The 2006 OPPS final rule adopts an ASP+6% payment methodology for specified covered outpatient drugs, rather than the ASP+8% under the proposed rule. Accordingly, under the ASP-based system, payment for Aranesp would be $3.01 per mcg, versus $9.22 per 1,000 units of Procrit. Had CMS decided to use the ASP+8% basis for calculating payments, Aranesp would have been reimbursed at $3.28 per mcg.

By shifting from an AWP to ASP-based system, payments for both Aranesp and Procrit will decrease by "similar levels" in 2006, the rule notes. Procrit payment will fall by 17% and Aranesp by 18%. If a dose conversion ratio had been applied, Aranesp would have been paid at $3.04 per mcg, according to CMS.

CMS' promise to revisit dose conversion ratios and its equitable adjustment policy (formerly known as "functional equivalence") puts pressure on J&J to produce more data demonstrating the clinical and cost effectiveness of Procrit.

J&J maintains that "when dosed to achieve a comparable effect with Procrit, the cost of treatment for Aranesp is greater for both the Medicare program and its patients," and that equitable payment policy "minimizes the role of financial incentives in the choice of drug."

Similarly, in his Nov. 2 statement, Rep. Thomas says the rule "incentivizes providers to choose one drug over a therapeutically-equivalent drug in order to maximize reimbursement." Functional equivalence policy derives from statutory intent, he claims, arguing that CMS' analysis "is not supported by recent, peer-reviewed and respected scientific literature, as well as the prudent practices of private sector payers."

"The willingness to play politics as evidenced by the Administration's actions...will result in an increase in the Part B premium and higher co-payments for Medicare beneficiaries," Thomas concludes.

The growth rate for Part B cost-sharing has already come under scrutiny: in September, CMS announced premiums for the benefit will rise 13% to $88.50 in 2006. The Part B deductible will climb to $124 next year, compared with the current $110. ♦♦

Biologics Under Part D: Coinsurance, Cost Containment And Coverage Overlap

Coinsurance appears to be the preferred cost-sharing method for biologics in Medicare Part D plans, according to an analysis of plan formularies by *"The Pink Sheet."*

Based on formularies provided on the websites of seven of the 10 prescription drug plans offered nationwide, five plans use a percentage of the drug's cost for biologic cost-sharing, while only two plans use flat copays (*see chart, p. 29*).

YouRx (Medco), AARP Medicare Rx (United-Healthcare/Ovations) and SilverScript (Caremark) all established separate formulary tiers for most biologics, with 25% coinsurance beneficiary cost-sharing.

Prescription Solutions (PacifiCare) also uses an across-the-board coinsurance rate for biologics, although at a higher level (33%). Wellcare's level of coinsurance varies by plan region, rather than adhering to a standard nationwide level.

The remaining two plans – AdvantraRx (Coventry) and Aetna – use copays ranging from $20 to nearly $60, depending on the plan option in which the beneficiary is enrolled and the formulary tiering of the product.

Formulary information was not available on the websites of Cigna, Community Care Rx (MemberHealth/National Community Pharmacists Association), or Wellpoint at the time of compilation.

Caremark VP-Specialty Pharmacy Services Marketing Adina Safer told the Pharmaceutical Care Management Association annual meeting Oct. 25 that she had expected most biologics covered by Part D plans "to be on the fourth tier with a percentage copay, presumably a 25% copay."

Specialty pharmacies have highlighted the opportunity to use pharmacy benefit manager-type formulary management tools to control biologics utilization ("The Pink Sheet" Nov. Oct. 31, 2005, p. 21).

The structure of the Part D benefit may provide little incentive for private plans to manage utilization of biologics and other high cost drugs ("The Pink Sheet" May 2, 2005, p. 19).

However, plans are using a variety of techniques to drive utilization towards preferred products in all four biologics categories analyzed: blood formation

products, hepatitis C therapies, TNF inhibitors and multiple sclerosis therapies.

In the red blood cell factor category, the Prescription Solutions and Wellcare formularies include Johnson & Johnson's ***Procrit***, but not Amgen's ***Epogen***, while YouRx covers Epogen, but not Procrit.

