



## ***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 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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<b>Overview</b>	
<b><u>Request Description</u></b>	<p>FDA has requested execution of Modular Program #9 (MP9), version 1.0, to investigate intravenous immunoglobulin (IVIG) procedure codes in the Mini-Sentinel Distributed Database. See Appendix A for a description of each code included in this request. This involved one run of MP9. The time window for the request is January 1, 2006 – December 31, 2012. The request was distributed to 18 Data Partners on July 29, 2013.</p> <p>Results provide counts of prevalent and incident IVIG patients, total claims, eligible members, and member-years. The request was run against the Mini-Sentinel Distributed Database (MSDD) for the time period of January 1, 2006 - December 31, 2012.</p>
<b><u>Request ID</u></b>	msy4_mpr47_v1
<b><u>Specifications</u></b>	Program parameter inputs and scenarios
<b><u>Glossary</u></b>	List of terms found in this report and their definitions
<b><u>Table 1</u></b>	Table displaying the number of prevalent and incident IVIG patients, new starts, total claims, eligible members, member-years, and number of patients per 100,000 eligible members by code grouping - January 1, 2006 - December 31, 2012.
<b><u>Figure 1</u></b>	A figure displaying the information in the prior tab.
<b><u>Table 2</u></b>	Table displaying the number of prevalent and incident IVIG patients, new starts, total claims, eligible members, member-years, and number of patients per 100,000 eligible members by code grouping, and age group - January 1, 2006 - December 31, 2012.
<b><u>Table 3</u></b>	Table displaying the number of prevalent and incident IVIG patients, new starts, total claims, eligible members, member-years, and number of patients per 100,000 eligible members by code grouping, and sex - January 1, 2006 - December 31, 2012.
<b><u>Table 4</u></b>	Table displaying the number of prevalent and incident IVIG patients, new starts, total claims, eligible members, member-years, and number of patients per 100,000 eligible members by code grouping, and year - January 1, 2006 - December 31, 2012.
<b><u>Appendix A</u></b>	Description of codes included in this request.
<b><u>Notes:</u></b>	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\_MPR47\_v1**

Modular Program #9, version 1.0, was used to investigate prevalence and incidence of IVIG procedure codes. 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: 0-21, 22-44, 45-64, and 65+ years. In total, 14 different scenarios were examined in this report with differing codes to define IVIG procedures. See below for a description of each of these scenarios. Please see Appendix A for a list of codes included in each incident exposure grouping.

Enrollment Gap	45 Days
Age Groups	0-21, 22-44, 45-64, 65+
Query Period	January 1 , 2006 - December 31, 2012

**Drug/Exposure Criteria**

Scenario	Incident exposure	Care Setting	Incident w/ respect to (incidence criteria):	Incident Only Care Setting	Washout (days)	Incidence type
1	Lyophilized Codes	Any	All IVIG Codes	Any	90	Multiple
2	Non-lyophilized intramuscular codes	Any	All IVIG Codes	Any	90	Multiple
3	Non-lyophilized intravenous codes	Any	All IVIG Codes	Any	90	Multiple
4	Non-lyophilized subcutaneous codes	Any	All IVIG Codes	Any	90	Multiple
5	Non-lyophilized unspecified route codes	Any	All IVIG Codes	Any	90	Multiple
6	Flebogamma	Any	All IVIG Codes	Any	90	Multiple
7	Gammagard	Any	All IVIG Codes	Any	90	Multiple
8	Gammaplex	Any	All IVIG Codes	Any	90	Multiple
9	Gamunex/Gamunex-C/Gammaked	Any	All IVIG Codes	Any	90	Multiple
10	Hizentra	Any	All IVIG Codes	Any	90	Multiple
11	Octagam	Any	All IVIG Codes	Any	90	Multiple
12	Privigen	Any	All IVIG Codes	Any	90	Multiple
13	Vivaglobin	Any	All IVIG Codes	Any	90	Multiple
14	All IVIG Codes	Any	All IVIG Codes	Any	90	Multiple

## Glossary of Terms in Modular Program 9\*

**Eligible Members (incidence-based cohort)** - Number of members eligible for incident diagnosis (defined by the washout period) with medical coverage during the query period.

**Eligible Members (prevalence-based cohort)** - Number of members with at least one day of 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** - *Minimum incidence type* will consider the first treatment episode in the query period as long as it is the first treatment episode 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 treatment episode whereas *Multiple* will consider all qualifying incident treatment episodes.

**Member-Years (incidence-based cohort)** - Sum of all years of enrollment with medical coverage in the query period preceded by a washout period.

**Member-Years (prevalence-based cohort)** - Sum of all years members are enrolled with medical coverage during the query period.

**New Patients** - Number of members with incident diagnosis during the query period. Member must have no evidence of diagnosis of interest (defined by incidence criteria) in the prior washout period. A patient may only be counted once in a query period.

**New Starts** - Number of incident diagnoses during the query period. Patient must have no prior diagnoses in the washout period. For a minimum incidence type, an individual may have no more than one new start. For a multiple incidence type, an individual may have more than one new start.

