Amgen Inc. v. F. Hoffmann-LaRoche LTD et al Doc. 49 Att. 4
Case 1:05-cv-12237-WGY Document 49-5 Filed 04/11/2006 Page 1 of 10

EXHIBIT 1, PART 4

The announcement followed Schering's acquisition in July of exclusive U.S. development and commercialization rights to Millennium's marketed thrombolytic product ***Integrilin*** (eptifibatide) to build on the company's strengths in cardiovascular care.

In January, Schering announced it would acquire most of the assets of the biopharmaceutical company NeoGenesis, which is focused on the development of small molecule drugs.

As Schering looks to extend its pipeline and portfolio, Hassan noted that the company will particularly seek to expand beyond its existing biotech brands, which include ***PEG-Intron*** (pegylated interferon alfa-2b) for hepatitis C and ***Remicade*** (infliximab) for inflammatory diseases, which Schering markets outside the U.S.

In May, the company consolidated its West Coast biotech facilities to create a new Biopharma unit in Palo Alto, Calif. Hassan reported that new molecules are beginning to emerge from that unit.

"Biotech is finally coming of age," Hassan asserted. "My expectation is that over the next couple of decades we will see a new explosion of health innovation in treating Alzheimer's disease, obesity, cardiovascular and metabolic syndrome, cancer, autoimmune diseases and infectious diseases."

"However, achieving this sunrise in our industry will require truly transformational change," he said. Big pharma will be outpaced by smaller, innovative competitors if it does not "adapt and transform," Hassan said.

In particular, "the companies that will succeed must unleash the R&D engine."

"We must create the winning attitude, the winning behaviors and the 'can do' spirit that you see in energized small companies," Hassan said. "At the same time, we must leverage the benefits of a big company environment, especially the financial staying power and the learning curve in downstream processes."

Hassan has previously described Schering's goal to "work as a small company in a big company," fostering innovation but still taking advantage of the size of a large company ("The Pink Sheet" June 6, 2005, p. 8).

Many in the industry have already adopted a strategy of acquiring pharmaceutical innovators but maintaining their independence.

Johnson & Johnson has a history of balancing its large-company, diversified model with specialized subsidiaries, bringing in companies like Centocor, Alza, Scion and Transform Pharmaceutical over the past three years and continuing to operate the businesses semi-independently.

Roche similarly established a majority stake in Genentech, which has brought the oncologics ***Avastin*** and ***Herceptin*** to market, while the biotech company operates independently as a cutting edge researcher.

Novartis announced a successful bid for Chiron Oct. 31; the Swiss drug maker has highlighted Chiron's potential to bring innovation in high growth areas where Novartis did not have a presence, like vaccines and diagnostics *(see related story, p. 15).*

The increased partnering and acquisition activity at Schering comes as the firm moves into the "turnaround" phase of its five-point, five-year action plan initiated in 2003.

"Turnaround" is third stage of the program; the first two phases were "stabilize" and "repair," while the last two will be "build the base" and "break out."

Hassan took the helm at Schering in April 2003 to implement a turnaround strategy in the wake of multiple business and regulatory challenges, including the implementation of an unprecedented consent decree and the OTC switch of ***Claritin***.

"What we found when I joined the company in spring 2003 [was] a wounded company in prolonged decline. This was the most challenging situation I have seen in our industry in my more than 30 years."

Two years later, however, "we are advancing our action agenda into a new period of building sustainable transformation and sustainable performance," he said.

The current goal at Schering, Hassan said, is to see top-line sales gains drive bottom-line earnings growth, followed up with continued reinvestment aimed at strengthening the business over the long term.

He also said the company is making steady progress on its FDA manufacturing consent decree. More than 90% of the obligations to FDA have been completed, with no penalty for missed deadlines, he reported. ♦♦

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Schering-Plough R&D Pipeline Sticks To Traditional Strengths

Schering-Plough's R&D efforts build on the company's existing therapeutic areas, according to the drug maker's R&D update Nov. 1.

"It's important to note how many of our new products and our lifecycle management opportunities actually extend franchises that we already have in the marketplace," Exec VP and President-Global Pharmaceuticals Carrie Cox said.

