May 1st 2024
To whom it may concern:

On behalf of the American Foregut Society, we are writing this letter to request an update to your medical policy to identify the EsoGuard® test as a covered service.

The American Foregut Society is comprised of gastroenterologists and surgeons collaborating to personalize treatment and improve patient outcomes in foregut disease. Our mission is driven by the belief that cross-specialty collaboration will translate into improved care, safety, and value for patients with Foregut disease. There is an unmet need to prevent Esophageal adenocarcinoma (EAC) altogether by early detection of Barrett's esophagus (BE), the only known precancerous condition of EAC. Once EAC develops, it is highly lethal with a >80% mortality and a poor prognosis. The incidence of EAC has surged by 500% over the recent decades because fewer than 10% of high-risk patients undergo screening with upper endoscopy. This low rate of endoscopic screening and subsequent disease detection is perpetuated by patient anxiety, limited access to endoscopy, and primary care barriers to upper endoscopy referrals. To reduce the number of cases that progress from BE to EAC, we must identify patients in the precancerous stage (BE). Effective treatment of BE has demonstrated 80- 90% success rate of complete disease eradication.

Members of the American Foregut Society use the EsoGuard test to screen high-risk patients for BE. EsoGuard offers an accessible and minimally invasive screening alternative to endoscopy. EsoGuard's value lies in its ability to enrich the patient population undergoing confirmatory endoscopy, improve the positive yield of endoscopy, and identify those who may safely forego endoscopy. Upon confirmation of a BE's diagnosis via endoscopy, there are established standard of care treatment and surveillance management guidelines for each stage of the disease. There is strong, supporting scientific evidence for EsoGuard. Its superior performance has been clinically validated in two independent, NIH-funded studies while three peer-reviewed clinical utility publications consistently showed> 99% concordance between EsoGuard results and referral (or non-referral) to endoscopy.

We are disappointed that your medical policy does not align with guidelines and biomarker legislation. The 2022 American College of Gastroenterology guideline and the American Gastroenterological Association clinical practice recommendations endorse the EsoCheck collection device combined with a biomarker test (e.g. EsoGuard) as an acceptable alternative to screening endoscopy for BE. Additionally, biomarker legislation in 15 states mandate coverage for biomarker testing like EsoGuard. EsoGuard meets the three general coverage provisions outlined in each state's legislation as it fulfills the statutory definition of a biomarker test, aids in the diagnosis of BE and guides management decisions, and has clinical utility as demonstrated by the aforementioned guidelines and scientific evidence.

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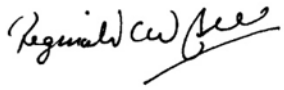
We are confident that expanding access to the EsoGuard test will empower providers with an essential triage for upper endoscopy that enables the early detection of BE. The goal of early BE detection is to facilitate prompt treatment and surveillance, ultimately reducing the risk of cancer progression. By being available as a point-of-care test in primary care offices, EsoGuard directly reduces health disparities in endoscopy access, aligning with the mission of the American Foregut Society. We urge you to consider the immediate coverage of the EsoGuard test.

Thank you for your attention to this important matter.

Respectfully,



Reginald Bell
Chair of the Board
The American Foregut Society

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