AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 801
(I-16)

Introduced by: Medical Student Section

Subject: Increasing Access to Medical Devices for Insulin-Dependent Diabetics

Referred to: Reference Committee J
(_____, Chair)

Whereas, The average list price of an insulin pump for Type 1 and Type 2 Diabetes Mellitus (T1DM and T2DM) is between $4,995 and $6,500, and pump supplies (infusion pump cartridges, glucose meter test strips, lancets, batteries, and syringes) can cost an additional $250 per month;[1,2] and

Whereas, Under Medicare Part B, diabetic patients must remit a 20% copayment for insulin pump devices and related supplies on an ongoing basis, after meeting their yearly Part B deductible;[3] and

Whereas, T1DM patients using insulin pumps experience significant reductions in HbA1c, lower rates of retinopathy and peripheral nerve abnormality, fewer hospitalizations, and superior quality of life as compared to patients who use multiple daily injections (MDI);[4,5,6] and

Whereas, Accumulating evidence has demonstrated the safety and efficacy of insulin pump therapy in T2DM patients, particularly among those with poor glycemic control on MDI, and has shown that pump therapy produces sustained and durable reductions in HbA1c, without increasing the risk of hypoglycemia;[7,8,9,10,11] and

Whereas, On September 1st, 2015, the Centers for Medicare & Medicaid Services announced a forthcoming initiative to test a "Medicare Advantage Value-Based Insurance Design Model" for chronic conditions, including diabetes, in which participating plans "choose to reduce or eliminate cost sharing for items or services, including covered Part D drugs, that they have identified as high-value for a given target population", with broad flexibility with respect to items and services eligible for reduced cost sharing;[12] and

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[1] Boyd LC, Boyd ST. Insulin pump therapy training and management: an opportunity for community pharmacists. J Manag Care Pharm. 2008;14(8):790-4.
[2] FamilyHealthOnline. (2015) "Insulin Pumps". Available at: http://www.familyhealthonline.ca/fho/diabetes/DI_insulinPumps_MDb08.asp. Accessed April 17th, 2016.
[3] Centers for Medicare and Medicaid Services. "Medicare's Coverage of Diabetes Supplies and Services." Available at: https://www.medicare.gov/Pubs/pdf/11022.pdf. Accessed March 30, 2016.
[4] Pérez-garcía L, Goñi-iriarte MJ, García-mouriz M. Comparison of treatment with continuous subcutaneous insulin infusion versus multiple daily insulin injections with bolus calculator in patients with type 1 diabetes. Endocrinol Nutr. 2015;62(7):331-7.
[5] Zabeen B, Craig ME, Virk SA, et al. Insulin Pump Therapy Is Associated with Lower Rates of Retinopathy and Peripheral Nerve Abnormality. PLoS ONE.
[6] Pickup JC. Management of diabetes mellitus: is the pump mightier than the pen?. Nat Rev Endocrinol. 2012;8(7):425-33.
[7] Leinung MC, Thompson S, Luo M, Leykina L, Nardacci E. Use of insulin pump therapy in patients with type 2 diabetes after failure of multiple daily injections. Endocr Pract. 2013;19(1):9-13.
[8] Reznik Y, Cohen O, Aronson R, et al. Insulin pump treatment compared with multiple daily injections for treatment of type 2 diabetes (OpT2mise): a randomised open-label controlled trial. Lancet. 2014;384(9950):1265-72
[9] Didangelos T, Iliadis F. Insulin pump therapy in adults. Diabetes Res Clin Pract. 2011;93 Suppl 1:S109-13.
[10] Aronson R, Reznik Y, Conget I, et al. Sustained efficacy of insulin pump therapy, compared with multiple daily injections, in type 2 diabetes: 12-month data from the OpT2mise randomized trial. Diabetes Obes Metab. 2016;
[11] Conget I, Castaneda J, Petrovski G, et al. The Impact of Insulin Pump Therapy on Glycemic Profiles in Patients with Type 2 Diabetes: Data from the OpT2mise Study. Diabetes Technol Ther. 2015;
[12] Centers for Medicare & Medicaid Services. (2015). "Medicare Advantage Value-Based Insurance Design Model." Available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-09-01.html. Accessed March 30, 2016.

