Preparing for Healthcare Reform

The Effect of Reform on Primary Care

Understanding the Reimbursement Rules

Evaluating and Restructuring Your Systems

10 Tips for a Successful Strategy

Preparing for an Uncertain Future

FREE Medical Application on the iPad!
In patients with type 2 diabetes, the TITRATE® study demonstrates

**Once-daily Levemir® gets the majority of patients to goal safely**

64% of patients achieved A1C goal <7% with once-daily Levemir®

> 24/7 glucose control & more

The Levemir® TITRATE trial shows how a majority of patients with type 2 diabetes taking a basal insulin, some with A1C levels as high as 9%, achieved the ADA-recommended target of A1C <7%.*! Patients experienced a mean A1C decrease of 1.2% ** and achieved goal safely with low rates of hypoglycemia, nearly all of which were minor or symptoms only.**

* 70 to 90 mg/dL group.

To see how Levemir® can help your patients achieve their goals, and to learn more about TITRATE, visit TITRATEstudy.com.

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**Indications and usage**
Levemir® is indicated for once- or twice-daily subcutaneous administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

**Important safety information**
Levemir® is contraindicated in patients hypersensitive to insulin detemir or one of its excipients.

Levemir® should not be diluted or mixed with any other insulin preparations.

Hypoglycemia is the most common adverse effect of all insulin therapies, including Levemir®. As with other insulins, the timing of hypoglycemic events may differ among various insulin preparations. Glucose monitoring is recommended for all patients with diabetes. Levemir® is not to be used in insulin infusion pumps. Any change of insulin dose should be made cautiously and only under medical supervision. Concomitant oral antidiabetes treatment may require adjustment.

Needles and Levemir® FlexPen® must not be shared.

Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic ketoacidosis. Insulin may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy. Dose and timing of administration may need to be adjusted to reduce the risk of hypoglycemia in patients being switched to Levemir® from other intermediate or long-acting insulin preparations. The dose of Levemir® may need to be adjusted in patients with renal or hepatic impairment.

Other adverse events commonly associated with insulin therapy may include injection site reactions (on average, 3% to 4% of patients in clinical trials) such as lipodystrophy, redness, pain, itching, hives, swelling, and inflammation. Less common but more serious are severe cases of generalized allergy, including anaphylactic reaction, which may be life threatening.

Please see brief summary of Prescribing Information on adjacent page.

Levemir® (insulin detemir [rDNA origin] injection)
Rx ONLY

BRIEF SUMMARY. Please see package insert for full prescribing information.

INDICATIONS AND USAGE: LEVEMIR® is indicated for once- or twice-daily subcutaneous administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long acting) insulin for the control of hyperglycemia.

CONTRAINDICATIONS: LEVEMIR® is contraindicated in patients hypersensitive to insulin detemir or one of its excipients.

WARNINGS: Hypoglycemia is the most common adverse effect of insulin therapy, including LEVEMIR®. As with all insulins, the timing of hypoglycemia may differ among various insulin formulations. Glucose monitoring is recommended for all patients with diabetes. LEVEMIR® is not to be used in insulin infusion pumps. Any change of insulin dose should be made cautiously and only under medical supervision. Changes in insulin strength, timing of dosing, manufacturer, type (e.g., regular, NPH, or insulin analogs), species (animal, human), or method of manufacture (rDNA versus animal-source insulin) may result in the need for a change in dosage. Concomitant oral antidiabetic treatment may need to be adjusted. Needles and LEVEMIR® FlexPen® must not be shared.

PRECAUTIONS: General: Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic ketoacidosis. The first symptoms of hyperglycemia usually occur gradually over a period of hours or days. They include nausea, vomiting, drowsiness, flushed skin, dry mouth, increased urination, thirst and loss of appetite as well as acetone breath. Untreated hyperglycemic events are potentially fatal. LEVEMIR® is not intended for intravenous or intramuscular administration. The prolonged duration of activity of insulin detemir is dependent on injection into subcutaneous tissue. Intravenous administration of the usual subcutaneous dose could result in severe hypoglycemia. Absorption after intramuscular administration is both faster and more extensive than absorption after subcutaneous administration. LEVEMIR® should not be diluted or mixed with any other insulin preparations (see PRECAUTIONS, Mixing of Insulins). Insulin may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy. Lipodystrophy and hypersensitivity are among potential clinical adverse effects associated with the use of all insulins. As with all insulin preparations, the time course of LEVEMIR® action may vary in different individuals or at different times in the same individual and is dependent on site of injection, blood supply, temperature, and physical activity. Adjustment of dosage of any insulin may be necessary if patients change their physical activity or their usual meal plan.

