Prohibiting Midyear Formulary Changes is Bad for Consumers and Bad for Business

What is a formulary?

A drug formulary is a continually updated list of drugs that, as recommended, represents the best clinical judgment of a Pharmacy and Therapeutics (P&T) Committee comprising independent clinicians who are specialists in the diagnosis and treatment of specific diseases. The clinicians evaluate medications using current evidence and best practices, making recommendations on drugs that should be included on a health plan's formulary. Health plans and pharmacy benefit managers (PBMs) then apply benefit design techniques to the P&T committee's formulary list, typically with tiered cost-sharing for generics, brands, and specialty products, to encourage patients and prescribers to choose the safest, most effective and highest-value medications.

What are the benefits of a formulary?

Formularies comprise a list of prescription drugs that have been clinically evaluated by specialists before being included in a drug benefit. They limit use of ineffective and low-value drugs, while also ensuring that coverage is provided for any drug deemed necessary by the P&T Committee. Because benefits are designed to promote use of high-value drugs based on the P&T committee's recommendations, the application of formularies helps patients and plan sponsors get the best outcomes for the money they spend.

Rather than protecting patients, frozen formularies primarily increase costs:

Limiting a payer to a one-time per-year formulary update encourages drug manufacturers to increase prices, knowing that the consumer will be insulated from the price increase, while health insurers absorb the cost and premiums increase. Currently, there is no similar federal requirement on other health care benefits that must be provided without changes over the course of a plan year.

- For example, if legislation limiting mid-year formulary changes had been enacted when Abbvie's hepatitis C drug Viekira Pak came to market to compete with Gilead's Sovaldi and Harvoni, health insurers and PBMs would not have had the leverage to negotiate significant rebates on all of these expensive drugs in exchange for placement on the formulary as the preferred drug in such a timely fashion.
- If specific drugs are mandated to be covered by health insurers, union and Taft-Hartley plans, or any other employer-sponsored plan, brand drug manufacturers have no incentive

to provide price concessions on their drugs to make them more affordable for patients. Market forces to drive down the cost of drugs will be delayed.

Freezing formularies could keep plans from excluding even unsafe drugs:

Under some proposed legislation, health insurers and PBMs would not be able to quickly adjust coverage as evidence shows serious safety problems.

- For example, some health insurers stopped covering Vioxx, thereby protecting their enrollees, well before the FDA acted on reports that the drug resulted in serious, even fatal, cardiac problems.

Adequate processes for accessing non-formulary drugs already exists:

If a patient needs to access a non-formulary drug, health plans and PBMs have in place appeals processes for patients to request coverage. The health insurer or PBM works with a patient and his or her provider to provide access to non-formulary dugs where medically necessary and/or likely to create the best outcome.

Medicare Part D allows for mid-year formulary changes:

Currently the Medicare handbook states that, "[p]rescription drug therapies are constantly evolving, and new drug availability, medical knowledge, and opportunities for improving safety and quality in prescription drug use at a low cost will inevitably occur over the course of the year… these new developments may require formulary changes during the year in order to provide high-quality, low-cost prescription drug coverage."[1] Thus, the Medicare program recognizes the importance of flexibility in formulary design for patient safety and quality of care.

The HHS OIG found that the majority of all formulary changes in Medicare Part D were for adding drugs:

More importantly, only thirty-six percent of formulary changes were to remove drugs and of those, 62 percent involved generic substitution.[2]

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[1] CMS, "Medicare Prescription Drug Benefit Manual," January 15, 2016, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf

[2] HHS OIG, "Midyear Formulary Changes in Medicare Prescription Drug Plans," December, 2009, https://oig.hhs.gov/oei/reports/oei-01-08-00540.pdf