ORTHOBIOLOGICS AND CARTILAGE REPAIR
NEW BUSINESS AND REGULATORY CHALLENGES

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Outline
• Review FDA regulations and environment
  ▪ PRP
  ▪ Stem cells
• Review Surgical reimbursement issues
• Review Cartilage codes and costs
• Review general insurance criteria for reimbursement for cartilage procedures

FDA Regulations
• The FDA by law does not regulate or assert legal jurisdiction over the practice of medicine.
• State law provides the authority and legal standards for the practice of medicine.

FDA Regulations
• "Promotion" means all proactive activities (written, oral or otherwise) that directly or indirectly market, sell or support product sales and use, or that contribute to the sales growth of a company's products.
• FDA regulations do allow the exchange and dissemination of scientific information on a product's unapproved uses in certain circumstances.

Types of scientific exchange
• Responses to unsolicited requests from physicians;
• Continuing medical education (CME) programs;
• Peer-reviewed scientific and medical journals.
Off-Label Product Use

- The use of pharmaceutical drugs for an unapproved indication or in an unapproved age group, unapproved dosage, or unapproved form of administration.
- This means any use that is not specified in the labeling approved by the U.S. Food and Drug Administration (FDA).

Off-Label Product Use

- The FDA does not have the legal authority to regulate the practice of the medicine, and the physician may prescribe a drug off-label.
- Is generally legal unless it violates specific ethical guidelines or safety regulations, but it does carry health risks and differences in legal liability.

Enforcement Actions and Trends

- The off-label promotion of medical devices is expected to have increased scrutiny from federal authorities.
- Violations of the federal False Claims Act are cited in qui tam suits.

Position Statement OF AAOS Off-Label Use of Medical Products

- The government has long recognized that physicians may prescribe or administer any legally marketed product for an off-label use within the practice of medicine.
- Physicians have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain awareness of the product’s use and effects.

Platelet Rich Plasma (PRP)

- Platelet Rich Plasma (PRP) comes from a patient's own blood.
- PRP is a concentrated source of growth factors and cellular signaling factors that play a significant role in the biology of healing.
- Basic science studies show that PRP treatment may improve healing in many tissues.
- Few clinical studies in humans show the effectiveness of PRP treatment.

Platelet Rich Plasma (PRP)

- Autologous PRP has been used for over 30 years as an aid in recovery following certain surgical, orthopaedic and dental procedures.
- Thousands of research articles are published on the safety of PRP.
- No risk of a transmissible infection.
- Very low risk of allergic reaction.
MESENCHYMAL STEM CELLS
- Can make several types of cells belonging to our skeletal tissues, such as cartilage, bone and fat.
- Make up about 0.001-0.01% of all the cells in your bone marrow
- Can differentiate – or specialize – into cartilage cells (chondrocytes), bone cells (osteoblasts) and fat cells (adipocytes).

MESENCHYMAL STEM CELLS
- MSCs were originally found in the bone marrow.
- There have since been many claims that they also exist in a wide variety of other tissues, such as umbilical cord blood, adipose (fat) tissue and muscle.
- It has not yet been established whether the cells taken from these other tissues are really the same.

BMA
- A bone marrow aspirate (BMA) is typically done by taking a small amount of bone marrow from the back of your pelvis.
- It is centrifuged in an FDA approved device to concentrate the bone marrow and receive a predictable number of stem cells and growth factors.

STEM CELLS
- Cell therapies have been applied by using bone marrow stromal cells to repair or rebuild bone within focal cavities.
- The current inability to manage or direct the multiple growth pathways available to stem cells presents difficulties in using stem cells to combat systemic diseases like osteoarthritis.

ORTHOPEDIC STEM CELL USE SOARED IN 2012
- An estimated 1 million U.S. patients had been treated with stem cells over the course of the previous 15 years.
- By the end of 2012, Orthopedics This Week estimates that that number of patients treated rose by an astonishing 100,000!
- Physician users now number in the thousands.
REGENERATIVE PROCEDURES at KJOC

- 2013 total: 337 procedures
- 2015 total: 430 procedures
- 40 BMAC stem cell procedures for 2015
- Trend showing a 33% increase in two years

PRP Pricing @ KJOC

- $1000 per single injection site
  - tendon elbow
  - tendon achilles
  - tendon knee
- $3000 to add stem cells from bone marrow aspirate per single injection site

PRP Pricing (KNEE GURU)

- In NYC, I was quoted $1000-2000 per knee.
- In Florida I have been charged $800 per knee for PRP
- In India it is around $125 [8000 INR]
- In Atlanta I paid $800 per knee
- Europe the max I found is 200 euros (250 dollars more or less).
- Birmingham, Alabama I was told last week PRP would be $200

WHO REGULATES ?