**Query Period** - Period in which the modular program looks for diagnoses of interest.

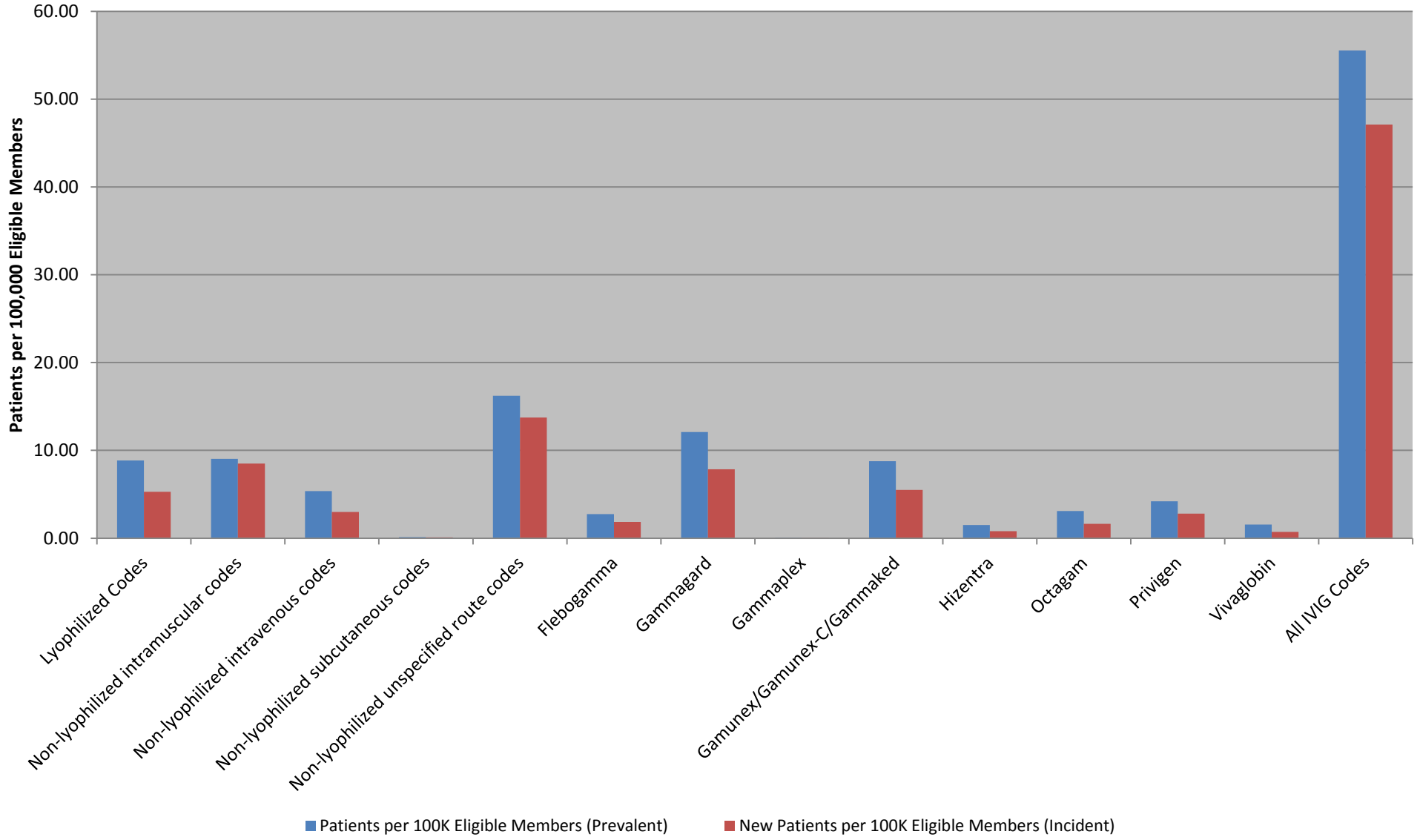
**Washout Period** - Number of days a patient is required to have no evidence of prior diagnosis and continuous medical coverage.

\*all terms may not be used in this report

**Table 1. Summary of IVIG Codes in the MSDD between January 1, 2006 and December 31, 2012, by Code Group**

Group	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Years	Patients per 100K Eligible Members	New Patients	New Claims	Number of Total Claims	Eligible Members	Member-Years	New Patients per 100K Eligible Members
Lyophilized codes	9,005	84,700	101,689,799	239,754,212	8.86	5,005	6,306	33,813	94,644,513	214,953,410	5.29
Non-lyophilized intramuscular codes	9,199	19,001	101,689,799	239,754,212	9.05	8,048	8,742	13,696	94,644,513	214,953,410	8.50
Non-lyophilized intravenous codes	5,462	37,703	101,689,799	239,754,212	5.37	2,835	3,173	12,938	94,644,513	214,953,410	3.00
Non-lyophilized subcutaneous codes	132	717	101,689,799	239,754,212	0.13	94	99	304	94,644,513	214,953,410	0.10
Non-lyophilized unspecified route codes	16,505	27,706	101,689,799	239,754,212	16.23	13,008	14,193	19,989	94,644,513	214,953,410	13.74
Flebogamma	2,783	21,781	101,689,799	239,754,212	2.74	1,765	2,251	10,644	94,644,513	214,953,410	1.86
Gammagard	12,285	127,071	101,689,799	239,754,212	12.08	7,426	9,442	56,624	94,644,513	214,953,410	7.85
Gammaplex	70	328	101,689,799	239,754,212	0.07	33	33	105	94,644,513	214,953,410	0.03
Gamunex/Gamunex-C/Gammaked	8,910	96,006	101,689,799	239,754,212	8.76	5,202	6,619	38,200	94,644,513	214,953,410	5.50
Hizentra	1,525	31,346	101,689,799	239,754,212	1.50	755	852	14,496	94,644,513	214,953,410	0.80
Octagam	3,143	25,288	101,689,799	239,754,212	3.09	1,542	1,824	9,038	94,644,513	214,953,410	1.63
Privigen	4,260	36,062	101,689,799	239,754,212	4.19	2,636	3,205	15,862	94,644,513	214,953,410	2.79
Vivaglobin	1,592	32,279	101,689,799	239,754,212	1.57	686	754	11,638	94,644,513	214,953,410	0.72
All IVIG codes	56,480	539,988	101,689,799	239,754,212	55.54	44,584	56,508	310,500	94,644,513	214,953,410	47.11

