window	47,146	303,574	303,574	329	94,647,756	214,947,327	49.81	0.70
10 day risk window	47,146	303,574	3,025,039	434	94,647,756	214,947,327	49.81	0.92

Table 2. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Age Group

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Lyophilized								
1 day risk window								
0-17 years	738	4,119	4,119	2	22,804,425	48,238,889	3.24	0.27
18-44 years	1,888	11,215	11,215	5	42,662,459	78,146,279	4.43	0.26
45-64 years	3,356	21,305	21,305	7	26,386,726	61,502,611	12.72	0.21
65+ years	1,865	11,565	11,565	12	8,011,310	22,169,415	23.28	0.64
10 day risk window								
0-17 years	738	4,119	41,190	5	22,804,425	48,238,889	3.24	0.68
18-44 years	1,888	11,215	112,150	7	42,662,459	78,146,279	4.43	0.37
45-64 years	3,356	21,305	213,050	13	26,386,726	61,502,611	12.72	0.39
65+ years	1,865	11,565	115,650	19	8,011,310	22,169,415	23.28	1.02
Non-lyophilized intramuscular								
1 day risk window								
0-17 years	621	915	915	0	22,804,455	48,239,768	2.72	0.00
18-44 years	1,075	2,209	2,209	0	42,662,379	78,147,763	2.52	0.00
45-64 years	1,306	3,734	3,734	0	26,386,617	61,504,656	4.95	0.00
65+ years	405	1,248	1,248	0	8,011,222	22,169,526	5.06	0.00
10 day risk window								
0-17 years	621	915	9,150	0	22,804,455	48,239,768	2.72	0.00
18-44 years	1,075	2,209	22,090	0	42,662,379	78,147,763	2.52	0.00
45-64 years	1,306	3,734	37,340	0	26,386,617	61,504,656	4.95	0.00
65+ years	405	1,248	12,480	0	8,011,222	22,169,526	5.06	0.00
Non-lyophilized intravenous								
1 day risk window								
0-17 years	488	2,304	2,304	1	22,804,423	48,238,894	2.14	0.20
18-44 years	964	4,269	4,269	0	42,662,368	78,146,489	2.26	0.00
45-64 years	1,593	7,697	7,697	8	26,386,559	61,502,722	6.04	0.50
65+ years	723	3,351	3,351	2	8,011,207	22,168,948	9.02	0.28

Table 2. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Age Group

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Non-lyophilized intravenous (Continued)								
10 day risk window								
0-17 years	488	2,304	23,040	2	22,804,423	48,238,894	2.14	0.41
18-44 years	964	4,269	42,690	2	42,662,368	78,146,489	2.26	0.21
45-64 years	1,593	7,697	76,970	11	26,386,559	61,502,722	6.04	0.69
65+ years	723	3,351	33,510	6	8,011,207	22,168,948	9.02	0.83
Non-lyophilized unspecified route								
1 day risk window								
0-17 years	4,157	6,183	6,183	48	22,804,641	48,244,710	18.23	1.15
18-44 years	3,453	4,469	4,469	49	42,662,748	78,150,725	8.09	1.42
45-64 years	3,371	4,648	4,648	50	26,386,760	61,506,762	12.78	1.48
65+ years	2,196	3,063	3,063	42	8,011,382	22,172,062	27.41	1.91
10 day risk window								
0-17 years	4,157	6,183	61,830	54	22,804,641	48,244,710	18.23	1.30
18-44 years	3,453	4,469	44,690	53	42,662,748	78,150,725	8.09	1.53
45-64 years	3,371	4,648	46,480	54	26,386,760	61,506,762	12.78	1.60
65+ years	2,196	3,063	30,630	43	8,011,382	22,172,062	27.41	1.96
Non-lyophilized subcutaneous								
1 day risk window								
0-17 years	0	0	0	0	22,804,377	48,238,810	0.00	---
18-44 years	0	0	0	0	42,662,278	78,146,180	0.00	---
45-64 years	0	0	0	0	26,386,420	61,502,483	0.00	---
65+ years	0	0	0	0	8,011,147	22,168,830	0.00	---
10 day risk window								
0-17 years	0	0	0	0	22,804,377	48,238,810	0.00	---
18-44 years	0	0	0	0	42,662,278	78,146,180	0.00	---
45-64 years	0	0	0	0	26,386,420	61,502,483	0.00	---
65+ years	0	0	0	0	8,011,147	22,168,830	0.00	---

