BioTend™ Reimbursement Assessment & Strategy

April 17, 2020

Process Overview

- Market insights, utilization trends and analytics to guide strategic thinking and focus
- Comparative pricing analysis to reference products
- Analysis of coding, coverage and payment for Achilles and rotator cuff repair in the hospital outpatient and ASC venues

Outline

- Introduction to select reimbursement topics
- Market insights, utilization trends and analytics to guide strategic thinking and focus
  - Utilization trends by provider, venue of care and payer
  - Comparative pricing analysis of reference products
- Commercial insurance coverage and payment landscape
- Hospital buying stakeholder analysis
- Worker's comp payment landscape (rotator cuff)
- Hospital Value Analysis Slides, Achilles & Rotator Cuff

Executive Summary - Overview

- BioTend™ can leverage **existing** coverage, coding and payment mechanisms that will **enable adoption** in hospitals and ASCs
  - CPT® codes exist to describe rotator cuff and Achilles procedures of interest to BioTend
  - Existing commercial insurance payment mechanisms are available immediately upon marketing clearance
  - Claim denials and/or negative coverage policies may affect adoption in the short term
- Orthopedic services are **highly scrutinized** by hospital and ASC business managers
  - Perceived as a profit center for the facility and highly scrutinized to prevent loss leader procedures/devices
  - Hospital/ASC buying stakeholders may view any additional cost as negative margin pressure
  - However, commercial insurers generally pay in full for implants bolstering episode of care economics
- BioTend™ must **collect clinical data** and focus on **best-use population**
  - BioTend should define a best-use population, for which limited treatment options exist
  - Commercial insurers already have negative coverage policies, a niche coverage population will be critical
  - Quality clinical trial outcomes (likely at least 2 quality clinical studies) will be necessary to begin to influence coverage

Executive Summary – Pricing and Execution

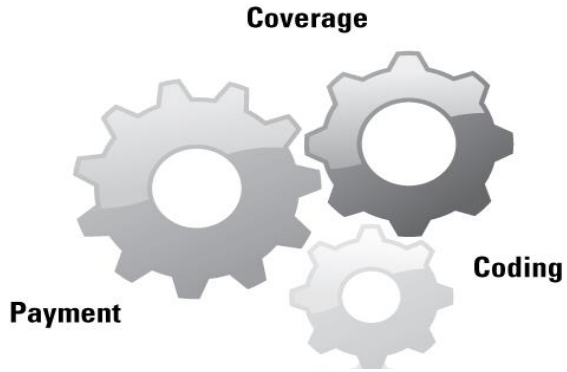
- BioTend™ can expect more **price resistance** at ASP's >$2,000, but this will vary by account
  - Payer mix and insurance contract terms will have the biggest impact on adoption
  - Coverage issues may require reimbursement support to obtain prior auths/resolve claim denials

- An emphasis on **reimbursement support** of the sales force and **nuanced messaging** around provider economics is needed
  - Fixed payments from Medicare will need to be subsidized by other payers to attract broad adoption, particularly in the ASC setting
  - Non-coverage by commercial insurers will require prior authorization appeals on a case-by-case basis for most patients
  - Worker's compensation may prove valuable for rotator cuff repair

Reimbursement Overview

- Reimbursement is how medical services are paid and is a function of **three** variables:

Coverage + Coding + Payment = Reimbursement



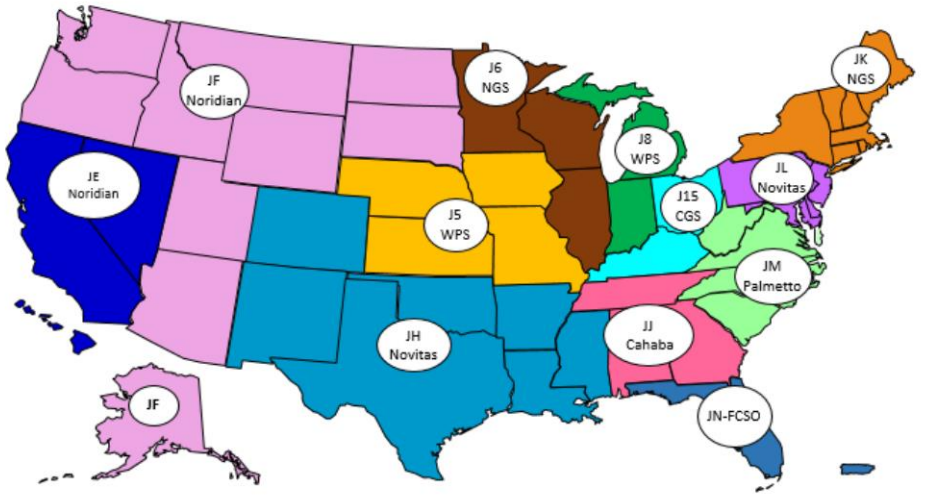
Coverage	**Have payers evaluated the service or device? In what circumstances are they willing to pay?**
Coding	**Are procedure and/or device codes in place to describe the service or technology?**
Payment	**What are the payment terms for the venue of care? What are the payment amounts for the applicable procedure?**

1 –
2 –

Introduction to Medicare Coverage

- Medicare may issue National Coverage Decisions or allow for coverage to be determined at the “local” level
- Local coverage decisions are made by regional medical directors
- CMS policies apply to Medicare Advantage plans
- National coverage decisions are made by the CMS Coverage and Analysis Group (CAG) and typically reserved for items subject to Coverage with Evidence Development (CED) Status – i.e. PRP for use in Wound Care, TAVR

Medical Administrative Contractors (MACs)



CMS Part A/B MAC Map December 2015.
https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/AB-MAC-Jurisdiction-Map-Dec-2015.pdf

1 –
2 –

Introduction to Commercial Insurance Coverage

- Coverage policies follow the studied populations and indications
  - Coverage can either be silent, positive or non-covered
  - Positive coverage policies typically limit use to specific patient populations or indications

- One clinical study is no longer enough to drive broad coverage
  - Numerous publications with “quality” studies are required
  - Non-inferiority (i.e. at least as good as) to standard of care is sufficient
  - For orthopedic procedures, often AAOS society support, in the form of a guideline opinion is needed

- Increasing reliance on technology assessment groups
  - Commercial insurers increasingly rely on technology assessment groups like Evidence Street (BCBS), EviCore, ECRI, etc.
  - Cost does not determine coverage, but high cost will drive insurers to “limit” coverage

1 –
2 –

Introduction to Coding

- Coding is the language of reimbursement

Scope	Code-Set	Description	Who "Owns" the Data?	Where are they Used?
Diagnosis Coding	**ICD-10-CM** (International Classification of Diseases – Clinical Modification)	Describe patients' diseases and/or conditions (69,000+ codes)	CMS (Centers for Medicare and Medicaid Services)	All venues of care
Procedure Coding (inpatient only)	**ICD-10-PCS** (International Classification of Diseases – Procedure Coding System)	Describe hospital services/procedures (72,000+ codes)	CMS (Centers for Medicare and Medicaid Services)	Hospital inpatient only
Procedure Coding	**CPT®** (Common Procedural Terminology)	Describe physician services/procedures (7,000+ codes)	AMA® (American Medical Association)	All venues of care
Device/Drug Codes (and CMS-granted temporary codes)	**HCPCS** (Healthcare Common Procedural Coding System)	Describes drugs, devices, temporary codes (5,000+ codes)	CMS (Centers for Medicare and Medicaid Services)	All venues of care

Your Own CPT® Code? Be Careful What You Wish For

- AMA CPT® code pathway takes years and introduces selling barriers
- New technologies seldom meet both the Level of Evidence and the use requirement, so a Category III code is issued as a precursor to Category I code
  - Category III codes result in non-coverage from payers
  - Category III codes are carrier priced for physician payment