Figure 1. Number of Prevalent and Incident IVIG Patients per 100,000 Eligible Members in the MSDD between January 1, 2006 and December 31, 2012 by Code Group



**Table 2. Summary of IVIG Codes in the MSDD between January 1, 2006 and December 31, 2012, by Code Group and Age Group**

Group	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Years	Patients per 100K Eligible Members	New Patients	New Claims	Number of Total Claims	Eligible Members	Member-Years	New Patients per 100K Eligible Members
<b><i>Lyophilized codes</i></b>											
0 to 21 years	1,135	9,064	31,384,520	68,496,147	3.62	584	684	3,491	28,632,288	60,845,825	2.04
22 to 44 years	2,059	18,949	41,541,834	78,453,704	4.96	1,067	1,282	7,407	38,111,881	68,780,009	2.80
45 to 64 years	3,948	38,195	28,677,492	68,685,302	13.77	2,094	2,645	14,287	26,890,851	62,758,506	7.79
65+ years	2,132	18,492	8,414,793	24,119,059	25.34	1,304	1,695	8,213	8,159,694	22,569,069	15.98
<b><i>Non-lyophilized intramuscular codes</i></b>											
0 to 21 years	2,456	3,578	31,384,520	68,496,147	7.83	2,089	2,172	2,723	28,632,288	60,845,825	7.30
22 to 44 years	2,752	4,915	41,541,834	78,453,704	6.62	2,372	2,528	3,560	38,111,881	68,780,009	6.22
45 to 64 years	3,226	8,191	28,677,492	68,685,302	11.25	2,860	3,203	5,770	26,890,851	62,758,506	10.64
65+ years	824	2,317	8,414,793	24,119,059	9.79	751	839	1,527	8,159,694	22,569,069	9.20
<b><i>Non-lyophilized intravenous codes</i></b>											
0 to 21 years	927	6,485	31,384,520	68,496,147	2.95	487	556	2,330	28,632,288	60,845,825	1.70
22 to 44 years	1,322	8,573	41,541,834	78,453,704	3.18	684	739	2,781	38,111,881	68,780,009	1.79
45 to 64 years	2,309	16,404	28,677,492	68,685,302	8.05	1,147	1,287	5,575	26,890,851	62,758,506	4.27
65+ years	1,011	6,241	8,414,793	24,119,059	12.01	526	591	2,050	8,159,694	22,569,069	6.45
<b><i>Non-lyophilized subcutaneous codes</i></b>											
0 to 21 years	21	189	31,384,520	68,496,147	0.07	11	13	92	28,632,288	60,845,825	0.04
22 to 44 years	50	187	41,541,834	78,453,704	0.12	39	39	45	38,111,881	68,780,009	0.10
45 to 64 years	45	324	28,677,492	68,685,302	0.16	28	31	151	26,890,851	62,758,506	0.10
65+ years	17	17	8,414,793	24,119,059	0.20	16	16	16	8,159,694	22,569,069	0.20
<b><i>Non-lyophilized unspecified route codes</i></b>											
0 to 21 years	6,333	10,859	31,384,520	68,496,147	20.18	4,504	4,808	7,295	28,632,288	60,845,825	15.73
22 to 44 years	3,551	5,105	41,541,834	78,453,704	8.55	2,937	3,126	4,032	38,111,881	68,780,009	7.71
45 to 64 years	4,137	7,599	28,677,492	68,685,302	14.43	3,416	3,779	5,365	26,890,851	62,758,506	12.70
65+ years	2,529	4,143	8,414,793	24,119,059	30.05	2,171	2,480	3,275	8,159,694	22,569,069	26.61
<b><i>Flebogamma</i></b>											
0 to 21 years	248	1,425	31,384,520	68,496,147	0.79	140	157	685	28,632,288	60,845,825	0.49
22 to 44 years	514	3,873	41,541,834	78,453,704	1.24	308	382	1,899	38,111,881	68,780,009	0.81
45 to 64 years	1,194	9,489	28,677,492	68,685,302	4.16	738	939	4,460	26,890,851	62,758,506	2.74
65+ years	883	6,994	8,414,793	24,119,059	10.49	589	773	3,423	8,159,694	22,569,069	7.22

**Table 2. Summary of IVIG Codes in the MSDD between January 1, 2006 and December 31, 2012, by Code Group and Age Group**

