

Caring *for the Ages*



An Official Publication of
**THE SOCIETY
FOR POST-ACUTE AND
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CARE MEDICINE™**

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Good Nutrition Becoming a Potent Tool to Boost Immune System in Elderly

Christine Kilgore

Few nursing home residents have escaped the process of immunosenescence. With age comes a sweeping and well-studied decline in immune responsiveness that leaves older individuals increasingly susceptible to developing infections and more likely to have prolonged and difficult recoveries.

T-cell mediated activity is significantly altered, and a host of other changes occur in the composition and functioning of immune system components. Even “healthy aging,” researchers believe, is accompanied by some level of impaired immune response.

The role of nutrition in reversing or diminishing this impaired immune function has also been studied for decades, and in recent years its umbrella has increasingly covered micronutrients as well as probiotics and prebiotics. Today, as nursing homes work to improve antibiotic stewardship, decrease hospital transfers, and strengthen their approaches to infection prevention and control, nutrition has increasing relevance, sources say.

“We need to appreciate that there is significant change in the immune system with aging, both in terms of reductions in the parts of the immune system



Photo courtesy of Simin Meydani, PhD

Dr. Simin Meydani's study on nutrition found nursing home residents were deficient in zinc, and subsequent supplementation improved the number and function of T cells.

that are involved in fighting bacteria and viruses, and increases in the formation of inflammatory products that can have an impact on other parts of the immune system,” said Simin Meydani, PhD, director of the Jean Mayer U.S. Department of Agriculture Human

Nutrition Research Center on Aging at Tufts University in Boston, and of the Center's Nutritional Immunology Lab.

“And we also need to appreciate that changes in the nutritional status of older

See **GOOD NUTRITION** • page 6

CMS Releases Final Rule Revising Nursing Home Regulations

Carey Cowles

The Centers for Medicare & Medicaid Services has issued the long-awaited final rule that will revise the requirements that long-term care facilities must meet to participate in Medicare and Medicaid programs. This is the first change in the nursing home regulations since the Omnibus Budget Reconciliation Act that was implemented in 1990. According to CMS, these changes reflect advances that have been made in

the theory and practice of how care is administered to residents in these facilities, as well as address safety issues. “These revisions are also an integral part of our efforts to achieve broad-based improvements both in the quality of health care furnished through federal programs and in patient safety, while at the same time reducing procedural burdens on providers,” CMS stated in the final rule.

The first phase of regulations will be implemented Nov. 28 of this year, while subsequent phases must be implemented by the same date in 2017 and 2019.

Resident Services

Facilities will be required to investigate and report allegations of abuse of residents and patients. In addition,

See **FINAL RULE** • page 4

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Final Rule

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facilities cannot employ practitioners who have faced disciplinary action by a state licensure body resulting from a finding of neglect, abuse, mistreatment of residents, or misappropriation of the resident's property.

Transfers or discharges will be required to be documented in the patient's medical record, and specified information must be exchanged with the receiving facility or hospital upon transfer.

Look for a Society webinar on this final rule later this month.

Facilities will be required to develop and implement a discharge planning process that "focuses on the resident's discharge goals and prepares residents to be active partners in post-discharge care, in effective transitions, and in the reduction of factors leading to preventable readmissions," according to the final rule. Discharge planning requirements specific to LTC facilities will be added to the discharge planning requirements mandated by the IMPACT Act (Improving Medicare Post-Acute Care Transformation Act of 2014).

Attending physicians will be permitted to delegate dietary orders to qualified dietitians or other qualified nutrition professionals, and to delegate therapy orders to appropriate therapists.

A nurse aide and a member of the food and nutrition services staff will be required to participate on the interdisciplinary team that develops a resident's comprehensive care plan.

A competency requirement will be implemented to determine the sufficiency of nursing staff, "which includes but is not limited to the number of residents, resident acuity, range of diagnoses, and the content of individual care plans."

Residents must receive necessary behavioral health care and services based on their comprehensive assessment and care plan.

