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The Challenge of Orthobiologics: Navigating the Coverage and Reimbursement Landscape in a Complex Marketplace

Tim Hunter – Director of Reimbursement



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This document is intended to provide a general overview of coverage and reimbursement scenarios investors, inventors, and manufacturers are likely to face upon market entry. The information in this document is not intended to answer specific coverage and reimbursement questions for the entire field of orthobiology and should not replace a thorough product-specific coverage and reimbursement review and/or assessment. Manufacturers are strongly encouraged to perform an individual reimbursement assessment for each product.

The Challenge of Orthobiologics: Navigating the Coverage and Reimbursement Landscape in a Complex Marketplace

EXECUTIVE SUMMARY

The field of orthobiology includes a wide range of technologies which can include a biological or biochemical component or non-biologically enhanced materials that provide novel alternatives to traditional orthopedic treatments that utilize fusion techniques, metal plates, screws, and implants. Orthobiologics make up as much as 10 percent of the orthopedic market and are among the fastest growing technology segments. Manufacturers will likely face coverage and reimbursement challenges upon market entry, but can attempt to minimize or capitalize on these barriers through early development and execution of a sound reimbursement strategy.

Coverage and reimbursement for orthobiologics continue to evolve, particularly for novel technologies that can replace more traditional orthopedic procedures and materials. In general, public (e.g. Medicare and Medicaid) and commercial payors (e.g. HMOs and PPOs) assess the clinical and scientific literature to determine whether a product is safe and effective, whether it is reasonable and necessary, how it works compared to existing treatments, and how cost-effective the product is. These standards and requirements often are more demanding than the original Food and Drug Administration (FDA) approval or clearance. Coverage and reimbursement for a particular orthobiologic depend on a number of factors that, in some cases, are indicative of the product's FDA designation as a device or biological and the subsequent requirements for FDA clearance or approval. For example, an orthobiologic approved by the FDA as a device under a Pre-Market Approval (PMA) pathway will come to market much sooner than it would as a biologic, but with significantly less clinical data to support coverage. Manufacturers of orthobiologics can take advantage of less rigorous FDA device reviews and better position their products for coverage by performing additional clinical studies beyond FDA approval and incorporating reimbursement principles into the study design.

Once coverage is established, payors determine how much (if anything) they will pay for the new product or procedure. Actual payments to providers will depend on the setting of care (who is performing the procedure and where), what other procedures or services are provided, and the value and cost of the new product relative to the current standard of care. The degree to which a manufacturer can demonstrate the uniqueness and the value of an orthobiologic and establish a coding pathway for appropriately describing the service performed ultimately will help determine whether providers are adequately and appropriately reimbursed when using the product.

Manufacturers of orthobiologics can limit, and in some cases eliminate, barriers to market access by:

- understanding fully the product market space,
- identifying coverage and reimbursement hurdles as early in the development process as possible,
- developing meaningful clinical data that address coverage and reimbursement criteria,
- developing a strategic reimbursement plan to address the obstacles, and
- committing the necessary resources (monetary and otherwise) to execute the plan.

WHAT IS AN ORTHOBIOLOGIC?

The term orthobiologic has two distinct definitions within the orthopedic lexicon. More narrowly, the field of orthobiology includes a wide range of technologies that contain a biological or biochemical component. Examples include tissue regeneration technologies, resorbable scaffolds to reinforce soft tissue, stem cell therapies and biologics delivered through a device. More broadly, it includes a wide variety of technologies that do not include a biological or biochemical component but which, nonetheless, provide novel alternatives to traditional orthopedic treatments that utilize metal plates, screws, and implants. Examples include materials used for kyphoplasty or vertebroplasty, bone cements, and bio-absorbable pins or nails used to enhance healing of fractures.

ORTHOLOGIC EXAMPLES

Bone and Soft Tissue Substitutes
Bone and Tissue Allografts
Tissue-Engineered Substances
Growth Factors
Bone Proteins
Stem Cells
Viscosupplements
Kyphoplasty and Vertebroplasty Cements
Bone Growth Stimulators

The field of orthobiologics is among the fastest growing market segments in the orthopedic field. According to the Orthopedic Industry Annual Report, orthobiologic revenues reached \$3 billion in 2006, a 13-percent increase over 2005.¹ Revenue from orthobiologics makes up as much as 10 percent of the entire orthopedics market. Over 200 companies have or currently are developing orthobiologic technology, with the majority of products still in the development stage.²

HOW ARE ORTHOBIOLOGICS REVIEWED FOR MARKET CLEARANCE OR APPROVAL?

The FDA regulatory pathway required (or in some cases selected) for an orthobiologic can significantly impact the coverage and reimbursement strategy for that product. The FDA pathway dictates not only how quickly an orthobiologic comes to market but often the quality and quantity of clinical data available at launch. Manufacturers should carefully consider how the regulatory strategy might impact the coverage and reimbursement strategy and develop a concise plan for addressing the impact.

Products can be cleared or approved for commercialization through one of several regulatory processes which are highlighted on page 3. With some exceptions, orthobiologics typically receive market clearance from the FDA as medical devices, either through the PMA process or the 510(k) process. Occasionally, a product will be classified and approved as a drug or biologic. The number of orthobiologics approved as biologics is expected to increase as emerging technologies incorporate more sophisticated biological components.

FDA REVIEW FOR DEVICES

Pre-Market Notification (510(k))	<p>In the 510(k) process the applicant typically must show that the new technology is substantially equivalent to a device that is already on the market. The vast majority of 510(k) submissions include little to no clinical data on outcomes and comparability to other therapies currently on the market. The 510(k) process is the most frequently utilized process for device clearance; the FDA received 3,913 510(k) applications in FY 2006.³</p>
Investigational Device Exemption (IDE)	<p>The IDE process allows a manufacturer to ship and utilize a device for the purposes of conducting a clinical study for an investigational device or for an investigational use of a previously approved/cleared device. The purpose of the exemption is to facilitate the collection of safety and efficacy data for the device, primarily to support a PMA or 510(k) application.⁴ The IDE designation also provides an avenue for coverage and reimbursement of portions of the clinical trial by Medicare and some private payors. The FDA received 262 IDE submissions and 4,520 IDE supplements in FY 2006.⁵</p>
Pre-Market Approval (PMA)	<p>The PMA process is the most rigorous FDA review process for devices. PMA submissions most often require clinical data, which can include a controlled clinical trial, but often these trials include a small number of patients. The PMA process (including FDA requirements, preparing and submitting a PMA application, and review) is more complex and time-consuming than the 510(k) process, and is also used less frequently. The FDA received 51 original PMA applications and 131 PMA supplemental applications in FY 2006.⁶</p>