Hypoglycemia: As with all insulin preparations, hypoglycemic reactions may be associated with the administration of LEVEMIR®. Hypoglycemia is the most common adverse effect of insulin. Early warning symptoms of hypoglycemia may be different or less pronounced under certain conditions, such as long duration of diabetes, diabetic nerve disease, use of medications such as beta-blockers, or intensified diabetes control (see PRECAUTIONS, Drug Interactions). Such situations may result in severe hypoglycemia (and, possibly, loss of consciousness) prior to patients' awareness of hyperglycemia. The time of occurrence of hypoglycemia depends on the action profile of the insulin used and may, therefore, change when the treatment regimen or timing of dosing is changed. In patients being switched from other intermediate- or long-acting insulin preparations to once- or twice-daily LEVEMIR®, dosages can be prescribed on a unit-to-unit basis, however, as with all insulin preparations, dose and timing of administration may need to be adjusted to reduce the risk of hypoglycemia. Renal Impairment: As with other insulins, the requirements for LEVEMIR® may need to be adjusted in patients with renal impairment. Hepatic Impairment: As with other insulins, the requirements for LEVEMIR® may need to be adjusted in patients with hepatic impairment. Injection Site and Allergic Reactions: As with any insulin therapy, lipodystrophy may occur at the injection site and delay insulin absorption. Other injection site reactions with insulin therapy may include redness, pain, itching, hives, swelling, and inflammation. Continuous rotation of the injection site within a given area may help to reduce or prevent these reactions. Reactions usually resolve in a few days to a few weeks. On rare occasions, injection site reactions may require discontinuation of LEVEMIR®. In some instances, these reactions may be related to factors other than insulin, such as irritants in a skin cleansing agent or poor injection technique. Systemic allergy. Generalized allergy to insulin, which is less common but potentially more serious, may cause rash (including pruritus) over the whole body, shortness of breath, wheezing, reduction in blood pressure, rapid pulse, or sweating. Severe cases of generalized allergy, including anaphylactic reaction, may be life-threatening.

