



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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Overview

Request Description

FDA has requested execution of Modular Program #3 (MP3), version 6.0, to investigate use of immunoglobulin products (see Appendix A for products and codes) and subsequent diagnosis of hemolysis (see Appendix B for codes) among patients with certain pre-existing conditions (see Appendix C for pre-existing conditions and codes). This involved one run of MP3. The query was run against the Mini-Sentinel Distributed Database (MSDD) for the time period of January 1, 2006 to December 31, 2012. The request was distributed to 18 Data Partners on October 4, 2013.

Results provide counts of new immunoglobulin users, dispensings, total days supplied, eligible members (patients with the pre-existing condition of interest), member-years for patients, and number of hemolysis events. In total, 14 scenarios were examined (7 pre-existing condition groups and 2 exposure extension periods). Please see the Specifications for more details on each scenario.

Request ID

msy5_mpr02_v1, Report 1 of 1

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, Years at Risk, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and events per 1,000 Years at Risk by Pre-Existing Condition and Exposure Extension Period between January 1, 2006 and December 31, 2012

Table 2

Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Years at Risk, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and events per 1,000 Years at Risk by Pre-Existing Condition, Exposure Extension Period, and Age Group between January 1, 2006 and December 31, 2012

Table 3

Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Years at Risk, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and events per 1,000 Years at Risk by Pre-Existing Condition, Exposure Extension Period, and Sex between January 1, 2006 and December 31, 2012

Table 4

Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Years at Risk, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and events per 1,000 Years at Risk by Pre-Existing Condition, Exposure Extension Period, and Year between January 1, 2006 and December 31, 2012

Appendix A

Table of Procedure Codes for Immunoglobulin Use.

Appendix B

Table of International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes for Hemolysis Events.

Appendix C

Table of ICD-9 Diagnosis Codes for Pre-Existing Conditions.

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 MSY5_MPR02_V1

Modular Program #3, version 6.0 will be used to investigate hemolysis events (see Appendix A) following new use of several IVIg products among patients with several pre-existing conditions, including primary immune deficiency, chronic inflammatory demyelinating polyneuropathy (CIDP), Kawasaki Disease, idiopathic thrombocytopenic purpura (ITP), Guillain-Barre syndrome (GBS), and myasthenia gravis. An additional scenario will not restrict the cohort to a pre-existing condition. The query period was from January 01, 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. In total, 14 different scenarios will be examined in this report with differing pre-existing condition cohorts and episode 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	90
Age Stratifications	0-17, 18 - 44, 45-64, 65+
Minimum Days Supplied and Minimum Episode Duration	0 Days

Scenario	Pre-Existing Condition				Drug/Exposure						Event/Outcome						
	Pre-Existing Condition	Inclusion/Exclusion	Lookback Start	Lookback End	Care Setting PDX	Incident exposure	Incident w/ respect to:	Episode Gap	Episode Extension Period	Washout t (days)	Incidence Type*	Event/Outcome	Incident w/ respect to:	Washout (days)	Incidence Type**	Care Setting PDX	Blackout Period
1	Primary immune deficiency	Include	-90	7	IP*, ED*, OA*, AV*	All Specified IVIg	All Specified IVIg	2	3	20	Multiple	Hemolysis	Hemolysis	90	Multiple	IP*, ED*, OA*, AV*	0
2	CIDP	Include	-90	7	IP*, ED*, OA*, AV*	All Specified IVIg	All Specified IVIg	2	3	20	Multiple	Hemolysis	Hemolysis	90	Multiple	IP*, ED*, OA*, AV*	0
3	Kawasaki Disease	Include	-14	7	IP*, ED*, OA*, AV*	All Specified IVIg	All Specified IVIg	2	3	20	Multiple	Hemolysis	Hemolysis	90	Multiple	IP*, ED*, OA*, AV*	0
4	ITP	Include	-14	7	IP*, ED*, OA*, AV*	All Specified IVIg	All Specified IVIg	2	3	20	Multiple	Hemolysis	Hemolysis	90	Multiple	IP*, ED*, OA*, AV*	0
5	Myasthenia gravis	Include	-14	7	IP*, ED*, OA*, AV*	All Specified IVIg	All Specified IVIg	2	3	20	Multiple	Hemolysis	Hemolysis	90	Multiple	IP*, ED*, OA*, AV*	0
6	GBS	Include	-14	7	IP*, ED*, OA*, AV*	All Specified IVIg	All Specified IVIg	2	3	20	Multiple	Hemolysis	Hemolysis	90	Multiple	IP*, ED*, OA*, AV*	0
7	None	NA	NA	NA	NA	All Specified IVIg	All Specified IVIg	2	3	20	Multiple	Hemolysis	Hemolysis	90	Multiple	IP*, ED*, OA*, AV*	0