Table 2. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Age Group

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Flebogamma								
1 day risk window								
0-17 years	178	754	754	0	22,804,391	48,238,844	0.78	0.00
18-44 years	472	2,273	2,273	3	42,662,300	78,146,273	1.11	0.64
45-64 years	1,046	5,199	5,199	4	26,386,482	61,502,550	3.96	0.38
65+ years	809	4,473	4,473	6	8,011,183	22,168,950	10.10	0.74
10 day risk window								
0-17 years	178	754	7,540	0	22,804,391	48,238,844	0.78	0.00
18-44 years	472	2,273	22,730	4	42,662,300	78,146,273	1.11	0.85
45-64 years	1,046	5,199	51,990	4	26,386,482	61,502,550	3.96	0.38
65+ years	809	4,473	44,730	9	8,011,183	22,168,950	10.10	1.11
Gammagard								
1 day risk window								
0-17 years	1,222	7,317	7,317	5	22,804,469	48,238,783	5.36	0.41
18-44 years	2,777	16,599	16,599	6	42,662,541	78,146,465	6.51	0.22
45-64 years	4,829	34,723	34,723	12	26,386,811	61,502,544	18.30	0.25
65+ years	2,378	16,274	16,274	11	8,011,300	22,168,874	29.68	0.46
10 day risk window								
0-17 years	1,222	7,317	73,170	5	22,804,469	48,238,783	5.36	0.41
18-44 years	2,777	16,599	165,990	12	42,662,541	78,146,465	6.51	0.43
45-64 years	4,829	34,723	347,230	20	26,386,811	61,502,544	18.30	0.41
65+ years	2,378	16,274	162,740	17	8,011,300	22,168,874	29.68	0.71
Gammaplex								
1 day risk window								
0-17 years	2	6	6	0	22,804,378	48,238,811	0.01	0.00
18-44 years	14	33	33	0	42,662,275	78,146,182	0.03	0.00
45-64 years	34	96	96	1	26,386,422	61,502,476	0.13	2.94
65+ years	14	44	44	0	8,011,146	22,168,837	0.17	0.00

Table 2. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Age Group

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Gammaplex (Continued)								
10 day risk window								
0-17 years	2	6	60	0	22,804,378	48,238,811	0.01	0.00
18-44 years	14	33	330	0	42,662,275	78,146,182	0.03	0.00
45-64 years	34	96	960	1	26,386,422	61,502,476	0.13	2.94
65+ years	14	44	440	0	8,011,146	22,168,837	0.17	0.00
Gamunex/Gamunex-C/Gammaked								
1 day risk window								
0-17 years	1,348	8,283	8,283	5	22,804,467	48,238,984	5.91	0.37
18-44 years	1,846	11,400	11,400	2	42,662,442	78,146,202	4.33	0.11
45-64 years	3,409	24,725	24,725	4	26,386,671	61,502,057	12.92	0.12
65+ years	1,572	9,951	9,951	3	8,011,222	22,168,783	19.62	0.19
10 day risk window								
0-17 years	1,348	8,283	82,830	8	22,804,467	48,238,984	5.91	0.59
18-44 years	1,846	11,400	114,000	6	42,662,442	78,146,202	4.33	0.33
45-64 years	3,409	24,725	247,250	12	26,386,671	61,502,057	12.92	0.35
65+ years	1,572	9,951	99,510	5	8,011,222	22,168,783	19.62	0.32
Hizentra								
1 day risk window								
0-17 years	304	1,780	1,780	0	22,804,397	48,238,617	1.33	0.00
18-44 years	377	2,217	2,217	1	42,662,306	78,145,971	0.88	0.27
45-64 years	542	3,705	3,705	0	26,386,450	61,502,159	2.05	0.00
65+ years	120	1,186	1,186	0	8,011,151	22,168,755	1.50	0.00
10 day risk window								
0-17 years	304	1,780	17,800	0	22,804,397	48,238,617	1.33	0.00
18-44 years	377	2,217	22,170	1	42,662,306	78,145,971	0.88	0.27
45-64 years	542	3,705	37,050	0	26,386,450	61,502,159	2.05	0.00
65+ years	120	1,186	11,860	0	8,011,151	22,168,755	1.50	0.00

Table 2. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Age Group

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Octagam								
1 day risk window								
0-17 years	130	626	626	0	22,804,391	48,238,835	0.57	0.00
18-44 years	616	3,415	3,415	5	42,662,329	78,146,315	1.44	0.81
45-64 years	1,263	7,754	7,754	1	26,386,545	61,502,606	4.79	0.08
65+ years	688	3,839	3,839	5	8,011,188	22,168,912	8.59	0.73
10 day risk window								
0-17 years	130	626	6,260	0	22,804,391	48,238,835	0.57	0.00
18-44 years	616	3,415	34,150	6	42,662,329	78,146,315	1.44	0.97
45-64 years	1,263	7,754	77,540	4	26,386,545	61,502,606	4.79	0.32
65+ years	688	3,839	38,390	5	8,011,188	22,168,912	8.59	0.73
Privigen								
1 day risk window								
0-17 years	326	1,688	1,688	3	22,804,401	48,238,824	1.43	0.92
18-44 years	889	4,475	4,475	1	42,662,330	78,146,204	2.08	0.11
45-64 years	1,626	8,964	8,964	6	26,386,521	61,502,434	6.16	0.37
65+ years	973	5,640	5,640	5	8,011,174	22,168,705	12.15	0.51
10 day risk window								
0-17 years	326	1,688	16,880	3	22,804,401	48,238,824	1.43	0.92
18-44 years	889	4,475	44,750	2	42,662,330	78,146,204	2.08	0.22
45-64 years	1,626	8,964	89,640	10	26,386,521	61,502,434	6.16	0.62
65+ years	973	5,640	56,400	7	8,011,174	22,168,705	12.15	0.72
Vivaglobin								
1 day risk window								
0-17 years	360	3,337	3,337	1	22,804,420	48,238,678	1.58	0.28
18-44 years	448	3,673	3,673	0	42,662,331	78,146,104	1.05	0.00
45-64 years	509	4,313	4,313	1	26,386,462	61,502,340	1.93	0.20
65+ years	123	1,080	1,080	0	8,011,156	22,168,804	1.54	0.00

