

September 6, 2013

Marilyn Tavenner
Administrator
Chief Operating Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

ELECTRONIC DELIVERY

Re: CMS–1601–P (Hospital Outpatient Prospective Payment System Calendar Year 2014 Proposed Rule)

Dear Administrator Tavenner,

The Plasma Protein Therapeutics Association (PPTA) appreciates this opportunity to comment on the proposed rule that the Centers for Medicare & Medicaid Services (CMS) has issued regarding the Hospital Outpatient Prospective Payment System (OPPS) for calendar year (CY) 2014 (Proposed Rule).¹ Our comments on the Proposed Rule are intended to ensure that all Medicare beneficiaries who require plasma protein therapies as part of their treatment regimen have access to the full range of therapies in each therapeutic class. PPTA respectfully urges CMS to take the following actions:

1. Finalize its proposal to pay at average sales price (ASP) + 6% for separately payable, non-pass-through drugs and biologicals in CY 2014;
2. Continue its longstanding policy for payment of the furnishing fee for blood clotting factors administered or dispensed in the hospital outpatient department at the same level as in the physician office setting; and
3. Continue to make separate payment for all drug administration services, including those billed with an “add-on” code.

BACKGROUND

PPTA represents human plasma collection centers and the manufacturers of lifesaving medicinal therapies, including albumin, alpha₁-proteinase inhibitor, antithrombin III, blood clotting factors, C1 esterase inhibitor, fibrin sealant, immune globulin, hyperimmune immune globulin, prothrombin complex concentrate and protein C concentrate, from this human plasma.² Some PPTA members also use recombinant

¹ See 78 Fed. Reg. 43534 (July 19, 2013).

² Human plasma is the clear liquid portion of blood that remains after the red cells, leukocytes, and platelets are removed. Due to its human origin, complexity, and richness in therapeutically useful proteins, human plasma is a

DNA technology to produce blood clotting factors. Collectively, these therapies – both plasma-derived and recombinant – are known as “plasma protein therapies.” The manufacturer membership of PPTA in the United States (U.S.) currently includes Baxter BioScience, Biotest, CSL Behring, Grifols, and Kedrion.

The majority of plasma protein therapies are approved for marketing in the U.S. by the Food and Drug Administration (FDA) solely for the treatment of one or more rare disease, disorder, or condition. In the U.S., a “rare disease or condition” is generally defined as a disease or condition that affects less than 200,000 people.³ Most of the rare conditions that require treatment with plasma protein therapies are genetic, chronic, and life-threatening⁴. As representatives of a segment of the biopharmaceutical industry with considerable experience in treating rare diseases, PPTA recognizes the importance of adequate reimbursement levels for maintaining access to rare disease therapies. Previous reimbursement cuts for Medicare Part B drugs have resulted in some rare disease patient populations experiencing access difficulties. For example, it is well documented that primary immune deficiency disease (PIDD) patients requiring regular infusions of intravenous immune globulin (IVIG) have experienced treatment delays and shifts in site of service due to previous reductions in Medicare reimbursement. Additionally, the unintended consequences of payment reductions have led providers to switch some patients that require regular infusions of IVIG from a brand on which they had been stabilized. Because of the rare, chronic, life-threatening nature of PIDDs and other rare diseases like alpha-1 antitrypsin deficiency and hemophilia, such impediments to treatment are particularly dangerous. PPTA believes adequate reimbursement levels will prevent future patient access issues for users of plasma protein therapies.

unique biological material. See Thierry Burnouf, *Plasma Proteins: Unique Biopharmaceuticals – Unique Economics*, in 7 PHARMACEUTICALS POLICY AND LAW, BLOOD, PLASMA AND PLASMA PROTEINS: A UNIQUE CONTRIBUTION TO MODERN HEALTHCARE 209 (2005, 2006).

³ See 21 U.S.C. § 360bb(a)(2) (2006).