Schering's strategy of concentrating on areas where it has existing products and experience "makes us stronger competitors in those areas and leverages commercial strengths and infrastructures that we already have," Cox stated.

Schering will target vicriviroc filing for treatment-experienced HIV patients after discontinuing a treatment-naive study.

The company's headline projects fall into a familiar category: antivirals.

Schering is aiming to build on its existing treatments for hepatitis C virus with a new HCV protease inhibitor discovered in Schering's laboratory, Exec VP-Global Development Thomas Koestler reported. Schering markets ***PEG-Intron*** (pegylated interferon alfa-2b) and ***Rebetol*** (ribavirin) in the U.S.; the two drugs represent the current standard of care for chronic HCV infection.

Schering initiated a *Phase II*, 300-patient study of the new oral protease inhibitor in October after *Phase I* results showed a reduction in viral load in patients who failed PEG-Intron therapy when treated with the novel protease inhibitor and PEG-Intron in combination.

The *Phase II* trial will evaluate the HCV protease inhibitor plus PEG-Intron at different doses and also will compare the dual combination against treatment with the protease inhibitor, PEG-Intron and Rebetol.

Additionally, the company is planning future studies in treatment-naive patients, African Americans and patients co-infected with HCV and HIV.

Launch is expected to come in 2009-2010, Cox said.

Schering's antiviral pipeline also includes the CCR5 receptor antagonist, vicriviroc, for treatment of HIV. Koestler noted the agent is "the first new orally active class for HIV therapy in a decade."

Schering will focus initial registration of vicriviroc on treatment-experienced HIV patients, Koestler said. The decision comes after a study in treatment-naive patients was halted due to virological breakthrough. The discontinuation of the treatment-naive trial was announced Oct. 27.

Schering-Plough ended the *Phase II*, 92-patient study of vicriviroc plus GlaxoSmithKline's ***Combivir*** in treatment-naive patients because a return to detectable viral levels was seen in some patients late in therapy compared to the control regimen of Combivir and Bristol-Myers Squibb's ***Sustiva***.

The *Phase II* study in treatment-experienced HIV patients is continuing, Schering said.

Koestler maintained vicriviroc is well-suited for treatment-experienced therapy because of its "powerful activity" against drug resistant HIV.

Despite the decision to stop the trial in treatment-naive patients, Koestler said Schering will continue to study vicriviroc within that patient population. The drug maker is planning to initiate another *Phase II* trial in treatment-naive patients using a different treatment regimen, he said.

"The activity of vicriviroc is at least additive to all other classes of drugs...so it's important for us to find the optimal combination therapy," Koestler said.

Schering is currently "studying vicriviroc in combination with the appropriate background therapies for all patient populations," Koestler reported. "We are focusing on the treatment-experienced patients, but we are also looking at naive, and we intend to expand the program to pediatrics," he added. Launch for vicriviroc is slated for the 2008-2009 period.

In the anti-infective category, Schering's most advanced agent is the oral triazole antifungal ***Noxafil*** (posaconazole). The firm is planning to submit a complete response to FDA's "approvable" letter next year, Koestler said. The letter, which was received in June, seeks additional data on the treatment for refractory invasive fungal infections.

Schering is preparing to submit Noxafil for prophylaxis as well. Data from recent clinical trials will be the basis for prophylaxis filings in the U.S. and EU for high-risk patients with graft versus host disease undergoing hematopoietic stem cell transplant and high-risk patients who have prolonged neutropenia.

Schering recently completed two *Phase III* trials of Noxafil in over 1,200 patients, Koestler reported.

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Results of the first study showed that Noxafil reduced the incidence of all invasive fungal infections by 50% at any given time in the study. For the primary endpoint of invasive fungal disease in the 16-week study period, Noxafil produced a 67% reduction in incidence of aspergillosis, the company reported.

The second study, which evaluated Noxafil in 602 patients with leukemia or myelodysplastic syndromes at risk of invasive fungal infections, also met its primary endpoint. Data will be presented at the American Society of Hematology annual meeting in December.