Table 2. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Age Group

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Vivaglobin (Continued)								
10 day risk window								
0-17 years	360	3,337	33,370	2	22,804,420	48,238,678	1.58	0.56
18-44 years	448	3,673	36,730	1	42,662,331	78,146,104	1.05	0.22
45-64 years	509	4,313	43,130	3	26,386,462	61,502,340	1.93	0.59
65+ years	123	1,080	10,800	0	8,011,156	22,168,804	1.54	0.00
All Ig								
1 day risk window								
0-17 years	8,672	39,111	39,111	68	23,322,663	49,330,022	37.18	0.78
18-44 years	12,544	68,997	68,997	80	43,845,518	80,295,856	28.61	0.64
45-64 years	18,108	131,723	131,723	95	26,892,676	62,757,693	67.33	0.52
65+ years	9,245	63,743	63,743	87	8,160,233	22,563,756	113.29	0.94
10 day risk window								
0-17 years	8,672	39,111	389,874	84	23,322,663	49,330,022	37.18	0.97
18-44 years	12,544	68,997	686,974	104	43,845,518	80,295,856	28.61	0.83
45-64 years	18,108	131,723	1,312,520	138	26,892,676	62,757,693	67.33	0.76
65+ years	9,245	63,743	635,671	111	8,160,233	22,563,756	113.29	1.20

Table 3. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Sex

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Lyophilized								
1 day risk window								
Female	4,199	27,244	27,244	9	46,979,785	108,071,345	8.94	0.21
Male	3,424	20,960	20,960	17	45,490,833	101,978,732	7.53	0.50
Unknown	0	0	0	0	4,599	7,116	0.00	---
10 day risk window								
Female	4,199	27,244	272,440	18	46,979,785	108,071,345	8.94	0.43
Male	3,424	20,960	209,600	26	45,490,833	101,978,732	7.53	0.76
Unknown	.	.	.	.	4,599	7,116	#VALUE!	---
Non-lyophilized intramuscular								
1 day risk window								
Female	2,111	5,525	5,525	0	46,979,608	108,074,253	4.49	0.00
Male	1,249	2,581	2,581	0	45,490,700	101,980,345	2.75	0.00
Unknown	0	0	0	0	4,599	7,116	0.00	---
10 day risk window								
Female	2,111	5,525	55,250	0	46,979,608	108,074,253	4.49	0.00
Male	1,249	2,581	25,810	0	45,490,700	101,980,345	2.75	0.00
Unknown	.	.	.	.	4,599	7,116	#VALUE!	---
Non-lyophilized intravenous								
1 day risk window								
Female	2,006	9,634	9,634	7	46,979,616	108,071,376	4.27	0.35
Male	1,675	7,987	7,987	4	45,490,712	101,978,561	3.68	0.24
Unknown	0	0	0	0	4,599	7,116	0.00	---
10 day risk window								
Female	2,006	9,634	96,340	14	46,979,616	108,071,376	4.27	0.70
Male	1,675	7,987	79,870	7	45,490,712	101,978,561	3.68	0.42
Unknown	0	0	0	0	4,599	7,116	0.00	---
Non-lyophilized unspecified route								
1 day risk window								
Female	6,989	9,731	9,731	101	46,979,861	108,080,553	14.88	1.45
Male	6,136	8,630	8,630	88	45,490,925	101,986,589	13.49	1.43
Unknown	2	2	2	0	4,599	7,118	43.49	0.00

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Table 3. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Sex

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Non-lyophilized unspecified route (Continued)								
10 day risk window								
Female	6,989	9,731	97,310	110	46,979,861	108,080,553	14.88	1.57
Male	6,136	8,630	86,300	94	45,490,925	101,986,589	13.49	1.53
Unknown	2	2	20	0	4,599	7,118	43.49	0.00
Non-lyophilized subcutaneous								
1 day risk window								
Female	0	0	0	0	46,979,477	108,070,997	0.00	---
Male	0	0	0	0	45,490,599	101,978,191	0.00	---
Unknown	0	0	0	0	4,599	7,116	0.00	---
10 day risk window								
Female	0	0	0	0	46,979,477	108,070,997	0.00	---
Male	0	0	0	0	45,490,599	101,978,191	0.00	---
Unknown	0	0	0	0	4,599	7,116	0.00	---
Flebogamma								
1 day risk window								
Female	1,252	6,649	6,649	5	46,979,540	108,071,124	2.66	0.40
Male	1,204	6,050	6,050	8	45,490,650	101,978,377	2.65	0.66
Unknown	0	0	0	0	4,599	7,116	0.00	---
10 day risk window								
Female	1,252	6,649	66,490	7	46,979,540	108,071,124	2.66	0.56
Male	1,204	6,050	60,500	10	45,490,650	101,978,377	2.65	0.83
Unknown	0	0	0	0	4,599	7,116	0.00	---
Gammagard								
1 day risk window								
Female	6,074	43,374	43,374	17	46,979,878	108,071,037	12.93	0.28
Male	4,825	31,538	31,538	17	45,490,919	101,978,513	10.61	0.35
Unknown	1	1	1	0	4,599	7,116	21.74	0.00
10 day risk window								
Female	6,074	43,374	433,740	25	46,979,878	108,071,037	12.93	0.41
Male	4,825	31,538	315,380	29	45,490,919	101,978,513	10.61	0.60
Unknown	1	1	10	0	4,599	7,116	21.74	0.00

