PacificDx
Seamless Results.

May 31, 2020

VIA Electronic Submission to MolDX@PalmettoGBA.com

RE: MolDx Coverage Request and Technical Assessment of EsoGuard® Esophageal DNA Test

To Whom It May Concern:

On behalf of Pacific Diagnostics ("PacificDx"), I am pleased to submit this technical assessment of the EsoGuard® Esophageal DNA Test ("EsoGuard®"). EsoGuard® is a novel non-endoscopic, qualitative diagnostic test to detect Barret's esophagus (BE) by evaluating epigenetic changes in esophageal cells. EsoGuard® employs EsoCheck™, an FDA-cleared swallowable, encapsulated balloon device (K183262) that selectively samples the distal esophagus. This test is intended for the qualitative detection of Barrett's esophagus (BE) and BE associated precancers (dysplasia) and cancers correlating with methylated DNA markers in esophageal lining. A positive result may indicate the presence of BE, a precancerous lesion (dysplasia), or esophageal cancer (EAC) and should be followed by diagnostic endoscopy.

EsoGuard® allows gastroenterologists to manage GERD patients consistent with clinical guidelines without subjecting patients unnecessarily to endoscopy. EsoGuard® is both reasonable and necessary – (1) EsoGuard® performs well clinically with a sensitivity of 88% across BE, EAC and GE junction cancers and a specificity of 91.7%; (2) EsoGuard® facilitates guideline recommended patient care; and (3) there is an existing clinical need for EsoGuard® — an accurate and non-invasive diagnostic test supported by research. We respectfully request that you consider our technical assessment and coverage request.

To support this request, we are submitting the following:

- Checklist (M00151) for EsoGuard®
- Technical Assessment including Summary Form (M00116)
- Supporting documentation
- Draft language for a new proposed LCD

Thank you for your time and consideration of this request. Please do not hesitate to contact me at sgunn@researchdx.com or 949.812.6902 ext. 107.

Sincerely,

Shelly Gunn

Shelly Gunn MD, PhD, FCAP
Chief Medical Officer