Modular Program Specifications MSY5_MPR02_V1

Scenario	Pre-Existing Condition					Drug/Exposure						Event/Outcome					
	Pre-Existing Condition	Inclusion/Exclusion	Lookback Start	Lookback End	Care Setting	Incident exposure	Incident w/ respect to:	Episode Gap	Extension Period	Washout t (days)	Incidence Type*	Event/Outcome	Incident w/ respect to:	Washout (days)	Incidence Type**	Care Setting	Blackout Period
					PDX											PDX	
8	Primary immune deficiency	Include	-90	7	IP*, ED*, OA*, AV*	All Specified	All Specified	2	10	20	Multiple	Hemolysis	Hemolysis	90	Multiple	IP*, ED*, OA*, AV*	0
9	CIDP	Include	-90	7	IP*, ED*, OA*, AV*	All Specified	All Specified	2	10	20	Multiple	Hemolysis	Hemolysis	90	Multiple	IP*, ED*, OA*, AV*	0
10	Kawasaki Disease	Include	-14	7	IP*, ED*, OA*, AV*	All Specified	All Specified	2	10	20	Multiple	Hemolysis	Hemolysis	90	Multiple	IP*, ED*, OA*, AV*	0
11	ITP	Include	-14	7	IP*, ED*, OA*, AV*	All Specified	All Specified	2	10	20	Multiple	Hemolysis	Hemolysis	90	Multiple	IP*, ED*, OA*, AV*	0
12	Myasthenia gravis	Include	-14	7	IP*, ED*, OA*, AV*	All Specified	All Specified	2	10	20	Multiple	Hemolysis	Hemolysis	90	Multiple	IP*, ED*, OA*, AV*	0
13	GBS	Include	-14	7	IP*, ED*, OA*, AV*	All Specified	All Specified	2	10	20	Multiple	Hemolysis	Hemolysis	90	Multiple	IP*, ED*, OA*, AV*	0
14	None	NA	NA	NA	NA	All Specified	All Specified	2	10	20	Multiple	Hemolysis	Hemolysis	90	Multiple	IP*, ED*, OA*, AV*	0

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

*Multiple incidence type for the exposure will consider all incident episodes for each user during the query period that satisfies the Washout Period criteria.

**Multiple incidence type for the event will only consider the first event for each episode that satisfies the Washout Period criteria of 90 days, but there can be more than one event per user since the Mult exposure incidence type will allow for more than one episode.

Glossary of Terms in Modular Program 3*

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 Ambulatory Visit (OA).

Days at Risk - number of days supplied plus any episode gaps and exposure extension periods.

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 Days - irrespective of what query incidence type (WASHTYP) is specified, this is an optional parameter to further restrict the number of days of continuous enrollment prior to start of new incident treatment episode to reach a certain minimum. This parameter is used to ensure that appropriate enrollment requirements are met. Since at least washout period days of enrollment must be found prior to index date this minimum enrollment days requirement can only be binding if enrollment days > washout period days.

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled" sequence.

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode.

Incidence Type (drug/exposure)- *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.

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 treatment episodes. The program will only consider one event per episode, but the *Multiple incidence type* will consider more than one event per user if a user has more than one incident 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-Days - sum of all days of enrollment with medical and drug coverage** in the query period preceded by an exposure washout period.

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 bridged by the episode gap).

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.

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 looks for exposures and outcomes of interest.

Total Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

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 Immunoglobulin Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Pre-Existing Condition and Exposure Extension Period

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 1K Years at Risk
CIDP													
3 day exposure extension	4,212	31,822	43,380	43,380	385.0	1	18,537	10,453.4	227.22	10.30	10.30	1.00	2.60
10 day exposure extension	4,212	31,822	43,380	43,380	977.5	2	18,537	10,453.4	227.22	10.30	10.30	1.00	2.05
GBS													
3 day exposure extension	2,013	4,178	5,598	5,598	50.4	8	22,548	3,730.2	89.28	2.78	2.78	1.00	158.77
10 day exposure extension	2,013	4,178	5,598	5,598	127.9	9	22,548	3,730.2	89.28	2.78	2.78	1.00	70.38
ITP													
3 day exposure extension	7,433	13,867	17,510	17,510	163.3	143	693,233	99,443.9	10.72	2.36	2.36	1.00	875.63
10 day exposure extension	7,433	13,867	17,510	17,510	417.9	174	693,233	99,443.9	10.72	2.36	2.36	1.00	416.41
Kawasaki Disease													
3 day exposure extension	1,391	1,409	1,426	1,426	15.4	14	11,451	1,382.5	121.47	1.03	1.03	1.00	908.91
10 day exposure extension	1,391	1,409	1,426	1,426	41.8	15	11,451	1,382.5	121.47	1.03	1.03	1.00	358.96
Myasthenia gravis													
3 day exposure extension	2,047	11,014	14,816	14,816	132.7	7	55,053	14,283.1	37.18	7.24	7.24	1.00	52.75
10 day exposure extension	2,047	11,014	14,816	14,816	337.3	11	55,053	14,283.1	37.18	7.24	7.24	1.00	32.61
PID													
3 day exposure extension	16,709	187,534	191,927	191,927	2,065.7	110	284,527	129,490.8	58.73	11.49	11.49	1.00	53.25
10 day exposure extension	16,709	187,534	191,927	191,927	5,618.8	155	284,527	129,490.8	58.73	11.49	11.49	1.00	27.59
No Pre-Existing Criteria													
3 day exposure extension	49,745	307,991	343,833	343,833	3,483.3	388	96,306,654	220,975,457.9	0.52	6.91	6.91	1.00	111.39
10 day exposure extension	49,745	307,991	343,833	343,833	9,284.4	473	96,306,654	220,975,457.9	0.52	6.91	6.91	1.00	50.95

