A Look Back at a Half Century in Diabetes Care

Treatments now exist that we only dreamt about, but the workability of some programs has been compromised by Medicare and CMS.

BY PAUL KESSELMAN, DPM

Many advances have been made in diabetes treatment over the past half century, with many having implications on treating the diabetic foot. Continuous glucose monitoring was a dream back in the mid-70s. There were also only a handful of agents to treat hyperglycemia and were categorized as either oral or short and long-acting injectable insulin agents. The class on diabetes agents was perhaps less than week-long. Today, it's impossible to imagine that a comprehensive lesson on the current diabetes agents could be covered in only a week.

Finger sticks were painful and laborious leading to high non-compliance rates amongst patients. Today, these have largely been replaced by glucometers which reduce the sting and repeated painful sticks of yesteryear. Continuous glucose monitoring through painless skin sensors allows patients and their health care providers to respond in real time with implantable insulin pumps, thus allowing for critical adjustments in medication dosing based on current glucose levels.

Today, there are a myriad of agents to treat diabetes, rendering useless a fifty-year-old classification system of diabetes agents. The same may also be said of simply classifying patients as IDDM and NIDDM, where the thought was that those who injected were IDDM and those who did not were NIDDM. Today there are many non-insulin injectable medications providing long term (a week) glucose control.

Replacing injectable insulin with a nasal delivery system may finally be closer than it has been in the last quarter of a century.

Many anti-diabetic, non-insulin injectable agents have seen their utilizations skyrocket as many non-diabetic patients use these off-label for weight loss. The off-label use of these drugs is another controversial subject. Losing weight and reducing the potential for the patient progressing to diabetes and avoiding all the horrible diabetic sequalae is to be applauded. However, simply relying on an injection allowing patients to eat whatever they want cannot be condoned.

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Hemoglobin A1C and fructosamine testing is now standard of care with the former available as an at-home testing kit. Neither of these were available back in the 1970s.

In the 1980s, Congress passed the Therapeutic Shoe Program for Beneficiaries with Diabetes. At the time, this program was widely embraced by providers and patients as a way to incentivize patients to wear proper footwear in order to reduce the incidence of diabetic foot ulcers.

Remote monitoring systems are also available for diabetes patients and to monitor blood pressure and other parameters. There are numerous studies of RPM measures that can identify pedal complications of diabetes early on. This earlier intervention often can preclude the development of more serious complications resulting from diabetic foot ulcers.

Radiology

Digital enhancement radiology and MRI were mostly not available to office or most community hospitals 50 years ago. Advanced radiology fifty years ago usually consisted of pairing x-rays with CT and nuclear scanning and biopsy.

The gold standard today for differentiating Charcot foot from infection and other pathologies remains bone biopsy and bone culture, but MRI can often assist the clinician in diagnosis and developing the right treatment protocol.

Antibiotics

Second and third generation cephalosporins, quinolones, and other oral agents, now commonplace, have

Continued on page 62

A Look Back (from page 61)

largely replaced penicillins, sulfa drugs and some tetracyclines, all of which were widely used in the 1970s.

In-Office Neurovascular Technologies

In the mid-1970s, non-invasive vascular technology required a large dedicated laboratory with fixed permanent equipment. With computer technology, non-digital equipment has been replaced by instrumentation, which is portable, paperless and digital, allowing results to easily be imported into the patient's electronic medical record. While doppler technology is the most often performed test, photoplethysmography, pulse volume recording, skin perfusion pressure and other technologies have a much more important role in predicting microvascular disease than does ABI. Other testing of microvascular segments is also available using differing wavelengths of light. There will be more over the next few years.

Non-invasive neurological testing for diabetic neuropathy is available far more so than previously. Invasive testing with skin biopsy to test nerve fiber size/density is also a relatively recent newcomer, within the last decade.

Cellular Tissue Products (CTP)

Of all the advances revolutionizing modern diabetic foot ulcer treatments, this one often draws the greatest attention. Twenty years ago, there were only a handful of these products on the market and the wound care issue of this publication easily covered a summary of these products. Their invention was predicated on the need to eliminate the need for a donor site, with all the associated inherent complications resulting from creating yet another wound.