FDA Approval for Drugs and Biologics

Some orthobiologics will be designated as biologics for the purpose of FDA approval. Specifically, an orthobiologic will be designated as a biologic if the primary mode of action is attributable to the biological component of the product.⁷ Drugs and biologics primarily are approved by the FDA through the New Drug Approval (NDA) and Biological Licensing Application (BLA) processes, respectively. Both the NDA and BLA require considerable clinical data, including controlled clinical trials, as a prerequisite for FDA approval. The FDA reviewed 204 NDAs and BLAs in FY 2006.⁸

Combination Products

Some orthobiologics contain multiple components that require FDA review, such as a device containing a biological agent. Alone, the device would be reviewed by the FDA's Center for Devices and Radiological Health (CDRH) and the biologic would be reviewed by the Center for Biologics Evaluation and Research (CBER). The FDA uses an orthopedic example in its description of combined products on its website, stating that “[b]iologics are being incorporated into

novel orthopedic implants to facilitate the regeneration of bone required to permanently stabilize the implant.”⁹

The FDA Office of Combined Products (OCP) determines which FDA Center has jurisdiction over a particular technology seeking review based on a number of factors, including the primary mode of action for the technology. It is possible for a technology to require approval through more than one Center, with the OCP assigning primary oversight to one Center.¹⁰

Implications for Orthobiologics

Because orthobiologics can have either a drug or device designation, the FDA designation is a critically important component of the coverage and reimbursement strategy. In general, orthobiologics approved or cleared as devices likely will not have the same quantity and/or quality of clinical data as their counterparts approved as drugs or biologics for one simple reason—the studies and data were not required. Post-approval opportunities for clinical study and data collection can be utilized to fill this void and are discussed later in this document.

COVERAGE AND REIMBURSEMENT LANDSCAPE FOR ORTHOBIOLOGICS

Given that the field of orthobiologics is relatively new offers enormous opportunities for innovation. It also offers enormous challenges from a coverage and reimbursement standpoint. While the field of orthobiologics is diverse, manufacturers of most products will face many of the same obstacles to widespread coverage and reimbursement. Coverage and reimbursement for products that treat debilitating orthopedic conditions can vary widely by payor type, availability of clinical evidence and medical literature, effectiveness of current treatment options, and support from relevant specialty groups and societies.

Regardless of the mechanism of action, mode of delivery, or makeup of components, the successful private and public payor adoption of an orthobiologic depends on several critical factors:

- Is the product approved or cleared for marketing?
- What information is available to demonstrate a product's safety and effectiveness, its impact on patient outcomes, and its value to payors?
- How well does the technology compare against the current standard of care?
- Do billing codes currently exist that accurately describe the product, its application, the diagnosis being treated, and the procedure?
- How involved are the relevant specialty provider societies, key opinion leaders, and individual specialists in the adoption of the technology?
- What is the current coverage and reimbursement landscape for alternative treatment options?
- What is the cost of the new technology compared to the current technology? What is the total cost of the new procedure compared to the current procedure?
- Why or how does the new technology warrant a price premium?

GENERAL COVERAGE, REIMBURSEMENT, AND CODING CHALLENGES

FDA clearance or approval is just the first hurdle faced by manufacturers of orthobiologics. The manufacturer can market the product and providers can begin to utilize the technology, but often payors have not yet determined whether it will be covered. Further, payors have not determined how much a provider will be reimbursed for using the technology. Finally, in many cases, there is no precise pathway for providers to code an insurance claim to adequately describe the procedure performed and/or the use of the technology.

Most manufacturers will face the following coverage and payment challenges:

- Convincing payors to cover the new technology and its associated procedure;
- Convincing payors to appropriately reimburse for the new technology and associated procedure; and
- Identifying the appropriate diagnosis, procedure, and product-specific codes for use on the insurance claim form.

Coverage

Once a product receives FDA clearance or approval, it is available for use by providers and the general public and for coverage by private and public payors. It is extremely important, however, to note that FDA approval does not equate to automatic coverage. Payors often evaluate new technologies for coverage, particularly those that have high per-treatment costs and/or are likely to be utilized by a large number of plan participants.

The timeline for securing coverage for a new technology varies greatly depending on the payor type, the existence of relevant federal and state laws and regulations, the type of product, the availability of clinical data, scheduled review cycles, and a host of other variables. For example, the Medicare program typically covers new drugs and biologics for their FDA approved indications immediately upon approval, due to the extensive FDA

review processes for these technologies. State Medicaid agencies, however, can take up to a year or more to provide coverage for the same drug or biologic. Commercial payors typically have review processes for new technologies that can delay coverage for several months to several years, particularly for devices.

In the era of evidence-based medicine, most payors rely heavily on clinical data in determining coverage for a particular technology. The quality, quantity, and source of clinical and scientific data all count. Ideally, health plans want to see controlled, double-blinded trials that establish both the safety and efficacy of the new technology. In the absence of such data, health plans consider data from less rigorous clinical trials, peer-reviewed articles published in respected journals, and other third-party analyses. Manufacturer-sponsored presentations and articles typically are scrutinized by the health plan community and may not meet a plan’s requirements for clinical evidence. Case series and opinion are afforded little weight, but may provide verification over time.¹¹

Securing Coverage for New Orthobiologics

The speed with which a particular payor adopts a new orthobiologic will vary and will be dependent on a number of factors. New orthobiologics for established treatment markets approved as 510(k) devices may avoid coverage pitfalls by virtue

of the class it falls under or the condition it treats. However, in many cases (especially for novel technologies that change the treatment paradigm) the speed to adoption likely will be measured most closely by the product’s FDA regulatory review path. It stands to reason that orthobiologics approved through the FDA BLA or NDA application processes are best situated for quicker coverage success because of the stringent FDA requirements for approval. These requirements include well-controlled, randomized clinical trials and more extensive human experience with the product, due to the need for multiple clinical trials. By contrast, orthobiologics receiving market clearance through a 510(k) have the least amount of clinical and scientific information, the least amount of information comparing the new product to existing treatment options, and, therefore, would be the most likely candidates for delayed coverage.