Group	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Years	Patients per 100K Eligible Members	New Patients	New Claims	Number of Total Claims	Eligible Members	Member-Years	New Patients per 100K Eligible Members
<b><i>Gammagard</i></b>											
0 to 21 years	1,724	15,224	31,384,520	68,496,147	5.49	984	1,167	6,882	28,632,288	60,845,825	3.44
22 to 44 years	2,842	26,670	41,541,834	78,453,704	6.84	1,638	1,956	11,512	38,111,881	68,780,009	4.30
45 to 64 years	5,444	59,745	28,677,492	68,685,302	18.98	3,180	4,080	25,511	26,890,851	62,758,506	11.83
65+ years	2,616	25,432	8,414,793	24,119,059	31.09	1,681	2,239	11,756	8,159,694	22,569,069	20.60
<b><i>Gammaplex</i></b>											
0 to 21 years	2	16	31,384,520	68,496,147	0.01	1	1	1	28,632,288	60,845,825	0.00
22 to 44 years	17	59	41,541,834	78,453,704	0.04	9	9	17	38,111,881	68,780,009	0.02
45 to 64 years	37	202	28,677,492	68,685,302	0.13	14	14	66	26,890,851	62,758,506	0.05
65+ years	15	51	8,414,793	24,119,059	0.18	9	9	21	8,159,694	22,569,069	0.11
<b><i>Gamunex/Gamunex-C/Gammaked</i></b>											
0 to 21 years	1,782	16,380	31,384,520	68,496,147	5.68	1,112	1,405	6,750	28,632,288	60,845,825	3.88
22 to 44 years	1,851	19,098	41,541,834	78,453,704	4.46	991	1,205	6,712	38,111,881	68,780,009	2.60
45 to 64 years	3,803	44,527	28,677,492	68,685,302	13.26	2,097	2,683	16,811	26,890,851	62,758,506	7.80
65+ years	1,750	16,001	8,414,793	24,119,059	20.80	1,045	1,326	7,164	8,159,694	22,569,069	12.81
<b><i>Hizentra</i></b>											
0 to 21 years	400	8,069	31,384,520	68,496,147	1.27	192	218	3,654	28,632,288	60,845,825	0.67
22 to 44 years	389	7,784	41,541,834	78,453,704	0.94	197	220	3,891	38,111,881	68,780,009	0.52
45 to 64 years	634	13,515	28,677,492	68,685,302	2.21	304	342	5,818	26,890,851	62,758,506	1.13
65+ years	142	1,978	8,414,793	24,119,059	1.69	64	72	804	8,159,694	22,569,069	0.78
<b><i>Octagam</i></b>											
0 to 21 years	217	1,559	31,384,520	68,496,147	0.69	83	92	343	28,632,288	60,845,825	0.29
22 to 44 years	705	5,692	41,541,834	78,453,704	1.70	358	404	2,147	38,111,881	68,780,009	0.94
45 to 64 years	1,510	12,232	28,677,492	68,685,302	5.27	684	802	4,294	26,890,851	62,758,506	2.54
65+ years	780	5,805	8,414,793	24,119,059	9.27	431	526	2,153	8,159,694	22,569,069	5.28
<b><i>Privigen</i></b>											
0 to 21 years	453	3,161	31,384,520	68,496,147	1.44	264	318	1,422	28,632,288	60,845,825	0.92
22 to 44 years	956	7,081	41,541,834	78,453,704	2.30	571	661	3,355	38,111,881	68,780,009	1.50
45 to 64 years	1,872	16,760	28,677,492	68,685,302	6.53	1,120	1,346	6,750	26,890,851	62,758,506	4.16
65+ years	1,076	9,060	8,414,793	24,119,059	12.79	704	880	4,108	8,159,694	22,569,069	8.63



**Table 2. Summary of IVIG Codes in the MSDD between January 1, 2006 and December 31, 2012, by Code Group and Age Group**

Group	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Years	Patients per 100K Eligible Members	New Patients	New Claims	Number of Total Claims	Eligible Members	Member-Years	New Patients per 100K Eligible Members
<b><i>Vivaglobin</i></b>											
0 to 21 years	465	9,193	31,384,520	68,496,147	1.48	187	214	3,475	28,632,288	60,845,825	0.65
22 to 44 years	457	8,777	41,541,834	78,453,704	1.10	179	190	2,349	38,111,881	68,780,009	0.47
45 to 64 years	587	11,738	28,677,492	68,685,302	2.05	254	278	4,543	26,890,851	62,758,506	0.94
65+ years	140	2,571	8,414,793	24,119,059	1.66	67	72	975	8,159,694	22,569,069	0.82
<b><i>All IVIG codes</i></b>											
0 to 21 years	13,169	85,202	31,384,520	68,496,147	41.96	9,840	11,533	49,866	28,632,288	60,845,825	34.37
22 to 44 years	13,686	116,763	41,541,834	78,453,704	32.95	10,593	12,537	63,321	38,111,881	68,780,009	27.79
45 to 64 years	20,992	238,921	28,677,492	68,685,302	73.20	16,214	21,073	132,022	26,890,851	62,758,506	60.30
65+ years	10,119	99,102	8,414,793	24,119,059	120.25	8,353	11,365	58,715	8,159,694	22,569,069	102.37