AARP Medicare Rx requires step therapy for patients to receive Epogen, but not for Procrit. AdvantraRx places Procrit on a lower cost-sharing tier than Epogen.

Of Amgen's two white blood cell factor products - ***Neupogen*** (filgrastim) and filgrastim's pegylated version ***Neulasta*** - Prescription Solutions and Wellcare do not include Neulasta on formulary, while AdvantraRx places Neulasta on a higher cost-sharing tier.

In the hepatitis C category, four plans cover either Roche's ***Pegasys*** or Schering-Plough's ***PEG-Intron***, but not both. The remaining plans cover both products.

For the anti-TNF agents, Medco employs the most complex utilization management, placing Amgen/Wyeth's ***Enbrel***, Abbott's ***Humira*** and J&J's ***Remicade*** on separate tiers: three, two and five, respectively.

Enbrel has the highest cost-sharing on Medco's YouRx formulary, with 75% coinsurance, compared to a $17 copay for Humira and 25% coinsurance for Remicade.

AdvantraRx places Enbrel on a lower cost-sharing tier than Humira and Remicade. Prescription Solutions does not include Humira on its formulary.

AdvantraRx also uses formulary tiering to drive utilization to preferred products in the multiple sclerosis category, positioning Biogen Idec's ***Avonex*** and Teva's ***Copaxone*** on a lower cost-sharing tier than Pfizer/Serono's ***Rebif***.

Both Aetna and Wellcare do not cover Rebif, while the remaining four plans cover all three products on the same tier.

Another challenge in managing biologics under Part D is that many of the products may also be reimbursed under Medicare Part B for different diagnoses and in different settings. Part D plans cannot cover drugs for uses already reimbursed under Part B ("The Pink Sheet" April 18, 2005, p. 20).

During the Avalere Medicare Prescription Drug Congress in Washington, D.C. Nov. 1, Caremark Chief Medical Officer Janet Berger noted that there are over 600 drugs that could be covered under either Part B or Part D.

Caremark's SilverScript formulary includes "drugs that were required by CMS to be on there or drugs that are at some time Part D-delivered drugs," she explained.

One practice consistently used across the Part D plans for biologics management is prior authorization.

Berger said that one reason PDPs use prior authorization is to ensure that drugs that could be reimbursed under either Part D or Part B are reimbursed under the correct program. Caremark requires prior authorization for nearly all of the fifteen biologics included in *"The Pink Sheet"* analysis.

"The area in the short term that we will probably all have to utilize" to separate Part B and Part D uses "is the prior authorization system," Berger said.

When reimbursement requests are submitted for drugs that could be reimbursed under Part B or Part D, we will "call the physicians and...ask them 'what is this drug being used for?' and 'under what arena will it be given?'" she explained.

"The problem with this is, it's disruptive, it's inconvenient, it's very resource intensive and therefore costly," Berger said. "It will be something [about which] we will all hear a great deal from physicians and patients."

One alternative to using prior authorization to differentiate between Part B and Part D would be for the Centers for Medicare & Medicaid Services, health plans and PBMs to establish lists of Part B and Part D drugs, she suggested.

Another option is to develop "a better way of getting diagnosis codes, so we can decrease that overlap of B versus D. This can be done through prescription information, through sharing of data, through diagnoses from the physician's office and ultimately, we hope, through e-prescribing," Berger said. ♦♦

Biologics Under Medicare Part D

This chart lists formulary placement of selected biologics for seven nationwide Part D prescription drug plans, as compiled by "The Pink Sheet" from data available on the plans' websites. For companies offering more than one plan, the mid-priced option was used.