12 – 18 Months' Work

Commercialize Under NOC CPT
Apply for **Category III**

Category III CPT Granted

2 – 4 Years' Work

Commercialize Under Category III
Apply for **Category I**

Category I CPT Granted

- Commercialize under NOC CPT
  - Significant selling barriers
  - Increased selling costs to support providers with prior auth, denials, etc.
- Generate society support and definitions for Category III Code

- Commercialize under category III code
  - Significant selling barriers
  - Increased selling costs to support providers with prior auth, denials, etc.
- Generate clinical evidence, substantial use and society support to meet Category I requirements

AMA Level of Evidence Requirement

- 5 peer-reviewed publications of at least 2 different patient populations
  - Follow-up studies on same patients are acceptable
  - At least 1 study must be of U.S. patients

Category I Literature Requirements[1]	**Utilization**	Typical	Typical	Limited, Specialized or Humanitarian	Limited, Specialized or Humanitarian
	Technology	New	Existing or Non-Contributory	New	Existing or Non-Contributory
# of Peer-Reviewed Publications		5	5	5	3-5
Minimum # with U.S. Patient Populations		1	1	1	1
Minimum # with Different Patient Populations		2	2	1	1
Minimum Level of Evidence for at least One Article		2a	3a/3b	3b	4

Adopted from AMA Level of Evidence 2019

Introduction to Payment

- **Medicare payments** are driven by the codes reported and based upon published fee schedules

- **Commercial insurance payments** are based upon individual contracts between the hospital/physicians
  - Payments are typically 1.3 – 2.5X Medicare payment amounts
  - Carve-out payment schemes may apply to allogenic implants

- **Worker's Comp payment** is managed at the State level with wide disparity in what hospitals/ASCs receive in payment

Commercial Insurance Payment

- Reimbursement of orthopedic procedures in hospital and ASC setting typically follows one of three methodologies

Contract Type	Key Features/Methodology	Example Payment Terms
Case-Rate	A single, fixed payment intended to reimburse the entire encounter. Each procedure (CPT) is assigned to a payment amount.	- Percentage of Medicare Payment (i.e. 130% of Medicare Payment) - Other flat-fee amount
Percent-of-Billed-Charges	A payment based on a percentage of the billed charges. Typically paired with a stop-loss or maximum payment amount.	- 80% of billed charges up to $5,185 - 60% of billed charges
Carve-Out Scheme	Carve-out implies that implants are paid separately – often at invoice cost or a % of billed charges. Carve-out schemes are typically paired with a case-rate.	- $2,725 plus 60% of billed implant charges - Implants paid at invoice cost (typical in ASC contracts)

Overview of Hospital Buying Stakeholder Analysis

- Functional composition of the Value Analysis Committee

OR Management

- Device cost: Impact to OR budget/spend
- Ease of use: Set-up, tear-down, intra-op, disposable vs central sterile processing
- Consigned vs owned

- Lower device cost +
- Disposable +
- Simple prep, handling +
- Consigned inventory +
- Scheduling, operations +

Purchasing/Contracting

- Benchmark pricing to existing technology
- Perceived discount/rebate
- Contract terms
- Contract landscape

- Equal to/less cost than existing tech +
- Discount from list price +
- Favorable contract terms +
- Consigned inventory +

Reimbursement & Finance

- Payer mix & reimbursement analysis
- Incremental cost
- Net budget impact

- Net budget impact…
- "Hard" cost reduction relative to existing tech +
- Theoretical cost reduction and/or increased reimbursement +

Materials Management

- Inventory management
- Inventory/storage conditions

- Follows typical inventory flow +
- Inventory managed by rep/OR +

Budget Impact (i.e. Episode-of-Care Economics)

- Net budget impact accounts for the mix of payers and assumptions about the cost of the implant

Payer Type	% of Patients	Reimbursement Terms (Examples only)	Payment	Weighted Payment
Medicare	50%	Medicare Payment	$6,048	$3,024
Commercial Insurer #1	20%	125% of Medicare	$7,087	$1,417
Commercial Insurer #2	20%	175% of Medicare	$9,923	$1,985
Commercial Insurer #3	10%	150% of Medicare	$8,675	$868
TOTAL	**100%**		**TOTAL**	**$7,294**

