Closer Look

MEMORANDUM

J&J's Invokana (canagliflozin) receives positive government cost-effectiveness ruling in UK, negative ruling in Germany - June 26, 2014

Executive Highlights

- J&J's SGLT-2 inhibitor Invokana (canagliflozin) received a positive recommendation from the UK's National Institute for Health and Care Excellence (NICE), securing NHS reimbursement.
- The German Institute for Quality and Efficiency in Healthcare (IQWiG) handed down a "no additional benefit" ruling for Invokana due to a lack of "suitable data."

The United Kingdom's National Institute for Health and Care Excellence (NICE) announced its final appraisal on Tuesday of J&J's SGLT-2 inhibitor Invokana (canagliflozin), which was launched in the UK earlier this year - the launch was a major point during this year's Diabetes UK meeting. NICE is recommending canagliflozin for type 2 diabetes patients as an add-on to metformin, but only in patients who cannot take a sulfonylurea or who are at significant risk for hypoglycemia or its consequences (we hope this is interpreted broadly). Additionally, canagliflozin is recommended as an addition to therapy on metformin and an SFU, metformin and a TZD, or insulin (with or without other drugs). AZ's SGLT-2 inhibitor Forxiga (dapagliflozin), which was approved in Europe early last year and received a positive appraisal from NICE in June 2013 following a preliminary negative decision, had a slightly different NICE recommendation. Specifically, dapagliflozin was recommended for use in addition to metformin without the restrictions applied for canagliflozin. However, it was not recommended for use in addition to metformin and a sulfonylurea. We imagine these nuanced differences might be due to some extent to differences in the sponsors' clinical trial program. Sulfonylureas factor fairly prominently in the NICE recommendations because NICE guidelines suggest them as a second-line therapy following metformin in most type 2 diabetes patients. The positive NICE recommendation secures coverage by the UK National Health Service (NHS). For a window into NICE's decision-making process, see our coverage of a talk at Excellence in Diabetes 2013 by Dr. Amanda Adler (Addenbrooke's Hospital, Cambridge, UK).

On the continent, Invokana recently received some less positive news: the German Federal Joint Committee's (G-BA) Institute for Quality and Efficiency in Health Care (IQWiG) ruled that Invokana shows "no additional benefit" to standard of care (sulfonylureas) because J&J's dossier did not meet the G-BA's requirements (read the IQWiG press release) for "suitable data" and interpretability, not because of the actual data on efficacy. If the G-BA agrees with IQWiG's ruling (which it generally does), it would strip Invokana of its pricing premium and effectively relegate it to generic-level pricing. Many other companies and drugs have run into a similar IQWiG/G-BA rulings; the result has been the withdrawal of products from the market or a pre-emptive decision not to launch a product in Germany. However, as we learned with AZ's Forxiga, a negative G-BA ruling is not the end of the road. Late last year, AZ announced that it would withdraw Forxiga from the German market following a G-BA "no additional benefit" ruling, but the company later announced during its 1Q14 update that it was re-launching the product following successful re-arbitration on pricing. We imagine the pushback from the public on the G-BA's vendetta against new diabetes drugs has been substantial, which hopefully is driving the G-BA to be more reasonable in its demands.

We always knew that the differential reimbursement processes in different European countries posed challenges for drug manufacturers, but this paired set of announcement evinces how confusing and (on occasion) contradictory the quest for reimbursement has become.

-- by Manu Venkat and Kelly Close