

Insulin Access and Affordability Working Group: Conclusions and Recommendations

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CONCLUSIONS

- List prices of insulin have risen precipitously in recent years. Between 2002 and 2013 the average price of insulin nearly tripled.
- The current pricing and rebate system encourages high list prices:
 - » As list prices increase, the profits of the intermediaries in the insulin supply chain (wholesalers, pharmacy benefit managers [PBMs], pharmacies) increase since each may receive a rebate, discount, or fee calculated as a percentage of the list price.
- There is a lack of transparency throughout the insulin supply chain. It is unclear precisely how the dollars flow and how much each intermediary profits.
 - » Manufacturers are rarely paid the list price for insulin. The so-called net price—which reflects what the manufacturers receive—is much lower; however, in most cases, the data are not publicly available.
 - » In the vast majority of cases, discounts and rebates negotiated between PBMs and manufacturers, and between PBMs and pharmacies that affect the cost of insulin for the person with diabetes, are confidential.
- PBM clients (often large employers in most cases) are not privy to these negotiations, nor do they know the net price obtained by the PBM for insulins.
 - » Formulary considerations and decisions are not transparent.
- PBMs have substantial market power.
 - » PBMs' primary customers are health plans and employers, not patients.
 - » PBMs negotiate rebates from manufacturers using formulary placement as leverage.
- PBMs often exclude from the formulary insulins made by the manufacturer that offers the lowest rebate.
- As a result of negotiation, rules for coverage differ from plan to plan and year to year, or even within the same plan year.
- When insulins are excluded from the formulary, moved to a different cost-sharing tier or removed during the plan year, it places a burden on people with diabetes and providers and may have a negative health impact.

- » PBMs receive administrative fees from their clients (health insurance plans) for utilization management services (prior authorization, etc.). Often, it is the PBM that determines which and how many drugs on the formulary are subject to utilization management.
- People with diabetes are financially harmed by high list prices and high out-of-pocket costs:
 - » Regardless of the negotiated net price, the cost of insulin for people with diabetes is greatly influenced by the list price for insulins.
 - Out-of-pocket costs vary depending on the type of insurance each individual has and the type of insulin prescribed. The costs can be significantly higher for people who are uninsured, who have an insurance plan with a high deductible, and who are in the Medicare Part D donut hole.
 - » Manufacturer rebates often are not directly passed on to people with diabetes.
- Patients' medical care can be adversely affected by formulary decisions;
 - » People with high cost-sharing are less adherent to recommended dosing, which results in harm to their health.
 - » Formulary exclusions and frequent formulary changes cause uncertainty, increase financial costs for people with diabetes, and could have serious negative consequence on the health of people with diabetes.
- The regulatory framework for development and approval of biosimilar insulins is burdensome for manufacturers.
 - » There are not enough biosimilar insulins on the market.
 - » Prices for biosimilar insulins are not likely to be reduced unless there are multiple biosimilars that can be substituted for the brand name analog insulin. Prices for biosimilar insulins are not likely to be reduced unless there are several biosimilars that can be substituted for the brand name analog insulin.
 - » Prescribing patterns have favored newer, more expensive insulins:
 - » Newer insulins, including analogs, are more expensive than older insulins, including human insulins.
 - » Human insulin may be an appropriate alternative to more expensive analog insulins for some people with diabetes.

RECOMMENDATIONS

- Providers, pharmacies, and health plans should discuss the cost of insulin preparations with people with diabetes to help them understand the advantages, disadvantages, and financial implications of potential insulin preparations.
- Providers should prescribe the lowest price insulin required to effectively and safely achieve treatment goals.
 - » This may include using human insulin in appropriately selected patients.
 - » Providers should be aware of the rising cost of insulin preparations and how this negatively impacts adherence to the clinical treatment by people with diabetes.

- » Providers should be trained to appropriately prescribe all forms of insulin preparations based on evidence-based medicine.
- Cost-sharing for insured people should be based on the lowest price available.
- Uninsured people with diabetes should have access to high quality, low-cost insulins.
- Researchers should study the comparative effectiveness and cost-effectiveness of the various insulins.
- List price for insulins should more closely reflect net price, and rebates based on list price should be minimized. The current payment system should rely less on rebates, discounts, and fees based on list price.
- Health plans should ensure that people with diabetes can access their insulin without undue administrative burden or excessive cost.
 - » Payers, insurers, manufacturers, and PBMs should design pharmacy formularies that include a full range of insulin preparations, including human insulin and insulin analogs, in the lowest cost-sharing tier.
- PBMs and payers should use rebates to lower people with diabetes' costs for insulin at the point of sale.
- There needs to be more transparency throughout the insulin supply chain.
- Payers, insurers, manufacturers, PBMs, and people with diabetes should encourage innovation in the development of more effective insulin preparations.
- The U.S. Food and Drug Administration should continue to streamline the process to bring biosimilar insulins to market.
- Organizations like the American Diabetes Association should:
 - » Advocate for access to affordable and evidence-based insulin preparations for people with diabetes.
 - » Ensure that health providers receive on-going medical education on how to prescribe all insulin preparations, including human insulins, based on scientific and medical evidence.
 - » Develop and regularly update clinical guidelines or standards of care based on scientific evidence for prescribing all forms of insulin, and make these guidelines easily available to health care providers.
 - » Make information about the advantages, disadvantages, and financial implications of all insulin preparations easily available to people with diabetes.