Medicare Device Offset Trends

- Medicare calculates a “device offset” for each procedure code, which represents the implant-related costs reported for that procedure each year
- Device offset increases correlate to increased use of implants for these procedures
- The 2020 increase for 27650 results from a change in claims accounting

Medicare Device Offset Amounts by year					
Code	Description	2017	2018	2019	2020
Rotator Cuff Repair Indication					
29827	Repair of shoulder rotator cuff using an endoscope	$1,226	$1,348	$1,373	$1,541
Achilles Tendon Repair Indication					
27650	Repair, primary, of ruptured Achilles tendon, open procedure	$365	$427	$422	$1,486
27654	Repair, secondary, of ruptured Achilles tendon	$1,488	$1,631	$1,652	$1,789

Amounts obtained from CMS OPPS Final Rule Device Offset by HCPCS

Payer Mix of Achilles and Rotator Cuff Repair

- Payer Mix for Achilles and Rotator Cuff
  - Private insurance dominates the market for both procedures
  - Payer mix trends toward higher commercial % in ASC venue

Achilles	
Payer	**Repair of non-traumatic Achilles rupture[2]**
Private Insurance	**46.6%**
Medicare	21.8%
Worker's Compensation	4.2%
Medicaid	14.4%
Uninsured/Other	16.6%

Rotator Cuff	
Payer	**Repair of non-traumatic rotator cuff[1]**
Private Insurance	**52.4%**
Medicare	32.4%
Worker's Compensation	17.4%
Medicaid	5.2%
Uninsured/Other	7.1%

Note: Amounts may not total 100% due to truncation and rounding

1 – AHRQ Hospital inpatient, outpatient and ASC procedures 2016 with a primary diagnosis of tendinosis of the shoulder rotator cuff or by ICD-10-PCS procedures with root 0LQ1, OLQ2
2 – AHRQ Hospital inpatient, outpatient and ASC procedures 2016 with a primary diagnosis of nontraumatic rupture of the Achilles or by ICD-10-PCS procedures with root 0LQN, OLQM

Venue Analysis for Achilles and Rotator Cuff Repair

- Setting of use drives reimbursement methodology
  - Figures are listed for all repairs (not exclusive of those with graft)
  - Achilles utilization skews more toward hospital outpatient

Venue of Care	Achilles Repair[1]	Rotator Cuff Repair[1]
Hospital Outpatient	62%	53%
ASC	29%	44%
Hospital Inpatient	7%	3%

Note: Amounts may not total 100% due to truncation and rounding

1 – AMA Provider Data 2017. CPT code 29827 (rotator cuff), 27650, 27654 (Achilles)

Utilization Trends in the Medicare Population Extrapolated

- Medicare utilization suggests sustained growth
  - Total Achilles repair volume in 2017[1] = ~16K+ procedures (Medicare and non-Medicare)
  - Rotator cuff volume in 2017[2] = ~250K+ procedures (Medicare and non-Medicare)

Total number of Medicare procedures by year					
Code	**Description**	**2014**	**2015**	**2016**	**2017**
Rotator Cuff Repair Indication					
29827	**Repair of shoulder rotator cuff using an endoscope**	**108,598**	**114,023**	**117,385**	**121,717**
23410	Repair of torn tendons of shoulder, open procedure, acute	6,978	7,047	6,208	6,154
23412	Repair of torn tendons of shoulder, open procedure, chronic	30,501	28,734	26,725	24,631
23420	Repair of torn shoulder tendons	8,109	6,740	5,581	4,462
23929	Shoulder procedure	392	280	279	235
Achilles Tendon Repair Indication					
27650	**Repair, primary, of ruptured Achilles tendon, open procedure**	**3,219**	**3,703**	**3,680**	**3,895**
27652	Repair of ruptured Achilles tendon with graft, open procedure	318	377	363	331
27654	**Repair, secondary, of ruptured Achilles tendon**	**2,926**	**3,418**	**3,749**	**4,244**
27899	Leg or ankle procedure	268	257	263	235