At the time, they were simply referred to as skin substitutes, their identity having changed several times before most recently being referred to as cellular tissue products (CTP). A comparative article on all CTP had to be abandoned a decade or more ago due to the sheer number of these products on the market. Currently, the number of CTP available on the market easily exceeds 200. The costs of utilizing these products escalate every year over the previous year but is well worth it for the tens of thousands of recipients whose limbs have been salvaged and saved every year.

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Present Day: Medicare and Diabetes

Let's now take a second look at these advances and see what using Medicare (as an example) has done with many of the programs previously outlined.

The one thing all the following programs have is they have been hard hit by Medicare Contractor audits, often leading to providers abandoning these programs and creating accessibility to care issues.

Medications

Generic agents have largely replaced brand name agents. The FDA has a very liberal allowance for generics having a bioavailability from 80-125 percent of the brand name equivalent. For some patients the lower numbers are clinically ineffective. For others, they may have found a generic equivalent which works, but their pharmacies cannot guarantee patients will receive the identical generic with each refill. This can lead patients on a downhill spiral due to lack of control, the need for multi-pharmaceuticals and further complications. All in the name of saving a few pennies on generics.

Insulin

Recent legislation passed by Congress to limit patients' monthly out-of-pocket costs for Insulin was a lifesaver for many. The costs of Insulin, especially during the Covid-19 pandemic, skyrocketed. This left many vulnerable patients having to choose between paying for other essentials, such as rent or food, before purchasing more Insulin. Of course, many patients then ended up in their hospitals' ED, costing the system far more.

Continuous Glucose Monitoring (CGM)

As with other DME, CGM has been hit very hard by auditing. If the doctor's orders are not perfect with every "I" dotted and every "T" crossed, with the exact LCD verbiage incorporated into the patient's chart note, the supplier will fail their audit. Along with untenable profit margins, this has led many local DME providers to abandon this marketplace.—and in some cases leaving patients with accessibility issues.

Therapeutic Shoes

A recent phone call with a podiatrist in Oregon was poignant because of the many frustrations felt by many DME professionals who have abandoned this program. Audits have become merciless in this space. The provisions of the program seem to get progressively more complicated as the carriers attempt to simplify matters.The DME MAC Medical Directors have confirmed accessibility to care issues in certain areas of the country and have asked what can be done to ease this problem.

The answer is staring them in the face. It's their interpretation of the policy. The DME MAC Medical directors claim that only a Congressional Act can make changes to the policy. Yet over the last ten years there have been numerous changes, including removing the need for shoes to be PDAC approved (inserts still must be). PAs and NPs can now perform the certifying exam with the MD/DO still needing to co-sign. In some cases, the NP can perform the exam and sign the certification statement without any MD/DO. These are all but a few of the changes the DME MAC and Carrier Medical Directors have made without Congressional action.

Continued on page 63

A Look Back *(from page 62)*

Meetings with CMS by a multitude of industry and medical professionals have done little to gain any traction for the removal of the absurd need for the supervising entity to co-sign the chart notes of the prescribing entity.It has been made very clear to CMS and the DME MAC that this is not an MD/DO vs. DPM issue. In all other areas of medicine, the provider performing or prescribing the service is responsible for their own actions or inactions. If the Carrier Medical Directors are true to their word and tired of hearing complaints from patients and providers alike, it is high time they bring this program into the 21st century.

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and it appears that while the Carrier Medical Directors claim they are powerless to change this, it appears this is not the case.Perhaps the DME MAC are more concerned about the opinions of a few CMS officials who secretly desire this program to go away and this is their way of justifying its demise?

Perhaps the answer is to provide a direct correlation between other escalating costs attributed to the 50% reduction in payments made over the last few years for therapeutic shoes. The $30M yearly reduction in costs saved on therapeutic shoes is no doubt a drop in the bucket. This as compared to the significant escalating costs associated with diabetic foot disease, which includes hospitalizations for diabetic foot ulcers and infections, often with tragic results.