Table 2: Summary of Incident Immunoglobulin Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Pre-Existing Condition, Exposure Extension Period, and Age Group

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 1K Years at Risk
CIDP													
3 day exposure extension													
0 to 17 Years	114	824	907	907	9.3	0	349	178.2	326.65	7.96	7.96	1.00	0.00
18 to 44 Years	870	5,658	7,860	7,860	68.9	0	3,617	1,576.3	240.53	9.03	9.03	1.00	0.00
45 to 64 Years	2,233	17,731	23,662	23,662	213.0	0	9,011	5,063.6	247.81	10.60	10.60	1.00	0.00
65+ Years	1,166	7,609	10,951	10,951	93.8	1	6,174	3,635.2	188.86	9.39	9.39	1.00	10.66
10 day exposure extension													
0 to 17 Years	114	824	907	907	24.8	0	349	178.2	326.65	7.96	7.96	1.00	0.00
18 to 44 Years	870	5,658	7,860	7,860	173.9	0	3,617	1,576.3	240.53	9.03	9.03	1.00	0.00
45 to 64 Years	2,233	17,731	23,662	23,662	543.2	0	9,011	5,063.6	247.81	10.60	10.60	1.00	0.00
65+ Years	1,166	7,609	10,951	10,951	235.6	2	6,174	3,635.2	188.86	9.39	9.39	1.00	8.49
GBS													
3 day exposure extension													
0 to 17 Years	194	309	327	327	3.5	1	1,132	186.3	171.38	1.69	1.69	1.00	287.60
18 to 44 Years	591	1,232	1,596	1,596	14.7	3	5,595	809.0	105.63	2.70	2.70	1.00	203.71
45 to 64 Years	840	1,703	2,457	2,457	21.1	0	9,482	1,586.0	88.59	2.93	2.93	1.00	0.00
65+ Years	406	934	1,218	1,218	11.1	4	6,749	1,148.8	60.16	3.00	3.00	1.00	360.83
10 day exposure extension													
0 to 17 Years	194	309	327	327	9.3	1	1,132	186.3	171.38	1.69	1.69	1.00	108.09
18 to 44 Years	591	1,232	1,596	1,596	37.6	3	5,595	809.0	105.63	2.70	2.70	1.00	79.87
45 to 64 Years	840	1,703	2,457	2,457	52.6	0	9,482	1,586.0	88.59	2.93	2.93	1.00	0.00
65+ Years	406	934	1,218	1,218	28.5	5	6,749	1,148.8	60.16	3.00	3.00	1.00	175.33
ITP													
3 day exposure extension													
0 to 17 Years	1,649	2,707	2,817	2,817	29.7	30	39,455	5,246.3	41.79	1.71	1.71	1.00	1009.07
18 to 44 Years	1,756	3,138	4,154	4,154	37.7	45	146,828	18,678.7	11.96	2.37	2.37	1.00	1193.89
45 to 64 Years	2,246	4,519	6,002	6,002	54.4	34	245,493	34,660.2	9.15	2.67	2.67	1.00	624.55
65+ Years	1,848	3,503	4,537	4,537	41.4	34	271,727	40,858.7	6.80	2.46	2.46	1.00	820.30

Table 2: Summary of Incident Immunoglobulin Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Pre-Existing Condition, Exposure Extension Period, and Age Group

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 1K Years at Risk
ITP (continued)													
10 day exposure extension													
0 to 17 Years	1,649	2,707	2,817	2,817	79.9	34	39,455	5,246.3	41.79	1.71	1.71	1.00	425.67
18 to 44 Years	1,756	3,138	4,154	4,154	94.2	53	146,828	18,678.7	11.96	2.37	2.37	1.00	562.81
45 to 64 Years	2,246	4,519	6,002	6,002	137.4	45	245,493	34,660.2	9.15	2.67	2.67	1.00	327.60
65+ Years	1,848	3,503	4,537	4,537	106.5	42	271,727	40,858.7	6.80	2.46	2.46	1.00	394.54
Kawasaki Disease													
3 day exposure extension													
0 to 17 Years	1,382	1,400	1,417	1,417	15.3	14	9,459	1,185.4	146.10	1.03	1.03	1.00	914.76
18 to 44 Years	6	6	6	6	0.1	0	1,405	139.6	4.27	1.00	1.00	1.00	0.00
45 to 64 Years	2	2	2	2	0.0	0	445	39.4	4.49	1.00	1.00	1.00	0.00
65+ Years	1	1	1	1	0.0	0	244	18.1	4.10	1.00	1.00	1.00	0.00
10 day exposure extension													
0 to 17 Years	1,382	1,400	1,417	1,417	41.5	15	9,459	1,185.4	146.10	1.03	1.03	1.00	361.30
18 to 44 Years	6	6	6	6	0.2	0	1,405	139.6	4.27	1.00	1.00	1.00	0.00
45 to 64 Years	2	2	2	2	0.1	0	445	39.4	4.49	1.00	1.00	1.00	0.00
65+ Years	1	1	1	1	0.0	0	244	18.1	4.10	1.00	1.00	1.00	0.00
Myasthenia gravis													
3 day exposure extension													
0 to 17 Years	76	278	326	326	3.2	0	6,329	1,283.3	12.01	4.29	4.29	1.00	0.00
18 to 44 Years	503	2,798	3,483	3,483	32.9	1	11,396	2,245.8	44.14	6.92	6.92	1.00	30.43
45 to 64 Years	896	5,166	6,842	6,842	61.9	5	21,174	4,951.4	42.32	7.64	7.64	1.00	80.79
65+ Years	628	2,772	4,165	4,165	34.7	1	17,540	5,802.5	35.80	6.63	6.63	1.00	28.78
10 day exposure extension													
0 to 17 Years	76	278	326	326	8.4	0	6,329	1,283.3	12.01	4.29	4.29	1.00	0.00
18 to 44 Years	503	2,798	3,483	3,483	84.7	2	11,396	2,245.8	44.14	6.92	6.92	1.00	23.60
45 to 64 Years	896	5,166	6,842	6,842	157.6	8	21,174	4,951.4	42.32	7.64	7.64	1.00	50.75
65+ Years	628	2,772	4,165	4,165	86.5	1	17,540	5,802.5	35.80	6.63	6.63	1.00	11.56