1 – Imputed based on payer mix data identified in AMA Utilization Data, 29827 only.
2 – Imputed based on payer mix data identified in AMA Utilization Data, 27650 & 27654 only

Provider Specialty Analysis for Achilles and Rotator Cuff Repair

- Provider Specialty Analysis
  - Achilles includes significant podiatrist specialty group
  - Rotator cuff is almost exclusively orthopedic surgeons

Provider Specialty	Achilles Repair[1]	Rotator Cuff Repair[1]
Orthopedic Surgery	57%	93%
Podiatry	42%	0%
Sports Medicine	0%	5%
All Other	1%	3%

1 – AMA Provider Data 2017. CPT code 29827 (rotator cuff), 27650, 27654 (Achilles)

Reference Pricing Analysis

- Comparative product reference pricing

Brand	Material	Manufacturer	Average Price
Allopatch HD	Human Dermis	MTF	$923
ArthroFlex	Human Dermis	Arthrex	NA
Arthrex DX	Dermal Extracellular Matrix	Arthrex	$2,460
BioArthro	Human Amniotic membrane	BioArthro	NA
Conexa	Porcine Dermis	Tornier	$2,502
CuffPatch	Dermal Extracellular Matrix	Biomet	$3,333
Dermaspan	Human Dermis	Biomet	NA
Graftjacket	Human Dermis	WMT	$1,837
Integra	Porcine Dermal collagen, multiple layers, crosslinked	Integra	$1,625
OrthADAPT	Equine Pericardium	Pegasus	$2,495
Regeneten	Bovine Tendon	Smith & Nephew	$3,830
Restore	Porcine Small intestinal submuco	DePuy Synthes	NA
TissueMend	Bovine Fetal dermis	Stryker	$1,738
Zimmer	Collagen Patch Porcine Dermis, cross-linked	Zimmer	NA
Artelon	Polycaprolactone and polyurethane-urea co-polymer	Artelon	$1,650

Data Obtained from hospital purchasing data (2017 and 2018) from 54 hospitals across 5 states. Prices reported are average contracted prices across all product sizes.

Coverage Analysis

- Several medical policies review specifically name BioTend™ as a non-covered product
- Coverage policies generally do not cover the use of orthobiologics in any indication
  - Only GraftJacket, Conexa and Permacol have stated coverage with any commercial payer
  - Studies are small and results do not include randomization/appropriate comparators

Product Name/Category	Cigna	Aetna	BCBS Assoc, Anthem, etc.	United Healthcare	Medicare	Worker's Compensation
Rotator Cuff Repair Indication						
Graftjacket	Non-Covered	Non-Covered	Mixed	Non-Covered	Covered	Mixed
Conexa	Non-Covered	Non-Covered	Mixed	Non-Covered	Covered	Mixed
Permacol	Non-Covered	Non-Covered	Mixed	Non-Covered	Covered	Mixed
ALL OTHER PRODUCTS	Non-Covered	Non-Covered	Non-Covered	Non-Covered	Covered	Mixed
Achilles Tendon Repair Indication						
ALL OTHER PRODUCTS	Non-Covered	Non-Covered	Non-Covered	Non-Covered	Covered	NA

1 - Aetna Policy Number 0411: Bone and Tendon Graft Substitutes and Adjuncts. 04/22/2020
2 - BCBS Association Medical Policy SURG.00011. Allogeneic, Xenographic, Synthetic and Composite Products for Wound Healing and Soft Tissue Grafting. 2/23/2020
3 - BCBS Excellus Medical Policy Number 7.01.35. BIOENGINEERED TISSUE PRODUCTS FOR WOUND TREATMENT AND SURGICAL INTERVENTIONS
4 - BCBS Northeastern NY Medical Policy 701113. Bio-Engineered Skin and Soft Tissue Substitutes
5 - BCBS Arizona Medical Policy. Bio-Engineered Skin and Soft Tissue Substitutes
6 - Cigna Medical Policy 0118. Bone, Cartilage and Ligament Graft Substitutes. 2/19/2020.
7 - UHC Medical Policy MMG159.D. SKIN AND SOFT TISSUE SUBSTITUTES. 2/1/2020

