Issues and Updates

Proposed Medicare Changes Not Favorable for Individuals With Diabetes

Health-care providers are sounding the alarm over proposed changes in Medicare reimbursements for durable medical equipment and supplies. If the changes take effect as scheduled on 1 October 1993, Medicare patients with diabetes stand to lose critical benefits, including coverage for some blood glucose monitoring devices and supplies, prostheses, and orthotics. However, Medicare will now accept claims for prescription therapeutic shoes from people with diabetic foot complications.

In the past, Medicare's 31 insurance carriers for durable equipment and supplies set reimbursement policies locally, soliciting input from local health-care providers and consumer groups. Now Medicare is replacing the 31 local carriers with four durable medical equipment regional insurance carriers (DMERCs). The DMERCs developed the proposals, which would constitute a uniform national reimbursement policy. However, according to the Health Care Financing Administration (HCFA), which supervises the Medicare and Medicaid programs, notification and requests for comment were solicited only at the local level. As a result, major national health-care provider and consumer groups were not necessarily involved in the policy development process.

The DMERC reorganization at first appears laudable. It limits the number of people eligible for certain benefits, standardizes equipment, eliminates opportunities for fraud, and defines prescription procedures. However, many physicians, diabetes educators, podiatrists, pedorthists, orthotists, and prosthetists have challenged aspects of the plan and raised questions about its assumptions and implications.

The draft policies now being discussed could have serious ramifications not just for Medicare patients, but for all consumers of durable medical goods. Many health-care professionals expect to see the DMERC regulations in the Clinton Administration's new health policy and believe the regulations could also filter into HMOs, PPOs, and commercial insurance policies. In the past, when Medicare began to pay for kidney transplants, other third-party payers did likewise. On the other hand, because Medicare still considers insulin pumps experimental and refuses to pay for them, other third-party payers also refuse such claims.

Francine R. Kaufman, MD, chair of the American Diabetes Association (ADA) Government Relations Committee, warned that "if these DMERC measures are finally approved, they will erase the positive impact that years of research have had in improving the lives of people with diabetes.

"It could be done with a sweep of a pen, restricting access to medical goods that could benefit so many individuals. Concerned members of the diabetes community should contact their legislators, despite the fact that the official comment period is over."

In addition to the suggested cuts, the proposed guidelines would limit reimbursement for self-monitoring blood glucose devices to "insulin-treated diabetics" in "poor diabetic control." The guidelines also state that "more than one bottle/box of strips and lancets per month will rarely be medically necessary." More would be available only with additional paperwork by health-care providers.

In a letter written earlier this year to the four medical directors of DMERC, the ADA strongly disagreed with some of the proposed limitations, saying that "any person who is insulin-treated should monitor blood glucose levels." The letter also noted that results of the Diabetes Control and Complications Trial (DCCT) were expected to show that tight control of blood glucose levels (which requires 3 or more blood tests a day) lowers the incidence of complications in people with insulin-dependent diabetes mellitus.

The ADA also urged the DMERCs not to place arbitrary limits on the number of test strips or lancets covered and invited DMERC officials to attend its consensus development conference on blood glucose self-monitoring in September 1993.

Diabetes nurse educator Virginia Peragallo-Dittko, RN, MA, CDE, of the Winthrop University Hospital Diabetes Education Center in Minneola, NY, is one of the organizers of the association

consensus meeting. She said limiting glucose self-monitoring to insulin-treated patients with poorly controlled diabetes might be "short-sighted in terms of cost containment." Effective self-management prevents emergency room visits for hypoglycemia and shortens hospital stays, she said. And she added that glucose testing is also important for people with diet- and oral agent-controlled diabetes.

"Self-monitoring data provides information on the impact of food and activity on blood glucose," Peragallo-Dittko said. "This data is often a critical turning point for tying together the principles of self-management and daily living." The issue of self-monitoring for people with non-insulin-dependent diabetes mellitus will be addressed at the September consensus conference.

Peragallo-Dittko hailed one aspect of the proposed policy, which allows reimbursement for blood glucose monitors with voice synthesizers, automatic timers, and other special equipment for visually impaired people.

