Amgen’s Neulasta Distribution Change for 340B Entities Draws Criticism and Praise

In recent years, 340B pricing has grown in profile on health plans’ radar screens as more hospitals purchase smaller physician offices and as providers shift patients to outpatient hospital facilities, where care often costs twice as much as the same service provided in a community practice. Entities participating in the 340B program purchase drugs at deeply discounted rates and can treat all patients, both insured and uninsured, with those cheaper drugs — but then bill plans at higher contracted rates.

But it’s not only plans that are concerned with the 340B program. Manufacturers must sell their drugs at deeply discounted rates, which can make a huge difference when it comes to expensive specialty drugs. But Amgen Inc. has instituted a change to how covered entities access its drug Neulasta (pegfilgrastim) that for once has spurred 340B facilities to take an offensive stance — and left industry experts uncertain as to whether the effort ultimately will be successful.

On June 6, Amgen shifted distribution for Neulasta for 340B entities from AmerisourceBergen to the wholesaler’s specialty distributor, ASD Healthcare. The change did not apply to Neulasta that is acquired using non-340B pricing.

Safety Net Hospitals for Pharmaceutical Access (SNHPA), an organization of more than 900 safety-net hospitals that qualify for the 340B federal drug discount program, called on Amgen to withdraw its plan in a letter to Chairman and CEO Robert A. Bradway. According to the May 29 letter, “SNHPA is concerned that Amgen’s distribution plan violates federal policy by imposing substantial administrative and financial burdens on 340B hospitals that would not apply to non-340B hospitals.” If the manufacturer refuses, “SNHPA will ask the Health Resources and Services Administration (HRSA) [i.e., the HHS agency that administers and oversees the 340B program] to investigate this issue. (SNHPA has already shared its concerns with HRSA’s 340B Prime
continued on p. 7

Clinical Pathways Reduced Costs of Care 15%; Success Led to Medical Home Pilot

When P4 Healthcare LLC launched its first clinical pathways program with CareFirst BlueCross BlueShield in 2008 (SPN 4/09, p. 8), its goals were to help rein in cancer care costs without sacrificing patient outcomes and get physicians on board by providing fair reimbursement. At the time, to say this was a tall order may have been an understatement, as payers traditionally had been very hands off when it came to oncology.

While P4 — whose parent company, Healthcare Solutions Holding, LLC, was purchased by Cardinal Health, Inc. in 2010 (SPN 7/10, p. 1), making P4 part of Cardinal Health Specialty Solutions — and CareFirst have released data showing the savings from this program, a recent study provided third-party validation of those benefits. Additional studies from Cardinal and CareFirst — as well as a medical home pilot program the two are partnering on — have demonstrated that the program is meeting its goals.
continued
When the program started, it focused on breast, lung and colon cancers, which made up the bulk of CareFirst’s oncology costs. Cardinal and CareFirst compared claims from January 2007 to December 2010 for patients with these cancers who were treated by physicians in the pathways program with a control group identified by Truven Health’s MarketScan database. The findings show that CareFirst reduced its overall costs to treat these cancers by 15%.

“The overall reduction in hospital services was 7%, through a combination of decreased ER visits, decreased hospital admissions and decreased length of stay,” explains Bruce Feinberg, D.O., chief medical officer, oncology for Cardinal Health Specialty Solutions. “We believe one of the key factors leading to fewer ER visits was the more appropriate use of medications — particularly chemotherapy.” He adds that while the company does not have specific information as to the lengths of stay, “we intend to measure and report that level of detail in future studies.”

According to Feinberg, “The biggest surprises [among the studies’ findings] were around physician behavior and reimbursement. Despite the accepted dogma that physician prescribing will follow their economic interest, we found that doctors could be paid more but prescribe less and that they could be paid less for drugs and prescribe the same. We see this as reinforcement that the evidence-based pathways were the driver of the physician behavior, not the drug reimbursement.”

He tells SPN that physician “participation has been excellent in the community, upwards of 85% including both salaried and academic practices.” Of note, he says, is that “85% of community oncologists in the network participate, but those doctors represent 95% of community oncology cancer spend.”

Participation in the clinical pathways programs is “collaborative and voluntary,” points out Feinberg. His company is working on other programs with various plans across the country, “and each has financial incentives for participation, above and beyond historical reimbursements. Incentives vary from fee schedule enhancements to participation bonuses to shared savings. We encourage reimbursement methodologies that incent providers to participate and comply with clinical pathways.”

During the second year of the pathways program, CareFirst expanded it to 10 cancers, including prostate, ovarian, lymphoma and myeloma, notes Feinberg. In addition, in December 2011, CareFirst and Cardinal launched the first clinical pathways program for rheumatoid arthritis (SPN 12/11, p. 11), which also has proven successful (SPN 5/13, p. 1).

Organizations Launched Medical Home Pilot

Following the initial pathways program’s success as measured in financial savings and physician participation and compliance, the two organizations launched a medical home pilot program in January 2011, “with the hope of further decreasing cancer care costs while continuing consistency and quality of care,” according to an abstract (#E1782) of a study presented at the recent American Society of Clinical Oncology meeting. The new program “offered a new physician reimbursement model that shifted the source of revenue from margin on drug sales to cognitive services allowing physicians to focus on optimal patient care without the financial incentive to prescribe chemotherapy. Physicians were encouraged to commit to an intensive continuous quality improvement (CQI) program, which included an end-of-life [i.e., EOL] initiative and a post chemotherapy nurse call-back program that would lower costs by decreasing emergency room and hospital admissions.”

Physicians who had participated in the initial pathways program were eligible to participate in the medical home pilot. Fourteen practices with 31 physicians joined the pilot. The study compared data from the pilot with data from 103 physicians from 39 practices who were not participating. And although all cancers were included in the medical home program, “for the purposes of this
study, we measured compliance only for breast, colon and lung cancers,” says Feinberg.