Table 2: Summary of Incident Immunoglobulin Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Pre-Existing Condition, Exposure Extension Period, and Age Group

	New Users	New Episodes	New Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 1K Years at Risk
PID													
3 day exposure extension													
0 to 17 Years	2,543	25,161	25,757	25,757	277.1	26	51,441	24,169.5	49.44	10.13	10.13	1.00	93.84
18 to 44 Years	3,989	42,054	42,987	42,987	463.0	24	92,436	36,529.7	43.15	10.78	10.78	1.00	51.83
45 to 64 Years	7,266	80,746	82,685	82,685	889.7	29	108,077	50,123.4	67.23	11.38	11.38	1.00	32.59
65+ Years	3,704	39,573	40,498	40,498	435.9	31	39,984	18,668.2	92.64	10.93	10.93	1.00	71.12
10 day exposure extension													
0 to 17 Years	2,543	25,161	25,757	25,757	753.4	33	51,441	24,169.5	49.44	10.13	10.13	1.00	43.80
18 to 44 Years	3,989	42,054	42,987	42,987	1,258.5	32	92,436	36,529.7	43.15	10.78	10.78	1.00	25.43
45 to 64 Years	7,266	80,746	82,685	82,685	2,418.5	48	108,077	50,123.4	67.23	11.38	11.38	1.00	19.85
65+ Years	3,704	39,573	40,498	40,498	1,188.4	42	39,984	18,668.2	92.64	10.93	10.93	1.00	35.34
No Pre-Existing Criteria													
3 day exposure extension													
0 to 17 Years	9,420	40,075	41,308	41,308	441.9	77	23,738,645	50,620,185.7	0.40	4.39	4.39	1.00	174.23
18 to 44 Years	13,499	70,621	79,099	79,099	800.3	88	44,701,876	82,579,319.7	0.30	5.86	5.86	1.00	109.96
45 to 64 Years	18,889	133,778	151,481	151,481	1,520.0	113	27,381,698	64,617,573.1	0.69	8.02	8.02	1.00	74.34
65+ Years	9,266	63,517	71,945	71,945	721.1	110	8,252,019	23,158,379.4	1.12	7.76	7.76	1.00	152.55
10 day exposure extension													
0 to 17 Years	9,420	40,075	41,308	41,308	1,198.7	90	23,738,645	50,620,185.7	0.40	4.39	4.39	1.00	75.08
18 to 44 Years	13,499	70,621	79,099	79,099	2,125.8	105	44,701,876	82,579,319.7	0.30	5.86	5.86	1.00	49.39
45 to 64 Years	18,889	133,778	151,481	151,481	4,037.8	141	27,381,698	64,617,573.1	0.69	8.02	8.02	1.00	34.92
65+ Years	9,266	63,517	71,945	71,945	1,922.2	137	8,252,019	23,158,379.4	1.12	7.76	7.76	1.00	71.27

Table 3: Summary of Incident Immunoglobulin Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Pre-Existing Condition, Exposure Extension Period, and Sex

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 1K Years at Risk
CIDP													
3 day exposure extension													
Female	1,810	14,121	19,120	19,120	170.7	0	8,664	4,745.8	208.91	10.56	10.56	1.00	0.00
Male	2,402	17,701	24,260	24,260	214.3	1	9,873	5,707.6	243.29	10.10	10.10	1.00	4.67
Unknown	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---
10 day exposure extension													
Female	1,810	14,121	19,120	19,120	433.4	0	8,664	4,745.8	208.91	10.56	10.56	1.00	0.00
Male	2,402	17,701	24,260	24,260	544.1	2	9,873	5,707.6	243.29	10.10	10.10	1.00	3.68
Unknown	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---
GBS													
3 day exposure extension													
Female	910	1,911	2,498	2,498	23.0	5	11,309	1,823.6	80.47	2.75	2.75	1.00	217.41
Male	1,103	2,267	3,100	3,100	27.4	3	11,239	1,906.6	98.14	2.81	2.81	1.00	109.53
Unknown	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---
10 day exposure extension													
Female	910	1,911	2,498	2,498	58.2	6	11,309	1,823.6	80.47	2.75	2.75	1.00	103.04
Male	1,103	2,267	3,100	3,100	69.7	3	11,239	1,906.6	98.14	2.81	2.81	1.00	43.07
Unknown	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---
ITP													
3 day exposure extension													
Female	3,751	7,270	9,186	9,186	85.8	77	330,055	47,512.0	11.36	2.45	2.45	1.00	897.33
Male	3,682	6,597	8,324	8,324	77.5	66	363,155	51,929.9	10.14	2.26	2.26	1.00	851.61
Unknown	0	0	0	0	0.0	0	23	2.1	0.00	---	---	---	---
10 day exposure extension													
Female	3,751	7,270	9,186	9,186	218.9	93	330,055	47,512.0	11.36	2.45	2.45	1.00	424.83
Male	3,682	6,597	8,324	8,324	198.9	81	363,155	51,929.9	10.14	2.26	2.26	1.00	407.15
Unknown	0	0	0	0	0.0	0	23	2.1	0.00	---	---	---	---