⁴ Diseases treated with plasma protein therapies include alpha-1 antitrypsin deficiency, chronic B-cell lymphocytic leukemia, chronic inflammatory demyelinating polyneuropathy (CIDP), hereditary angioedema, hereditary antithrombin III deficiency, protein C deficiency, primary immune deficiency diseases (PIDDs), such as common variable immunodeficiency, X-linked agammaglobulinemia (Bruton’s disease), DiGeorge syndrome, Wiskott-Aldrich syndrome, Nezelof’s syndrome, severe combined immunodeficiency, graft-versus-host diseases, and bleeding disorders, such as hemophilia A, hemophilia B, congenital fibrinogen deficiency, von Willebrand disease, and factor XIII deficiency. Cytomegalovirus disease associated with transplant patients, hepatitis B reinfection in liver transplant patients, idiopathic thrombocytopenic purpura (ITP), infant botulism, and Kawasaki’s disease. Rabies, rhesus incompatible pregnancies, and tetanus are examples of acute rare conditions that are treated with plasma protein therapies.

DISCUSSION

I. **PPTA Urges CMS to Finalize Its Proposed Payment Level of ASP + 6% for Separately Payable, Non-Pass-Through Drugs and Biologicals Under OPPS**

Adequate Medicare reimbursement is vital to preserve patient access to therapeutic interventions for rare diseases. It affects decisions by manufacturers to invest in the research and development required to improve formulations and routes of administration for existing therapies and also investment needed to bring new therapies to market. As it did for CY 2013, CMS is proposing to set the payment for separately paid drugs and biologicals without pass-through status at ASP + 6% for CY 2014.⁵ We again commend CMS for this proposal and recommend that CMS finalize the proposed payment mechanism for separately payable, non-pass-through drugs and biologicals under OPPS for the reasons discussed below.

Pursuant to section 1833(t)(14)(A)(iii)(II) of the Social Security Act (SSA), CMS has broad statutory authority to set the payment level for specified covered outpatient drugs administered or dispensed in the hospital outpatient department. This broad authority has resulted in the reimbursement level for separately payable, non-pass-through drugs and biologicals constantly changing over the last several years (prior to the current year) – ASP + 6% in CYs 2006 and 2007, ASP + 5% in CY 2008, ASP + 4% in CYs 2009 and 2010, ASP + 5% in 2011, and ASP + 4% in 2012. For CY 2010 through CY 2012, CMS arrived at the payment rate through a complicated methodology that included redistributing some overhead costs from packaged drugs and biologicals to separately paid products.

Based on several recent years of basing reimbursement on claims data, CMS believes that the range between ASP + 4% and ASP + 6% is an appropriate payment rate for separately payable drugs and biologicals. However, CMS has been concerned that the continued use of its standard drug payment methodology still may not appropriately account for average acquisition and pharmacy overhead cost and, therefore, may result in payment rates that are not as predictable, accurate, or appropriate for hospitals as they could be due to limitations in the submitted hospital charge and claims data for drugs.⁶

In response to these concerns, which led to use of ASP + 6% for CY 2013, CMS again proposes to set reimbursement for separately paid drugs and biologicals without pass-through status at ASP + 6%. The agency believes this policy will improve payment predictability for separately payable, non-pass-through drugs and biologicals under the OPPS.⁷

⁵ 78 Fed. Reg. at 43607-09.

⁶ *Id.* at 43608.

⁷ *Id.*

We also believe that there are strong policy reasons to continue to reimburse for separately payable, non-pass-through drugs at ASP + 6%. Adequate Medicare reimbursement is imperative for the preservation of patient access to plasma protein therapies in the hospital outpatient setting. Both the U.S. Department of Health and Human Services (HHS)⁸ and the Immune Deficiency Foundation (IDF)⁹ issued reports in 2007 that concluded insufficient reimbursement was a leading factor in the difficulties patients faced in accessing IVIG. At that time, reimbursement differences resulted in patient migration from the physician office to the hospital outpatient department.¹⁰ We believed then and continue to believe that it is imperative that Medicare beneficiaries be able to obtain IVIG and other plasma protein therapies best suited for their individual needs in the most appropriate site of service, and thus hospital outpatient departments must remain a viable option for beneficiaries to receive IVIG. Therefore, we applaud the proposal to pay hospital outpatient departments at ASP + 6%, just as these products are reimbursed in physicians' offices. Just as CMS has correctly decided to pay the same furnishing fee for blood clotting factors in physician offices and hospital outpatient departments to avoid a financial advantage for one setting over another, so too should CMS set payments at ASP + 6% in hospital outpatient departments. By establishing payment equity across settings, CMS helps to ensure that the choice of setting will be driven by clinical, rather than financial, considerations – as it should be.