Findings from the study showed that the medical home provided gross savings of $2.0 million compared with the first program. “Significant savings can be achieved in a provider group already compliant with a mature pathways program,” concluded the study.

“Most of the savings was driven by a reduction in hospital events, and some savings were also created by drug margin change due to the rise in ASP [i.e., Average Sales Price],” explains Feinberg. “However, participating practices were promised to be made whole on drug margin delta.”

Another study looked at the potential cost savings of a CQI program. Of that study, Feinberg says that “the two outcomes that stand out are related to nurse surveillance and end-of-life awareness. Nurse calls likely prevented five to 15 ER visits and three to 10 hospitalizations. The EOL program raised awareness of EOL options and best practices, increasing hospice referrals to 80%. However, short lengths of stay in hospice (seven days or less) and high hospitalization rates leave room for improvement.”

That study also revealed that only one patient out of 15 — which was out of 38 patients receiving clinical interventions that involved a return visit to the provider office — received chemotherapy within 14 days of death. “This is significant because it challenges dogma as do many of the observations in this research,” Feinberg says. “Doctors did not change their care despite a dramatic change in reimbursement method. Chemotherapy was not a major expense at end-of-life — hospitalization was.”

Contact Feinberg through Tara Schumacher at Tara.Schumacher@cardinalhealth.com.

**Molecular Diagnostics Initiative Should Improve Care, Reduce Costs**

As molecular diagnostics becomes more important in the treatment of cancer, a new partnership hopes to bring some efficiency and clarity to a field that is evolving quickly. McKesson Specialty Health has selected medfusion and Foundation Medicine as the preferred diagnostic laboratories for The US Oncology Network, the division of McKesson Corp. said May 30.

The motivation behind selecting preferred labs, says Catherine Swick, senior director of lab services and precision medicine for McKesson Specialty Health and The US Oncology Network, was due to the fact that the company “recognized a few things.” First is that there is an “increasing amount of testing in oncology care,” which can make it hard for physicians to determine what test is

---

**Post-Discharge Medication Reconciliation Strategies for Health Plans and PBMs**

- How can payers and providers measure whether medication reconciliation is effective and includes not just a routine check of prescribed medications, but also patient education and outcomes measurement?
- Which model for staffing and coordinating medication reconciliation efforts works best — and for which types of patient groups and plan sponsors?
- What outcomes have different types of medication reconciliation programs achieved?
- How should payers reimburse for medication reconciliation — and what role can incentives play in making sure this crucial function is done effectively?
- How can payers harness the value of the pharmacist to intervene in issues stemming from multiple prescribers?
- How can integrating medical and pharmacy claims data serve to better manage issues around medication reconciliation?


Visit www.AISHealth.com/webinars or call 800-521-4323
needed, she explains. Working with the companies will “increase consistency” and offer “guidance as to what is appropriate and when.” In addition, there continues to be an increase in molecular testing of actual mutations, so it’s important for physicians to really be on top of this, Swick tells SPN.

Clinical Trials Are Important Aspect of Deal

Clinical trials were another consideration for McKesson Specialty. “Clinical trials are really an important part of oncology care,” giving many patients “access to lifesaving treatments,” contends Swick. She notes that more clinical trials require testing just for patients to be involved in them. With the molecular diagnostic data provided electronically to McKesson Specialty, the firm can populate its electronic health network and can search those files to find out which patients may be eligible for particular trials.

One of the country’s largest networks of community-based oncologists and integrated cancer care practices, The US Oncology Network also has “a robust research network within its larger network,” notes Marcus Neubauer, M.D., medical director of oncology services for McKesson Specialty Health and The US Oncology Network. The physicians now will be “given the opportunity to help design panels.”

Initially, “the feeling was we wanted to partner with one company, but it turned out to be two,” says Neubauer. He explains that there are “many companies out there with high variability in a lot of things,” including how they run tests and even which tests they use.

“There is a lot of difference of opinion in what the tests mean and how they apply to practicing physicians.”

There are essentially two types of molecular diagnostics. A panel provides information on multiple genetic markers based on one test on one sample. For example, Neubauer says, in non-small cell lung cancer, a panel looks at eight or nine different markers. Second is next-generation sequencing, which Neubauer calls the “future of molecular diagnostics.” It’s also the reason why McKesson Specialty is partnering with two companies. Foundation Medicine “is a leader in this area,” he contends. Its FoundationOne “offers a fully informative genomic profile useful in many cancer types and clinical scenarios….Most labs, including med fusion, do not do this at this time.”

Med fusion will complement Foundation Medicine because of its “logistical capabilities and broad clinical testing menu,” according to McKesson Specialty. In addition, it will function as the “diagnostic gateway for The US Oncology Network,” explains Swick. Nowadays, practices may send samples out to “20, 30, 100 vendors….The technology interface to get all that data can get complicated.” But now, “all testing goes through med fusion, which can send it out” to labs if needed. “All data comes back through med fusion, which helps ensure that redundant testing isn’t done,” she explains. In addition, a more efficient process should mean better turnaround times on results.

Neubauer notes that med fusion “has access to all FDA-approved” tests. However, some tests must be outsourced; the BRACAnalysis, for example, must be processed by Myriad Genetic Laboratories, and the Oncotype DX assay must be processed by Genomic Health, Inc. Med fusion will be able to “carve out” those tests and handle sending out and receiving the data.

Partnering with med fusion and Foundation Medicine will “reduce variability and improve our approach to precision medicine,” maintains Neubauer. The US Oncology Network has the “reputation of functioning as a network,” and it is “really truly a cohesive group,” he explains to SPN. Oncologists within the network provide “high patient care, drive care and are dealing with the rising costs of cancer care.” So McKesson Specialty wanted to “wrap our arms around” value-based precision medicine.

