ENDOCRINE SOCIETY
Hormone Science to Health

August 14, 2014

Medical Policy Dept
BCBS of Massachusetts
Landmark Center, 401 Park Drive
Boston, MA 02215-3326

Good morning,

The Endocrine Society, representing more than 17,500 physicians and scientists engaged in the treatment and research of endocrine disorders, such as diabetes, is concerned about recent proposals to eliminate coverage for artificial pancreas device systems (APDS) due to the fact that they are unproven and not medically necessary. These determinations further state that APDS have not been shown to improve health outcomes and that larger, randomized controlled trials are needed to determine the long-term impact of these devices on diabetes management. The Society is strongly opposed to this determination and urges payers to reconsider this decision.

APDS are approved by the Food and Drug Administration (FDA) as of 2013 and prior to that have been used in numerous countries for several years. In studies published in the two major medical journals in the United States these systems have been shown to reduce the frequency and duration of hypoglycemia – particularly nocturnal hypoglycemia. A head-to-head trial comparing patients on an insulin pump to those using a low-threshold suspend pumps demonstrated a 3.6 fold reduction in moderate and severe hypoglycemia (Ly TT et al. J Amer Med Assoc 310: 1240-1247, 2013).

Even more relevent are the results of the study published in the New England Journal of Medicine (Bergenstal et al. N Eng J Med 369: 224-232, 2013) that compared patients using a sensor-augmented insulin pump (the closest thing to the low-threshold suspend pump). Those using the threshold suspend pump had almost 1/3 the rate of nocturnal hypoglycemia and there was no worsening of HbA1c in either of these trials and no episodes of ketoacidosis.

The Endocrine Society believes that this technology represent a significant step forward in our ability to safely and effectively treat our patients with Type 1 diabetes since these results are directly translatable into fewer emergency room visits, seizures, and loss of consciousness and, most importantly, an improved sense of safety.

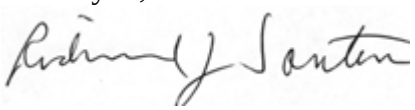
2055 L Street NW
Suite 600
Washington, DC
20036

T. 202.971.3636
F. 202.736.9705

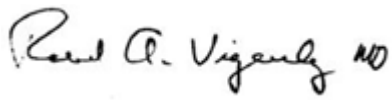
endocrine.org

The Society is supportive of coverage for FDA-approved technologies, including APDS, and urges payers to reconsider eliminating coverage for these devices. Should you have any questions, please do not hesitate to contact Meredith Dyer, Associate Director, Health Policy, at mdyer@endocrine.org.

Thank you,



Richard J. Santen, M.D.
President
Endocrine Society



Robert Vigersky, M.D.
Past-President, Endocrine Society