Walgreens, Prime Are Teaming Up on New Model to Improve Outcomes, Efficiencies

Last month two industry stakeholders unveiled a novel industry model that could usher in a new type of pharmacy arrangement. Walgreens Boots Alliance, Inc. and Prime Therapeutics LLC on Aug. 29 said they will combine their central specialty pharmacy and mail service businesses into a new organization. In addition, per a “long-term” agreement, Walgreens will be the “core participant” in Prime’s preferred national network as of Jan. 1. The deal, the companies maintain, aligns pharmacy, PBM and health plan stakeholders and is aimed at coordinating health care, boosting patient outcomes and providing cost efficiencies. One industry expert predicts the arrangement could restructure the pharmacy and PBM industries.

Prime has 14 Blues plan owner clients and about 22 million members. In 2015, it managed $22.5 billion in drug spend, with a projected $25 billion for this year. Last year it filed 337 million claims, with 329 million estimated for this year. For fiscal 2015, Walgreens filled about 894 million prescriptions, including immunizations. The company
has 8,173 stores in all 50 states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands. Walgreens says it interacts with 8 million customers daily, both in its stores and online.

Starting Jan. 1, in Prime’s preferred national network, “Walgreens would be an important anchor,” but it will not be the exclusive participant, clarifies Jim DuCharme, Prime president and CEO. Others include “independent pharmacies, retail pharmacy chains, grocery offerings and mass merchandise offerings” that vary from region to region, he says. Participants “know what kind of cost savings and competitive pricing levels they need to get to….That’s the price of admission.”

The joint venture also should “be able to come online Jan. 1,” but “it could be sooner due to a contractual agreement,” says DuCharme. The deal, he explains, “needs to be regulatorily approved. As soon as the regulatory hurdle is cleared, we could start to transfer clients.” The new company, he says, should be “fully formed and final within the first quarter of 2017.”

“The combined company will leverage existing central specialty and mail service assets from both Prime and Walgreens, to deliver competitive pricing, and operational and purchasing efficiencies for central specialty and mail services that are on par with industry leaders,” says Walgreens spokesperson Jim Cohn.

DuCharme says that both Walgreens and Prime have limited- and sole-distribution deals for specialty drugs, some of which one company had that the other didn’t. The new offering “dramatically improves our overall coverage of limited-distribution drugs,” he says. “Prime did have some [agreements] that Walgreens didn’t have, but Walgreens had considerably more. Jointly we have almost everything,” and there are only “a few drugs missing….It’s a material uplift for both sides, in particular our Blue Cross Blue Shield plans. This is one of the bigger gets out of the joint venture.”

According to DuCharme, the entity will be able to “procure pharmaceuticals using our combined leverage and clout,” which is considerable since Walgreens is “one of the largest purchasers in the U.S., if not the world.” In addition, he points to the “scale and capacity this pooling of assets will affect,” including “shipping efficiencies” due to the geography of locations.

And if Walgreens’ planned purchase of Rite Aid Corp. is approved (see box, p. 3), that will only boost the current number. The acquisition would impact the Prime-Walgreens agreement “only in incredibly positive ways,” DuCharme asserts. First, the additional stores would make Walgreens the largest retail pharmacy — “35% to 50% larger than the next-largest” one. And second, “the placement of stores by geography” would help by “filling network gaps [benefiting both] current clients and prospective clients,” he says.

**Name, Structure Are Being Finalized**

The Walgreens-Prime joint venture “will absolutely have its own name and identity,” says DuCharme. Options for the name are being discussed, but it has not been finalized, although that will happen “in the near future.” He points out that because the agreement still must be approved through the Hart-Scott-Rodino Act process, “we don’t want to be presumptuous.” He says he expects this process to take 30 to 60 days.

The company’s structure still is being finalized as well. According to Cohn, “Walgreens has five central specialty locations and a mail service facility,” and Prime spokesperson Karen Lyons says that “Prime has two home delivery pharmacies and one specialty pharmacy.” However, she tells SPN, “which assets will fold into the combined company is currently being determined by the transition team and will be announced at a later date. The formation of the combined company is undergoing regulatory approval so it’s premature to discuss these specifics until more is known and the agreement is approved.”

Asked if the agreement was for a set period of time, DuCharme says that the “partners agreed that if this is truly going to be a strategic alliance….it had to be viewed...
as perpetual...versus [having] an arbitrary finish line.”
There has to be an “incentive to make a marriage nobody wants to get out of.”

DuCharme declines to give any details, such as annual revenues or scripts processed, behind the combination of the companies’ central specialty pharmacy and mail service businesses, but he does say that the new company will result in “a geometric increase in Prime’s scale and in Prime’s capacity to deliver high volumes of script fulfillment.” This, in turn, will “position us for more large-scale customers and clients.” Walgreens doesn’t break out these numbers, says Cohn.

“The company will be a Walgreens subsidiary, governed by a separate board of directors and executive team, which will be selected by Walgreens and Prime,” Cohn tells SPN. DuCharme says that “Walgreens will have a slightly higher ownership” stake than Prime in the new company, which is “going to be an independent, stand-alone” company that will “have its own...financial responsibilities and business objectives.”

As far as the motivation behind forming this kind of arrangement as opposed to a different relationship structure, “One of the differences is that through this alliance, together it aligns pharmacy, PBM and health plans in a new model, that’s aimed at coordinating patient care and improving outcomes,” maintains Cohn.

