Indication-based pricing isn’t just coming. It’s here.

Drug companies have historically priced drugs equally across indications, regardless of the variation in value. But using indication-specific pricing, payers – and PBMs in particular – see a new opportunity to break the market-share dominance of several key therapeutics, boost their near-term rebate and distribution income, and re-shape traditional contracting. Already Express Scripts has used this new contracting concept in cancer and it’s rolling it out in inflammatory disease. And CVS is touting the idea in its communications to its customers.

In this article pack, you’ll get new insights into indication-based pricing: the major players, which drug companies stand to benefit, its relationship to other value-based contracting approaches, and the implications for players with drugs in development for multiple uses.

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Indication-Based Pricing Could Be Windfall For Interleukin Inhibitors

Emily Hayes

Express Scripts Holding Co.’s implementation of indication-based pricing in inflammatory diseases could spur a big market shift toward anti-interleukin-17 drugs for psoriasis – Novartis AG’s Cosentyx in particular – at the expense of TNF-inhibitors. It also signals an important shift in reimbursement strategy with implications across other markets.

The pharmacy benefit manager announced plans on Sept. 8 to implement indication-specific pricing as part of its Inflammatory Conditions Care Value Plan, with rollout set for 2017. The plan also includes a broad rebate program for patients who drop out of therapy.

Indication-based pricing is a new approach to reimbursement that involves contracting for drugs for specific uses, rather than across all indications.

In the anti-inflammatory category, anti-tumor necrosis factor (TNF) drugs like AbbVie Inc.’s Humira (adalimumab), Amgen Inc.’s Enbrel (etanercept) and Johnson & Johnson’s Remicade (infliximab) are approved for a broad range of indications and have benefited from broad contracts, at the expense of new entrants, such as interleukin inhibitors, approved for a smaller number of conditions.

With TNF inhibitors in such a dominant position, in the past it has been very difficult for payers, PBMs and employers to convince physicians to switch stabilized patients from these drugs, commented Roger Longman, CEO of the reimbursement intelligence company Real Endpoints. Manufacturers have maintained this domination through rebate dollars and PBMs have found it difficult to ease themselves off the rebates to allow use of newer drugs, even where there are proven benefits over TNF biologics.

J&J’s IL-12/IL-23 inhibitor Stelara (ustekinumab) has managed to pry its way in to the psoriasis/pсорiatic arthritis market and produced worldwide sales of $2.5bn in 2015, but its market share could be a lot higher if the field was wide open.

During an American Academy of Dermatology meeting where data were presented showing superiority of new interleukin inhibitors over the standard of care, experts said that it was still unclear how the results would affect prescribing patterns, because decisions were often dictated by insurance coverage. (Also see “New Interleukin Inhibitors May Give Stelara A Run For The Psoriasis Money” - Pink Sheet, 30 Mar, 2015.)

Novartis’ IL-17 inhibitor Cosentyx (secukinumab) launched last year and is off to a strong start. (Also see “Does Novartis Need A Big Immuno-Oncology Deal? Jimenez Says No” - Scrip, 19 Jul, 2016.) Eli Lilly & Co.’s Taltz (ixekizumab) was approved in March. AbbVie Inc., UCB Group and J&J have IL-17 inhibitors in Phase II for inflammatory diseases.

Express Scripts New Regime Promises To Shake Up Field

Starting in 2017, Express Scripts will be breaking up the inflammatory disease category in negotiations with drug manufacturers, for seven different indications: rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, ulcerative colitis and Crohn’s disease.

Express Scripts says it will still be using a “blended” price at the drug level, regardless of indication, so a client still pays the same amount for each condition. But there are additional discounts and enhanced competition at the indication level. Medications will get formulary placement on the indication level, instead of the entire category of inflammatory conditions.

This will allow smaller drugs that have only one or two indications to better compete with a drug that has all seven indications – leveling the playing field and helping to drive more competition, Adam Kautzner, VP of Express Scripts Drug Trend and Formulary Solutions, explained in an interview.

Payment will be tied to value, with higher rebates for indications where drugs don’t work as well.

Indication-based pricing is part of a move toward value-based pricing, Longman commented. The first big area is inflammatory disease, but the model could make
sense for any drug approved for multiple indications – the industry has already seen experiments in oncology demonstrating proof-of-concept, Longman noted.

