A Survey-Based Analysis of Formulary Decision Making and Utilization Management Trends Across Managed Care Organizations

Authors: Isha Bangia, *PharmD MBA*[1]; Ulrich Neumann *MSc, MA, FRSA*[1,2]; Maximilian Vargas, *PhD, MBA*[1]

[1] *Certara (New York, NY)*
[2] *Imperial College for Medicines, Science and Technology (London, UK)*

BACKGROUND

- Volume and prices of marketed specialty products continue to rise, leading to a severe cost burden for healthcare stakeholders. Managed care organizations (MCOs) employ a host of strategies and tools to manage specialty drug utilization. The specific level of implementation today, and the prospect of future expansion of these measures is often unclear though

OBJECTIVES

- To assess the current and future extent of formulary decision and utilization management (UM) for specialty products in Commercial and Medicare lives
- To illustrate key emerging trends and implications for developers around prior authorizations, reauthorizations, product exclusion and preferred status for drugs on the medical benefit, use of split-fill programs, evidence-based pathways, step edits and quantity limits

METHODOLOGY

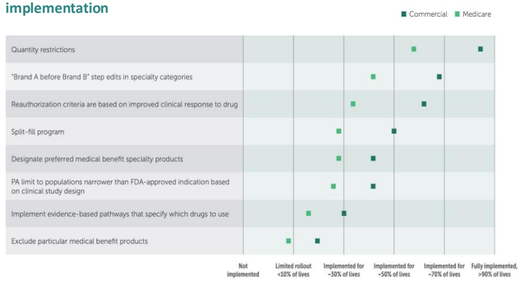
- Using Certara's Compass research network, we conducted an online survey among active voting members of P&T committees in US MCOs, followed by a set of semi-structured interviews
- A targeted literature review was conducted to contextualize the research in the current landscape of specialty pharmacy drugs
- Of 31 respondents, 19 were pharmacy directors and 12 were medical directors. These payers represent 198.8M US lives (169.6M Commercial and 29.2M Medicare lives). All 31 respondents were responsible for Commercial lives and 25 of the 31 responsible for Medicare as well
- Respondents were comprised of national (n=17) and regional health plans (n=14), pharmacy benefit managers (PBMs; n=7) and integrated delivery networks (IDNs; n=6)
- MCOs were also categorized by size, based on the number of covered lives, into large, mid-sized and small health plans:
  - Small plans: <920,000 lives; n=7 plans
  - Mid-sized/medium plans: (≥920,000 lives and <3.4M lives) (n=8 plans)
  - Large plans: (≥3.4M lives) (n=11 plans)
  - PBMs: 59.5M lives (6 unique organizations)
  - IDNs: 24.4M lives (6 unique organizations)
  - Small plans: 3.4M lives (7 unique plans; includes PBMs and IDNs)
  - Mid-sized/medium plans: 13.5M lives (8 plans; incl. PBMs and IDNs)
  - Large plans: 182M lives (11 unique plans; includes PBMs and IDNs)

LIMITATIONS

- Estimates and findings are based on a qualitative methodology. Certara has not accounted for any overlap in covered lives between health plans. As such, findings on the trends we document should be considered indicative rather than conclusive

RESULTS

Figure 1 | Average level of UM among payers, ranked by current level of implementation



TREND I & II: Prior Authorizations and Reauthorizations

- Currently 55% of surveyed payers utilize PAs beyond the label for an estimated 70% or more of their commercial and Medicare lives
- All commercial payers plan to expand the use of more stringent PA criteria for specialty medications. All PBM respondents and nearly 80% of IDNs are likely to expand implementation of narrow PA in the future
- Two-thirds of payers utilize reauthorization criteria based on improved clinical response to drug for at least 70% of commercial lives, including 86% of PBMs, 80% of small and mid-sized plans, 66% of IDNs , and 56% of larger MCO plans
- There will be a 62% increase in the number of payers using reauthorization criteria for Medicare lives, up from 42% to 68% of payers.. Nearly 9 in 10 commercial payers are likely to expand future use of reauthorization criteria as a means for cost containment

Figure 2 | PA use beyond the label

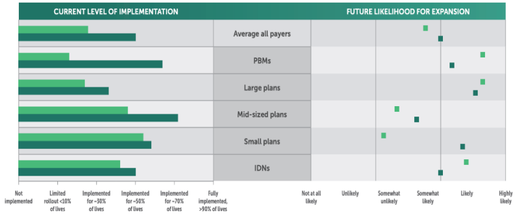
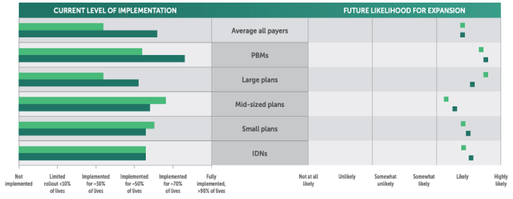