“If I had to boil it down, the magic in this is it represents a complete alignment of strategic objectives and intentions,” DuCharme says. Walgreens has “little to no interest in owning or controlling a PBM” — it exited the space in 2011 — “but it was very open to partnering with a PBM in a special way to provide value. On Prime’s side, it was created in part because the Blues plans wanted a PBM to be truly transparent and singly focused on the total cost of care” and to be able to have some control over it.

Walgreens Earlier This Year Expressed Interest in Partnerships

Many industry experts are hailing the new model that Walgreens Boots Alliance, Inc. and Prime Therapeutics LLC recently unveiled. But Walgreens CEO Stefano Pessina actually had hinted at such an arrangement during an earnings call in January when asked about his company’s planned acquisition of Rite Aid Corp.

Last year Walgreens agreed to buy Rite Aid for $17.2 billion; the transaction is awaiting approval. If that’s granted, the deal would include PBM EnvisionRx, which Rite Aid acquired earlier in 2015 when it purchased Envision Pharmaceutical Services for $2 billion (SPN 2/15, p. 11). Among EnvisionRx’s offerings are Orchard Pharmaceutical Services, which provides mail-order and specialty pharmacy services, and Design Rx, LLC, which provides fertility services. In a Drug Channels blog posted the morning the Envision deal was announced, Adam Fein, Ph.D., president of Pembroke Consulting, Inc., maintained that “Rite Aid now has a legitimate specialty growth platform.”

In addition, he said, EnvisionRx “mail and specialty pharmacies currently buy drugs from AmerisourceBergen. Once the deal closes, EnvisionRx will purchase drugs via Rite Aid’s partnership with McKesson.” But that stands to change if Walgreens’ purchase goes through, since the company has a distribution deal that includes specialty drugs with AmerisourceBergen that recently was extended through 2026 (SPN 4/13, p. 1).

Since the Rite Aid acquisition was unveiled, investors and the health care industry at large have been wondering if Walgreens would make an additional PBM acquisition. When asked about that possibility during a Jan. 7 conference call to discuss fiscal-year 2016 first-quarter earnings, Pessina said, “I am really convinced that vertical integration is a necessity for the market….It is part of what we have to do…to control the costs in the health care arena. Any kind of vertical integration is good. It depends on the opportunities that we will have. It depends on the availability of partners.”

He added that there are multiple ways to do vertical integration, including the ideal path of a merger or even a “very strong commercial agreement, and very strong partnerships. As we have said many times, we are always open even for a partnership.” When asked to clarify whether that meant a strong commercial partnership with a PBM or more than one PBM, Pessina reminded analysts that the company has done two large deals in less than one year and needs time to “organize” to figure out “what we can do, what we can digest, what we can afford.”

Evercore ISI in a Jan. 6 research note suggested that Walgreens was more likely to pursue a “creative structure” with a PBM or managed care organization than additional “large-scale” mergers and acquisitions.

Visit the Drug Channels blog at www.drugchannels.net.
Walgreens, says Cohn, “had an opportunity to form this strategic alliance, and it’s one that grew out of conversations with Prime over a period of time. It’s one that makes sense for our business, and that can benefit patients and payers. We’re continuing to work with all of our PBM partners to bring new drug delivery models to the marketplace.”

According to DuCharme, the process of how the companies came together to form the joint venture is “one of the cooler parts of the whole story.” Walgreens, he says, was “a valued retail pharmacy partner, not dissimilar to other national retail pharmacies” that Prime worked with. But there was a “serendipitous moment” he had during a discussion with Walgreens CEO Stefano.

**Survey: Insurance for Most Workers at Large Firms Had Specialty Coverage**

Almost all employees with employer-provided health insurance work for a company whose largest plan covers prescription drugs, according to responses featured in the 18th annual Kaiser Family Foundation/Health Research and Educational Trust Employer Health Benefits Survey, released Sept. 14. Among covered workers at large firms — defined as those with 200 or more employees — with drug coverage, 98% were in a plan that provided specialty drug coverage. These companies use a variety of management strategies to contain the cost of specialty drugs, including mail order, which 89% of respondents used; prior authorization, 82%; and utilization management programs, 70% (see chart below).

The findings were gathered through telephone interviews with employee benefit managers from 1,933 firms with three or more employees from January through June 2016.

Among workers in large firms who were enrolled in a plan that covered specialty drugs, 43% had a separate coverage tier for them. Among these workers, 43% had a plan requiring a copayment for specialty drugs, while 46% had coinsurance. The average coinsurance for these workers was 26%, and 78% had a cost-sharing structure with a cap on how much they had to pay.

Contact Craig Palosky at the Kaiser Family Foundation at cpalosky@kff.org. View the survey at http://kff.org.