Whereas, UnitedHealthcare recently studied implementation of a Value-Based Insurance Design in their Diabetes Health Plan, which concluded that offering diabetes supplies, office visits, and related prescription drugs at low or no cost to patients increased plan adherence and improved patient health;[13,14] and

Whereas, Existing AMA policy supports Medicare coverage of continuous glucose monitoring systems for insulin-dependent diabetics (Medicare Coverage of Continuous Glucose Monitoring Devices for Patients with Insulin-Dependent Diabetes H-330.885), and existing AMA Ethical Opinion assigns physicians individually and collectively the ethical responsibility to ensure that all persons have access to needed care regardless of their economic means (11.1.4 Financial Barriers to Health Care Access); and

Whereas, Pursuant to its strategic focus area of Improving Health Outcomes, our AMA is committed to a national effort to prevent Type 2 diabetes; and

Whereas, The estimated direct medical costs and indirect costs (disability, work loss, and premature death) from diabetes in the United States in 2012 was $245 billion;[15] therefore be it

RESOLVED, That our American Medical Association work with relevant stakeholders to encourage the development of plans for inclusion in the Medicare Advantage Value Based Insurance Design Model that reduce copayments/coinsurance for diabetes prevention, medication, supplies, and equipment including pumps and continuous glucose monitors, while adhering to the principles established in AMA Policy, Value-Based Insurance Design, H-185.939. (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 08/29/16

[13] Managed Care. "Value-Based Insurance Design Helps Cut Plan's Diabetes Costs." Available at: http://www.managedcaremag.com/archives/2013/2/value-based-insurance-design-helps-cut-plan's-diabetes-costs. Accessed March 30, 2016.
[14] Healthcare Web Summit. "Value-Based Plan Design for Diabetes" Available at: http://www.healthwebsummit.com/diabetes030713.htm. Accessed March 30, 2016.
[15] Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014. Atlanta, GA; 2014. Accessed Aug. 23, 2015. Available at: http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf.

RELEVANT AMA POLICY

Value-Based Insurance Design H-185.939
Our AMA supports flexibility in the design and implementation of value-based insurance design (VBID) programs, consistent with the following principles:
a. Value reflects the clinical benefit gained relative to the money spent. VBID explicitly considers the clinical benefit of a given service or treatment when determining cost-sharing structures or other benefit design elements.
b. Practicing physicians must be actively involved in the development of VBID programs. VBID program design related to specific medical/surgical conditions must involve appropriate specialists.
c. High-quality, evidence-based data must be used to support the development of any targeted benefit design. Treatments or services for which there is insufficient or inconclusive evidence about their clinical value should not be included in any targeted benefit design elements of a health plan.
d. The methodology and criteria used to determine high- or low-value services or treatments must be transparent and easily accessible to physicians and patients.
e. Coverage and cost-sharing policies must be transparent and easily accessible to physicians and patients. Educational materials should be made available to help patients and physicians understand the incentives and disincentives built into the plan design.
f. VBID should not restrict access to patient care. Designs can use incentives and disincentives to target specific services or treatments, but should not otherwise limit patient care choices.
g. Physicians retain the ultimate responsibility for directing the care of their patients. Plan designs that include higher cost-sharing or other disincentives to obtaining services designated as low-value must include an appeals process to enable patients to secure care recommended by their physicians, without incurring cost-sharing penalties.
h. Plan sponsors should ensure adequate resource capabilities to ensure effective implementation and ongoing evaluation of the plan designs they choose. Procedures must be in place to ensure VBID coverage rules are updated in accordance with evolving evidence.
i. VBID programs must be consistent with AMA Pay for Performance Principles and Guidelines (Policy H-450.947), and AMA policy on physician economic profiling and tiered, narrow or restricted networks (Policies H-450.941 and D-285.972).
Citation: CMS Rep. 2, A-13; Reaffirmed in lieu of Res. 122, A-15; Reaffirmed in lieu of: Res. 121, A-16

Medicare Coverage of Continuous Glucose Monitoring Devices for Patients with Insulin-Dependent Diabetes H-330.885
Our AMA supports efforts to achieve Medicare coverage of continuous glucose monitoring systems for patients with insulin-dependent diabetes.
Res. 126, A-14

Diabetic Documentation Requirements D-185.983
1. Our AMA Board of Trustees will consider a legal challenge, if appropriate, to the authority of the Centers for Medicare & Medicaid Services (CMS) and other health care insurers placing onerous barriers on diabetic patients to procure medically necessary durable medical equipment and supplies.
2. Our AMA Board of Trustees will consider a legal challenge, if appropriate, to the authority and policy of CMS and other insurers to practice medicine through their diabetes guidelines, and place excessive time and financial burdens without reimbursement on a physician assisting patients seeking reimbursement for supplies needed to treat their diabetes.
Citation: (Res. 730, A-13)

CMS Required Diabetic Supply Forms H-330.908
Our AMA requests that CMS change its requirement so that physicians need only re-write prescriptions for glucose monitors every twelve months, instead of a six month requirement, for Medicare covered diabetic patients and make the appropriate diagnosis code sufficient for the determination of medical necessity.
Citation: (Sub. Res. 102, A-00; Reaffirmation and Amended: Res. 520, A-02; Modified: CMS Rep. 4, A-12)

Drug Issues in Health System Reform H-100.964
The AMA: (1) consistent with AMA Policy H-165.925, supports coverage of prescription drugs, including insulin, in the AMA standard benefits package.