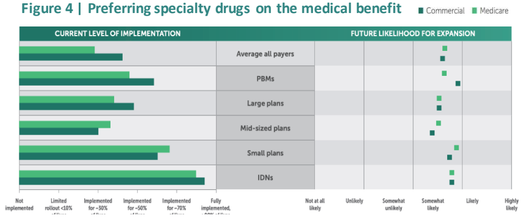
Figure 3 | Reauthorization based on clinical response



TREND III: Preferred Specialty Products on the Medical Benefit

- Compared to treatments on the medical benefit, medications covered on the pharmacy benefit traditionally allow payers to have more control on management and utilization
- All surveyed IDNs currently implement preferred medical products for 70% or more lives and 1 in 2 MCO plans, regardless of plan size, implement this UM tactic for medical benefit drugs
- Going forward, all payers will likely expand, or in the case of IDNs continue, this model of preferred medical treatments

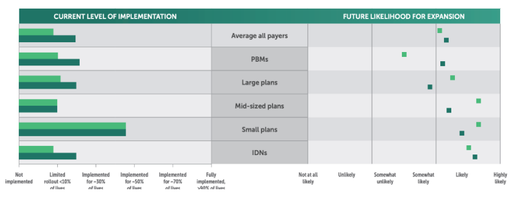
Figure 4 | Preferring specialty drugs on the medical benefit



TREND IV: Increasing Product Exclusions of Specialty Drugs

- Despite reported rise in formulary exclusion lists, there is still overall limited implementation of product exclusions across all payers today, with a quarter of payers currently excluding specialty products covered on the medical benefit for 70% or greater covered commercial lives; a majority of these are smaller plans
- More than two-thirds of the 31 payer respondents are likely to begin excluding particular medical benefit products

Figure 5 | Product exclusions



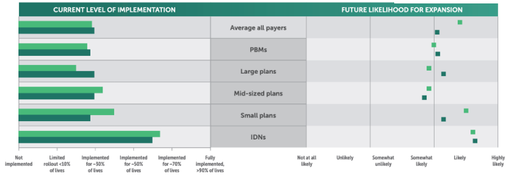
TREND V: Split-Fill Programs

- Only about 30% of all payers have not implemented any split fill programs for specialty products within their organizations, half of them PBM and IDN payers
- In the future, the use of split-fills is likely to remain relatively constant, with 75% of payers continuing use. Oncology, inflammatory conditions and multiple sclerosis are top indications in which payers implement split fills, though split-fill is present in other indications like diabetes, asthma and hypercholesterolemia

TREND VI: Increased Use of Evidence-Based Pathways

- PBMs and IDNs report the highest level of implementation of evidence-based pathways, as well as the highest expressed interest to expand them further
- Rheumatology, cardiology, diabetes and multiple sclerosis are reported as having the most uptake of evidence-based pathways outside of oncology. Clinical guidelines and randomized controlled trials are the most common sources payers list for establishing evidence-based pathways
- 60% of payers (of which half are large health plans), are likely to implement evidence-based pathways that specify which drugs to use in the near future; this is an almost 4-fold increase from the status quo of payers fully utilizing evidence-based pathways for Commercial lives. As larger plans are more likely to adopt evidence-based pathways, smaller and mid-sized plans may follow suit
- Oncology, diabetes, and multiple sclerosis are key therapeutic areas where payers rely on evidenced-based pathways in formulary decision-making

Figure 6 | Evidence-based pathways

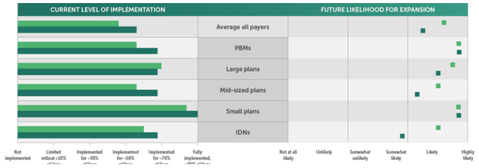


RESULTS (cont'd)

TREND VII & VIII: Quantity Restrictions and Step Edits

- Not surprisingly, quantity limits and step edits are cited as two prolific types of UM restrictions payers use in drug management
- Quantity restrictions and step edits are the most implemented UM tactics, with the latter seeing further expansion across all payer types in the future

Figure 7 | Step Edits



CONCLUSIONS

- Developers of specialty pharmaceuticals will be subject to more stringent reauthorization criteria which will likely align with clinical response, while clinical trial designs are subject to scrutiny to limit product use with a narrower PA than the FDA label
- Developers must be proactive with payer engagement to understand the current reauthorization environment for their product's respective indication and competition. A robust assessment of clinical trial designs through the payer perspective, early on in the clinical development, is warranted
- Strong engagement with payers via advisory board and primary research provides vital insight on PA management and criteria that may be included in PAs
- Payers express a strong desire to manage the medical benefit like the pharmacy benefit and increasingly integrate coverage decisions across both categories. In shifting the medical benefit to parity with the pharmacy benefit, they hope to draw more heavily on UM tactics such as product exclusions and preferred products
- The interest in an expanded use of product exclusions by payers suggests that they are unable to distinguish value across products and report using exclusions to engender a negotiation for deeper rebates with developers
- More then even, developers must demonstrate and leverage attributes of product value that may warrant a preferred status, outside of, and beyond price

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