Along with other health-care professionals, many foot-care professionals are disturbed by the proposed policy. "Misguided and counterproductive," is how John H. Bowker, MD, described the proposed DMERC policy on prosthetic and/or orthotic devices. Bowker, of the University of Miami Department of Orthopedics and Rehabilitation, is vice chair of the ADA Foot Care Council and co-author of the *Atlas of Lim Prosthetics: Surgical, Prosthetic, and Rehabilitaion Principles*, a definitive text on prosthetics. He said DMERC is, "looking for generic, lowest-common-denominator approaches to problems that require prescriptions related to physiologic, not chronologic, age and avocational as well as vocational needs." He objects to a standardized approach in what he calls "the art of prosthesis prescription"—an art in which patient needs (vocational and avocational), availability of prosthetic services, costs, and health conditions should be taken into consideration.

Medicare currently reimburses for modern foot and knee prostheses—devices that are lightweight, mobile, and energy-absorbent. But under the new plan, it would pay only for the SACH foot (an unarticulated, carved wood prosthesis), and nonhydraulic, nonpneumatic knees for most patients. Only patients with arteriosclerotic heart disease with angina, chronic pulmonary disease, or some limited medical conditions would qualify for reimbursement for the more sophisticated prostheses or braces, such as the dynamic response foot—now the standard in the field.

The proposed policy would force younger people to cut down on exercise and activity, said Edward Jeffries, MD, an orthopedic surgeon at the University of Tennessee Medical Center in Knoxville. Jeffries, a spokesman for the Amputee Coalition of America, said that for many, this type of prosthesis would also limit ability to work. Although the SACH foot works for some patients, he said, for others it simply doesn't. "They're making rules that don't make sense," he said. "We need a much more complex scheme."

For some patients with diabetes complications, the proposed cutbacks may pose even more serious threats. The agency would not pay for neuropathic walkers, for example. These padded, short-leg, removable casts are considered indispensable in preventing Charcot's joint condition from progressing to amputation. Instead, only an "off-the-shelf" ankle-foot orthosis (AFO) would be reimbursed.

Treating Charcot's joint with an AFO would almost certainly lead to amputation, predicted Keith Vinnecour, a California certified prosthetist and orthotist (CPO). AFOs would also be inadequate for many people with "foot drop," another result of diabetic neuropathy. Patients would either suffer from poorly-fitting orthotics, or incur additional costs for molded orthotics to prevent ulceration of their insensitive feet.

The proposed policy may actually increase costs instead of saving money, Jeffries said. "People on Medicare will get the poorest care from prosthetists," he said. "As a result, people will wear ill-fitting prostheses and walk ulcers onto their feet."

However, the good news is that prescription footwear will now be covered. Medicare is now required by law to extend coverage to therapeutic footwear for people with diabetes. Patients who are certified as needing the special shoes will be reimbursed, annually, $100 for one pair depth shoes or $300 for a pair of custom-molded shoes. (Depth shoes provide additional vertical depth for the foot, allowing extra room for custom insoles. They are used to treat deformities, hypersensitive, and insensate feet. Custom-molded shoes are fashioned from the actual shape of the foot.) Medicare will also reimburse shoe inserts at $50 each, up to three per year for depth shoes and two per year for custom-molded shoes. Although reimbursement was scheduled to begin in July, it will retroactively cover shoes that were purchased on or after 1 May 1993.

Congress passed the prescription shoe law after the ADA worked closely with Rep. Chris Smith (R-N.J.) and groups such as the Prescription Footwear Association (PFA) to include the benefit in the Omnibus Budget Reconciliation Act of 1987.

In its support of the new coverage rule, ADA pointed out that of the more than 2 million individuals with diabetes over age 65, about 3% have significant diabetic foot disease. Proper foot care is expected to reduce surgery and amputation among beneficiaries.

"We feel very strongly that 80% of lower limb amputations can be prevented by providing therapeutic footwear and orthotic devices," said Janis Gregory, director of government affairs for the PFA.