Drug Name Manufacturer	**AARP (UnitedHealth/ Ovations)**	**AdvantraRx (Coventry)**	**Aetna**	**Prescription Solutions (PacifiCare)**	**Silverscript (Caremark)**	**Wellcare**	**YouRx (Medco)**
Aranesp Amgen	Specialty Tier PA, ST	Tier 2 PA	Not Covered	Tier 4 PA	Tier 3 PA	Specialty Tier PA	Tier 5 PA, QL
Epogen Amgen	Specialty Tier PA, ST	Tier 3 PA	Not Covered	Tier 5 (Non-formulary)	Tier 3 PA	Not Covered	Tier 5 PA, QL
Procrit J&J	Specialty Tier PA	Tier 2 PA	Not Covered	Tier 4 PA	Tier 3 PA	Specialty Tier PA	Not Covered
Neupogen Amgen	Specialty Tier	Tier 2 PA	Not Covered	Tier 4 PA	Tier 3	Specialty Tier PA	Tier 5 PA, QL
Neulasta Amgen	Specialty Tier	Tier 3 PA	Not Covered	Tier 5 (Non-formulary)	Tier 3	Not Covered	Tier 5 PA, QL
Pegasys Roche	Specialty Tier QL	Tier 2 PA	Tier 2	Not Covered	Tier 3 PA	Specialty Tier PA	Not Covered
PEG-Intron Schering	Specialty Tier QL	Not Covered	Tier 2	Tier 4 PA	Tier 3 PA	Not Covered	Tier 2 PA, QL
Enbrel Amgen/Wyeth	Specialty Tier PA, QL	Tier 2 PA	Tier 2	Tier 4 PA	Tier 3 PA	Specialty Tier PA	Tier 3 PA, QL
Humira Abbott	Specialty Tier PA, QL	Tier 3 PA	Tier 2	Tier 5 (Non-formulary)	Tier 3 PA	Specialty Tier PA	Tier 2 PA, QL
Remicade J&J	Specialty Tier PA	Tier 3 PA	Tier 2	Tier 4 PA	Tier 3	Special Tier PA	Tier 5 PA
Raptiva Genentech	Specialty Tier PA, QL	Tier 2 PA	Not Covered	Tier 5 (Non-formulary)	Tier 3	Not Covered	Tier 5 PA, QL
Avonex Biogen Idec	Specialty Tier QL	Tier 2 PA	Tier 2	Tier 4 PA	Not Covered	Special Tier PA	Tier 5 PA, QL
Copaxone Teva	Specialty Tier QL	Tier 2 PA	Tier 2	Tier 4 PA	Tier 3 PA	Specialty Tier PA	Tier 5 PA, QL
Rebif Pfizer/Serono	Specialty Tier QL	Tier 3 PA	Not Covered	Tier 4 PA	Tier 3 PA	Not Covered	Tier 5 PA, QL
Gleevec Novartis	Specialty Tier QL	Tier 3 PA	Tier 2	Tier 4 PA	Tier 3	Specialty Tier PA	Tier 5 PA
Plan Design	*Specialty Tier: 25% co-insurance*	*Tier 2: $20-25 copay Tier 3: $50-60 copay (varies by region)*	*Tier 2: $35 copay*	*Tier 4: 33% co-insurance*	*Tier 3: 25% co-insurance*	*Specialty Tier: 30-35% co-insurance (varies by region)*	*Tier 2: $17 copay Tier 3: 75% co-insurance Tier 5: 25% co-insurance*

PA – prior authorization; QL – quantity limit; ST – step therapy.

Topic	Advisory Committee	Date
Unfulfilled *Phase IV* Commitments Of Accelerated Approval Oncologic Drugs	Oncologic Drugs	Nov. 8
Prescription Drug User Fee Act	Public Meeting	Nov. 14
Translation Of Pharmacogenomics Information Into Labeling; Biomarker Surrogate Endpoints Project Update	Pharmaceutical Science	Nov. 14-15
Ethics Of Leuprolide Test Protocol For Puberty Disorders	Pediatric Ethics Subcommittee	Nov. 15
Novartis ***Certican*** (Everolimus) For Prophylaxis Of Rejection In Heart Transplants	Cardiovascular & Renal Drugs	Nov. 16
Flu Vaccine Manufacturing With Canine Kidney Cells; Pneumococcal Vaccine	Vaccines	Nov. 16-17
Pediatric Obesity And Clinical Trial Designs For Related Devices	Pediatrics	Nov. 16-17
Pediatric Adverse Events Reports: ***Tamiflu***, ***Vioxx***, ***Agrylin***, ***Paraplatin***, ***Diflucan***, ***Camptosar***, ***Ferrlecit*** And ***Imitrex***	Pediatrics	Nov. 18
Shire/Noven ***MethyPatch*** For Attention Deficit/Hyperactivity Disorder	Psychopharmacologic Drugs	Dec. 2
Drug Risk Communication Tools: Strengths And Weaknesses	Public Meeting	Dec. 7-8