Intermittent Conditions: Insulin requirements may be altered during intermittent conditions such as illness, emotional disturbances, or other stresses. Information for Patients: LEVEMIR® must only be used if the solution appears clear and colorless with no visible particles. Patients should be informed about potential risks and advantages of LEVEMIR® therapy, including the possible side effects. Patients should be offered continued education and advice on insulin therapies, injection technique, life-style management, regular glucose monitoring, periodic glycosylated hemoglobin testing, recognition and management of hypo- and hyperglycemia, adherence to meal planning, complications of insulin therapy, timing of dosage, instruction for use of injection devices and proper storage of insulin. Patients should be informed that frequent, patient-performed blood glucose measurements are needed to achieve effective glycemic control to avoid both hyperglycemia and hypoglycemia. Patients must be instructed on handling of special situations such as intermittent conditions (illness, stress, or emotional disturbances), an inadequate or skipped insulin dose, inadvertent administration of an increased insulin dose, inadequate food intake, or skipped meals. Refer patients to the LEVEMIR® Patient Information” circular for additional information. As with all patients who have diabetes, the ability to concentrate and/or react may be impaired as a result of hyperglycemia or hypoglycemia. Patients with diabetes should be advised to inform their health care professional if they are pregnant or are contemplating pregnancy (see PRECAUTIONS, Pregnancy). Laboratory Tests: As with all insulin therapy, the therapeutic response to LEVEMIR® should be monitored by periodic blood glucose tests. Periodic measurement of HbA1c is recommended for the monitoring of long-term glycemic control. Drug Interactions: A number of substances affect glucose metabolism and may require insulin dose adjustment and particularly close monitoring. The following are examples of substances that may reduce the blood-glucose-lowering effect of insulin: corticosteroids, danazol, diuretics, sympathomimetic agents (e.g., epinephrine, albuterol, terbutaline), isoniazid, phenolamine derivatives, somatropin, thyroid hormones, estrogens, progestogens (e.g., in oral contraceptives). The following are examples of substances that may increase the blood-glucose-lowering effect of insulin and susceptibility to hypoglycemia: oral antidiabetic drugs, ACE inhibitors, disopyramide, fibrates, fluoxetine, MAO inhibitors, propantheline, salicylates, somatostatin analog (e.g., octreotide), and sulfonamide antibiotics. Beta-blockers, clonidine, lithium salts, and alcohol may either potentiate or weaken the blood-glucose-lowering effect of insulin. Pentamidine may cause hypoglycemia, which may sometimes be followed by hyperglycemia. In addition, under the influence of sympathomimetic medicinal products such as beta-blockers, clonidine, guanethidine, and reserpine, the signs of hypoglycemia may be reduced or absent. The results of in-vitro and in-vivo protein binding studies demonstrate that there is no clinically relevant interaction between insulin detemir and fatty acids or other protein bound drugs. Mixing of Insulins: If LEVEMIR® is mixed with other insulin preparations, the profile of action of one or both individual components may change. Mixing LEVEMIR® with insulin aspart, a rapid acting insulin analog, resulted in about 40% reduction in AUC0-2h and Cmax for insulin aspart compared to separate injections when the ratio of insulin aspart to LEVEMIR® was less than 50%. LEVEMIR® should NOT be diluted or mixed with any other insulin preparations. Carcinogenicity, Mutagenicity,
Impairment of Fertility: Standard 2-year carcinogenicity studies in animals have not been performed. Insulin detemir tested negative for genotoxic potential in the in-vitro reverse mutation study in bacteria, human peripheral blood lymphocyte chromosome aberration test, and the in-vivo mouse micronucleus test. Pregnancy: Teratogenic Effects: Pregnancy Category C: In a fertility and embryonic development study, insulin detemir was administered to female rats before mating, during mating, and throughout pregnancy at doses up to 300 nmol/kg/day (3 times the recommended human dose, based on plasma Area Under the Curve (AUC) ratio). Doses of 150 and 300 nmol/kg/day produced numbers of litters with visceral anomalies. Doses up to 900 nmol/kg/day (approximately 135 times the recommended human dose based on AUC ratio) were given to rabbits during organogenesis. Drug-dose related increases in the incidence of fetuses with gall bladder abnormalities such as small, bilobed, bifurcated and missing gall bladders were observed at a dose of 900 nmol/kg/day. The rat and rabbit embryo/fetal development studies that included concurrent human insulin control groups indicated that insulin detemir and human insulin had similar effects regarding embryotoxicity and teratogenicity. Nursing mothers: It is unknown whether LEVEMIR® is excreted in significant amounts in human milk. For this reason, caution should be exercised when LEVEMIR® is administered to a nursing mother. Patients with diabetes who are lactating may require adjustments in insulin dose, meal plan, or both. Pediatric use: In a controlled clinical study, HbA1c concentrations and rates of hypoglycemia were similar across patients treated with LEVEMIR® and patients treated with NPH human insulin. Geriatric use: Of the total number of subjects in intermediate and long-term clinical studies of LEVEMIR®, 85 (type 1 studies) and 363 (type 2 studies) were 65 years and older. 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. 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.

