PCSK9 INHIBITORS: Payer Dynamics

THERAPEUTIC CLASS OVERVIEW

PCSK9 inhibitors are monoclonal antibodies. They target and inactivate a specific protein in the liver. Knocking out this protein, called proprotein convertase subtilisin kexin 9, dramatically reduces the amount of harmful LDL cholesterol circulating in the bloodstream. They work differently than statins first by promoting the modulation of the receptor that clears cholesterol, prolonging the receptor and clearing more cholesterol. Second, they are delivered by injection, so dosing occurs every 2-4 weeks instead of a daily dose in pill form. These powerful new drugs lower LDL which leads to healthier arteries and fewer heart attacks, strokes, and other problems related to cholesterol-clogged arteries.

PAYER DYNAMICS

During 2016, patients who were attempting to get a new prescription for a PCSK9 and made an initial attempt to fill the drug were approved 11.6 % of the time in Commercial Pay Type, and were rejected at a rate of 88.4 %. In Medicare, the initial approval rate was 27.2% with an initial rejection rate of 72.8%.

After a 14 day look forward, patients in the Commercial Pay Type saw a final approval rate of 27.2% with a final rejection rate of 72.8%. In patients that were classified under the Medicare Pay Type a final approval rate of 61.3% was seen along with a final rejection rate of 38.7%.

As a point of comparison, looking at the post-launch activity of a PDE4 inhibitor and an HCV nucleotide analog inhibitor, both of which share certain parallels to the PCSK9 class in that they were revolutionary new biologic treatments with high treatment costs relative to existing therapies used to treat the respective disease states, we see similar payer dynamics.

Using the PDE4 as an example, the denial rate for claims of this drug was 77% for the initial prior authorization attempt during the first 12 months post-launch. Of the rejected claims, 23% were eventually overturned and ultimately were approved as a final claim status.** The reason for denial in 40% of these cases was due to prior authorization. Of those that were rejected due to prior authorization, 33% of those claims were eventually converted into an approval.

Looking at the HCV drug, we see a similar pattern. The denial rate during the first 12 months post-launch for these claims was 88%. Of these rejected claims, 32% were converted ultimately into a payer approved claim.* * The top reason for rejection of these claims was prior authorization, as seen with the PDE4 drug. For the HCV drug, prior authorizations made up 40% of the initial and final rejected claims. Ultimately 40% of those prior authorization rejections were overcome and payer approved.

Comparing the PCSK9 post launch activity with the PDE4 and HCV drugs, we find that nine months post launch the PSCK9 drugs continue to experience similar patterns of high initial denial, suggesting that patients still face challenges in gaining access to the treatment. We anticipate the full 12 months post launch will follow a similar trajectory to the comparison classes.

*New Claims refer to all new prescriptions irrespective of new or existing patients.
**Look forward period in these studies was 30 days or less.

Note: This analysis is based on data through 12/31/2016 that was available as of 2/10/2017.

ABOUT THE DATA

Symphony Health Solution's IDV® (Integrated Dataverse) is the first and only HIPAA-compliant information resource in the life science industry that fully integrates multiple dimensions of anonymized healthcare treatment data into a single, comprehensive, patient-centered view of the entire treatment journey. Active patients in IDV represent 17 out of 20 people in the current US population. Each anonymized patient's related medical, hospital, and prescription events are linked in IDV – and on average, IDV contains more than four years of health history for each active patient. With more than 12 years of historical information, IDV incorporates data from over 10,000 health plans and over 100 billion patient-based health transactions aggregated from more than 124,000 data sources, housing three petabytes of data.