AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 119
(JUN-21)

Introduced by: Texas

Subject: Caps on Insulin Copayments with Insurance

Referred to: Reference Committee A

Whereas, Diabetes affects over 10% of the population in the United States and is a leading cause of death nationally; and

Whereas, The annual average medical cost per diabetic patient is $13,240 with approximately 44% of expenditures stemming from prescription medications, including insulin; and

Whereas, From 2012 to 2016, the average point-of-sale price of insulin nearly doubled from 13 cents per unit to 25 cents per unit, translating to a daily cost increase from $7.80 to $15 for a type 1 diabetic patient using an average amount of insulin (60 units per day); and

Whereas, One in four patients reported cost-related insulin underuse, including taking smaller doses and skipping doses, which was independent of the patient's prescription drug coverage plan; and

Whereas, Patients who report cost-related underuse were more likely to have poor glycemic control, increasing their risk for complications such as hypertension, chronic kidney disease, neuropathy, lower limb amputations, retinopathy, stroke, coronary heart disease, depression, and cancer; and

Whereas, AMA does not have an explicit policy regarding insulin pricing for patients; and

Whereas, The American Medical Association has policy consistent with the principle of increasing access to prescription medications including insulin for patients; and

Whereas, some private insurance programs have shown the capability to offer a capped copayment on insulin for their customers; therefore be it

RESOLVED, That our American Medical Association support limiting the copayments insured patients pay per month for prescribed insulin. (New HOD Policy)

Fiscal Note: Not yet determined

Received: 05/20/21

AUTHOR'S STATEMENT OF PRIORITY

The delegation leadership feels there is good policy at the AMA concerning the cost of insulin but no specific policy on the amount that patients might have to pay for the prescription. We feel our AMA should be an advocate for the patient in these situations.

References:
1. National and State Diabetes Trends. Centers for Disease Control and Prevention. June 10, 2019. Accessed Feb. 5, 2020.
2. Centers for Disease Control and Prevention. *National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States*. Atlanta, Ga.: U.S. Department of Health and Human Services; 2017.
3. Centers for Disease Control and Prevention. Stats of the State of Texas. www.cdc.gov/nchs/pressroom/states/texas/texas.htm. April 9, 2018. Accessed Feb. 5, 2020.
4. Dall T, et al. The Economic Burden of Elevated Blood Glucose Levels in 2017: Diagnosed and Undiagnosed Diabetes, Gestational Diabetes, and Prediabetes. *Diabetes Care* 2019 Apr; dc181226.
5. Zhuo X, et al., The Lifetime Cost of Diabetes and Its Implications for Diabetes Prevention. *Diabetes Care* 2014 Sep; 37(9): 2557-2564.
6. Biniek JF, Johnson W. Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices. Health Care Cost Institute. Jan. 21, 2019. Accessed Feb. 6, 2020.
7. Herkert D, Vijayakumar P, Luo J, et al. Cost-Related Insulin Underuse Among Patients with Diabetes. *JAMA Intern Med*. 2019;179(1):112-114.
8. Zheng Y, Ley SH, Hu FB. Global aetiology and epidemiology of type 2 diabetes mellitus and its complications. *Nat Rev Endocrinol*. 2018;14(2):88-98.
9. Texas Diabetes Council. 2019 State Plan to Prevent and Treat Diabetes. November 2019, Accessed February 15, 2020.
10. Cigna and Express Scripts Introduce Patient Assurance Program to Cap Out of Pocket Costs at $25 per 30-Day Insulin Prescription (news release). Cigna. April 3, 2019.

RELEVANT AMA POLICY

Additional Mechanisms to Address High and Escalating Pharmaceutical Prices H-110.980
1. Our AMA will advocate that the use of arbitration in determining the price of prescription drugs meet the following standards to lower the cost of prescription drugs without stifling innovation:
a. The arbitration process should be overseen by objective, independent entities;
b. The objective, independent entity overseeing arbitration should have the authority to select neutral arbitrators or an arbitration panel;
c. All conflicts of interest of arbitrators must be disclosed and safeguards developed to minimize actual and potential conflicts of interest to ensure that they do not undermine the integrity and legitimacy of the arbitration process;
d. The arbitration process should be informed by comparative effectiveness research and cost-effectiveness analysis addressing the drug in question;
e. The arbitration process should include the submission of a value-based price for the drug in question to inform the arbitrator's decision;
f. The arbitrator should be required to choose either the bid of the pharmaceutical manufacturer or the bid of the payer;
g. The arbitration process should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases;
h. The arbitration process should include a mechanism for either party to appeal the arbitrator's decision; and
i. The arbitration process should include a mechanism to revisit the arbitrator's decision due to new evidence or data.
2. Our AMA will advocate that any use of international price indices and averages in determining the price of and payment for drugs should abide by the following principles:
a. Any international drug price index or average should exclude countries that have single-payer health systems and use price controls;
b. Any international drug price index or average should not be used to determine or set a drug's price, or determine whether a drug's price is excessive, in isolation;
c. The use of any international drug price index or average should preserve patient access to necessary medications;
d. The use of any international drug price index or average should limit burdens on physician practices; and
e. Any data used to determine an international price index or average to guide prescription drug pricing should be updated regularly.
3. Our AMA supports the use of contingent exclusivity periods for pharmaceuticals, which would tie the length of the exclusivity period of the drug product to its cost-effectiveness at its list price at the time of market introduction.
Citation: CMS Rep. 4, I-19; Reaffirmed: CMS Rep. 3, I-20