- Concentrated autologous MSCs do not require approval by the FDA

The D.C. Circuit Court of Appeals Ruled 2-4-14

Culturing a patient’s stem cells for therapeutic use falls under the aegis of the US Food and Drug Administration (FDA). FDA has said therapeutic stem cells should be regulated as drugs. Regenerative Sciences’s process of culturing stem cells “alters the MSCs’ relevant biological characteristics and is therefore more than minimal manipulation.”

CONSENT

- Is the consent process sufficient for the off-label use of a medical product?
- Surgeons may want to document the planned use of off-label products in the medical chart.
- An off-label use of a medical product cannot be described by the company as safe and effective for a particular use.
STANDARD OF CARE

- Standard of care changes over time due to the available literature, use of medical products, and outcomes of medical and product liability legal cases.
- It is not uncommon for some technologies to become standard of care in the practice of medicine before there is formal regulatory approval or clearance of a particular product.

SURGICAL REIMBURSEMENT

- Accounts Receivable Duration
  - Driven by 'controllable' activities
    - Creating appropriate coding supported by appropriate documentation
    - Time between surgery and submission of a 'clean claim'
  - Driven by 'uncontrollable' activities
    - Time between submission of 'clean claim' and receipt of reimbursement

TECHNOLOGY

A SURGEON’S PARTNER
Enhance accuracy
Enhance Reimbursement

Summary of Findings – Faster Claim Submission

- Duration between surgery and claim submission
  - Manual: 9.9 Days
  - Technology enabled: 7.4 Days (a 25% reduction)
- Percent of claims submitted within 10 days
  - Manual: 72.0%
  - Technology enabled: 86.6% (a 20% improvement)
- Percent of claims submitted within one week
  - Manual: 49.6%
  - Technology enabled: 81.8% (a 65% improvement)
Summary of Findings – Faster Reimbursement

Duration between claim submission and reimbursement
- Manual: 62.8 Days
- Technology enabled: 43.7 Days (a 30% reduction)

Percent of reimbursements received within 40 days
- Manual: 44.1%
- Technology enabled: 49.2% (a 11% improvement)

Summary of Findings – Fewer Past Due Accounts

Percentage of claims with reimbursement cycle > 90 days
- Manual: 31.2%
- Technology enabled: 14.4% (a 54% reduction)

Summary of Findings – Faster Reimbursement

Duration between claim submission and reimbursement
- Manual: 51.2 Days
- Technology enabled: 32.5 Days (a 36% reduction)

Percent of reimbursements received within 40 days
- Manual: 40.8%
- Technology enabled: 63.1% (a 36% improvement)

Summary of Findings – Fewer Past Due Accounts

Percentage of claims with reimbursement cycle > 90 days
- Manual: 30.6%
- Technology enabled: 18.5% (a 45% reduction)

ARTICULAR CARTILAGE SURGICAL CODES
- CPT 29877 Chondroplasty/Debridement
- CPT 29874 Removal of Loose Body
- CPT 29879 Microfracture
- CPT 29866 Arthroscopic Osteochondral Autograft
- CPT 29867 Arthroscopic Osteochondral Allograft
- CPT 27415 Open Osteochondral Allograft
- CPT 27416 Open Osteochondral Autograft
ARTICULAR CARTILAGE SURGICAL CODES

• CPT 29886 OCD drill intact lesion
• CPT 29887 OCD intact lesion with internal fixation
• CPT 29885 OCD with bone graft with or without internal fixation

ARTICULAR CARTILAGE SURGICAL CODES

• CPT 27412 Autologous Chondrocyte Implantation
• CPT 29868 Meniscal Transplantation
• CPT 27457 Osteotomy after epiphyseal closure
• CPT 27418 Anterior Tibial Tubercleplasty
• CPT 29870 Arthroscopy with biopsy

ARTICULAR CARTILAGE SURGICAL CODES

• CPT 27442 Arthrosurface Trochlea
• CPT 27438 Arthrosurface Patella
• CPT 27446 Unicompartmental Knee

ARTICULAR CARTILAGE SURGICAL CODES

• CPT 27599 unlisted knee (DeNovo, Biocartilage, Trufit plugs, etc.)
• CPT 28446 open autograft talus
• CPT 28899 unlisted foot or toes
• CPT 29892 arthroscopically aided repair OCD talus
• CPT 29999 unlisted arthroscopy repair of other joints

ARTICULAR CARTILAGE SURGICAL CODES

• HCPCS J7330: Autologous cultured chondrocytes, implant
• HCPCS S2112: Arthroscopy knee for harvesting of cells

