Rapid growth in PBM exclusion lists poses challenge to drug developers

Rising drug prices help drive PBM and payer exclusion list growth

- The number of drugs on the exclusion lists (i.e., containing non-covered drugs) of the two largest pharmacy benefit managers (PBMs) in the U.S. has grown by around 65% from 2014 to 2016.

- Drug manufacturer rebates to PBMs appear to play a key role in exclusion decisions, as do coupon or co-pay offset provisions offered by drug manufacturers to patients.

- For 10 of 16 drugs excluded by both PBMs, no comparative clinical or cost-effectiveness studies had been conducted, which increases PBM or payer uncertainty regarding a drug’s value, making it more likely that a drug will be excluded.

- Cost-effectiveness does not appear to correlate with exclusion status.

- More cost-effective brand name (single source) drugs are not always recommended over other less cost-effective brand name drugs in the same therapeutic class.

Payers are responding to rising drug costs with new, more restrictive formulary management policies, including exclusion lists. These lists contain drugs that are not eligible for reimbursement, as well as recommended alternatives in the same therapeutic class that are covered. Exclusion lists are intended to reflect a drug’s clinical and cost-effectiveness, based on establishing clinical equivalency of drugs in a therapeutic class and assessing the costs of therapeutic alternatives. Excluded drugs are those that purportedly offer no additional benefit over alternative treatments in the same therapeutic class.

With prescription drug spending in the United States rising—having grown more than 8.5% in 2015, and projected to continue rising—payers and PBMs can be expected to expand their exclusion lists. For example, CVS Caremark and Express Scripts, the two largest PBMs in the U.S., have significantly enlarged their exclusion lists in recent years. Going forward, PBMs and payers will continue to respond to rising drug costs by embracing novel approaches to formulary management, which will challenge the biopharmaceutical industry to provide more concrete evidence of clinical superiority and cost-effectiveness of their products.