II. PPTA Urges CMS to Continue Its Longstanding Policy of Applying the Furnishing Fee for Blood Clotting Factors under the OPPTS

Section 303(e) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (“MMA”) (Pub. L. No. 108-173, 117 Stat. 2066 et. seq. (2003)) established a “furnishing fee” for blood clotting factors provided in the physician office.¹¹ Pursuant to the statute, this fee is updated annually according to inflation for medical care.¹² The fee for CY 2014 is \$0.192 per unit.¹³

⁸ OFFICE OF THE ASSISTANT SEC’Y FOR PLANNING & EVALUATION, U.S. DEP’T OF HEALTH AND HUMAN SERVS., ANALYSIS OF SUPPLY, DISTRIBUTION, DEMAND, AND ACCESS ISSUES ASSOCIATED WITH IMMUNE GLOBULIN INTRAVENOUS (IGIV): FINAL REPORT (2007), at Section 4 (discussing reimbursement levels and noting difficulties Medicare beneficiaries confront in finding infusion sites). OFFICE OF INSPECTOR GENERAL, U.S. DEP’T OF HEALTH AND HUMAN SERVS., INTRAVENOUS IMMUNE GLOBULIN: MEDICARE PAYMENT AND AVAILABILITY (2007), at 15 (concluding that a significant percentage of sales of IVIG to hospitals and physicians were at prices equal to or above the Medicare payment rate for the third quarter of 2006).

⁹ IMMUNE DEFICIENCY FOUNDATION, ASSESSING THE IMPACT OF CHANGES IN REIMBURSEMENT REGULATIONS AND PRODUCT AVAILABILITY ON ACCESS TO INTRAVENOUS GAMMAGLOBULIN TREATMENT AMONG PRIMARY IMMUNE DEFICIENCY PATIENTS 17 (2006) (revealing that a significant majority of Medicare beneficiaries who use IVIG attribute access difficulties to poor reimbursement for these therapies).

¹⁰ See, e.g., Ricardo Alonso-Zaldivar, Crucial But Costly Treatment Is Drying Up With Funding: Thousands Of Elderly Patients Who Need Intravenous Antibodies Are Hurt By Medicare Cutbacks - More Pain Could Be On The Way, L.A. TIMES, February 28, 2006, at A8 (illustrating the challenges, including shifts in sites of service, patients must overcome to receive IVIG therapies because of the Medicare reimbursement cuts).

¹¹ See MMA, 117 Stat. 2066, 2252 (2003); Social Security Act (“SSA”) § 1842(o)(5) (2006).

¹² SSA, § 1842(o)(5)(C).

¹³ See <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2760CP.pdf> (CMS transmittal announcing blood clotting factor furnishing fee for CY 2014).

Since 2006, CMS has rightly paid hospitals the same furnishing fee¹⁴ and again provides for a furnishing fee for hospital outpatient departments in the Proposed Rule.¹⁵ In arriving at its original decision to also provide for the furnishing fee under the OPPTS, CMS determined that similar resources were required to furnish blood clotting factors “across all types of service settings.”¹⁶ As such, the agency concluded that, moving forward, “it is appropriate to adopt a methodology for paying for clotting factors under the OPPTS that is consistent with the methodology applied in the physician office setting and the inpatient hospital setting.”¹⁷

PPTA agrees that the agency’s conclusion continues to be correct. Indeed, we believe this furnishing fee has been instrumental in preserving patient access to blood clotting factors since its inception in the physician office in 2005; thus, PPTA appreciates CMS’ inclusion of the furnishing fee under OPPTS to date. We urge CMS to finalize its proposal and continue the furnishing fee for blood clotting factors administered in the hospital outpatient department in CY 2014.