Schering also is looking to build on its inflammatory portfolio with golimumab, a fully human antibody offering once monthly subcutaneous therapy for rheumatoid arthritis. Golimumab is licensed from Centocor; Schering holds worldwide marketing and development rights outside of the U.S. and Japan.

The company recently completed *Phase II* trials with the therapy showing rapid, sustained responses in RA patients. Golimubab has also demonstrated an "attractive safety profile," which is expected to make the drug competitive in the anti-TNF market. Cox projected a launch in 2009-2010.

Schering reported that it is making several advances in its primary care pipeline as well, building on its core cardiovascular and respiratory franchises.

The drug maker is developing a thrombin receptor antagonist for arterial thrombosis that "has a unique mechanism of action by which it will directly block thrombin induced platelet activation," Koestler said. The antithrombotic has potential for use as a single agent or in combination therapy.

The mechanism of action suggests efficacy can be achieved without bleeding liability, so Schering plans to target the therapy to reduce vascular events in high-risk patients, including those with acute coronary syndrome, as well as moderate-risk patients, such as those who have had a myocardial infarction or stroke.

The company has initiated *Phase II* studies of the thrombin receptor antagonist and is actively planning for *Phase III*, Koestler said.

"Our data suggests an early onset of action of 90% inhibition within 60 minutes, which may prove to be particularly beneficial to patients in the ER," Cox said.

"It's too early to say what the clinical profile will be, but if it lives up to its potential expectations, this could be a major product for us in the marketplace," she added. Launch could come in 2010-2011.

Of the projects highlighted during the R&D review, Koestler and Cox noted that several were developed in Schering's labs, including Noxafil, vicriviroc and the HCV protease inhibitor. Schering is also turning to licensing to augment its portfolio (*see preceding story*).

Faced with a "late-stage pipeline gap," as CEO Fred Hassan noted, Schering has concentrated on maximizing the performance of its existing brands.

"Our core products do have long periods of expected exclusivity and about 85% of our current sales should be protected well through the next decade," Cox said.

Top-line sales growth at Schering is being driven by the company's cholesterol franchise, which consists of ***Zetia*** (ezetimibe) and ***Vytorin*** (ezetimibe/simvastatin).

In the U.S., Schering's cholesterol franchise ranks among the top three and is continuing to grow, Hassan reported. Cox cited trends towards lower cholesterol goals and combination therapy as evidence of further growth opportunities for the brands. Vytorin offers "a very compelling value proposition. We believe we are very well positioned for the future."

Cox also described the respiratory franchise as an area with a "strong heritage, but also a strong opportunity for the future." She said there is a "vigorous lifecycle management program in place for ***Nasonex***."

"Two and a half years ago, this brand seemed flat and dull. We were getting advice to dump the respiratory category all together," Hassan said. "Today, we have rejuvenated Nasonex."

Cox also pointed to opportunities with the asthma drug ***Asmanex*** (mometasone), the firm's most recent product launch in the U.S. "Asmanex can be positioned along the treatment spectrum in this important market but clearly this is a challenge for us and one that will be difficult [because] there are well-established brands in the market and we are late as an entrant."

"It won't be easy, but we think there is a good place for Asmanex along this spectrum," she said.

Respiratory therapies in the pipeline include pleconaril, which would be the first antiviral for the common cold, a fixed combination of mometasone and formoterol with Novartis and a combination of loratadine (***Claritin***) and montelukast with Merck; all three could reach the market in 2009-2010. ♦♦

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Medco Generic Rate Hits Record High, But Margins Drag From Retail Contracts

Medco's generic dispensing rate in the third quarter was 51.5%, the firm's highest rate ever. The rate was 5% above the year-ago quarter and a half percentage point above the previous record – 51% in the second quarter 2005.

The pharmacy benefit manager attributed the high rate to a move away from COX-2s and the prominent products that went generic in 2004, including Forest's ***Celexa*** and Pfizer's ***Neurontin*** and ***Accupril***.

Medco seems well positioned to improve on the dispensing rate next year. Nearly $9 bil. of drug spend, led by Merck's ***Zocor***, goes off-patent in the second half of 2006.