Table 3: Summary of Incident Immunoglobulin Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Pre-Existing Condition, Exposure Extension Period, and Sex

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 1K Years at Risk
Kawasaki Disease													
3 day exposure extension													
Female	579	582	589	589	6.3	9	4,706	531.6	123.03	1.02	1.02	1.00	1422.44
Male	812	827	837	837	9.1	5	6,745	850.9	120.39	1.03	1.03	1.00	550.90
Unknown	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---
10 day exposure extension													
Female	579	582	589	589	17.2	10	4,706	531.6	123.03	1.02	1.02	1.00	582.81
Male	812	827	837	837	24.6	5	6,745	850.9	120.39	1.03	1.03	1.00	203.01
Unknown	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---
Myasthenia gravis													
3 day exposure extension													
Female	1,125	7,028	9,469	9,469	84.8	2	30,150	7,475.9	37.31	8.42	8.42	1.00	23.59
Male	922	3,986	5,347	5,347	47.9	5	24,900	6,807.0	37.03	5.80	5.80	1.00	104.29
Unknown	0	0	0	0	0.0	0	3	0.2	0.00	---	---	---	---
10 day exposure extension													
Female	1,125	7,028	9,469	9,469	215.3	3	30,150	7,475.9	37.31	8.42	8.42	1.00	13.93
Male	922	3,986	5,347	5,347	122.0	8	24,900	6,807.0	37.03	5.80	5.80	1.00	65.56
Unknown	0	0	0	0	0.0	0	3	0.2	0.00	---	---	---	---
PID													
3 day exposure extension													
Female	9,436	107,527	109,880	109,880	1,184.1	41	175,163	77,639.2	53.87	11.64	11.64	1.00	34.62
Male	7,272	80,005	82,045	82,045	881.5	69	109,350	51,845.3	66.50	11.28	11.28	1.00	78.27
Unknown	1	2	2	2	0.0	0	14	6.3	71.43	2.00	2.00	1.00	0.00
10 day exposure extension													
Female	9,436	107,527	109,880	109,880	3,220.9	60	175,163	77,639.2	53.87	11.64	11.64	1.00	18.63
Male	7,272	80,005	82,045	82,045	2,397.8	95	109,350	51,845.3	66.50	11.28	11.28	1.00	39.62
Unknown	1	2	2	2	0.1	0	14	6.3	71.43	2.00	2.00	1.00	0.00

Table 3: Summary of Incident Immunoglobulin Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Pre-Existing Condition, Exposure Extension Period, and Sex

	New Users	New Episodes	New Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 1K Years at Risk
No Pre-Existing Criteria													
3 day exposure extension													
Female	27,143	173,916	193,359	193,359	1,965.1	199	48,884,275	113,616,980.9	0.56	7.12	7.12	1.00	101.27
Male	22,601	134,073	150,472	150,472	1,518.2	189	47,416,873	107,349,298.0	0.48	6.66	6.66	1.00	124.49
Unknown	1	2	2	2	0.0	0	5,506	9,179.0	0.18	2.00	2.00	1.00	0.00
10 day exposure extension													
Female	27,143	173,916	193,359	193,359	5,240.2	239	48,884,275	113,616,980.9	0.56	7.12	7.12	1.00	45.61
Male	22,601	134,073	150,472	150,472	4,044.2	234	47,416,873	107,349,298.0	0.48	6.66	6.66	1.00	57.86
Unknown	1	2	2	2	0.1	0	5,506	9,179.0	0.18	2.00	2.00	1.00	0.00