Diagnosis Coding - Achilles

- Achilles repair is typically performed following an acute injury such as a sprain or rupture
- ICD-10-CM root S86.0X is commonly reported, although other diagnoses may be more appropriate
- Specific injury type (i.e. laceration) should be coded as the 5th digit in addition to external causes

ICD-10-CM Diagnosis Coding	
ICD-10-CM Root	**Root Description**
S86.0X	Injury of Achilles tendon

Coding & Facility Medicare Reimbursement - Achilles

Coding Note:

- Secondary repair is performed after 2 weeks of injury
- "Primary repairs usually involve direct surgical correction of an injury, while secondary repairs may include tendon grafts or other more complex procedures"[1]

CPT®* Coding		Hospital Outpatient Payment[2]			Ambulatory Surgery Center[3]	
CPT®* Code	Code Description	SI	APC	Medicare National Average Payment CY2020	SI	Medicare National Average Payment CY2020
27650	Repair, primary, open or percutaneous, ruptured Achilles tendon	J1	5114	$6,048	A2	$2,803
27654	Repair, secondary, Achilles tendon, with or without graft	J1	5114	$6,048	A2	$2,803

*Current Procedural Terminology © 2019 American Medical Association

[1]American Podiatric Medical Association. 2019 Clinical Coding Scenarios. Harry Goldsmith, DPM.

[2]CMS-1717-FC; April 2020 Addenda Updates– Hospital Outpatient Prospective Payment Addendum B

J1 - Procedures subject to complexity adjustment

[3]CMS-1717-FC; Ambulatory Surgical Center Payment Systems Addendum AA

A2 - Surgical procedure on ASC list in CY 2007; payment based on OPPS relative payment weight

Device Coding- Achilles

- BioTend™ is a fully-synthetic bio-integrative matrix
- Unlike some biologics, BioTend™ does not require reporting in per square cm units

HCPCS* Code	Code Description
C1763	Connective tissue, non-human (includes synthetic)

*2020 CMS HCPCS release

Hospital Value Analysis Framework - Achilles

- Episode-of-Care value framework should include payer mix
- Example provided for secondary Achilles repair (27654), with implant cost of $2,000

Payer Type	% of Patients[1]	Reimbursement Terms[2]	Estimated Payment Amount[3]	Weighted Payment (Estimated Payment X % of Patients)
Medicare	32%	Medicare Hospital Outpatient APC Amount[4]	$6,048	$1,935
Commercial Insurer #1	41%	Base payment of 95% of Medicare APC Amount + invoice cost for implant	$7,746	$2,876
Commercial Insurer #2	16%	175% of Medicare APC Amount	$10,584	$1,582
Commercial Insurer #3	12%	153% of Medicare APC Amount	$9,253	$1,006
TOTAL	**100%**		**TOTAL**	**$7,399**

1 – Figures provided are examples and for information purposes only
2 – Commercial insurance reimbursement terms are based on actual hospital contracts, but are not intended to represent any specific hospital – hospitals should reference their own commercial insurance contracts to determine payment terms
3 – Medicare payment is the National Average Unadjusted OPPS Addendum B Payment for CPT 27654

ASC Value Analysis Framework - Achilles

- Episode-of-Care value framework should include payer mix
- Example provided for secondary Achilles repair (27654), with implant cost of $2,000

Payer Type	% of Patients[1]	Reimbursement Terms[2]	Estimated Payment Amount[3]	Weighted Payment (Estimated Payment X % of Patients)
Medicare	28%	Medicare Hospital Outpatient APC Amount[4]	$2,803	$785
Commercial Insurer #1	55%	Base payment of 93% of Medicare APC Amount + invoice cost for implant	$4,607	$2,534
Commercial Insurer #2	17%	181% of Medicare APC Amount	$5,073	$862
TOTAL	**100%**		**TOTAL**	**$4,181**

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Diagnosis Coding – Rotator Cuff

