NATIONAL HEMOPHILIA FOUNDATION

for all bleeding disorders

REIMBURSEMENT ISSUES FACING THE BLEEDING DISORDERS COMMUNITY

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Reimbursement for clotting factor is an extremely complex issue within the bleeding disorder community.

Marketplace changes are rapidly occurring with all payers as they seek to lower prescription drug costs.

In response, manufacturers and providers of clotting factor have been aggressive in seeking contracts for their products and services.

Such agreements and changes in reimbursement potentially affect which products are available and from which providers consumers can receive products and services.

Such agreements and some changes in reimbursement also assume that clotting factor products are interchangeable or equivalent.

Clotting factor products are biologicals and are not recognized as functionally equivalent by the Food and Drug Administration.

Each product is manufactured using different fractionation and viral inactivation processes.

Each product also reacts differently in each consumer.

In general, the desire for choice of products and providers now must be balanced with the desire for lower costs.

This balancing act often is made more complex by the additional issues of product safety and availability.

Reimbursement Concerns

- Insurance Coverage
- Product Choice
- Provider Choice
- Out-of-Pocket Costs
- Lifetime Caps

Concerns with New Part B Medicare Reimbursement

- 20% Copayment Responsibility
- Access to Product Choice

20% Copayment

- Copayment responsibility can equal $40,000+ annually
- Generally assumed that sometimes copayment is waived for beneficiaries without supplemental coverage

20% Copayment

- Previous reimbursement made waiver more easily possible; providers were still able to cover costs
- New drug payment levels are closer to acquisition, making absorption of copayment more difficult

PART B 2005 MEDICARE REIMBURSEMENT OF CLOTTING FACTOR (per iu)

HCPS	Product	Estimated Acquisition	Medicare Approved Charge	Medicare Payment	20% Copayment
J7190	Plasma-derived Factor VIII	$.41 - $.58	$.66	$.53	$.13
J7191	Porcine	$2.05	$1.86	$1.49	$.37
J7192	Recombinant - Factor VIII	$.75 - $.96	$1.06	$.85	$.21
J7193	Factor IX Monoclonal	$.67 - $.78	$.89	$.71	$.18
J7194	Prothrombin Complexes	$.36 - $.40	$.63	$.50	$.13
J 7195	Recombinant Factor IX	$.83	$.98	$.78	$.20
J7198	Anti-inhibitor Complex	$1.06	$1.23	$.95	$.25
Q0187	Recombinant Factor VIIa, 1.2mg	$948	~$1215.58	$972.46	$243.12
Q2002	Von Willebrand	$.75	$.86	$.69	$.17

[1] Final ASP pricing data announced by CMS on December 17, 2004 +$0.14 per unit Add-on payment

[2] 80% of Maximum Allowed Charge

20% Copayment

New payment formula creates clear "winners" and "losers" that could affect access to certain brands

20% Copayment

There is concern that beneficiaries without supplemental coverage may be forced to switch products or seek care in other settings, i.e., hospital emergency rooms.

Discussed Possible Solutions

Clotting factor reimbursement at 100% of Medicare approved charge

Copayment subsidy for beneficiaries with bleeding disorders

Supplemental coverage options for disability qualified beneficiaries

Reinsurance

Recommendations

Pursue legislation seeking payment for clotting factor payment at 100% of the Medicare approved amount

- Aggregate provider data on supplemental coverage
- Data collection on utilization to disprove myth of excess product use patterns

Other Medicare Concerns

- Part D Prescription Drug Plan
  - Impact of any possible transition of clotting factor from Part B to Part D
- Lack of coverage of clotting factor in short- and long-term health facilities

Medicaid Concerns

- Lack of separate inpatient hospital payment for clotting factor
- Changes in enrollment criteria
- Contracts with providers with little or no hemophilia experience
- Restrictions of product choice