At press time, Medicare was still developing regulations for the new provision. Many health-care providers hoped the regulations would address the politically sensitive issue of who should

write and fill therapeutic shoe prescriptions, by including clear training and certification requirements. Providers were also looking to HCFA for guidance on which patients should receive depth shoes or custom-molded shoes.

Lee Sanders, DPM, new chair of ADA's Council on Foot Care, said he hopes the council will develop a new consensus statement on such issues within the next year.

The proposed reimbursement policy for durable medical equipment has created a crisis among prosthesics/orthotics professionals. The plan would require any practitioner who fitted a patient with a prosthesis or orthosis to provide free follow-up care for the life of the device. Presently, most practitioners offer free follow-up for only about 3 months. However, a prosthesis can last up to 8 years and require periodic adjustment and repairs. Prosthesis follow-up care is especially important to people with diabetes, who often require frequent adjustments because of special problems with loss of sensation, tissue break-down, edema, ulcerations, and other problems.

Follow-up visits to a prosthetist can cost up to $300 per visit, depending on the severity of the problem. California CPO Vinnecour estimates that certified prosthetist/orthotists could stand to lose from $1500 to $3000 over the life of a single device.

The proposed regulations would allow new devices every 2 years, which might create an incentive for prosthetists to prescribe and fit new devices more frequently, instead of adjusting or repairing existing ones at no charge for 8 years. Many prosthetists are even considering refusal of all Medicare patients if the proposals are enacted, Vinnecour said. "This will force patients to visit 'low end' practitioners," he said, or suffer deteriorating medical conditions.

The DMERC reimbursement plan was proposed at the end of April 1993 as part of a massive overhaul of Medicare handling of durable equipment claims. Gary Cavanaugh, deputy director of the HCFA's Bureau of Program Operations, said the streamlined carrier system and proposed national reimbursement policy for durable goods were designed to curb serious abuses, much of which took place in the past decade. He recalled scandals involving telemarketing of reclining chairs that could be paid for through Medicare, and foam mattress bed pads that customers could buy anywhere for $10, but for which Medicare was charged $200 to $300. The new system will allow administrators to keep better track of practices in the field, and the proposed uniform reimbursement policy will eliminate opportunities for abuse, Cavanaugh said.

However, many health-care provider and consumer groups have taken issue with the manner in which DMERC officials sought input on their reimbursement plan. Although each regional carrier administers durable goods claims for one-fourth of the country, they formally notified and sought input from physicians, interest groups, and suppliers only on a local level—as they would have done under the old system, when they were among 31 carriers setting local policies, Cavanaugh said. Many key national professional associations and interest groups were neither notified nor invited to comment, although some—including ADA—learned of the proposals through their own representatives in Washington and quickly submitted comments. Other groups, such as the American Orthotic and Prosthetic Association were consulted, but claim that their specific recommendations have been largely ignored.

The DMERC plan is not inherently bad, observers said. The problem, said Tennessee orthopedic surgeon Jeffries, is that the four DMERC directors formulated real changes in the system without inviting qualified health-care practitioners or the affected public to participate in the process.

When asked whether he worried that the DMERCs might be missing important input from major groups, Cavanaugh responded, "We have concerns about that, and we're trying to figure out how to get their input. We do want comments." However, he added, HCFA has no plans to reopen its comment period, which closed June 15.

DMERC officials are now reviewing comments received before June 15 and hope to have a revised final policy in place, with supplier manuals rewritten, by mid-August, Cavanaugh said. But he assured Medicare clients that even after the final policy is in place, "there is never an absolute." If health-care providers appeal with a specific medical basis, he said, exceptions can be made. In addition, DMERC policies will be reviewed on a continuing basis.

Medicare policy is under "ongoing medical review," Cavanaugh said. "When new information comes, we will respond."

—*Leslie Y. Dawson*
Assistant Managing Editor
Diabetes Spectrum,
Clinical Diabetes, *and*
IDF Bulletin

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ADA Events

Consensus Development Conference: Self-Monitoring of Blood Glucose: 28–30 September 1993, Seattle, WA.

Prevention of Diabetes and Its Complications: 5 November 1993, Sheraton Inn, Minot, ND.