The FDA considers most orthobiologics to be Class II medical devices. This designation provides a faster pathway to market but also can create coverage and reimbursement hurdles. The figure below provides an illustration of the relationship between the relative timeline for approval and the availability of data that payors look for during the coverage and reimbursement processes.

	Time to Approval or Clearance	Available Clinical Data	Patient Experience Prior to Launch
510(k) Device Clearance	<i>Shortest</i>	<i>Least</i>	<i>Least</i>
PMA Device Approval	<i>Longer</i>	<i>Moderate</i>	<i>Some</i>
NDA Drug Approval or BLA Biologic Approval	<i>Longest</i>	<i>Most</i>	<i>Most</i>

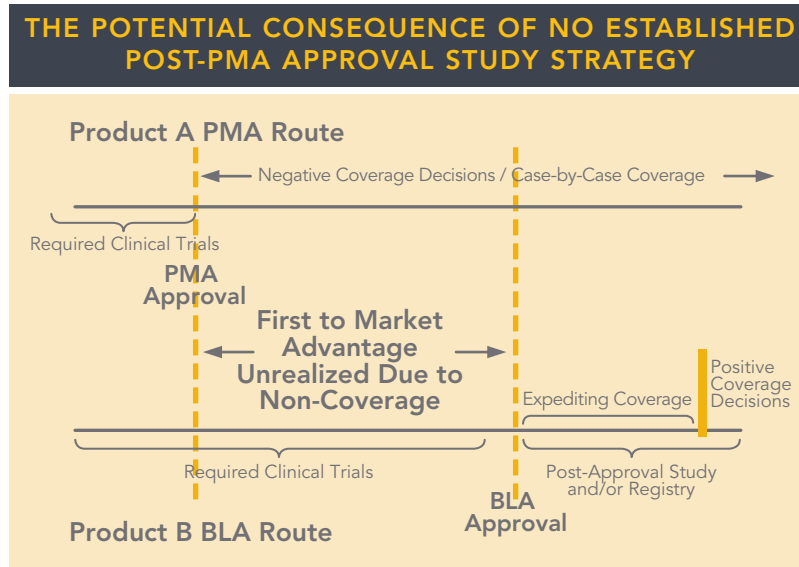
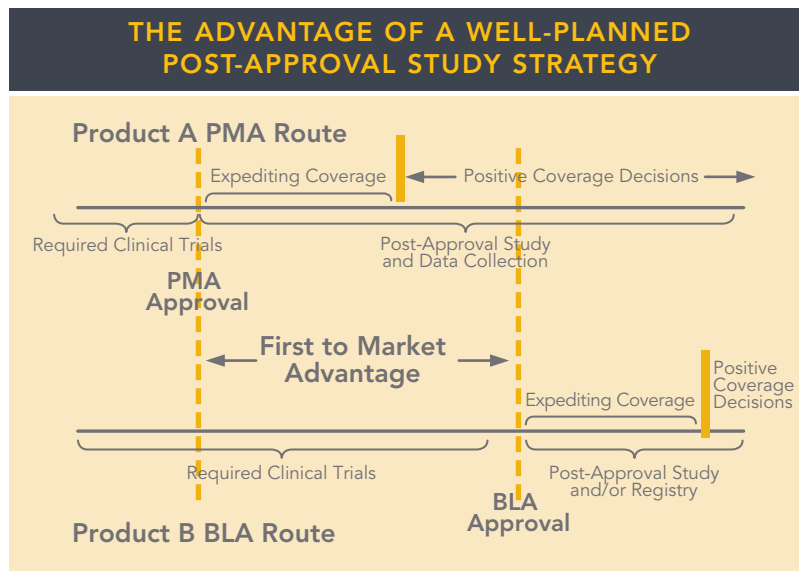
Speed to Approval Versus Speed to Coverage

If given the choice by the FDA, most manufacturers would opt for the quickest and least expensive pathway to market. After all, a faster pathway allows the product to be marketed sooner which theoretically leads to earlier sales. In new markets, that faster pathway can allow the first product to realize a longer first-to-market advantage. In the case of orthobiologics, a device designation (510(k) or PMA) provides that faster pathway to market.

However, a market advantage requires one critical component—a market. What happens if payors require clinical data that simply does not exist or more data than the manufacturer can provide? Unfortunately, this scenario occurs quite often. The result can be devastating, particularly if the manufacturer does not have a strategic

plan for supplying the requested data. Commercial plans can describe the technology as “experimental” or “investigational” which typically is followed with a non-coverage statement. Suddenly, what was anticipated to be a market advantage becomes stagnated as the manufacturer struggles to develop a clinical study plan, execute on that plan, analyze study results, and report findings.

Manufacturers can have it both ways with careful planning and commitment to continued clinical study. The challenge is to combine early market entry advantage of PMA with the clinical data payors expect. The figures below illustrate the role post-market studies, registries, and data collection can play in product adoption and market advantage.



However, not all clinical data are created equally. The availability of impactful and extensive clinical data can prompt health plan coverage for a new technology. However, marginal data can have the opposite effect. The following excerpt from a United Healthcare document on “Clinical Data Sharing” illustrates another way that health plans can use clinical data.¹²

EVIDENCE-BASED DATA AT WORK

*“We have found that sharing evidence-based standards of care and relevant patient-specific information with physicians positively impacts behavior. In 2002, we shared a *New England Journal of Medicine* study with physicians who were using an arthroscopy procedure for the treatment of osteoarthritis. The study found that this treatment was actually ineffective for relief of symptoms. After we shared the data with our network physicians there was a dramatic change in the treatment of osteoarthritis. This evidence-based information sharing resulted in a decrease in the use of an ineffective treatment.”*

–2003 United Healthcare Publication on “Clinical Data Sharing”

The Role of Technology Assessments

Public and private payors often utilize technology assessments to identify new and emerging technologies, evaluate the available clinical and scientific data, and assist in the plan’s coverage determination for the product. CMS engages the Agency for Healthcare Research and Quality (AHRQ) and outside vendors for Medicare technology assessments. The Blue Cross Blue Shield system performs its own technology assessments. Other payors contract with one of several services, such as Hayes, Inc., the ECRI Institute, and the California Technology Assessment Forum (CTAF). International technology assessment organizations also are becoming more readily recognized by payors, offering potential opportunities to leverage ex-US clinical data and clinical experience.