Table 3. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Sex

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Gammaplex								
1 day risk window								
Female	44	127	127	1	46,979,479	108,070,991	0.09	2.27
Male	18	52	52	0	45,490,600	101,978,200	0.04	0.00
Unknown	0	0	0	0	4,599	7,116	0.00	---
10 day risk window								
Female	44	127	1,270	1	46,979,479	108,070,991	0.09	2.27
Male	18	52	520	0	45,490,600	101,978,200	0.04	0.00
Unknown	0	0	0	0	4,599	7,116	0.00	---
Gamunex/Gamunex-C/Gammaked								
1 day risk window								
Female	4,174	29,796	29,796	7	46,979,751	108,070,751	8.88	0.17
Male	3,747	24,563	24,563	7	45,490,820	101,978,159	8.24	0.19
Unknown	0	0	0	0	4,599	7,116	0.00	---
10 day risk window								
Female	4,174	29,796	297,960	12	46,979,751	108,070,751	8.88	0.29
Male	3,747	24,563	245,630	19	45,490,820	101,978,159	8.24	0.51
Unknown	0	0	0	0	4,599	7,116	0.00	---
Hizentra								
1 day risk window								
Female	824	5,619	5,619	0	46,979,531	108,070,488	1.75	0.00
Male	496	3,268	3,268	1	45,490,637	101,977,897	1.09	0.20
Unknown	1	1	1	0	4,599	7,116	21.74	0.00
10 day risk window								
Female	824	5,619	56,190	0	46,979,531	108,070,488	1.75	0.00
Male	496	3,268	32,680	1	45,490,637	101,977,897	1.09	0.20
Unknown	1	1	10	0	4,599	7,116	21.74	0.00
Octagam								
1 day risk window								
Female	1,530	9,544	9,544	6	46,979,598	108,071,191	3.26	0.39
Male	1,113	6,090	6,090	5	45,490,676	101,978,362	2.45	0.45
Unknown	0	0	0	0	4,599	7,116	0.00	---

Table 3. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Sex

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Octagam (Continued)								
10 day risk window								
Female	1,530	9,544	95,440	8	46,979,598	108,071,191	3.26	0.52
Male	1,113	6,090	60,900	7	45,490,676	101,978,362	2.45	0.63
Unknown	0	0	0	0	4,599	7,116	0.00	---
Privigen								
1 day risk window								
Female	2,047	11,970	11,970	6	46,979,584	108,070,864	4.36	0.29
Male	1,686	8,797	8,797	9	45,490,671	101,978,188	3.71	0.53
Unknown	0	0	0	0	4,599	7,116	0.00	---
10 day risk window								
Female	2,047	11,970	119,700	9	46,979,584	108,070,864	4.36	0.44
Male	1,686	8,797	87,970	13	45,490,671	101,978,188	3.71	0.77
Unknown	0	0	0	0	4,599	7,116	0.00	---
Vivaglobin								
1 day risk window								
Female	842	7,271	7,271	0	46,979,558	108,070,772	1.79	0.00
Male	560	5,132	5,132	2	45,490,647	101,978,037	1.23	0.36
Unknown	0	0	0	0	4,599	7,116	0.00	---
10 day risk window								
Female	842	7,271	72,710	0	46,979,558	108,070,772	1.79	0.00
Male	560	5,132	51,320	6	45,490,647	101,978,037	1.23	1.07
Unknown	0	0	0	0	4,599	7,116	0.00	---
All Ig								
1 day risk window								
Female	25,801	172,845	172,845	168	48,055,789	110,557,212	53.69	0.65
Male	21,343	130,725	130,725	161	46,587,052	104,382,733	45.81	0.75
Unknown	2	4	4	0	4,915	7,381	40.69	0.00
10 day risk window								
Female	25,801	172,845	1,722,095	216	48,055,789	110,557,212	53.69	0.84
Male	21,343	130,725	1,302,904	218	46,587,052	104,382,733	45.81	1.02
Unknown	2	4	40	0	4,915	7,381	40.69	0.00

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Table 4. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Year

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Lyophilized								
1 day risk window								
2006	1,678	6,082	6,082	1	21,293,967	15,129,266	7.88	0.06
2007	1,829	7,144	7,144	5	24,799,708	18,531,490	7.38	0.27
2008	2,984	11,745	11,745	9	48,959,665	34,518,766	6.09	0.30
2009	2,182	9,267	9,267	5	49,080,211	38,452,833	4.45	0.23
2010	1,459	5,866	5,866	5	47,311,440	37,149,805	3.08	0.34
2011	1,167	5,030	5,030	1	46,195,485	36,492,552	2.53	0.09
2012	836	3,070	3,070	1	42,913,781	29,782,482	1.95	0.12
10 day risk window								
2006	1,678	6,082	60,820	2	21,293,967	15,129,266	7.88	0.12
2007	1,829	7,144	71,440	8	24,799,708	18,531,490	7.38	0.44
2008	2,984	11,745	117,450	13	48,959,665	34,518,766	6.09	0.44
2009	2,182	9,267	92,670	11	49,080,211	38,452,833	4.45	0.50
2010	1,459	5,866	58,660	8	47,311,440	37,149,805	3.08	0.55
2011	1,167	5,030	50,300	3	46,195,485	36,492,552	2.53	0.26
2012	836	3,070	30,700	2	42,913,781	29,782,482	1.95	0.24
Non-lyophilized intramuscular								
1 day risk window								
2006	462	1,329	1,329	0	21,293,826	15,129,510	2.17	0.00
2007	514	914	914	0	24,799,627	18,531,930	2.07	0.00
2008	873	1,686	1,686	0	48,959,567	34,519,407	1.78	0.00
2009	747	1,456	1,456	0	49,080,354	38,453,567	1.52	0.00
2010	724	1,328	1,328	0	47,311,778	37,150,606	1.53	0.00
2011	388	777	777	0	46,196,122	36,493,490	0.84	0.00
2012	348	616	616	0	42,914,380	29,783,203	0.81	0.00