Express Scripts began contracting on an indication basis for cancer drugs earlier in 2016. (Also see “Payer Briefs: Express Scripts Pricing Pilot; HHS Risk Adjustment; Value Frameworks” - Pink Sheet, 1 Apr, 2016.) Rival PBM CVS Health Corp. is also planning to introduce indication-specific pricing in oncology. (Also see “CVS Indication-Based Pricing For Cancer Drugs May Roll Out Later In 2016” - Pink Sheet, 4 Mar, 2016.)

Datamonitor Healthcare analyst Astrid Kurniawan expects the model will be adopted by other commercial payers as well.

**Biosimilars Will Boost Trend**

The emergence of biosimilars will give payers more leverage in a number of therapeutic areas, including inflammatory diseases, Longman noted.

The TNF inhibitors represent one of the major areas for biosimilar development. Sandoz Inc.’s Erelzi (etancercept-szsz) still has some legal hurdles to clear, but the Enbrel biosimilar is expected to launch in October. (Also see "FDA Biosimilar Policy Continues To Evolve With Approval Of Sandoz Erelzi" - Pink Sheet, 30 Aug, 2016.) Pfizer Inc./Celltrion Inc. also expect to launch Inflectra (infliximab-dyyb), a biosimilar version of Remicade, in October. (Also see "Pfizer/Celltrion Prep For October Inflectra Launch" - Scrip, 23 Aug, 2016.)

Kautzner said that indication-based pricing lays the groundwork for biosimilars, allowing Express Scripts to “slot them in at an indication level.”

Inclusion as a preferred treatment will need to be in line with guidelines from the American College of Rheumatology and Express Scripts’ Pharmacy and Therapeutics Committee will ensure that clinical value comes first, the exec said.

Manufacturers need to realize that the discounts may need to be very deep for biosimilars to compete, Kautzner said.

For new entrants, the new regime represents opportunity – at a price. Those with high-value products may be willing to deal more aggressively on pricing and rebates in order to win preferred status and gain market share, Longman said.

“Whereas before you could not break in, now you can,” Longman predicted.

Kautzner notes that products need to be priced competitively and envisions that there will be broad access to a variety of preferred products, with a “large selection from the physician standpoint.”

**Cosentyx Well-Placed**

Within the inflammatory category, there is likely to be big shift in psoriasis favor of interleukin inhibitors, with Cosentyx particularly well placed to benefit, Datamonitor’s Kurniawan expects.

Interleukin inhibitors have proven superior to Enbrel in head-to-head studies. Payers appreciate this difference in efficacy but pricing is still an important factor.

Instead of competing under the entire umbrella of inflammation, new entrants will compete in a narrow spectrum, and “especially in psoriasis, this will really give interleukins a chance,” Kurniawan said.

Cosentyx is likely to have the upper hand over Taltz and Stelara, because it proved superior to Stelara in a head-to-head study, whereas Lilly’s Taltz met the less rigorous standard of superiority against Enbrel. (Also see “FDA OK’s Lilly’s Taltz; Rival To Novartis’ Cosentyx ” - Scrip, 22 Mar, 2016.) However, the US market is very competitive on pricing and that upper hand could be diminished if Lilly offers a better price, the analyst explained.

As for Humira, the market implications are somewhat unclear. The drug is the market leader and is perceived as being more efficacious than Enbrel, but head-to-head data against Enbrel are not available, nor are head-to-head data for Humira against the interleukin inhibitors.

J&J has tested its IL-23 inhibitor guselkumab, one of three drugs in the class in Phase III for inflammatory diseases, successfully against Humira in psoriasis in a mid-stage study.

Novartis recently unveiled comparative efficacy data for Cosentyx against Humira in ankylosing spondylitis and plans to run head-to-head studies of the two drugs in ankylosing spondylitis and psoriatic arthritis (Also see "New Data Bolsters Cosentyx In AS & PsA; Humira Head-To-Head Planned" - Scrip, 8 Jun, 2016.).

These smaller indications are now more in play,
Kurniawan said, and head-to-head data will help sponsors make the value case.

**How Sponsors Should Respond**

Asked to comment on what manufacturers should be doing in response to the introduction of indication-based pricing, Express Scripts’ Kautzner said that "they need to understand flexibility will be key."

Companies will need to have an understanding that other products with more competitive prices for a given indication may provide better care at a lower net cost and that just because a drug has multiple indications doesn’t mean it has better overall value, Kautzner said.

