

Health Reform '09: Major Overhaul—Or Not?

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Publication Editor

WASHINGTON — Can President-elect Barack Obama really shepherd through major health reform? Not until the Medicare physician payment system gets fixed, according to Robert Laszewski.

“How do you plan a health care budget in Medicare and the private sector for years on out if you haven’t agreed on how you’re going to pay the doctors?” Mr.

Laszewski said at a conference on the impact of the November elections sponsored by Congressional Quarterly and the Public Affairs Council.

Unfortunately, many obstacles lie ahead before the payment system can be fixed, said Mr. Laszewski, president of Health Policy and Strategy Associates, a health care consulting firm. “The primary care physicians are clearly underpaid, and a lot of people think that specialists are overpaid.”

Although everyone agrees that the

Medicare payment system needs to be reformed and that Medicare costs need to be trimmed, “the problem is, who’s going to give up the money?” he continued. “The definition of physician payment reform is to pay the primary care physicians more and pay the rest of us more, and that’s not going to fly.”

Congress can’t keep making temporary fixes, Mr. Laszewski said, because a fix that lasts for, say, 3 years will be followed by a 36% fee cut because of the way the Sus-

tainable Growth Rate (SGR) payment formula works.

In the meantime, analysts and legislative aides are considering whether smaller health reforms might be possible.

“Do you have to do something big?” asked Robert Blendon, Ph.D., professor of health policy and political analysis at the Harvard University School of Public Health. “I believe not, but it has to be something that looks like a big down payment.”

And policy makers have to be clear about what their overall goals are, said Christine Ferguson, J.D., of the department of health policy at George Washington University, Washington. “There is a group of people who want to use health reform to improve health outcomes; another group that wants to control costs [in terms of] the percentage of gross domestic product that goes to health care; and a third group that wants to protect people from high [out-of-pocket] costs,” she said. “So it’s very important we’re very clear about which of those goals we’re trying to achieve.”

Rather than passing a major health reform bill right away, the panelists suggested that President-elect Obama could urge Congress to pass a package of smaller reforms, which could include less-controversial items as expanding the State Children’s Health Insurance Program (SCHIP), setting up a cost containment board to come up with ideas for reducing health spending, and helping individuals and small businesses buy health insurance—possibly by giving them subsidies to help pay for it.

“These items are all no-brainers,” according to Mr. Laszewski.

But some Senate Democrats are looking to take a more aggressive approach. Sen. Edward M. Kennedy (D-Mass.), who chairs the Senate Health, Education, Labor and Pensions Committee, wants to craft comprehensive health reform legislation that follows the framework of the Obama plan, said Michael Myers, staff director for the committee.

“With the Obama victory, the question is no longer whether we’ll pursue comprehensive health reform but when and exactly what form,” Mr. Myers said during a postelection briefing sponsored by the advocacy group, Families USA.

While there are many health reform proposals circulating on Capitol Hill, the best chance for success is a single-bill strategy, Mr. Myers said, and Sen. Kennedy is urging fellow Democrats to unite behind the proposal from President-elect Obama.

No legislation has been drafted yet, but whatever comes out of the Congress will need to address both the cost and quality of health care and expanding coverage to the uninsured, Mr. Myers said.

The interest in achieving comprehensive health reform and the cooperation among stakeholders is higher now than at any point in the last 25 years, said Ron Pollack, executive director of Families USA. “There’s a very significant likelihood that meaningful health reform will be a top and early priority for action in the 111th Congress,” Mr. Pollack said. ■

Mary Ellen Schneider, New York Bureau, contributed to this report.

HUMALOG® Mix75/25™ 75% INSULIN LISPRO PROTAMINE SUSPENSION AND 25% INSULIN LISPRO INJECTION (rDNA ORIGIN) BRIEF SUMMARY: Consult package insert for complete prescribing information.

INDICATIONS AND USAGE: Humalog Mix75/25, a mixture of 75% insulin lispro protamine suspension and 25% insulin lispro injection (rDNA origin), is indicated in the treatment of patients with diabetes mellitus for the control of hyperglycemia. Humalog Mix75/25 has a more rapid onset of glucose-lowering activity compared with Humulin 70/30 while having a similar duration of action. This profile is achieved by combining the rapid onset of Humalog with the intermediate action of insulin lispro protamine suspension.

CONTRAINDICATIONS: Humalog Mix75/25 is contraindicated during episodes of hypoglycemia and in patients sensitive to insulin lispro or any of the excipients contained in the formulation.

WARNINGS: Humalog differs from regular human insulin by its rapid onset of action as well as a shorter duration of activity. Therefore, the dose of Humalog Mix75/25 should be given within 15 minutes before a meal.

Hypoglycemia is the most common adverse effect associated with the use of insulins, including Humalog Mix75/25. As with all insulins, the timing of hypoglycemia may differ among various insulin formulations. Glucose monitoring is recommended for all patients with diabetes. Any change of insulin should be made cautiously and only under medical supervision.