(2) supports consumer choice of at least two options for their pharmaceutical benefits program. This must include a fee-for-service option where restrictions on patient access and physician autonomy to prescribe any FDA-approved medication are prohibited.
(3) reaffirms AMA Policy H-110.997, supporting the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourage physicians to supplement medical judgments with cost considerations in making these choices.
(4) reaffirms AMA Policies H-120.974 and H-125.992, opposing the substitution of FDA B-rated generic drug products.
(5) supports a managed pharmaceutical benefits option with market-driven mechanisms to control costs, provided cost control strategies satisfy AMA criteria defined in AMA Policy H-110.997 and that drug formulary systems employed are consistent with standards defined in AMA Policy H-125.991.
(6) supports prospective and retrospective drug utilization review (DUR) as a quality assurance component of pharmaceutical benefits programs, provided the DUR program is consistent with Principles of Drug Use Review defined in AMA Policy H-120.978.
(7a) encourages physicians to counsel their patients about their prescription medicines and when appropriate, to supplement with written information; and supports the physician's role as the "learned intermediary" about prescription drugs.
(7b) encourages physicians to incorporate medication reviews, including discussions about drug interactions and side effects, as part of routine office-based practice, which may include the use of medication cards to facilitate this process. Medication cards should be regarded as a supplement, and not a replacement, for other information provided by the physician to the patient via oral counseling and, as appropriate, other written information.
(8) recognizes the role of the pharmacist in counseling patients about their medicines in order to reinforce the message of the prescribing physician and improve medication compliance.
(9) reaffirms AMA Policies H-115.995 and H-115.997, opposing FDA-mandated patient package inserts for all marketed prescription drugs.
(10) opposes payment of pharmacists by third party payers on a per prescription basis when the sole purpose is to convince the prescribing physician to switch to a less expensive "formulary" drug because economic incentives can interfere with pharmacist professional judgment.
(11) reaffirms AMA Policy H-120.991, supporting the voluntary time-honored practice of physicians providing drug samples to selected patients at no charge, and to oppose legislation or regulation whose intent is to ban drug sampling.
(12) supports CEJA's opinion that physicians have an ethical obligation to report adverse drug or device events; supports the FDA's MedWatch voluntary adverse event reporting program; and supports FDA efforts to prevent public disclosure of patient and reporter identities.
(13) opposes legislation that would mandate reporting of adverse drug and device events by physicians that would result in public disclosure of patient or reporter identities.
(14) reaffirms AMA Policy H-120.988, supporting physician prescribing of FDA-approved drugs for unlabeled indications when such use is based upon sound scientific evidence and sound medical opinion, and supporting third party payer reimbursement for drugs prescribed for medically accepted unlabeled uses.
(15) encourages the use of three compendia (AMA's DRUG EVALUATIONS; United States Pharmacopeial-Drug Information, Volume I; and American Hospital Formulary Service-Drug Information) and the peer-reviewed literature for determining the medical acceptability of unlabeled uses.
(16) reaffirms AMA Policy H-100.989, supporting the present classification of drugs as either prescription or over-the-counter items and opposing the establishment of a pharmacist-only third (transitional) class of drugs.
(17) reaffirms AMA Policy H-120.983, urging the pharmaceutical industry to provide the same economic opportunities to individual pharmacies as given to mail service pharmacies.
Citation: (BOT Rep. 53, A-94; Reaffirmed by Sub. Res. 501, A-95; Reaffirmed by CSA Rep. 3, A-97; Amended: CSA Rep. 2, I-98; Renumbered: CMS Rep. 7, I-05; Reaffirmation A-10; Reaffirmed in lieu of Res. 201, I-11)

Expansion of National Diabetes Prevention Program H-440.844
Our AMA: (1) supports evidence-based, physician-prescribed diabetes prevention programs, (2) supports the expansion of the NDPP to more CDC-certified sites across the country; and (3) will support coverage of the NDPP by Medicare and all private insurers.
Citation: (Sub. Res. 911, I-12)

Strategies to Increase Diabetes Awareness D-440.935
Our AMA will organize a series of activities for the public in collaboration with health care workers and community organizations to bring awareness to the severity of diabetes and measures to decrease its incidence.
Citation: (Res. 412, A-13)

Dysmetabolic Syndrome and Type 2 Diabetes in Children D-440.949
Our AMA (1) supports efforts to develop national-level data that would provide for the monitoring of the prevalence of diabetes among youth by type; and (2) encourages greater awareness by physicians of type 2 diabetes and its complications in children and will promote the availability of resources and information about the prevention and treatment of this growing public health threat.
Citation: (Res. 418, A-07)