"Clearly, the number one topic of conversations of clients right now is how they need to make certain their benefits are aligned properly to drive the generic opportunity," Medco CEO David Snow said during the firm's Nov. 1 earnings call.

"To the extent that they do not have proper drivers to move to generics, they're looking at making those adjustments. To the extent that they have a lot of branded products in their customized formularies, in therapeutic categories with blockbuster generics coming out, they're looking at changing their formularies to better encourage generic use. They're all reviewing those, they're making changes, particularly in the cholesterol lowering category and in the PPI category."

"We won five very large states with heavy retail use. That's in exchange for FEP, which was 100% mail," Snow said.

Express Scripts is making an aggressive push to capitalize on the availability of generic Zocor by switching its formularies from Pfizer's ***Lipitor*** to the soon-to-be patentless statin ("The Pink Sheet" Oct. 24, 2005, p. 19).

Asked if Medco's clients are switching from Lipitor to Zocor, Snow said, "we're not seeing a lot of shift from Lipitor to Zocor, but we're seeing from existing customers stickiness on the brand of Zocor in anticipation of the generic coming out. What the clients are looking at is what the implications are for Lipitor to generic Zocor and what kind of things they might want to do or need to do to optimize the value of that benefit."

Medco's performance for the quarter was also helped by the closing of its acquisition of the higher-margin Accredo Health ("The Pink Sheet" Feb. 28, 2005, p. 24). "We expect our specialty pharmacy business to continue to be a major growth driver in the years beyond 2006," Snow said.

Despite these positive trends, Medco's gross margin was relatively flat, up only 0.1% for the quarter. The PBM is still trying to recover from the December 2004 loss of the Federal Employee Health Benefit Plan's mail-order business.

Medco made up much of the difference in scripts with the mid-year addition of five major state clients – Pennsylvania, Illinois, North Carolina, New Hampshire and Ohio. However, state employees primarily use retail pharmacies, rather than the higher-margin mail-order services Medco had provided federal employees.

Asked why the quarter's 5% gross margin wasn't better, Snow said, "it's the big change in the proportion of mail to our total versus retail. We won five very large states with heavy retail use. That's in exchange for FEP, which was 100% mail. So it's simply a matter of the mix of mail versus retail within the business that's coming on board right now. I don't think it indicates anything other than a change in channel mix."

Additionally, the seasonal third-quarter increase in antibiotic and antihistamine scripts, which are primarily retail, was greater than usual this year, Medco Chief Financial Officer JoAnne Reed said.

Medco administered 21.4 mil. mail-order prescriptions during the last quarter, down from 22.2 mil. a year before. During the same period, retail prescriptions increased to 109.2 mil from 99.3 mil.

The PBM's mail-penetration rate declined to 37.0%, down from 40.1% during the same period in 2004 (with mail-order scripts multiplied by three to adjust for their greater size). EBITDA earnings per adjusted script were $1.81, up two cents from the year before and down one cent from the quarter before.

Reed described the acquisition of retail-heavy state clients as an opportunity. "We're looking forward to continuing to take some of the new retail business that we were able to obtain and move it over to mail service in the quarters to come," she said. "So I think you'll see the EBITDA per adjusted script continuing to climb as we increase the mail penetration on a going forward basis." ♦♦