Table 4: Summary of Incident Immunoglobulin Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Pre-Existing Condition, Exposure Extension Period, and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 1K Years at Risk
CIDP													
3 day exposure extension													
2006	417	1,556	2,200	2,200	19.1	0	1,829	543.2	227.99	5.28	5.28	1.00	0.00
2007	526	2,152	2,888	2,888	26.0	0	2,430	724.6	216.46	5.49	5.49	1.00	0.00
2008	1,139	4,762	6,434	6,434	57.7	0	5,203	1,552.4	218.91	5.65	5.65	1.00	0.00
2009	1,285	5,908	8,001	8,001	71.4	0	5,537	1,815.0	232.08	6.23	6.23	1.00	0.00
2010	1,236	5,422	7,417	7,417	65.5	1	5,520	1,852.1	223.91	6.00	6.00	1.00	15.28
2011	1,313	6,037	8,270	8,270	73.1	0	5,481	1,934.7	239.55	6.30	6.30	1.00	0.00
2012	1,366	5,985	8,170	8,170	72.2	0	5,635	2,031.4	242.41	5.98	5.98	1.00	0.00
10 day exposure extension													
2006	417	1,556	2,200	2,200	47.9	1	1,829	543.2	227.99	5.28	5.28	1.00	20.88
2007	526	2,152	2,888	2,888	66.0	0	2,430	724.6	216.46	5.49	5.49	1.00	0.00
2008	1,139	4,762	6,434	6,434	145.9	0	5,203	1,552.4	218.91	5.65	5.65	1.00	0.00
2009	1,285	5,908	8,001	8,001	181.8	0	5,537	1,815.0	232.08	6.23	6.23	1.00	0.00
2010	1,236	5,422	7,417	7,417	166.9	1	5,520	1,852.1	223.91	6.00	6.00	1.00	5.99
2011	1,313	6,037	8,270	8,270	185.9	0	5,481	1,934.7	239.55	6.30	6.30	1.00	0.00
2012	1,366	5,985	8,170	8,170	183.2	0	5,635	2,031.4	242.41	5.98	5.98	1.00	0.00
GBS													
3 day exposure extension													
2006	137	247	377	377	3.1	0	2,094	239.4	65.43	2.75	2.75	1.00	0.00
2007	179	332	460	460	4.0	0	2,743	307.3	65.26	2.57	2.57	1.00	0.00
2008	326	619	798	798	7.4	2	5,075	588.2	64.24	2.45	2.45	1.00	271.16
2009	410	752	1,004	1,004	9.2	0	5,637	679.0	72.73	2.45	2.45	1.00	0.00
2010	405	696	938	938	8.3	2	5,395	641.7	75.07	2.32	2.32	1.00	239.98
2011	430	749	985	985	9.0	0	5,421	644.1	79.32	2.29	2.29	1.00	0.00
2012	427	783	1,036	1,036	9.4	4	5,168	630.5	82.62	2.43	2.43	1.00	426.44

Table 4: Summary of Incident Immunoglobulin Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Pre-Existing Condition, Exposure Extension Period, and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 1K Years at Risk
GBS (continued)													
10 day exposure extension													
2006	137	247	377	377	7.6	1	2,094	239.4	65.43	2.75	2.75	1.00	130.91
2007	179	332	460	460	10.2	0	2,743	307.3	65.26	2.57	2.57	1.00	0.00
2008	326	619	798	798	19.0	2	5,075	588.2	64.24	2.45	2.45	1.00	105.34
2009	410	752	1,004	1,004	23.2	0	5,637	679.0	72.73	2.45	2.45	1.00	0.00
2010	405	696	938	938	21.2	2	5,395	641.7	75.07	2.32	2.32	1.00	94.37
2011	430	749	985	985	22.9	0	5,421	644.1	79.32	2.29	2.29	1.00	0.00
2012	427	783	1,036	1,036	23.8	4	5,168	630.5	82.62	2.43	2.43	1.00	168.12
ITP													
3 day exposure extension													
2006	528	802	1,025	1,025	9.4	5	48,854	4,663.1	10.81	1.94	1.94	1.00	529.19
2007	690	1,148	1,434	1,434	13.4	14	73,874	6,948.3	9.34	2.08	2.08	1.00	1046.99
2008	1,354	2,161	2,680	2,680	25.3	31	127,858	12,822.8	10.59	1.98	1.98	1.00	1224.88
2009	1,546	2,368	3,115	3,115	28.6	28	161,226	16,864.0	9.59	2.01	2.01	1.00	977.63
2010	1,547	2,401	2,985	2,985	28.0	19	181,836	19,077.9	8.51	1.93	1.93	1.00	678.11
2011	1,599	2,578	3,242	3,242	30.3	23	184,745	19,237.2	8.66	2.03	2.03	1.00	759.29
2012	1,488	2,409	3,029	3,029	28.2	23	189,800	19,830.5	7.84	2.04	2.04	1.00	814.74
10 day exposure extension													
2006	528	802	1,025	1,025	24.2	7	48,854	4,663.1	10.81	1.94	1.94	1.00	289.29
2007	690	1,148	1,434	1,434	34.4	19	73,874	6,948.3	9.34	2.08	2.08	1.00	551.91
2008	1,354	2,161	2,680	2,680	64.6	31	127,858	12,822.8	10.59	1.98	1.98	1.00	479.96
2009	1,546	2,368	3,115	3,115	71.9	35	161,226	16,864.0	9.59	2.01	2.01	1.00	486.89
2010	1,547	2,401	2,985	2,985	72.4	21	181,836	19,077.9	8.51	1.93	1.93	1.00	290.03
2011	1,599	2,578	3,242	3,242	77.9	28	184,745	19,237.2	8.66	2.03	2.03	1.00	359.21
2012	1,488	2,409	3,029	3,029	72.4	33	189,800	19,830.5	7.84	2.04	2.04	1.00	455.75