**Among Large Firms Whose Plan with the Largest Enrollment Covers Specialty Drugs, Percentage of Firms Which Use the Following Strategies to Contain Specialty Drug Cost, 2016**

<table>
<thead>
<tr>
<th>Strategy</th>
<th>All Large Firms (200 or More Workers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialty drug carve out</td>
<td>38%</td>
</tr>
<tr>
<td>Specialty pharmacy dispensing program</td>
<td>28%</td>
</tr>
<tr>
<td>Stop Therapies</td>
<td>68%</td>
</tr>
<tr>
<td>Tight limits on the number of units administered at a single time</td>
<td>61%</td>
</tr>
<tr>
<td>Utilization Management Programs</td>
<td>70%</td>
</tr>
<tr>
<td>Prior Authorization</td>
<td>82%</td>
</tr>
<tr>
<td>Mail Order</td>
<td>89%</td>
</tr>
</tbody>
</table>

**NOTES:** Specialty drugs such as biologics may be used to treat chronic conditions and often require special handling and administration. 98% of covered workers at large firms are enrolled in a plan that covers specialty drugs. Step therapies require enrollees to try alternatives before specialty drugs are covered. Utilization management programs review the discharges, care settings, and effectiveness of drugs.

**SOURCE:** Kaiser/HRET Survey of Employer Sponsored Health Benefits, 2016.
Pessina about “why couldn’t there be more transparency in the U.S. prescription benefit space, and why couldn’t there be deeper integration” among industry stakeholders? That initial dialogue “caused us to further that conversation over a series of months.” When Prime’s board of directors began “exploring strategic options for controlling drug costs,” what had been simply personal, creative discussions between the two CEOs turned into “more concrete conversations” between the companies themselves.

The deal does not involve Prime’s PBM business, DuCharme tells SPN. Prime, he says, will “retain 100% control over the governance of the PBM operation that the Blues owners have formed.” Prime “continues to persist, to thrive,” he says, and it is focused on its mission “to be the PBM of choice for Blue Cross and Blue Shield plans, to be the only PBM focused on the total cost of care management as opposed to earnings.” It is focused on making sure members have access to the “medication they need to get better and feel well.”

“With the combined purchasing scale, this should help Prime be more competitive in the marketplace and creates a new platform for Walgreens Specialty Pharmacy to be disruptive in the payer landscape,” maintains Stephen Cichy, founder and managing director of Monarch Specialty Group, LLC.

Model Could ‘Reshape’ Industries

In a Sept. 7 entry on the Drug Channels blog, Adam Fein, Ph.D., president of Pembroke Consulting, Inc., called the agreement a “novel union” and maintained that “if executed properly, it will be a best-of-breed business model that could reshape the PBM and pharmacy industries. For manufacturers, organized customer management just got even more complicated. The new business could also pose a serious challenge to pure-play PBMs that lack a health insurer partner or an economically-aligned retail dispensing channel.”

“This is simultaneously interesting and troubling news,” maintains Elan Rubinstein Pharm.D., principal at EB Rubinstein Associates. “Overall I really like it and think it will be a great success. It is interesting because it combines the successful Prime with Walgreens Specialty, which increases specialty volume and market power, and brings Prime’s Blues owners into a new grand relationship. Together these will constitute a direct challenge to CVS Caremark, while differentiating from Express Scripts and Diplomat, which do not have owned community pharmacies.”

However, he continues, “It’s troubling because it is a tacit acknowledgment that Walgreens Specialty — the OptionCare acquisition [in 2007] — has not worked out. But that is not so bad because the experience gave Walgreens time to learn about and develop ways to integrate specialty pharmacy. All in all a great business construct.”

Contact Cichy at scichy@monarchsp.com, Cohn at jim.cohn@walgreens.com, DuCharme through Lyons at klyons@primetherapeutics.com and Rubinstein at elan.b.rubinstein@gmail.com. Visit the Drug Channels blog at www.drugchannels.net. ✦

Court Ruling Allows for Oct. 3 Launch of Biosimilar Remicade

Six months after the FDA approved the second biosimilar, that drug now is poised to launch. On April 5, the FDA approved Celltrion, Inc.’s biosimilar Inflectra (infliximab-dyyb). The infusible monoclonal antibody is a biosimilar version of Janssen Biotech, Inc.’s Remicade (infliximab), which received its initial FDA approval in 1998. The drug had been held up in patent litigation, but last month, a U.S. district court gave the launch a green light, ruling it could come onto the market no sooner than Oct. 3. In terms of health care system savings, a biosimilar Remicade is likely to be much more significant than the first biosimilar on the U.S. market, Zarxio (filgrastim-sndz), reference drug Neupogen (filgrastim), as inflammatory conditions routinely rank at the top of specialty drug spend categories for payers — and increased costs and utilization for this class of drugs show no sign of slowing (see story, p. 1).

The FDA approved Inflectra to treat moderately to severely active Crohn’s disease in adults and children, moderately to severely active ulcerative colitis in adults, moderately to severely active rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and chronic severe plaque psoriasis. Those are the same indications that Remicade has, except the reference drug also has approval for moderately to severely active ulcerative colitis in pediatric patients. For this indication, Janssen has orphan drug marketing exclusivity until 2018.

Express Scripts Holding Co. has estimated that biosimilar versions of Neupogen and Remicade could bring about a combined $22.7 billion in savings over their first decade on the U.S. market (SPN 12/14, p. 1). Biosimilar Neupogen is projected to make up $5.7 billion of that total, with biosimilar Remicade responsible for $17 billion. The estimates assume a 30% discount in price for the bio-

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founder of and managing director at Monarch Specialty

According to this year’s Medical Pharmacy Trend Report from Magellan Rx Management, Remicade ranked No. 1 among commercial payers’ top 25 medical benefit drugs by allowed amount per member per month, annual cost per patient and average sales price/average wholesale price trends for 2013-2014. It was No. 5 among Medicare medical benefit drugs.

