State Insurance Regulations Regarding Benefit Design (Deductible and Co-Pay Waivers). FoCUS has identified an issue that may be a barrier to timely patient access to durable therapies. The advent of expensive, one-time durable therapies will require changes in private payer benefit packages in order to avoid onerous financial burdens on patients and their families, which could result in delays due to state insurance review processes.

THE CHALLENGE TO EXISTING BENEFIT PACKAGES FROM DURABLE THERAPIES

The current price-points of durable therapies is markedly higher on average than previous pharmaceutical products, which is a trend that is expected to continue for the foreseeable future. These new, expensive treatments often require only a single administration which can create an onerous financial burden on patients and their families. Current private insurer benefit packages include deductible and coinsurance rates that may not mitigate out of pocket expenses sufficiently to enable patients and their families to access these products. For the twenty percent of those with employer-based health insurance in 2018 who had a plan that required policyholders to pay more than $6000 in maximum out of pocket expenses before reaching 100% insurance coverage, for example, these treatments would immediately require the payment of any remaining annual out of pocket payment in one sum. Patients and their families would likely face an even greater financial burden if the provider were not part of their plan’s network.

In previous Design Labs payers have noted that because durable therapies are selectively targeted to very specific patients the use of copays to discourage overuse are inappropriate in these cases and a waiver of patient contributions might be appropriate. Modifying insurance plan designs to accommodate copay waivers requires approval from state insurance regulators, however, which can take as long as 18 months to complete. This delay could pose

KEY TAKEAWAYS

The advent of expensive, one-time durable therapies will require changes in private payer benefit packages to make these treatments accessible for patients and their families.

Any change by private insurers to their existing products will trigger state insurance board reviews, even if these changes lower the cost of treatment for patients.

It appears likely that states would allow expedited review on a case-by-case basis in extraordinary circumstances.

One solution that would allow insurers and state regulators to avoid excessive expedited review requests would be for payers to include policy language that automatically lowers copays to a pre-determined amount when a treatment crosses a specified cost threshold.

Determining the copay rate for durable therapies will require payers to balance patient accessibility with marketplace competitiveness.
significant problems for patients who are in dire and immediate need of newly approved therapies.

FoCUS reached out to seven state insurance offices across the US to understand how they manage situations in which private payers submit patient-favorable changes to their benefit plans. We posed two questions: Would a benefit change trigger a state review even if that change would lower the cost to consumers for treatment under that new insurance product? If so, had the state ever expedited this process for extraordinary circumstances?

We gathered data from a geographically diverse set of states across the US: Alaska, Arkansas, Iowa, Massachusetts, New Mexico, Oregon, and Virginia.

RESULTS
Our research indicates that there is a broad consensus around both questions. All seven state insurance offices replied unequivocally that any change in a private payer benefit package would trigger a state review, no matter what the private payer said about who was to benefit from those changes. Several officials explained that they believed it to be incumbent upon them to verify the private insurers’ assertions of a reduction in cost to consumers.

There was also consensus around the issue of expediting the review process under extraordinary circumstances, though on this question there was a more diverse set of explanations. One state official noted that their state requires this process to be completed in 60 days no matter what the circumstance, while two other officials offered specific examples of their state expediting this process in life-or-death situations. The other four state regulators simply answered that there was a precedent for expediting this review process if the situation warranted it.

CONCLUSIONS AND RECOMMENDATIONS
This research suggests the strong likelihood that private payers could receive an expedited review process for lowering or eliminating copays in extraordinary circumstances on a case-by-case, state-by-state, basis. This approach could be laborious for both payers and states, however, especially as more and more relevant therapies hit the market.

Recommendations:
- One alternative that private payers could pursue would be to update their benefit packages to include specific language indicating that they will lower copay rates to a specific amount if the cost of a treatment crosses a pre-determined threshold.
- Determining what rate to set for copays on these more expensive therapies could involve at least two factors for private payers. The first would be the need to lower copays to a level that would allow patients and their families access to the product while monitoring competitor actions to avoid situations in which patients might switch insurers to access the therapy (i.e. adverse selection). The second may be the need to include language that targets durable therapies specifically, since the automatic lowering of copays above a certain cost threshold may incentivize manufacturers to raise prices on other products to hit this diminished copay price-point.

REFERENCES

ABOUT FOCUS
The MIT NEWDIGS consortium FoCUS Project (Financing and Reimbursement of Cures in the US) seeks to collaboratively address the need for new, innovative financing and reimbursement models for durable and curable therapies that ensure patient access and sustainability for all stakeholders. Our mission is to deliver an understanding of financial challenges created by these therapies leading to system-wide, implementable precision financing models. This multi-stakeholder effort gathers developers, providers, regulators, patient advocacy groups, payers from all segments of the US healthcare system, and academics working in healthcare policy, financing, and reimbursement in this endeavor.

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