Longman said that pharma need to spend more time on determining value for each indication. A number of models are now available for measuring value, including Real Endpoints’ RxScorecard. The Institute for Clinical and Economic Review plans to issue a value report on anti-inflammatory drug classes in October.

Indication-specific pricing will also allow pricing for subpopulations within a particular disease. For example, in oncology, PD-1 inhibitors work better in lung cancer patients with higher levels of PD-1 expression.

"Pharmas should be focusing a lot more attention on proving value in specific subpopulations in which they are uniquely advantaged" against the competition, Longman said.

Kautzner said that indication-specific pricing for subpopulations is not part of the new program but that many possibilities are open for the future. There is always opportunity to enhance these programs and go to greater depths if the market warrants it, he said.

"This is the first great step," Kautzner said.

**The Great Rebate Plan**

Express Scripts’ Inflammatory Conditions Care Value Program also includes a plan to offer rebates to payers in cases where patients stop taking their biologics in the first 90 days on therapy.

One in four patients stops therapy after the first, second or third fill of a prescription, for a variety of reasons, Kautzner noted.

In the past, Express Scripts has partnered with a few manufacturers on a one-off basis for rebates related to early discontinuation of drugs, but notes that this is the first time the industry has ever seen refunds across a category of drugs.

Payers surveyed for Datamonitor’s psoriatic arthritis and psoriasis market reports expressed concern about drugs that fail to demonstrate sustained effects for patients over time, so this offering is in line with demand, Kurniawan noted.

Payers are increasingly looking for evidence of sustained effects in real world settings, beyond standard measures used to assess skin clearance used in clinical trials, she added.

Manufacturers will need to think of more innovative ways to assess factors that contribute to increased adherence of drugs, such as dosing and ease-of-use, in order to differentiate their product from other biologics available, she said.

Going forward, PBMs and payers alike will be looking at these tangible and more economically relevant and real-world pertaining endpoints when they think about placing products in preferred tiers, she said.

The fact that this is being done on a broad scale, for an entire class of medications for multiple diseases, and that the inflammatory market is being split into indication-specific contracts means that manufacturers will really need to understand the nuances of each indication, including the factors that lead to non-compliance in specific indications, Kurniawan said.

"It will become more challenging for one product to win across all inflammatory markets, without showing demonstrated superiority in each indication segment," the analyst concluded.
Multi-Indication Pricing: Big Hurdles And Actionable Options

Jessica Merrill

Multi-indication pricing presents an intriguing pricing scheme for certain drugs used for more than one indication because it could better align the cost of the medicine to value in different diseases. But the challenges to implementing multi-indication pricing are daunting, requiring changes across the entire health care spectrum, from systems used by patients and physicians to pharmacists and payers.

However, as payers and drug manufacturers look for new ways to better align the cost of drugs to value, alternative pricing and reimbursement schemes are gaining momentum, despite challenges. That makes it worthwhile for industry and other stakeholders to take a harder look at the potential benefits and issues facing alternative pricing and reimbursement schemes.

“Can we still achieve some kind of the outcomes of a multi-indication pricing type of process without actually having a pure multi-indication pricing process put into place?”

– OmedaRx’s Sean Karbowicz

Outcomes-based reimbursement and multi-indication pricing were two key issues debated during the International Society For Pharmacoeconomic And Outcomes Research (ISPOR) annual meeting May 21-25 in Washington, DC, highlighting the growing interest in...
new payment models.

The aim of outcomes-based reimbursement is to link the cost of a drug to a measureable outcome in patients like improvement in cholesterol or reduction in hospital admissions. Multi-indication pricing would require assessing value but assigning different value depending on what disease the drug is used in and how beneficial it is perceived to be.

The prospect is logical in theory, given that drugs are very often used in multiple indications with varying benefits across disease states – often even within subpopulations in the same indication. But the pricing scheme poses many challenges, the biggest of which is arguably that in the US and many other countries, prescriptions aren’t always monitored for how they are used.

“The problem becomes taking that information and linking it all the way through the system so that what is captured at the point of sale can be aggregated and interrogated and systematically analyzed for policies and reimbursement on a mass scale. That journey is very difficult here in the US,” Bill Dreitlein, director of pharmaceutical policy at the Institute for Clinical and Economic Review (ICER), said during a panel presentation at ISPOR.