III. CMS Should Not Package the Payment for any Drug Administration Services

Under the Proposed Rule, CMS would package the payment for all “add-on” codes – which describe procedures which are always performed in addition to a primary procedure.¹⁸ Under the proposed policy, all procedures described by add-on codes would be packaged with the primary procedure. PPTA believes that this proposed policy is overly broad and, particularly with respect to drug administration codes, will create incentives that will be contrary to the best interests of patients.

To explain this view, PPTA will focus on the impact of the proposal on payment for intravenous infusions of IVIG. There are nine approved brands of IVIG indicated by the FDA for the treatment of PIDD.¹⁹ Some brands of IVIG also are indicated to treat multifocal motor neuropathy, B-cell chronic lymphocytic leukemia, immune thrombocytopenic purpura (ITP), Kawasaki syndrome and chronic inflammatory demyelinating polyneuropathy (CIDP). The dosage of IVIG varies greatly and is determined based on the patient’s weight and specific diagnosis. The decision to infuse IVIG for a PIDD patient in a hospital, hospital outpatient department or another setting must be based upon clinical characteristics of the patient.²⁰ Further, a specific IVIG product needs to meet the needs and characteristics of the individual patient to ensure safety given that IVIG therapies are not generic and are not interchangeable.²¹

¹⁴ See 70 Fed. Reg. 68516, 68661 (Nov. 10, 2005).

¹⁵ 78 Fed. Reg. at 43609.

¹⁶ 70 Fed. Reg. at 68661.

¹⁷ *Id.*

¹⁸ 78 Fed. Reg. at 43573.

¹⁹ See www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/

[LicensedProductsBLAs/FractionatedPlasmaProducts/ucm133691.htm](http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/ucm133691.htm), last visited Aug. 28, 2013

²⁰ “Eight Guiding Principles for Effective Use of IVIG for Patients with Primary Immunodeficiency,” AAAAI.

²¹ *Id.*

We are specifically concerned with IVIG infusions that occur over a period of four, five, six, or even seven hours. In such circumstances, hospitals currently bill a single service unit of 96365 (Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour) for the first hour of the infusion and anywhere from three to six service units of 96366 (Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour) to capture the subsequent hours for the infusion. Under the current payment rates, using the national average figures, a hospital would receive the following amounts for a multiple hour drug administration service depending on the length of the infusion.

Table 1 – Comparison of 2013 and 2014 Payments for Multiple Hour Infusions of IVIG

Length of Infusion	2013 Payment for 96365	2013 Payment for 96366	2013 Total Payment	2014 Payment	2014 Payment Compared to 2013 Payment
2 Hours	\$146.24	\$27.01	\$173.25	\$198.69	+\$25.44
3 Hours	\$146.24	\$54.02	\$200.26	\$198.69	-\$1.57
4 Hours	\$146.24	\$81.03	\$227.27	\$198.69	-\$28.58
5 Hours	\$146.24	\$108.04	\$254.28	\$198.69	-\$55.59
6 Hours	\$146.24	\$135.05	\$281.29	\$198.69	-\$82.60
7 Hours	\$146.24	\$162.06	\$308.30	\$198.69	-\$109.61
8 Hours	\$146.24	\$189.07	\$335.31	\$198.69	-\$136.62

Since CPT code 96366 is an add-on code, CMS would no longer pay separately for this code regardless of the length of the infusion and, instead, would package 96366 into the primary procedure – 96365. Based on the add-on code packaging proposal, the 2014 payment amount for administering IVIG over multiple hours would be \$198.69 regardless of whether the infusion occurred over a one hour period, a seven hour period, or anywhere in between.

As is evident by comparing the total current payment amounts for multiple hour intravenous infusions of IVIG to the \$198.69 total payment amounts for 2014 under the Proposed Rule (far right column of Table 1 above), hospitals will see the payment amounts they will receive from infusions of four, five, six, seven, or eight hours decrease significantly. These projected losses are not merely theoretical.