Technology assessments typically address safety and effectiveness, and also compare the subject to competing technologies or procedures. The Blue Cross Blue Shield Association’s Technology Evaluation Center, for example, uses the following criteria:¹³

- Appropriate approval for the technology;
- The scientific evidence must permit conclusions about the effect on health outcomes;

- The technology must improve the net outcome;
- The technology must be at least as beneficial as any established technology; and
- The improvement must be attainable outside the investigational setting.

Technology assessments are a critical component in the coverage process and are performed for a variety of reasons and audiences. Some technology assessments focus on a particular type of patient characteristic. For example, CMS contracts with outside entities to perform technology assessments of relevance to the Medicare population. Some technology assessments evaluate a single product or technology while others examine the entire scope of treatment options available and pending for a particular condition.

The Role of Providers, Specialty Societies, and Other Interested Stakeholders

Providers and their relevant specialty societies are critical allies for manufacturers introducing new orthobiologic technologies into the marketplace. In addition to being the primary end users of orthobiologics, specialists and their societies are critical advocates for the establishment of coverage and reimbursement for the product and its associated procedure. They provide a third-party assessment of the technology and its role within a particular procedure.

Public and private payors rely on key opinion leaders within the specialty community to provide guidance regarding when and how a new product should be used. The contractors that process Medicare claims in the physician and hospital outpatient settings have advisory committees made up of specialists that guide Medicare coverage for products and procedures.¹⁴ Private payor health plans also rely on providers and societies to alert them to new technologies and provide evidence for or against coverage and reimbursement for products and services. An educated, engaged, and enrolled key opinion leader within the treating community or an active specialty society can significantly impact coverage (and payment) for orthobiologics.

Coverage Landscape for Orthobiologics

Coverage for orthobiologics will depend on a number of factors, including the availability of reliable clinical data, the involvement of key specialists and specialty societies, and the payor type assessing the technology. In some cases, Medicare may be the quickest adopter of the technology while in other cases it will issue a national decision prohibiting coverage.¹⁵

Commercial payors in particular may label an orthobiologic as experimental and investigational for some period of time after the product receives FDA market clearance or approval. The primary rationale expressed by payors for noncoverage is that the scientific and/or clinical literature does not establish the safety and efficacy of the product. In addition, health plans can choose to cover some uses of a technology while excluding other uses as investigational and/or experimental. Clinical data, collected before or after FDA approval or clearance, may be even more relevant when competing products receive market approval or clearance through different FDA pathways (i.e. PMA versus BLA).

Reimbursement

While the terms “coverage” and “reimbursement” often are used interchangeably, it is important to understand that these terms are not synonymous. Coverage (whether or not to allow payment for an item or service) provides the pathway for a provider to use the technology, but it does not indicate how or how much the provider will be paid (reimbursed) for performing the service.

Reimbursement includes both what a particular provider is paid for a product or service and how that payment is determined. Payors can reimburse for items or services based on a variety of methods, including fee schedules, prospective payment systems, or based on submitted charges. Additionally, payors can pay for items or services individually or can make one payment for a collection of services that typically are performed together.

Reimbursement for the same item or service can vary by payor and even by setting of care. For example, Medicare, Medicaid, and many private payors reimburse hospitals a set amount for all hospital inpatient procedures, services, and items (including orthobiologics) furnished to a patient for the entire length of the patient’s stay in the hospital. In the hospital outpatient setting, many payors, including Medicare, will pay separately for some items and services in addition to set payments for each particular procedure. In this example, surgeons and other physician specialists most often are reimbursed based on a fee schedule for each procedure and or service performed.

A number of variables and rules influence how a provider is reimbursed when an orthobiologic (or any product) is used in a particular procedure. Those variables ultimately are expressed through coding on a health insurance claim form.

The Role of Coding

An essential component for reimbursement is the coding for the item or service. Reimbursement for a product or service is inextricably linked to coding; medical codes entered onto an insurance claim form identify why the provider is treating the patient (the diagnosis), what the provider is doing to treat the patient (the procedure), and in some cases what specific products have been used. These codes help payors to establish that the services are covered and to authorize specified payment.

Each of the three code types discussed below is important in determining the marketability of emerging orthobiologics.

- **Diagnosis Codes**—Diagnosis codes identify why the patient is being treated. This is particularly important when a payor limits coverage to certain diagnoses.
- **Procedure Codes**—Procedure codes identify the specific treatment that is performed on the patient. It is possible to report more than one procedure code, and the type of payor and setting of care often dictate whether the services are paid independently or as a single bundled payment. When a procedure or service is performed by a physician in a non-physician setting, it is important to remember that the procedure code often drives reimbursement for both the facility in which the procedure is performed as well as the physician who performs the procedure.
- **HCPCS Level II Codes**—HCPCS Level II codes identify specific products and services that can be provided in a variety of settings. Some code sets are used only by specific payor types while other sets are used only in certain settings.

Code Type	Description	Settings Used	Impact Reimbursement?
ICD-9-CM Diagnosis	Describes why the patient is being treated	All (Including physician office, hospital inpatient, hospital outpatient, ASC, etc.)	Yes, impacts payment in hospital inpatient setting (Example: DRGs)
ICD-9-CM Procedure	Describes what the provider is doing to the patient	Primarily hospital inpatient	Yes, impacts payment in hospital inpatient setting (Example: DRGs)
CPT Level I	Describes what the provider is doing to the patient	Primarily outpatient, including physician office	Yes, CPT codes equate to specific payments in outpatient settings
HCPCS Level II Permanent	Describes items or services used during treatment	Various (Including hospital outpatient, physician office, ASC)	Yes, HCPCS Level II codes can equate to separate payments in the various outpatient settings
HCPCS Temporary	Temporary codes that describe a product or service until a permanent code can be established	Various (In some cases, a class of codes have been established for specific settings of care or payment types)	Yes, temporary codes can link to payment in the Medicare hospital outpatient and ASC settings (C-codes), physician setting (Q-codes), and with private payors (S-codes)

When determining a coding pathway for a new orthobiologic, manufacturers need to consider what the procedure will entail, who will be performing the procedure associated with the orthobiologic, and the various settings of care in which the orthobiologic can be used.