ARTICULAR CARTILAGE ICD-9 CODES

• 717.9 Unspecified internal derangement
• 719.96 Unspecified disorder of joint
• 732.7 Osteochondritis Dissecans
• 733.90 Disorder of bone and cartilage
• 733.92 Chondromalacia
• 836.0 Tear medial meniscus
• 836.1 Tear lateral meniscus
ARTICULAR CARTILAGE ICD-10 DIAGNOSTIC CODES

- M23.000-M23.92 Internal Derangement Knee
- M93.261-M93.269 OCD Knee
- M93.861-M93.869 Other Specified Osteochondropathies Lower Leg
- M94.8X6 Other Specified Disorders of Cartilage Lower Leg

ARTICULAR CARTILAGE ICD-10 CODES

- S83.511 (2) ACL tear
- M94.261 (2) Chondromalacia knee
- M22.41 (2) Chondromalacia Patella
- S83.231 (2) Tear medial meniscus
- S83.711 (2) Tear lateral meniscus
- M93.26_ OCD knee
- M79.4 Impingement fat pad

ARTICULAR CARTILAGE CODES

- Modifiers
  - 59 is used to identify a distinct procedural service
  - Separate incision or lesion
  - Separate compartment
  - Separate injury
  - 22 is for extraordinary situation (i.e., obesity)
  - Must document with cover letter

SURGICENTER REIMBURSEMENT

- Hospital or Surgicenter Problems
  - Global Contract for services
    - Differs for different payors
    - Differs for different geographic areas

ARTICULAR CARTILAGE REIMBURSEMENT

- Surgical Implant and Disposable Costs
  - Shaver ( $40-100 )
  - RF Device ( $125-200 )
  - Osteochondral autograft kit ( $400-600 )
  - Osteochondral allograft kit (Free-Rental)
  - Chondral pins/screws ( $500 )
  - Meniscal repair implants ( $100-300 )
ARTICULAR CARTILAGE REIMBURSEMENT

- **IMPLANT MATERIALS**
  - Osteochondral allografts ($10,000)
  - Meniscal allografts ($5,000)
  - ACL allografts ($3,000)
  - Osteotomy implants ($795)
  - Cell implants
    - Carticel was ($20,000)
    - Carticel NOW ($0) 3rd Party Payor Program plus $1,000 (Kit, Bio Guide and glue)
    - Denovo ($4,500-5,000) plus $250 glue
  - Arthrex Biocartilage ($1,000/cc) plus $450 delivery system

- **DME's**
  - Braces
  - Cold Therapy
  - Pain pumps

- Viscosupplementation ($800-$1,500)
- Medications
- Physical Therapy

**GENERAL CRITERIA CARTILAGE REPAIR**

- Age 15-50 (60) years
- Disabling localized knee pain for six months which has failed conservative treatment
- An intact meniscus is present
- Lesion must be discrete, single and unipolar
- Lesion is largely contained with near normal surrounding cartilage (Gr <3)
- A normal joint space is present
- No active infection
- No osteoarthritis or inflammation
- Knee is stable with normal mechanical alignment
- Patient can comply with post-operative restrictions for wt. bearing

**General Criteria for Cartilage Repair**

- No history of cancer in bones fat or muscle of affected limb
- Body Mass Index (BMI) of < or = to 35
ACI Criteria
- Inadequate response to prior surgery
- Defect size ≥ 1.5 cm²
- Cartilage only defect
- No allergy to gentamicin, bovine cultures
- Focal, full thickness (Gr. III or IV) isolated to MFC, LFC or trochlea
- Defect from acute or repetitive trauma
- ALL General Criteria met

Osteochondral Autograft Criteria
- Arthroscopic or MRI examination
- Defect size between 1.0 to 2.5 cm²
- Focal, full thickness (Gr. III or IV) isolated to MFC, LFC or trochlea
- Defect from acute or repetitive trauma
- ALL General Criteria met

Osteochondral Allograft Criteria
- Arthroscopic or MRI examination
- Defect size ≥ 2.0 cm²
- Focal, full thickness (Gr. III or IV) isolated to MFC, LFC or trochlea
- Defect from acute or repetitive trauma
- ALL General Criteria met

Investigational Procedures
- ALL procedures on joints other than the knee
- ANY procedure that does not meet ALL of the criteria
- ALL use of non-autologous synthetic bone filler materials
- ALL use of minced cartilage

CONCLUSIONS
- Get involved early in your career with the business end of what you do
- Be a leader and embrace industry as your partner to help improve your practice and improve your patients outcomes

THANK YOU