

Emerging Barriers to Launch Access – the Impact of New Drug Coverage Policies

New drug coverage policies provide guidance around a payer’s coverage of new drugs in the time period between FDA approval and P&T committee review. As these policies proliferate, manufacturers may find initial new drug launch access to be more limited than anticipated.

Key Findings

Commercial and Medicare Part D payers have implemented new drug coverage policies which do not provide access for the majority of lives in those lines of business across the US (see Figure 1).

Some large payer such as Tricare and the BCBS Federal Employees program provide generous initial access for new brands. This suggests that manufacturers consider targeting similar types of payers during the critical first 6 months post-launch time period.

Implications for Life Science Manufacturers

In the commercial line of business, major payers such as Express Scripts, CVS, United Healthcare, Anthem and Aetna have implemented “not covered” policies for new drugs (see Figure 2).

In Medicare Part D, access is particularly limited as literally all payers have implemented policies which do not provide any initial coverage among the non-protected therapeutic classes.

While payers can make exceptions to new drug coverage policy, this is typically dependent upon therapeutic class management goals and the clinical profile of the new drug of interest.

Payer	Policy (majority of lives)	Targeted P&T review timeline
Express Scripts	Not Covered	6 months
CVS		
United		
Anthem		
Aetna		
Tricare	Covered	4 months

~70%
of lives are Not Covered at launch

Top 3 with Coverage and No PA (not including Tricare)
BCBS FEP
Horizon BCBS NJ
Excellus

~30%
Covered (15%) or Covered with PA (15%) at launch

Figure 2: Commercial New Drug Policy Summary

Many new brand revenue forecasts are based on access assumptions which reflect post P&T review access; manufacturers need to account for the impact of new drug coverage policies to accurately inform new brand forecasts.

Conclusions / Action Steps

Manufacturers must distinguish between new drug coverage policy access and post P&T review access – failure to do so may result in revenue forecast errors which can have material impact on projected new brand earnings.

To counter the unfavourable access created by new drug coverage policies, manufacturers need to consider alternative strategies such as out-of-pocket cost offset programs to create initial demand for new to market brands.

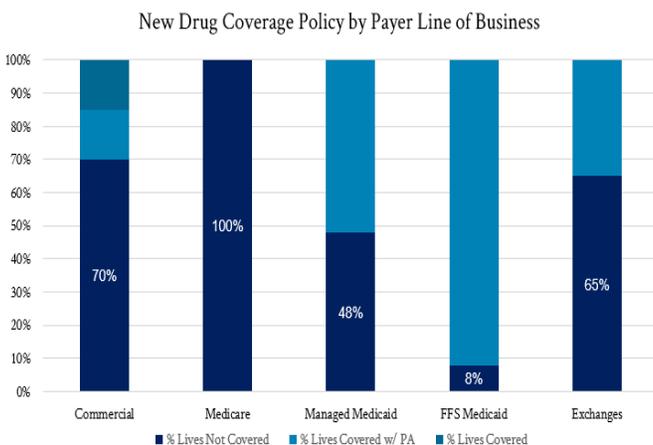


Figure 1: New Drug Coverage Policy Summary