

May 10, 2018

CMS HCPCS Workgroup
c/o Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop C5-09-14
Baltimore, Maryland 21244

Dear HCPCS Workgroup:

The Endocrine Society is writing in support of the HCPCS J code application under consideration for MACRILEN (macimorelin). The Society represents over 18,000 members who are dedicated to advancing hormone research and excellence in clinical endocrinology. Endocrinologists are at the core of solving some of the most pressing health problems of our time, from diabetes and obesity to infertility, thyroid conditions, and rare diseases like Growth Hormone Deficiency.

MACRILEN is the first FDA-approved oral agent for growth hormone stimulation testing (GHST) to diagnose Adult Growth Hormone Deficiency (AGHD), a rare disease that affects at least 50,000 people in the United States. Currently, provocative testing for AGHD requires the intravenous or intramuscular administration of growth hormone stimulating medications.

The availability of a stimulation test that does not require injections represents a significant advance in our ability to identify patients with AGHD without the discomfort of intravenous medication administration. It also avoids the potential hazards of inducing clinically-significant hypoglycemia during an insulin tolerance test. We also note that MACRELIN is similar to other drugs for this condition that have received J codes and differs only in the method of administration.

The Society supports the development of a J Code for MACRILEN because evocative/stimulation agents are not included in current CPT codes and MACRELIN must be prepared and administered by a healthcare professional. MACRILEN would be provided as an “incident to” service as four sequential blood draws must take place at specific intervals after administering the agent.

The Endocrine Society’s clinical practice guideline, “Evaluation and Treatment of Adult Growth Hormone Deficiency,” recommends GHST for the diagnosis of AGHD. While various agents can be used for GHST, including insulin and arginine, MACRILEN is the first FDA-approved oral evocative



agent specifically for the diagnosis of AGHD. The Society believes that the development of a J code for MACRILEN will help endocrinologists and other healthcare professionals safely and effectively diagnose the 6,000 individuals who are diagnosed with AGHD each year.

We hope that the HCPCS workgroup will consider the development of a J code for MACRILEN given the details outlined above. Should you have any questions about our support for the J code, please contact Meredith Dyer, Director of Health Policy, at mdyer@endocrine.org

Thank you,

A handwritten signature in blue ink, appearing to read "Robert W. Lash".

Robert W. Lash, MD
Chief Professional and Clinical Affairs Officer
Endocrine Society