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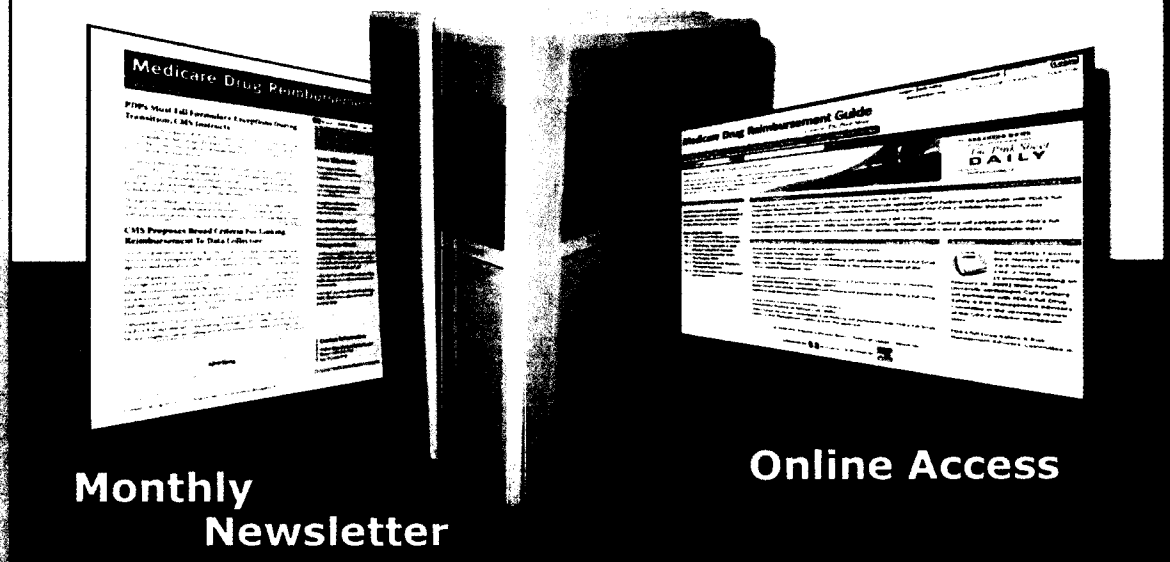

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King's Best Price Settlement Covers Entire Product Portfolio

King's settlement of charges that it failed to properly calculate Medicare best price rebates is far larger than most such settlements because it includes the company's entire portfolio.

The case began with whistleblower allegations that the firm had failed to calculate quarterly Medicaid Best Price rebates correctly for its ***Altace*** ACE inhibitor, but King realized it had a systematic problem.

For nine years, the Bristol, Tenn., drug maker had been operating without the processes needed to properly calculate any best prices or average manufacturer prices it reported to government agencies under the Medicaid drug rebate program for any of its drugs.

"This settlement is unique because King agreed to redo its pricing on its entire product line over a period of several years."

The company shared what it had learned with federal enforcement authorities, leading to an Oct. 31 settlement for $124 mil. plus interest that is far broader than most, correcting price reporting of 83 drugs over a nine-year period ending Dec. 31, 2002.

"Unlike prior settlements, which involved the misreporting of prices relating to a specific transaction or drug, this settlement is unique because King agreed to redo its pricing on its entire product line over a period of several years," the Philadelphia U.S. Attorney's office said in a release.

Because King's misreporting stemmed from company-wide system failures, the repercussions were wide ranging. It affected not only the federal Medicaid program, but also the Public Health Service's drug pricing program, which keeps prices below AMP for AIDS drug purchasing assistance programs, community health centers and certain disproportionate share hospitals, as well as King's Federal Supply Schedule contract.

"Once the company realized it had a problem, it threw the resources into fixing it," Assistant U.S. Attorney Barbara Rowland said in an interview with "The Pink Sheet."

"While none of these issues resulted from intentional misconduct," a King press release states, "we nevertheless have taken them very seriously and believe we have taken the necessary steps to avoid any recurrence."

King asserted in the consent agreement that it may even have gone overboard when it changed its price reporting methodology, overpaying quarterly rebates in the first quarter of 2003.

As part of the settlement, King agreed to a five-year corporate integrity agreement that covers not only Medicaid best price and AMP but also Medicare average sales prices.

Training on average sales price is also a component of GlaxoSmithKline's corporate integrity agreement, negotiated to settle charges of inflated AWPs for ***Zofran*** and ***Kytril*** ("The Pink Sheet" Sept. 26, 2005, p. 6). Prosecutors may be focusing on ASPs because of their increased prominence in Medicare Part B.

Under the CIA, King must continue employing a corporate compliance officer, maintain its Compliance Committee, promote its code of conduct in evaluating employee performance, provide training, and maintain its disclosure program.

