ACMG
American College of Medical Genetics and Genomics
Translating Genes Into Health®

April 16, 2021

The Honorable Jackie Speier
US House of Representatives
2465 Rayburn House Office building
Washington, DC 20515

The Honorable Tom Cole
US House of Representatives
2207 Rayburn House Office building
Washington, DC 20515

Dear Representatives Speier and Cole,

On behalf of the American College of Medical Genetics and Genomics (ACMG), we want to thank you for your interest in ensuring that pregnant patients enrolled in Medicaid have access to noninvasive prenatal screening and express our support for the Expanded Genetic Screening Act of 2021.

ACMG is the only nationally recognized medical professional organization solely dedicated to improving health through the practice of medical genetics and genomics, and the only medical specialty society in the US that represents the full spectrum of medical genetics disciplines in a single organization. ACMG is the largest membership organization specifically for medical geneticists, providing education, resources, and a voice for more than 2,400 clinical and laboratory geneticists, genetic counselors, and other healthcare professionals, nearly 80% of whom are board-certified in the medical genetics specialties. ACMG's mission is to improve health through the clinical and laboratory practice of medical genetics as well as through advocacy, education, and clinical research, and to guide the safe and effective integration of genetics and genomics into all of medicine and healthcare, resulting in improved personal and public health.

Noninvasive prenatal screening (NIPS) using cell-free DNA has been integrated rapidly into prenatal care over the past decade. Current evidence strongly suggests that NIPS can replace other invasive conventional screening methods for certain chromosome abnormalities for pregnant patients regardless of their age or other risk factors, including aneuploidies such as Patau syndrome (trisomy 13), Edwards syndrome (trisomy 18), and Down syndrome (trisomy 21), and sex chromosome abnormalities such as Klinefelter syndrome and Turner syndrome. Because this process analyzes small fragments of fetal DNA that can be isolated from a sample of the pregnant woman's blood, it significantly reduces risks to the fetus that may be caused by more conventional invasive procedures.

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New applications of NIPS are being studied, and pregnant patients should have access to all NIPS supported by clinical evidence. In 2019, the ACMG established an Evidence-Based Guidelines Program to help clinicians make the best decisions regarding the use of genetic and genomic testing, and to help both government and private health insurers determine coverage options for new tests and treatments. Because of its significant clinical importance, NIPS was selected as one of the first topics to be reviewed through this new program, and the supporting systematic evidence review is expected to be published in summer 2021[1].

Access to appropriate pre- and post-test counseling are also critical and need to be covered as a component of testing. With pre-test counseling, the patient can make an educated decision about the current use of NIPS and the significance of a positive, negative, or "no-call" result. For example, it is important that patients understand that NIPS is a screening test and not a diagnostic test. Therefore, any positive findings will require subsequent diagnostic testing, including confirmatory testing at the time of birth. Further, not all conditions or chromosome anomalies may be detected by prenatal screening and testing. Patients also should be advised that children with certain conditions may benefit from early treatment or special accommodations, and that identifying such conditions during pregnancy can help families and their healthcare teams prepare appropriately.

ACMG strongly supports the Expanded Genetic Screening Act of 2021, and we appreciate your attention to ensuring that pregnant patients covered by Medicaid have access to NIPS should they choose such testing. For questions or additional information, please contact Dr. Michelle McClure at mmcclure@acmg.net.

Sincerely,

Anthony R. Gregg, MD, MBA, FACOG, FACMG
President
American College of Medical Genetics and Genomics

Max Muenke

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Chief Executive Officer
American College of Medical Genetics and Genomics

[1] Evidence Based Guidelines Program Semi-Annual Updates on Development and Work Group Actions, Press Release, February 2021. https://www.acmgfoundation.org/PDFLibrary/EBGupdateJanuary2021.pdf

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