

Please see recommended additions in red.

Changes to Prescription Drug Benefits

Ability to define a preferred drug list for pharmacy benefits

Oregon seeks the ability to more closely manage pharmacy costs in its Medicaid program, through a two-part strategy:

Adopt a commercial-style closed formulary approach

Taking a closed formulary approach for adult members, including at least a single drug **with traditional approval** per therapeutic class, would enable OHA and CCOs to negotiate more favorable rebate agreements with manufacturers. Oregon would keep an open formulary for children. For each therapeutic class, manufacturers could be offered an essentially guaranteed volume in exchange for a larger rebate. Currently, OHA and CCOs have limited ability to offer such volume deals to manufacturers, given the requirement to cover all drugs in the Medicaid rebate program. OHA would create a collaborative process that includes CCOs to select drugs for the closed formulary. In recent years the majority of commercial pharmacy benefit managers (PBMs) have adopted such closed formularies, which allow them to customize their drug offerings based on clinical efficacy and cost considerations. As an example, for 2021 CVS Health excluded from its formulary 57 additional products—some because a less expensive, medically equivalent drug had become available and some because the drugs were hyperinflationary, having dramatically increased in price without clear justification. Medicare Part D commercial plans **are** also permitted to employ such closed formularies (as authorized under 42 CFR 423.120) with at least two drugs per therapeutic class. Medicare Part D plans may also include just a single drug per class if only one drug is available, or if only two drugs are available but one drug is clinically superior. Given that Medicare and other commercial plans are permitted to adopt closed formularies, we believe Oregon should have the same flexibility for Medicaid.

Allow exclusion of drugs with limited or inadequate evidence of clinical efficacy

Many drugs coming to market through the FDA's accelerated approval pathway have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints. Oregon seeks the ability to use its own rigorous review process to determine coverage of **drugs previously granted accelerated approval but have not confirmed benefit with conversion to full FDA approval in the expected time interval**. Through this process, the state could incentivize drug sponsors to complete their regulatory obligations to demonstrate clinical benefit as laid out by the FDA upon approval. This will allow Oregon to avoid exorbitant spending on high-cost drugs **marketed to treat conditions on the Prioritized List of Services that have yet to demonstrate a clinical benefit despite ample time to do so**. Many stakeholders agree that national policy changes are necessary to ensure proper oversight after approval of accelerated pathway drugs based on surrogate endpoints. Current rules do not allow Medicaid programs to exercise discretion about whether these drugs should be

covered without being fully clinically proven and despite drug sponsors not meeting obligations set forth as a condition of accelerated approval.

To that end, Oregon proposes to build on the success of the Prioritized List of Services and limit the coverage of drugs approved through the accelerated pathway without traditional approval. Under this proposal, Oregon would utilize the timelines set out in the FDA approval letter and review confirmation of benefit data in peer reviewed literature or clinicaltrials.gov. Applying the FDA developed guidance and timetables ensures a universal standard, clinically feasibility, and drug sponsor agreement.

New drugs approved under the FDA's accelerated approval pathway tend to be specialty medications that represent a significant portion of pharmacy expenditures. As such, it is our responsibility to ensure we are following through with the promise of expedited approval pathways. In addition, re-formulations of older, existing drugs that provide no incremental clinical benefit might be labeled non-formulary as well. While commercial payers can exercise discretion to exclude drugs from their formularies in certain situations, OHA and CCOs currently do not have this ability.