Manufacturers should consider the following questions regarding the current coding pathways:

- Do the codes exist to accurately describe the procedure, including the complexity of the procedure?
- Does the introduction of an orthobiologic component change the current treatment procedure or does it simply replace or supplement another product?
- Does the introduction of the orthobiologic make the procedure easier or more difficult, longer or shorter?
- Do the codes accurately compensate the provider for the time, skill, and instrumentation necessary to complete the procedure?
- Will the orthobiologic meet the statutory or health plan requirements for separate payment or will it be rolled into the procedure payment? Are competing products treated similarly?

Securing New Codes

In some cases, currently available codes will allow for appropriate payment, particularly for follow-on orthobiologics that do not change the procedure and those entering established markets. Manufacturers of novel orthobiologics must be prepared to identify a set of new procedure and product-specific codes and committed to navigating the various code creation processes to ensure that providers are appropriately compensated for their use of the product and related procedures. The processes and timelines for securing new or revised codes that accurately reflect an orthobiologic item or procedure can vary from several months to several years. For example, the process for securing a temporary HCPCS code, such as a C-code for use in the Medicare hospital outpatient setting, can take a few months but it can take two to three years to establish a CPT procedure code for the technology.¹⁶ While miscellaneous coding is an available short-term option for new technologies and procedures, the ultimate coding solution should involve permanent codes.

Additional coding dilemmas can surface due to the relationship between the product and its route of utilization. For most drugs and biologics injected or infused into a patient by a health care

provider, the injection or infusion method is not complicated and coding for the procedure is well established. The injection or infusion is fairly simple, often is non-invasive, and often does not entail the performance of previous and subsequent procedures. Orthobiologics, on the other hand, often are associated with at least minimally invasive procedures with components beyond the actual placement of the product, including anesthesia, a surgical component, and monitoring or recovery time.

Setting of Care

Appropriate reimbursement for orthobiologics requires more than just securing payment for the technology, either separately or as part of a bundled payment. It requires that all providers involved with the procedure are appropriately reimbursed for the resources they expend when the procedure is performed. The setting of care for procedures involving the use of orthobiologics tends to be hospital- or facility-based, meaning that the technology typically is used in a hospital inpatient, hospital outpatient, or, in some cases, ambulatory surgical center setting. In some cases, an orthobiologic can be used in the physician office setting. This compounds the magnitude of coding issues because it increases the number of provider types billing for services related to the procedure. Not only must the facility be able to bill for the resources used to perform the procedure, including the orthobiologic, the physician performing the procedure must be able to adequately bill for his time and resource allocations.

Manufacturers of novel technologies must also understand both the current settings of care for the related procedure as well as the eventual transition to other settings of care. A complicated procedure may start out in the hospital inpatient setting and migrate over time to less intensive settings as providers become more experienced, new technologies are introduced, or clinical research and reviews enhance the medical community's understanding of the procedure. This transition can create new reimbursement challenges and opportunities.

CASE STUDIES

While the field of orthobiologics is wide ranging and disparate, the three technologies below represent a variety of the coverage and reimbursement hurdles manufacturers of new orthobiologics might expect to face. The purpose of the case studies is not to generalize the field of orthobiology. Instead, they illustrate the challenges faced by manufacturers in three separate therapeutic

market spaces, how each set of players responded to those challenges, and the ultimate impact on coverage and reimbursement for the novel technologies.

Hyaluronic Acids (Viscosupplements)

Overview of Technology

Viscosupplementation is an FDA-approved treatment option for osteoarthritis of the knee that currently involves a series of (usually three to five) intra-articular injections of hyaluronic acid into the knee. Hyaluronic acid (HA) is a naturally occurring material found in the synovial fluids.¹⁷ The hyaluronic acid acts as a lubricant to allow smoother movement of bones at the knee joint.¹⁸ There currently are five different viscosupplements on the market in the United States: Synvisc®, Hyalgan®, Supartz®, Orthovisc®, and Euflexxa™.

All five hyaluronic acids on the market received FDA approval through the PMA process. The FDA approved Hyalgan® and Synvisc® in 1997. Subsequent approvals occurred for Supartz® in 2001, Orthovisc® in 2004, and Euflexxa™ in 2006.¹⁹ Generally, coverage is limited to osteoarthritis of the knee in patients who have failed more conservative therapies, including anti-inflammatories and physical therapy.

Coverage and Reimbursement

Viscosupplements hold an unusual status among products approved as devices by the FDA in that the medical and payor communities treat these products as if they were drugs or biologics. These products have FDA-issued national drug codes (NDCs) and Healthcare Common Procedure Coding System (HCPCS) J-codes (codes typically reserved for drugs), and are priced like drugs and biologics. In essence, the FDA regulatory decision to treat these products like devices allowed each of these products to enter the US market much more quickly than would have been the case if they were reviewed by the FDA as drugs.

HA products each have an established wholesale acquisition cost (WAC) and a product-specific Average Wholesale Price (AWP) for the purpose of rate setting as drugs. Further, each of these products has been assigned an Average Sales Price (ASP) for the purpose of reimbursement under the Medicare program (and, subsequently, an increasing number of private health plans) and the product class conforms to all Medicare and Medicaid rules and regulations governing drugs and biologics. This designation provided both opportunities and challenges related to coverage and reimbursement.

Upon FDA approval, the original HA products were eligible for coverage and reimbursement under the Medicare program when used in the physician office, but lacked HCPCS codes that uniquely identified the product used. A CPT code existed, CPT 20610, which described the intra-articular injection and facilitated payment for the physician's time and resource requirements for performing the procedure. Coverage under the Medicare hospital outpatient prospective payment system (upon its establishment in August 2000) provided a higher separate payment for these and other drugs. Revisions to the Medicare rules in the hospital outpatient system allowed more immediate reimbursement for newer drugs, such as Orthovisc®, through the use of a miscellaneous HCPCS C-code.