Based on analysis of the 2012 claims data involving the administration of IVIG, performed by Braid-Forbes Health Research, for all infusions billed with code 96366,

8% are for infusions lasting more than three hours and for infusions of drugs other than IVIG, 5% are for infusions lasting more than three hours. By contrast, 35% of claims for infusion code 96366 are associated with an IVIG administration taking longer than three hours.²²

Further, the analysis shows the average length of an infusion of IVIG is 3.26 hours,²³ meaning that 96365 and three service units of 96366 are billed. Thus, on average, hospitals would see their payments for administering IVIG reduced by approximately 13% due to the proposal to package CPT code 96366, because it is an add-on code. Further, for the 15% of the infusions of IVIG which are five hours or more, hospital reimbursement would decrease by roughly 20% or more. Consequently, for patients whose IVIG infusion administration is beyond three hours, there would be a strong disincentive to administer the infusion in a hospital outpatient department, possibly forcing patients to locate other settings for their IVIG infusions.

CMS just this year (and proposed again for CY 2014) ended the difference in the payment amounts for IVIG, and other separately payable, non-pass-through drugs, in the physician office setting versus the hospital outpatient department setting. Ironically, the proposal to package all add-on codes would again create a reimbursement disparity across these two settings.

Not only is PPTA concerned about the potential disparity between reimbursement of administering IVIG therapy in the hospital outpatient department and the physician office setting that might result from this packaging proposal, but with ensuring that patients using IVIG in any setting receive the best possible health outcome from their treatment. This means proper matching of the therapy to the individual patient's clinical needs and administration of the product, which can be lengthy. For example, a loading dose of IVIG for CIPD, a rare, serious neurological disorder, could be as long as 16 hours over two to four consecutive days.²⁴ Administering IVIG is complex and requires a step-wise approach. The selection of the therapy for the individual patient requires careful evaluation and consideration by the treating physician and patient, because each brand has unique characteristics that will react differently in each patient.²⁵ Any time a patient changes brands of therapy, it is important to approach the infusion as if he or she has never received an immune globulin product and apply conservative infusion times.²⁶ Each patient has a maximum tolerated rate, and this will differ for each individual patient and is different for each brand of IVIG therapy, and it is recommended that the therapy initially be administered

²² August 27, 2013 Report from Briad-Forbes Health Research titled, "Analysis of Administration of Intravenous Immune Globulin in 2012 Hospital Outpatient Claims Data" (copy attached), p.3.

²³ *Id.*

²⁴ Based on 175 pound patient. See Package Insert, Gammunex-C, Dosing and Administration, (<http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM069968.pdf>), last visited Sept. 4, 2013

²⁵ See "IVIG Medicare Safety: A stepwise Guide to Product Selection and Use," Jerry Siegel, PharmD, FASHP, *Pharmacy Practice News*, September 2010, p.2.

²⁶ See "Immune Globulins: Therapeutic, Pharmaceutical, Cost, and Administration Considerations," Jerry Siegel, PharmD, FASHP, *Pharmacy Practice News*, January 2013, p.1

slowly.²⁷ Further, Medicare patients in particular require more careful monitoring of their IVIG infusions to ensure tolerability of the therapy. Patients aged 65 and older are more sensitive to the specifics of the therapy brand and its composition including sugars and salts, again making it imperative that these infusions are administered at the recommended rate and carefully observed to minimize the potential for adverse events.²⁸

To the extent CMS finalizes its proposal to package add-on codes into primary procedures, PPTA asks that CMS exempt from this policy the add-on codes for drug administration services, or at a minimum, exempt code 96366. Failure to do so will create disincentives to treat complex cases involving four or more hours of an IVIG infusion in the hospital outpatient setting, which could hamper patient access to important, life-saving and life-enhancing therapies like IVIG.