Proving this may be more difficult than simply stating it, but perhaps only the proof will move CMS. Certainly, the problem is that each medical director only cares about their own piece of the Medicare expenditure pie but fails to look at the bigger picture. Perhaps the problem also appears to be myopia at CMS.

Non-Invasive Laboratory Testing (Vascular and neurological)

Unfortunately, CMS and its contractors have not kept up with the times. ABI is largely dependent on the

Continued on page 64

A Look Back (from page 63)

relatively larger vessels in the extremities and by itself is unreliable to predict treatment outcomes. CMS needs to adapt itself to modern laboratory testing methods for physicians to determine which therapies may be best suited for a specific patient.

Cellular Tissue Products

The past two years have seen CMS and Medicare Contractors attempting to rein in the number of these products based on significant cost escalations. However, it appears that CMS and a muti-jurisdictional task force of contractors may have overreacted by significantly reducing the number of products from over 200 to fewer than 20 and significantly reducing the number of allowable applications. This is in response not only to the escalating costs, but due to abuse by select providers. They allege that some providers proceed to CTP prior to exhausting standard wound care protocols (30 days) and/or use CTP on medically unstable patients (i.e., poor limb perfusion, poor glucose control, presence of infection, etc.).

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Other abuses include ordering CTP product in large excess of the amount needed when smaller exact product or similar product sizes are both available and more affordable. CMS and its contractors may be correct in that a small percentage of providers may be overutilizing these products. Better enforcement of the policy, perhaps via pre-payment review or mandatory prior authorization for those habitually failing audits, seems more logical than an overly restrictive policy.

Remote Patient Monitoring (RPM):

RPM in general has been subject to audits and a recent unfavorable OIG report on RPM. A recent discussion with a pulmonologist practice administrator revealed that despite favorable audit results and responses from patients, the physician was abandoning the program due to what he felt was harassment by CMS. The emotional costs along with those of exposure to increased liability coverage as the professional liability carriers handling these audits just became too high.

The same can be true for RPM in any medical specialty. With a decrease in Relative Value Units (RVU) and the Conversion Factor (CF), many who originally provided RPM have abandoned providing this valuable service. This, despite the fact that many studies have borne out that earlier intervention translates to reduced expenditures as complications are averted.

Adopting strict rules for engaging patients who de-

Continued on page 65

A Look Back (from page 64)

sire the benefits of Therapeutic Shoes is mandatory. Only those willing to advocate for themselves should be enrolled in this program. Chasing paperwork from an uncooperative MD/DO is unaffordable.Practices must adopt a strict policy on which patients are to be provided with this service, because it is from you who Medicare will request money back, not the MD/DO, not the patient and not your vendor.

As for RPM, insisting on strict protocols with the staff performing the daily monitoring is imperative. Be sure they are licensed in your state and comply with all Federal and State regulations for RPM. Ask who their compliance team is, so as to ensure they are subject-matter expert and that their legal team is well versed in healthcare policies. Be sure daily logs are maintained on every patient to insure that monthly minimum requirements are met. Be sure patients' consents are obtained prior to initiating RPM and be sure you have documented medical necessity requirements. If the patient is reluctant or in your opinion unable to be trained to utilize a proposed device, don't enroll them.

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Conclusion

Presently, there are many advanced technologies available for treating diabetic patients. Technologies used for controlling your patients' blood glucose of course must be left to the physician managing the diabetes. However, there are a number of technologies available for assisting the podiatric physician in diagnosing and treating the diabetic patient's lower extremities. Judicious use and documentation of these devices is mandatory to avoid the overzealous attempts at financial recoupment from the various Medicare and third-party payer agencies. Staying abreast of ever-expanding healthcare technologies is a daunting task and made even more complicated by third-party payers reluctant to embrace the vision to adapt to more preventative care measures. It is best that all providers stay abreast of current trends in health policy by subscribing to their third-party payer website. **PM**

Dr. Kesselman is board certified by ABFAS and ABMSP. He is a member of the Medicare Jurisdictional Council for the DME MACs' NSC and provider portal subcommittees. He is a noted expert on durable medical equipment (DME) and an expert for Codingline.com and many third-party payers. Dr. Kesselman is also a medical advisor and consultant to many medical manufacturers and compliance organizations.