Ongoing Coverage and Reimbursement Challenges for Viscosupplements

Because viscosupplements were approved by the FDA through the PMA process, these products did not require exhaustive clinical trials with comparative effectiveness endpoints. While the FDA's decision to approve these products through the PMA process negated the regulatory requirement to perform multiple clinical trials, public and private payors wanted exactly those data for coverage determination purposes. As a result, manufacturers of all products, including those originally approved in 1998, have continuously been asked to provide prospective and retrospective clinical evidence to demonstrate the comparable effectiveness of

their products. Additionally, recent revisions to (and interpretations of) the Medicare regulations have forced manufacturers to defend each product's place within the HCPCS coding system, which directly impacts Medicare reimbursement for these products.

Aetna's current coverage policy for hyaluronic acids demonstrates the challenges discussed above. Initial coverage for the five products is restricted to plan members with osteoarthritis of the knee who meet six criteria, including documented symptomatic osteoarthritis, pain which interferes with functional activities, unsuccessful treatment with physical therapy or steroidal and non-steroidal anti-inflammatory drugs, and the inability to attribute the pain to other forms of joint disease. Further, the patient cannot have active joint infection, a bleeding disorder, or other contraindications. Patients must meet additional conditions for coverage of subsequent injections.²⁰

Coding for Hyaluronic Acid Products

As the table below demonstrates, a series of HCPCS coding changes has occurred within the HA market space. Some of the changes resulted from changes to federal law while others were borne out of manufacturer attempts to establish unique codes for their products.²¹ Not only did the products receive new J-codes, but the billing unit for the codes changed from dose units to "per dose."

HCPCS CODING FOR HYALURONIC ACIDS—2002 TO 2008							
Excluding C-codes Used in the Medicare Hospital Outpatient Setting							
Product	2002	2003	2004	2005	2006	2007	2008
Synvisc®	J7320	J7320	J7320	J7320	J7318*/ J7320	J7319**/ Q4084	J7322
Hyalgan®	J7316	J7316/ Q3030/ J7317	J7317	J7317	J7318*/ J7317	J7319**/ Q4083	J7321
Supartz®	J7316	J7316/ Q3030/ J7317	J7317	J7317	J7318*/ J7317	J7319**/ Q4083	J7321
Orthovisc®	N/A	N/A	J3490	J3490	J7318*/ J3490	J7319**/ Q4086	J7324
Euflexxa™	N/A	N/A	N/A	N/A	J3490	J7319**/ Q4085	J7323

*HCPCS J7318 was announced to replace J7317 and J7320 in 2006, but was never created. Source: 71 Federal Register, No. 37, February 24, 2006. Page 9459.

**HCPCS J7319 was created for dates of service beginning on January 1, 2007 but was deleted soon after. Source: CMS Change Request 5438, December 22, 2006.

The interpretation of applicable laws and regulations can significantly impact the market for HA products. Medicare is a significant payor for HA products. Beginning in 2006, Medicare began paying physicians for injectable drugs, including HA products, based on an ASP methodology. The ASP methodology sets payment rates based on the average price paid across all payors, providers, and settings of care, minus nearly all discounts and rebates. If more than one drug falls within a single HCPCS code, the ASP is set at the weighted average of the multiple products. For example, the decision to group all products under a single code in 2007 would have resulted in a single payment rate for all HA products. Providers would have received the same payment unit regardless of which product was used. By virtue of the methodology, providers would have been financially advantaged when using the least expensive product (the product with a cost below the average) and disadvantaged when using the most expensive product (the product with a cost higher than the average).

The Next Generation of Hyaluronic Acids

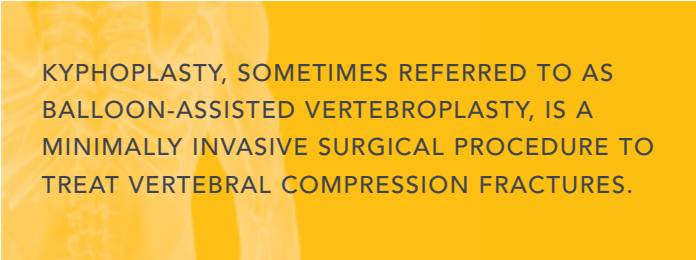
The next generation of hyaluronic acids might further complicate the coverage and reimbursement landscape. Two products currently under review by the FDA, Genzyme's Synvisc One® and Q-Med's Durolane®, will be marketed as single injection alternatives to the current three-shot and five-shot regimens. One or both products could receive market clearance by the end of 2008.

The introduction of these products likely will touch off yet another round of the HCPCS coding battle in this market space. The manufacturers of the single injection products likely will seek separate HCPCS codes that allow for increased payment as the price point for the single injection likely will be higher than that for each individual injection in multi-injection regimens. CMS's most recent interpretation of the Medicare Modernization Act of 2003 appears to support the case for separate HCPCS codes for these products.²² Permanent HCPCS codes for Synvisc One® and Durolane® could become effective as early as 2010 if either product is approved in 2008.

Kyphoplasty

Overview of the Technology

Kyphoplasty, sometimes referred to as balloon-assisted vertebroplasty, is a minimally invasive surgical procedure to treat vertebral compression fractures.²³ The procedure entails the use of a device, a balloon tamp, to restore the height of the vertebral body, at which point a bone cement is inserted to fill the cavity created by the balloon. Kyphoplasty is most closely related to vertebroplasty, a similar surgical procedure in which bone cement is injected directly into the cavity without the use of a balloon tamp.



KYPHOPLASTY, SOMETIMES REFERRED TO AS BALLOON-ASSISTED VERTEBROPLASTY, IS A MINIMALLY INVASIVE SURGICAL PROCEDURE TO TREAT VERTEBRAL COMPRESSION FRACTURES.

Coverage and Reimbursement Hurdles

The KyphX® technology, marketed by Kyphon,²⁴ was the first market entrant specifically for kyphoplasty. As a result, there were no product or procedure codes to accurately represent the kyphoplasty kit itself, the procedure of using a balloon to encapsulate the cement, or the specialist or hospital resources necessary to complete the procedure. The existing codes for vertebroplasty did not provide adequate reimbursement for providers who performed the kyphoplasty procedure.

