



Public Health Service
DEPARTMENT OF HEALTH AND HUMAN SERVICES National Institutes of Health

**Diabetes Branch
National Institute of Diabetes and
Digestive and Kidney Diseases
Mark O. Hatfield Clinical Research
Center, Room 5/5940
Bethesda, Maryland 20892
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November 17, 2009

Tamara Syrek-Jensen, J.D.
Division Director of Coverage and Analysis
CMS-OCSQ-CAG
7500 Security Boulevard
Baltimore, MD 21244.

Dear Ms. Syrek-Jensen:

At Dr. Koller's request, I have reviewed the claims pertaining to pulsatile intravenous insulin delivery's ability to reverse diabetes complications, or to improve clinical islet transplantation outcomes, whether that pulsatile insulin is delivered in the peri-operative period, in the post surgical period, or for rescue therapy. I am unaware of any data I consider scientifically credible to justify those claims.

Please feel free to contact me should you have questions.

Sincerely,

A handwritten signature in black ink that reads "David M. Harlan".

David M. Harlan, M.D.
Chief, Diabetes Branch
and
Professor of Medicine
Uniformed Services University of the Health Sciences

Copy to:
Elizabeth A. Koller, MD, FACE
Medical Officer
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