A pharmacist will be required to review the resident's medical chart during monthly drug regimen reviews. Particular attention will be focused on reducing and eliminating the need for psychotropic drugs.

SNFs and NFs will be prohibited from charging a Medicare resident for the damage to or loss of dentures, and facilities will be required to have a policy that identifies when such loss or damage is the facility's responsibility. A referral for lost or damaged dentures must be made within 3 business days.

Facilities will be required to provide residents with a "nourishing, palatable, well-balanced diet" that addresses special dietary needs and preferences.

Respiratory services will be considered a specialized rehabilitative service.

Administration

Facilities must "conduct, document and annually review a facility-wide assessment to determine what resources are necessary to care for its residents competently" during daily operations and emergencies.

The use of predispute binding arbitration agreements will be prohibited.

All LTC facilities will be required to develop, implement, and maintain a

comprehensive quality assurance/performance improvement program that focuses on outcomes and systems of care, as well as quality of life.

All LTC facilities will be required to have an infection control and prevention program that includes an "antibiotic stewardship program and at least one infection preventionist."

New Sections

Comprehensive person-centered care planning (§483.21). CMS will require

facilities to develop an individualized baseline care plan for each resident within 48 hours of admission. The care plan should include instructions necessary to "provide effective and person-centered care that meets professional standards of quality care," according to the final rule.

Laboratory, radiology, and other diagnostic services (§483.50). This section will clarify that a physician's assistant, nurse practitioner, or clinical nurse specialist may order these services.

BASAGLAR (insulin glargine injection) Brief Summary: Consult the package insert for complete prescribing information.

INDICATIONS AND USAGE

BASAGLAR® is indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.

Limitations of Use: BASAGLAR is not recommended for the treatment of diabetic ketoacidosis.

DOSAGE AND ADMINISTRATION

- In patients with Type 1 diabetes, BASAGLAR must be used concomitantly with short-acting insulin.
- In patients with Type 2 diabetes, one may need to adjust the amount and timing of short or rapid acting insulins and dosages of any antidiabetic drugs.
- Inject BASAGLAR subcutaneously once daily any time of day, but at the same time every day.

DOSE ADJUSTMENT AND MONITORING

Glucose monitoring is essential for patients receiving insulin therapy. Changes to an insulin regimen should be made cautiously and only under medical supervision. Changes in insulin strength, manufacturer, type, or method of administration may result in the need for a change in insulin dose. Concomitant oral antidiabetic treatment may need to be adjusted.

As with all insulin preparations, the time course of action for BASAGLAR may vary in different individuals or at different times in the same individual and is dependent on many conditions, including the site of injection, local blood supply, or local temperature. Patients who change their level of physical activity or meal plan may require adjustment of insulin dosages.

IMPORTANT DOSING INFORMATION

- Always check insulin labels before administration. Administer BASAGLAR subcutaneously into the abdominal area, thigh, or deltoid, and rotate injection sites within the same region from one injection to the next to reduce the risk of lipodystrophy [see Adverse Reactions].
- Do not dilute or mix BASAGLAR with any other insulin or solution as the onset of action or time peak effect of BASAGLAR and the mixed insulin may be altered in an unpredictable manner.
- Do NOT administer intravenously or via an insulin pump because this could result in severe hypoglycemia.
- Dosage adjustments may be needed with changes in physical activity, changes in meal patterns (i.e., macronutrient content or timing of food intake), during acute illness, or changes in renal or hepatic function and should be made under medical supervision with appropriate glucose monitoring [see Warnings and Precautions].
- If changing patients from another insulin glargine product, 100 units/mL, to BASAGLAR, the dose of BASAGLAR should be the same as the other insulin glargine product, 100 units/mL, and the time of day for administration should be determined by the physician.
- If changing patients from a once-daily insulin glargine product 300 units/mL, to once-daily BASAGLAR, the recommended initial BASAGLAR dosage is 80% of the insulin glargine product, 300 units/mL, dose that is being discontinued in order to lower the likelihood of hypoglycemia [see Warnings and Precautions].
- If changing patients from twice-daily NPH insulin to once-daily BASAGLAR, the recommended initial BASAGLAR dosage is 80% of the total NPH dosage that is being discontinued in order to lower the likelihood of hypoglycemia [see Warnings and Precautions].