In August, with respect to a patent infringement lawsuit (No. 1:15-cv-10698-MLW) filed by Janssen against Inflectra manufacturer Celltrion Healthcare Co., Ltd. and marketing partner Hospira, Inc. — which was acquired by Pfizer Inc. in September 2015 — the U.S. District Court for the District of Massachusetts denied a Janssen request for a preliminary injunction preventing the companies from selling the biosimilar. As part of the voluntary dismissal, the defendants agreed not to sell Inflectra before Oct. 3.

The day after the ruling, on Aug. 19, The Korea Times reported that Celltrion, which is headquartered in Incheon, South Korea, shipped the first batch of Inflectra to the United States.

The drug is approved for use in more than 50 countries, and it has been available in Europe since 2013, where it is known as Remsima.

Asked if payers have been reviewing the drug since its April approval in order to have management strategies in place at launch, Ritu Malhotra, senior vice president of pharmacy benefits consulting for Pharmaceutical Strategies Group, says, “I’m not sure if payers are looking at it, but we are looking at it.”

“I’d expect that most payers will have already addressed the pending launch of Inflectra through their P&T [i.e., pharmacy and therapeutics] committee process, including coverage review,” says Stephen Cichy, founder of and managing director at Monarch Specialty Group, LLC. “Inflectra was not approved with interchangeability designation, which means that pharmacies cannot substitute the biosimilar in a prescription written for the original drug. But payers will have the ability to give the biosimilar agent a preferred position in their formularies or refuse to cover the original product at all.”

**Second Biosimilar Is Hot on Pfizer’s Heels**

With Inflectra, “It’s fairly significant not only that the patent was not upheld, but also that someone is at their heels,” says an industry expert who declines to be identified. That’s in reference to Samsung Bioepis Co., Ltd., whose application for its biosimilar Remicade has been accepted for review by the FDA. The source says that the action date for the product, known as Flixabi in the European Union, is Jan. 17, 2017. Merck & Co. would handle the marketing of the Samsung drug in the U.S.

Even if the FDA approves the drug in January, though, it seems likely that Samsung and Merck will need to give 180 days’ notice to Janssen of their intent to market the drug. Two different court rulings have said that regardless of whether a biosimilar manufacturer participates in the so-called “patent dance” outlined in the Biologics Price Competition and Innovation Act of 2009, the companies still must wait until the FDA approves the biosimilar to notify the reference drug manufacturer of their intent to market the biosimilar, essentially giving the reference drug another six months of exclusivity (SPN 7/16, p. 11; 8/15, p. 1).

Requiring that notification from all biosimilar manufacturers upon FDA approval “was a surprise to a lot of people,” says the source. Still, “the assumption is even if Flixabi were approved in January,” it would be another 180 days before it could launch.

Inflectra should get a boost from Pfizer, a company traditionally “very experienced in marketing,” says the source, who assumes biosimilars will be treated for marketing purposes as brand drugs rather than generics. “I anticipate a fairly aggressive launch compared with” Zarxio, in that Sandoz is a traditional generic, not a brand, company. Pfizer is “very well regarded in terms of commercialization,” maintains the source.

When asked if Pfizer plans to launch Inflectra Oct. 3, as well as what its sales and marketing strategies and pricing intentions are for the drug, Rachel Hooper, a spokesperson for the manufacturer, tells SPN, “As the leading global biosimilars company, Pfizer is working to expand access to these important medicines. We are committed to bringing biosimilars to patients in the U.S. as quickly as possible, and are continuing with the preparation of our launch plans for Inflectra for 2016.”

When the drug was approved earlier this year, Hooper told SPN that “We cannot comment on our
future development and commercialization strategies for Inflectra at this time. Each biosimilar molecule has specific drivers that determine market price. The overall cost savings and generally positive reception of Inflectra in other markets to date is consistent with our belief that biosimilars can be an important and a welcome option for patients, prescribers and payers.”

The SPN source has not heard what Inflectra’s price will be but points out that it’s “launching into a changing world” that now includes indication-based pricing (see story, p. 1). “There’s an awful lot of room for another model,” including “the opportunity for different prices for different indications.”

Neither the unidentified source nor Malhotra are aware of any additional rebates or price concessions — or, conversely, price increases before facing competition — that Janssen has put in place for Remicade leading up to the potential impending launch of Inflectra.

In response to questions around Remicade pricing, Janssen spokesperson Linda Davis tells SPN that “Patients are our first priority. Our approach to pricing our medicines builds on a long history of caring for patients and a commitment to discovering and developing innovative medicines that transform the lives of patients with serious disease.” She points out that 2.4 million people worldwide have taken Remicade since 1998.

According to Davis, “The list price of Remicade has not increased since April 2016. However, we do take moderate price increases from time to time, generally below our competitors.”

In addition, she says, “It is important to note that the infliximab biosimilar is not approved for interchangeability, which is a higher FDA standard. To be deemed interchangeable, a biosimilar must demonstrate it can be expected to produce the same clinical result as the innovator product in any given patient, and prove that the risk of alternating or switching between the products (in terms of safety or diminished efficacy) is no greater than the risk of using the innovator product without alternating or switching.

“We are committed to ensuring patients and healthcare professionals continue to have easy and affordable access to Remicade through a variety of patient support programs. When a biosimilar comes to market, we will compete with it as we would any competitor. We’re confident Remicade will remain an important treatment option.”

