PATIENTS RISING NOW

Patients Rising Now's Comments on Oregon's 1115 Waiver and Impact on Access

The FDA's Accelerated Approval Program provides a path for earlier approval of drugs being developed to treat serious diseases and address unmet medical need. The process allows the use of a surrogate endpoint—an indirect marker of clinical benefit that allows the drug to be approved and in the hands of patients earlier, while the company continues to conduct post-marketing "confirmatory trials" to establish the drug's benefits. It is important to understand that the FDA has processes in place to remove the drug from the market in case clinical benefit is not established with confirmatory trials.

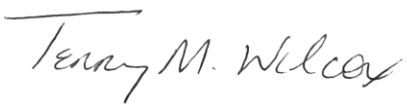
Oregon's 1115 Waiver Will Block Much-Needed Access to These Drugs

Oregon is asking to waive a key criterion that requires coverage for all FDA-approved drugs under the Medicaid Drug Rebate Program. If the waiver is approved, Oregon's Medicaid program would have a closed formulary for all adults, meaning there may only be one drug for each therapeutic class included in the formulary—a common restrictive strategy followed by commercial health plans. The decision for formulary inclusion would be based on the drug's price and the rebate being offered by the manufacturer. There are no exceptions or protected drug classes—unlike the closed formulary demonstration program that has been piloted by Tennessee Medicaid. Additionally, there is no mention of a process for enrollees to seek coverage for drugs not included in the formulary.

Oregon excludes coverage for children from its waiver request, undermining its stated justification of a waiver for a program for adults. The waiver gives Medicaid the power to decide which drugs have limited clinical benefit or "no incremental clinical benefit" compared to other drugs in the same class, even if they are approved by the FDA—this includes drugs that have received accelerated approval. This means that the Oregon Health Authority, may undermine and question the rigorous scientific and regulatory drug approval processes implemented by the FDA for the sake of cost savings.

Importantly, the proposed restrictive closed formulary will create access barriers for patients with chronic and debilitating conditions seeking prescription drugs and in turn have an adverse effect on their health outcomes. Patients Rising strongly opposes the implementation of such a restrictive program for Medicaid beneficiaries in Oregon—employing such policies will barricade patient access to innovative, life-altering treatment options.

Sincerely,



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