CONTRAINDICATIONS

BASAGLAR is contraindicated:

- During episodes of hypoglycemia.
- In patients who are hypersensitive to insulin glargine or to any of its excipients.

BASAGLAR (insulin glargine injection)

BV HCP BS 12SEP2016

WARNINGS AND PRECAUTIONS

- **Never Share a BASAGLAR KwikPen Between Patients**, even if the needle is changed. Sharing poses a risk for transmission of blood-borne pathogens.
- **Changes in Insulin Regimen:** Changes in insulin strength, manufacturer, type, or method of administration may affect glycemic control and predispose to hypoglycemia or hyperglycemia. These changes should be made cautiously under close medical supervision and the frequency of blood glucose monitoring should be increased. For patients with type 2 diabetes, dosage adjustments of concomitant anti-diabetic products may be needed.
- **Hypoglycemia:** Hypoglycemia is the most common adverse reaction of BASAGLAR. Severe hypoglycemia may be life threatening and can cause seizures or death. The patient's ability to concentrate and react may be impaired as a result of hypoglycemia. Hypoglycemia can happen suddenly and symptoms may vary for each person and may change over time. Symptomatic awareness of hypoglycemia may be less pronounced in patients with longstanding diabetes, in patients with diabetic nerve disease, in patients using medications that block the sympathetic nervous system, or in patients who experience recurrent hypoglycemia.

The risk of hypoglycemia after an injection is related to the duration of action of the insulin which may vary in different individuals or at different times in the same individual. Other factors such as changes in food intake, injection site, exercise, and concomitant medications may increase the risk of hypoglycemia. Patients with renal or hepatic impairment may be at higher risk of hypoglycemia

Educate patients and caregivers to recognize and manage hypoglycemia. Self-monitoring of blood glucose plays an essential role in the prevention and management of hypoglycemia. In patients at higher risk for hypoglycemia and patients who have reduced symptomatic awareness of hypoglycemia, increased frequency of blood glucose monitoring is recommended. The long-acting effect of BASAGLAR may delay recovery from hypoglycemia

- **Medication Errors:** Accidental mix-ups between insulin glargine product, 100 units/mL, and other insulins, particularly rapid-acting insulins, have been reported. To avoid medication errors between BASAGLAR and other insulins, instruct patients to always check the insulin label before each injection.
- **Hypersensitivity and Allergic Reactions:** Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulin products including BASAGLAR. If hypersensitivity reactions occur, discontinue BASAGLAR and treat per standard of care and monitor until symptoms and signs resolve.
- **Hypokalemia:** All insulin products, including BASAGLAR, cause a shift in potassium from the extracellular to intracellular space, possibly leading to hypokalemia. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk for hypokalemia if indicated (e.g., patients using potassium-lowering medications, patients taking medications sensitive to serum potassium concentrations).
- **Fluid Retention and Heart Failure with Concomitant Use of PPAR-gamma Agonists:** Thiazolidinediones (TZDs), which are PPAR-gamma agonists, can cause dose-related fluid retention, particularly when used in combination with insulin, including BASAGLAR. This may lead to or exacerbate heart failure. Observe patients for signs and symptoms of heart failure and consider discontinuation or dose reduction of the PPAR-gamma agonist.

DRUG INTERACTIONS

Some medications may alter glucose metabolism, insulin requirements, and the risk for hypoglycemia or hyperglycemia. Signs of hypoglycemia may be reduced or absent in patients taking anti-adrenergic drugs. Particularly close monitoring may be required.

ADVERSE REACTIONS

Adverse reactions commonly associated with insulin glargine products (5% or greater incidence) are: hypoglycemia, allergic reactions, injection site reaction, lipodystrophy, pruritus, rash, edema, and weight gain.

BASAGLAR (insulin glargine injection)

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Compliance and ethics program (§483.85). Facilities will be required to have a compliance and ethics program with written standards, and policies and procedures that can reduce the prospect of criminal, civil and administrative violations.

