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Plasma Protein Therapeutics Association

Reimbursement Priorities: Plasma Derived and Recombinant Analog Therapies

Advisory Committee on Blood Safety and Availability

Bethesda, MD

January 25, 2005

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Outline

- PPTA Positions
  - Federal Medicare
  - State Medicaid
- 2005 Issues
- Conclusions

Physician Fee Schedule (Part B)

- Impact of new payment methodologies on access

2005

Major unknown: Can/Will ASP+ 6 sustain access?

- Blood clotting factor add-on
  - $0.14 final rule
  - Issue a program transmittal to carriers immediately clarifying ASP+6 +14
- IVIG
  - Major concerns about access from providers and patients
  - Home Infusion Benefit (PID & supplies only)
- AIPI
  - Rate must take into consideration all brands on market

2006

- Competitive Acquisition Program (only IVIG exempt)
- Access to all brands of plasma protein therapies is critical

- Impact on manufacturers
  - ASP reporting -- timely instructions to clarify filings and prompt quarterly release of calculations
    - Confirmed by an auditor

Title I (Part D)

- Part D is intended to fill any gaps in existing coverage of drugs and 'wrap around' existing Part B drug benefits
  - CMS needs to issue guidance on how the two programs will work together
  - Access to all brands is critical
- Could necessary services and supplies not currently covered under Part B for home infusion be covered under Part D?
  - Use of DME - infusion pump to administer IVIG in the home

HOPPS

- Hospitals have unique regulatory requirements that increase overhead costs

- Reimbursement should be based on all brands currently on the market and encourage development new life-saving treatments (innovation)

2005

A1PI

- Single indication orphan status
- Higher of 106% ASP or 88% AWP – can this sustain access?

IVIG & Blood Clotting Factors

- Must consider unique nature of each brand

2006

GAO Hospital Acquisition Cost Study

- Cyclical price trends
- Cycle adjustment methodology
- Analysis must include best data sources

Strategy for 109th Congress

Continue to work in coalition with stakeholders

- Possible area for stakeholder lead and PPTA support : Co-Pay Issue

Ensure coverage in all sites of service

- Eliminate coverage gaps

Competitive bid exemption for BCF and A1PI

Medicaid Reform

Standards of Care Legislation

- Requires private insurers to contract with providers familiar with disease states
- New Jersey standards law adopted by Council of State Governments as Suggested State Legislation
- PPTA working with other public official groups (i.e. NCSL/ALEC)
- Legislation possible in CA, FL, MN, PA
- Extend to IVIG and A1PI, public payors

PDL/Prior Authorization

- Some states currently have PDLs for IVIG & require PA for non-preferred therapies (FL)
- PDLs may require payment of state supplemental rebates
- PA reduces Medicaid spending by approx.10%
- PPTA worked to avoid PA for clotting factors in IL, MN, NV, NC, SC, TX
- PPTA working to expand exemptions to IVIG
- ’05 priority = Minnesota

Single Source Provider Contracts

- States looking to control Medicaid costs by contracting with a single provider of plasma therapeutics
  - AZ, FL, MA, MN
- Could lead to limitations on choice of therapies

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Limits on Brand Name Drugs

- States have enacted limitations on access to brand name drugs
  - Alabama - no more than four brand name prescriptions per month
- Users of IVIG often have co-morbidities that require the use of >4 prescriptions drugs/month
- Beneficiaries forced to “prioritize” drug usage
- Could result in decision not to use IVIG
- PPTA works to enact exemptions for “high risk” disease states

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Conclusions

- Outreach to consumer and provider organizations, education of policymakers about unique nature of the plasma protein therapeutics industry

- Coalition-based approach to address reimbursement priorities – access, choice and innovation

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CMS Questions

1. With regard to the HOPPS, A1P1 has been designated as a single indication orphan. The HOPPS Final Rule states that "in order to ensure continued beneficiaries' access to this important drug, (CMS) will base the payment rate for HCPCS code J0256 on all three brands of the alpha-1 proteinase inhibitor currently available on the market…The adjusted AWP of HCPCS code J0256 will be based on the volume-weighted average of the three drugs. The adjusted AWP will be updated each quarter, as necessary, to reflect any changes in the individual AWP or relative weight of each drug in the calculation of the AWP..." However, a HOPPS update issued on December 31, 2004 reduced the rate, basing it on the ASPs and not the volume weighted average of the three AWPs. Can you explain the rationale behind this? Furthermore, how can CMS be sure that quarterly fluctuations in the rate will not hinder access by the fragile patient population to these life sustaining therapies?

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CMS Questions – contd.

2. Has CMS begun to work with the GAO on their Part A, Hospital Acquisition Cost Survey? Is the April 2005 deadline for data still realistic? How is the survey process going and when will preliminary results be released?

3. Will the upcoming Medicare Part D outpatient prescription drug benefit ultimately take over drug reimbursement under Part B? If not, how will the two wrap around each other? What sort of timeline can we expect and what opportunities will there be for public input on such decisions?

4. Can CMS give an update with regard to the Competitive Acquisition Program under Part B as it relates to plasma derived and recombinant therapies? Will CMS make public the final RTI report and its recommendations? Will therapies such as blood clotting factors and alpha-1 proteinase inhibitors be excluded from the competitive acquisition program as IVIG is?