

# Assessment of Immunoglobulin Utilization and Shortage

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## VERSION CONTROL

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Acumen	04/23/2020	0.2	Contains first round of edits from IBM and Acumen teams
IBM	05/19/2020	0.3	Revised version with additional edits based on call discussions
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Acumen	07/01/2020	0.9	Revised version based on FDA comments
Acumen	07/12/2020	1.0	Revised version based on IBM comments
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Acumen	07/14/2020	1.2	Revised version based on FDA and IBM comments
FDA/Acumen/IBM/	08/31/2020	1.3	Revised version with workgroup member names filled out and additional edits incorporated

## ABBREVIATIONS

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<b>CDC</b>	Centers for Disease Control and Prevention
<b>CPT</b>	Current Procedural Terminology
<b>FDA</b>	U.S. Food and Drug Administration
<b>HCPCS</b>	Healthcare Common Procedure Coding System
<b>ICD-9-CM</b>	International Classification of Diseases, Ninth Revision, Clinical modification
<b>ICD-10-CM/PCS</b>	International Classification of Diseases, Tenth Revision, Clinical modification/Procedure Coding System
<b>IP</b>	Inpatient
<b>OP</b>	Outpatient
<b>PB</b>	Physician Billing/Supplier Part B Claims file /Carrier file

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## 1. EXECUTIVE SUMMARY

### **Background**

In recent years, there has been an increase in the demand for intravenous (IV) and subcutaneous (SC) immunoglobulin for a wide range of on- and off-label indications. Due to the products' expanded usage, increased demand, and their complex manufacturing process, there have been ongoing shortages of IG products reported at the national level. In 2019, multiple healthcare providers and medical societies contacted U.S. Food and Drug Administration's (FDA) Drug Shortage Office and Office of Compliance and Biologics Quality regarding an acute national shortage of immunoglobulin. Despite the increased supply of immunoglobulin products, the rapid demand increases necessitate better understanding of other factors that may contribute to a severe shortage like this one.

### **Objective**

The objective of the current study is to 1) summarize trends in intravenous immunoglobulin (IVIG) and subcutaneous immunoglobulin (SCIG) utilization in the last decade using Medicare and IBM MarketScan Commercial data, and 2) assess indirect evidence in the administrative data for the potential immunoglobulin shortage perceived on the demand side that started in 2019 and potential factors that might have contributed to the shortage.

### **Methods**

This study will include individuals enrolled in IBM MarketScan Commercial plans between January 1, 2009 and September 30, 2019 and those enrolled in Medicare Parts A/B fee-for-service (FFS) between January 1, 2009 and December 31, 2019. The study will assess changes in overall immunoglobulin usage for specific IVIG and SCIG products based on metrics including 1) administrations, 2) treatment episodes, 3) patients, and 4) dosage administered. The study will also explore changes in diagnoses associated with immunoglobulin administrations over time as indirect evidence for a potential contributing factor to the perceived shortage that started in 2019.

## 2. BACKGROUND

Immunoglobulin (IG) is a plasma-derived biologic used to treat a variety of immune-related disorders and deficiencies. The US FDA has approved the use of intravenous immunoglobulin (IVIG) and subcutaneous immunoglobulin (SCIG) for six indications including

- Treatment of primary immunodeficiencies.
- Prevention of bacterial infections in patients with hypogammaglobulinemia and recurrent infection caused by B-cell chronic lymphocytic leukemia.
- Prevention of coronary artery aneurysms in Kawasaki disease.
- Prevention of infections, pneumonia and acute graft versus host disease (GVHD) after bone marrow transplantation.
- Reduction of serious bacterial infection in children with HIV.
- Increase of platelet count in idiopathic thrombocytopenic purpura to prevent or control bleeding.

Over the last decade, there has been an increase in off-label utilization of immunoglobulin for a wide range of clinical conditions. For example, during the 2007-2014 period an estimated 80% of IVIG use by patients hospitalized in the major US-based pediatric hospitals were for off-label indications.<sup>2</sup> Although the use of IG therapy for some of these conditions is supported by significant evidence of clinical benefit or by evidence-based guidelines<sup>1,3-5</sup>, evidence is insufficient to support their use for a substantial proportion of unapproved indications.<sup>1</sup>

As IG usage has continued to expand, the US is currently facing domestic short fall of IG products. The FDA has received reports indicating a severe shortage at the national level due to their increased demand, and complex manufacturing process. Consequently, the ongoing shortage may negatively impact patient care, and is particularly detrimental for patients with disorders (e.g. humoral immunodeficiencies) that currently have no other alternative treatments. Understanding the scope of and factors related to the current shortage as well as recent past shortages is crucial to designing policies and strategies to effectively resolve this issue and improve patient access to immunoglobulins.

### 3. OBJECTIVES

#### 3.1 Primary Objective - Utilization Patterns and Trends Analysis

To summarize trends in IVIG and SCIG utilization from 2009 to 2019 among the Medicare Fee-for-service (FFS) population and a privately insured population in the IBM® MarketScan® Research Databases.

#### 3.2 Secondary Objective - Condition Category-Related Immunoglobulin Utilization Analyses

To explore indirect evidence for the perceived immunoglobulin shortage that started in 2019 by examining potential factors that might have contributed to the shortage.

Two complementary analyses will be conducted to achieve this objective. The first analysis will investigate diagnoses associated with IG administrations by focusing on all IG administrations, anchoring on the administration date, and looking for related diagnoses in a time window surrounding that date. This analysis will provide a picture of the conditions coinciding with IG administrations, and changes in those patterns over time. The second analysis will focus on evaluating the IG treatment patterns among populations of different condition categories over time. This analysis will provide a picture of whether patients within the same condition category were receiving similar IG treatment over time and can help identify utilization trend breaks within homogenous groups.

## 4. METHODS

### 4.1 Data sources

We will assess IVIG and SCIG utilization and evidence of potential shortage from January 1, 2009 through December 31, 2019 using Medicare enrollment and claims data from the Centers of Medicare and Medicaid Services (CMS) and through September 30, 2019 using IBM MarketScan commercial claims data. Since the current COVID-19 pandemic has altered healthcare utilization in the US in 2020, we decided to end the study period in 2019. If deemed necessary, additional analyses can be run using a more extended study period.

#### 4.1.1 CMS Medicare Parts A/B fee for service (FFS) and Part D prescription drug data

Medicare provides federal health insurance coverage to persons age 65 years and older as well as to persons under age 65 who have end-stage renal disease (ESRD) or are disabled. This study will utilize Medicare enrollment data and claims data for patients with Part A (inpatient hospital care), Part B (outpatient care and physician services) and Part D (prescription drugs) coverage. We will use the monthly Medicare Enrollment Database (EDB) to assess patients' Medicare enrollment eligibility and the Common Working File (CWF) and Prescription Drug Event (PDE) claims data to capture patients' medical services, diagnoses, and prescription drug use.

#### 4.1.2 IBM MarketScan Commercial Databases

The MarketScan Commercial Databases capture person-specific clinical utilization, expenditures, and enrollment across inpatient, outpatient, prescription drug, and carve-out services. The data have claims from active employees, early retirees, Consolidated Omnibus Budget Reconciliation Act (COBRA) continues, and dependents insured by employer-sponsored plans.

### 4.2 Study Population

#### 4.2.1 Immunoglobulin Products of Interest

The study will focus on following IVIG and SCIG products approved by FDA<sup>6</sup>.

- **IVIG:** Asceniv, Bivigam, Carimune, Flebogamma, Gammagard S/D, Gammalex, Gammar-P IV, Gamunex, Iveegam, Octagam, Panzyga, Panglobulin, Polygam, Privigen, Sandoglobulin;
- **SCIG:** Cutaquig, Cuvitru, Hizentra, Hyqvia, Vivaglobin, Xembify;
- **IV/SCIG:** Gammagard Liquid, Gammaked, Gamunex-C

All intravenous (IV) and subcutaneous (SC) administrations of immunoglobulin (IG) codes will be identified via Healthcare Common Procedure Coding System codes (HCPCS), National Drugs Codes (NDCs), and ICD-9-CM/ICD-10-PCS procedure codes observed in Medicare or MarketScan claims from institutional inpatient and outpatient, professional services, and pharmacy settings. Complete lists of ICD-9-CM/ICD-10-PCS procedure codes, HCPCS codes, and NDCs for identifying IVIG and SCIG are given in Appendix 1 and Appendix 2.

