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# Enbrel's First Outcomes Contract Is With Harvard Pilgrim; Others May Follow

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by Cathy Kelly

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## Executive Summary

Amgen seeking additional outcomes-based contracts in rheumatoid arthritis through collaboration with Inovalon/Avalere.

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**Amgen Inc.** launched its first outcomes-based contract for *Enbrel* (etanercept) in the US with Harvard Pilgrim Health Care earlier this year as it seeks to defend its blockbuster against heightened pressure from payers and new competition.

The two-year contract went into effect on Jan. 1 and is based on an "effectiveness algorithm" driven by six criteria, Harvard Pilgrim said. The criteria include patient compliance, switching or adding drugs to Enbrel therapy, dose escalation and steroid interventions, which the insurer believes "can serve as a global measure of the positive impact" of Enbrel on its members.

If patient scores derived from the criteria are below a specified level, Harvard Pilgrim will pay less for Enbrel because the drug's real life effectiveness will have been lower, the insurer explained. The contract with Harvard Pilgrim for Enbrel is the only outcomes-based contract of its kind in the market for the treatment of moderate to severe rheumatoid arthritis, the health services organization said.

"Real world performance of new medicines frequently differs from the well-controlled clinical trial setting," Harvard Pilgrim Chief Medical Officer Michael Sherman said in a release. "And we know that historically, only about a third of patients on Enbrel and others in this class meet all six criteria. By linking the ultimate cost of this drug to its real-world clinical efficacy, this agreement truly puts patients at the center of focus."

Outcomes will be tracked through Harvard Pilgrim's pharmacy and medical claims data. The contract also calls for tracking patient adherence to the drug. It applies to Harvard Pilgrim's commercial plans and is the latest in a series of innovative prescription drug contracts announced by Harvard Pilgrim over the last couple of years (*see box*).

For Amgen, the arrangement "aims to demonstrate the value of using Enbrel to effectively treat patients and provides powerful evidence to be considered by formulary decision-makers in the future," Amgen Senior VP Global Value Access & Policy Joshua Ofman said in the release.

Amgen has collaborated with Harvard Pilgrim before on outcomes-based payments – a deal involving its PCSK9 inhibitor *Repatha* (evolocumab). The manufacturer has around 25 value-based programs in place in the US, also including a contract for Repatha with Cigna, an Amgen spokesperson said. The firm has an

## Harvard Pilgrim Outcomes-Based Contracts

Amgen's **Repatha**: pay for performance agreement provides Harvard Pilgrim an enhanced discount if the drug does not reduce LDL cholesterol levels for members as observed during clinical trials. Provides additional discounts if utilization of the drug exceeds certain levels. This enables those patients who can most benefit to receive it while continuing to encourage utilization of lower cost statins for the majority of people. Announced fall 2015. (Also see "Amgen's *Repatha* Pricing Deal With Harvard Pilgrim Hinges On Results, Utilization" - Pink Sheet, 9 Nov, 2015.)

Novartis' **Entresto**: Provides insurer with a discount if Entresto does not perform as well in Harvard Pilgrim patients with chronic heart failure as it did in clinical trials. Entresto is used in place of ace inhibitors. Announced spring 2016. (Also see "Novartis Woos Payers With Data Showing Entresto Earns Its Keep" -

additional 12 program in the "concept" phase.

## Amgen Seeking Other Outcomes-Based Opportunities In RA

Amgen is also collaborating with data analytics company Inovalon and its Avalere research and consulting unit to explore and support outcomes-based contracts for rheumatoid arthritis drugs, including Enbrel.

Under that agreement, Inovalon/Avalere "will deploy its data, analytics capabilities, and subject matter expertise with outcomes based contracts (OBCs) to support further development of OBCs based on the value of Amgen's products," Inovalon announced March 29.

## Enbrel Price Concessions To Payers

Enbrel is a leader in the RA market but has had to make significant price concessions to payers for 2017 to maintain its current level of access. (*See sidebar for related story.*)

Exec VP Global Commercial Operations Anthony Hooper said in a Feb. 2 year-end earnings call the company expects to realize "minimal net selling price growth throughout 2017 based on contracts that went into effect on January 1." He added "we also expect volume trends in 2017 to be similar to 2016."

Enbrel is expected to face competition from two new drugs this year in RA – **Sanofi** and **Regeneron**

Scrip, 16 Nov, 2016.)

**Lilly's Trulicity:** Value-based arrangement gives Trulicity preferred status on Harvard Pilgrim's formulary and provides that Harvard Pilgrim will pay a lower net cost if fewer of its members with diabetes reach a preferred endpoint (HbA1c less than 8%) as compared to individuals taking other GLP-1 receptor agonists, and a higher net cost if patients taking Trulicity do better than patients taking competing drugs. Announced spring 2016 (Also see "Lilly's Performance Contract For Trulicity Hinges On Head-To-Head Superiority" - Pink Sheet, 29 Jun, 2016.)

**Amgen's Enbrel:** Contract is based on an effectiveness algorithm driven by six criteria, including patient compliance, switching or adding drugs, dose escalation and steroid interventions that can serve as a global measure of the positive impact of the medication on Harvard Pilgrim members with moderate to severe rheumatoid arthritis. If patient scores are below a specified level, Harvard Pilgrim will pay less for Enbrel. Announced winter 2017.

**Lilly's Forteo:** Value-based contract rewards improvement in patient persistence in the osteoporosis medication as compared to the baseline level of adherence seen in the Harvard Pilgrim population. If meaningful improvements to Forteo persistence are realized in Harvard Pilgrim's patients, Lilly will reduce the cost of the drug for the health plan. Harvard Pilgrim will work with its pharmacy network and Lilly to drive improvements in patient persistence. Announced winter 2017.

### Market Failure? Lower Drug Prices Don't Improve Access In Rheumatoid Arthritis

By Cathy Kelly

07 Apr 2017

'Perverse incentives' guide US pricing for rheumatoid arthritis drugs, stakeholders say at policy roundtable convened by Institute for

**Pharmaceuticals Inc.** IL-6 receptor agonist *Kevzara* (sarilumab) and **Eli Lilly & Co.**'s oral JAK inhibitor, *Olumiant* (baricitinib). FDA decisions on both drugs are expected in the coming weeks.

Clinical and Economic Review.

[Read the full article here >](#)

Competition from biosimilars is also on the horizon. Biosimilars to Enbrel and **AbbVie Inc.**'s *Humira* (adalimumab) have been approved but are entangled in patient litigation. As a result, they are not expected to reach the market until 2018 and 2019, respectively. (Also see "Biosimilars In 2017: Crowded US FDA Review Queue, Key Legal Decisions" - Pink Sheet, 24 Jan, 2017.)

Enbrel sales could additionally be challenged by payer efforts to reimburse anti-inflammatory drugs based on indication. For example, pharmacy benefit manager **Express Scripts Holding Co.** launched an initiative using an indication-specific approach earlier in 2017. (Also see "Express Scripts Indication-Based Contracts For Inflammatory Drugs Begin In 2017" - Pink Sheet, 19 Jul, 2016.)

Amgen's efforts to generate real world outcomes data to support the value of Enbrel could help defend the drug against these kinds of challenges, suggests Roger Longman, CEO of reimbursement analytics firm Real Endpoints.

"My sense is that the deals that Amgen has signed are in part to counteract this kind of attack ... by trying to show in some real-world way that Enbrel has particular outcomes that can be tracked and therefore to offer some kind of advantage to plan sponsors to cause them to resist this sort of PBM pressure," Longman said in an interview.

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