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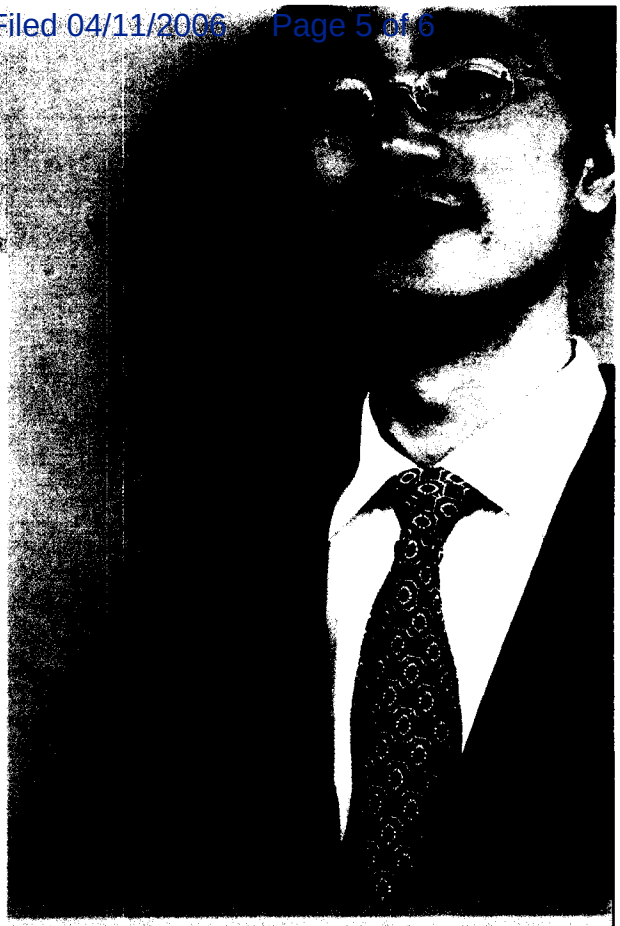

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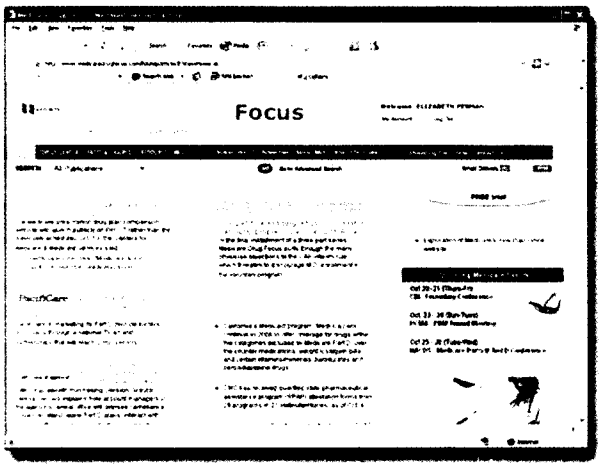

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In Brief

Breaking news from "The Pink Sheet" DAILY: Visit www.ThePinkSheetDAILY.com for coverage of the latest developments in the pharmaceutical industry, including Ortho-McNeil's partnership with Biovail for its extended-release tramadol. To sign up for a free trial, visit our website or call 800-332-2181....

Tamiflu, Vioxx* adverse events:** Pediatric adverse event reports for Roche's Tamiflu (oseltamivir) and Merck's Vioxx will be presented to FDA's Pediatric Advisory Committee on Nov. 18. The committee will also hear reports, mandated by the Best Pharmaceuticals for Children Act, for Shire's ***Agrylin (anagrelide), Bristol-Myers Squibb's ***Paraplatin*** (carboplatin), Pfizer's ***Diflucan*** (fluconazole) and ***Camptosar*** (irinotecan), Watson's ***Ferrlecit*** (sodium ferric gluconate complex) and GlaxoSmithKline's ***Imitrex*** (sumatriptan). The meeting will be held at the Hilton in Gaithersburg, Md. beginning at 8 a.m. ***[Editor's Note: To watch a webcast or order a video/DVD of this meeting, visit FDAAdvisoryCommittee.com.]***....