## 4.2.2 Study Population Eligibility Criteria

### 4.2.2.1 Utilization Patterns and Trends Analysis

All patients enrolled with medical benefit (MarketScan) or with Medicare fee-for-service (FFS) Part A and Part B during any given month will be included. Patients enrolled for part of a month are considered to be enrolled for the entire month.

Preliminary investigations in Medicare showed that although some immunoglobulin usage (13%) is captured by NDCs, the majority of usage (83%) is captured via HCPCS in the outpatient or professional services setting. Thus enrollment in the Medicare Part D benefit is not required, as it reduces precision of the estimates with a smaller sample size and the estimates' generalizability to the overall Medicare FFS population. One source of bias comes from the potential under-capture in immunoglobulin prescriptions of the Medicare FFS population not enrolling in Part D, which we expect to be minimal.

As Medicare beneficiaries' health status may vary depending on their reason for entry, the analysis will separately assess utilization patterns, trends, and associated diagnoses among patients who aged into Medicare (without ESRD) vs. those qualify due to disability or ESRD.

### 4.2.2.2 *Condition Category-Related Immunoglobulin Utilization Analyses*

**Analysis 1:** When assessing relevant diagnosis codes coinciding with each administration, the patient is required to be enrolled in Medicare FFS or with MarketScan medical benefit for at least 3 months prior to administration date through at least 1 month after administration date to allow for a complete assessment of all diagnoses that have occurred around the time of IG administration. Medicare-based analysis will be stratified based on patients' reason for entry into Medicare.

**Analysis 2:** Analysis focusing on populations of specific condition categories will include patients enrolled with MarketScan medical benefit or Medicare FFS with at least 180 days of continuous enrollment any time during study period, allowing for up to 31 days of enrollment gap. After the index diagnosis date, patients are followed for as long as they are enrolled in Medicare FFS or MarketScan medical benefit for chronic conditions and within the specified follow-up window for acute conditions, where diagnoses for specific acute and chronic conditions will be determined through clinical input. If a patient dis-enrolls and re-enrolls after the index diagnosis date, the patient will still be followed for the time they are enrolled before dis-enrollment and after re-enrollment.

## 4.3 Diagnosis Categorization

Though FDA labels specify indications for immunoglobulin therapy, there are a wide range of accepted uses in other conditions (off-label). However, claims data include medical diagnoses but often lack the granularity to assess the specific indication for the use of a specific product/drug. As such, the indication for immunoglobulin use was inferred from the most plausible diagnoses included in the claim. A data-driven approach was used where the team identified the most common 50 diagnoses associated with immunoglobulin use on/surrounding the date of immunoglobulin administration in both databases and classified them into broad categories ("condition category") as listed below.

Guided by physician input and review of the literature, condition categories are designated as groups of diagnoses that are evidence-based or are common clinical practice ("plausible conditions"). Any conditions that are not commonly treated with immunoglobulin therapy are considered to be "implausible conditions". For example, whereas it is likely that patients receiving immunoglobulin may have a diagnosis of infection, the majority of patients with

infection are unlikely to receive immunoglobulin therapy. As such, infection will be considered as an implausible diagnosis. This categorization will be used to assess changes in conditions/diseases associated with immunoglobulin use over time and to assess changes in immunoglobulin use over time among specific patient groups (see Section 5.2 and Section 5.3).

List of condition categories for plausible conditions:

- Autoimmune/Connective tissue disorder
- Hematologic
- Immunodeficiency
- Neonatal
- Neurologic
- Oncologic
- Transplantation

To identify the diagnosis associated with IG administration we will use:

- Discharge diagnosis codes (regardless of position) on hospital inpatient claims
- Diagnosis codes (regardless of position) on institutional outpatient claims and professional services claims

All diagnosis codes are identified using the International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM) diagnosis codes (until September 30, 2015) and International Classification of Diseases, 10th revision, Clinical Modification (ICD-10-CM) diagnosis codes (October 1, 2015 onward). As the study period spans both the ICD-9-CM and ICD-10-CM eras, code list harmonization for both common ICD-9-CM and ICD-10-CM codes will be performed to minimize the influence of coding system change on the trends observed. More specifically, the General Equivalence Mappings (GEMS) will be used to map identified ICD-9-CM diagnosis codes to their ICD-10-CM equivalents and vice versa. Clinicians will then review the mappings for each condition category and provide any clinical input. Finally, the original diagnosis codes and their mapped counterparts will be used collectively to assess trends in IG use-associated diagnoses and identify patients within each plausible condition category. A list of observed common diagnoses associated with immunoglobulin use and their condition categories is included as Appendix 3A and Appendix 3B. The final list of diagnosis codes will be a revised list that also incorporates the codes derived from the code list harmonization.

## 5. ANALYTICAL PLAN

The descriptive study will primarily focus on summarizing IVIG and SCIG utilization trends during the study period. For the secondary objective, the study will also assess potential factors associated with the perceived shortage that started in 2019 using two sets of analyses.

### 5.1 Unit of analysis

The study will assess changes in overall immunoglobulin usage based on metrics including 1) administrations, 2) treatment episodes, 3) patients, and 4) dosage administered. Units of analysis are defined in detail as follows. Additionally, analysis will be stratified by immunoglobulin type (intravenous vs subcutaneous) or product brand. Time unit of analysis can be month or year. When assessing utilization trends and associated diagnoses among Medicare beneficiaries, the analyses will be further stratified by beneficiaries' reason for entry into Medicare.

- **Administration:**

Each administration will be defined as a unique date on which a patient receives an IG product.

- **Outpatient setting:** Each administration will be defined as a unique date on which a patient receives an IG product. If multiple claims are billed on the same day, this is counted as a single administration.
- **Pharmacy:** Dispensing on a single fill date for a patient are considered as a single administration, regardless of the quantity and days of supply.
- **Inpatient setting:** Immunoglobulin use identified based on ICD-9-CM/ICD-10-PCS procedure codes during a single hospitalization is considered as a single administration.

- **Treatment episode**

An immunoglobulin treatment episode is defined as consecutive days of immunoglobulin administration for a patient. A gap of 2 days is allowed for treatment pause over a weekend or for an unexpected intervening medical procedure or an unexpected medical event. When defining treatment episodes, administrations in the inpatient and pharmacy settings will be excluded, as administration dates and episode duration cannot be reliably assessed with those claims. Treatment episodes involving multiple brands or routes will also be excluded from the analysis due to their rarity (<1% of episodes) and the added complexity they bring to the interpretation of the analytical results.

The start date of the episode will be based on the episode initiation date – service date of the first administration. A treatment episode spanning across months will be counted as a single episode and attributed towards the month when the episode was initiated.

- **Patients:**

A patient is defined as a unique individual who (1) received immunoglobulin products during the study period (for analyses outlined in Section 5.2 and 5.3.1), or (2) had specific conditions for immunoglobulin use and received immunoglobulin while enrolled following diagnosis (for analysis outlined in Section 5.3.2).

- **Dosage:**

- For immunoglobulin uses identified by HCPCS codes with specified quantity information, dose of the administration will be calculated as quantity \* units and converted to grams as needed.
- For immunoglobulin uses identified by NDCs, dose will be calculated as quantity \* strength and converted to grams as needed.

- For immunoglobulin uses identified by ICD-9-CM/ICD-10-PCS procedure codes, dose cannot be calculated.
  - These administrations will be excluded from the dosage analysis.

Based on initial investigation on dosage of IG administrations in both databases, the study will exclude administrations with an outlier dosage of <1 gram or >500 grams when assessing changes in dosage. Treatment episodes involving administrations of such outlier amounts are also excluded from any dosage-related analyses.