Before and after receiving FDA market clearance for spinal uses KyphX®, Kyphon worked with a number of stakeholders to differentiate kyphoplasty from vertebroplasty when performed in both the hospital inpatient and outpatient settings. These efforts resulted in the creation of two ICD-9-CM procedure codes as well as temporary and permanent HCPCS/CPT coding for kyphoplasty.

The table on the next page illustrates the evolution of Medicare coverage and payment for kyphoplasty in the hospital outpatient setting.

EVOLUTION OF CODING AND REIMBURSEMENT FOR KYPHOPLASTY IN THE HOSPITAL OUTPATIENT SETTING

2001-2003	2004	2005	2006	2007	2008
Kyphoplasty added to some commercial coverage policies as investigational and non-covered	FDA approves KyphX® for spine	HCPCS C - codes for kyphoplasty added	Permanent CPT codes for kyphoplasty added	2005 claims data, including C9157 used to set 2007 APC rates	2006 claims data, including permanent CPT codes, used to set 2008 APC rates
Example: BCBS of NC September 2001		Medicare OPPS National Average Payment Rate is \$2,043	Medicare OPPS National Average Payment Rate is \$2,592	Medicare OPPS National Average Payment Rate is \$4,092	Medicare OPPS National Average Payment Rate is \$5,059

In 2004, providers used miscellaneous codes to bill kyphoplasty procedures. By 2005, hospitals could bill a temporary HCPCS C-code for kyphoplasty procedures, but physicians continued to use a miscellaneous code. The creation of CPT codes specific to kyphoplasty in 2006 allowed both hospitals and surgeons to bill for kyphoplasty procedures and created a clear coding differentiation from vertebroplasty. CMS used 2005 claims data, the first year of claims data that included a temporary code for kyphoplasty, to set 2007 rates, resulting in a substantial increase in hospital reimbursement for kyphoplasty procedures. For 2008, the Medicare national average payment amount for kyphoplasty is \$5,059, versus \$1,859 for vertebroplasty.²⁵

Future Landscape for Kyphoplasty and Vertebroplasty
Manufacturers, investors, and researchers throughout the field of orthobiologics are attempting to replicate the extraordinary success of the kyphoplasty story. However, the next wave of innovation in the treatment of vertebral compression fractures may come from the bone cements that are used to fill the cavity left by the deteriorated bone. Manufacturers are developing new cements that mimic or otherwise compliment the surrounding healthy bone, require lower volumes to achieve fixation, or otherwise attempt to improve patient outcomes associated with both vertebroplasty and kyphoplasty.

MANUFACTURERS ARE DEVELOPING NEW CEMENTS THAT MIMIC OR OTHERWISE COMPLIMENT THE SURROUNDING HEALTHY BONE, REQUIRE LOWER VOLUMES TO ACHIEVE FIXATION, OR OTHERWISE ATTEMPT TO IMPROVE PATIENT OUTCOMES ASSOCIATED WITH BOTH VERTEBROPLASTY AND KYPHOPLASTY.



Knee Cartilage Repair

Treatment options for repairing knee cartilage damage are evolving quickly. These treatment options primarily are for patients who are nonresponsive to conservative therapy or established arthroscopic procedures but are not yet candidates for total knee replacement. Additionally, a new generation of treatment options is on the horizon just as yesterday's cutting-edge technology seeks coding clarification.

One current treatment option is Autologous Chondrocyte Implantation (ACI) or Autologous Chondrocyte Transplantation (ACT). ACI/ACT "is a two-part surgical procedure involving the biopsy of healthy cartilage and implantation of chondrocytes extracted from the cartilage and cultivated in cell culture. The cultured cells are re-implanted in the patient's knee 14-21 days after obtaining the biopsy, during a second outpatient procedure, in which the cultured cells will regenerate during a post-implantation period of six months to a year."²⁶ The lab-grown cells are contained in a cellular product that is implanted at the treatment site. Currently, Carticel[®], manufactured by Genzyme Biosurgery, is the only FDA-approved product on the market in the United States. Carticel[®] received FDA clearance through the BLA process on August 22, 1997.²⁷ Over the past 10 years, the FDA approval has been modified to narrow the indication to second line therapy²⁸ and to include safety and efficacy data from the post-approval study.²⁹

The ACI/ACT procedure gradually has migrated from the hospital inpatient setting to the hospital outpatient setting. Medicare and private payor coverage policies generally restrict coverage to patients age 15-55.³⁰ According to published policies, this restriction is due to the existence of other joint diseases inherent in older populations that are contraindications for ACI/ACT treatment. The age restriction precludes most Medicare coverage, as the majority of Medicare-eligible beneficiaries are over the age of 65.³¹

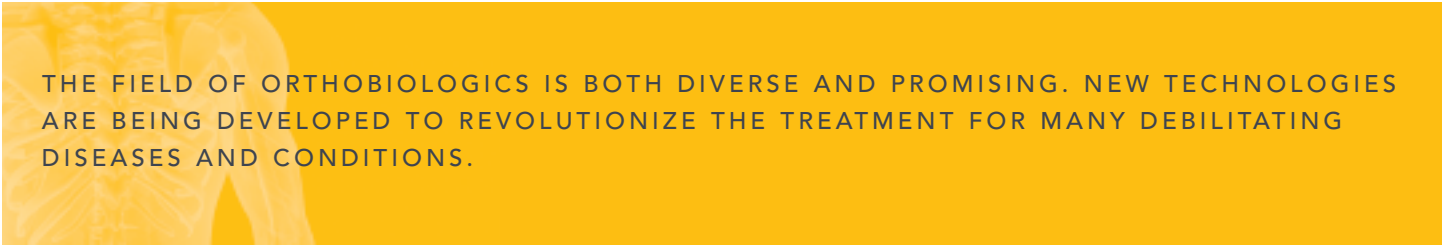
Coverage and Reimbursement for ACI/ACT Product & Related Procedures

Although Medicare likely does not cover many ACI/ACT procedures due to the age restriction, the Medicare Hospital Outpatient Prospective Payment System still provides the best proxy for likely private payor reimbursement. The procedures involved in the extraction of cartilage cells and subsequent re-implantation constitute the least expensive components of the procedure. The two procedures—the biopsy of healthy cartilage cells and the autochondrocyte knee implant—have Medicare national average payment amounts of \$1,833.13 and \$2,911.27, respectively, when performed in the hospital outpatient setting.³² As a biologic, Carticel[®] has a unique HCPCS J-code and is eligible for separate payment in outpatient settings. This designation is significant as the Third Quarter 2008 ASP, the price at which Medicare reimburses for covered uses, for Carticel[®] is \$21,918.42.³³ Reimbursement rates for Carticel[®] vary among private payors that cover ACI/ACT.