Changes in insulin strength, manufacturer, type (eg, regular, NPH, analog), species, or method of manufacture may result in the need for a change in dosage.

PRECAUTIONS: *General*—Hypoglycemia and hypokalemia are among the potential clinical adverse effects associated with the use of all insulins. Because of differences in the action of Humalog Mix75/25 and other insulins, care should be taken in patients in whom such potential side effects might be clinically relevant (eg, patients who are fasting, have autonomic neuropathy, or are using potassium lowering drugs or patients taking drugs sensitive to serum potassium level). Lipodystrophy and hypersensitivity are among other potential clinical adverse effects associated with the use of all insulins.

As with all insulin preparations, the time course of Humalog Mix75/25 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. Insulin requirements may be altered during illness, emotional disturbances, or other stress.

Hypoglycemia—As with all insulin preparations, hypoglycemic reactions may be associated with the administration of Humalog Mix75/25. Rapid changes in serum glucose concentrations may induce symptoms of hypoglycemia in persons with diabetes, regardless of the glucose value. 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.

Renal Impairment—As with other insulins, the requirements for Humalog Mix75/25 may be reduced in patients with renal impairment.

Hepatic Impairment—Although impaired hepatic function does not affect the absorption or disposition of Humalog, careful glucose monitoring and dose adjustments of insulin, including Humalog Mix75/25, may be necessary.

Allergy—Local Allergy—As with any insulin therapy, patients may experience redness, swelling, or itching at the site of injection. These minor reactions usually resolve in a few days to a few weeks. 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—Less common, but potentially more serious, is generalized allergy to insulin, which 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. Localized reactions and generalized myalgias have been reported with the use of cresol as an injectable excipient.

Antibody Production—In clinical trials, antibodies that cross-react with human insulin and insulin lispro were observed in both human insulin mixtures and insulin lispro mixtures treatment groups.

Information for Patients—Patients should be informed of the potential risks and advantages of Humalog Mix75/25 and alternative therapies. Patients should not mix Humalog Mix75/25 with any other insulin. They should also be informed about the importance of proper insulin storage, injection technique, timing of dosage, adherence to meal planning, regular physical activity, regular blood glucose monitoring, periodic hemoglobin A1C testing, recognition and management of hypoglycemia and hyperglycemia, and periodic assessment for diabetes complications.

Patients should be advised to inform their physician if they are pregnant or intend to become pregnant.

Refer patients to the “PATIENT INFORMATION” leaflet for information on normal appearance, timing of dosing (within 15 minutes before a meal), storing insulin, and common adverse effects.

For Patients Using Insulin Pen Delivery Devices: Before starting therapy, patients should read the “PATIENT INFORMATION” leaflet that accompanies the drug product and the User Manual that accompanies the delivery device. They should also re-read these materials each time the prescription is renewed. Patients should be instructed on how to properly use the delivery device, prime the Pen, and properly dispose of needles. Patients should be advised not to share their Pens with others.

Laboratory Tests—As with all insulins, the therapeutic response to Humalog Mix75/25 should be monitored by periodic blood glucose tests. Periodic measurement of hemoglobin A1C is recommended for the monitoring of long-term glycemic control.

Drug Interactions—Insulin requirements may be increased by medications with hyperglycemic activity, such as corticosteroids, isoniazid, certain lipid-lowering drugs (eg, niacin), estrogens, oral contraceptives, phenothiazines, and thyroid replacement therapy.

Insulin requirements may be decreased in the presence of drugs that increase insulin sensitivity or have hypoglycemic activity, such as oral antidiabetic agents, salicylates, sulfa antibiotics, certain antidepressants (monoamine oxidase inhibitors), angiotensin-converting-enzyme inhibitors, angiotensin II receptor blocking agents, beta-adrenergic blockers, inhibitors of pancreatic function (eg, octreotide), and alcohol. Beta-adrenergic blockers may mask the symptoms of hypoglycemia in some patients.

Pregnancy—Teratogenic Effects—Pregnancy Category B—Reproduction studies with insulin lispro have been performed in pregnant rats and rabbits at parenteral doses up to 4 and 0.3 times, respectively, the average human dose (40 units/day) based on body surface area. The results have revealed no evidence of impaired fertility or harm to the fetus due to insulin lispro. There are, however, no adequate and well-controlled studies with Humalog, Humalog Mix75/25, or Humalog Mix50/50 in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Although there are limited clinical studies of the use of Humalog in pregnancy, published studies with human insulins suggest that optimizing overall glycemic control, including postprandial control, before conception and during pregnancy improves fetal outcome. Although the fetal complications of maternal hyperglycemia have been well documented, fetal toxicity also has been reported with maternal hypoglycemia. Insulin requirements usually fall during the first trimester and increase during

the second and third trimesters. Careful monitoring of the patient is required throughout pregnancy. During the perinatal period, careful monitoring of infants born to mothers with diabetes is warranted.