## 5.2 Utilization Patterns and Trends Analysis

We will first describe patient demographic characteristics and geographic area distribution of immunoglobulin users. We will also summarize overall, route-specific (IVIG or SCIG), and product-specific utilization trends over time for IVIG and SCIG in the Medicare and MarketScan populations during the study period by month and year.

### 5.2.1 Statistical Analysis

Immunoglobulin users' basic demographics (e.g., age, sex, race) and geographic area (by census region) information will be summarized. Utilization trends will be assessed based on the number and rate of administrations, treatment episodes, and patients, as well as dosage administered, regardless of potential associated conditions. Table 2 below outlines the specific utilization patterns and trends analyses utilizing different units of analysis within monthly or yearly time periods.

**Table 2. Utilization patterns and trends analysis specifications**

Metric	Numerator	Denominator	Additional Stratifications
Immunoglobulin Administration Rate	Number of immunoglobulin administrations received by the patients in the denominator in the same period	(i) Number of person-periods enrolled in a period (ii) Number of person-periods enrolled and received immunoglobulin in a period	<b>Product type:</b> By route or brand name  <b>Time unit:</b> Month, year  <b>Reason for entry into Medicare:</b> Aged-in without ESRD, non-aged in (due to disability or ESRD)
Immunoglobulin Treatment Episode Rate	Number of immunoglobulin episodes initiated in the same period and received by the patients in the denominator	(i) Number of person-periods enrolled in a period (ii) Number of person-periods enrolled and received immunoglobulin in a period	
Days per Treatment Episode	Number of total days on treatment within a period	Number of total treatment episodes initiated within a period	
Average Dose per Patient	Total dose received by the patients in the denominator in a period	(i) Number of person-periods enrolled in a period (ii) Number of person-periods enrolled and	

		received immunoglobulin with estimated dose information in a period	
Average Dose per Administration	Total dose of immunoglobulin used in the administrations in the denominator	Number of immunoglobulin administrations with estimated dose information within a period	
Average Dose per Treatment Episode	Total dose of immunoglobulin used in the episodes in the denominator	Number of immunoglobulin episodes initiated in a period, with estimated dose information	
Proportion of Patients Receiving Immunoglobulin	Number of patients from the denominator who received immunoglobulin in the same period	Number of patients enrolled in a period	

### 5.3 Condition Category-Related Immunoglobulin Utilization Analyses

To assess the evidence and understand the possible contributing factors of a perceived shortage that started in 2019, we will perform two sets of diagnosis-based analyses.

#### 5.3.1 Statistical Analysis

##### **Analysis 1:**

This analysis aims to assess, for the individuals who received immunoglobulin in a given time interval (month or year), how the proportion of users receiving immunoglobulin for each broad diagnosis group changes over time.

For this analysis we will first identify all diagnosis codes for each administration or treatment episode, using a clinically relevant assessment window of [-3,1] months around the administration date or the start date of the treatment episode. To ensure that we can equally assess diagnoses for all administrations or treatment episodes included in the analysis, continuous enrollment will be imposed during the assessment window. Administrations or treatment episodes will be assigned broader condition categories based on all coinciding diagnosis codes during the assessment window. One administration or treatment episode can be assigned to multiple condition categories. Changes in proportions of usage for different condition categories will then be summarized.

To summarize the changes in proportions of immunoglobulin administrations or treatment episodes for a specific condition category:

- Denominator: number of immunoglobulin administrations or treatment episodes in a given time interval (e.g., month)
- Numerator: number of immunoglobulin administrations or treatment episodes with a specific diagnosis or condition category in a given time interval (e.g., month) which are included in the denominator

In examining changes in diagnoses associated with immunoglobulin use in Medicare, the analysis will be stratified by patients' reason for entry into Medicare.

***Analysis 2:***

This analysis will aim to assess, for patients within a plausible condition category, how the treatment patterns change over time. Proportion or average dose as defined below will be calculated by month and the trend over the study period will be described.

Patients who meet inclusion criteria will be classified to condition categories defined in Section 4.3 and Appendix 3A, 3B based on the presence of diagnosis codes in claims data during the study period. The time of the first diagnosis of a condition category will be set as the index date for that condition. For chronic diagnoses, a patient will be included in that condition category from the month of the index date onwards while the patient is enrolled. For acute diagnoses, a patient will be included in that condition category from the month of the index date for a specified time period while the patient is enrolled. More specifically, the follow-up window for patients with Kawasaki disease (acute diagnosis) will be 2 months and for patients with Guillain-Barré syndrome (GBS) 3 months (acute diagnosis). If a patient has diagnoses included within multiple condition categories during the same time period, the patient will be categorized into each condition category as deemed clinically appropriate. Within the population of each condition category, the timing of immunoglobulin administration and treatment episodes will be determined based on the service date of the administration, pharmacy fill date, admission date of a hospitalization during which immunoglobulin was used, or the date of the episode initiation.

The same analyses as outlined in Table 2 will be performed, restricting to patients in a condition category enrolled in given a period. For example, for the measure of immunoglobulin administration rate, the denominator will include (i) number of person-periods enrolled in a period among patients with diagnosis code(s) from a certain condition category either previously or in the same month, or (ii) number of person-periods enrolled who received immunoglobulin in a period among patients with diagnosis code(s) from a certain condition category either previously or in the same month. Numerator will include the number of immunoglobulin administrations received by the patients in the denominator in the same period. In addition to the measures specified in Table 2, prevalence of a condition category will be calculated in the enrolled population by dividing number of patients that are in a condition category and enrolled (the numerator) by the number of patients enrolled in a period (the denominator).

## 6. ETHICAL CONSIDERATIONS

This surveillance was approved by the FDA's Research Involving Human Subjects Committee.

## 7. REFERENCES

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## 8. APPENDIX

### Appendix 1. ICD-9/10-CM Procedure Codes and HCPCS Codes for IVIG and SCIG Drugs

Product Name	Code	Code Type	Short Description	Long Description	Brand Names
Intravenous immunoglobulin (IVIG)	90283	CPT	Human ig, iv	Immune globulin (igiv), human, for intravenous use	Nonspecific
Intravenous immunoglobulin (IVIG)	90399	CPT	Human ig, iv	Unlisted immune globulin injection or infusion	Nonspecific
Intravenous immunoglobulin (IVIG)	J1459	HCPCS	Inj ivig privigen 500 mg	Injection, immune globulin (privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg	PRIVIGEN
Intravenous immunoglobulin (IVIG)	J1556	HCPCS	Inj, imm glob bivigam, 500mg	Injection, immune globulin (bivigam), 500 mg	BIVIGAM
Intravenous immunoglobulin (IVIG)	J1557	HCPCS	Gammaflex injection	Injection, immune globulin, (gammaflex), intravenous, non-lyophilized (e.g., liquid), 500 mg	GAMMAPLEX
Intravenous immunoglobulin (IVIG)	J1563	HCPCS		IV IMMUNE GLOBULIN	Nonspecific
Intravenous immunoglobulin (IVIG)	J1566	HCPCS	Immune globulin, powder	Injection, immune globulin, intravenous, lyophilized (e.g. powder), not otherwise specified, 500 mg	Nonspecific POLYGAM, GAMMAGARD S/D, PANGLOBULIN, IVEEGAM, CARIMUNE
Intravenous immunoglobulin (IVIG)	J1567	HCPCS	Immune globulin, liquid	Injection, immune globulin, intravenous, non-lyophilized (e.g. liquid), 500 mg	Nonspecific
Intravenous immunoglobulin (IVIG)	J1568	HCPCS	Octagam injection	Injection, immune globulin, (octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg	OCTAGAM