**Table 3. Summary of IVIG Codes in the MSDD between January 1, 2006 and December 31, 2012, by Code Group and Sex**

Group	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Years	Patients per 100K Eligible Members	New Patients	New Claims	Number of Total Claims	Eligible Members	Member-Years	New Patients per 100K Eligible Members
<b><i>Lyophilized codes</i></b>											
Female	4,969	47,324	51,495,612	123,095,065	9.65	2,730	3,437	18,918	48,053,977	110,561,254	5.68
Male	4,036	37,376	50,187,893	116,650,411	8.04	2,275	2,869	14,895	46,585,621	104,384,775	4.88
Unknown	0	0	6,294	8,736	0.00	0	0	0	4,915	7,382	0.00
<b><i>Non-lyophilized intramuscular codes</i></b>											
Female	5,272	12,498	51,495,612	123,095,065	10.24	4,597	5,078	8,572	48,053,977	110,561,254	9.57
Male	3,927	6,503	50,187,893	116,650,411	7.82	3,451	3,664	5,124	46,585,621	104,384,775	7.41
Unknown	0	0	6,294	8,736	0.00	0	0	0	4,915	7,382	0.00
<b><i>Non-lyophilized intravenous codes</i></b>											
Female	2,967	20,073	51,495,612	123,095,065	5.76	1,534	1,714	6,880	48,053,977	110,561,254	3.19
Male	2,495	17,630	50,187,893	116,650,411	4.97	1,301	1,459	6,058	46,585,621	104,384,775	2.79
Unknown	0	0	6,294	8,736	0.00	0	0	0	4,915	7,382	0.00
<b><i>Non-lyophilized subcutaneous codes</i></b>											
Female	92	511	51,495,612	123,095,065	0.18	69	74	255	48,053,977	110,561,254	0.14
Male	40	206	50,187,893	116,650,411	0.08	25	25	49	46,585,621	104,384,775	0.05
Unknown	0	0	6,294	8,736	0.00	0	0	0	4,915	7,382	0.00
<b><i>Non-lyophilized unspecified route codes</i></b>											
Female	8,789	14,480	51,495,612	123,095,065	17.07	6,905	7,588	10,643	48,053,977	110,561,254	14.37
Male	7,714	13,222	50,187,893	116,650,411	15.37	6,101	6,603	9,342	46,585,621	104,384,775	13.10
Unknown	2	4	6,294	8,736	31.78	2	2	4	4,915	7,382	40.69
<b><i>Flebogamma</i></b>											
Female	1,418	10,777	51,495,612	123,095,065	2.75	875	1,148	5,033	48,053,977	110,561,254	1.82
Male	1,365	11,004	50,187,893	116,650,411	2.72	890	1,103	5,611	46,585,621	104,384,775	1.91
Unknown	0	0	6,294	8,736	0.00	0	0	0	4,915	7,382	0.00
<b><i>Gammagard</i></b>											
Female	6,814	72,660	51,495,612	123,095,065	13.23	4,071	5,216	32,814	48,053,977	110,561,254	8.47
Male	5,470	54,408	50,187,893	116,650,411	10.90	3,355	4,226	23,810	46,585,621	104,384,775	7.20
Unknown	1	3	6,294	8,736	15.89	0	0	0	4,915	7,382	0.00

**Table 3. Summary of IVIG Codes in the MSDD between January 1, 2006 and December 31, 2012, by Code Group and Sex**

Group	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Years	Patients per 100K Eligible Members	New Patients	New Claims	Number of Total Claims	Eligible Members	Member-Years	New Patients per 100K Eligible Members
<b><i>Gammaplex</i></b>											
Female	49	226	51,495,612	123,095,065	0.10	26	26	89	48,053,977	110,561,254	0.05
Male	21	102	50,187,893	116,650,411	0.04	7	7	16	46,585,621	104,384,775	0.02
Unknown	0	0	6,294	8,736	0.00	0	0	0	4,915	7,382	0.00
<b><i>Gamunex/Gamunex-C/Gammaked</i></b>											
Female	4,663	51,965	51,495,612	123,095,065	9.06	2,632	3,334	19,581	48,053,977	110,561,254	5.48
Male	4,247	44,041	50,187,893	116,650,411	8.46	2,570	3,285	18,619	46,585,621	104,384,775	5.52
Unknown	0	0	6,294	8,736	0.00	0	0	0	4,915	7,382	0.00
<b><i>Hizentra</i></b>											
Female	950	19,406	51,495,612	123,095,065	1.84	483	549	8,958	48,053,977	110,561,254	1.01
Male	574	11,939	50,187,893	116,650,411	1.14	271	302	5,537	46,585,621	104,384,775	0.58
Unknown	1	1	6,294	8,736	15.89	1	1	1	4,915	7,382	20.35
<b><i>Octagam</i></b>											
Female	1,795	15,390	51,495,612	123,095,065	3.49	888	1,064	5,649	48,053,977	110,561,254	1.85
Male	1,348	9,898	50,187,893	116,650,411	2.69	654	760	3,389	46,585,621	104,384,775	1.40
Unknown	0	0	6,294	8,736	0.00	0	0	0	4,915	7,382	0.00
<b><i>Privigen</i></b>											
Female	2,351	19,903	51,495,612	123,095,065	4.57	1,425	1,714	8,748	48,053,977	110,561,254	2.97
Male	1,909	16,159	50,187,893	116,650,411	3.80	1,211	1,491	7,114	46,585,621	104,384,775	2.60
Unknown	0	0	6,294	8,736	0.00	0	0	0	4,915	7,382	0.00
<b><i>Vivaglobin</i></b>											
Female	964	19,664	51,495,612	123,095,065	1.87	426	463	7,165	48,053,977	110,561,254	0.89
Male	628	12,615	50,187,893	116,650,411	1.25	260	291	4,473	46,585,621	104,384,775	0.56
Unknown	0	0	6,294	8,736	0.00	0	0	0	4,915	7,382	0.00
<b><i>All IVIG codes</i></b>											
Female	30,816	304,877	51,495,612	123,095,065	59.84	24,284	30,863	175,831	48,053,977	110,561,254	50.53
Male	25,662	235,103	50,187,893	116,650,411	51.13	20,298	25,642	134,661	46,585,621	104,384,775	43.57
Unknown	2	8	6,294	8,736	31.78	2	3	8	4,915	7,382	40.69