King also must retain an independent review organization, or auditor, to perform systems reviews of the company's systems, processes, policies and practices for calculating and reporting Medicaid Best Prices and Average Manufacturer Prices, as well as Medicare Average Sales Prices. The reviews must occur in the second and fourth year of the five-year agreement, with additional focused system reviews required in any other years that King makes relevant changes.

The system reviews must address matters such as how King decides which customers and transactions, discounts or rebates to include in its best price, AMP and ASP calculations, how data flows into its calculations, and how it addresses variations, exceptions and outliers.

The auditor also must test samples of transactions to see if King is correctly calculating best prices for the Medicaid drug rebate program. After choosing a quarter randomly, the auditor must randomly select 10 large and 10 small customers, based on the volume of Medicaid rebate eligible drug sales during the quarter. The review must cover the five drugs for which King paid the most Medicaid rebates that year and five that are randomly selected from the remainder.

For average manufacturer prices, the auditor must do a similar analysis focused on the top three rebate drugs and two randomly selected from the remainder. ♦♦

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Part B Competitive Acquisition: CMS Bows To Pressure On ASP Exemption

Bowing to a major demand of both vendors and physicians, the Centers for Medicare & Medicaid Services will exempt Part B competitive acquisition program drug prices from average sales price calculations, at least for the first three years of the CAP.

The CAP, a new voluntary program for physician-administered drugs under Medicare Part B, will now start July 1, 2006, CMS says. A 30-day vendor bidding process is set to begin Nov. 21, after two CAP-related interim final rules are published in the *Federal Register*.

The initial physician election process will start April 3, 2006. For 2006, physicians who opt in will participate in a partial-year program; beginning in 2007 this will change to an annual opt-in program. Under the program, approved CAP vendors will sign three-year contracts.

The CAP originally was slated to begin Jan. 1, but CMS suspended that timetable after physician and vendor groups expressed displeasure with many aspects of a July 6 interim final rule ("The Pink Sheet" Aug. 8, 2005, p. 19).

The two new rules address some, but not all, of these stakeholder concerns.

In a new interim final rule, published Nov. 2, CMS announced that it will exempt CAP prices from ASP. In doing so, the agency said it was swayed by commenters who argued that Congress intended CAP and ASP to work separately.

In the July rule, CMS had insisted that it lacked statutory authority to exempt CAP prices from ASP, even though it had received numerous comments to the contrary from physicians, vendors and House Ways & Means Committee Chair Bill Thomas (R-Calif.) ("The Pink Sheet" July 4, 2005, p. 16).

At the heart of the controversy is a belief that ASP exemption is required to ensure manufacturer discounts for CAP drugs. "We acknowledge the possibility that the Congress intended the programs to be completely independent of each other," the new rule states.

"We believe it is appropriate to implement [the CAP] exclusion from the ASP calculation because this exclusion is necessary for implementing the CAP, a program that the Congress has expressly identified as an alternative to the ASP payment methodology." CMS also agreed that exempting CAP prices from ASP would encourage manufacturers to offer deeper discounts to CAP vendors.

The rule notes that the agency may revisit its decision after three years. In the meantime, manufacturers must exclude rebates and lagged price concessions for CAP drugs from ASP calculations, CMS advised.

PCMA applauds the change, saying it will "eliminate the possibility of artificial price floors tied to ASP."

Medicare Part B currently reimburses physicians for drugs they administer at 106% of ASP. After CAP takes effect, physicians my choose to receive drugs from a CAP vendor or continue to purchase drug directly and be reimbursed at the ASP rate. Under another CMS rule issued Nov. 2, hospitals will also be reimbursed for outpatient drugs at 106% of ASP *(see related story, p. 26)*.

At least one major stakeholder already has applauded the agency's decision on the ASP exemption for CAP. Calling the change "a significant improvement," the Pharmaceutical Care Management Association claimed that it will "eliminate the possibility of artificial price floors tied to ASP."

In another concession to stakeholders, CMS will reimburse vendors for the unused portion of a CAP drug provided it is shipped in a single-use vial and both the vendor and physician make "good faith efforts" to minimize drug wastage. Under the July CAP rule, CMS said it would pay only for the portion of the drug administered to the patient – a position at odds with reimbursement policies under the ASP system, CMS now says.

