
CVS Caremark and Express Scripts release 2016 formulary exclusions - August 24, 2015

Executive Highlights

- CVS Caremark and Express Scripts released their 2016 formulary exclusion lists this month. The CVS list includes 124 products while Express Scripts' includes 80 products.
- J&J's Invokana (canagliflozin) and Invokamet (canagliflozin/metformin) are newly excluded from the CVS formulary.
- AZ saw losses on both lists with Bydureon (exenatide once-weekly) excluded from the CVS formulary and Onglyza (sitagliptin) excluded from both CVS and Express Scripts.
- Vivus' Qsymia (phentermine/topiramate extended-release) was newly excluded from both formularies - the only anti-obesity drug to be excluded.

Pharmacy benefit managers (PBMs) [CVS Caremark](#) and [Express Scripts](#) recently released their 2016 formulary exclusion lists, which will go into effect January 2016. In terms of diabetes products, CVS and Express Scripts' exclusion lists demonstrated clear preference for certain diabetes and obesity drug companies over others. On the CVS formulary, AZ and J&J lost out in the GLP-1 agonist and SGLT-2 inhibitor arenas, respectively, while Novo Nordisk remained a clear favorite. In contrast, Express Scripts has continued to exclude several Novo Nordisk products in favor of AZ and Lilly alternatives. On the device front, J&J's OneTouch strips and kits continue to be preferred by both CVS and Express Scripts over strips by Abbott, Bayer, Roche, or any other company. In obesity, Vivus' Qsymia (phentermine/topiramate extended-release) was dropped from both formulary lists - it is currently the first and only anti-obesity drug to be excluded from either formulary.

As CVS and Express Scripts are two of the largest PBMs in the US, a drug's exclusion from either or both formulary lists could spell little to no commercial insurance coverage and pose significant barriers to patient access. Formulary exclusion lists have become the new normal since CVS published the first list of 34 exclusions in 2012 - the threat of exclusion has been frequently used as leverage in drug price negotiations with pharmaceutical companies. From the very beginning, we've seen significant impacts on drug sales following formulary exclusion - Lilly's Humalog [took a hit](#) in 2012 when it was excluded from CVS' formulary. Since then, formulary exclusion lists have only grown - CVS' list now stands at 124 products (up from 95 on the 2015 list) and Express Scripts' list comes in at 80 products (up from 66 in 2015). Though individual health plan clients of each PBM can customize their own formulary lists and may choose to continue coverage for some drugs on the exclusion list, we expect to see a notable impact on overall sales nonetheless - Novo Nordisk, for example, saw a significant impact in [1Q14](#) after losing major Express Scripts contracts for NovoLog and Victoza that continued to ripple throughout 2014.

- **J&J lost out on CVS' list - both SGLT-2 inhibitor Invokana (canagliflozin) and the fixed-dose combination Invokamet (canagliflozin/metformin) are newly excluded from the formulary.** In its place, AZ's Farxiga (dapagliflozin) and Xigduo XR (dapagliflozin/metformin) and Lilly/BI's Jardiance (empagliflozin) are preferred alternatives. Invokana currently dominates the SGLT-2 inhibitor market with \$318 million in [2Q15](#) sales and 69% market share, compared to Farxiga's 28% and Jardiance's 2%. To be sure, the product likely owes much of its success to strong reimbursement - J&J has repeatedly highlighted its achievement of 80% preferred access at recent company updates and exhibit hall displays - and this news could potentially represent a significant stumbling block in 2016. Notably, all currently available SGLT-2 inhibitors remain included on Express Scripts' formulary.

- **AZ's Bydureon (exenatide once-weekly) joins its other GLP-1 agonist Byetta (exenatide twice daily) on the CVS exclusion list.** Market leader Novo Nordisk's Victoza (liraglutide) and newcomer Lilly's Trulicity (dulaglutide) are preferred alternatives. In contrast, Express Scripts continues to prefer AZ's products and Trulicity over Victoza and GSK's Tanzeum (albiglutide). As a reminder, Victoza currently leads the market with 70% of sales, followed by a combined 23% for Byetta and Bydureon. Trulicity holds 5% of the market but we expect to see that number grow as the product becomes more established (it's still early in its launch cycle) due to its ease of use and enviable position as a preferred GLP-1 agonist for both major PBMs.
- **AZ's Onglyza (saxagliptin) was newly moved from Express Scripts' preferred list to its exclusion list, where it joins Takeda's Nesina (alogliptin).** This exclusion comes on the heels of recent concerns surrounding a class effect on heart failure (see our [coverage](#) of the FDA meeting on SAVOR and EXAMINE, CVOTs for Onglyza and Nesina, respectively), although FDA panelists favored a vote on an acceptable CV risk profile. Both Onglyza and Nesina are excluded from the CVS formulary as well. Merck's Januvia (sitagliptin) and Lilly/BI's Tradjenta (linagliptin) are the preferred alternatives for both formularies. We suspect that Januvia's [positive TECOS results](#) may have contributed to this decision, maintaining the drug's unwavering leadership in the DPP-4 inhibitor class.
- **There were no notable changes to the two exclusion lists on the rapid-acting insulin side** Express Scripts continues to exclude Novo Nordisk's NovoLog (insulin aspart) and Novolin in favor of Lilly's Humalog (insulin lispro) and Humulin while CVS continues to exclude Humalog and Humulin in favor of NovoLog and Novolin. The awarding of the exclusive Express Scripts contract to Humalog in 2014 gave the product a significant boost in sales (though likely at the expense of increased rebates) last year. We have [heard](#) that NovoLog made the greater formulary gains in the 2015 cycle overall, but any changes do not appear to have had a major impact on sales. Barring any major changes from other payers, the situation looks to remain fairly stable in 2016. Novo Nordisk continues to modestly lead the rapid-acting insulin market with 51% of total sales compared to Lilly's 43%. Sanofi's Apidra (insulin glulisine) is excluded from both formulary lists and holds a mere 7% of the market.
- **Vivus' anti-obesity drug Qsymia (phentermine/topiramate extended-release) was newly added to the exclusion lists of both CVS and Express Scripts.** Express Scripts lists generic phentermine as the preferred alternative while CVS included Arena/Eisai's Belviq (lorcaserin), Orexigen/Takeda's Contrave (bupropion/naltrexone extended-release), and Novo Nordisk's Saxenda (liraglutide) as preferred alternatives. We find it notable that generic phentermine is the sole preferred alternative under Express Scripts, as it is not approved for chronic use and its widespread use and low cost remains a barrier for Qsymia's uptake. During the Q&A of Vivus' [2Q15](#) call, management noted that it was unaware of the Express Scripts exclusion, maintaining its belief that the company has good coverage with Express Scripts and that there should not be a huge impact on sales since only certain payers users use this exclusion list. We're a bit surprised to hear this view considering Express Scripts is indisputably the largest PBM and much larger companies have faced significant setbacks as a result of exclusion from its formulary. We note that it is probably important to take into account Vivus' recent financial challenges and that this exclusion may indicate a lack of resources to negotiate favorable formulary contracts. We are glad to see all other obesity drugs move forward on the reimbursement front, increasing patient access for such costly, but much needed, medications.

-- by Helen Gao, Melissa An, Emily Regier, and Kelly Close