Precision Medicine vs. Personalized Medicine

This area is different from the broader “personalized medicine,” which encompasses not only a person’s genetic characteristics but also a tumor’s and informs whether one drug would work better than another.

“This is too all-encompassing and doesn’t serve our purpose,” which is to “put a process, a plan around the fact that there are DNA alterations” that cause tumors. Understanding the characteristics of a tumor can help tailor treatment for a person, which can “have a positive impact on outcomes,” Neubauer says. “Certain targets are identified and then certain ways to attack those targets.” Precision medicine “better defines what we’re interested in.”

McKesson Specialty contends that the initiative will help improve care and potentially reduce the cost of care. Neubauer elaborates that “it sounds corny, but if you look at this as doing the right test at the right time, this will improve care.” In addition, “any information that can be used in an effective way can lower costs.” He points out that there is both overutilization and underutilization of molecular diagnostics. Overutilization could lead to ordering tests that aren’t really needed and won’t make a difference in treatment, while underutilization could lead to people missing out on treatments that could truly make a difference.

The program should help “reduce the unnecessary ordering of tests,” he maintains. “That’s not to say that physicians are doing the wrong thing, but this can
provide guidance on when to order them” — something that Neubauer says he would have appreciated having when he was practicing. He adds that “we’re developing a very detailed education piece as part of this initiative for providers.”

The partnership stands to benefit health plans as well, contends Neubauer. “Molecular diagnostics are very expensive,” and many times, plans have “trouble seeing what they’re paying for.” For example, it wouldn’t be uncommon for a plan to receive a “nonspecific bill for $4,000.” The program hopefully should bring some clarity to this aspect of care. And “as the strategy unfolds,… there could be additional contracting opportunities to providers and health plans,” he says.

With many insurers having a network of preferred labs, usually for more basic labs, says Swick, “our hope is to have these vendors be in-network for as many payers as we can.”

According to Neubauer, “There are no financial rewards for physicians in ordering certain tests.” The collaboration is “meant to be a facilitator for them,” since determining “what test to order, when and from whom” can be a “major hassle.” Ultimately, he explains, “We feel there needs to be a best-practices model in handling molecular diagnostics” that includes giving “guidance to physicians in the network…to help them order tests appropriately.”

Contact Neubauer and Swick through Claire Crye at claire.crye@mckesson.com.

**Anthem Settles Suit Over Mandatory Mail Order for HIV/AIDS Drugs**

Almost six months following the filing of a lawsuit over how Anthem Blue Cross members get their HIV/AIDS drugs, a settlement finally has been reached. These members will now be able to opt out permanently from being required to get their medications through the mail and can instead get the drugs from community pharmacies.

Last year, the insurer created a specialty drug list and notified members taking one of those drugs that rather than being able to get the drugs through a local pharmacy, they would have to receive them by mail from specialty pharmacy CuraScript. If a member filled a prescription for one of the specialty drugs included on a list that was sent to members along with a letter explaining the change, that would be considered going out of network, and the member would have been responsible for the full price of the drug, which could have cost patients thousands of dollars per month (SPN 2/12, p. 12). Members who wished to continue getting their drugs from a retail pharmacy could have applied for a hardship waiver every six months.

However, California consumer advocacy group Consumer Watchdog filed a proposed class-action lawsuit alleging that the WellPoint, Inc. unit illegally targeted members with HIV/AIDS. That resulted in numerous delays of the program’s implementation (SPN 2/12, p. 12). In late May, the groups said a settlement had been reached.

“In response to the concerns from our members, Anthem Blue Cross has agreed to simplify the ‘opt-out’ procedure for members who receive HIV/AIDS specialty drugs through mail-order pharmacies,” Darrel Ng, spokesperson for Anthem Blue Cross, tells SPN. “Anthem Blue Cross members who prefer to receive their HIV/AIDS specialty prescription drugs from a local specialty pharmacy can ‘opt-out’ permanently of the mail-order program by making one convenient phone call. We are pleased that we have been able to accommodate our members and serve them better by amending this policy.”

Ng confirms that the policy change was effective June 1. In addition, he says, “an HIV/AIDS patient can opt out at any time for any reason from the HIV/AIDS medications mandate, and the opt-out will be perpetual.”

Opponents of the policy change applauded the settlement.

California Insurance Commissioner Dave Jones (D) said the decision was “another important win for consumer protection in California. Pharmacists are an extension of a patient’s treatment team, providing medication expertise and consultation that a mail order pharmacy may not be able to offer. Patients should not have to rely on an off-site vendor call center when they need assistance with medication management.”

**Patient Can Maintain Pharmacist Relationship**

According to Jones, “the decision also ensures patients are able to maintain their relationship with a qualified pharmacist, who is essential in protecting their health information privacy rights. Decisions regarding medication management and a patient’s treatment regimen should be made by a patient’s treatment team and be driven by what is best for the patient — the court-approved settlement ensures additional protection for Anthem’s policyholders by allowing them to choose the option that is most appropriate in managing their care, whether that is the mail-order program or through a pharmacist.”

“This settlement will preserve access and choice for thousands of HIV/AIDS patients that are covered by Anthem,” says David Balto, attorney for many of the affected California pharmacies specializing in HIV patient
care. “HIV patients value their longstanding relationships with their community pharmacies, which provide valuable services in assuring drug adherence, counseling, monitoring and aid in securing financial assistance to afford expensive drugs. Many of these pharmacies have been working with the disease since the emergence of HIV in the early 1980s, and many of these patients have long term relationships with their community pharmacy.”

“Anthem’s mail order program would have harmed thousands of vulnerable HIV patients, preventing them from receiving the health care they need,” says Balto. The settlement, he maintains, “will allow some of the most vulnerable HIV/AIDS patients unfettered and uninterrupted access to medications through their trusted community pharmacists.”