CMS made additional changes to the CAP as part of a separate interim final rule incorporated into the 2006 physician fee schedule rule that went on display Nov. 2. In particular, CMS responded to manufacturer and physician requests to accelerate the inclusion of new drugs in the CAP by enhancing a pathway for vendors to petition the agency during their three-year contracts.

[Editor's note: F-D-C Reports' new publication, Medicare Drug Focus, provides in-depth coverage of Part B drug reimbursement, including the competitive acquisition program. Register for your 30-day free trial at www.MedicareDrugFocus.com or call 800-332-2181.] ♦♦

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CMS Extends Oncology Demo, Shifts Focus To Clinical Guideline Adherence

The Centers for Medicare & Medicaid Services is revising its cancer "quality of care" demonstration project to evaluate oncologists' adherence to evidence-based practice guidelines.

"We have decided to retain the demonstration project for one more year, but we will revise the G-codes for reporting in order to take a further step toward encouraging quality care and promoting best clinical practices," CMS said in its final Physician Fee Schedule for 2006, released Nov. 3.

The demo project "will emphasize evidence-based practice guidelines that have been shown to lead to better patient outcomes as the source for standard of care, permitting us to monitor and encourage quality care to cancer patients," CMS states.

CMS expects to spend $150 mil. on the 2006 demo project, half the funding devoted to the 2005 program.

Under the current demo, physicians are reimbursed for assessing pain, nausea, vomiting and fatigue during the administration of chemotherapy ("The Pink Sheet" Nov. 18, 2004, p. 18).

For the 2006 project, "reporting will no longer be specific to chemotherapy administration services, but instead will be associated with physician [evaluation and management] visits for established patients with cancer, visits that are frequent and essential to assuring quality of care and life for patients," the agency says.

In a Sept. 8 letter to Sen. Charles Grassley (R-Iowa) assessing the 2005 program, the HHS Office of Inspector General raises questions about the "reliability and usefulness" of the project data.

Physicians gather the data in a variety of ways and at a variety of times, the letter notes. In addition, the demo does not collect data on the interventions oncologists use to treat the conditions. "Our interviewees suggested that omitting this piece of information would limit the usefulness of the demonstration data," the letter says.

In urging CMS to extend the demo, commenters recommended that the project be revised "to capture better data on quality and outcomes," the rule notes.

CMS is establishing three categories of G-codes for the project concerning "(1) the primary focus of the E/M service; (2) the current disease state; and (3) whether current management adheres to clinical guidelines."

Physicians will receive a $23 payment for submitting one G-code from each of the three categories, rather than the $130 paid for each assessment of pain, nausea, vomiting and fatigue under the current demo.

"While we recognize that reimbursement for services provided under a demonstration projection need not follow fee schedule rules, it is interesting to note that the average reimbursement during the first six months of 2005 for the most complex office visit for an established patient was $118.63," the IG states.

CMS is allocating $150 mil. for the project in 2006, a significant drop-off from the $300 mil. allotment for the current demo.

One of the primary purposes of the 2005 demo was to ease the financial burden on oncologists that was expected to accompany the change in Medicare Part B's reimbursement methodology to average sales price plus 6%.

Amgen has pointed to the program as one factor in the continued strength of its oncology franchises despite the reimbursement change ("The Pink Sheet" Feb. 7, 2005, p. 13).

The company had anticipated the demo would continue in some form in 2006; continuation of the program had also received support from Congress ("The Pink Sheet" July 25, 2005, p. 27).

However, the decision to continue the demo follows a September report by the IG finding that oncologists were generally able to purchase cancer drugs for less than the ASP+6% reimbursement rate ("The Pink Sheet" Oct. 17, 2005, p. 6).

In the Physician Fee Schedule, CMS states that the current demonstration project "accounts for approximately three percent of Medicare revenues for oncologists." The agency projects that the combined impact of changes in the physician fee schedule and demonstration services on oncologists is -10%.