IV. Conclusion

PPTA greatly appreciates the opportunity to provide comments to CMS on its proposed rule implementing payment policies in the OPPS for CY 2014. We strongly support the agency's proposal to adopt a payment level for separately payable, non-pass-through drugs and biologicals of ASP + 6%. We also appreciate the agency's proposal to continue the furnishing fee for blood clotting factors administered or dispensed in the hospital outpatient department. Finally, PPTA is quite concerned however, with the proposal to package all add-on codes, and urges CMS not to finalize the proposal or to make an exception for drug administration add-on codes. Please do not hesitate to contact me at 443-458-4682 or by email (kkilbourne@pptaglobal.org) if you have any questions regarding these comments.

Sincerely,



Kym H. Kilbourne
Director, Federal Affairs

Attachment

²⁷ *Id.*

²⁸ See "IVIG Medicare Safety: A stepwise Guide to Product Selection and Use," Jerry Siegel, PharmD, FASHP, *Pharmacy Practice News*, September 2010, p.2.



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Data analysis informing sound policy

**Analysis of Administration of
Intravenous Immune Globulin in
2012 Hospital Outpatient Claims Data**

Mary Jo Braid-Forbes,
Braid-Forbes Health Research, LLC

Presented to:
Plasma Protein Therapeutics Association

August 30, 2013

In this report we explore the effect of CMS's new policies on their estimate of cost for infusions (CPT 96365) when an intravenous immune globulin (IVIG) drug was listed. CMS's new policies included packaging the 'add-on' code 96366 which is billed for each additional hour of infusion. This is potentially problematic for therapies with longer average infusion times as the additional hours of infusion will not be paid separately. Code 96365 showed a 34% increase in geometric mean cost compared to last year and a 36% increase in payment (\$198.69 proposed in 2014 compared to \$146.24 in 2013). In 2013 96366 was paid \$27.01. The payment increase between 2013 and 2014 is equivalent to approximately two additional hours of infusion, before accounting for other items that are newly packaged this year.

The analysis answered the following questions:

- What is the cost of the 'single' claims for 96365 when a IVIG drug is present compared to when it is not present?
- What is the average length of an infusion when a IVIG drug is present compared to when it is not present?
- What is the distribution of length of infusion for claims where IVIG codes appear? Compare this distribution to the distribution for cases without IVIG code.
- Did claims with IVIG codes disproportionately get dropped from rate-setting?
- What is contributing to the increase in cost for 96365?
- Did claims with 96366 add-on codes also have 96365 on the claim?

Because there were over a million infusion codes on the OPSS file, in order to cut down on the computer processing time, a 10% sample was selected and the analysis was performed on the 10% sample. The national estimate is presented in the tables unless otherwise noted.

This analysis used the 2012 Medicare hospital outpatient claims data file released with the 2014 proposed rule. A list of the IVIG codes used is in the appendix at the end of the memo.

What is the cost of the ‘single’ claims for 96365 when an IVIG drug is present compared to when it is not present?

- The geometric mean cost of the ‘single’ claims used in rate-setting for 96365 was 23% higher when a IVIG drug was present compared with the geometric mean cost overall for 96365.

Table 1: Geometric mean cost with and without IVIG drugs

	Geometric mean cost
Total 96365	\$ 201
No IVIG drug	\$ 196
IVIG drug present	\$ 247

What is the average length of an infusion when an IVIG drug is present compared to when it is not present?

- The average length of an infusion when an IVIG drug is present is 3.26 hours, using the units of 96366 to estimate this. That is the initial hour and 2.26 units of 96366. The accuracy of this estimate relies on hospitals coding 96366 appropriately on their billed claims.
- IVIG infusions are more than twice as long as the 1.38 hour average infusion length when other drugs are administered.

Table 2: Average length of infusion with and without IVIG drugs

	Sample	Total estimate	% of single claims with any 96366	Average number of units of 96366
All singles	111,419	1,114,190	31%	0.61
No IVIG drug	98,249	982,490	22%	0.38
IVIG drug present	13,170	131,700	94%	2.26

What is the distribution of length of infusion for claims where an IVIG drug codes appears? Compare this distribution to the distribution for cases without an IVIG drug.