Malhotra tells SPN that “I heard they [i.e., rebates or price concessions] were going to be inevitable. As it was, they were starting to lose market share” due to payer “programs targeting overutilization and inappropriate dosing.”

And with Janssen already having experience with biosimilar competition in Europe, the company likely “learned a lot…that must be impacting its approach here,” says the unidentified source. “Europe is different from the U.S., but not that different.”

Contact Cichy at scichy@monarchsp.com and Malhotra via Ron Trujillo at Halldin Public Relations at ron@halldinpr.com.

**NEW FDA SPECIALTY APPROVALS**

- **August 30:** The FDA approved Sandoz Inc.’s Erelzi (etanercept-szszs) for the treatment of moderate to severe rheumatoid arthritis, moderate to severe plaque psoriasis, psoriatic arthritis, ankylosing spondylitis and moderate to severe polyarticular juvenile idiopathic arthritis. The injectable is a biosimilar of Amgen Inc.’s Enbrel (etanercept), which the FDA first approved in 1998; Erelzi was approved for all of Enbrel’s indications. Website GoodRx lists the price of four 50 mg autoinjectors of Enbrel as more than $4,000. It’s unclear when Erelzi will launch, as it is embroiled in litigation (see story, p. 9). Visit www.erelzi.com.

- **August 31:** The FDA granted an additional indication to Arzerra (ofatumumab) in combination with fludarabine and cyclophosphamide for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL). The FDA has approved four CLL indications for the Novartis Pharmaceuticals Corp. and Genmab A/S infusible, which initially was given accelerated approval in October 2009 (SPN 11/09, p. 8). According to data from Memorial Sloan Kettering, Arzerra’s monthly price in 2013 was $14,196. Visit www.arzerra.com.

- **September 1:** The FDA gave accelerated approval to Blincyto (blinatumomab) for the treatment of pediatric patients with Philadelphia chromosome-negative (Ph-) relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). The FDA initially gave accelerated approval to the Amgen Inc. infusible in December 2014 to treat adults with Ph- relapsed or refractory B-cell precursor ALL (SPN 12/14, p. 6). Its price at launch was $178,000 per year. Visit www.blincyto.com.
CMS Proposes Including Drug Data in Exchange Risk Adjustment

Starting in 2018, prescription drug utilization data could be used to improve the predictive ability of the public health insurance exchanges’ risk adjustment program, CMS said in its proposed Notice of Benefit and Payment Parameters, which outlines payments and requirements for the 2017 benefit year. The notice, released Aug. 29, proposes several changes to the risk-adjustment methodology, but the inclusion of pharmacy data for 11 conditions might be the most significant. Pharmacy data could help carriers with sicker enrollees get higher payments, even if the plans don’t collect diagnosis or severity data for them.

Small carriers have grown increasingly vocal about CMS’s risk-adjustment methodology, which they say gives an unfair advantage to large and established health plan operators that have detailed information about the health status of the communities they serve. But the risk-adjustment methodology has had a destabilizing effect on established, experienced plans, too. For example, Aetna Inc. President and CEO Mark Bertolini recently said that carriers weren’t being properly reimbursed through the program because the current risk-adjustment methodology doesn’t include pharmacy (SPN 8/16, p. 4).

In the proposed notice, CMS identified a dozen prescription drug categories (RXCs) that are “closely associated with a specific HCC [i.e., hierarchical condition category] or group of HCCs,” which it dubbed “drug-diagnosis pairs (RXC-HCC pairs)” (see table, below). In some cases, the drug-diagnosis pair includes more than one HCC.

CMS said it was cautious in choosing high-cost drugs “to avoid overly reducing the incentives for issuers to strive for efficiency in prescription drug utilization.” It also avoided drugs in areas with rapid technological advancement. After the 2018 plan year, the agency will consider “whether to continue, broaden, or reduce this set of factors.”

View the proposed notice at http://tinyurl.com/zjgoq4x.