In the US, the drug industry has been singularly focused on a sole price for drugs across indications, possibly to the detriment of society in some cases, say if a manufacturer were to delay development of a drug in an indication that might command a lower price to focus on a higher-priced opportunity. Sanofi decided in 2012 to pull the chronic lymphocytic leukemia drug Campath (alemtuzumab) from the commercial market altogether before launching the same drug under a different brand name, Lemtrada, for multiple sclerosis in 2014. Sanofi agreed to offer Campath free of charge to patients on a compassionate use basis so that it could pave the way for the higher priced launch of Lemtrada for MS (Also see “Sanofi/Genzyme Primed Patient Community For Campath’s Removal From Commercial Distribution” - Pink Sheet, 27 Aug, 2012.).

Learnings From ICER’s Summit

ICER – the non-profit research institute that analyzes drug effectiveness and value – has undertaken a deep review of indication-specific pricing, bringing together leaders from 22 payer organizations and life science companies at a summit on the issue in 2015. ICER released a white paper outlining the findings of that meeting and analyzing the challenges in March, which Dreitlein highlighted at ISPOR.

The research group’s interest in evaluating the feasibility of indication-specific pricing was fueled by a couple of key events, Dreitlein said. One was an article published in the Journal of the American Medical Association in 2014 by Peter Bach, the director of Memorial Sloan Kettering’s Center for Health Policy and Outcomes, that questioned why the same drug deserves the same price when it offers different benefits in different indications. The article seemed to resonate with the public and was picked up by several media outlets, he added.

Then, in June 2015, the pharmacy benefit manager Express Scripts Holding Co. announced it was testing an indication-based formulary for certain cancer medicines in 2016. The company has been keeping the details about the pilot program close to its vest, but did confirm that the program has launched.

The ESI pilot program was a reality check that led ICER to ask a lot of questions. “Is this something that is going to gain traction? Is it a flash in the pan? What does it mean for development? What does it mean for us as payers,” Dreitlein said.

The biggest question is if indication-specific pricing is a good idea at all, he noted. In the plus column, ICER determined the benefits are that it would align drug reimbursement closer to value and potentially save the health care system money – though that’s no guarantee – and it also reflects positively on industry and payers that they are thinking actively and creatively about drug prices.

On the other hand, the administrative cost and
burden would be substantial, and indication-specific pricing could conflict with existing government pricing policies. A specific concern of drug manufacturers is that payers might not acknowledge the added clinical value of follow-on indications if they end up being more substantial than the initial indication, according to Dreitlein.

**A Drug Maker And A Payer Perspective**

Roche is one company that is proactively evaluating alternative pricing models including multi-indication pricing, largely because of its heavy involvement in cancer R&D, where it is expected that high-priced combination regimens will eventually be the standard of care, according to Ansgar Hebborn, head of global HTA & payment policy, global pricing & market access. “We need to think about this area much more innovatively, not just on the disease side, but also the evolution of pricing and reimbursement systems,” he said. “We believe that it is important to think about how we can move away from a typical unit based pricing approach, or per kg, to something that is a lot more tied to how the drug is used.”

The ability to implement multi-indication pricing varies by country, Hebborn said, noting that following interactions with health care authorities around the world, there are some countries that have the capacity to implement such a program. Italy, for example, already has a number of drugs reimbursed in a flexible infrastructure, he said, while France and Spain are running pilot programs exploring drug utilization. Feasibility has also been established for a number of cancer centers in the UK, he added. One study evaluating the feasibility of multi-indication pricing in the UK was presented at ISPOR with a positive conclusion.

“There are other countries where we face more substantial barriers,” Hebborn said.

“Value-based outcomes and learning are big themes, but how much interest is there beyond rhetoric,” he queried. “When it is about offering data, data sharing, working on governance models, there is often a display of considerable distrust or reluctance to engage.”

Sean Karbowicz, director, innovation and pharmacy policy for the pharmacy benefit manager OmedaRx, offered the perspective of a US commercial payer. His point of view was that while a pure indication-specific pricing system might be too challenging to implement in the US in the near-term, there are actionable steps payers can take to align value to indication.

The fractured US health care system poses many challenges, he pointed out. “Sometimes, on the prescription side, diagnoses are not needed. The pharmacist does not need to know what the drug is being used for,” he pointed out. “There has to be a way to capture that diagnoses for that patient so that we could tell what it is used for. That could be a barrier. That might require prior authorization and additional paper work.”