Intravenous immunoglobulin (IVIG)	J1572	HCPCS	Flebogamma injection	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg	FLEBOGAMMA
Intravenous immunoglobulin (IVIG)	30230S1	PRC10		Transfusion of Nonautologous Globulin into Peripheral Vein, Open Approach	Nonspecific
Intravenous immunoglobulin (IVIG)	30233S1	PRC10		Transfusion of Nonautologous Globulin into Peripheral Vein, Percutaneous Approach	Nonspecific
Intravenous immunoglobulin (IVIG)	30240S1	PRC10		Transfusion of Nonautologous Globulin into Central Vein, Open Approach	Nonspecific
Intravenous immunoglobulin (IVIG)	30243S1	PRC10		Transfusion of Nonautologous Globulin into Central Vein, Percutaneous Approach	Nonspecific
Intravenous immunoglobulin (IVIG)	30253S1	PRC10		Transfusion of Nonautologous Globulin into Peripheral Artery, Percutaneous Approach	Nonspecific
Intravenous immunoglobulin (IVIG)	30263S1	PRC10		Transfusion of Nonautologous Globulin into Central Artery, Percutaneous Approach	Nonspecific
Intravenous immunoglobulin (IVIG)	C9270	HCPCS	Gammaplex, 500 mg	Injection, immune globulin (gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg	GAMMAPLEX
Intravenous immunoglobulin (IVIG)	C9130	HCPCS	Bivigam, 500 mg	Injection, immune globulin (bivigam), 500 mg	BIVIGAM
Intravenous immunoglobulin (IVIG)	Q4087	HCPCS	Octagam, 500 mg	INJECTION, IMMUNE GLOBULIN, (OCTAGAM), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG	OCTAGAM
Intravenous immunoglobulin (IVIG)	Q4091	HCPCS	Flebogamma, 500 mg	INJECTION, IMMUNE GLOBULIN, (FLEBOGAMMA), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG	FLEBOGAMMA
Intravenous immunoglobulin (IVIG)	Q4092	HCPCS	Gamunex, 500 mg	INJECTION, IMMUNE GLOBULIN, (GAMUNEX), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG	GAMUNEX

Intravenous immunoglobulin (IVIG)	Q4097	HCPCS	Privigen, 500 mg	INJECTION, IMMUNE GLOBULIN, (PRIVIGEN), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG	PRIVIGEN
Intravenous immunoglobulin (IVIG)	30250S1	PRC10		Transfusion of Nonautologous Globulin into Peripheral Artery, Open Approach	Nonspecific
Intravenous immunoglobulin (IVIG)	30260S1	PRC10		Transfusion of Nonautologous Globulin into Central Artery, Open Approach	Nonspecific
Intravenous immunoglobulin (IVIG)	99.14	PRC9		Injection or infusion of immunoglobulin	Nonspecific
Subcutaneous immunoglobulin (SCIG)	90284	CPT	Human ig, sc	Immune globulin (scig), human, for use in subcutaneous infusions, 100 mg, each	Nonspecific
Subcutaneous immunoglobulin (SCIG)	J1559	HCPCS	Injection, immune globulin (hizentra), 100 mg	Injection, immune globulin (hizentra), 100 mg	HIZENTRA
Subcutaneous immunoglobulin (SCIG)	J1562	HCPCS	Immune globulin 5 gms	Injection, immune globulin (vivaglobin), 100 mg	VIVAGLOBIN
Subcutaneous immunoglobulin (SCIG)	J1555	HCPCS	Inj, imm glob cuvitr, 100mg	Injection, immune globulin (cuvitr) 100 mg	CUVITRU
Subcutaneous immunoglobulin (SCIG)	J1575	HCPCS	Hyqvia 100mg immunoglobulin	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immunoglobulin	HYQVIA
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	J1564	HCPCS		IMMUNE GLOBULIN 10 MG	Nonspecific
Subcutaneous immunoglobulin (SCIG) and Intravenous	J1561	HCPCS	Immune globulin 500 mg	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg	GAMUNEX-C /GAMMAKED

immunoglobulin (IVIG)					
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	J1569	HCPCS	Gammagard liquid injection	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g. liquid), 500 mg	GAMMAGARD Liquid
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	Q4088	HCPCS	Gammagard liquid injection, 500 mg	INJECTION, IMMUNE GLOBULIN, (GAMMAGARD), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG	GAMMAGARD Liquid
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	J1599	HCPCS	Ivig non-lyophilized, nos	Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified, 500 mg	Nonspecific PANZYGA, ASCENIV, CUTAQUIG

**Appendix 2. NDCs for IVIG/SCIG Drugs**

Product Name	11-digit Code	9-digit Code	Medispan Generic Name
Intravenous immunoglobulin (IVIG)	00026064612	000260646	Immune globulin (human) iv soln 5%
Intravenous immunoglobulin (IVIG)	00026064620	000260646	Immune globulin (human) iv soln 5%
Intravenous immunoglobulin (IVIG)	00026064624	000260646	Immune globulin (human) iv soln 5%
Intravenous immunoglobulin (IVIG)	00026064625	000260646	Immune globulin (human) iv soln 5%
Intravenous immunoglobulin (IVIG)	00026064671	000260646	Immune globulin (human) iv soln 5%
Intravenous immunoglobulin (IVIG)	00053748605	000537486	Immune globulin (human) iv for soln 5 gm
Intravenous immunoglobulin (IVIG)	00053748610	000537486	Immune globulin (human) iv for soln 10 gm
Intravenous immunoglobulin (IVIG)	00078012094	000780120	Immune globulin (human) iv for soln 1 gm
Intravenous immunoglobulin (IVIG)	00944047169	009440471	Immune globulin (human) iv for soln 0.5 gm

Intravenous immunoglobulin (IVIG)	00944047172	009440471	Immune globulin (human) iv for soln 2.5 gm
Intravenous immunoglobulin (IVIG)	00944047175	009440471	Immune globulin (human) iv for soln 5 gm
Intravenous immunoglobulin (IVIG)	00944047180	009440471	Immune globulin (human) iv for soln 10 gm
Intravenous immunoglobulin (IVIG)	00944280701	009442807	Immune globulin (human) iv for soln 5 gm
Intravenous immunoglobulin (IVIG)	00944280704	009442807	Immune globulin (human) iv for soln 10 gm
Intravenous immunoglobulin (IVIG)	00944262001	009442620	Immune globulin (human) iv for soln 0.5 gm
Intravenous immunoglobulin (IVIG)	00944262002	009442620	Immune globulin (human) iv for soln 2.5 gm
Intravenous immunoglobulin (IVIG)	00944262003	009442620	Immune globulin (human) iv for soln 5 gm
Intravenous immunoglobulin (IVIG)	00944262004	009442620	Immune globulin (human) iv for soln 10 gm
Intravenous immunoglobulin (IVIG)	00944265503	009442655	Immune globulin (human) iv for soln 5 gm
Intravenous immunoglobulin (IVIG)	00944265504	009442655	Immune globulin (human) iv for soln 10 gm
Intravenous immunoglobulin (IVIG)	00944265603	009442656	Immune globulin (human) iv for soln 5 gm
Intravenous immunoglobulin (IVIG)	00944265804	009442658	Immune globulin (human) iv for soln 10 gm
Intravenous immunoglobulin (IVIG)	00026064515	000260645	Immune globulin (human) iv soln 10%
Intravenous immunoglobulin (IVIG)	00026064520	000260645	Immune globulin (human) iv soln 10%
Intravenous immunoglobulin (IVIG)	00026064524	000260645	Immune globulin (human) iv soln 10%
Intravenous immunoglobulin (IVIG)	00026064571	000260645	Immune globulin (human) iv soln 10%
Intravenous immunoglobulin (IVIG)	13533064515	135330645	Immune globulin (human) iv soln 10%
Intravenous immunoglobulin (IVIG)	13533064571	135330645	Immune globulin (human) iv soln 10%
Intravenous immunoglobulin (IVIG)	13533064520	135330645	Immune globulin (human) iv soln 10%