Drug Costs, Use in Hepatitis C, HIV Will Boost Specialty Trend

Although inflammatory conditions, multiple sclerosis and cancer continue to make up the top three specialty spend areas for one PBM, other classes such as hepatitis C and HIV are growing factors in not only last year’s specialty trend but also the next few years to come.

Express Scripts Holding Co.’s commercial clients had an 18.4% overall specialty trend for pharmacy benefit-adjudicated prescriptions, with a $207.19 per-member per-year (PMPY) spend (see table, below). Last year specialty drugs represented 1% of overall prescriptions filled for these clients — but this was 25% of the total spend on prescription medications.

With a $50.62 PMPY spend and a 23.0% trend, inflammatory conditions remained the No. 1 class in 2012. The category with the highest utilization and the highest overall trend, though, was hepatitis C, which welcomed two new oral protease inhibitors in May 2011 (SPN 6/11, p. 8), Victrelis (boceprevir) and Incivek (telaprevir). The drugs, however, were not approved as stand-alone therapies but rather adjunctive treatments to the existing regimen of pegylated interferon and ribavirin, which essentially doubled costs to treat the condition. Hepatitis C had a 28.9% utilization increase and a 4.8% unit cost for a 33.7% overall trend.

And according to Sharon Frazee, Ph.D., vice president of Research & New Solutions at Express Scripts, costs in this class could “quadruple by 2015” due to multiple factors. For one, interferon-free treatments are expected in 2014. This is significant because “interferon creates a lot of side effects, including flu-like symptoms, which make it hard to stay on therapy,” she explains. So if someone with hepatitis C is doing fine now, many physicians are opting to wait for the new drugs and warehousing patients. And because these are novel drugs and look to be more effective than current therapies based on clinical trials, they “tend to be more expensive,” says Frazee. In addition, the Centers for Disease Control and Prevention now recommends that anyone born between 1945 and 1965 be tested for the virus (SPN 6/12, p. 5),

<table>
<thead>
<tr>
<th>Specialty Trend by Therapy Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components of Trend for the Top 10 Commercial Specialty Therapy Classes, Ranked by PMPY Spend, 2012</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Therapy Class</th>
<th>PMPY Spend</th>
<th>Utilization</th>
<th>Unit Cost</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflammatory Conditions</td>
<td>$50.62</td>
<td>9.0%</td>
<td>14.0%</td>
<td>23.0%</td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>$37.98</td>
<td>0.5%</td>
<td>17.3%</td>
<td>17.8%</td>
</tr>
<tr>
<td>Cancer</td>
<td>$31.98</td>
<td>3.4%</td>
<td>22.3%</td>
<td>25.8%</td>
</tr>
<tr>
<td>HIV</td>
<td>$20.78</td>
<td>-2.1%</td>
<td>11.1%</td>
<td>9.0%</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>$7.82</td>
<td>28.9%</td>
<td>4.8%</td>
<td>33.7%</td>
</tr>
<tr>
<td>Growth Deficiency</td>
<td>$7.41</td>
<td>1.7%</td>
<td>7.7%</td>
<td>9.5%</td>
</tr>
<tr>
<td>Anticoagulant</td>
<td>$6.74</td>
<td>1.7%</td>
<td>0.3%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Pulmonary Hypertension</td>
<td>$5.71</td>
<td>5.1%</td>
<td>6.2%</td>
<td>11.3%</td>
</tr>
<tr>
<td>Respiratory Conditions</td>
<td>$5.56</td>
<td>1.5%</td>
<td>25.7%</td>
<td>27.2%</td>
</tr>
<tr>
<td>Transplant</td>
<td>$4.92</td>
<td>2.2%</td>
<td>-6.9%</td>
<td>-4.7%</td>
</tr>
<tr>
<td>Other</td>
<td>$27.68</td>
<td>24.9%</td>
<td>43.7%</td>
<td>18.8%</td>
</tr>
<tr>
<td>TOTAL SPECIALTY</td>
<td>$207.19</td>
<td>-0.4%</td>
<td>18.7%</td>
<td>18.4%</td>
</tr>
</tbody>
</table>

PMPY = per-member per-year
which in theory will boost the number of people receiving treatment.

The respiratory conditions class — which includes illnesses such as cystic fibrosis, alpha 1 antitrypsin deficiency and asthma — came in with the highest unit cost increase, 25.7%, among the top 10 categories, boosted by drugs such as Xolair (omalizumab), Pulmozyme (dornase alfa) and TOBI Podhaler (tobramycin inhalation solution).

With a $20.78 PMPY spend, HIV was the No. 4 class. However, while it had a unit cost of 11.1%, its utilization actually dropped 2.1%, for an overall trend of 9.0%. “It’s not that the utilization is less, but that there are combination pills available now,” explains Frazee. So, for example, if someone had been taking three or four pills before but is now taking one, this would show up as less utilization. But with the combination therapies tending to be more expensive than older therapies, this boosted unit costs.

Looking ahead, HIV is a condition “to keep an eye on. It’s pretty much a chronic disease,” she says. And although the combination therapies are more expensive, they also are “easier to take,” which improves adherence — a critical aspect since “it’s important to take these drugs 90% to 95% of the time,” Frazee says.

These are only some of the classes that the PBM expects will drive a consistently high specialty trend over the next few years. Express Scripts is projecting that overall specialty trend for drugs in the pharmacy benefit will be 17.8% this year, rising to 19.6% in 2014 and then 18.4% in 2015.

More Cancer Drugs Are Expected

The pipeline has many specialty drugs for various cancers such as metastatic melanoma, renal cell carcinoma, breast and metastatic non-small cell lung cancer, says Frazee. And more drugs with companion diagnostics are expected. However, she says, don’t expect cancer to overtake inflammatory conditions and multiple sclerosis in the next few years as the top specialty condition in rankings such as this one. That’s because “inflammatory conditions and multiple sclerosis are treated almost entirely by drugs in the pharmacy benefit, while cancer has a lot of drugs on the medical side.”

