
REIMBURSEMENT BASICS FOR PEDIATRIC DEVICE DEVELOPERS

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THE REIMBURSEMENT CHALLENGE

- Critically important element in
 - Business plan development
 - Investor due diligence
 - Commercial success
- Requires early and careful analysis and planning
- May require resource-intensive advocacy before and after market entry



THE GOOD NEWS

- Medical technologies or therapeutics that effectively address unmet clinical needs, or that clearly improve outcomes, always get reimbursed in the U.S. ...
 - Counter-examples?
- *If the case is made effectively*
 - Understanding of payers' wants/needs
 - Effective execution of a well constructed plan
 - Compelling empirical demonstration of value

THREE DISTINCT BUT RELATED ELEMENTS

- Coding
 - A unique and objective identification of the service or item provided
- Coverage
 - The determination of whether and under what circumstances to pay for the service or item
- Payment
 - The specification of a methodology and amount

CODING AND PAYMENT CONCERNS ARE LESS FOR PEDIATRIC DEVICES

- Most pediatric interventions are adaptations of existing adult interventions
 - Codes are not age-specific
- For truly innovative pediatric procedures, low volumes allow use of NOS codes
 - Cases likely to require manual processing in any case
- Pediatric case payment is more cost-responsive than for adult cases

COVERAGE POSES THE MOST DIFFICULT CHALLENGES

- ***Clinical utility*** is the touchstone
- Incremental clinical benefit is key
 - Reinforced by recent CER initiatives
- Cost does enter the equation
 - Covertly in fee-for-service environment
 - More rigorous analysis for high cost technologies?
 - Increasingly overtly important in era of ACOs, full and partial capitation, and focus on cost control

MORE GOOD NEWS FOR PEDIATRIC DEVICES

- The evidentiary hurdle is lower when addressing serious children's health issues
 - Smaller market size means financial impact on insurers and the system as a whole is limited
 - “helping kids” has a privileged societal status
 - Refusing to help ... when you can ... carries a high societal and commercial cost
- Individual case advocacy can work for pediatric technologies / interventions

COVERAGE DECISIONS ARE DATA DRIVEN – PLAN ACCORDINGLY

- Evaluate what payers will want/need to know
- Integrate your regulatory and reimbursement strategies
 - Integrated data effort is cost and time efficient
 - Clinical trial staff can monitor and control to establish data validity
 - Include cost data capture



BUILD SUPPORT IN THE RELEVANT CLINICAL COMMUNITY

- Testimony from unaffiliated key opinion leaders can strengthen the empirical case
 - Critically important for pediatrics, where definitive clinical trial data are difficult to secure due to small trial size
- Create ties to key individuals, specialty societies and advocacy groups
 - Develop a mobilizable base of support



REIMBURSEMENT ADVOCACY BEGINS BEFORE REGULATORY CLEARANCE

- Initiate information flow to selected target audiences as soon as you have a clear sense of FDA requirements
- Educate about your product, status and plan
 - Get formal or informal feedback and take it seriously
- Provide periodic progress updates to build relationship and knowledge base

INFORMATION IS THE KEY TO OPTIMIZING REIMBURSEMENT

- Understand the clinical, regulatory and institutional environment
 - Anticipate the data and other needs of the critical decision makers
 - Perform or commission the needed analyses
 - Demonstrate command of all the available information
- Construct a compelling, empirically sound rationale for coverage and payment

BUILD A ROBUST RESEARCH CAPABILITY

- Get your results out as early as possible
 - Peer-reviewed papers carry the most weight
 - Conference presentations have some worth
 - Data collected in monitored trial or study can be useful
 - But control and validation will be questioned
 - Sponsor-conducted retrospective or ad hoc studies can be dismissed
 - But not if you've made yourself an unimpeachable source

AGGRESSIVELY PLAN AND MANAGE YOUR REIMBURSEMENT STRATEGY

- Define your evidentiary requirements clearly and realistically
- Determine whether you need a new billing code and plan accordingly
- Find the shortest and simplest path that gets you to your goal(s)
- Build your base of external support
- Manage the process like any project

Thank You

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