Table 4. Summary of IVIG Codes in the MSDD between January 1, 2006 and December 31, 2012, by Code Group and Year

Group	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Years	Patients per 100K Eligible Members	New Patients	New Claims	Number of Total Claims	Eligible Members	Member-Years	New Patients per 100K Eligible Members
<b><i>Lyophilized codes</i></b>											
2006	8,416	11,931	229,698,542	19,040,069	3.66	772	772	1,211	187,011,667	15,358,686	0.41
2007	9,168	12,555	251,136,146	20,827,386	3.65	977	977	1,415	231,759,698	18,820,386	0.42
2008	15,274	21,026	516,864,309	42,949,263	2.96	1,432	1,432	2,110	449,374,269	35,188,283	0.32
2009	11,594	15,682	509,909,480	42,278,953	2.27	1,231	1,231	1,839	478,192,977	39,213,184	0.26
2010	7,358	9,910	492,443,661	40,839,829	1.49	841	841	1,258	461,553,354	37,846,304	0.18
2011	6,316	8,507	483,081,425	40,062,561	1.31	643	643	974	453,570,289	37,204,312	0.14
2012	3,846	5,089	406,718,712	33,756,151	0.95	410	410	572	384,514,635	31,322,255	0.11
<b><i>Non-lyophilized intramuscular codes</i></b>											
2006	2,671	2,935	229,698,542	19,040,069	1.16	1,335	1,335	1,362	187,011,667	15,358,686	0.71
2007	2,267	2,546	251,136,146	20,827,386	0.90	1,596	1,596	1,630	231,759,698	18,820,386	0.69
2008	3,518	4,445	516,864,309	42,949,263	0.68	1,746	1,746	1,828	449,374,269	35,188,283	0.39
2009	2,606	3,011	509,909,480	42,278,953	0.51	1,425	1,425	1,502	478,192,977	39,213,184	0.30
2010	2,298	2,747	492,443,661	40,839,829	0.47	1,272	1,272	1,348	461,553,354	37,846,304	0.28
2011	1,541	2,011	483,081,425	40,062,561	0.32	813	813	896	453,570,289	37,204,312	0.18
2012	1,026	1,306	406,718,712	33,756,151	0.25	555	555	662	384,514,635	31,322,255	0.14
<b><i>Non-lyophilized intravenous codes</i></b>											
2006	12,844	18,112	229,698,542	19,040,069	5.59	1,228	1,228	1,771	187,011,667	15,358,686	0.66
2007	10,770	14,868	251,136,146	20,827,386	4.29	1,141	1,141	1,610	231,759,698	18,820,386	0.49
2008	935	1,234	516,864,309	42,949,263	0.18	247	247	309	449,374,269	35,188,283	0.05
2009	691	993	509,909,480	42,278,953	0.14	194	194	270	478,192,977	39,213,184	0.04
2010	422	641	492,443,661	40,839,829	0.09	123	123	187	461,553,354	37,846,304	0.03
2011	829	1,237	483,081,425	40,062,561	0.17	168	168	256	453,570,289	37,204,312	0.04
2012	393	618	406,718,712	33,756,151	0.10	72	72	94	384,514,635	31,322,255	0.02

Table 4. Summary of IVIG Codes in the MSDD between January 1, 2006 and December 31, 2012, by Code Group and Year