Frazee contends that payers can “drop their specialty spend significantly” through better management of these drugs and members taking them. “They don’t need to wait for biosimilars; there are things to do now to manage cost and care.” Making sure that patients receive the “right care and right support” is important. Plans can “drive out waste” by making sure there is “no duplication of service” and that members receive care in the most appropriate site of administration.

Contact Frazee through Jennifer Luddy at jennifer_luddy@express-scripts.com.

340B Sees Neulasta Change

continued from p. 1

Vendor Program (PVP), and we understand that that PVP has already been in touch with Amgen about this issue.)”

Chris Hatwig, president of Apexus Inc., the government’s prime vendor for the 340B program, confirms to SPN that “We have had conversations with Amgen on this topic. We also engaged our hospital advisory council and shared their concerns with Amgen.”

SNHPA Cites Various ‘Burdens’

One problem with the restriction, says SNHPA, is that hospitals use split-billing software programs that “automatically load purchases made from wholesalers into their system. Purchases made from specialty distributors, however, often must be entered manually, increasing staff costs as well as the risk of noncompliance due to human error when entering the information.”

Second, “SNHPA has also been informed that the restriction will force entities to pay more for Neulasta because wholesalers normally sell the drug at a lower price than specialty distributors. One SNHPA member hospital reported that the restriction would cost the hospital approximately $200,000 annually.” In addition, “we understand that shipments will take longer under the proposed distribution model,” says the letter.

All of these examples are “burdens that the new distribution plan will impose on 340B hospitals, but not on non-340B hospitals.” Amgen’s plan, says the association, violates the HRSA prohibition against manufacturers imposing so-called “restrictive conditions” on transactions that could “discourage[e] entities from participating in the...program.”

“Amgen is fully compliant with all 340B Program requirements and is committed to serving the needs of uninsured and under-insured patients,” says Christine Regan, a spokesperson for Amgen. “Like several of Amgen’s specialty products, Neulasta has predominantly been distributed through a specialty channel, where we have seen a long history of customer satisfaction.”

Regan tells SPN that the change “does not impact the wholesale acquisition price (WAC) for Neulasta or the statutory discounts offered by Amgen to 340B entities. This distribution channel change is also anticipated to allow Amgen to more efficiently and accurately track and audit sales to the 340B entity segment.”

Dan Mendelson, CEO of Avalere Health LLC, says that this approach is a “clever way to…track and trace a product moving through the [distribution] pipeline…. What’s happening here is Amgen has figured out a way to track and monitor 340B use that makes some nervous.”
F. Randy Vogenberg, Ph.D., principal at the Institute for Integrated Healthcare, tells SPN that the manufacturer may be trying “to minimize lost revenue as well as maximize control over the supply chain for Neulasta.” With ASD Healthcare being a division of AmerisourceBergen, “net pricing is likely the same for 340B patients,” he says. “The issue is more likely about the non-340B patients that a hospital can sell to and make a larger margin.”

According to Vogenberg, “based on SNHPA legal counsel,” it would seem that Amgen could not take this route. “It is a test of the intent for sure and has never been done before like this successfully. My guess is that there will be significant pushback and political fallout on pharma for this approach.” He adds that “it does not make sense at face value to take this type of distribution approach even though there are problems with 340B” (see stories, p. 9 and p. 10).

However, says Mendelson, “I don’t see anything that would preclude them from doing this,” although he adds that he expects the effort “is going to be tested.”

**NEW FDA SPECIALTY APPROVALS**

♦ **May 14:** The FDA granted an additional approval to Tarceva (erlotinib) for the first-line treatment of metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations. The agency also approved a companion diagnostic, Roche Group’s cobas EGFR Mutation test, to help select appropriate candidates for the drug. The recommended dose of the tablet, which is marketed by Roche subsidiary Genentech and Astellas Pharma US, Inc., is 150 mg once daily until the disease progresses or the drug’s toxicity is unacceptable. The drug also is approved as a second or third line NSCLC treatment and for advanced pancreatic cancer. Visit www.tarceva.com.

♦ **May 15:** The FDA granted an additional approval to Simponi (golimumab) for the treatment of moderate to severe ulcerative colitis. The Janssen Biotech, Inc. injectable tumor necrosis factor inhibitor also is approved for rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis; its initial approval was in 2009. Dosing for the ulcerative colitis indication is a 200 mg subcutaneous injection initially, a 100 mg dose at week two and then 100 mg every four weeks. GoodRx shows a range of prices for five 0.5 ml syringes of 50 mg/0.5 ml starting at $12,531.20 with a coupon. Visit www.simponi.com.

♦ **May 15:** The FDA approved Bayer Pharmaceuticals’ Xofigo (radium Ra 223 dichloride) for the treatment of symptomatic metastatic castration-resistant prostate cancer that has spread to bones in men who have received medical or surgical therapy to lower testosterone. The injectable is the second drug for metastatic prostate cancer to gain FDA approval within the past year, following Xtandi’s (enzalutamide) August approval (SPN 9/12, p. 8). The agency gave the drug priority-review status and approved Xofigo more than three months before its action date. Visit http://xofigo-us.com.