Table 4: Summary of Incident Immunoglobulin Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Pre-Existing Condition, Exposure Extension Period, and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 1K Years at Risk
Kawasaki Disease													
3 day exposure extension													
2006	83	83	85	85	0.9	0	1,062	91.1	78.15	1.02	1.02	1.00	0.00
2007	96	96	97	97	1.1	0	1,263	108.2	76.01	1.01	1.01	1.00	0.00
2008	226	227	230	230	2.5	3	2,495	217.7	90.58	1.02	1.02	1.00	1212.11
2009	293	293	297	297	3.2	2	3,037	278.6	96.48	1.01	1.01	1.00	622.76
2010	251	252	254	254	2.7	3	2,811	246.0	89.29	1.01	1.01	1.00	1092.47
2011	245	248	251	251	2.7	2	2,730	236.7	89.74	1.02	1.02	1.00	735.65
2012	203	210	212	212	2.3	4	2,371	204.2	85.62	1.04	1.04	1.00	1758.12
10 day exposure extension													
2006	83	83	85	85	2.5	0	1,062	91.1	78.15	1.02	1.02	1.00	0.00
2007	96	96	97	97	2.9	0	1,263	108.2	76.01	1.01	1.01	1.00	0.00
2008	226	227	230	230	6.7	3	2,495	217.7	90.58	1.02	1.02	1.00	448.16
2009	293	293	297	297	8.7	3	3,037	278.6	96.48	1.01	1.01	1.00	345.23
2010	251	252	254	254	7.4	3	2,811	246.0	89.29	1.01	1.01	1.00	403.15
2011	245	248	251	251	7.4	2	2,730	236.7	89.74	1.02	1.02	1.00	269.66
2012	203	210	212	212	6.1	4	2,371	204.2	85.62	1.04	1.04	1.00	650.78
Myasthenia gravis													
3 day exposure extension													
2006	151	447	587	587	5.4	0	5,545	761.2	27.23	3.89	3.89	1.00	0.00
2007	224	734	943	943	8.8	0	7,669	1,083.8	29.21	4.21	4.21	1.00	0.00
2008	479	1,648	2,186	2,186	19.8	0	15,291	2,168.5	31.33	4.56	4.56	1.00	0.00
2009	580	2,121	2,773	2,773	25.3	1	16,134	2,496.9	35.95	4.78	4.78	1.00	39.55
2010	587	2,007	2,755	2,755	24.4	1	15,930	2,520.9	36.85	4.69	4.69	1.00	41.02
2011	596	2,093	2,822	2,822	25.1	3	16,582	2,596.1	35.94	4.73	4.73	1.00	119.35
2012	580	1,964	2,750	2,750	23.9	2	16,629	2,655.7	34.88	4.74	4.74	1.00	83.52

Table 4: Summary of Incident Immunoglobulin Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Pre-Existing Condition, Exposure Extension Period, and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 1K Years at Risk
Myasthenia gravis (continued)													
10 day exposure extension													
2006	151	447	587	587	13.5	0	5,545	761.2	27.23	3.89	3.89	1.00	0.00
2007	224	734	943	943	22.4	0	7,669	1,083.8	29.21	4.21	4.21	1.00	0.00
2008	479	1,648	2,186	2,186	50.5	0	15,291	2,168.5	31.33	4.56	4.56	1.00	0.00
2009	580	2,121	2,773	2,773	64.8	1	16,134	2,496.9	35.95	4.78	4.78	1.00	15.44
2010	587	2,007	2,755	2,755	61.8	3	15,930	2,520.9	36.85	4.69	4.69	1.00	48.56
2011	596	2,093	2,822	2,822	64.0	5	16,582	2,596.1	35.94	4.73	4.73	1.00	78.16
2012	580	1,964	2,750	2,750	60.4	2	16,629	2,655.7	34.88	4.74	4.74	1.00	33.09
PID													
3 day exposure extension													
2006	2,067	10,900	11,085	11,085	119.8	8	22,748	6,072.9	90.87	5.36	5.36	1.00	66.77
2007	2,509	14,736	15,002	15,002	162.1	11	30,466	8,459.0	82.35	5.98	5.98	1.00	67.85
2008	5,300	29,483	30,078	30,078	324.5	22	68,374	19,045.7	77.51	5.68	5.68	1.00	67.80
2009	5,610	34,207	35,091	35,091	377.3	18	76,927	22,810.7	72.93	6.26	6.26	1.00	47.70
2010	5,460	31,850	32,577	32,577	350.8	15	76,815	23,029.8	71.08	5.97	5.97	1.00	42.76
2011	5,737	33,580	34,455	34,455	370.0	18	80,851	24,693.2	70.96	6.01	6.01	1.00	48.65
2012	5,754	32,778	33,639	33,639	361.1	18	81,797	25,379.5	70.34	5.85	5.85	1.00	49.85
10 day exposure extension													
2006	2,067	10,900	11,085	11,085	326.3	11	22,748	6,072.9	90.87	5.36	5.36	1.00	33.72
2007	2,509	14,736	15,002	15,002	442.0	17	30,466	8,459.0	82.35	5.98	5.98	1.00	38.46
2008	5,300	29,483	30,078	30,078	883.5	27	68,374	19,045.7	77.51	5.68	5.68	1.00	30.56
2009	5,610	34,207	35,091	35,091	1,025.6	26	76,927	22,810.7	72.93	6.26	6.26	1.00	25.35
2010	5,460	31,850	32,577	32,577	955.2	20	76,815	23,029.8	71.08	5.97	5.97	1.00	20.94
2011	5,737	33,580	34,455	34,455	1,006.4	26	80,851	24,693.2	70.96	6.01	6.01	1.00	25.84
2012	5,754	32,778	33,639	33,639	979.8	28	81,797	25,379.5	70.34	5.85	5.85	1.00	28.58