- For claims with IVIG drugs, only 6% showed only one hour of infusion, almost a third showed 2 hours of infusion, almost third showed 3 hours of infusion, a fifth showed 4 hours of infusion and the 15% showed 5 or more hours.
- In contrast the majority of infusion claims without IVIG (78%) showed only one hour of infusion.

Table 3: Distribution of hours of infusion for IVIG and other drugs

Number of units of 96366	Hours of infusion	All claims		No IVIG		With IVIG	
		Count	%	Count	%	Count	%
0	1	770,980	69%	763,700	78%	7,280	6%
1	2	179,840	16%	142,270	14%	37,570	29%
2	3	72,550	7%	32,560	3%	39,990	30%
3	4	54,720	5%	28,530	3%	26,190	20%
4	5	16,830	2%	6,020	1%	10,810	8%
5	6	11,110	1%	5,310	1%	5,800	4%
6	7	3,420	0%	1,350	0%	2,070	2%
7	8	2,580	0%	1,410	0%	1,170	1%
8	9	770	0%	400	0%	370	0%
9	10	430	0%	260	0%	170	0%
10 or more	11 or more	960	0%	680	0%	280	0%
<i>Total</i>		<i>1,114,190</i>	<i>100%</i>	<i>982,490</i>	<i>100%</i>	<i>131,700</i>	<i>100%</i>

Did claims with IVIG codes disproportionately get dropped from rate-setting?

- On the contrary, claims with IVIG drugs are more likely to become ‘single’ and be used in rate-setting. While only 54% of 96365 claims without a IVIG drug could be used in rate-setting as a ‘single’ claim, 90% of claims with IVIG drugs were used.
- However, since the number of claims with IVIG codes is only 12% of the total single claims their higher average cost does not raise the total average cost very much.

Table 4: Percent of claims that are ‘single’ and used in rate-setting

	Single claim		Total	% single
	No	Yes		
No IVIG drug	852,730	982,490	1,835,220	54%
IVIG drug present	14,420	131,700	146,120	90%
<i>Total</i>	<i>867,150</i>	<i>1,114,190</i>	<i>1,981,340</i>	<i>56%</i>

What is contributing to the increase in cost for 96365?

- When IVIG is not present on the claim, approximately 80% of the cost associated with code 96365 is the cost of things traditionally packaged and 7% is the cost associated with the add on code 96366.
- By contrast, when IVIG is present only half of the cost associated with code 96365 is the cost of things traditionally packaged and 36% is the cost associated with the add on code 96366.

Note that this analysis is an approximation using arithmetic means rather than geometric means. It is unfeasible to do this detailed analysis using geometric means due to the mathematical properties of a geometric mean calculation. Also note that the clinical lab test cost is overstated relative to the clinical lab fee schedule payments.

Table 5: Contribution to costs of traditionally packaged items and new packaging policy items

	No IVIG	IVIG
<i>Total, all lines on claim</i>	100%	100%
Items traditionally packaged	80%	50%
Add on codes Except 96366	5%	8%
96366	7%	36%
Clinical Lab Tests	7%	6%
Other policies	1%	<1%

Did claims with 96366 add-on codes also have 96365 on the claim?

CPT 96366 is on a claim with 96365 approximately 88% of the time; leaving 12% of the time it was billed without 96365.

Appendix
Intravenous Immune Globulin (IVIG) codes

J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1557	Injection, immune globulin, (gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg
J1559	Injection, immune globulin (hizentra), 100 mg
J1561	Injection, immune globulin, (Gamunex), intravenous, non-lyophilized (e.g. liquid), 500mg
J1566	Injection, immune globulin, intravenous lyophilized (e.g. powdered), not otherwise specified, 500 mg
J1568	Injection, immune globulin, (Octagam), intravenous, non-lyophilized (e.g. liquid), 500mg
J1569	Injection, immune globulin, ,(Gammagard Liquid), intravenousnon-lyophilized (e.g. liquid), 500mg
J1572	Injection, immune globulin, (flebogamma/flebogamma DIF), intravenous , non-lyophilized (e.g. liquid), 500mg