

Medicare's drug rule could penalize better treatments

By Peter J. Pitts

A cancer patient has better things to do than spend hours in an infusion chair. A medicine that safely reduces that burden represents progress, even when its ingredients are familiar.

Washington should encourage the research that makes such improvements possible. However, a proposed Medicare rule could make the next investment harder to justify.

Federal officials aim to finalize a change to how Medicare groups medicines for price negotiation. The Centers for Medicare & Medicaid Services wants certain combination drugs that enable a different route of administration to inherit the negotiation timetable of the older treatments they build upon.

CMS sees an opportunity to prevent manufacturers from shifting patients and spending into products outside negotiation. Fair enough. A policy aimed at protecting Medicare's negotiating power needs to account for what patients gain from the new product, and what it took to develop it.

Under the Inflation Reduction Act, medicines become eligible for negotiation after they've been on the market for a legally defined period, subject to spending rankings, competition, exclusions and other requirements. CMS groups different dosage forms and strengths of medicines that share an active ingredient and a manufacturer, with related rules applying to biological products.

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Grouped products generally share the earliest applicable eligibility date. Eligibility does not mean automatic selection, and negotiated prices take effect later.

CMS is proposing to group combination products with their predecessors as well. The problem is that inheriting an older negotiation clock can fundamentally change the economics of developing those products, which can have significant benefits for patients.

The proposed expansion concerns certain fixed combinations in which an added component enables a different administration route. Hyaluronidase, for example, helps make that switch from intravenous infusion to subcutaneous injection possible. Calling the resulting product another formulation of the same medicine does not answer the scientific question: What had to be developed and tested before a patient could receive it safely?

Consider PHESGO, which combines the breast cancer medicines pertuzumab and trastuzumab with hyaluronidase. It delivers the antibody treatments through a subcutaneous injection that takes eight minutes for the initial dose and five minutes for subsequent maintenance

doses. Required observation follows, and patients may need chemotherapy or other care.

A five-minute injection is not a five-minute clinic visit. Reducing administration time compared with IV treatment can still matter considerably to someone repeatedly returning for cancer care.

Developing that combination required more than putting familiar ingredients into a new package. The program included a randomized study of 500 patients that compared it with intravenous pertuzumab and trastuzumab, assessing drug exposure alongside efficacy and safety. The study showed that the combination could deliver these medicines differently while maintaining their established therapeutic effects.

PHESGO illustrates the investment concern. Its particular Medicare negotiation treatment requires a review of ownership, licensure history and other eligibility facts. If a new combination inherits a clock that has already been running for years, will the expected return still justify the research? Having recouped an earlier investment does not make the next clinical trial worth

funding. Developers must commit additional money before knowing whether the new formulation will succeed.

That's why CMS should reconsider its proposal and develop a more targeted approach. For combination products, the Food and Drug Administration can help examine which earlier findings were reused, what substantial new work was necessary, and whether the resulting product offers a meaningful patient benefit. CMS should then explain how that evidence affects its determination.

A separate eligibility clock should be available for qualifying products where legally authorized, with Congress providing authority where needed. Simply having a new application number or making a modest change should earn no automatic exemption, and the original product's clock should keep running.

The same concern extends to studying established medicines

for different diseases. A familiar molecule may require an entirely new clinical program to establish another use. Supplemental indications also need investment, although protecting that research requires a policy mechanism separate from restarting the clock for an entire product. Policy should reward useful development without sheltering established sales.

Drug innovation rarely arrives in a Hollywood "Eureka!" moment. Researchers build on accumulated knowledge, test another use, solve a delivery problem, and sometimes fail. Treating shared ingredients as sufficient reason to discount that work risks discouraging advances patients would value.

Medicare should negotiate firmly with manufacturers. It should also demand evidence for its own assumption that earlier price negotiations will still make investments in combination products worthwhile.

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