♦ **May 29:** The FDA approved two GlaxoSmithKline drugs for the treatment of metastatic or unresectable melanoma that has specific gene mutations. The agency also approved a companion diagnostic, the THxID BRAF test, manufactured by bioMérieux of Grenoble, France, to determine whether patients have those mutations. Tafinlar (dabrafenib), a BRAF inhibitor, is for people whose tumors express the BRAF V600E gene mutation, and Mekinist, a MEK inhibitor, is for people whose tumors express the BRAF V600E or V600K gene mutation. The recommended dose of Tafinlar, which is available as 50 mg and 75 mg capsules, is 150 mg twice daily until the disease progresses or the drug is too toxic. The recommended dose of Mekinist, which is available as 0.5 mg, 1 mg and 2 mg tablets, is 2 mg once daily until the disease progresses or the drug is too toxic. Their approval follows the 2011 approvals of metastatic melanoma drugs Zelboraf (vemurafenib) and Yervoy (ipilimumab). The drugs will be available by the early third quarter of 2013. Visit www.tafinlar.com and www.mekinist.com.

♦ **June 5:** The FDA granted an additional approval to Revlimid (lenalidomide) for the treatment of mantle cell lymphoma that has relapsed or progressed after two prior therapies, including one with bortezomib. The capsule will be the first oral treatment for the condition, says manufacturer Celgene Corp. The recommended dose is 25 mg orally once daily on the first through 21st days of repeated 28-day cycles. The FDA also approved a new 20 mg strength capsule. Revlimid already has approval for the treatment of multiple myeloma and myelodysplastic syndromes. GoodRx.com shows a range of prices for 30 of the 25 mg capsules starting at $12,402.20 with a coupon. Visit www.revlimid.com.
According to Bill Sullivan, principal with Specialty Pharmacy Solutions LLC, “a manufacturer has the right to decide the channels through which its products are made available.” He points out that “manufacturers regularly set limits on which wholesalers they use and even which purchasers are eligible to purchase a product. Some specialty pharmacy products are limited to only one or a few specialty pharmacies...[and] others may require certification of the pharmacy demonstrating that they have the clinical competency to handle the product.”

**Issue Comes Down to Channel Access**

“On the other hand, my ‘general’ knowledge of the 340B program is clear,” continues Sullivan. A “product must be purchased directly by the qualified entity to qualify for the 340B price (even if the product is shipped to a pharmacy which, on behalf of the qualified entity, does the actual dispensing and patient support for a dispensing fee). The pharmacy may submit a bill on behalf of the qualified entity for reimbursement, but it is acting as a third-party billing company in that case. In short, the pharmacy never ‘owns’ the product outright.”

“So, the legal question is channel access,” concludes Sullivan, who terms the situation “quite fascinating.” He tells SPN that “Amgen has an army of lawyers that have probably been pouring over this for weeks, and I am confident that they feel that they have a case to be made in the courts, which is where this is very likely to end up.”

So why did Amgen choose to implement this policy for only Neulasta, a colony-stimulating factor that helps boost white blood cell counts in people undergoing cancer treatment who are at risk of infection due to a compromised immune system?

Amgen declined to respond to that question.

But Mendelson has some thoughts on the issue. “If you look at their other products, I think this makes sense because of its reach and the scope of its sales.” He points out that Neulasta is “broadly...deployed into the health care system,” as opposed to a drug such as epoetin, which is administered in “very specific settings” and largely to a Medicare-covered group of patients.

In terms of Neulasta’s 340B sales, “I’m not privy to the specifics,” says Mendelson, but he adds that he’d be curious to know whether there has been increased utilization in 340B sales of the drug.

Amgen did not respond to a question about whether there has been an increase in sales of Neulasta at 340B pricing.

However, the third edition of Magellan Pharmacy Solutions’ Medical Pharmacy & Oncology Trend Report, released in February, noted that recently some cancer drugs, including Neulasta, have “had material increases in portions of drug administered in the hospital, and this was a result of the cannibalization of office administration.” In 2009, 72% of Neulasta claims were from administration in a medical office, a percentage that fell to 68% in 2010 and then 67% in 2011. Conversely, the percent of claims from administration in a hospital rose from 24% in 2009 to 30% in 2010 and 31% in 2011. Claims from home infusion/specialty pharmacy provider administration fell from 2% in 2009 to 1% in 2011, while those for administration through other sites of service rose from 1% to 2%.

In addition, among the top 25 specialty drugs under the medical benefit, Neulasta was the No. 2 drug in 2011 across all sites of service, with an overall spend of $18.2 million per 1 million covered lives, an increase of 17% from the previous year.

Ultimately, says one industry expert who declines to be identified, “many companies are reconsidering what to do with the 340B program and pricing.” The source, who had not heard of Amgen’s approach, contends that “This has the potential for getting really nasty for Amgen and pharma, but someone had to stick their head up to see what’s going to happen.”

View the SNHPA letter to Amgen at http://tinyurl.com/lrq32hx. Contact Mendelson at (202) 207-1310, Sullivan at wsullivan@specialtyrxsolutions.com and Vogenberg at frandy627@comcast.net. ♦

**Oversight of 340B Program, Its Intentions Are Questioned**

The 340B program has been in the news recently as it has come under fire from various sectors that are questioning oversight of the program and whether it is fulfilling its purpose.

“I think what’s happening is that it’s very clear that the 340B program is expanding past its original mandate” because it’s being “offered to people who are not vulnerable, low-income individuals,” Dan Mendelson, CEO of Avalere Health LLC, says.

A September 2011 Government Accountability Office report (GAO-11-836), Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, explained that “Covered entities are permitted to use drugs purchased at the 340B price for all individuals who meet the definition of a patient, whether or not they are low income, uninsured, or underinsured.” However, it says that “the 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater, in part because they serve both 340B and non-340B eligible patients.” The GAO report noted that from 2001 to 2011, the number of covered entities in the 340B program rose from 8,605 to 16,572.

continued
**Practice Is ‘Contrary’ to Program’s Purpose**

In a March 27 letter to Mary K. Wakefield, administrator of the Health Resources and Services Administration, questioning the HRSA’s oversight of the program, Sen. Charles Grassley (R-Iowa) pointed out that “because hospitals who participate in the 340B program have broad discretion as to whom to sell their deeply discounted 340B drugs, hospitals can elect to sell all of their 340B drugs to only fully insured patients while not passing any of the deeply discounted prices to the most vulnerable, the uninsured. This is contrary to the purpose of the 340B program since much of the benefit of the discounted drugs flows to the covered entity rather than to the vulnerable patients that the program was designed to help.”