Group	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Years	Patients per 100K Eligible Members	New Patients	New Claims	Number of Total Claims	Eligible Members	Member-Years	New Patients per 100K Eligible Members
<b><i>Non-lyophilized subcutaneous codes</i></b>											
2006	0	0	229,698,542	19,040,069	0.00	0	0	0	187,011,667	15,358,686	0.00
2007	1	1	251,136,146	20,827,386	0.00	0	0	0	231,759,698	18,820,386	0.00
2008	47	77	516,864,309	42,949,263	0.01	21	21	24	449,374,269	35,188,283	0.00
2009	73	114	509,909,480	42,278,953	0.01	20	20	20	478,192,977	39,213,184	0.00
2010	128	236	492,443,661	40,839,829	0.03	29	29	40	461,553,354	37,846,304	0.01
2011	101	161	483,081,425	40,062,561	0.02	17	17	21	453,570,289	37,204,312	0.00
2012	93	128	406,718,712	33,756,151	0.02	12	12	15	384,514,635	31,322,255	0.00
<b><i>Non-lyophilized unspecified route codes</i></b>											
2006	2,256	2,583	229,698,542	19,040,069	0.98	859	859	937	187,011,667	15,358,686	0.46
2007	2,407	2,714	251,136,146	20,827,386	0.96	1,112	1,112	1,196	231,759,698	18,820,386	0.48
2008	5,236	5,932	516,864,309	42,949,263	1.01	2,472	2,472	2,711	449,374,269	35,188,283	0.55
2009	4,583	5,071	509,909,480	42,278,953	0.90	2,720	2,720	2,929	478,192,977	39,213,184	0.57
2010	3,916	4,287	492,443,661	40,839,829	0.80	2,493	2,493	2,642	461,553,354	37,846,304	0.54
2011	4,059	4,415	483,081,425	40,062,561	0.84	2,617	2,617	2,788	453,570,289	37,204,312	0.58
2012	2,570	2,704	406,718,712	33,756,151	0.63	1,920	1,920	1,999	384,514,635	31,322,255	0.50
<b><i>Flebogamma</i></b>											
2006	0	0	229,698,542	19,040,069	0.00	0	0	0	187,011,667	15,358,686	0.00
2007	530	670	251,136,146	20,827,386	0.21	82	82	108	231,759,698	18,820,386	0.04
2008	2,422	3,296	516,864,309	42,949,263	0.47	328	328	471	449,374,269	35,188,283	0.07
2009	3,076	4,295	509,909,480	42,278,953	0.60	470	470	732	478,192,977	39,213,184	0.10
2010	3,184	4,385	492,443,661	40,839,829	0.65	457	457	719	461,553,354	37,846,304	0.10
2011	3,662	5,407	483,081,425	40,062,561	0.76	490	490	736	453,570,289	37,204,312	0.11
2012	2,689	3,728	406,718,712	33,756,151	0.66	424	424	641	384,514,635	31,322,255	0.11

Table 4. Summary of IVIG Codes in the MSDD between January 1, 2006 and December 31, 2012, by Code Group and Year

Group	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Years	Patients per 100K Eligible Members	New Patients	New Claims	Number of Total Claims	Eligible Members	Member-Years	New Patients per 100K Eligible Members
<b>Gammagard</b>											
2006	27	56	229,698,542	19,040,069	0.01	6	6	14	187,011,667	15,358,686	0.00
2007	1,900	2,739	251,136,146	20,827,386	0.76	190	190	301	231,759,698	18,820,386	0.08
2008	15,806	22,238	516,864,309	42,949,263	3.06	1,485	1,485	2,258	449,374,269	35,188,283	0.33
2009	17,726	24,111	509,909,480	42,278,953	3.48	1,769	1,769	2,597	478,192,977	39,213,184	0.37
2010	18,151	24,496	492,443,661	40,839,829	3.69	1,889	1,889	2,731	461,553,354	37,846,304	0.41
2011	21,284	28,977	483,081,425	40,062,561	4.41	2,145	2,145	3,047	453,570,289	37,204,312	0.47
2012	17,917	24,454	406,718,712	33,756,151	4.41	1,958	1,958	2,746	384,514,635	31,322,255	0.51
<b>Gammalex</b>											
2006	0	0	229,698,542	19,040,069	0.00	0	0	0	187,011,667	15,358,686	0.00
2007	0	0	251,136,146	20,827,386	0.00	0	0	0	231,759,698	18,820,386	0.00
2008	0	0	516,864,309	42,949,263	0.00	0	0	0	449,374,269	35,188,283	0.00
2009	0	0	509,909,480	42,278,953	0.00	0	0	0	478,192,977	39,213,184	0.00
2010	2	2	492,443,661	40,839,829	0.00	0	0	0	461,553,354	37,846,304	0.00
2011	18	24	483,081,425	40,062,561	0.00	4	4	4	453,570,289	37,204,312	0.00
2012	211	302	406,718,712	33,756,151	0.05	29	29	49	384,514,635	31,322,255	0.01
<b>Gamunex/Gamunex-C/Gammaked</b>											
2006	3	3	229,698,542	19,040,069	0.00	1	1	1	187,011,667	15,358,686	0.00
2007	2,223	3,061	251,136,146	20,827,386	0.89	203	203	302	231,759,698	18,820,386	0.09
2008	12,784	17,448	516,864,309	42,949,263	2.47	1,071	1,071	1,543	449,374,269	35,188,283	0.24
2009	13,877	19,236	509,909,480	42,278,953	2.72	1,282	1,282	1,953	478,192,977	39,213,184	0.27
2010	13,533	19,063	492,443,661	40,839,829	2.75	1,475	1,475	2,204	461,553,354	37,846,304	0.32
2011	14,223	20,239	483,081,425	40,062,561	2.94	1,385	1,385	2,081	453,570,289	37,204,312	0.31
2012	11,963	16,956	406,718,712	33,756,151	2.94	1,202	1,202	1,815	384,514,635	31,322,255	0.31

Table 4. Summary of IVIG Codes in the MSDD between January 1, 2006 and December 31, 2012, by Code Group and Year