Insulin Affordability H-110.984
Our AMA will: (1) encourage the Federal Trade Commission (FTC) and the Department of Justice to monitor insulin pricing and market competition and take enforcement actions as appropriate; and (2) support initiatives, including those by national medical specialty societies, that provide physician education regarding the cost-effectiveness of insulin therapies.
Citation: CMS Rep. 07, A-18

Pharmaceutical Costs H-110.987
1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.
4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
7. Our AMA supports legislation to shorten the exclusivity period for biologics.
8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
10. Our AMA supports: (a) drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase; (b) legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and (c) the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10% or more each year or per course of treatment.
11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.
12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.
Citation: CMS Rep. 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Appended: Res. 201, A-17; Reaffirmed in lieu of: Res. 207, A-17; Modified: Speakers Rep. 01, A-17; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Appended: BOT Rep. 14, A-19; Reaffirmed: Res. 105, A-19

Controlling the Skyrocketing Costs of Generic Prescription Drugs H-110.988
1. Our American Medical Association will work collaboratively with relevant federal and state agencies, policymakers and key stakeholders (e.g., the U.S. Food and Drug Administration, the U.S. Federal Trade Commission, and the Generic Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs.
2. Our AMA will advocate with interested parties to support legislation to ensure fair and appropriate pricing of generic medications, and educate Congress about the adverse impact of generic prescription drug price increases on the health of our patients.
3. Our AMA encourages the development of methods that increase choice and competition in the

development and pricing of generic prescription drugs.
4. Our AMA supports measures that increase price transparency for generic prescription drugs.
Citation: Sub. Res. 106, A-15; Reaffirmed: CMS 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: BOT Rep. 14, A-18

Cost of Prescription Drugs H-110.997
Our AMA:
(1) supports programs whose purpose is to contain the rising costs of prescription drugs, provided that the following criteria are satisfied: (a) physicians must have significant input into the development and maintenance of such programs; (b) such programs must encourage optimum prescribing practices and quality of care; (c) all patients must have access to all prescription drugs necessary to treat their illnesses; (d) physicians must have the freedom to prescribe the most appropriate drug(s) and method of delivery for the individual patient; and (e) such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs;
(2) reaffirms the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourages physicians to supplement medical judgments with cost considerations in making these choices;
(3) encourages physicians to stay informed about the availability and therapeutic efficacy of generic drugs and will assist physicians in this regard by regularly publishing a summary list of the patient expiration dates of widely used brand name (innovator) drugs and a list of the availability of generic drug products;
(4) encourages expanded third party coverage of prescription pharmaceuticals as cost effective and necessary medical therapies;
(5) will monitor the ongoing study by Tufts University of the cost of drug development and its relationship to drug pricing as well as other major research efforts in this area and keep the AMA House of Delegates informed about the findings of these studies;
(6) encourages physicians to consider prescribing the least expensive drug product (brand name or FDA A-rated generic); and
(7) encourages all physicians to become familiar with the price in their community of the medications they prescribe and to consider this along with the therapeutic benefits of the medications they select for their patients.
Citation: BOT Rep. O, A-90; Sub. Res. 126 and Sub. Res. 503, A-95; Reaffirmed: Res. 502, A-98; Reaffirmed: Res. 520, A-99; Reaffirmed: CMS Rep. 9, I-99; Reaffirmed: CMS Rep.3, I-00; Reaffirmed: Res. 707, I-02; Reaffirmation A-04; Reaffirmed: CMS Rep. 3, I-04; Reaffirmation A-06; Reaffirmed in lieu of Res. 814, I-09; Reaffirmed in lieu of Res. 201, I-11; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: BOT Rep. 14, A-18

Reducing Prescription Drug Prices D-110.993
Our AMA will (1) continue to meet with the Pharmaceutical Research and Manufacturers of America to engage in effective dialogue that urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs; and (2) encourage state medical associations and others that are interested in pharmaceutical bulk purchasing alliances, pharmaceutical assistance and drug discount programs, and other related pharmaceutical pricing legislation, to contact the National Conference of State Legislatures, which maintains a comprehensive database on all such programs and legislation.
Citation: (CMS Rep. 3, I-04; Modified: CMS Rep. 1, A-14; Reaffirmation A-14; Reaffirmed in lieu of Res. 229, I-14)

Prescription Drug Prices and Medicare D-330.954
1. Our AMA will support federal legislation which gives the Secretary of the Department of Health and Human Services the authority to negotiate contracts with manufacturers of covered Part D drugs.
2. Our AMA will work toward eliminating Medicare prohibition on drug price negotiation.
3. Our AMA will prioritize its support for the Centers for Medicare & Medicaid Services to negotiate pharmaceutical pricing for all applicable medications covered by CMS.
Citation: Res. 211, A-04; Reaffirmation I-04; Reaffirmed in lieu of Res. 201, I-11; Appended: Res. 206, I-14; Reaffirmed: CMS Rep. 2, I-15; Appended: Res. 203, A-17; Reaffirmed: CMS Rep. 4, I-19; Reaffirmed: CMS Rep. 3, I-20;