Table 4. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Year

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Non-lyophilized intramuscular (Continued)								
10 day risk window								
2006	462	1,329	13,290	0	21,293,826	15,129,510	2.17	0.00
2007	514	914	9,140	0	24,799,627	18,531,930	2.07	0.00
2008	873	1,686	16,860	0	48,959,567	34,519,407	1.78	0.00
2009	747	1,456	14,560	0	49,080,354	38,453,567	1.52	0.00
2010	724	1,328	13,280	0	47,311,778	37,150,606	1.53	0.00
2011	388	777	7,770	0	46,196,122	36,493,490	0.84	0.00
2012	348	616	6,160	0	42,914,380	29,783,203	0.81	0.00
Non-lyophilized intravenous								
1 day risk window								
2006	2,387	9,170	9,170	7	21,294,041	15,129,226	11.21	0.29
2007	2,257	8,006	8,006	4	24,799,948	18,531,651	9.10	0.18
2008	51	81	81	0	48,959,424	34,519,136	0.10	0.00
2009	13	23	23	0	49,079,720	38,452,861	0.03	0.00
2010	0	0	0	0	47,310,879	37,149,646	0.00	---
2011	108	285	285	1	46,194,960	36,492,348	0.23	0.93
2012	20	56	56	0	42,913,237	29,782,185	0.05	0.00
10 day risk window								
2006	2,387	9,170	91,700	13	21,294,041	15,129,226	11.21	0.54
2007	2,257	8,006	80,060	9	24,799,948	18,531,651	9.10	0.40
2008	51	81	810	0	48,959,424	34,519,136	0.10	0.00
2009	13	23	230	0	49,079,720	38,452,861	0.03	0.00
2010	0	0	0	0	47,310,879	37,149,646	0.00	---
2011	108	285	2,850	1	46,194,960	36,492,348	0.23	0.93
2012	20	56	560	0	42,913,237	29,782,185	0.05	0.00

Table 4. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Year

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Non-lyophilized unspecified route								
1 day risk window								
2006	947	1,487	1,487	13	21,293,848	15,129,612	4.45	1.37
2007	1,168	1,683	1,683	18	24,799,969	18,532,266	4.71	1.54
2008	2,696	3,695	3,695	44	48,960,341	34,520,395	5.51	1.63
2009	2,609	3,439	3,439	28	49,082,016	38,455,464	5.32	1.07
2010	2,437	2,903	2,903	33	47,314,268	37,153,266	5.15	1.35
2011	2,551	3,158	3,158	23	46,199,217	36,496,842	5.52	0.90
2012	1,835	1,998	1,998	31	42,918,236	29,786,414	4.28	1.69
10 day risk window								
2006	947	1,487	14,870	13	21,293,848	15,129,612	4.45	1.37
2007	1,168	1,683	16,830	20	24,799,969	18,532,266	4.71	1.71
2008	2,696	3,695	36,950	45	48,960,341	34,520,395	5.51	1.67
2009	2,609	3,439	34,390	31	49,082,016	38,455,464	5.32	1.19
2010	2,437	2,903	29,030	35	47,314,268	37,153,266	5.15	1.44
2011	2,551	3,158	31,580	25	46,199,217	36,496,842	5.52	0.98
2012	1,835	1,998	19,980	36	42,918,236	29,786,414	4.28	1.96
Non-lyophilized subcutaneous								
1 day risk window								
2006	0	0	0	0	21,293,778	15,129,443	0.00	---
2007	0	0	0	0	24,799,366	18,531,604	0.00	---
2008	0	0	0	0	48,958,955	34,518,775	0.00	---
2009	0	0	0	0	49,079,419	38,452,600	0.00	---
2010	0	0	0	0	47,310,649	37,149,471	0.00	---
2011	0	0	0	0	46,194,807	36,492,254	0.00	---
2012	0	0	0	0	42,913,149	29,782,156	0.00	---