Merck Vioxx Pain Subsides: An Atlantic City, N.J. state court jury verdict clears Merck of allegations the drug maker failed to properly warn patients of risks associated with the use of ***Vioxx*** (rofecoxib). "We presented a case that was solidly based on scientific evidence," Merck said. The case, *Humeston v. Merck*, is the second Vioxx case to reach trial; an Angleton, Texas jury found Merck liable for the death of Robert Ernst in August, awarding his widow $253.5 mil. in damages ("The Pink Sheet" Aug. 29, 2005, p. 3)....

AARP Rx Watchdog Report: AARP's latest drug price study, issued Nov. 2, found prices rose 6.1% for nearly 200 of the most common brand name prescriptions during the 12 month period ending in June. The rate is slightly less than the 7.1% increase reported by AARP in 2004 ("The Pink Sheet" April 18, 2005, p. 16). Products with the "sharpest" price increases over the first six months of 2005 included Sanofi-Aventis' ***Ambien*** 5 mg (14.4%) and Boehringer Ingelheim's ***Atrovent*** (18.6%). The Pharmaceutical Research & Manufacturers of America disputed the report, stating the Consumer Price Index price for prescription drugs increased only 3.4% for the same period....

Omacor* medication errors:** The Institute of Safe Medication Practices is recommending that the name of Reliant's hypertriglyceridemia therapy ***Omacor (omega-3-acid ethyl esters) be changed due to similarity with Xanodyne's antifibrinolytic agent ***Amicar*** (aminocaproic acid). "Prescriptions for Omacor have just begun to arrive in pharmacies, but we've already heard name-related safety issues. A pharmacist reported an error in which a telephone order of Omacor 1 g B.I.D. was misheard as Amicar 1 g B.I.D.," the Nov. 3 issue of ISMP's *Medication Safety Alert!* says. Reliant launched Omacor in October, following approval in November 2004 ("The Pink Sheet" June 6, 2005, p. 9)....

DSOB adds staffer: Mary Mease joins FDA's Drug Safety Oversight Board as a science policy analyst, the agency announced Nov. 4. Mease previously worked in the Center for Drug Evaluation & Research's Division of Scientific Investigators; she has also worked as a safety evaluator in the Office of Drug Safety's Division of Drug Risk Evaluation. Mease's appointment is expected to complete the board's staff ("The Pink Sheet" Oct. 24, 2005, p. 5)....

Wyeth vaccine R&D head: Wyeth appoints Emilio Emini as exec VP-vaccines research & development, effective Nov. 7. Emini will report to R&D President Robert Ruffalo. He previously served as senior VP-vaccine development at the International AIDS Vaccine Initiative. Emini has also held vaccine research positions at Merck....

Immune Response Corp. gets new president: Joseph O'Neill is the new CEO and president of Carlsbad, Calif.-based Immune Response Corp. O'Neill, architect of President Bush's $15 bil. global plan for AIDS relief, succeeds John Bonfiglio. Immune Response's HIV vaccine ***Remune*** is in *Phase II* clinical trials....**NPS CEO succession:** N. Anthony Coles will succeed Hunter Jackson as NPS Pharmaceuticals CEO in six months. In the interim, he will serve in the new position of president and chief operating officer at the Salt Lake City-based company. Following the transition period, Jackson, who founded the company in 1986, will stay on as a director. Coles had been senior VP-commercial operations for Vertex Pharmaceuticals. He also previously held positions in the cardiovascular franchises of Bristol-Myers Squibb and Merck....

Diabetes lobbyist joins Novo's new D.C. office: Washington lobbyist and former Hill staffer Christopher Porter joins Novo Nordisk as director of government affairs in the firm's new Washington, D.C. office. Porter, who has lobbied for clients such as the American Diabetes Association, formerly served as co-staff director of the Congressional Diabetes Caucus....