41st Annual Advanced Postgraduate Course: 28–30 January 1994, Boston, MA.

Research Symposium: Pancreas and Islet Cell Transplantation, April 1994.

54th Annual Meeting and Scientific Sessions: 11–14 June 1994, New Orleans, LA. Deadline: 7 January 1994 for submission of abstracts.

Contact: ADA, Professional Education Department, 1660 Duke Street, Alexandria, VA 22314. Tel: 703–549–1500, x212 or x215.

Other Events

19th Annual Meeting of the International Study Group of Diabetes in Children and Adolescents
2–6 September 1993
On board the cruise ship Neptune in the Aegean Sea
Contact: Dr. C. Bartsocas, Department of Pediatrics, P & A Kyriakou Children's Hospital, GR-11527 Athens, Greece. Fax: 30–1-7796461.

3rd International Symposium on Diabetes and Atherosclerosis
4–6 September 1993
Klasses, near Istanbul, Turkey
Deadline: 1 July 1993 for submission of abstracts.
Contact: Professor Gerald H. Tomkin, 1 Fitzwilliam Square, Dublin 2, Ireland. Fax: 01–768074.

29th Annual Meeting of the European Association for the Study of Diabetes
6–9 September 1993
Istanbul, Turkey
Contact: Serpil Bagriacik, Osmanli Sok 23, 80090 Taksim-Istanbul, Turkey. Tel: 90–1-245–04–15; Fax: 90–1-251–75–60.

Type I Diabetes: New Frontiers for Prevention and Immunotherapy
10 September 1993
Istanbul, Turkey
Sponsorship: The International Diabetes Immunotherapy Group and the European Association for the Study of Diabetes.
Topics include: Autoimmunity and new therapeutic approaches, strategy for prevention, and immunology. Abstracts are invited.
Contact: Dr. Hasan Ilkova, Turkish Diabetes Association. Tel: 90-1-529-9947; Fax: 90-1-530-6891.

International Congress on Obesity Management
19–22 September 1993
Antwerp, Belgium
Location: Antwerp University
Sponsorship: Ministry of Health of the Flemish government, Eurocheque, Quorn, Howard Foundation, Weight Watchers, Coca Cola.
Topics include: Safety and efficacy in obesity treatment; evaluating health risks, management, and appetite control (with a satiety index as a prime innovation); obesity in children; psychological facets; and effects of exercise.
Conditions: Simultaneous translation into Dutch, French, and German.
Contact: Obesitas, vzw, secretariaat Bunderbeeklaan 19, B-2950, Kapellen, Belgium. Tel: 32–3-664–17–12; Fax: 32–3-665–12–30.

International Diabetes Epidemiology Group Meeting
22–23 September 1993
Noumea, New Caledonia
Deadline: 1 May 1993 for submission of abstracts.
Sponsorship: Cosponsored by the International Diabetes Epidemiology Association
Topics include: Diabetes in the tropics; IDDM, NIDDM, and malnutrition related diabetes; diabetic pregnancy and fetal development; sex hormones and glycoregulation; the insulin resistance syndrome; prevention of IDDM and NIDDM and their complications: feasibility, methods, and program evaluation.
Contact: Dr. B. Baulkau, Secretary IDEG, INSERM unit 21, 16 Ave. Paul Vaillant Couturier, 94807 Villejuif Cedex, France. Tel: 33–1-45–59–51–61; Fax: 33–1-47–26–94–54.

12th Danube Symposium on Diabetes Mellitus
7–10 October 1993
Krakow, Poland
Deadline: 1 April 1993 for registration and abstracts.
Topics include: Long-term diabetes complication, insulin therapy, diabetes mellitus in children, and gestational diabetes mellitus.
Contact: Associate Professor Jacek Sieradzki, Department of Endocrinology, Medical Academy in Krakow, 31–501 Krakow, Kopernika 17, Poland. Tel: 48–12–21–01–44; Fax: 48–12–21–40–54.