Nursing Mothers—It is unknown whether insulin lispro is excreted in significant amounts in human milk. Many drugs, including human insulin, are excreted in human milk. For this reason, caution should be exercised when Humalog Mix75/25 is administered to a nursing woman. Patients with diabetes who are lactating may require adjustments in Humalog Mix75/25 dose, meal plan, or both.

Pediatric Use—Safety and effectiveness of Humalog Mix75/25 in patients less than 18 years of age have not been established.

Geriatric Use—Clinical studies of Humalog Mix75/25 did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently than younger patients. In general, dose selection for an elderly patient should take into consideration the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy in this population.

ADVERSE REACTIONS: Clinical studies comparing Humalog Mix75/25 with human insulin mixtures did not demonstrate a difference in frequency of adverse events between the 2 treatments.

Adverse events commonly associated with human insulin therapy include the following:

Body as a Whole—allergic reactions (see PRECAUTIONS).

Skin and Appendages—injection site reaction, lipodystrophy, pruritus, rash.

Other—hypoglycemia (see WARNINGS and PRECAUTIONS).

OVERDOSAGE: 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. Sustained carbohydrate intake and observation may be necessary because hypoglycemia may recur after apparent clinical recovery.

DOSE AND ADMINISTRATION: Humalog Mix75/25 is intended for subcutaneous administration. Humalog Mix75/25 should not be administered intravenously. Dosage regimens of Humalog Mix75/25 will vary among patients and should be determined by the healthcare provider familiar with the patient’s metabolic needs, eating habits, and other lifestyle variables. Humalog has been shown to be equipotent to regular human insulin on a molar basis. One unit of Humalog has the same glucose-lowering effect as one unit of regular human insulin, but its effect is more rapid and of shorter duration. Humalog Mix75/25 has a similar glucose-lowering effect as compared with Humulin 70/30 on a unit-for-unit basis. The quicker glucose-lowering effect of Humalog is related to the more rapid absorption rate of insulin lispro from subcutaneous tissue.

Humalog Mix75/25 starts lowering blood glucose more quickly than regular human insulin, allowing for convenient dosing immediately before a meal (within 15 minutes). In contrast, mixtures containing regular human insulin should be given 30 to 60 minutes before a meal.

The rate of insulin absorption and consequently the onset of activity are known to be affected by the site of injection, exercise, and other variables. As with all insulin preparations, the time course of action of Humalog Mix75/25 may vary considerably in different individuals or within the same individual. Patients must be educated to use proper injection techniques.

Humalog Mix75/25 should be inspected visually before use. Humalog Mix75/25 should be used only if it appears uniformly cloudy after mixing. Humalog Mix75/25 should not be used after its expiration date.

HOW SUPPLIED:

Humalog Mix75/25 (75% insulin lispro protamine suspension and 25% insulin lispro injection [rDNA origin]) is available in the following package sizes (with each presentation containing 100 units insulin lispro per mL [U-100]):

10 mL vials	NDC 0002-7511-01	(VL-7511)
5 x 3 mL cartridges ¹	NDC 0002-7516-59	(VL-7516)
5 x 3 mL disposable insulin delivery devices (Pen)	NDC 0002-8794-59	(HP-8794)
5 x 3 mL disposable insulin delivery devices (KwikPen [®])	NDC 0002-8797-59	(HP-8797)

¹ 3 mL cartridge is for use in Eli Lilly and Company’s HumaPen[®] MEMOIR[™] and HumaPen[®] LUXURA[™] HD insulin delivery devices, Owen Mumford, Ltd.’s AutoPen[®] 3 mL insulin delivery device, and Disetronic D-TRON[®] and D-TRONplus[®] pumps. AutoPen[®] is a registered trademark of Owen Mumford, Ltd. HumaPen[®], HumaPen[®] MEMOIR[™], and HumaPen[®] LUXURA[™] HD are trademarks of Eli Lilly and Company.

Other product and company names may be the trademarks of their respective owners.

Storage—Humalog Mix75/25 should be stored in a refrigerator (2° to 8°C [36° to 46°F]), but not in the freezer. Do not use Humalog Mix75/25 if it has been frozen. Unrefrigerated (below 30°C [86°F]) vials must be used within 28 days or be discarded, even if they still contain Humalog Mix75/25. Unrefrigerated (below 30°C [86°F]) Pens and KwikPens must be used within 10 days or be discarded, even if they still contain Humalog Mix75/25. Protect from direct heat and light.

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KwikPens manufactured by Eli Lilly and Company, Indianapolis, IN 46285, USA.
Pens manufactured by Eli Lilly and Company, Indianapolis, IN 46285, USA or Lilly France, F-67640 Fegersheim, France.
Vials manufactured by Eli Lilly and Company, Indianapolis, IN 46285, USA or Hospira, Inc., Lake Forest, IL 60045, USA or Lilly France, F-67640 Fegersheim, France.
Cartridges manufactured by Lilly France, F-67640 Fegersheim, France for Eli Lilly and Company, Indianapolis, IN 46285, USA.
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