NAMSA Reimbursement and Health Economics

Edward Black, MBA ,
Director-Global Reimbursement Strategy

Jacqueline Madison, COC,
Senior Reimbursement Strategist

Daniel Lace, MD, CPE, FAAPL
Medical Director

Partners Worldwide in Every Major MedTech Market

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NAMSA Continues to Grow

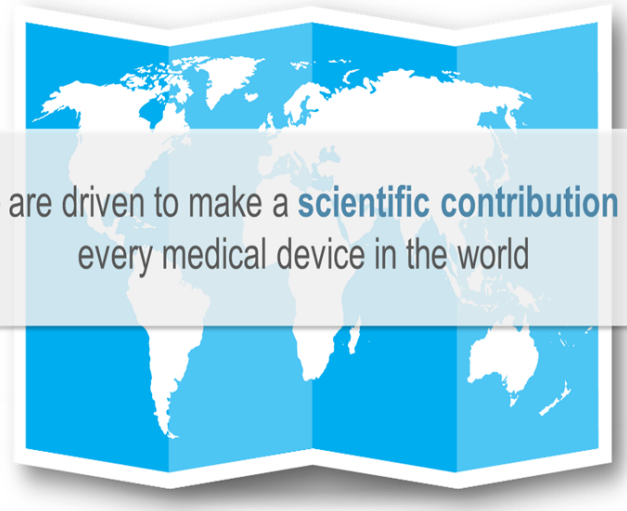
Founded in 1967

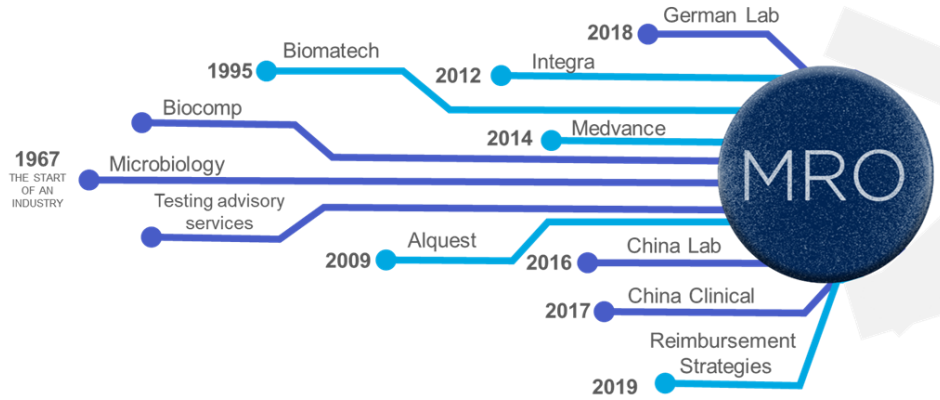
Major contributor to the original U.S. FDA medical device testing regulations (1970s)

First independent company in the world to focus solely on safety testing medical device materials

Built through organic growth, geographic expansion and best in class acquisitions

Our mission

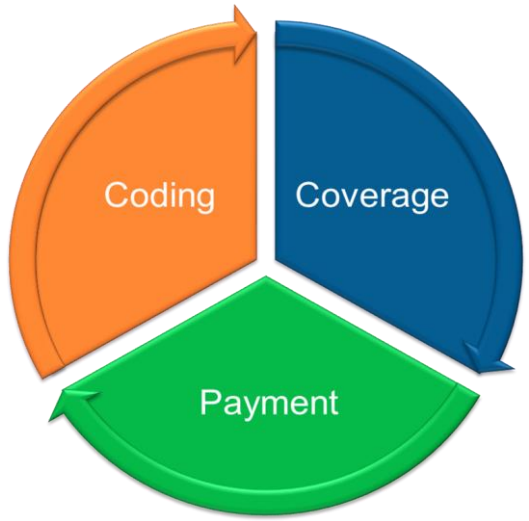




Our desire to deliver value to our clients and to live our mission has lead to the development and growth of NAMSA

What is Reimbursement?

- "Reimbursement" encompasses health economics, market access and the broad range of reimbursement consulting services common to the industry.
- Reimbursement is the set of strategies, activities, and processes that medical technology companies require to ensure that their devices are adequately paid and covered by government and commercial insurance companies. The essential barriers to reimbursement are:
  - Product and procedure Coding
  - Payment methodology(ies) and amounts
  - Government and commercial insurance Coverage
- The greatest of essential barriers is Coverage:
  - There is no standard for how much is enough
  - Evidence requirements vary by payer
  - More evidence is needed for Coverage than for FDA clearance or coding



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Reimbursement Fundamentals

- Coding – Is there a code that describes your device or the manner in which physicians will use it?
- Payment – Will physicians and hospitals be paid enough to encourage product adoption without being too expensive which might prohibit government and commercial insurance coverage?