Table 4. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Year

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Non-lyophilized subcutaneous (Continued)								
10 day risk window								---
2006	0	0	0	0	21,293,778	15,129,443	0.00	---
2007	0	0	0	0	24,799,366	18,531,604	0.00	---
2008	0	0	0	0	48,958,955	34,518,775	0.00	---
2009	0	0	0	0	49,079,419	38,452,600	0.00	---
2010	0	0	0	0	47,310,649	37,149,471	0.00	---
2011	0	0	0	0	46,194,807	36,492,254	0.00	---
2012	0	0	0	0	42,913,149	29,782,156	0.00	---
Flebogamma								
1 day risk window								
2006	0	0	0	0	21,293,782	15,129,436	0.00	---
2007	189	420	420	0	24,799,385	18,531,571	0.76	0.00
2008	567	1,868	1,868	3	48,959,001	34,518,721	1.16	0.53
2009	710	2,560	2,560	1	49,079,525	38,452,585	1.45	0.14
2010	756	2,699	2,699	1	47,310,847	37,149,543	1.60	0.13
2011	816	2,966	2,966	7	46,195,080	36,492,371	1.77	0.86
2012	641	2,186	2,186	2	42,913,470	29,782,390	1.49	0.31
10 day risk window								
2006	0	0	0	0	21,293,782	15,129,436	0.00	---
2007	189	420	4,200	0	24,799,385	18,531,571	0.76	0.00
2008	567	1,868	18,680	4	48,959,001	34,518,721	1.16	0.71
2009	710	2,560	25,600	1	49,079,525	38,452,585	1.45	0.14
2010	756	2,699	26,990	2	47,310,847	37,149,543	1.60	0.26
2011	816	2,966	29,660	9	46,195,080	36,492,371	1.77	1.10
2012	641	2,186	21,860	2	42,913,470	29,782,390	1.49	0.31

Table 4. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Year

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Gammagard								
1 day risk window								
2006	5	17	17	0	21,293,769	15,129,418	0.02	0.00
2007	547	1,398	1,398	1	24,799,391	18,531,459	2.21	0.18
2008	3,071	12,432	12,432	6	48,959,254	34,518,408	6.27	0.20
2009	3,360	14,244	14,244	10	49,080,055	38,452,438	6.85	0.30
2010	3,501	14,846	14,846	8	47,311,509	37,149,504	7.40	0.23
2011	3,901	17,422	17,422	7	46,195,917	36,492,512	8.44	0.18
2012	3,481	14,554	14,554	3	42,914,664	29,782,927	8.11	0.09
10 day risk window								
2006	5	17	170	0	21,293,769	15,129,418	0.02	0.00
2007	547	1,398	13,980	1	24,799,391	18,531,459	2.21	0.18
2008	3,071	12,432	124,320	10	48,959,254	34,518,408	6.27	0.33
2009	3,360	14,244	142,440	16	49,080,055	38,452,438	6.85	0.48
2010	3,501	14,846	148,460	11	47,311,509	37,149,504	7.40	0.31
2011	3,901	17,422	174,220	13	46,195,917	36,492,512	8.44	0.33
2012	3,481	14,554	145,540	6	42,914,664	29,782,927	8.11	0.17
Gammaplex								
1 day risk window								
2006	0	0	0	0	21,293,778	15,129,443	0.00	---
2007	0	0	0	0	24,799,366	18,531,605	0.00	---
2008	0	0	0	0	48,958,955	34,518,775	0.00	---
2009	0	0	0	0	49,079,419	38,452,601	0.00	---
2010	1	2	2	0	47,310,650	37,149,474	0.00	0.00
2011	7	12	12	0	46,194,803	36,492,253	0.02	0.00
2012	56	165	165	1	42,913,147	29,782,156	0.13	1.79

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Gammaplex (Continued)								
10 day risk window								
2006	0	0	0	0	21,293,778	15,129,443	0.00	---
2007	0	0	0	0	24,799,366	18,531,605	0.00	---
2008	0	0	0	0	48,958,955	34,518,775	0.00	---
2009	0	0	0	0	49,079,419	38,452,601	0.00	---
2010	1	2	20	0	47,310,650	37,149,474	0.00	0.00
2011	7	12	120	0	46,194,803	36,492,253	0.02	0.00
2012	56	165	1,650	1	42,913,147	29,782,156	0.13	1.79
Gamunex/Gamunex-C/Gammaked								
1 day risk window								
2006	2	2	2	0	21,293,770	15,129,409	0.01	0.00
2007	598	1,675	1,675	1	24,799,376	18,531,431	2.41	0.17
2008	2,331	10,035	10,035	4	48,959,131	34,518,382	4.76	0.17
2009	2,559	11,167	11,167	3	49,079,787	38,452,335	5.21	0.12
2010	2,671	10,861	10,861	2	47,311,210	37,149,431	5.65	0.07
2011	2,568	11,303	11,303	5	46,195,553	36,492,395	5.56	0.19
2012	2,345	9,316	9,316	2	42,914,092	29,782,642	5.46	0.09
10 day risk window								
2006	2	2	20	0	21,293,770	15,129,409	0.01	0.00
2007	598	1,675	16,750	2	24,799,376	18,531,431	2.41	0.33
2008	2,331	10,035	100,350	9	48,959,131	34,518,382	4.76	0.39
2009	2,559	11,167	111,670	8	49,079,787	38,452,335	5.21	0.31
2010	2,671	10,861	108,610	5	47,311,210	37,149,431	5.65	0.19
2011	2,568	11,303	113,030	10	46,195,553	36,492,395	5.56	0.39
2012	2,345	9,316	93,160	3	42,914,092	29,782,642	5.46	0.13

