Coalition for Access to Prenatal Screening

Improve Access to cfDNA-based Non-Invasive Prenatal Testing

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

Overview

NIPT represents a major advance in screening for fetal chromosomal aneuploidies through the analysis of millions of cfDNA fragments in the blood of a pregnant woman. Chromosomal aneuploidies are characterized by an abnormal number of chromosomes that may cause genetic disorders in a newborn baby, including some birth defects. Prenatal screening for chromosomal aneuploidies using analysis of serum proteins has been the standard of care for decades. However, cfDNA-based NIPT has become the preferred method of prenatal screening for many healthcare providers and patients since its introduction to clinical practice in 2011.

The high sensitivity and specificity, and low failure rate, of cfDNA-based NIPT 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 NIPT 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 testing (NIPT)

Extensive data have been published in peer-reviewed literature that establish the performance of cfDNA-based NIPT as a powerful screening tool for fetal chromosomal aneuploidies.[1-5] In addition to having a significantly higher detection rate, cfDNA-based NIPT can simultaneously test for a larger number of specific chromosomal aneuploidies than traditional serum screening methods. Furthermore, the markedly lower false positive rates of cfDNA-based NIPT provide significantly improved positive predictive values compared to traditional screening tests.[5] NIPT 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) have recognized cfDNA-based NIPT as a screening option for all pregnancies, given appropriate patient counseling regarding the performance, risks and benefits of such testing.

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

Since 2011, cfDNA-based NIPT has become increasingly available around the country. However, some private insurance still do not cover this type of testing for all pregnant women, or they provide coverage only at very low reimbursement rates that severely limit access. Further, no state fee-for-service Medicaid programs cover NIPT for average risk, but 83% of U.S. Medicaid patients (representing about 60 million people) are covered for high risk. The remaining 17% of Medicaid patients (12.2 million people) have no coverage for NIPT -- even if they are considered high risk. A number of Medicaid Managed Care Organizations (MMCOs) do cover NIPT for both average risk and high risk pregnant women even though the state's fee-for-service program does not, thus creating another level of confusion and disparity among women in the same state Medicaid program.

CAPS aims to help ensure that cfDNA-based NIPT is readily accessible to all pregnant women who stand to benefit from it – 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 testing (NIPT) 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 NIPT, CAPS member companies are working together to promote public awareness about the value of this innovative and highly sensitive screening method and to advocate for the highest standards of quality, service and education. The CAPS Coalition provides reliable and useful information about cfDNA-based NIPT to patients, healthcare providers, and public and private insurers.

CAPS encourages appropriate legislative measures and reimbursement coverage policy changes for this medically-actionable testing service that has the potential to improve personalized patient care.

CAPS Member Companies: Illumina, Inc.; Counsyl, Inc.; Progenity, Inc.; Natera, Inc.; Laboratory Corporation of America® Holdings (LabCorp®) through its Integrated Genetics specialty laboratory; and Roche

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Footnotes:

1. McCullough R. et al. (2014) Non-Invasive Prenatal Chromosomal Aneuploidy Testing - Clinical Experience: 100,000 Clinical Samples. PLoS ONE 9(10): e109173.
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 testing 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.