The GAO report said that “About half of the covered entities we interviewed reported that they generated 340B program revenue that exceeded drug-related costs — the costs of purchasing and dispensing a drug.”

**Grassley Cited ‘Upselling’ of Drugs**

In his letter, Grassley included data from three North Carolina hospitals on revenue generated by the 340B program and a breakdown of their 340B patients. “These numbers paint a very stark picture of how hospitals are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their spread,” he noted. “For example, only 5 percent of the patients who received discounted drugs under Duke University Hospital’s 340B program were uninsured. The vast majority of the remaining patients who received discounted drugs paid Duke University Hospital full price through private insurance.” Grassley called on HRSA to get “an understanding of where 340B dollars are being reinvested to ensure that covered entities are fulfilling their mission.”

According to a report released in February on the program, “An analysis performed by Avalere Health estimated that under the 340B program, covered entities currently receive annual discounts of $2 billion on brand-name drugs alone.” Moreover, said the report, which was from the Biotechnology Industry Organization, the Community Oncology Alliance, the National Community Pharmacists Association, National Patient Advocate Foundation, the Pharmaceutical Care Management Association and the Pharmaceutical Research and Manufacturers of America, “rapid 340B growth is projected to continue in future years: the Berkeley Research Group, for instance, estimates that 340B drug purchases will double from $6 billion annually in 2010 to $12 billion annually by 2016.”

According to Mendelson, “the dramatic increases in 340B sales go way beyond what would be expected given demographic trends.”

When the 340B program gains financially, though, do those benefits translate into negative impacts on health insurers and patients alike?

An article in the May 15 issue of the *Journal of the American Medical Association* asserts that the 340B program “may be having paradoxical effects on the costs of patient care, in particular for patients with cancer, for 3 reasons” (see story, below).

In a May 8 memorandum, Grassley says that “certain hospitals appear to be making sizeable profits from the program at the expense of Medicare, Medicaid and private health insurance.”

**Opinions Are Opposed on 340B Program’s Impact on Costs of Care**

The intent of the 340B federal drug program and whether that goal is being met have become hot topics recently (see story, p. 1). And a recent article in the *Journal of the American Medical Association (JAMA)* may add another layer of discussion to the overall impact of the program itself.

In the May 15 issue of *JAMA*, Rena M. Conti, Ph.D., an assistant professor of hematology/oncology in the pediatrics department at the University of Chicago, and Peter Bach, M.D., director of the Center for Health Policy and Outcomes at Memorial Sloan-Kettering Cancer Center, say that regardless of whether the program is “fair” to hospitals or manufacturers, “the 340B program drives down
the acquisition costs of drugs but not their reimbursement. Therefore, it may be having paradoxical effects on the costs of patient care, in particular for patients with cancer.”

According to the authors, typical 340B discounts on drugs administered by physicians in the outpatient setting and oral drugs dispensed by contract pharmacies range from 30% to 50% of the list price of a drug. When patients and health plans pay list price for drugs obtained through the 340B program, hospitals, practices and contract pharmacies can retain whatever profit is made from that sale, explain the authors. “A recent report suggests that a single practicing oncologist can generate about $1 million in profits for a hospital by obtaining drugs at 340B-discounted prices and using them to treat well-insured patients,” they note.

Conti and Bach cite three reasons for the program driving up cost of care:

1) The profits physicians receive from administering drugs influence their prescribing behavior. “For oncologists practicing in 340B-affiliated outpatient clinics, prescribing may shift toward more expensive drugs because profit margins will in general be larger,” they say.

2) The program creates a disparity in profits between what 340B and non-340B entities “are able to obtain from the care of well-insured patients with cancer.” The discrepancy, contend the authors, “is likely underlying trends toward consolidation and affiliations between community cancer clinics and 340B-eligible hospitals, which in turn may lead to shifts in care from community practices to infusion suites in hospitals. “These trends will tend to increase total spending,” say Conti and Bach. “Cancer care delivered in a hospital-based outpatient infusion suite is typically more expensive than that delivered in a physician’s community-based office. Moreover, market consolidation may increase private insurance contracted rates and thus private insurance premiums and other patient costs.”

3) “Drug manufacturers will likely seek to increase list prices even further to offset revenue losses incurred as a larger number of drug sales become eligible for 340B discounts (and thus fewer drugs are sold at full price).” The authors point out that “an analogous response was seen when Congress enacted mandatory rebates for the purchase of drugs for Medicaid-eligible patients.”

Ultimately, conclude the authors, drug manufacturers now bear “most of the costs of the program;…the financial benefits of the 340B discounts are accruing almost entirely to hospitals, clinics, and physicians; and patients’ out-of-pocket costs and total cost of care are being increased.”

However, Conti and Bach say there are “a number of available options” for reconfiguring the program. One approach is that drugs obtained at 340B prices would be given only to poor and uninsured patients. The authors say this is a similar approach to that of Medicaid “and probably most consistent with the original intent of the program.” Manufacturers would have to provide fewer discounted drugs, which in turn could help keep down the costs of new drugs. Hospitals and providers affiliated with them, however, would lose these profits. “Patients and insurers would directly benefit through the elimination of 340B-created incentives to overprescribe expensive drugs and indirectly benefit through a slowdown in consolidation of hospitals with community-based clinical centers and physicians.”

Another option would be for 340B hospitals and providers “to pass on their savings from drug purchases to patients and their insurance providers, including Medicare. This approach would reduce the incentive for overutilization of high-priced drugs and lessen (but not eliminate) competition between outpatient cancer centers for well-insured patients.”