Another challenge would be making the necessary changes to coverage contracts with members and getting the changes approved by the insurance commission and employers. And perhaps most importantly, would be the value assessment required for each drug by indication.

“Can we still achieve some kind of the outcomes of a multi-indication pricing type of process without actually having a pure multi-indication pricing process put into place,” Karbowicz asked.

He proposed a scenario in which a payer and manufacturer would sit at the negotiating table and hammer out a blended multi-indication price for a particular product by evaluating the cost of therapy, the number of people in the plan estimated to be impacted by each particular indication the drug is approved for, and potential rebates for those indications that are perceived as having less value. The rates would be blended together to reach an estimated reasonable rebate to be applied.

“This is an example of how we may be able to leverage the work that would go into a multi-indication pricing process without the regulatory changes that could be needed,” he said.
Indication-specific pricing could help insurers manage the cost of Intercept Pharmaceuticals Inc.’s Ocaliva (obeticholic acid) in nonalcoholic steatohepatitis (NASH), assuming it is approved, a recent roundtable convened by the Institute for Clinical and Economic Review (ICER) suggested.

A summary of the roundtable discussion is included in a cost-effectiveness report on Ocaliva and NASH released by ICER July 26. The report focuses on the NASH indication, even though Ocaliva is not yet approved for that use, because there is significant clinical interest in treating NASH.

Ocaliva was approved in late May for primary biliary cholangitis (PBC), an orphan disease affecting approximately 130,000 US adults. (Also see “‘Clean Label’ For Intercept’s Ocaliva In PBC Bodes Well For NASH Claim” - Pink Sheet, 6 Jun, 2016.) Its wholesale acquisition cost – $69,350 per year – is in keeping with its orphan status.

However, the prospect of paying more than $60,000 annually for the estimated 10 million to 15 million US adults with NASH has raised significant cost concerns among payers. (Also see “NASH Drug Cost Concerns On Level With HCV Treatments For Payers” - Pink Sheet, 20 Apr, 2016.)

ICER estimated that use of Ocaliva in NASH would be cost-effective according to the commonly-used willingness to pay threshold of $150,000 per quality-adjusted life year “only when the annual price … is below approximately $5,100 per year (more than a 90% discount from the list price).”

As a result, “insurers and manufacturers should explore possible steps to manage … affordability in the much larger NASH population,” the ICER report summarizes. “These could include agreement on a different price specific to the NASH indication or a weighted price for both indications.”

Indication-specific pricing could address the “tension” between initial pricing of Ocaliva for an orphan condition and later use for a different indication in a large patient population, the report adds.

Indication-specific pricing could involve applying separate discounts to the price of Ocaliva in PBC and NASH, presumably with the aim of lowering the price more in the broader indication. Alternatively, a single weighted average price could be developed using estimates of indication use across the population, with possible retrospective reconciliation through rebates based on actual use.

Indication-based pricing is gaining increasing attention in the biopharma market as payers push to align price more closely with value. Despite the many challenges involved in pricing by indication, some manufacturers have begun to test approaches in oncology with pharmacy benefit manager Express Scripts Holding Co.

The PBM is also planning to implement a program involving anti-inflammatory drugs in the first half of 2017 (Also see “Express Scripts Indication-Based Contracts For Inflammatory Drugs Begin In 2017” - Pink Sheet, 19 Jul, 2016.).

Off-Label Use Not Yet Supported

The roundtable discussion involved the New England Comparative Effectiveness Public Advisory Council (CEPAC), a core program of ICER, and clinical representatives from Massachusetts General Hospital, Harvard Pilgrim Health Care, the Vermont Department of Health Access and Intercept.

CEPAC did not endorse indication-based pricing for NASH based on currently available data. Ocaliva is in Phase III study in patients with NASH and interim data from the trial are expected to be available in the early part of 2017. Industry watchers are anticipating approval for the indication in the second half of 2018.

There was unanimous consensus that existing data are insufficient to “demonstrate a net health benefit of Ocaliva in comparison to usual care for NASH, given the preliminary nature of the clinical trial data for the condition and ongoing status of a large Phase III trial with interim data not expected to be available until 2017,” the report states.