- Rotator cuff repair is typically a chronic/degenerative condition and not associated with injury
- ICD-10-CM root M75.1x is reported in the #1 diagnosis position with laterality

ICD-10-CM Diagnosis Coding		
ICD-10-CM Root	**Root Description**	**Tear Type**
M75.10	Unspecified rotator cuff tear or rupture, not specified as traumatic	Unspecified
M75.11	Incomplete rotator cuff tear or rupture not specified as traumatic	Partial Thickness
M75.12	Complete rotator cuff tear or rupture not specified as traumatic	Full Thickness

Coding & Facility Medicare Reimbursement – Rotator Cuff

- Single CPT® code to report all rotator cuff repair procedures
- "Primary repairs usually involve direct surgical correction of an injury, while secondary repairs may include tendon grafts or other more complex procedures"[1]

CPT®* Coding		Hospital Outpatient Payment[1]			Ambulatory Surgery Center[2]	
CPT®* Code	Code Description	SI	APC	Medicare National Average Payment CY2020	SI	Medicare National Average Payment CY2020
29827	Arthroscopy, shoulder, surgical; with rotator cuff repair	J1	5114	$6,048	A2	$2,803

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Worker's Compensation Reimbursement

- Worker's compensation represents at least 17% of the rotator cuff repair market
  - Some hospital and/or ASC accounts have >33% worker's comp patients
- Insurance payments vary from state to state, but payments and coverage terms can be very favorable - examples from several states provided below

State	Hospital Outpatient Summary	Hospital OP Payment	ASC Summary	ASC Payment
CA	Case-Rate ○ Medicare payment amount	$6,048 Estimated Max	Case-Rate ○ Medicare payment amount	$2,803 Estimated Max
DC	Case-Rate ○ Medicare amount + 13% ($6,048 X 1.13)	$6,834 Estimated Max	Case-Rate ○ Medicare amount +13% ($2,803 X 1.13)	$3,167 Estimated Max
DE	Case-Rate ○ Medicare amount X 183% or 206% ($6,048 X 1.83 or 2.06), depending on area code	$11,068 - $12,459 Estimated Max	Case-Rate ○ Medicare amount X 260% or 289% ($2,803 X 2.60 or 2.89), depending on area code	$7,287 - $8,101 Estimated Max
FL	Case-Rate + Carve-Out ○ Case-Rate (29827) = $3,915.75; plus ○ Carve-Out = 60% of billed charges ($2,000*3*.6)	$10,576 Estimated Max	Case-Rate + Carve-Out ○ Case-Rate (29827) = $5,280; plus ○ Carve-Out = Invoice Cost ($2,000) + 50%	$10,830 Estimated Max

20120 hospital and ASC worker's compensation analysis for rotator cuff repair (29827). Assumes $2,000 ASP.

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  - Payer mix and insurance contract terms will have the biggest impact on adoption
  - Coverage issues may require reimbursement support to obtain prior auths/resolve claim denials
- An emphasis on **reimbursement support** of the sales force and **nuanced messaging** around provider economics is needed
  - Fixed payments from Medicare will need to be subsidized by other payers to attract broad adoption, particularly in the ASC setting
  - Non-coverage by commercial insurers will require prior authorization appeals on a case-by-case basis for most patients
  - Worker's compensation may prove valuable for rotator cuff repair

Initial Recommendations

- Leverage existing coverage, coding and payment mechanisms
  - Existing CPT® codes can be used to describe BioTend™ without immediate validation from AAOS
  - Claim denials and/or negative coverage policies may inhibit adoption in some accounts in the short term
  - Field reimbursement support will be necessary to support prior auth appeals, claims denials and to solidify episode of care economics
- Build clinical foundation to show reduction in re-tear rates – Achilles and Rotator Cuff
  - Payers only care about re-tear rates – patient reported outcomes don't change policies
  - Non-inferiority study design with good randomization is sufficient for coverage
- Collect economic data within clinical studies
  - Collecting economic data can substantiate economic claims going forward
  - Consent enrollees to release hospital financial information
  - Include economic data in the clinical trial agreements/CRFs (i.e. copy of UB04)