CMS Proposes 12 Drug-Diagnosis Pairs to Use in Exchange Risk Adjustment

<table>
<thead>
<tr>
<th>RXC</th>
<th>RXC Label</th>
<th>HCC</th>
<th>HCC Label</th>
<th>Proposed RXC Use</th>
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<tbody>
<tr>
<td>1</td>
<td>Hepatitis C Antivirals</td>
<td>037C, 036, 035, 034</td>
<td>Chronic Hepatitis C, Cirrhosis of Liver, End-Stage Liver Disease, and Liver Transplant Status/Complications</td>
<td>Imputation/Severity</td>
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<tr>
<td>2</td>
<td>HIV/AIDS Antivirals</td>
<td>001</td>
<td>HIV/AIDS</td>
<td>Imputation/Severity</td>
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<tr>
<td>3</td>
<td>Antiarrhythmics</td>
<td>142</td>
<td>Specified Heart Arrhythmias</td>
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<td>End Stage Renal Disease (ESRD) Phosphate Binders</td>
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<td>End Stage Renal Disease, Kidney Transplant Status, Chronic Kidney Disease, Stage 5, Chronic Kidney Disease, Severe (Stage 4)</td>
<td>Imputation/Severity</td>
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<td>Anti-inflammatories for inflammatory bowel disease (IBD)</td>
<td>048, 041</td>
<td>Inflammatory Bowel Disease, Intestine Transplant Status/Complications</td>
<td>Imputation/Severity</td>
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<td>Anti-Diabetic Agents, Except Insulin and Metformin Only</td>
<td>019, 020, 021, 018</td>
<td>Diabetes with Acute Complications, Diabetes with Chronic Complications, Diabetes without Complication, Pancreas Transplant Status/Complications</td>
<td>Imputation/Severity</td>
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<tr>
<td>6b</td>
<td>Insulin</td>
<td>019, 020, 021, 018</td>
<td>Diabetes with Acute Complications; Diabetes with Chronic Complications; Diabetes without Complication, Pancreas Transplant Status/Complications</td>
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<td>8</td>
<td>Immune Suppressants and Immunomodulators</td>
<td>056, 057, 048, 041</td>
<td>Rheumatoid Arthritis and Specified Autoimmune Disorders, Systemic Lupus Erythematosus and Other Autoimmune Disorders, Inflammatory Bowel Disease, Intestine Transplant Status/Complications</td>
<td>Imputation/Severity</td>
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<tr>
<td>9</td>
<td>Cystic Fibrosis Agents</td>
<td>159, 158</td>
<td>Cystic Fibrosis, Lung Transplant Status/Complications</td>
<td>Imputation/Severity</td>
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<td>10</td>
<td>Ammonia Detoxicants</td>
<td>036, 035, 034</td>
<td>Cirrhosis of Liver, End-Stage Liver Disease, Liver Transplant</td>
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<tr>
<td>11</td>
<td>Diuretics, Loop and Select Potassium-Sparing</td>
<td>130, 129, 128</td>
<td>Congestive Heart Failure, Heart Transplant, Heart Assistive Device/Artificial Heart</td>
<td>Severity-only</td>
</tr>
</tbody>
</table>

FDA OKs Biosimilar Enbrel, but Litigation Could Delay Launch

On Aug. 30, the FDA approved the third biosimilar and second one within the anti-inflammatory class. Sandoz Inc.’s Erelzi (etanercept-szzs) is a biosimilar of Amgen Inc.’s Enbrel (etanercept), which the FDA first approved in 1998. And although the drug is consistently among the top — if not the top — in terms of payer spend on specialty drugs, patent litigation could mean that it may be a while before we see this drug launch in the U.S.

Erelzi was approved for all of Enbrel’s indications:
- **Moderate to severe rheumatoid arthritis,**
- **Moderate to severe plaque psoriasis,**
- **Psoriatic arthritis,**
- **Ankylosing spondylitis,** and
- **Moderate to severe polyarticular juvenile idiopathic arthritis.**

In Express Scripts Holding Co.’s 2015 Drug Trend Report, released this past March, the company noted that for the seventh year in a row, the class of inflammatory conditions was No. 1 in specialty spend.

According to an Alliance of Community Health Plans publication on rheumatoid arthritis released in March, Enbrel’s cost is more than $4,000 for a 30-day supply — an increase of 80% since 2013. In addition, said the report, annual treatment costs for RA are expected to almost double from 2013 to 2020 in the U.S., rising more than $9 billion. And “the cost of RA drugs can exceed more than $1 million over the course of a lifetime,” concluded researchers.

**FDA Took Lead on Approval**

“This is the first approval in the U.S. of a biosimilar that has not been approved anywhere else,” points out an industry expert who declines to be identified. And if the FDA heeds the advice of its advisory committee, we could see the second such approval later this month: The FDA action date for Amgen’s biosimilar of AbbVie Inc.’s Humira (adalimumab) is Sept. 25.

Approving a biosimilar not approved anywhere else “is actually a big deal,” maintains the source. “It is a real step for FDA and their confidence” around biosimilars in that the agency has “not waited for post-launch data.” At the advisory committee meetings for the first two FDA-approved biosimilars — white blood cell count modifier Zarxio (filgrastim-sndz) and anti-inflammatory Inflectra (infliximab-dyyb) — the number of patient days the drugs had outside the U.S. came up. “Compared with the last two advisory committees, FDA was almost an advocate” for Erelzi at its committee meeting, says the source.

“You don’t always want to be the subsequent reviewer,” the source says. “But the FDA is comfortable doing that.”

Erelzi is Sandoz’s second biosimilar to receive FDA approval, behind Zarxio (SPN 3/15, p. 1), and it’s “the most complex biosimilar that Sandoz has gotten approved,” says the industry expert. The manufacturer does have approvals for the “more complicated” drugs enoxaparin (Lovenox) and glatiramer acetate (Copaxone), but they are technically generics and were not approved through the 351(k) biosimilar pathway.

“The approval is no surprise, given the unanimous backing an FDA advisory committee gave Erelzi back in July,” asserts Stephen Cichy, founder of and managing director at Monarch Specialty Group, LLC. “It may still be awhile before Erelzi actually sees the market, though. Earlier this year Amgen cuffed Sandoz with a patent infringement suit, including an injunction request to block Erelzi sales.”

At issue is the so-called “submarine” patent — one that wasn’t previously known about — covering the fusion protein in Enbrel that could protect it until at least 2028, says the source. An Aug. 11 decision in the case (No. 2:16-cv-01118-CCC-JBC) prohibits the commercialization of Erelzi, but the stipulation is sealed, so details around it are not public. The case is scheduled to go to trial in April 2018.