Group	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Years	Patients per 100K Eligible Members	New Patients	New Claims	Number of Total Claims	Eligible Members	Member-Years	New Patients per 100K Eligible Members
<b>Hizentra</b>											
2006	0	0	229,698,542	19,040,069	0.00	0	0	0	187,011,667	15,358,686	0.00
2007	0	0	251,136,146	20,827,386	0.00	0	0	0	231,759,698	18,820,386	0.00
2008	0	0	516,864,309	42,949,263	0.00	0	0	0	449,374,269	35,188,283	0.00
2009	0	0	509,909,480	42,278,953	0.00	0	0	0	478,192,977	39,213,184	0.00
2010	8	8	492,443,661	40,839,829	0.00	2	2	2	461,553,354	37,846,304	0.00
2011	7,638	17,462	483,081,425	40,062,561	1.58	573	573	1,099	453,570,289	37,204,312	0.13
2012	6,809	13,876	406,718,712	33,756,151	1.67	277	277	430	384,514,635	31,322,255	0.07
<b>Octagam</b>											
2006	0	0	229,698,542	19,040,069	0.00	0	0	0	187,011,667	15,358,686	0.00
2007	716	905	251,136,146	20,827,386	0.29	79	79	111	231,759,698	18,820,386	0.03
2008	5,660	8,080	516,864,309	42,949,263	1.10	525	525	816	449,374,269	35,188,283	0.12
2009	5,895	7,921	509,909,480	42,278,953	1.16	486	486	798	478,192,977	39,213,184	0.10
2010	3,640	4,577	492,443,661	40,839,829	0.74	335	335	466	461,553,354	37,846,304	0.07
2011	329	394	483,081,425	40,062,561	0.07	53	53	71	453,570,289	37,204,312	0.01
2012	2,455	3,411	406,718,712	33,756,151	0.60	346	346	506	384,514,635	31,322,255	0.09
<b>Privigen</b>											
2006	0	0	229,698,542	19,040,069	0.00	0	0	0	187,011,667	15,358,686	0.00
2007	1	1	251,136,146	20,827,386	0.00	1	1	1	231,759,698	18,820,386	0.00
2008	1,470	2,279	516,864,309	42,949,263	0.28	174	174	292	449,374,269	35,188,283	0.04
2009	3,266	4,632	509,909,480	42,278,953	0.64	386	386	595	478,192,977	39,213,184	0.08
2010	5,749	8,091	492,443,661	40,839,829	1.17	682	682	1,066	461,553,354	37,846,304	0.15
2011	7,933	10,951	483,081,425	40,062,561	1.64	996	996	1,465	453,570,289	37,204,312	0.22
2012	7,519	10,108	406,718,712	33,756,151	1.85	966	966	1,414	384,514,635	31,322,255	0.25

Table 4. Summary of IVIG Codes in the MSDD between January 1, 2006 and December 31, 2012, by Code Group and Year

Group	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Years	Patients per 100K Eligible Members	New Patients	New Claims	Number of Total Claims	Eligible Members	Member-Years	New Patients per 100K Eligible Members
<b><i>Vivaglobin</i></b>											
2006	4	5	229,698,542	19,040,069	0.00	1	1	2	187,011,667	15,358,686	0.00
2007	993	1,512	251,136,146	20,827,386	0.40	96	96	141	231,759,698	18,820,386	0.04
2008	4,420	7,741	516,864,309	42,949,263	0.86	221	221	319	449,374,269	35,188,283	0.05
2009	6,243	10,408	509,909,480	42,278,953	1.22	233	233	360	478,192,977	39,213,184	0.05
2010	5,203	11,073	492,443,661	40,839,829	1.06	166	166	272	461,553,354	37,846,304	0.04
2011	744	1,510	483,081,425	40,062,561	0.15	27	27	51	453,570,289	37,204,312	0.01
2012	24	30	406,718,712	33,756,151	0.01	10	10	15	384,514,635	31,322,255	0.00
<b><i>All IVIG codes</i></b>											
2006	25,311	35,625	229,698,542	19,040,069	11.02	4,136	4,136	5,371	187,011,667	15,358,686	2.21
2007	29,883	41,572	251,136,146	20,827,386	11.90	5,391	5,391	6,926	231,759,698	18,820,386	2.33
2008	65,427	93,796	516,864,309	42,949,263	12.66	9,542	9,542	12,903	449,374,269	35,188,283	2.12
2009	67,915	95,474	509,909,480	42,278,953	13.32	10,025	10,025	13,840	478,192,977	39,213,184	2.10
2010	62,244	89,516	492,443,661	40,839,829	12.64	9,573	9,573	13,139	461,553,354	37,846,304	2.07
2011	67,229	101,295	483,081,425	40,062,561	13.92	9,783	9,783	13,679	453,570,289	37,204,312	2.16
2012	56,502	82,710	406,718,712	33,756,151	13.89	8,058	8,058	11,107	384,514,635	31,322,255	2.10



**Appendix A. List of Codes included in this Request**

Code	Code Type	Description
<b>Lyophilized Codes</b>		
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
<b>Non-lyophilized intramuscular codes</b>		
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
<b>Non-lyophilized intravenous codes</b>		
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
<b>Non-lyophilized subcutaneous codes</b>		
90284	HCPCS	Immune globulin (SCIg), human, for use in subcutaneous infusions, 100 mg, each
<b>Non-lyophilized unspecified route codes</b>		
90399	HCPCS	Unlisted immune globulin
9914	ICD-9-CM	Injection or infusion of immunoglobulin
<b>Flebogamma</b>		
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]