- Coverage – Will Medicare and private insurers cover the device or procedure and if so, under what clinical circumstances (e.g., medical necessity)?

Reimbursement is like a three-legged stool – you need all three components in place to have a Reimbursement Strategy.

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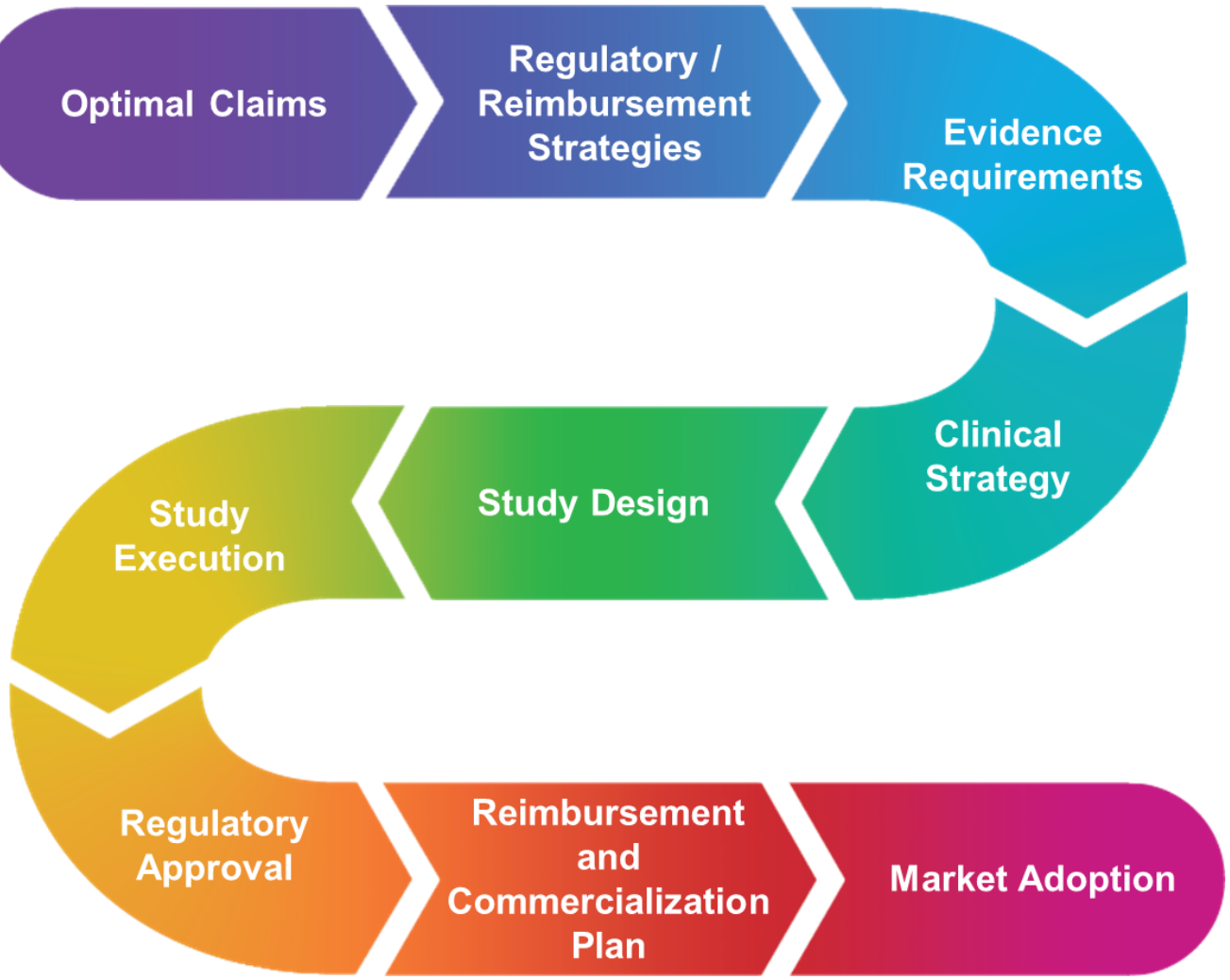
NAMSA Reimbursement Services

A Reimbursement Assessment (also referred to as a Landscape Assessment) is an important first step in understanding potential barriers to commercialization and the formulation of a Reimbursement Strategy. An Assessment requires an examination of issues of Coding, Payment and Coverage.

