Plasma Protein Therapeutics Association

Maintain Access to Life Sustaining Plasma Protein Therapies
Oppose Cuts to Medicare Drug Reimbursement

Plasma protein therapies are unique, sole source biological therapies that are provided to Medicare patients primarily under the Part B benefit that covers physician-administered drugs. There are multiple brands of plasma protein therapies in each therapeutic class including alpha-1 proteinase inhibitors, blood clotting factors and immune globulin products. Patients suffering from the chronic, rare disorders that require these therapies must have access to the full range of therapies to ensure they receive the treatment best suited for their individual medical needs in collaboration with their physician. The complexity of the storage requirements, delivery method and need for careful monitoring of patients receiving plasma protein therapies adds to the importance of ensuring that patients continue to receive access to these specialized therapies.

Plasma protein therapy patients rely on regular, often weekly, infusions of these life-sustaining treatments. Recent analysis of the use of intravenous immune globulin (IVIG) by Medicare patients who have a primary immune deficiency disease (PID) confirms that the physician office setting is sensitive to changes in reimbursement for treating PID patients with IVIG. [1] This analysis was undertaken to provide one example of the potential for negative health outcomes for a rare disease patient population that already has seen disruption in the site where care is provided, potentially putting patients at risk.

Any reductions in the ASP +6 percent physician office payment would likely result in more shifts of immune compromised patients into the hospital outpatient department, exposing them to hospital acquired infections and risking significant interruption of care for these fragile, rare disease patients. Physicians expressed reasons for preferring office-based care, including a concern with the greater risk of infection in hospital settings, particularly for immune-compromised patients.[2] The analysis found:

- **When reimbursement changes for IVIG in Medicare part B were implemented in 2005, the dominant site of service immediately and sharply shifted from the physician office to the hospital outpatient setting.** Treatment in the physician office setting fell from 54% in 2003 to 31% in 2006. This sharp decline leveled out from 2006 to 2010; however in 2010 64% of Medicare PID patients using IVIG were treated in the hospital outpatient department compared with 33% in the physician office.

- **Nearly double the number of Medicare beneficiaries with PID that use IVIG are treated in the hospital outpatient department than in the physician office, and the outpatient department setting has continued to rise sharply after 2006.**

- **Despite lower rates of payment per gram and per beneficiary, the total number of beneficiaries receiving IVIG in the outpatient setting is higher and has increased at a much faster rate over time than in the physician office**, especially after 2005.

[1] 2003-2010 Trends in IVIG/SCIG utilization by PID patients, by site of service, December 21, 2012, The Moran Company (which noted a significant shift in the site of service of IVIG utilization after implementation of reimbursement cuts as a result of the Medicare Modernization Act).
[2] Medicare Payment Advisory Commission, *Report to Congress: Impact of Changes in Medicare Payments for Part B Drugs*, p. 18, Available at http://www.medpac.gov/documents/jan07_partb_mandated_report.pdf.

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The Immune Deficiency Foundation conducted research on changes in site of care for primary immune deficiency (PID) patients after the change in reimbursement methodology in for Medicare Part B therapies and drugs in 2005 and found negative consequences for PID patients.

- Medicare patients are much less likely than private insurance patients to receive their IVIG infusion at home and more likely to receive them as hospital outpatients and in hospital clinics. **The most noticeable change took place between 2004 and 2006 with a sharp drop in the percent of Medicare beneficiaries who received their infusions in the doctor's office, which was reduced by more than half.** In contrast the number of privately insured persons getting IVIG treatments in doctors' offices remained virtually stable.[3]

- **More Medicare patients than private insurance patients have changed their location of treatment since the beginning of 2005.** [4] Over twice as many Medicare patients as private insurance patients reported more problems overall in obtaining IVIG treatments since January 1, 2005. [5]

- While they were much more likely than privately insured patients to get their treatments in the doctor's office before January 1, 2005, after the change in reimbursement policy, **Medicare IVIG users experienced a sharp drop in doctor's office infusions and became less likely to receive infusion in that location as compared to the privately insured patients.** [6] During this same time period, the privately insured IVIG user experienced little change in the doctor's office as a site for infusion.

- **More than 2 ½ times as many Medicare patients as private insurance patients reported negative health consequences as a result of difficulties of getting or paying for IVIG treatment since the beginning of 2005.** They were also more likely to experience health problems serious enough to require hospitalization.[7]

--February 2013

[3] Assessing the Impact of Changes in Reimbursement Regulations and Product Availability on Access to Intravenous Gammaglobulin treatment Among Primary Immune Deficiency Patients, November 2006, p.15.
[4] *Ibid*, p. 15.
[5] *Ibid*, p. 24
[6] *Ibid*, p. 24.
[7] *Ibid*, p. 26.