ADVERSE REACTIONS: Adverse events commonly associated with human insulin therapy include the following: Body as Whole: allergic reactions (see PRECAUTIONS, Allergy). Skin and Appendages: lipodystrophy, pruritus, rash. Mild injection site reactions occurred more frequently with LEVEMIR® than with NPH human insulin and usually resolved in a few days to a few weeks (see PRECAUTIONS, Allergy). Other: Hypoglycemia: (see WARNINGS and PRECAUTIONS). In trials of up to 6 months duration in patients with type 1 and type 2 diabetes, the incidence of severe hypoglycemia with LEVEMIR® was comparable to the incidence with NPH, and, as expected, greater overall in patients with type 1 diabetes (Table 4). Weight gain: In trials of up to 6 months duration in patients with type 1 and type 2 diabetes, LEVEMIR® was associated with somewhat less weight gain than NPH (Table 4). Whether these observed differences represent true differences in the effects of LEVEMIR® and NPH insulin is not known, since these trials were not blinded and the protocols (e.g., diet and exercise instructions and monitoring) were not specifically directed at exploring hypotheses related to weight effects of the treatments compared. The clinical significance of the observed differences has not been established.

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*See CLINICAL STUDIES section for description of individual studies
**Major = requires assistance of another individual because of neurologic impairment
***Minor = plasma glucose <56 mg/dl, subject able to deal with the episode himself/herself

OVERDOSE: Hypoglycemia may occur as a result of an excess of insulin relative to food intake, energy expenditure, or both. Mild episodes of hypoglycemia usually can be treated with oral glucose. Adjustments in drug dosage, meal patterns, or exercise may be needed. More severe episodes with coma, seizure, or neurologic impairment may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous glucose. After apparent clinical recovery from hypoglycemia, continued observation and additional carbohydrate intake may be necessary to avoid reoccurrence of hypoglycemia.

More detailed information is available upon request.

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DOCTOR'S DIGEST

Preparing for Healthcare Reform

By Deborah Gesensway
Deborah Gesensway is a Toronto-based freelance writer and editor specializing in the business and practice of healthcare and clinical issues affecting primary care and hospital medicine. She writes regularly for Today’s Hospitalist magazine, edits academic papers, and has worked as a staff writer for the American College of Physicians and several daily newspapers in New York state and Japan. She is a frequent contributor to Doctor’s Digest.

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If you haven’t noticed, amid the debate and headlines, healthcare reform has already begun. Parts of the new law are in place and many more look ready to roll out over the next few years. Don’t understand it completely? Don’t worry. This issue of Doctor’s Digest is our most ambitious ever as we give you thorough—yet easy-to-understand—background in how healthcare reform is going to affect your practice and what you should do now to most efficiently and effectively change with the times.

Author Deborah Gesensway starts by explaining what the new law intends to accomplish, the most recent changes to the law, and what industry leaders think is really going to take place. She next gets down to specifics—the changes in reimbursement that may dramatically affect your practice. To best cope with these changes she then guides you in evaluating and restructuring your practice. Want the insider’s view? Don’t miss the 10 tips that experts say will help you not only survive but thrive in the new healthcare environment. Finally, Deborah looks ahead, a critical step to best understand and prepare for changes that experts say are sure to come, whether from this law or other reform effort.

Another way to stay on top of changes in healthcare is by checking out the new, FREE Doctor’s Digest Practice Solution Center iPad app. Just download it from iTunes for FREE in the MEDICAL category.

I remain dedicated to helping you bridge the gap between the practice of medicine and the business of medicine. As always, I look forward to hearing from you. Contact me at jbrandofino@doctorsdigest.net or by fax to 516-364-2575.

Jeannette Brandofino
Publisher
e-mail: jbrandofino@doctorsdigest.net
Don’t let the atmosphere of prolonged debate around healthcare reform fool you—some of the changes are already taking place, and more are scheduled for the near future. Prepare now to better understand and to make the most of the changes by reading this issue of Doctor’s Digest.

Author Deborah Gesensway first guides you through the key provisions and newest developments. Don’t miss her “At a Glance” summary of how reform will affect your primary care practice. She meticulously walks you through specific reimbursement rule changes, from the impact on preventive medicine to the upcoming ICD-10 coding changes, then shows you how you can be sure to take advantage of the primary care bonus program. She offers advice on how to evaluate and restructure your practice’s systems, from how you can absorb an influx of new patients to how you can accommodate new fraud-and-abuse and IRS rules. She next reveals what experts say you need to know to survive—and thrive—in this changing environment by offering ten valuable tips you won’t want to miss. Finally, Deborah shows you where healthcare reform (and the accompanying political debate) is heading and how those changes may impact your practice.
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