Clinicians should “instead encourage patients to participate in clinical research programs that can help establish a more solid evidence base for” Ocaliva, the roundtable agreed.
Indication-specific pricing may begin to reshape US reimbursement for anti-inflammatory drugs in the first half of 2017, when pharmacy benefit manager Express Scripts Holding Co. launches its new approach to contracting.

In a move away from paying for anti-inflammatory drugs as a broad category, Express Scripts will negotiate separate pricing for the crowded class within four smaller indications:

1) rheumatoid arthritis;  
2) psoriasis/psoriatic arthritis;  
3) ankylosing spondylitis; and  
4) inflammatory bowel disease (including ulcerative colitis and Crohn’s disease).

The approach will aim to match prices more closely to value, leading to lower reimbursement for indications that are less effective and higher reimbursement for more-effective uses, according to Express Scripts.

Most of the anti-inflammatory treatments are injectables and could be self-administered. A couple – Celgene Corp.’s Otezla (apremilast) and Pfizer Inc.’s Xeljanz (tofacitinib) – are orals.

But one of the category’s largest drugs, Johnson & Johnson’s Remicade (infliximab), is administered intravenously and it is unclear whether it would be included in the program. An Express Scripts spokesman declined to comment on specific drugs.

The current approach to contracting in the anti-inflammatory category has favored older, entrenched drugs in the TNF-inhibitor class, such as AbbVie Inc.’s Humira (adalimumab) and Amgen Inc.’s Enbrel (etanercept).

Those drugs have a wide range of approved indications as well as high volume use. That has made them more financially attractive targets for contracting and a significant source of rebates for payers. In return, Humira and Enbrel control a significant majority of the market and brought in US sales of more than $8bn and $5bn, respectively, in 2015.

Those large sales figures have made the products tempting targets for biosimilars, and FDA advisors endorsed a potential competitor for each last week. (Also see “Biosimilar Non-Medical Switching: Advocacy Groups, FDA Advisors Push For Action” - Pink Sheet, 14 Jul, 2016.) How much cheaper the biosimilars would be – and even when they might reach the market – remains uncertain.
However. (Also see “Enbrel Biosimilar Market In Sandoz’s Grasp; Will Cost, Litigation Derail It?” - Scrip, 11 Jul, 2016.)

In the shorter term, indication-specific pricing may offer drugs with relatively narrow labels new opportunities to gain favorable formulary status and expand access, especially if they are more effective than the category leaders for certain uses.

Among the drugs that could benefit are the interleukin inhibitors, including Johnson & Johnson’s Stelara (ustekinumab), Novartis AG’s Cosentyx (secukinumab), and Eli Lilly & Co.’s now launching Taltz (ixekizumab). Stelara is approved for psoriasis and psoriatic arthritis. Cosentyx is approved for those two indications plus ankylosing spondylitis and Taltz is approved for psoriasis (see chart).

**ICER Reviews Could Inform Contracting Changes**

Express Scripts’ contract negotiations may be aided by upcoming comparative effectiveness review of some anti-inflammatory classes by the Institute for Clinical and Economic Review. ICER reviews include recommended pricing benchmarks based on cost per quality-adjusted life year measures.

ICER is planning to release a final report on drugs for psoriasis in October and a report on treatments for rheumatoid arthritis in January 2017. The group is also considering a review of drugs for psoriatic arthritis.

Responses to a recent survey of US payers conducted by Datamonitor Healthcare illustrate the access challenges facing drugs with fewer indications. Excerpts from survey responses are included in a new Datamonitor report on reimbursement for drugs for psoriatic arthritis.

One payer commented that Cosentyx is becoming the “gold standard” for psoriasis “but it is not a preferred drug because it is a narrow-spectrum drug and if I contract for that, which of my broad-spectrum drugs am I going to boot off [formulary] and take a hit on? … So the challenge has been how to allow access to these more narrow-spectrum drugs that probably work a little bit better, but not take a financial hit that would be unacceptable.”

The survey also revealed that like Express Scripts, other US payers are considering “carving out” indications like psoriasis for the purpose of contracting.

According to another US payer, “as the data continue to emerge that the interleukin [inhibitor] drugs … are more effective and safer, at some point we are going to have to go to war with Amgen and AbbVie and say: ‘Guys, we are going to carve psoriasis out of this package deal. You are still going to be our preferred anti-TNF for all of the other things but we are taking psoriasis out of the category. You will have a chance to bid for the business in psoriasis as well, but your competition is now going to be the narrow-spectrum, safer drugs.’”

