Generic prices and the role of nonpreferred generic tiers in Part D

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Trends in generic drug industry

- Recently, the generic drug industry has experienced two concerning trends
  - Generic drug shortages in cardiovascular, anti-infective, and central nervous system drug classes
  - Very large price increases of some generics
- Over time, shortages and price increases can pose a problem for patients

Factors that may contribute to shortages

- Manufacturing delays due to quality problems or loss/change in manufacturing site
- Limited manufacturing capacity of drug producers
- Shortage of raw materials
- Industry argument: low provider reimbursement / low profit margin

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Factors that may contribute to price increases

- Drug shortages
- A lack of competition, too few manufacturers
- Barriers to entry
- Anti-competitive behavior of drug manufacturers
- Market exit by drug manufacturers

External ideas to combat shortages and price increases

- Removing barriers to entry to promote competition in generics market
- Price transparency
- Early reporting of potential shortages or increases to FDA/HHS
- Increased oversight by FTC of anti-competitive behavior
- Expediting FDA applications of potential manufacturers for drugs facing shortages

Part D plans’ use of tiered cost sharing

- Encourage enrollees to use lower-cost drugs:
  - Lower cost sharing for generics compared to brand-name drugs
  - Lower cost sharing for preferred brands (lower cost net of manufacturer rebates) than nonpreferred brands
- Move towards more tiers over time
- Most plans now have 5 tiers (2 generic tiers, 2 brand tiers, and a specialty tier)

Potential reasons to use a nonpreferred generic (NPG) tier?

- Encourage the use of lower-priced generics and share more of the costs of higher-priced generics
- Encourage the use of certain therapies (e.g., guideline-recommended medications)
- To meet actuarial equivalence (e.g., average cost-sharing of 25% across all drugs)
- Others?

- Effects on beneficiaries and Medicare spending depend on how NPG tiers are used

Use of nonpreferred generic tiers in 2015

- Widespread use of NPG tier
  - About 90%* of plans
  - Over 80%* of enrollment
- Strategy to encourage use of lower-cost generics or share cost of higher-cost generics?
  - LIS benchmark PDPs are <u>less</u> likely than non-benchmark PDPs to use NPG tier
  - Typically, a modest copay increase ($3 - $7) for NPG tier (vs. preferred generic, or PG tier)
  - Generics with large price increases are not always placed on NPG tier

➔ Factors other than cost / cost-shift may motivate plans to use an NPG tier

Note: *Figures exclude special needs plans.
Source: NORC/Social & Scientific Systems analysis for MedPAC of formularies submitted to CMS and Part D enrollment data from CMS.

Are certain classes more likely to be placed on PG or NPG tier?

- NPG tier is the most common placement across all classes
  - Overall, less than 15% of generics are on PG tier, while slightly over 40% are on NPG tier
  - Some generics are placed on brand tiers
- Varies widely across drug classes
  - Cardiovascular agents are more likely to be placed on PG tier (31%)
  - Antineoplastics and central nervous system agents less likely to be placed on PG tier (6% and 2%, respectively)
- Guideline-recommended medications* were mostly placed on NPG or brand tier

Note: *Oster G. and Fendrick M. 2014. Is All “Skin in the Game” Fair Game? The Problem With “Non-Preferred” Generics. *The American Journal of Managed Care* 20, no. 9 (September): 693-695.

Cost-sharing and low-income subsidy implications

- Generic drugs placed on
  - NPG tier (vs. PG tier) typically increase copay by $3 among PDPs and $7 among MA-PDs (comparable to generic tier copay of $5 in 2007)
  - Preferred brand tier (vs. PG tier) typically increase copay by about $40
  - Nonpreferred brand tier (vs. PG tier) typically increase copay by about $70 - $90
- Potentially larger copay/subsidy increases if filling prescriptions at pharmacies offering standard (not “preferred”) cost sharing

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Summary from an examination of the role of NPG tier in Part D

- Use of NPG tier does not appear to be related to:
  - Higher prices (based on rates of price increases)
  - Clinical criteria (most evidence-based therapies were on NPG tier)
- NPG tier appears to be the primary generic tier
  - Most generics and placed on an NPG tier
  - Only a modest increase in copay ($3 - $7) vs. PG tier
  - Copay amounts for NPG tier comparable to copays applied to "generic" tier
- Copays for NPG tier are not high enough to raise immediate access concerns, BUT could raise concerns for access and LIS costs, if:
  - NPG tier copays increase substantially, or
  - More generics are placed on brand/specialty tiers