

Screening for Diabetes Now Covered

As of January 1, Medicare will provide medical screening for diabetes and other new benefits helping people lead healthier lives.

The additional coverage also includes a "Welcome to Medicare" physical exam for new beneficiaries, and focuses on preventive medicine more than ever before, according to Lynn B. Nicholas, FACHE, chief executive officer of the ADA.

The association is helping to promote Medicare's new coverage, and helped obtain these new benefits at last year's Medicare Modernization Act meetings. They designed an easy-to-read flyer that lists Medicare benefits for those people with diabetes.

For more information on Medicare coverage, visit www.medicare.gov or www.diabetes.org.



FDA Approves Neuropathic Pain Treatment

The FDA has approved Lyrica (Pfizer Inc, Cambridge, Mass) for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN).

Lyrica has a newly-defined mechanism of action and is the first FDA-approved treatment for both neuropathic pain states. Neuropathic pain may be the result of nerve damage from underlying conditions such as diabetes or shingles. Nearly half of the 18 million Americans with diabetes will develop some form of diabetic neuropathy: One in six cases are painful diabetic neuropathy.

Efficacy was established in six double-blind, placebo-controlled trials. Patients with DPN were studied in three trials. Lyrica provided clinically meaningful pain reduction in a significant portion of patients, with pain relief beginning as early as the first week of treatment in some patients. Pain relief was sustained in studies of up to 12-weeks duration.

The safety of Lyrica was established in over 9,000 patients, and adverse events were mild to moderate. The most common side effects included dizziness, somnolence, dry mouth, peripheral edema, blurred vision, weight gain and difficulty with concentration/attention.

Lyrica is expected to be classified as a controlled substance in a category with lower potential for misuse or abuse relative to controlled substances in other categories. It is currently under review by the FDA for the adjunctive treatment of partial seizures in adults.

First At-Home Test to Measure Long-Term HbA1c

Bristol-Myers Squibb Company (New York, NY) announced the availability of the ChoiceDM HbA1c Home Test, the only over-the-counter test to measure HbA1c at home. The pager-sized disposable device allows diabetic patients to track their progress and assist their health care professionals in monitoring treatment responses. It is now available without prescription.

The ADA has identified HbA1c as the preferred standard indicator for measuring long-term blood sugar control. They recommend four yearly HbA1c tests for all patients with diabetes.

ChoiceDM is FDA-cleared, CLIA-waived and NGSP-certified. It is a three-step test providing HbA1c results in 8 minutes.

Orphan Drug For CR002 In Nephropathy Indication

CuraGen Corporation announced that the FDA has granted orphan drug designation to CR002, a fully human monoclonal antibody, as a potential treatment to slow the progression of IgA nephropathy and kidney failure.

"The ability to slow or prevent kidney failure in patients with IgA nephropathy has the potential to improve patient quality of life as well as to reduce a

portion of the billions of dollars spent annually on dialysis and renal transplantation," said Timothy M. Shannon, MD, executive vice president research and development and chief medical officer at CuraGen, in a news release. "We are excited to be developing one of the first specific therapies for the prevention of kidney disease and failure, and believe that CR002 could be broadly applicable in kidney diseases where PDGF-D is involved in the pathogenesis."

CR002 is a fully human monoclonal antibody that neutralizes PDGF-D, a mediator known to stimulate mesangial cell proliferation and implicated in the pathogenesis of IgA nephropathy. Results from animal models of kidney inflammation suggest that neutralization of PDGF-D by CR002 can reduce kidney tissue scarring and preserve kidney function. A phase I trial will determine the safety, tolerability and pharmacokinetics of CR002. Currently, there is no FDA-approved treatment for IgA nephropathy.

For more information, call 888-GENOMICS or visit www.curagen.com.

VIVO Water Good for Hydration



Diabetic patients who drank VIVO water (CSI Beverages, Rancho Santa Margarita, Calif) increased their intracellular hydration 13.4 times more than diabetic patients who drank distilled water during a hydration study.

Investigators from The Chinese Health Care Science and Technology Society selected diabetic patients from five hospitals in China. Diabetic patients were chosen because of the disease's known symptom of thirst. During a double-blind study, they found that the hydration provided from one bottle of VIVO water was equal to that of 13 bottles of distilled water.

"We are excited with the results of this study because it proves that cell water turnover is critical to health, especially in diabetics," Zhi Y.

Wang, MD, said in a news release. "Proper hydration is critical for people with diabetes because water has to

be organized around insulin, for every one insulin molecule, you need 440 water molecules."

VIVO is made with clustered water technology, and is produced through extensive purification. The solution has been proven in laboratory analyses conducted in California, Japan, China and France to maximize hydration and improve cell function. It is the first and only patented clustered water product on the market with proven hydration studies.

For more information, visit www.drinkvivo.com or call 877-848-6246.

New Products from Lilly

Eli Lilly and Company (Indianapolis) expects to add three products this year, including exenatide in the diabetic market. The company also announced that it is on track for its 2005 submission of ruboxistaurin for symptoms related to diabetic nerve damage.

Lilly detailed nine additional compounds and 10 new indications expected to be in mid-to-late stages of development later this year. These compounds and indications may be potential breakthrough treatments for cardiovascular disease, diabetes and other diseases. Potential treatments for obesity were also reviewed, according to a news release.

A list of the pipeline compounds is available at www.lilly.com.

Diabetic Foot Ulcer Pilot Study Initiated

KeraPac (KeraCure Inc, Chicago), an investigational device for use in the treatment of diabetic foot ulcers, has received FDA approval to start a single-center study.

Investigators have treated the first set of patients with the device and plan on enrolling up to 15 more patients with stage 3 and 4 diabetic foot ulcers. The studies are being conducted at the General Clinical Research Center at the University of Michigan in Ann Arbor, Mich.

Patients will complete a 4-week active treatment phase and a 4-week follow-up. KeraPac, which is comprised of human keratinocytes grown on microcarrier beads, will be externally placed on the clean wounds of patients. Investigators will analyze the preliminary data during the first quarter of 2005.

For more information, visit www.keracure.com/keracpac.asp. ■