**Price Increases, Product Development Driving Costs**

The indication-specific program will give Express Scripts more leverage to drive down prices in the category, which has ranked as the highest-cost specialty drug class tracked by the PBM for the past several years.

Spending in the inflammatory class rose 25% in 2015, driven by unit cost increases of greater than 17% for Humira and Enbrel that reflect higher pricing and utilization, according to the PBM’s most recent Drug Trend Report. (Also see “Rx Spending Growth Won’t Exceed 8% In Coming Years – Express Scripts” - Pink Sheet, 15 Mar, 2016.)

List prices for Humira and Enbrel are at the high end of the range of prices in the category at around $48,000 per year, according to Truven Health Analytics’ Red Book. Newer agents like Cosentyx and Taltz have list prices of more than $50,000 per year.

Higher spending in the category has persisted in 2016. Virtually all of the branded drugs recorded significant increases in first quarter US sales, reflecting price increases and new product development. For example, Cosentyx added new indications in psoriasis and psoriatic arthritis and Xeljanz gained an extended-release dosage form in early 2016.

New product activity will continue this year and into 2017. Two new drugs for rheumatoid arthritis are on track to launch in the US in late 2016/early 2017 – Lilly’s baricitinib (Also see “JAK Inhibitors Start To Come Of Age In Rheumatoid Arthritis” - Pink Sheet, 16 Nov, 2015.) and Sanofi and Regeneron Pharmaceuticals Inc.’s sarilumab (Also see “Why There’s Still Room For Sarilumab In RA, According To Sanofi” - Pink Sheet, 9 Nov, 2015.).

And Valeant Pharmaceuticals International Inc. is developing brodalumab for psoriasis and psoriatic arthritis after licensing the candidate from AstraZeneca PLC. (Also see “AstraZeneca Unburdens Itself Of Brodalumab” - Scrip, 1 Sep, 2015.) But the drug has been associated with serious side effects and seems to be facing regulatory headwinds. (Also see “Valeant’s Brodalumab Faces Conflicting FDA Views On Suicide Risk” - Pink Sheet, 15 Jul, 2016.)
### US Branded Anti-Inflammatory Specialty Drugs

**Indications:** rheumatoid arthritis (RA); juvenile idiopathic arthritis (JIA); psoriasis (Ps); psoriatic arthritis (PsA); ulcerative colitis (UC); hidarentitis suppurative (HS)

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<td><strong>Tissue necrosis factor inhibitors</strong></td>
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<td>Humira (adalimumab); injectable</td>
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<tr>
<td>Cosentyx (secukinumab); injectable</td>
<td>Novartis</td>
<td>$123m</td>
<td>NA</td>
</tr>
<tr>
<td>Taltz (ixekizumab); injectable</td>
<td>Eli Lilly</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Integrin receptor antagonist</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entyvio (vedolizumab); intravenous</td>
<td>Takeda</td>
<td>$524m</td>
<td>192.5%</td>
</tr>
<tr>
<td><strong>Phosphodiesterase-4 inhibitor</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Otezla (apremilast); oral</td>
<td>Celgene</td>
<td>$174.8m</td>
<td>194%</td>
</tr>
<tr>
<td><strong>Janus kinase inhibitor</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Xeljanz (tofacitinib); oral</td>
<td>Pfizer</td>
<td>$175m</td>
<td>98%</td>
</tr>
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</table>
CVS Indication-Based Pricing For Cancer Drugs May Roll Out Later In 2016

Cathy Kelley

CVS Health Corp.’s pharmacy benefit manager unit is hoping to launch an indication-based pricing program for cancer drugs in the second half of 2016, according to CVS VP and Head of Specialty Client Solutions Surya Singh.

Singh discussed indication-based pricing – a novel contracting strategy in which payers and manufacturers settle on different prices for different indications based on relative value – at the National Business Group on Health’s Business Health Agenda conference in Washington, D.C. March 3. The National Business Group on Health is a non-profit representing the perspective of large employers on health issues.

“I think we want to pay more for drugs that work better…to push [manufacturers] to think about pricing things that have a better impact on survival at a higher price point and pricing things that don’t have as much impact on survival at a lower price point,” Singh said.