Table 4: Summary of Incident Immunoglobulin Use and Hemolysis in the MSDD between January 1, 2006 and December 31, 2012, by Pre-Existing Condition, Exposure Extension Period, and Year

	New Users	New Episodes	New Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 1K Years at Risk
No Pre-Existing Criteria													
3 day exposure extension													
2006	5,743	19,285	21,487	21,487	218.1	21	21,810,089	15,557,647.5	0.26	3.74	3.74	1.00	96.29
2007	7,041	25,855	28,614	28,614	291.8	34	25,459,515	19,115,309.5	0.28	4.06	4.06	1.00	116.52
2008	12,953	49,755	55,357	55,357	562.7	86	50,343,498	35,529,663.9	0.26	4.27	4.27	1.00	152.84
2009	13,318	56,546	63,082	63,082	640.0	66	50,040,272	39,558,514.0	0.27	4.74	4.74	1.00	103.12
2010	12,616	51,988	57,940	57,940	587.4	57	48,226,380	38,170,458.1	0.26	4.59	4.59	1.00	97.03
2011	12,593	53,786	60,244	60,244	608.6	60	47,045,928	37,511,522.5	0.27	4.78	4.78	1.00	98.58
2012	11,762	50,776	57,109	57,109	574.7	64	45,072,793	35,532,342.4	0.26	4.86	4.86	1.00	111.37
10 day exposure extension													
2006	5,743	19,285	21,487	21,487	581.2	29	21,810,089	15,557,647.5	0.26	3.74	3.74	1.00	49.89
2007	7,041	25,855	28,614	28,614	779.6	44	25,459,515	19,115,309.5	0.28	4.06	4.06	1.00	56.44
2008	12,953	49,755	55,357	55,357	1,499.6	94	50,343,498	35,529,663.9	0.26	4.27	4.27	1.00	62.68
2009	13,318	56,546	63,082	63,082	1,705.5	81	50,040,272	39,558,514.0	0.27	4.74	4.74	1.00	47.49
2010	12,616	51,988	57,940	57,940	1,568.4	67	48,226,380	38,170,458.1	0.26	4.59	4.59	1.00	42.72
2011	12,593	53,786	60,244	60,244	1,622.4	79	47,045,928	37,511,522.5	0.27	4.78	4.78	1.00	48.69
2012	11,762	50,776	57,109	57,109	1,527.6	79	45,072,793	35,532,342.4	0.26	4.86	4.86	1.00	51.71

Appendix A. Procedure Code List for Immunoglobulin Products

Immunoglobulin 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, P901	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. ICD-9-CM Diagnosis Codes for 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

Appendix C. ICD-9 Diagnosis Codes for Pre-Existing Conditions

Diagnosis Group	Code	Description
Primary Immunodeficiency (PID)	279.0	Deficiency of humoral immunity
	279.00	hypogammaglobulinemia, unspecified (279.00)
	279.01	Selective IgA immunodeficiency
	279.02	Selective IgM immunodeficiency
	279.03	Other selective immunoglobulin deficiencies
	279.04	Congenital hypogammaglobulinemia (includes Bruton's)
	279.05	Immunodeficiency with increased IgM
	279.06	Common variable immunodeficiency
	279.09	Deficiency of humoral immunity, other
	279.1	Deficiency of cell-mediated immunity
	279.10	Immunodeficiency with predominant T-cell defect, unspecified
	279.11	DiGeorge's syndrome
	279.12	Wiskott-Aldrich syndrome
	279.13	Nezelof's syndrome
	279.19	Deficiency of cell-mediated immunity, other
	279.2	Combined immunity deficiency
	279.3	Unspecified immunity deficiency
	279.4	Autoimmune disease, not elsewhere classified
	279.41	Autoimmune lymphoproliferative syndrome
	279.49	Autoimmune disease, not elsewhere classified
279.8	Other specified disorders involved the immune mechanism	
279.9	Unspecified disorder of immune mechanism	
Chronic inflammatory demyelinating polyneuritis (CIDP)	357.81	Chronic inflammatory demyelinating polyneuritis
Kawasaki Disease	446.1	Kawaski Disease/Acute febrile mucocutaneous lymph node syndrome

Appendix C. ICD-9 Diagnosis Codes for Pre-Existing Conditions

Diagnosis Group	Code	Description
ITP	287.1	Qualitative platelet defects
	287.3	Primary thrombocytopenia
	287.31	ITP
	287.33	Congenital and hereditary thrombocytopenic purpura
	287.39	Congenital and hereditary thrombocytopenic purpura
	287.4	Secondary thrombocytopenia
	287.5	Thrombocytopenia (unspecified)
Myasthenia Gravis	358*	Myasthenia gravis
	358.01	MG with exacerbation
	775.2	MG neonatal
Guillain-Barre Syndrome	357.0	GBS