Training requirements (§483.95). A section on training will require facilities to develop, implement, and maintain an effective training program for new and existing staff, contracted individuals, and volunteers.

CMS estimated that the projected estimated cost of the final rule will be \$831 million in the first year, and \$736 million annually thereafter. The average facility costs are estimated to be \$62,900 the first year, and \$55,000 per year for subsequent years.

The Society and many other stakeholders submitted comments to the proposed rule last summer, and CMS clearly responded to these by removing some of the original regulations, including a requirement that every resident be

evaluated by a physician or non-physician practitioner before any transfer to the emergency department.

Caring will provide more information on the final rule in future issues. The Society also will post a webinar on this topic sometime in November. For more information, go to <https://federalregister.gov/d/2016-23503>.

Carey Cowles is the managing editor of *Caring for the Ages*.

FDA: New Boxed Warning on Combining Opioids, Benzodiazepines

Sharon Worcester

Labeling for prescription opioid pain or cough medicines and benzodiazepines will now carry the strongest available warning regarding serious side effects and death associated with their combined use, according to the Food and Drug Administration.

The new boxed warnings urge health care professionals to limit prescribing opioid pain medicines with benzodiazepines or other central nervous system depressants only to patients for whom alternative treatment options are inadequate, and to limit dosages and treatment duration to the minimum possible while achieving the desired clinical effect.

Opioids will include a warning regarding prescribing with benzodiazepines and other central nervous system depressants, including alcohol. Benzodiazepines will include a warning regarding prescribing with opioids.

The action comes amid ongoing efforts to address an epidemic of opioid addiction across the United States, and in response to a first-of-its-kind “citizen petition” calling for the boxed warnings.

Sharon Worcester is with the Southeast bureau of Frontline Medical News.

EDITOR'S NOTE

Most of us should know the potentiation of respiratory depression with concomitant administration of benzodiazepines and opioids. Although the risk of clinically significant respiratory depression with pure opioids (e.g., morphine) has been overblown and is rare in clinical practice, mixing opioids with benzos is known to increase the risk of serious respiratory compromise. The new boxed warning won't mean we can't use them together, but we can expect to get the usual communications from our consultant pharmacists when we do. Benzodiazepines — although most of us still prescribe them at times — are pretty risky and not that effective for many conditions they're commonly used for, most notably dementia-related agitation. They disinhibit behavior and increase the risk of falls, among other adverse effects. The FDA is taking an appropriate step to remind us not to combine opioids and benzos indiscriminately. As always, let's keep our individual patients' situations always at the forefront of decision making.

—Karl Steinberg, MD, CMD, HMDC
Editor in Chief

Adverse reactions occurring in ≥5% of adult patients with type 1 diabetes treated with BASAGLAR (combined with insulin lispro) in a 52-week trial were infection (24%), nasopharyngitis (16%), and upper respiratory tract infection (8%). Adverse reactions occurring in ≥5% of adult patients with type 2 diabetes treated with BASAGLAR in a 24-week trial were infection (17%), nasopharyngitis (6%), and upper respiratory tract infection (5%).

Allergic Reactions

Some patients taking insulin therapy, including BASAGLAR have experienced erythema, local edema, and pruritus at the site of injection. These conditions were usually self-limiting. Severe cases of generalized allergy (anaphylaxis) have been reported [see Warnings and Precautions (5.5)].

Weight Gain

Weight gain can occur with insulin therapy, including BASAGLAR, and has been attributed to the anabolic effects of insulin and the decrease in glucosuria.

Peripheral Edema

Some patients taking BASAGLAR have experienced sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy.

Lipodystrophy

Administration of insulin subcutaneously, including BASAGLAR, has resulted in lipoatrophy (depression in the skin) or lipohypertrophy (enlargement or thickening of tissue) in some patients [see Dosage and Administration (2.1)].

Weight Gain

Weight gain has occurred with some insulin therapies including BASAGLAR and has been attributed to the anabolic effects of insulin and the decrease in glucosuria.