Intravenous immunoglobulin (IVIG)	13533064524	135330645	Immune globulin (human) iv soln 20 gm 200ml
Intravenous immunoglobulin (IVIG)	44206041501	442060415	Immune globulin (human) iv for soln 1 gm
Intravenous immunoglobulin (IVIG)	44206041603	442060416	Immune globulin (human) iv for soln 3 gm
Intravenous immunoglobulin (IVIG)	44206041706	442060417	Immune globulin (human) iv for soln 6 gm
Intravenous immunoglobulin (IVIG)	44206041812	442060418	Immune globulin (human) iv for soln 12 gm
Intravenous immunoglobulin (IVIG)	44206043605	442060436	Immune globulin (human) iv soln 5 gm 50ml
Intravenous immunoglobulin (IVIG)	44206043710	442060437	Immune globulin (human) iv soln 10 gm 100ml
Intravenous immunoglobulin (IVIG)	44206043820	442060438	Immune globulin (human) iv soln 20 gm 200ml
Intravenous immunoglobulin (IVIG)	44206043892	442060438	Immune globulin (human) iv soln 20 gm 200ml
Intravenous immunoglobulin (IVIG)	44206043940	442060439	Immune globulin (human) iv soln 40 gm 400ml
Intravenous immunoglobulin (IVIG)	44206050551	442060505	Immune globulin (human) iv for soln 1 gm
Intravenous immunoglobulin (IVIG)	44206050653	442060506	Immune globulin (human) iv for soln 3 gm
Intravenous immunoglobulin (IVIG)	44206050756	442060507	Immune globulin (human) iv for soln 6 gm
Intravenous immunoglobulin (IVIG)	44206050862	442060508	Immune globulin (human) iv for soln 12 gm
Intravenous immunoglobulin (IVIG)	52769026866	527690268	Immune globulin (human) iv for soln 6 gm
Intravenous immunoglobulin (IVIG)	52769026972	527690269	Immune globulin (human) iv for soln 12 gm
Intravenous immunoglobulin (IVIG)	52769027071	527690270	Immune globulin (human) iv for soln 1 gm

Intravenous immunoglobulin (IVIG)	52769027073	527690270	Immune globulin (human) iv for soln 3 gm
Intravenous immunoglobulin (IVIG)	52769041706	527690417	Immune globulin (human) iv for soln 6 gm
Intravenous immunoglobulin (IVIG)	52769041812	527690418	Immune globulin (human) iv for soln 12 gm
Intravenous immunoglobulin (IVIG)	52769047172	527690471	Immune globulin (human) iv for soln 2.5 gm
Intravenous immunoglobulin (IVIG)	52769047175	527690471	Immune globulin (human) iv for soln 5 gm
Intravenous immunoglobulin (IVIG)	52769047180	527690471	Immune globulin (human) iv for soln 10 gm
Intravenous immunoglobulin (IVIG)	61953000302	619530003	Immune globulin (human) iv soln 5%
Intravenous immunoglobulin (IVIG)	61953000303	619530003	Immune globulin (human) iv soln 5%
Intravenous immunoglobulin (IVIG)	61953000304	619530003	Immune globulin (human) iv soln 5%
Intravenous immunoglobulin (IVIG)	61953000400	619530004	Immune globulin (human) iv soln 20 gm 400ml
Intravenous immunoglobulin (IVIG)	61953000401	619530004	Immune globulin (human) iv soln 5%
Intravenous immunoglobulin (IVIG)	61953000402	619530004	Immune globulin (human) iv soln 2.5 gm 50ml
Intravenous immunoglobulin (IVIG)	61953000403	619530004	Immune globulin (human) iv soln 5 gm 100ml
Intravenous immunoglobulin (IVIG)	61953000404	619530004	Immune globulin (human) iv soln 10 gm 200ml
Intravenous immunoglobulin (IVIG)	61953000405	619530004	Immune globulin (human) iv soln 20 gm 400ml
Intravenous immunoglobulin (IVIG)	61953000406	619530004	Immune globulin (human) iv soln 0.5 gm 10ml
Intravenous immunoglobulin (IVIG)	61953000407	619530004	Immune globulin (human) iv soln 2.5 gm 50ml
Intravenous immunoglobulin (IVIG)	61953000408	619530004	Immune globulin (human) iv soln 5 gm 100ml
Intravenous immunoglobulin (IVIG)	61953000409	619530004	Immune globulin (human) iv soln 10 gm 200ml

Intravenous immunoglobulin (IVIG)	61953000501	619530005	Immune globulin (human) iv soln 5 gm 50ml
Intravenous immunoglobulin (IVIG)	61953000502	619530005	Immune globulin (human) iv soln 10 gm 100ml
Intravenous immunoglobulin (IVIG)	61953000503	619530005	Immune globulin (human) iv soln 20 gm 200ml
Intravenous immunoglobulin (IVIG)	61953000504	619530005	Immune globulin (human) iv soln 5 gm 50ml
Intravenous immunoglobulin (IVIG)	61953000505	619530005	Immune globulin (human) iv soln 10 gm 100ml
Intravenous immunoglobulin (IVIG)	61953000506	619530005	Immune globulin (human) iv soln 20 gm 200ml
Intravenous immunoglobulin (IVIG)	64193025050	641930250	Immune globulin (human) iv for soln 5 gm
Intravenous immunoglobulin (IVIG)	64208823401	642088234	Immune globulin (human) iv soln 2.5 gm 50ml
Intravenous immunoglobulin (IVIG)	64208823402	642088234	Immune globulin (human) iv soln 5 gm 100ml
Intravenous immunoglobulin (IVIG)	64208823403	642088234	Immune globulin (human) iv soln 10 gm 200ml
Intravenous immunoglobulin (IVIG)	64208823404	642088234	Immune globulin (human) iv soln 20 gm 400ml
Intravenous immunoglobulin (IVIG)	64208823405	642088234	Immune globulin (human) iv soln 2.5 gm 50ml
Intravenous immunoglobulin (IVIG)	64208823406	642088234	Immune globulin (human) iv soln 5 gm 100ml
Intravenous immunoglobulin (IVIG)	64208823407	642088234	Immune globulin (human) iv soln 10 gm 200ml
Intravenous immunoglobulin (IVIG)	64208823408	642088234	Immune globulin (human) iv soln 20 gm 400ml
Intravenous immunoglobulin (IVIG)	64208823501	642088235	Immune globulin (human) iv soln 5 gm 50ml
Intravenous immunoglobulin (IVIG)	64208823502	642088235	Immune globulin (human) iv soln 10 gm 100ml

Intravenous immunoglobulin (IVIG)	64208823503	642088235	Immune globulin (human) iv soln 20 gm 200ml
Intravenous immunoglobulin (IVIG)	64208823505	642088235	Immune globulin (human) iv soln 5 gm 50ml
Intravenous immunoglobulin (IVIG)	64208823506	642088235	Immune globulin (human) iv soln 10 gm 100ml
Intravenous immunoglobulin (IVIG)	64208823507	642088235	Immune globulin (human) iv soln 20 gm 200ml
Intravenous immunoglobulin (IVIG)	67467084301	674670843	Immune globulin (human) iv soln 5%
Intravenous immunoglobulin (IVIG)	67467084302	674670843	Immune globulin (human) iv soln 2.5 gm 50ml
Intravenous immunoglobulin (IVIG)	67467084303	674670843	Immune globulin (human) iv soln 5 gm 100ml
Intravenous immunoglobulin (IVIG)	67467084304	674670843	Immune globulin (human) iv soln 10 gm 200ml
Intravenous immunoglobulin (IVIG)	68209084302	682090843	
Intravenous immunoglobulin (IVIG)	68209084303	682090843	
Intravenous immunoglobulin (IVIG)	68209084304	682090843	
Intravenous immunoglobulin (IVIG)	68982082001	689820820	Immune globulin intravenous (human)
Intravenous immunoglobulin (IVIG)	68982082002	689820820	Immune globulin intravenous (human)
Intravenous immunoglobulin (IVIG)	68982082003	689820820	Immune globulin intravenous (human)
Intravenous immunoglobulin (IVIG)	68982082004	689820820	Immune globulin intravenous (human)
Intravenous immunoglobulin (IVIG)	68982082005	689820820	Immune globulin intravenous (human)
Intravenous immunoglobulin (IVIG)	68982082006	689820820	Immune globulin intravenous (human)
Intravenous immunoglobulin (IVIG)	68982084001	689820840	Immune globulin (human) iv soln 1 gm 20ml
Intravenous immunoglobulin (IVIG)	68982084002	689820840	Immune globulin (human) iv soln 2.5 gm 50ml
Intravenous immunoglobulin (IVIG)	68982084003	689820840	Immune globulin (human) iv soln 5 gm 100ml
Intravenous immunoglobulin (IVIG)	68982084004	689820840	Immune globulin (human) iv soln 10 gm 200ml