“There’s a lot of activity right now -- and there’s been some press around this -- that we and others are going to put increasing pressure to pay on the basis of indication, that we’re going to…negotiate harder for lower prices when the indication has not shown as much efficacy. And there are some very good examples of that in oncology.”

After the meeting, Singh said the program was in the early stages of development but may be launched in the second half of 2016. Rival pharmacy benefit manager Express Scripts Holding Co. has also been working on indication-based pricing for oncology drugs and plans to launch a pilot program in the coming weeks.

CVS is looking at a range of drugs and indications for the program, Singh said. He noted the company anticipates oncology approvals in the coming months that might also be eligible for the program.

Singh mentioned Roche’s Herceptin (trastuzumab) as an example during the meeting. “Herceptin has gotten a lot of attention for being very good in breast cancer. It’s very well studied and has great benefits...It’s also used in gastric cancer. The benefit in gastric cancer is minimal, but [the indication] is on label. Should we pay the same for the drug on a unit costs basis when it’s used for something where it doesn’t work as well? I don’t think so.”

Indication-based contracts should lead to lower reimbursement to providers for less effective indications, Singh pointed out. That could reduce prescribing incentives for indications considered to be of lower value.

“If you’re going to pay differently by indication, you’re also going to have to reimburse differently by indication ... Because the last thing you want to do is increase the amount of profit margin for the specialty pharmacy or physicians or hospitals on the less efficacious indication. So if you buy cheaper you need to also pay less when [the drug] is used.”

In cases where a drug may be “disadvantaged” in some indications because of indication-based reimbursement, CVS will consider whether patients have acceptable alternatives, Singh said.

Copay Coupons For Generic Specialty Drugs

The CVS executive also addressed manufacturer copay coupons, noting that the PBM response to such promotions can be somewhat “nuanced” because payer clients may be receptive to them in some situations.

“There is no one size fits all [response] here,” he said. “But I think coupons are not going away.”

Also speaking at the session, OptumRx Specialty Pharmacy Senior VP Michael Zeglinski agreed “there are different schools of thought. Some people love coupons. Some people hate them and some are in the middle. So in order to deal with the coupon issue, we like to customize it to what our clients are looking for. And we’re able to do it on either end -- completely eliminate it or use it when needed.”

However, he emphasized “we make sure [the value of the coupon] doesn’t get applied to the deductible.” OptumRx is the PBM owned by UnitedHealth Group Co.

Singh pointed out there is one area where PBMs and payers should promote the use of copay coupons – for generic specialty drugs. He noted the recent introduction...
of a generic version of Novartis AG’s blockbuster oncology drug, Gleevec (imatinib), offers an opportunity for such a push.

“As we start to see more important specialty generic launches like generic imatinib, collectively making sure early on...that the generic manufacturer, especially in the exclusivity period, has a coupon in place so that we can counteract the effect of the coupon from the brand name manufacturer is a critical piece of the strategy,” he said.

The generic launched Feb. 1 with a 180-day marketing exclusivity period, which suggests its price may start out at a relatively modest discount to Gleevec – possibly making it less appealing to prescriber and patients -- and increasing as more generic competition enters the market. Payers are still developing contracts and coverage policies for generic imatinib, Gleevec and the other branded tyrokinase inhibitors following the launch.

Medical Drug Carve-Out
Singh made a presentation at the meeting along with Equity Healthcare Chief Clinical Officer Michelle Harika to discuss programs the two had worked on together to control specialty drug costs. Equity works with 40 private equity firms and their portfolio companies to manage health care costs for approximately 300,000 individuals.

One program implemented in 2013 involved “carving out” certain oral and self-injectable drugs from the medical benefit to be managed by CVS, Harika noted. While initially very effective at reducing costs, that program has generated less in savings more recently because medical carriers are more actively engaged in managing medical benefit drugs, she said.

“In 2013, when we were carving out, there was definitely savings, there is absolutely no doubt about it,” Harika maintained. However, “if you look at what is happening with the medical carriers...we have two preferred medical carriers and both of them now have prior authorization and site of care strategies for some of the drugs that we carved out. So we’re starting to see less savings for carve out now because the medical carriers have caught up to what we did with CVS very early on.”

One other speaker at the session, Owens Corning Epidemiology and Data Management Director William Fayerweather, noted his company had considered a carve out for some medical benefit drugs but determined it would not be cost effective.
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