Severe Hypoglycemia

Hypoglycemia is the most commonly observed adverse reaction in patients using insulin, including BASAGLAR [see Warnings and Precautions]. The rates of reported hypoglycemia depend on the definition of hypoglycemia used, diabetes type, insulin dose, intensity of glucose control, background therapies, and other intrinsic and extrinsic patient factors. For these reasons, comparing rates of hypoglycemia in clinical trials for BASAGLAR with the incidence of hypoglycemia for other products may be misleading and also, may not be representative of hypoglycemia rates that will occur in clinical practice. Severe symptomatic hypoglycemia was defined as an event with symptoms consistent with hypoglycemia requiring the assistance of another person and associated with either a blood glucose below 50 mg/dL or prompt recovery after oral carbohydrate, intravenous glucose or glucagon administration. The incidence of severe symptomatic hypoglycemia in patients receiving BASAGLAR with type 1 diabetes mellitus and type 2 diabetes mellitus [see Clinical Studies] was 4% at 52 weeks and 1% at 24 weeks, respectively.

USE IN SPECIFIC POPULATIONS

Pregnancy—Pregnancy Category C. Female patients should be advised to tell their physicians if they intend to become, or if they become pregnant while taking BASAGLAR.

There are no well-controlled clinical studies of the use of insulin glargine in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers—It is unknown whether insulin glargine is excreted in human milk. Use of insulin glargine is compatible with breastfeeding, but women with diabetes who are lactating may require adjustments of their insulin doses.

Pediatric Use—The safety and effectiveness of BASAGLAR have been established in pediatric patients (age 6 to 15 years) with type 1 diabetes based on an adequate and well-controlled trial of another insulin glargine product, 100 units/mL, in pediatric patients (age 6 to 15 years) with type 1 diabetes and additional data in adults with type 1 diabetes [see Clinical Studies (14.2)]. The safety and effectiveness of BASAGLAR in pediatric patients younger than 6 years of age with type 1 diabetes and pediatric patients with type 2 diabetes has not been established.

In the pediatric clinical trial of another insulin glargine, pediatric patients (age 6 to 15 years) with type 1 diabetes had a higher incidence of severe symptomatic hypoglycemia compared to the adults in trials with type 1 diabetes [see Adverse Reactions].

Geriatric Use—Of the total number of subjects in clinical studies of patients with type 2 diabetes who were treated with BASAGLAR or another insulin glargine product, 100 units/mL, each in combination with oral agents in a controlled clinical trial environment, 28.3% were 65 and over, while 4.5% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Nevertheless, caution should be exercised when BASAGLAR is administered to geriatric patients. In elderly patients with diabetes, the initial dosing, dose increments, and maintenance dosage should be conservative to avoid hypoglycemic reactions. Hypoglycemia may be difficult to recognize in the elderly.

Renal Impairment—The effect of renal impairment on the pharmacokinetics of BASAGLAR has not been studied.

Hepatic Impairment—The effect of hepatic impairment on the pharmacokinetics of BASAGLAR has not been studied.

Obesity—In controlled clinical trials, subgroup analyses based on BMI did not show differences in safety and efficacy between BASAGLAR and another insulin glargine product, 100 units/mL.

OVERDOSAGE

Excess insulin administration relative to food intake, energy expenditure, or both may lead to severe and sometimes prolonged and life-threatening hypoglycemia and hypokalemia [see Warnings and Precautions (5.3, 5.6)]. Mild episodes of hypoglycemia can be treated with oral glucose. Adjustments in drug dosage, meal patterns, or physical activity level may be needed. More severe episodes with coma, seizure, or neurologic impairment may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous glucose. Sustained carbohydrate intake and observation may be necessary because hypoglycemia may recur after apparent clinical recovery. Hypokalemia must be corrected appropriately.

PATIENT COUNSELING INFORMATION: See FDA-approved patient labeling and Patient Counseling Information section of the Full Prescribing Information.

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Lilly

Marketed by: Lilly USA, LLC, Indianapolis, IN 46285, USA and Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877, USA

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Available by prescription only.

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