The launch of Amgen’s biosimilar Humira also is likely to be delayed due to patent litigation. “Presumably the day they [Amgen] get approval, they will give 180 days’ notice, but who knows how clear the patent issue will be at that point?” says the source, who adds that the AbbVie vs. Amgen battle will be “the clash of the titans.”

Unlike the first two biosimilars, which are professionally administered and generally fall under the medical benefit, Erelzi is self-administered, so it likely will fall under the pharmacy benefit, which offers more management strategies for payers. “There is pressure to put more things in the pharmacy benefit overall,” says the anonymous source. That means more and more biologics are falling under the pharmacy benefit.

Contact Cichy at scichy@monarchsp.com.

**PBM Zeros In on Anti-Inflammatories**

According to Express Scripts spokesperson David Whitrap, “Currently, 43.7% of patients with an inflammatory condition are not adherent to their medications.” The company hopes to change this by providing specialized pharmacy and nursing care to patients through specialty pharmacy Accredo’s Rheumatoid Arthritis and Inflammatory Disease Therapeutic Resource Center,
Seven Conditions Will Have Own Formularies

“Instead of establishing formulary placement for the entire category of inflammatory conditions,” says Whitrap, “we are preferring medications for each of the seven primary indications”: rheumatoid arthritis, psoriasis, Crohn’s disease, ulcerative colitis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis. Most management strategies of the conditions have offered formularies with therapies covering all of the conditions, says Express Scripts. But this approach will allow drugs with only one or two indications to compete with therapies covering all of the conditions.

Part of the program will focus on Express Scripts establishing an indication-specific formulary for various conditions within the therapeutic category, an approach it has taken with another SafeGuardRx program, the Oncology Care Value Program (SPN 8/16, p. 1).

According to Stephen Cichy, founder of and managing director at Monarch Specialty Group, LLC, “managing a formulary category around each individual inflammatory indication, rather than the therapy class in general…is similar to the ‘indications-based pricing’ model that CMS proposed in early March as a test of new Medicare Part B prescription drug models to improve quality of care and deliver better value for Medicare beneficiaries” (SPN 3/16, p. 1).

Choices Follow Clinical Recommendations

Whitrap declines to disclose what medications will be preferred for each of the seven conditions, but “patients and physicians will have multiple products to choose from in these categories…Patients will receive superior care and have access to the clinically superior products for their specific inflammatory condition. Our preferred products in this new program for each indication are consistent with the clinical recommendations from the American College of Rheumatology.”

Express Scripts’ “preferred alternatives” in its 2017 National Preferred Formulary and each drug’s FDA-approved indications are as follows:

◆ Actemra (tocilizumab), which is approved for rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and systemic juvenile idiopathic arthritis. Express Scripts notes that “this product may be assessed later this year to reflect anticipated product launches.”

◆ Cosentyx (secukinumab), approved for plaque psoriasis, psoriatic arthritis and ankylosing spondylitis.

◆ Enbrel, approved for the treatment of rheumatoid arthritis, plaque psoriasis, psoriatic arthritis, ankylosing spondylitis and polyarticular juvenile idiopathic arthritis.

◆ Humira, approved to treat rheumatoid arthritis, plaque psoriasis, Crohn’s disease in adults and pediatric patients, ulcerative colitis, psoriatic arthritis, ankylosing spondylitis and polyarticular juvenile idiopathic arthritis.

◆ Otezla (apremilast), which is approved for plaque psoriasis.

◆ Remicade (infliximab), which is approved for the treatment of rheumatoid arthritis, plaque psoriasis, Crohn’s disease in adults and pediatric patients, ulcerative colitis in adults and pediatric patients, psoriatic arthritis and ankylosing spondylitis.

◆ Simponi 100 mg, for ulcerative colitis only.

◆ Kinera (anakinra) for rheumatoid arthritis; the drug also is approved for the treatment of neonatal-onset multisystem inflammatory disease.

◆ Orencia (abatacept), approved for rheumatoid arthritis and polyarticular juvenile idiopathic arthritis.

◆ Simponi (golimumab) 50 mg; the drug also is available in a 100 mg formulation. It’s approved for once-monthly 50 mg dosing for the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. In addition, Simponi is approved to treat ulcerative colitis, with a 200 mg initial dose, followed by 100 mg at week two and then 100 mg every four weeks.

◆ Taltz (ixekizumab), which is approved to treat plaque psoriasis.
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**Report Shows More Than 300 Drugs, Vaccines in Autoimmune Pipeline**

More than 300 medicines and vaccines are in development for autoimmune diseases, according to a new report from the Pharmaceutical Research and Manufacturers of America (PhRMA) and Lupus Foundation of America. These diseases affect more than 23.5 million Americans, three-quarters of whom are women. And while researchers have identified more than 80 of these conditions — including juvenile idiopathic arthritis, Crohn’s disease, ulcerative colitis, lupus and multiple sclerosis — there are many more diseases that are suspected to be autoimmune but have not yet been proven to be. Because these conditions can have similar symptoms and impact similar parts of the body, they can be difficult to diagnose. The conditions with the most drugs in development are autoimmune arthritis, with 76; inflammatory bowel disease, with 58; and psoriasis, with 48 (see chart, below).

Contact PhRMA’s Jon Tripp for more information at jtripp@phrma.org. View the report, titled *Medicines in Development for Autoimmune Diseases*, at http://tinyurl.com/hrksurm.

