PPTA

Plasma Protein Therapeutics Association

Advisory Committee on Blood Safety and Availability

North Bethesda, MD

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Plasma Protein Therapeutics Association

HOPPS in 2006

- Impact on IVIG Access to Care unknown
  1. 2005 - $80.68
- 2006 proposed rates (to be updated quarterly):

Q9941	lyophilized 1 g	$39.46
Q9942	lyophilized 10 mg	$0.40
Q9942	liquid 1g	$57.26
Q9943	liquid 10 mg	$0.57

- Comments due September 16, 2005
- Final Rule expected November 1, 2005

HOPPS Current Status

MMA Impact

- Legislated major change in reimbursement methodology
- Switch from 83% AWP in 2005 –

  $80.68 (both liquid and lyophilized) to a system based on acquisition cost in 2006
- CMS proposes ASP+8% (6%, cost of the therapy and 2% for pharmacy overhead) for 2006

ASP Limitations

- Lag time
  1. Need Balance (6 mo. Part B, 9 mo. HOPPS)
  - Does NOT recognize the dynamic market
  - Individual company price fluctuations can and do occur within six month period
  - A CMS calculated ASP may not reflect actual ASPs by the time a payment rate is published
- Lack of verification by a CMS funded third-party auditor

Impact of ASP+6% on Access

Lessons Learned

- Restricts physician/patient freedom of choice
- Providers reporting ASP+6% is not a sustainable business model
- Reported disruptions in site of service

- IDF 2002 Survey – 67% of patients receive IVIG under physician payment system

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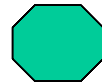
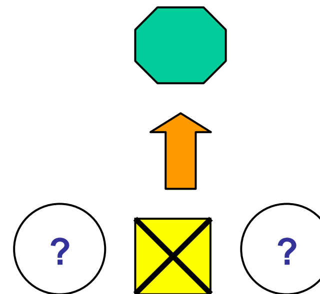
Consumer Organization Statistics

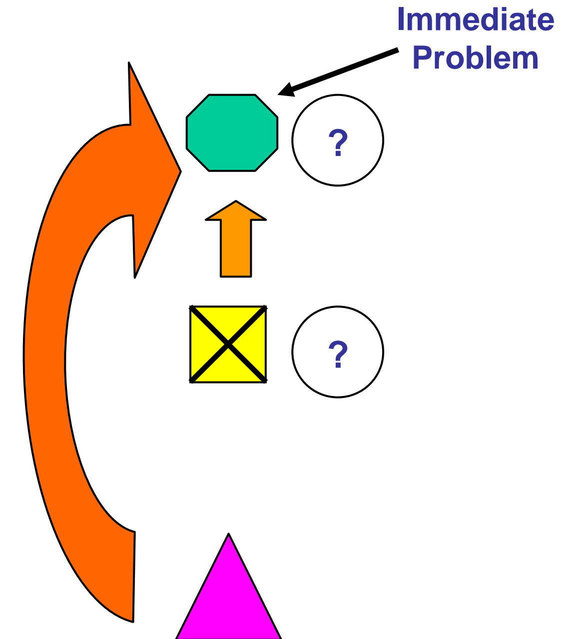
- 7,000 PID Medicare beneficiaries (most on disability) (IDF)
- 67% of patients receive IVIG infusions in non-hospital settings (IDF)
- 32% receive infusions in outpatient hospital settings (IDF)

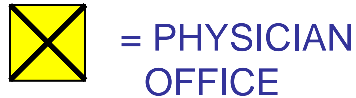
Migration in '05 | Worse in '06

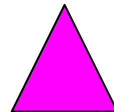
2004 | **2005** | **2006**











Where is the patient supposed to get treatment?

Suggested Part B Administrative Remedies

Proposals from interested parties:

- Increase provider reimbursement for administration of IVIG by **classifying IVIG as a biologic response modifier** to reflect the true resource level
- **De-bundle** the HCPCS codes and provide for an **add-on payment** to cover the cost of services and supplies
- Classify **IVIG as a blood product** and reimburse accordingly (Stakeholder Recommendation)
- Conduct an IVIG demonstration (survey) similar to that for chemotherapy infusions, additional payment per encounter is paid to participating providers

CMS Action

April 1, 2005 **Separation of liquid versus lyophilized forms of IVIG**

- This is NOT a complete solution
- Arbitrary split fails to recognize individual therapeutic values
  - Result: access problems still exist
    - Therapies still bundled
    - Same reported inadequacy issues with ASP +6%

- A better solution is to debundle entirely
  - NDC based reimbursement

2006 HOPPS Impact on Access

- Predict Negative
- Medicare is often seen as a "model”
- Draw upon conclusions from 2005 Part B, ASP +6

Major unknown: Can/Will ASP+ 8% sustain access in the hospital outpatient setting – the setting of “last resort” for some

Collective Solution

- Strategic Partnerships
  - IVIG HOPPS Reimbursement Summit
    a. Short term solution
    b. Issue specific
    c. HOPPS immediate focus

- Suggested Options
  - Add-on for IVIG and Dampening Provision

  - MedPAC - hospital overhead is estimated to be 25-33% of ASP
    1. hospital outpatient site requires greater pharmacy preparation time than do those provided to inpatients.
  - CMS' Ambulatory Payment Code Advisory Committee recommended that CMS reconsider the 2% add-on for pharmacy overhead costs in addition to reviewing industry data regarding such costs.

- 2006 HOPPS presents urgency and opportunity