1st Latin American Course on Diabetes Epidemiology
13-21 October 1993
Buenos Aires, Argentina
Sponsorship: Alberto Roemmers Foundation and WHO DiaMond Project.
Deadline: 15 June 1993 for submission of application forms.
Contact: Dr. Ronald LaPorte, WHO Collaborating Center for Diabetes Registries, Research and Training, 3460 Fifth Avenue, 5th Floor, Pittsburgh, PA 15213. Fax: 412-692-8329. Dr. Manuel Marti, Fundacion Alberto Roemmers, Irigoyen 460, 6to piso, 1310 Buenos Aires, Argentina. Fax: 54-1-334-9715-716.

American Board of Internal Medicine Examinations
23–24 August 1994
Deadline: 1 September 1993 through 1 December 1993 for registration.
Contact: Registration Section, American Board of Internal Medicine, 3624 Market Street, Philadelphia, PA 19104. Tel: 1-800-441-2246; Fax: 1-215-243-1500.

7th International Congress on Obesity
20–25 August 1994
Toronto, Ontario, Canada
Location: Westin Harbour Castle Hotel Participants may receive AMA Category 1 study credits.
Contact: Continuing Education, Faculty of Medicine, University of Toronto, Medical Sciences Building, Toronto, Ontario, M5S 1A8 Canada. Tel: 416-978-2718; Fax: 416-978-7144.

15th International Diabetes Federation Congress
6–11 November 1994
Kobe, Japan
Location: Convention Center
Topics include: Prevention of diabetes and clarification of goals to reach by the year 2000.
Contact: S. Ohsata, Kobe Convention Center, 6–9-1, Manatojima-nakamachi, Chuo-Ku, Kobe 650, Japan. Tel: 078-303-0055; Fax: 078-302-7303.

International Genetic Collaborative Study
The Institut de Morphologie Pathologique Loveral, Center for Human Genetics
Loveral, Belgium
Conditions: Clinicians with patients who have total lipodystrophy (lipotro-

phic diabetes, Berardinelli-Seip syndrome) can enter an international genetic collaborative study aimed at localizing the gene responsible for the disease. Participation consists of providing a single blood sampling of affected patients, unaffected siblings, and their parents.
Contact: Dr. Lionel Van Maldergem, Center for Human Genetics, IMPL, Allee des Templiers 41, 6280 Loveral, Belgium. Tel: 32–71–471520; Fax: 32–71–471520.

ADA Research Awards

ADA Career Development
Award: Up to $75,000/yr for 3 yr to support new researchers with 2–5 yr of postdoctoral/postfellowship research experience. Funds divided between salary and other grant support.
Deadline: 2 August 1993 for 1 January 1994 funding.
Conditions: Applicants must be U.S. citizens or have permanent resident status and hold full-time positions at U.S. university-affiliated institutes.

ADA Research
Award: Between $20,000 and $40,000/yr for 2 yr to assist researchers, new or established, who have a novel, exciting idea for which they need support.
Deadline: 2 August 1993 for 1 January 1994 funding.
Conditions: Applicants must be U.S. citizens or have permanent resident status and hold full-time faculty positions at U.S. university-affiliated institutions.

Clinical Research Grant Program
Award: Up to $75,000/yr for 3 yr for studies that involve humans.
Deadline: 1 February 1993 for 1 July 1993 funding.
Conditions: Studies must focus on intact human subjects in which the effect of a change in the individual's external or internal environment is evaluated. In vitro research on human blood or tissue samples does not qualify unless there has been a major in vivo intervention, and the protocol is designed specifically to quantitate the effect of the manipulation. Applicants must be U.S. citizens or have permanent resident status and hold full-time faculty positions at U.S. university-affiliated institutions.

Mentor-Based Postdoctoral Fellowship Program Award: $30,000/yr for 3/yr for a postdoctoral fellow working with an established diabetes investigator.
Deadline: 8 October 1993 for 1 July 1994 funding.
Conditions: The investigator must be a U.S. citizen or have permanent residence status and hold an appointment at a U.S. research institution. The fellow must have an MD or a PhD and no more than 3 yr of postdoctoral research experience.
Contact: American Diabetes Association, 1660 Duke Street, Alexandria, Va 22314. Tel: 703-549-1500, x362.