Table 4. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Year

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Hizentra								
1 day risk window								
2006	0	0	0	0	21,293,776	15,129,440	0.00	---
2007	0	0	0	0	24,799,351	18,531,586	0.00	---
2008	0	0	0	0	48,958,902	34,518,721	0.00	---
2009	0	0	0	0	49,079,340	38,452,494	0.00	---
2010	5	7	7	0	47,310,531	37,149,283	0.01	0.00
2011	962	4,509	4,509	1	46,194,767	36,491,944	2.08	0.10
2012	837	4,372	4,372	0	42,913,189	29,782,034	1.95	0.00
10 day risk window								
2006	0	0	0	0	21,293,776	15,129,440	0.00	---
2007	0	0	0	0	24,799,351	18,531,586	0.00	---
2008	0	0	0	0	48,958,902	34,518,721	0.00	---
2009	0	0	0	0	49,079,340	38,452,494	0.00	---
2010	5	7	70	0	47,310,531	37,149,283	0.01	0.00
2011	962	4,509	45,090	1	46,194,767	36,491,944	2.08	0.10
2012	837	4,372	43,720	0	42,913,189	29,782,034	1.95	0.00
Octagam								
1 day risk window								
2006	0	0	0	0	21,293,790	15,129,452	0.00	---
2007	221	621	621	2	24,799,394	18,531,591	0.89	0.90
2008	1,062	4,635	4,635	4	48,959,125	34,518,711	2.17	0.38
2009	1,055	5,020	5,020	3	49,079,716	38,452,630	2.15	0.28
2010	767	3,089	3,089	0	47,311,004	37,149,629	1.62	0.00
2011	98	257	257	1	46,195,059	36,492,438	0.21	1.02
2012	633	2,012	2,012	2	42,913,315	29,782,217	1.48	0.32

Table 4. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Year

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Octagam (Continued)								
10 day risk window								
2006	0	0	0	0	21,293,790	15,129,452	0.00	---
2007	221	621	6,210	2	24,799,394	18,531,591	0.89	0.90
2008	1,062	4,635	46,350	5	48,959,125	34,518,711	2.17	0.47
2009	1,055	5,020	50,200	5	49,079,716	38,452,630	2.15	0.47
2010	767	3,089	30,890	1	47,311,004	37,149,629	1.62	0.13
2011	98	257	2,570	1	46,195,059	36,492,438	0.21	1.02
2012	633	2,012	20,120	2	42,913,315	29,782,217	1.48	0.32
Privigen								
1 day risk window								
2006	0	0	0	0	21,293,776	15,129,433	0.00	---
2007	1	1	1	0	24,799,358	18,531,586	0.00	0.00
2008	349	1,130	1,130	1	48,958,968	34,518,700	0.71	0.29
2009	666	2,647	2,647	0	49,079,482	38,452,497	1.36	0.00
2010	1,209	4,650	4,650	3	47,310,741	37,149,317	2.56	0.25
2011	1,584	6,326	6,326	6	46,195,049	36,492,220	3.43	0.38
2012	1,644	6,013	6,013	5	42,913,622	29,782,414	3.83	0.30
10 day risk window								
2006	0	0	0	0	21,293,776	15,129,433	0.00	---
2007	1	1	10	0	24,799,358	18,531,586	0.00	0.00
2008	349	1,130	11,300	1	48,958,968	34,518,700	0.71	0.29
2009	666	2,647	26,470	0	49,079,482	38,452,497	1.36	0.00
2010	1,209	4,650	46,500	5	47,310,741	37,149,317	2.56	0.41
2011	1,584	6,326	63,260	8	46,195,049	36,492,220	3.43	0.51
2012	1,644	6,013	60,130	9	42,913,622	29,782,414	3.83	0.55

Table 4. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Year

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
Vivaglobin								
1 day risk window								
2006	2	3	3	0	21,293,774	15,129,438	0.01	0.00
2007	169	781	781	0	24,799,369	18,531,559	0.68	0.00
2008	624	3,273	3,273	1	48,959,070	34,518,662	1.27	0.16
2009	768	4,770	4,770	1	49,079,567	38,452,444	1.56	0.13
2010	677	3,183	3,183	0	47,310,829	37,149,370	1.43	0.00
2011	182	370	370	0	46,194,937	36,492,278	0.39	0.00
2012	13	23	23	0	42,913,176	29,782,174	0.03	0.00
10 day risk window								
2006	2	3	30	0	21,293,774	15,129,438	0.01	0.00
2007	169	781	7,810	0	24,799,369	18,531,559	0.68	0.00
2008	624	3,273	32,730	4	48,959,070	34,518,662	1.27	0.64
2009	768	4,770	47,700	2	49,079,567	38,452,444	1.56	0.26
2010	677	3,183	31,830	1	47,310,829	37,149,370	1.43	0.15
2011	182	370	3,700	0	46,194,937	36,492,278	0.39	0.00
2012	13	23	230	0	42,913,176	29,782,174	0.03	0.00
All Ig								
1 day risk window								
2006	5,026	18,856	18,856	22	21,453,517	15,358,424	23.43	0.44
2007	6,145	23,622	23,622	32	25,053,264	18,820,024	24.53	0.52
2008	13,169	52,571	52,571	80	49,874,176	35,187,280	26.40	0.61
2009	13,362	56,516	56,516	54	49,592,102	39,211,954	26.94	0.40
2010	12,860	51,007	51,007	53	47,795,506	37,845,084	26.91	0.41
2011	13,210	54,133	54,133	55	46,640,096	37,203,204	28.32	0.42
2012	11,727	46,869	46,869	51	43,721,024	31,321,358	26.82	0.43