Intravenous immunoglobulin (IVIG)	68982084005	689820840	Immune globulin (human) iv soln 25 gm 500ml
Intravenous immunoglobulin (IVIG)	68982085001	689820850	Immune globulin (human) iv soln 2 gm 20ml
Intravenous immunoglobulin (IVIG)	68982085002	689820850	Immune globulin (human) iv soln 5 gm 50ml
Intravenous immunoglobulin (IVIG)	68982085003	689820850	Immune globulin (human) iv soln 10 gm 100ml
Intravenous immunoglobulin (IVIG)	68982085004	689820850	Immune globulin (human) iv soln 20 gm 200ml
Intravenous immunoglobulin (IVIG)	69800025001	698000250	IMMUNE GLOBULIN,GAMMA (IGG)/SLRA HUMAN
Intravenous immunoglobulin (IVIG)	69800025002	698000250	IMMUNE GLOBULIN,GAMMA (IGG)/SLRA HUMAN
Intravenous immunoglobulin (IVIG)	59730650301	597306503	
Intravenous immunoglobulin (IVIG)	59730650201	597306502	
Intravenous immunoglobulin (IVIG)	76125091804	761250918	
Intravenous immunoglobulin (IVIG)	76125091809	761250918	
Subcutaneous immunoglobulin (SCIG)	00053759601	53759601	Immune globulin (human) subcutaneous inj 160 mg ml (16%)
Subcutaneous immunoglobulin (SCIG)	00053759603	53759603	Immune globulin (human) subcutaneous inj 160 mg ml (16%)
Subcutaneous immunoglobulin (SCIG)	00053759610	53759610	Immune globulin (human) subcutaneous inj 160 mg ml (16%)
Subcutaneous immunoglobulin (SCIG)	00053759615	53759615	Immune globulin (human) subcutaneous inj 160 mg ml (16%)
Subcutaneous immunoglobulin (SCIG)	00053759620	53759620	Immune globulin (human) subcutaneous inj 160 mg ml (16%)
Subcutaneous immunoglobulin (SCIG)	00053759625	53759625	Immune globulin (human) subcutaneous inj 160 mg ml (16%)
Subcutaneous immunoglobulin (SCIG)	00944251002	944251002	Immun glob inj 2.5 gm 25ml hyaluron inj 200 unt 1.25 ml kit
Subcutaneous immunoglobulin (SCIG)	00944251102	944251102	Immun glob inj 5 gm 50ml hyaluron inj 400 unt 2.5 ml kit

Subcutaneous immunoglobulin (SCIG)	00944251202	944251202	Immun glob inj 10 gm 100ml hyaluron inj 800 unt 5 ml kit
Subcutaneous immunoglobulin (SCIG)	00944251302	944251302	Immun glob inj 20 gm 200ml hyaluron inj 1600 unt 10 ml kit
Subcutaneous immunoglobulin (SCIG)	00944251402	944251402	Immun glob inj 30 gm 300ml hyaluron inj 2400 unt 15 ml kit
Subcutaneous immunoglobulin (SCIG)	00944285001	944285001	Immune globulin (human) subcutaneous inj 1 gm 5ml
Subcutaneous immunoglobulin (SCIG)	00944285002	944285002	Immune globulin (human) subcutaneous inj 1 gm 5ml
Subcutaneous immunoglobulin (SCIG)	00944285003	944285003	Immune globulin (human) subcutaneous inj 2 gm 10ml
Subcutaneous immunoglobulin (SCIG)	00944285004	944285004	Immune globulin (human) subcutaneous inj 2 gm 10ml
Subcutaneous immunoglobulin (SCIG)	00944285005	944285005	Immune globulin (human) subcutaneous inj 4 gm 20ml
Subcutaneous immunoglobulin (SCIG)	00944285006	944285006	Immune globulin (human) subcutaneous inj 4 gm 20ml
Subcutaneous immunoglobulin (SCIG)	00944285007	944285007	Immune globulin (human) subcutaneous inj 8 gm 40ml
Subcutaneous immunoglobulin (SCIG)	00944285008	944285008	Immune globulin (human) subcutaneous inj 8 gm 40ml
Subcutaneous immunoglobulin (SCIG)	44206045101	442060451	Immune globulin (human) subcutaneous inj 1 gm 5ml
Subcutaneous immunoglobulin (SCIG)	44206045190	442060451	Immune globulin (human) subcutaneous inj 1 gm 5ml
Subcutaneous immunoglobulin (SCIG)	44206045202	442060452	Immune globulin (human) subcutaneous inj 2 gm 10ml
Subcutaneous immunoglobulin (SCIG)	44206045291	442060452	Immune globulin (human) subcutaneous inj 2 gm 10ml
Subcutaneous immunoglobulin (SCIG)	44206045404	442060454	Immune globulin (human) subcutaneous inj 4 gm 20ml
Subcutaneous immunoglobulin (SCIG)	44206045492	442060454	Immune globulin (human) subcutaneous inj 4 gm 20ml

Subcutaneous immunoglobulin (SCIG)	44206045510	442060455	Immune globulin (human) subcutaneous inj 10 gm 50ml
Subcutaneous immunoglobulin (SCIG)	44206045593	442060455	Immune globulin (human) subcutaneous inj 10 gm 50ml
Subcutaneous immunoglobulin (SCIG)	00069106101	000691061	IMMUNE GLOBULIN,GAMMA(IGG)/HIPP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	00069106102	000691061	IMMUNE GLOBULIN,GAMMA(IGG)/HIPP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	00069147601	000691476	IMMUNE GLOBULIN,GAMMA(IGG)/HIPP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	00069147602	000691476	IMMUNE GLOBULIN,GAMMA(IGG)/HIPP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	00069150901	000691509	IMMUNE GLOBULIN,GAMMA(IGG)/HIPP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	00069150902	000691509	IMMUNE GLOBULIN,GAMMA(IGG)/HIPP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	00069196501	000691965	IMMUNE GLOBULIN,GAMMA(IGG)/HIPP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	00069196502	000691965	IMMUNE GLOBULIN,GAMMA(IGG)/HIPP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	13533081005	135330810	IMMUNE GLOBULIN,GAMMA (IGG)/KLHW HUMAN
Subcutaneous immunoglobulin (SCIG)	13533081006	135330810	IMMUNE GLOBULIN,GAMMA (IGG)/KLHW HUMAN
Subcutaneous immunoglobulin (SCIG)	13533081010	135330810	IMMUNE GLOBULIN,GAMMA (IGG)/KLHW HUMAN
Subcutaneous immunoglobulin (SCIG)	13533081011	135330810	IMMUNE GLOBULIN,GAMMA (IGG)/KLHW HUMAN

Subcutaneous immunoglobulin (SCIG)	13533081020	135330810	IMMUNE GLOBULIN,GAMMA (IGG)/KLHW HUMAN
Subcutaneous immunoglobulin (SCIG)	13533081021	135330810	IMMUNE GLOBULIN,GAMMA (IGG)/KLHW HUMAN
Subcutaneous immunoglobulin (SCIG)	13533081050	135330810	IMMUNE GLOBULIN,GAMMA (IGG)/KLHW HUMAN
Subcutaneous immunoglobulin (SCIG)	13533081051	135330810	IMMUNE GLOBULIN,GAMMA (IGG)/KLHW HUMAN
Subcutaneous immunoglobulin (SCIG)	68982081001	689820810	IMMUNE GLOBULIN,GAMMA(IGG)/HIP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	68982081002	689820810	IMMUNE GLOBULIN,GAMMA(IGG)/HIP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	68982081003	689820810	IMMUNE GLOBULIN,GAMMA(IGG)/HIP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	68982081004	689820810	IMMUNE GLOBULIN,GAMMA(IGG)/HIP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	68982081005	689820810	IMMUNE GLOBULIN,GAMMA(IGG)/HIP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	68982081006	689820810	IMMUNE GLOBULIN,GAMMA(IGG)/HIP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	68982081081	689820810	IMMUNE GLOBULIN,GAMMA(IGG)/HIP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	68982081082	689820810	IMMUNE GLOBULIN,GAMMA(IGG)/HIP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	68982081083	689820810	IMMUNE GLOBULIN,GAMMA(IGG)/HIP HUMAN/MALTOSE

