



February 1, 2022

Medical Directors
MoIDX Program
Palmetto GBA, LLC
17 Technology Circle
Columbia, SC 29203

Re: New LCD Request

Dear MoIDX Program Medical Directors,

We respectfully submit the enclosed request for an LCD concerning molecular biomarkers for decision-making in relapsed, recurrent, advanced, or metastatic prostate cancer.

The treatment of prostate cancer is complex, and with the availability of multiple treatment options in each clinical scenario, biomarkers to help determine optimal therapy have become important in guiding treatment decisions. There is a long history of research and development of the Decipher testing platform, and we continue to participate in research to further validate the Decipher Prostate test and develop new transcriptomic signatures. We are actively involved in over 42 trials, in localized, relapsed, recurrent, advanced, and metastatic prostate cancer. In these trials, Decipher Prostate and our new signatures are being studied for their ability to provide prognostic information as well as to predict treatment response for particular therapies.

We believe that providing Medicare beneficiaries access to these biomarkers will enable better treatment decisions and will improve patient outcomes.

Thank you for your consideration of this request.

Sincerely,

A handwritten signature in blue ink, appearing to read "Elai Davicioni". The signature is fluid and cursive, with a large initial "E" and "D".

Elai Davicioni, PhD
Medical Director, Urology