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Key US Entresto Barriers Are PA Process & Co-Payments – BMT Poll

By Sten Stovall

UPTAKE OF NOVARTIS AG'S HEART FAILURE drug Entresto in the US has been slow following approval in July 2015, partly due to the time it has taken to secure insurance coverage, but physicians also complain about other insurance barriers, a new survey by BioMedTracker shows.

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A BioMedTracker poll canvassing 23 US-based cardiologists about the main clinical and reimbursement hurdles causing the slow uptake there of Novartis's heart failure drug Entresto (valsartan/sacubitril) suggests insurance issues - namely pre-authorization and high co-payments - are the key causes. More than a third of respondents also listed reluctance to switch patients doing well on current medications, while only 9-13% listed lack of confidence about efficacy, concerns about hypotension, or titration issues as important barriers.

These were the main takeaways from replies by cardiologists to questions about the major barriers preventing use of Entresto in Class II-IV heart failure patients with reduced ejection fraction (HFrEF), the drug's current indication. Most of the 23 doctors surveyed had only a modest proportion of Class II-IV HFrEF patients on Entresto, consistent with its slow uptake.

The BioMedTracker survey presumed that some co-pays now are over $50 or over $100, so respondents were asked how the percent of their patients taking the drug might change if those high co-pays are lowered. Co-pay is a type of insurance policy where the insured pays a specified amount of out-of-pocket expenses and the insurer pays the rest.

Survey Scenarios And Responses

Survey respondents projected progressively increased Entresto usage with stronger guideline recommendations, with the median usage rising from a current 10%, to 21-30%, with a strong recommendation for second-line use of Entresto, and 31-50% for a strong recommendation for first-line use.

If prior authorization stayed the same but co-pays over $50 were reduced, there was a modest increase in median usage by respondents compared to currently – rising to 11-20% from 0-10% - but more than a third of respondents said they would use Entresto in 21-30%, while very few projected use in over 50%.

If the prior authorization process was simplified but co-pays stayed the same, then the median projected use increased to 21-30% of patients, from 0-10% currently, the survey showed. If both prior authorizations were simplified and co-pays over $50 were reduced, then the median rose to 31-50% usage.

There was also a progressive increase in projected Entresto use with stronger regulatory recommendations, but even with a strong recommendation for second- or first-line use, median projected usage was only 21-30% and 31-50%, respectively. Only about a third or fewer of the survey's respondents projected use in over 50% of patients, and that was likely due to other barriers, its authors said.

Prior Authorization Barrier

BioMedTracker noted that many insurance companies currently only require a prior authorization form to be filled out, but that, according to physician reports, insurers often call back with additional questions, and that consequentially a considerable amount of staff time is taken filling out pre-authorization.

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Novartis still believes Entresto will eventually have peak sales of $5bn officials – and says insurers are using the PA process as a barrier to Entresto and thus preventing the drug from reaching that level as quickly as the company had originally expected.

Novartis' CEO Joe Jimenez on April 27 told a first-quarter earnings call that "there still is prior authorization that's slowing some uptake, as well as physician reluctance to switch stable patients. But we're working very hard on this and we're still very confident in the long-term peak sales of Entresto just given the data on that drug."

Pharma division head David Epstein echoed that, adding: "Insurance companies and other payers have gotten much smarter about putting additional hurdles in place. In particular, they're very good at using prior authorizations. Each insurance company has a different prior authorization form for the product. And in fact, they have different prior authorization forms for Entresto."

Medicare Payments Incentives Seen Lacking

Real Endpoints CEO Roger Longman agreed that pre-authorization requirements pose a challenge.

"More importantly, however, from the reimbursement point of view, is that many of the plans who would have to reimburse Entresto are Medicare prescription drug plans, and they have virtually no incentive to pay for this drug."

"Unlike fully insured commercial plans or Medicare Advantage plans, PDPs (prescription drug plans) do not benefit from Entresto's ability to reduce cardiovascular events and hospitalization. And Entresto patients are likely to bring other co-morbidities - and thus will cost the PDPs more money. In our view, prescription drug plans will likely resist making access to Entresto straightforward until Medicare forces them to," Longman said in reaction to the BioMedTracker survey's findings.

Real Endpoints chief medical officer Beth Nash noted: "From the physician's point of view, these patients are very difficult to manage. If they are even quasi-stable on current therapy, physicians will want to keep them there - and not rock the boat!"

"And regarding guidelines: in truth, most doctors don't really think about them too much. But if Entresto were included in guidelines, it might decrease some of the pre-authorization obstacles and give the drug a bit more credibility," Nash added.

That view seemed to be reflected in comments by Novartis' David Epstein when he told analysts April 27 that "the only way prior authorizations will come off is when products become so common that the burden of processing the prior authorizations for the insurer outweighs their ability to actually inhibit prescribing, which means it will not be guidelines, but rather it will just be time and market and continued sales growth for the product. And when the product becomes standard of care, those PAs will go away. When is that going to be? It's not going to be this year and it's not going to be next year."

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