The agency estimates that drugs account for 70% of Medicare revenue for oncologists. Assuming historical growth in service revenue and Part B drug spending, "we estimate the total Medicare revenue to oncologists would increase by six percent between 2005 and 2006," CMS says. ♦♦

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CMS To Stop Linking Payment For *Aranesp*, *Procrit* But Vows To Revisit Issue

CMS remains open to aligning the payment rate for Amgen's ***Aranesp*** with Johnson & Johnson's ***Procrit*** in future years, although for now the agency is acting on its proposal to retire the "equitable adjustment" method for reimbursing the drugs.

After reviewing the "methodological rigor" and "generalizability" of several studies both firms submitted on the topic, the Centers for Medicare & Medicaid Services has found insufficient data to merit exempting Aranesp (darbepoetin alfa) from the market-based, average sales price payment system that will apply to other hospital outpatient drugs in 2006.

Likewise, "the results of these clinical studies were not consistent or conclusive in defining a single, different conversion ratio for dosing between these two products, particularly with respect to the timing of specific doses of the two drugs required to achieve several different meaningful clinical outcomes," CMS explains in the 2006 outpatient prospective payment system final rule, released Nov. 2.

By shifting from an AWP to ASP-based system, payments for both Aranesp and Procrit will decrease by "similar levels" in 2006.

[Editor's note: F-D-C Reports' new publication, Medicare Drug Focus, provides in-depth coverage of Part B drug reimbursement. Register for your 30-day free trial at www.MedicareDrugFocus.com or call 800-332-2181.]

The agency's move drew swift opposition on Capitol Hill. In a same-day statement, House Ways & Means Committee Chair Bill Thomas (R-Calif.) scolded CMS for denying comparable payment for the two drugs, which he claims are "functionally equivalent."

Since 2003, the agency has reimbursed the drugs at a ratio of 1 mcg of Aranesp to every 330 international units of Procrit, citing "equitable adjustment" as its rationale. The dose conversion ratio assumed an average wholesale price-based reimbursement rate. CMS' 2006 OPPS proposed rule, by contrast, suggested replacing the AWP methodology with ASP+8% for specified covered outpatient drugs, including Aranesp and Procrit ("The Pink Sheet" July 25, 2005, p. 23).

Instead of relying on a dose conversion ratio to set Aranesp's payment, therefore, CMS proposed dropping the equitable adjustment method.

Commenting on the proposal, Amgen agreed on allowing market forces to drive future reimbursement for Aranesp, rather than binding the drug's payment rate to that of Procrit.

Nevertheless, if a dose conversion ratio were to be invoked, Amgen said it should be set closer to 400 international units to 1 mcg. The company submitted an unpublished study by UCLA's John Glaspy and a cost analysis by The Moran Group to build its case.

For its part, J&J/Ortho Biotech filed study data by Roger Waltzman (St. Vincent's Comprehensive Cancer Center, New York), to justify retaining the equitable adjustment methodology for Aranesp. The data, which accompanied a clinical white paper summarizing seven other studies, pointed to a dose conversion ratio of 200:1, according to J&J. The company ultimately requested that CMS adopt 260:1 instead of the current 330:1.

In the OPPS final rule, the agency states: "With the limitations of the studies supporting either an increase or a decrease in the conversion factor, the quality and quantity of the currently available published evidence do not provide sufficient, clear evidence to support a change in the appropriate conversion factor at this time."

Although CMS cites a dearth of studies on comparative dosing for the two chemotherapy-related anemia treatments, the agency asserts: "It is not our intention to preclude the use of a conversion ratio to establish the OPPS payment rates for epoetin alfa [Procrit] and darbepoetin alfa in the future."

"Rather, as long as the market price for darbepoetin alfa is consistent with a payment rate derived from using a clinically appropriate conversion ratio, invoking our equitable adjustment authority would not lead to a different result," CMS adds. "However, we retain our authority to apply an equitable adjustment in the future to determine the payment rate for darbepoetin alfa."

The issue of payment for the drugs may be re-opened as early as next year. "We will once again assess the need to exercise this authority when we next update the payment rates under the OPPS based on the latest available clinical evidence on the appropriate conversion ratio and based on the actual pricing experience at the time."

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