Coalition for Access to Prenatal Screening

Improve Access to cfDNA-based Non-Invasive Prenatal Screening

All pregnant women who choose to pursue aneuploidy screening – regardless of their risk factors, income, age or geographic location – should have access to cell-free DNA (cfDNA)-based non-invasive prenatal screening (NIPS).

NIPS represents a major advance in screening for fetal chromosomal aneuploidies. Through the analysis of DNA fragments in a pregnant woman's blood, obtained through a simple maternal blood draw, NIPS detects chromosome abnormalities that may cause genetic disorders in a newborn baby. Prenatal screening for chromosomal aneuploidies using analysis of serum proteins has been the standard of care for decades. Since its introduction to clinical practice in 2011, cfDNA-based NIPS has become the preferred method of prenatal screening for many healthcare providers and patients. *All women choosing to pursue noninvasive prenatal screening should have access and coverage, regardless risk factor, income, age or geographic location.*

The high sensitivity and specificity, and low failure rate, of cfDNA-based NIPS result in fewer women undergoing invasive testing procedures. Although all prenatal screening results should be confirmed with diagnostic testing by chorionic villus sampling (CVS) or amniocentesis, cfDNA-based NIPS correctly identifies a higher proportion of pregnancies affected by chromosomal aneuploidies, including Trisomy 21/Down syndrome, Trisomy 18/Edwards syndrome, and Trisomy 13/Patau syndrome.

The Benefits of Cell-free DNA (cfDNA)-based Non-invasive Prenatal Screening (NIPS)

Extensive data, published in peer-reviewed literature, establishes cfDNA-based NIPS is a powerful screening tool for fetal chromosomal aneuploidies.[1-5] In addition to a significantly higher detection rate, cfDNA-based NIPS simultaneously tests for a larger number of specific chromosomal aneuploidies than traditional serum screening. Furthermore, the markedly lower false positive rates of NIPS provide significantly improved positive predictive values compared to traditional screening tests.[5] NIPS can be used as early as 9 to 10 weeks into the pregnancy.

Numerous professional organizations, including the American Congress of Obstetricians and Gynecologists (ACOG), the Society for Maternal-Fetal Medicine (SMFM), the International Society for Prenatal Diagnosis (ISPD), the American College of Medical Genetics and Genomics (ACMG), and the National Society of Genetic Counselors (NSGC) recognize cfDNA-based NIPS as a screening option for all pregnant women, given appropriate patient counseling regarding the performance, risks and benefits of such screening.

The Current Landscape: Inconsistent Access to cfDNA NIPS Across the Country

Since 2011, cfDNA-based NIPS has become increasingly available around the country. However, some private insurers still do not cover this type of screening for all pregnant women, or only provide coverage at very low reimbursement rates that severely limit access.

Currently, 17 state Medicaid programs, representing 23.9 million people or 32.7% of the Medicaid population, provide NIPS coverage for all (i.e. average-risk) women. 63.8% of US Medicaid enrollees, representing about 46.6 million people, live in one of the 28 states providing NIPS coverage only for women deemed high-risk. The remaining 3.5% of Medicaid enrollees, or 2.5 million people, live in one of the five states plus Washington D.C. denying NIPS coverage completely. Some Medicaid Managed Care Organizations (MMCOs) cover NIPS for both average and high-risk pregnant women, even if the state's fee-for-service program does not, creating another level of confusion and disparity among women in the same state Medicaid program.

CAPS aims to ensure cfDNA-based NIPS is readily accessible to all pregnant women seeking this screening– regardless of their risk factors, income, age or geographic location.

About CAPS

The Coalition for Access to Prenatal Screening (CAPS) is a collaborative alliance of six leading genetic testing companies in the United States that seeks to improve access to state-of-the-art prenatal screening using cell-free DNA (cfDNA)-based noninvasive prenatal screening (NIPS) for all pregnant women who choose to pursue aneuploidy screening – regardless of their risk factors, income, age or geographic location.

As leading providers of cfDNA-based NIPS, CAPS member companies work together to promote public awareness about the value of this innovative and highly sensitive screening and to advocate for the highest standards of quality, service, and education. CAPS provides reliable and useful information about NIPS to patients, providers, and public and private insurers.

CAPS encourages appropriate legislative measures and reimbursement coverage policy changes for this medically-actionable screening service that can improve personalized patient care.

CAPS Member Companies: Illumina, Inc.; Invitae Corporation; Laboratory Corporation of America® Holdings (LabCorp®) through its Integrated Genetics specialty laboratory; Myriad Women's Health, Inc.; Natera, Inc.; and Roche Diagnostics, Inc.

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Footnotes:

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2. Taneja, P. et al. (2016) Noninvasive prenatal testing in the general obstetric population: clinical performance and counseling considerations in over 85 000 cases . *Prenatal Diagnosis 36*(3), 237–243.
3. Dar P. et al. (2014) Clinical experience and follow-up with large scale single-nucleotide polymorphism—based noninvasive prenatal aneuploidy testing. Am J Obstet Gynecol 211:527.e1-17.
4. Mackie F. et al. (2016) The accuracy of cell-free fetal DNA-based non-invasive prenatal screening in singleton pregnancies: a systematic review and bivariate meta-analysis. BJOG DOI: 10.1111/1471-0528.14050.
5. Norton M et al (2015) Cell-free DNA Analysis for Noninvasive Examination of Trisomy N Engl J Med 372:1589-97.