- An analysis of CPT, HCPCS Level II and ICD-10 PCS coding and the manner in which the device is to be used by healthcare professionals and institutions.
- Payment methodologies and payment amounts in all settings of service, i.e. inpatient hospital, outpatient hospital, ambulatory surgery center, clinic-based practice, and patient home; Alternative Payment Models, New Technology Add-On Payments and Value-Based Payment Models must be understood.
- A review of Medicare and commercial insurance medical policies, as these determine the degree to which a device may or may not be covered for different populations and clinical circumstances. Clinical studies should be designed early to provide the breadth of evidence required for coverage and advocacy (e.g. publications, podium presentations, etc.). If not handled during the early planning phases, additional post-market clinical data and publications will be required for positive coverage decisions causing delays in commercialization. More clinical information is required to get a device covered than to get it cleared for regulatory purposes.

A full Reimbursement Assessment will often include formal interviews with current health plan medical directors to assess their willingness to cover a new device and the types of clinical evidence they would expect in order to cover it. NAMSA's health plan relationships extend to hundreds of medical policy decision makers based on prior experience working as health plan executives.

The Optimal Development Process



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Reimbursement Planning Process

Product Design / Clinical Planning

- **Product Design**
  - *Identify predicates for payment, not just FDA clearance*
  - *Understand payer perceptions regarding clinical need and evidence requirements*
  - *Understand clinical integration pathway into current practice patterns*
  - *Create coding strategy*
  - *Investigate medical policies for coverage*
  - *Prepare for coverage during IDE Study*
  - *Optimize clinical study design for coverage*

FDA Submission / Product Launch Prep

- **PreCommercialization**
  - *Develop publication strategy*
  - *Develop Health Economics position*
  - *Pursue medical society support for clinical guideline development and new CPT coding*
  - *Prepare product dossier for payer coverage*
  - *Plan Payer Coverage Advocacy Campaign to sync with Marketing/Sales*
  - *Prepare Reimbursement Guides for hospitals and physicians*

Post Market Launch / Ongoing Support

- **Commercialization**
  - *Monitor changes in Medicare LCDs and commercial insurer coverage policies*
  - *Monitor physician and hospital satisfaction*
  - *Provide support for continuous coverage and adequate payment as may be required when new, competing products are introduced*
  - *Continue clinical liaison support for post market evidence generation*

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Market Access Tools and Services

Clinical (or Product) Dossier – A comprehensive document detailing clinical indications, clinical evidence, clinical utility within the context of medical society guidelines and health economic valuations suitable for use with a hospital Value Assessment Committee (VAC).

Device Coverage During Clinical Trials. Covering the costs in these IDE studies removes a financial barrier that could otherwise discourage hospitals and physicians from participating.

Reimbursement Guides for Hospitals & Physicians to help them efficiently get paid for using your device.

Payer Advocacy / Medical Science Liaison – Our medical professionals meet with medical policy decision makers to advocate for coverage (as opposed to a sales presentation which payers will not accept).

Medical Society Relationships to develop clinical guidelines for the role of your technology in the continuum of care and for CPT code interpretation and application support.

Medical Advisory Board Development to provide direct, interactive meetings with company leadership on key issues of evidence and insurance coverage.

Key Opinion Leader Training to Support Advocacy – While competent in their medical specialties, most KOLs need coaching on how to work with health plans and communicate the right messages.

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Health Economic Analyses

Health Economic Analyses vary by type and purpose:

- **Cost Effectiveness** (also called a Clinical Utility Analysis) is used when the therapy is more expensive, but also more effective; important for payers
- **Cost Minimization** is used when a new treatment is less expensive and at least as effective; important for payers
- **Budget Impact Analysis** shows how costs will affect a provider organization; important for hospitals and payers
- **Quality of Life Assessment** to measure the health value of therapy to a population; important for payers.

NAMSA's Global Reimbursement Director is co-author to three peer-reviewed, published articles on Cost Effectiveness in international journals.

- Journal of Medical Economics - Cost-effectiveness of the Convergent Procedure and Catheter Ablation for Non-paroxysmal Atrial Fibrillation. July 2014, Vol 17, No. 7, Pages 481-491
- The Journal of Urology –Cost of Neuromodulation Therapies for the Treatment of OverActive Bladder: Percutaneous Tibial Nerve Stimulation vs. Sacral Nerve Stimulation; Vol. 189, 210-216, January 2013
- International Journal of Urogynecology – Cost Effectiveness of Radiofrequency Microremodeling for Stress Urinary Incontinence; 2014 Apr;25(4):517-23. doi: 10.1007/s00192-013-2230-8. Epub 2013 Oct 10.

Thank You

Edward Black, MBA
Director-Global Reimbursement Strategy
NAMSA, Inc.
400 Highway 169 S., Suite 500
Minneapolis, MN 55426
651.253.1143

eblack@namsa.com