Subcutaneous immunoglobulin (SCIG)	68982081084	689820810	IMMUNE GLOBULIN,GAMMA(IGG)/HIP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	68982081085	689820810	IMMUNE GLOBULIN,GAMMA(IGG)/HIP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG)	68982081086	689820810	IMMUNE GLOBULIN,GAMMA(IGG)/HIP HUMAN/MALTOSE
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	00944270002	009442700	Immune globulin (human) iv soln 1 gm 10ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	00944270004	009442700	Immune globulin (human) iv soln 5 gm 50ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	00944270006	009442700	Immune globulin (human) iv soln 20 gm 200ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	00944270007	944270007	Immune globulin (human) iv soln 10%
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	00944270003	944270003	Immune globulin (human) iv or subcutaneous soln 2.5 gm 25ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	00944270005	944270005	Immune globulin (human) iv or subcutaneous soln 10 gm 100ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	00944270008	944270008	Immune globulin (human) iv or subcutaneous soln 1 gm 10ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	00944270009	944270009	Immune globulin (human) iv or subcutaneous soln 2.5 gm 25ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	00944270010	944270010	Immune globulin (human) iv or subcutaneous soln 5 gm 50ml

Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	00944270011	944270011	Immune globulin (human) iv or subcutaneous soln 10 gm 100ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	00944270012	944270012	Immune globulin (human) iv or subcutaneous soln 20 gm 200ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	00944270013	944270013	Immune globulin (human) iv or subcutaneous soln 30 gm 300ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	13533080012	135330800	Immune globulin (human) iv or subcutaneous soln 1 gm 10ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	13533080013	135330800	Immune globulin (human) iv or subcutaneous soln 1 gm 10ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	13533080015	135330800	Immune globulin (human) iv or subcutaneous soln 2.5 gm 25ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	13533080016	135330800	Immune globulin (human) iv or subcutaneous soln 2.5 gm 25ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	13533080020	135330800	Immune globulin (human) iv or subcutaneous soln 5 gm 50ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	13533080021	135330800	Immune globulin (human) iv or subcutaneous soln 5 gm 50ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	13533080024	135330800	Immune globulin (human) iv or subcutaneous soln 20 gm 200ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	13533080025	135330800	Immune globulin (human) iv or subcutaneous soln 20 gm 200ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	13533080040	135330800	Immune globulin (human) iv or subcutaneous soln 40 gm 400ml

Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	13533080041	135330800	Immune globulin (human) iv or subcutaneous soln 40 gm 400ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	13533080071	135330800	Immune globulin (human) iv or subcutaneous soln 10 gm 100ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	13533080072	135330800	Immune globulin (human) iv or subcutaneous soln 10 gm 100ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	76125090001	761250900	Immune globulin (human) iv or subcutaneous soln 1 gm 10ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	76125090002	761250900	Immune globulin (human) iv or subcutaneous soln 1 gm 10ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	76125090010	761250900	Immune globulin (human) iv or subcutaneous soln 10 gm 100ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	76125090011	761250900	Immune globulin (human) iv or subcutaneous soln 10 gm 100ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	76125090020	761250900	Immune globulin (human) iv or subcutaneous soln 20 gm 200ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	76125090021	761250900	Immune globulin (human) iv or subcutaneous soln 20 gm 200ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	76125090025	761250900	Immune globulin (human) iv or subcutaneous soln 2.5 gm 25ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	76125090026	761250900	Immune globulin (human) iv or subcutaneous soln 2.5 gm 25ml
Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	76125090050	761250900	Immune globulin (human) iv or subcutaneous soln 5 gm 50ml

Subcutaneous immunoglobulin (SCIG) and Intravenous immunoglobulin (IVIG)	76125090051	761250900	Immune globulin (human) iv or subcutaneous soln 5 gm 50ml
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**Appendix 3A. Common Immunoglobulin Use-Associated ICD-9-CM Diagnoses and Diagnosis Categories in Both Medicare and MarketScan Databases (Prior to October 2015)**

ICD-9-CM	Diagnosis Description	Broader Categories
6944	Pemphigus	Autoimmune/CTD
7100	Systemic lupus erythematosus	Autoimmune/CTD
7103	Dermatomyositis	Autoimmune/CTD
7104	Polymyositis	Autoimmune/CTD
27949	Autoimmune disease NEC	Autoimmune/CTD
4461	Acute febrile mucocutaneous lymph node syndrome [MCLS]	Autoimmune/CTD
2830	Autoimmune hemolytic anemias	Hematologic
2859	Anemia NOS	Hematologic
2875	Thrombocytopenia NOS	Hematologic
28730	Primary thrombocytopenia NOS	Hematologic
28800	Neutropenia NOS	Hematologic
28731	Immune thrombocytopenic purpura	Hematologic
28733	Congenital and hereditary thrombocytopenia purpura	Hematologic
2793	Immunity deficiency NOS	Immunodeficiency
27900	Hypogammaglobulinemia NOS	Immunodeficiency
27901	Selective IGA immunodeficiency	Immunodeficiency
27903	Selective immunoglobulin deficiencies NEC	Immunodeficiency
27909	Deficiency humoral immunity NEC	Immunodeficiency
2662	Other B-complex deficiencies	Immunodeficiency
2772	Other disorders of purine and pyrimidine metabolism	Immunodeficiency
2776	Other deficiencies of circulating enzymes	Immunodeficiency
27902	Selective IgM immunodeficiency	Immunodeficiency
27904	Congenital Hypogammaglobulinemia	Immunodeficiency
27905	Immunodeficiency with increased immunoglobulin M (IgM)	Immunodeficiency
27906	Common variable immunodeficiency	Immunodeficiency
27910	Immunodeficiency with predominant T-cell defect, unspecified	Immunodeficiency
27911	Digeorge's syndrome	Immunodeficiency
27912	Wiskott-Aldrich Syndrome	Immunodeficiency
27913	Nezelof's syndrome	Immunodeficiency
27919	Other deficiency of cell-mediated immunity	Immunodeficiency
2792	Combined immunity deficiency	Immunodeficiency
2798	Other specified disorders involving the immune mechanism	Immunodeficiency
2799	Other specified disorders involving the immune mechanism	Immunodeficiency
V3000	Single liveborn, born in hospital w/o CD	Neonatal
V3001	Single liveborn, born in hospital by CD	Neonatal
340	Multiple sclerosis	Neurologic
3559	Mononeuritis NOS	Neurologic