Table 4. Summary of Incident Ig Use and Hemolysis Events in the MSDD between January 1, 2006 and December 31, 2012, by Drug Product, Risk Window, and Year

	New Users	New Lookup Periods	Lookup Period Duration	New Users with an Event	Eligible Members	Member-Days	New Users/ 100K Eligible Members	% New Users with an Event
All Ig (Continued)								
10 day risk window								
2006	5,026	18,856	188,026	32	21,453,517	15,358,424	23.43	0.64
2007	6,145	23,622	235,750	45	25,053,264	18,820,024	24.53	0.73
2008	13,169	52,571	524,285	102	49,874,176	35,187,280	26.40	0.77
2009	13,362	56,516	563,395	79	49,592,102	39,211,954	26.94	0.59
2010	12,860	51,007	508,646	71	47,795,506	37,845,084	26.91	0.55
2011	13,210	54,133	539,679	75	46,640,096	37,203,204	28.32	0.57
2012	11,727	46,869	465,258	67	43,721,024	31,321,358	26.82	0.57

Appendix A. Exposure and Event Codes

Exposures

Code	Code Type	Description
Lyophilized Codes		
J1566	HCPCS	Injection, immune globulin, intravenous, lyophilized (e.g., powder), 500 mg
Q9941	HCPCS	Injection, immune globulin, intravenous, lyophilized, 1g
Q9942	HCPCS	Injection, immune globulin, intravenous, lyophilized, 10 mg
Non-lyophilized intramuscular codes		
90281	HCPCS	Immune globulin (Ig), human, for intramuscular use
J1460	HCPCS	Injection, gamma globulin, intramuscular, 1 cc
J1470	HCPCS	Injection, gamma globulin, intramuscular, 2 cc
J1480	HCPCS	Injection, gamma globulin, intramuscular, 3 cc
J1490	HCPCS	Injection, gamma globulin, intramuscular, 4 cc
J1500	HCPCS	Injection, gamma globulin, intramuscular, 5 cc
J1510	HCPCS	Injection, gamma globulin, intramuscular, 6 cc
J1520	HCPCS	Injection, gamma globulin, intramuscular, 7 cc
J1530	HCPCS	Injection, gamma globulin, intramuscular, 8 cc
J1540	HCPCS	Injection, gamma globulin, intramuscular, 9 cc
J1550	HCPCS	Injection, gamma globulin, intramuscular, 10 cc
J1560	HCPCS	Injection, gamma globulin, intramuscular, over 10 cc
P9014	HCPCS	Globulin, gamma, 1 mL
Non-lyophilized intravenous codes		
90283	HCPCS	Immune globulin (IgIV), human, for intravenous use
J1563	HCPCS	Injection, immune globulin, intravenous, 1g
J1564	HCPCS	Injection, immune globulin, 10 mg
J1567	HCPCS	Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), 500 mg
J1599	HCPCS	Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified, 500 mg
Q9943	HCPCS	Injection, immune globulin, intravenous, non-lyophilized, 1g
Q9944	HCPCS	Injection, immune globulin, intravenous, non-lyophilized, 10 mg
S9545	HCPCS	Administration of immune globulin, intravenously, in the home setting, including all nursing care, equipment, and supplies; per diem
Non-lyophilized subcutaneous codes		
90284	HCPCS	Immune globulin (SCIg), human, for use in subcutaneous infusions, 100 mg, each
Non-lyophilized unspecified route codes		
90399	HCPCS	Unlisted immune globulin
9914	ICD-9-CM	Injection or infusion of immunoglobulin
Flebogamma		
J1572	HCPCS	Injection, immune globulin (Flebogamma), intravenous, non-lyophilized (e.g., liquid), 500 mg
Q4091	HCPCS	Injection, immune globulin (Flebogamma), intravenous, non-lyophilized, (e.g., liquid), 500 mg

Gammagard

J1569	HCPCS	Injection, immune globulin (Gammagard Liquid), intravenous, non-lyophilized, (e.g., liquid), 500 mg
Q4088	HCPCS	Injection, immune globulin (Gammagard Liquid), intravenous, non-lyophilized, (e.g., liquid), 500 mg

Gammaplex

C9270	HCPCS	Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1557	HCPCS	Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg

Gamunex/Gamunex-C/Gammaked

Q4092	HCPCS	Injection, immune globulin (Gamunex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1561	HCPCS	Injection, immune globulin (Gamunex/Gamunex-C/Gammaked), non-lyophilized (e.g., liquid), 500 mg

Hizentra

J1559	HCPCS	Injection, immune globulin (Hizentra), 100 mg

Octagam

J1568	HCPCS	Injection, immune globulin (Octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
Q4087	HCPCS	Injection, immune globulin (Octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg

Privigen

J1459	HCPCS	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg
Q4097	HCPCS	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg

Vivaglobin

J1562	HCPCS	Injection, immune globulin (Vivaglobin), 100 mg. [Code effective date: 20080101]

Hemolysis Events

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