Industry’s Contribution to Education for Prenatal Genetic Testing

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Chairman, Clinical Advisory Board
CAPS
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Agenda

• Introduction to CAPS
• Key Points
• Industry Role in Education
• Industry Perspective
• Commercial Insurance NIPT Coverage
• Medicaid NIPT Coverage
The Coalition for Access to Prenatal Screening (CAPS) is a collaborative alliance of six leading genetic testing companies in the U.S (: Illumina, Counsyl, Integrated Genetics (a LabCorp company), Natera, Progenity, and Roche )that seeks to improve access to state-of-the-art prenatal screening using cell-free DNA (cfDNA)-based noninvasive prenatal testing (NIPT)

- accessible to all pregnant women who choose to pursue aneuploidy screening, regardless of their risk factors, income, age or geographic location.
- work 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.
Clinical Advisory Board (CAB)

• The CAB provides advice and consults CAPS on non-invasive prenatal screening

• Its role includes, but is not limited to, promoting evidence-based clinical care and attending scientific meetings

• CAB Members:
  • Arnold W. Cohen, MD FACOG (Chair)
  • Jennifer M. Hoskovec, MS, CGC
  • Valerie Rappaport, MD
  • Annelise S. Swigert, MD
  • Thomas Westover, MD, FACOG
NIPT- the most widely and rapidly adopted molecular diagnostic test in history

- Previous diagnostics were marketed with equal force with lower uptake - testament to the value NIPT provides to both patients and clinicians.

Development and Research has been sponsored by industry

Academic verification of sensitivity, specificity, PPV, NPV and False positive rate has been done by industry

Peer reviewed publications have all been supported by industry

- High Risk
- Average Risk
# Clinical Evidence in the General Population

>15 Publications with > 87,000 Average Risk Patients

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<tr>
<th>Author</th>
<th>Date</th>
<th>Journal</th>
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<tr>
<td>Nicolaides et al.</td>
<td>Nov-2012</td>
<td>American Journal of Obstetrics and Gynecology</td>
<td>2,049</td>
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<td>Dan et al.</td>
<td>9-Nov-2012</td>
<td>Prenatal Diagnosis</td>
<td>1,387</td>
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<td>289</td>
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<td>Gil et al.</td>
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<td>101</td>
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<td>Bianchi et al.</td>
<td>27-Feb-2014</td>
<td>New England Journal of Medicine</td>
<td>1,914</td>
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<td>Zhou et al.</td>
<td>4-Jul-2014</td>
<td>Prenatal Diagnosis</td>
<td>26</td>
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<td>Pergament et al.</td>
<td>Aug-2014</td>
<td>Obstetrics &amp; Gynecology</td>
<td>518</td>
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cfDNA performance in the general obstetric population has been documented in at least 15 studies covering at least 87,000 subjects
Education

• Companies provide physician NIPT education,
  • medical affairs groups
  • sales force

• Education based on Professional Organizations Guidelines and Peer Reviewed Journal publications
  • Examples: Office brochures, websites, webinars, presentations at scientific conferences, educational grants to private educational providers and professional organizations, peer-reviewed publications

• Physicians play a key role in educating patients

• Companies also support programs aimed directly at patient education
  • Initially for high Risk
  • moved to average risk
Industry Supports Society Partnership & Educational Programs

The goal of the Perinatal Quality Foundation Genetic Education Modules (GEM) is to facilitate communication between providers and patients by providing baseline knowledge and common resources for support.

GEM helps providers comply with ACOG/SMFM standards regarding prenatal genetic testing.

Providers and staff can earn credentialing and CME, plus stay up-to-date through webinars, newsletters, reference guides, and more...

Industry & society partnership to promote education for routine prenatal genetic testing.
Various Presentations on NIPT & expanded panels

ACOG District presentations
- Non Invasive Prenatal Testing (NIPT) for all patients in an Obstetrical practice
- Interactive workshops on prenatal aneuploidy screening

Emerging Technology Session
iTalk Unplugged: Building a Comprehensive NIPT Program.
(View point of Physician, genetic alliance and patient advocates)

Donor lounge sponsorships
- Non Invasive Prenatal Testing (NIPT) for all patients
Industry Supports Patient Education Videos
Industry Perspective

• Companies continue to be active in new research that has a goal of providing comprehensive Prenatal Genetic Testing NON-INVASIVELY

• Companies continue to be active in patient and provider education around NIPT
  • Efforts have included providing educational and/or research grants to professional organizations (ACOG, ACMG, NSGC, SMFM, PQF) and many academic institutions
Barriers to Use of NIPT

Conflicting Professional organization opinions

• Organizations’ endorsement of invasive procedures (i.e. CVS, amnio), while not fully supporting a validated noninvasive blood test
• Organizations’ reliance on data obtained by invasive testing as the “Gold Standard”
• Organizations’ endorsement of counselling for all available options for prenatal genetic diagnosis
• Disconnect between Organizations’ endorsement and availability of counselors
• Organizations’ support of Patient Autonomy in decision making but not payment coverage
• Organizations’ reluctance to support insurers coverage policies that would allow patients access to NIPT
• Organizations’ reluctance to understand the significance of a 10x lower false positive rate that will decrease need for invasive testing and risk to the pregnancies
• Commercial insurance variation in coverage policies
  • High Risk
  • Average Risk
• Medicaid variation in coverage policies
  • High Risk
  • Average Risk
• Lack of explicit endorsement by the largest organizations (ACOG)
• Lack of explicit endorsement by SMFM
Reasons Precluding NIPT Use by OBGYNs

Exhibit 8
Reasons For Avoiding NIPT In Average Risk Mothers – Comparison To 2016-2017

- Lack of Clinical Data: 2018 - 29%, 2017 - 31%, 2016 - 35%
- Logistics: 2018 - 3%, 2017 - 7%, 2016 - 5%
- Private Reimbursement: 2018 - 65%, 2017 - 63%, 2016 - 55%
- Medicaid: 2018 - 21%, 2017 - 26%, 2016 - 27%
- Other: 2018 - 3%, 2017 - 12%, 2016 - 15%

Coalition for Access to Prenatal Screening
• Eager to learn about how to do better and further improve education efforts and access to appropriate prenatal genetic testing
• Eager to promote expanded content in non-invasive testing technology
• Eager to collaborate to ensure availability to the appropriate testing to all
Commercial Payer Coverage

Current commercial payer coverage of NIPT (average risk):

• 37 commercial plans, encompassing 107.9 million people, cover NIPT
• Major insurers providing coverage include Cigna and Anthem
• 2018 policy changes by WellMark and Blue Cross Blue Shield Tennessee

• However, several major insurers (and ALL state Medicaid programs) do not cover NIPT for average-risk patients
  • Divergent professional society opinions
  • Lack of explicit endorsement by the largest organizations (ACOG)
  • Leaves some of the most vulnerable populations without access to optimal management (disparity in care)
Medicaid Coverage

• **37** states cover NIPT (CPT Codes 81420 & 81507) for roughly 61 million Medicaid patients, for high risk pregnancies only
• The remaining 12.3 million people on Medicaid are from one of the 13 states + DC not covering NIPT

**13 States + DC that Do not Cover NIPT:**
Alabama, Arizona, Delaware, District of Columbia, Indiana, Louisiana, Maine, Missouri, Nebraska, Nevada, New Mexico, North Dakota, Pennsylvania, Rhode Island