340B Is ‘Essential Federal Program’

Chris Hatwig, president of Apexus Inc., the government’s prime vendor for the 340B program, says that “Without the 340B Drug Pricing Program, Apexus believes many of the nation’s uninsured and underinsured would not have adequate access to affordable medications, and the result would be additional financial burden on the nation’s safety net providers and American tax payers. Specifically, we firmly believe the 340B program is an essential federal program that lowers the costs of patient care. It is important to note that the 340B program targets a narrow and carefully defined group of safety-net providers.”

In addition, Hatwig tells SPN, “We also wanted to clarify a specific point in the JAMA Viewpoint article. In footnote 3 of the article, the authors cited Apexus as the source of a growth projection statistic. Unfortunately, this must be a result of a misunderstanding because this is an inaccurate attribution. We do not make projections such as these.”

Jeff Davis, associate counsel for Safety Net Hospitals for Pharmaceutical Access, says that SNHPA has just submitted a letter to the editor in response to the article. The association says there was “no evidence cited” by the authors for their claims. On the contrary, he says, “there is strong evidence showing how great of a benefit 340B is to vulnerable patients….This is a really important program that safety net providers are using.”

One factual inaccuracy Davis cites is the contention that 340B drugs cannot be used for Medicaid patients. In fact, he says, many providers in the program do use the program for their Medicaid patients and save state and federal government money.
In addition, SNHPA refutes the “idea that 340B is having a big negative impact in the market,” says Davis, who notes that the program represents “2% of total drug spending in the country. This is such a small footprint, so how could it have such a big negative impact?”

Hatwig agrees. “Drugs purchased at the 340B price are estimated to comprise less than 2% to 2.5% of sales of the entire drug market,” he tells SPN. “Due to its small participant base, the 340B program could not possibly increase the costs of patient care.”

One point that all stakeholders agree on, including Sen. Charles Grassley (R-Iowa), who has reached out to the Health Resources and Services Administration — the HHHS agency that administers and oversees the 340B program — (see story, p. 9), is that oversight of the program could use improvement.

According to Hatwig, “Because we believe that the 340B program should be monitored and operated under proper guidance, we actively support HRSA’s current integrity initiatives to improve program oversight. This is why Apexus has supported the development of the 340B University and provided compliance training for all 340B stakeholders since late 2010.”


**NEWS BRIEFS**

♦ **The New York attorney general’s office asked 15 health plans based in that state to allow members to get their specialty drugs at retail pharmacies instead of through mandatory mail order.** Attorney General Eric Schneiderman (D) negotiated “Specialty Prescription Drug Fulfillment Hardship Exception Criteria” with Empire BlueCross BlueShield earlier this year that allow those who qualify to be exempt from the requirement, and he is urging these 15 plans to adopt the same criteria. His office “has received dozens of hardship complaints” about mandatory mail-order requirements, according to a press release. Empire, a subsidiary of WellPoint, Inc., last year said it would change its coverage policies to require enrollees to purchase drugs on its “Exclusive Specialty Drug List” through CuraScript, its specialty mail-order pharmacy. Schneiderman said the coverage change prompted complaints about “compromised privacy, delivery challenges and interference in physician changes in drug dosing schedules.” Under the Empire agreement, retail pharmacies that dispense drugs on the insurer’s Exclusive Specialty Drug List must agree to provide “a 24-hour nurse or pharmacist hotline, toll-free access to patient care advocates, and disease management programs.” A settlement was recently reached in California over a lawsuit brought by consumer advocacy group Consumer Watchdog against Anthem Blue Cross over mandatory mail-order for HIV/AIDS drugs. That decision allows members receiving HIV/AIDS therapies to opt out permanently from that requirement (see story, p. 5). Contact the attorney general office’s health care bureau helpline at Attorney General’s Health Care Bureau Helpline at (800) 428-9071.

♦ **McKesson Specialty Health launched iKnowMed Generation 2, a Web-based electronic health record (EHR).** The company says the EHR was developed through collaboration with oncologists. Its goal is to help physicians at community cancer centers and their staff “deliver high-quality care while improving patient safety and optimizing practice workflow.” For more information about the next-generation product, email msh.providers@mckesson.com.

♦ **The Association of Community Cancer Centers named five ACCC-member cancer programs as Community Resource Centers (CRCs) for its Improving Quality Care in Small-Population Cancers initiative.** The project will focus on chronic myeloid leukemia, multiple myeloma and acute promyelocytic leukemia, low-incidence cancers that affect fewer than 40,000 patients in the U.S. annually. The CRCs will be “experts in residence” for ACCC members. Learn more at www.accc-cancer.org/SPC.

♦ **PEOPLE ON THE MOVE:** Armada Health Care named Mike Baldzicki executive vice president of industry relations and advocacy. He was previously vice president of strategic contracting and payer relations at Axelacare Health Solutions….Humana Inc. named Roy Beveridge, M.D., senior vice president and chief medical officer effective June 17. He is chief medical officer for McKesson Specialty Health….The Pharmaceutical Research and Manufacturers of America promoted Lori Reilly to executive vice president of policy and research. She was previously vice president of policy and research, and she succeeds Rick Smith, who is retiring.
If You Don’t Already Subscribe to the Newsletter, Here Are Three Easy Ways to Sign Up:

1. Return to any Web page that linked you to this issue

2. Go to the MarketPlace at www.AISHealth.com and click on “Newsletters.”

3. Call Customer Service at 800-521-4323

If you are a subscriber and want to provide regular access to the newsletter — and other subscriber-only resources at AISHealth.com — to others in your organization:

Call Customer Service at 800-521-4323 to discuss AIS’s very reasonable rates for your on-site distribution of each issue. (Please don’t forward these PDF editions without prior authorization from AIS, since strict copyright restrictions apply.)