<table>
<thead>
<tr>
<th>Autoimmune Disease</th>
<th>Number of Medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autoimmune Arthritis</td>
<td>76</td>
</tr>
<tr>
<td>Celiac Disease</td>
<td>5</td>
</tr>
<tr>
<td>CIDP</td>
<td>3</td>
</tr>
<tr>
<td>Dermatomyositis</td>
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<tr>
<td>Diabetes, Type 1</td>
<td>3</td>
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<tr>
<td>Glomerulonephritis</td>
<td>3</td>
</tr>
<tr>
<td>Immune Thrombocytopenia</td>
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<tr>
<td>Inflammatory Bowel Disease</td>
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<tr>
<td>Lupus</td>
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<tr>
<td>Multiple Sclerosis</td>
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<tr>
<td>Myasthenia Gravis</td>
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<td>Neuromyelitis Optica</td>
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<td>Pemphigus</td>
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<td>Other Diseases</td>
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</tr>
<tr>
<td>Nonspecific Diseases</td>
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</tbody>
</table>

NOTE: Some medicines may be in more than one category. For a complete list of the 311 medicines in development, visit http://phrma.org/sites/default/files/pdf/medicines-in-development-drug-list-autoimmune-diseases.pdf.

◆ *Xeljanz (tofacitinib citrate)/Xeljanz XR*, approved for use in rheumatoid arthritis.

Express Scripts also is offering refunds of up to $6,000 to plan sponsors when their members discontinue a preferred medication within 90 days of starting on it. “While Express Scripts has previously offered refunds for early discontinuation of a single medication, this new reimbursement approach is the country’s first value-based refund to span multiple preferred medications that treat a group of diseases,” says the PBM.

Whitrap tells SPN that within the anti-inflammatory class, “approximately one out of every four patients...
switches or discontinues their therapy within the first 90 days. In some instances, the patient doesn’t respond to the therapy, and in other instances, there may be side effects that lead the physician to switch to a different product. And with these medications costing more than $3,000 on average for a 30-day prescription, these switches and discontinuations are very costly for plan sponsors and are not adding any true health benefit to the patients.”

So if someone halts a preferred medication within the first three months, Express Scripts will refund the plan sponsor “two-thirds of each prescription, up to $2,000 per patient per month, or up to a total of $6,000 over the 90-day period,” explains Whitrap. Prescriptions for the drugs usually are for 30 days, especially when they are for people who have not been treated previously.

According to Whitrap, “This is the first time that we — or anybody else, for that matter — are able to offer a refund across an entire category of products. Just the refund part of this program could be worth a total of $250 million per year for our clients.”

With one biosimilar of Enbrel recently gaining FDA approval (see story, p. 9) and a biosimilar of Remicade potentially launching in the U.S. early next month (see story, p. 5), the class could see some competition that helps lower prices. Express Scripts has estimated that a biosimilar Remicade could bring about $17 billion in savings over its first decade on the U.S. market (SPN 12/14, p. 1).

Whitrap tells SPN that “this program positions us well to drive additional competition and more affordable pricing when the biosimilars and other emerging products in the pipeline become available in the U.S.”

Contact Whitrap at (314) 684-6514. ✦

**NEWS BRIEFS**

♦ Cigna Corp. expanded its Cigna Collaborative Care model in oncology. Three medical practices joined the cancer care initiative: Northwest Georgia Oncology Centers, P.C. in Atlanta, Oncology Consultants in Houston and Cedars-Sinai in Southern California. Cigna has more than 220 arrangements of the value-based physician engagement and reimbursement model with both primary care physicians and specialists. Participating oncology practices have an oncology care coordinator to act as a point of contact among stakeholders, among other components of the model (SPN 5/15, p. 4). Contact Mark Slitt at mark.slitt@cigna.com.


♦ The Congressional Budget Office (CBO) plans to publish its score of the Medicare Part B Drug Payment Model (81 Fed. Reg. 13230, March 11, 2016) soon, according to multiple press reports. CBO Deputy Director Mark Hadley testified Sept. 7 before the House Budget Committee on how his agency determines potential savings of demonstration projects from the Center for Medicare & Medicaid Innovation. After his testimony, he told reporters that the CBO has not finished scoring the demonstration project but that he expected it would be completed in several weeks. The Part B model has been met with opposition from a wide range of stakeholders since CMS unveiled it March 8 (SPN 3/16, p. 1). Visit http://tinyurl.com/zrgqy7c.

♦ Putting limits on physician dispensing of outpatient medications, as at least one PBM has said it is planning to do, will “disrupt the care of tens of millions of patients” with cancer, according to a new white paper. Titled Pharmacy Benefit Managers’ Attack on Physician Dispensing and Impact on Patient Care: Case Study of CVS Caremark’s Efforts to Restrict Access to Cancer Care, the report was prepared by Frier Levitt, LLC for the Community Oncology Alliance. The white paper cites various sources showing that when people receive drugs from their treating physician, this “has been routinely proven” to improve adherence and patient outcomes, as well as make sure they receive treatments in a timely manner. The report says that CVS Caremark Corp. has said that as of Jan. 1, 2017, “it will terminate dispensing physicians from its Medicare Part D networks,… due to a new ‘interpretation’ of existing Medicare Part D regulations.” View the white paper at http://tinyurl.com/zacarka.
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