3564	Idiopathic progressive polyneuropathy	Neurologic
3569	Idiopathic peripheral neuropathy NOS	Neurologic
3579	Inflammatory & toxic neuropathy NOS	Neurologic
33391	Stiff-man syndrome	Neurologic
35782	Critical illness polyneuropathy	Neurologic
35789	Inflammatory & toxic neuropathy NEC	Neurologic
35800	Myasthenia gravis w/o exacerbation	Neurologic
35801	Myasthenia gravis w exacerbation	Neurologic
3570	Acute infective polyneuritis	Neurologic
35781	Chronic inflammatory demyelinating polyneuritis	Neurologic
389	Septicemia NOS	Implausible
486	Pneumonia organism NOS	Implausible
4619	Acute sinusitis NOS	Implausible
4739	Chronic sinusitis NOS	Implausible
V072	Need for prophylactic immunotherapy	Implausible
V5811	Antineoplastic chemotherapy encounter	Implausible
V5812	Immunotherapy encounter for neoplastic cond	Implausible
20280	Malignant lymphoma NEC site NOS & extranodal	Oncologic
20300	Multiple myeloma w/o achieving remission	Oncologic
20400	Acute lymphoid leukemia w/o achieving remission	Oncologic
20401	Acute lymphoid leukemia in remission	Oncologic
20411	Chronic lymphoid leukemia in remission	Oncologic
20500	Acute myeloid leukemia w/o achieving remission	Oncologic
20501	Acute myeloid leukemia in remission	Oncologic
23875	Myelodysplastic syndrome NOS	Oncologic
20410	Lymphoid leukemia, chronic	Oncologic
20412	Chronic lymphoid leukemia, in relapse	Oncologic
2731	Monoclonal paraproteinemia	Oncologic
5856	End stage renal disease	Transplantation
99681	Comp transplanted kidney	Transplantation
99684	Comp transplanted lung	Transplantation
99685	Comp bone marrow transplant	Transplantation
V5844	Aftercare following organ transplant	Transplantation

**Appendix 3B. Common Immunoglobulin Use-Associated ICD-10-CM Diagnoses and Diagnosis Categories in Medicare and MarketScan Databases (In or After October 2015)**

ICD-10-CM	Diagnosis Description	Broader Categories
M3390	Dermatopolymyositis, unspecified, organ involvement unspecified	Autoimmune/CTD
M3320	Polymyositis, organ involvement unspecified	Autoimmune/CTD
M3300	Juvenile dermatomyositis, organ involvement unspecified	Autoimmune/CTD
M359	Systemic involvement of connective tissue, unspecified	Autoimmune/CTD

M3322	Polymyositis with myopathy	Autoimmune/CTD
M303	Mucocutaneous lymph node syndrome [Kawasaki]	Autoimmune/CTD
D696	Thrombocytopenia, unspecified	Hematologic
D649	Anemia, unspecified	Hematologic
D693	Immune thrombocytopenic purpura	Hematologic
D6942	Congenital and hereditary thrombocytopenia purpura	Hematologic
D800	Hereditary Hypogammaglobulinemia	Immunodeficiency
D801	Nonfamilial Hypogammaglobulinemia	Immunodeficiency
D802	Selective Deficiency of Immunoglobulin A (IgA)	Immunodeficiency
D803	Selective Deficiency of Immunoglobulin G (IgG) subclasses	Immunodeficiency
D804	Selective Deficiency of Immunoglobulin M (IgM)	Immunodeficiency
D805	Immunodeficiency with increased immunoglobulin M [IgM]	Immunodeficiency
D806	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia	Immunodeficiency
D807	Transient hypogammaglobulinemia of infancy	Immunodeficiency
D808	Other immunodeficiencies with predominantly antibody defects	Immunodeficiency
D809	Immunodeficiency with predominantly antibody defects, unspecified	Immunodeficiency
D810	Severe Combined Immunodeficiencies (SCID) with reticular dysgenesis	Immunodeficiency
D811	Severe Combined Immunodeficiencies (SCID) with low T- and B-cell numbers	Immunodeficiency
D812	Severe Combined Immunodeficiencies (SCID) with low or normal B-cell numbers	Immunodeficiency
D813	Adenosine deaminase (ADA) deficiency	Immunodeficiency
D8130	Adenosine deaminase deficiency, unspecified	Immunodeficiency
D8131	Severe combined immunodeficiency due to adenosine deaminase deficiency	Immunodeficiency
D8132	Adenosine deaminase 2 deficiency	Immunodeficiency
D8139	Other adenosine deaminase deficiency	Immunodeficiency
D814	Nezelof Syndrome	Immunodeficiency
D815	Purine nucleoside phosphorylase (PNP) deficiency	Immunodeficiency
D816	Major histocompatibility complex class I deficiency	Immunodeficiency
D817	Major histocompatibility complex class II deficiency	Immunodeficiency
D81810	Biotinidase deficiency	Immunodeficiency
D81818	Other biotin-dependent carboxylase deficiency	Immunodeficiency
D81819	Other biotin-dependent carboxylase deficiency, unspecified	Immunodeficiency
D8189	Other combined immunodeficiencies	Immunodeficiency
D819	Combined immunodeficiency, unspecified	Immunodeficiency
D820	Wiskott-Aldrich Syndrome	Immunodeficiency
D821	Di George syndrome	Immunodeficiency
D822	Immunodeficiency with short-limbed stature	Immunodeficiency
D823	Immunodeficiency following hereditary defective response to Epstein-Barr virus	Immunodeficiency
D824	Hyperimmunoglobulin E (IgE) syndrome	Immunodeficiency

D828	Immunodeficiency associated with other specified major defects	Immunodeficiency
D829	Immunodeficiency associated with major defect, unspecified	Immunodeficiency
D830	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function	Immunodeficiency
D831	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders	Immunodeficiency
D832	Common variable immunodeficiency with antibodies to B- or T-cells	Immunodeficiency
D838	Common Variable Immunodeficiency (CVID)	Immunodeficiency
D839	Common variable immunodeficiency, unspecified	Immunodeficiency
D848	Other specified immunodeficiencies	Immunodeficiency
D849	Immunodeficiency, unspecified	Immunodeficiency
D8989	Other specified disorders involving the immune mechanism, not elsewhere classified	Immunodeficiency
D899	Disorder involving the immune mechanism, unspecified	Immunodeficiency
J069	Acute upper respiratory infection, unspecified	Implausible
J0190	Acute sinusitis, unspec	Implausible
A419	Sepsis, unspecified organism	Implausible
J029	Acute pharyngitis, unspecified	Implausible
J189	Pneumonia, unspec organism	Implausible
G7000	Myasthenia gravis without (acute) exacerbation	Neurologic
G7001	Myasthenia gravis with (acute) exacerbation	Neurologic
G610	Guillain-Barre syndrome	Neurologic
G35	Multiple sclerosis	Neurologic
G6189	Other inflammatory polyneuropathies	Neurologic
G0481	Other encephalitis and encephalomyelitis	Neurologic
G629	Polyneuropathy, unspecified	Neurologic
G2582	Stiff-man syndrome	Neurologic
G6289	Other specified polyneuropathies	Neurologic
G619	Inflammatory polyneuropathy, unspecified	Neurologic
G609	Hereditary and idiopathic neuropathy, unspecified	Neurologic
G113	Cerebellar ataxia with defective DNA repair	Neurologic
G6181	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	Neurologic
G6182	Multifocal motor neuropathy (MNN)	Neurologic
Z0000	Encounter for general adult medical examination w/o abnormal findings	Implausible
Z23	Encounter for immunization	Implausible
I10	Essential (primary) hypertension	Implausible
G4733	Obstructive sleep apnea (adult) (pediatric)	Implausible
Z01419	Encounter for routine GYN exam (general) (routine) w/o abnormal findings	Implausible
Z1231	Encounter for screening mammogram for malignant neoplasm of breast	Implausible
M545	Low back pain	Implausible
R05	Cough	Implausible

Z5111	Encounter for antineoplastic chemotherapy	Implausible
Z5112	Encounter for antineoplastic immunotherapy	Implausible
C9000	Multiple myeloma not having achieved remission	Oncologic
C9101	Acute lymphoblastic leukemia, in remission	Oncologic
C9100	Acute lymphoblastic leukemia not having achieved remission	Oncologic
C8590	Non-Hodgkin lymphoma, unspecified, unspecified site	Oncologic
C9002	Multiple myeloma in relapse	Oncologic
C9110	Chronic Lymphocytic Leukemia of B-cell type not having achieved remission (CLL)	Oncologic
C9112	Chronic lymphocytic leukemia of B-cell type in relapse	Oncologic
D472	Monoclonal gammopathy of undetermined significance (MGUS)	Oncologic
T8611	Kidney transplant rejection	Transplantation
Z940	Kidney transplant status	Transplantation
I120	Hypertensive chronic kidney disease stage 5 or end stage renal disease	Transplantation