Holland & Knight

Moving Regenerative Medicine from the Lab to the Patient

A Primer on Reimbursement for Regenerative Medicine Products and Services

LESSONS

- Need a comprehensive strategy – never too early to start
- FDA approval is necessary but not sufficient for reimbursement
- Understand the data payers want to see
- Understand your product – where will it be used? What's the formulation? Who's the patient population?
- Learn the coding, coverage, and payment processes, decision-makers, and timetables
- Engage payers, physicians, patients, and policy-makers

THE WORLD'S GREATEST MEDICAL IDEA

- Will never reach the patient unless—
  - It is FDA approved
  - Medicare, Medicaid and private health plans have covered the product or service
  - Proper billing codes have been assigned
  - Payment rates, acceptable to customers like hospitals and physicians, have been established

U.S. FOOD AND DRUG ADMINISTRATION

- FDA approval of regenerative medicine products is the essential first step to getting to market and providing these new products to patients
- But FDA approval **is not the same** as health insurance coverage and does not guarantee a specific payment rate

UNIVERSAL CONCEPTS

- The market for regenerative medicine is worldwide and these principles are universal
- Agency names and processes may differ, but the fundamental elements are the same in the healthcare system of every developed nation

REIMBURSEMENT COMPONENTS

- CODING – Making sure products and services are properly identified so physicians, hospitals, manufacturers, etc. can get paid
- COVERAGE – Health plan determination that your product provides clinical benefit and should be included in the health plans for enrollees
- PAYMENT – How much the doctor, hospital and your company will be paid
- These are separate, though related processes
- Each has their own decision-makers and timetable
  - All are different from the FDA process
  - All are necessary for reimbursement

FDA APPROVAL IS INSUFFICIENT

- The questions the FDA wants answered are not always the same as those that health plan medical directors want answered
- Good science is key to success with FDA and health plans, but the FDA approves many products that may never be covered by health insurance plans
- This critical point is often missed in company planning and can be a serious barrier to market success

GETTING IT RIGHT

- Everyone knows that FDA approval is the essential first step
- Use that process to help with the coverage and payment process
- We know what the FDA wants to know because they tell us
- Health plans will tell us what they want to know, but we have to ask

GETTING IT RIGHT

- Figure out what the health plans want to know before FDA approves the product. Product design and FDA labeling can be important in getting health plan approval and the best possible payment so consider the implications early in the design process
- Get the answers to the questions health plans will ask while you are doing your FDA studies
- Don’t wait to ask these questions until after the FDA approval
- Plan your coding, coverage and reimbursement strategies while you are waiting for the FDA to act
- Engage third parties
  - Physicians (Specialty Societies)
  - KOLs
  - Patient advocacy groups

WHAT HEALTH PLANS WANT TO KNOW

- How does your product compare to existing therapies and how much will it cost?
- Is the clinical outcome for the patient batter than, or similar to, current treatments?
- What are the long term effects of your product? In the words of an AETNA Medical Director, “give me four year data.”
- Where is your head to head comparison study?
- These are particularly salient issues for RM products that are new and potentially high-priced
  - Consider doing a survey/analysis of health plans

WHAT ABOUT COST EFFECTIVENESS?

- Health plan medical directors/CMS coverage officials care about clinical benefit

- But demonstrating “value” and cost effectiveness – especially compared to existing treatments – is important

  – Be sure you are demonstrating value in an area a payer cares about

CODES—WHY ARE THEY IMPORTANT AND WHAT DO THEY DO?

- Codes describe healthcare products and services so payment can be made
- What kind of code do you need?
  - For a medical procedure, a CPT (Current Procedural Terminology) code
  - For many drugs, devices, and other medical products, a HCPCS (Healthcare Common Procedure Coding System) Level II Code
- CPT is governed by AMA; relationships with leaders in physician specialty societies is key
- HCPCS process is governed by CMS

PAYMENT

- Codes are essential to proper payment, but health plans do not often pay what you charge
- Medical services are usually paid on the basis of a fee schedule or bundled rate
- The site of service can be an important factor in overall payment policy
- Payments are influenced by where your product is used

COVERAGE

- The “coverage” process is the key step to making sure that the health plan will actually pay someone for using your product or providing the service
- By CMS or private insurer
  - Medicare has formal coverage process, usually local contractors based on advisory panel
  - Private insurers also use advisory panels to evaluate new technologies
- Coverage decisions are based on the best available science
  - The absence of any science usually means there will be no coverage and therefore little to no insurance payment for the product

HEALTH SYSTEM CHANGES

- Dramatic system changes are ongoing and will continue
  - Comparative effectiveness
  - Accountable Care Organizations (ACOS)
  - Medicare bundled payments
  - Health plan formulary “tiering” for new products
- Demonstrate clinical benefit and value in a way that matters
- Meet with CMS, Congress, Washington policy makers, and patient groups to ensure innovation is rewarded

COMPLETING THE CIRCLE

- Having the right data for coverage is a function of good scientific and clinical studies published in peer reviewed literature
- The best opportunity to collect this information early is during the clinical trials conducted for the FDA
- Figure out what you will need for coding and coverage purposes, and build the data collection into your FDA clinical studies
- Washington, DC roll out – educate Congress and policy environment about your product

CONCLUSION

- Having a reimbursement strategy early is critical.
- Reimbursement has its own process and timelines.
- Find out what health plans want to know about your product before FDA approval.
- Understand how and where your product will be used.
- Understand the impact of health system changes.
- Build relationships with physicians, patients, and Washington policy makers.

CONTACT INFORMATION

- Michael Werner, Holland & Knight
  michael.werner@hklaw.com

- Randy Fenninger, Creek Crossing Advisors
  randyf@creekcrossingadvisors.com