Landscape for Future Knee Cartilage Repair Technologies

The next wave of cartilage repair or replacement procedures augment ACI/ACT by introducing a biological or synthetic scaffold, condense the ACI/ACT process into a single procedure, and/or apply microfracture techniques to utilize bone marrow cells. Manufacturers of the next generation of products must closely examine the current coding and reimbursement pathway for cartilage repair to determine how it applies to new products or services. For example, new entrants should closely review the training and certification requirements for surgeons who perform ACI/ACT with Carticel[®] in the event that similar requirements are made for those products.

At the same time, each manufacturer should be looking to identify opportunities to differentiate its new technology and establish market niches. One extremely large niche within the cartilage repair market involves older patients. Payors typically limit coverage and reimbursement for ACI/ACT to patients between 15 and 55 years of age because of confounding factors such as the likelihood of joint disease in other parts of the knee. However,



THE FIELD OF ORTHOBIOLOGICS IS BOTH DIVERSE AND PROMISING. NEW TECHNOLOGIES ARE BEING DEVELOPED TO REVOLUTIONIZE THE TREATMENT FOR MANY DEBILITATING DISEASES AND CONDITIONS.

Medicare routinely covers surgical procedures, such as microfracture, in this same patient population. A new entrant may or may not have the same population restrictions as Carticel®, depending upon any number of variables, including the existence of age-appropriate clinical data or the composition and origin of the implanted material. A product that can avoid age restrictions will have a significantly untapped market opportunity.

Manufacturers may be able to follow the current coding and reimbursement pathway established by Genzyme Biosurgery to secure separate payment for the cartilage repair scaffold, but it is important that each entrant evaluate the composition, description, and function of its technology to ensure that the technology will be treated similarly. If the technology does not fit the parameters of the current pathway, the entrant might have to create an entirely new strategy. For example, the current reimbursement structure for the implantation of Carticel® in an outpatient setting is weighted heavily on separate payment for the product. If some element of the new technology does not allow the product to be reimbursed separately or if the new procedure must be performed in a hospital inpatient setting, the expense of the product may make the procedure prohibitively expensive relative to other available treatment options.

Finally, the knee cartilage repair market space likely will be one of the first to truly pit products approved as biologics (FDA approval through a BLA) against those approved as devices (FDA approval through a PMA). Products in this market space also could be approved as a combination product. Due to the myriad of options (or requirements) for FDA approval, it is vitally important that manufacturers harmonize the coverage and reimbursement strategy with the clinical and regulatory strategy.

CONCLUSION

The field of orthobiologics is both diverse and promising. New technologies are being developed to revolutionize the treatment for many debilitating diseases and conditions. The coverage and reimbursement hurdles that a particular technology faces will depend on a number of factors, including the condition being treated, the availability and efficacy of current treatment options, the quality of the clinical data, uptake and support from the provider and specialty societies, current coverage guidelines, and the need for new procedure and related codes.

In some cases, the path to coverage and reimbursement will be fairly smooth, particularly if the codes exist to accurately describe and reimburse for the product and/or the procedure. In other cases, manufacturers will need to develop entirely new coverage, coding and reimbursement pathways for their technologies. The process for establishing this pathway can take up to several years after FDA approval and should be initiated as early as is practical, taking into account both process regulations and budgetary concerns.

While many hurdles to coverage and reimbursement exist, these obstacles can be overcome through careful preparation and execution of a coverage and reimbursement plan.

WHILE MANUFACTURERS OF ORTHOBIOLOGICS FACE A NUMBER OF CRITICAL HURDLES TO MARKET ADOPTION AND ACCESS, THESE OBSTACLES CAN BE MINIMIZED AND AMELIORATED THROUGH PLANNING AND EXECUTION OF A COVERAGE AND REIMBURSEMENT STRATEGY.

Key Challenges

As the field of orthobiologics evolves, manufacturers will face a number of critical challenges.

- **Defining the product to payors**—An orthobiologic is not easily defined. Is the technology a product or a service? Is it a drug or a device? Manufacturers must identify ways to explain the technology, its application, and its place within the treatment paradigm.
- **Differentiating the product with clinical data**—Orthobiologics, particularly those approved through the 510(k) process, will face scrutiny from payors. The extent to which manufacturers invest in sound and well-focused clinical studies can impact eventual market adoption of the technology.
- **Explaining the higher cost**—Orthobiologics often will carry a premium price point relative to existing technologies, particularly novel orthobiologics that replace an inert substance with a biological alternative. Clinical data can help payors understand what they are paying for and why the new technology makes the most sense for both the patient and the payor.
- **Securing appropriate coding and reimbursement**—An orthobiologic that addresses an unmet clinical need or improves upon the standard of patient care will not be widely adopted by providers if it cannot be billed for and appropriately paid for by payors. Securing new coding to accurately define the technology and its procedure can be a long and tedious process and will require extensive coordination with providers and key opinion leaders within the specialty.

Conclusions

While manufacturers of orthobiologics face a number of critical hurdles to market adoption and access, these obstacles can be minimized and ameliorated through planning and execution of a coverage and reimbursement strategy. Key elements of a successful strategy include the following:

- **Plan early**—Develop a coverage and reimbursement plan early and incorporate it into the overall product development plan.
- **Understand the market**—Research, analyze, and understand the product marketplace prior to the FDA regulatory review for the product. Perform or contract out for a reimbursement landscape assessment during the product development phase to identify potential hurdles or deficiencies. Contemplate current competitors, future competitors, and the potential for the procedure to shift settings. Incorporate the findings into the study protocol and the product plan.
- **Understand payor needs**—Identify the types and quantities of evidence different payor types (Medicare, Medicaid, commercial plans, workers compensation plans) require as early as possible and determine how to meet those needs.
- **Consider ways to develop and report clinical data**—Identify how much clinical data important payor types will require for coverage and how clinical data can be used to establish product-specific procedure codes and payments. Most importantly, incorporate the reimbursement strategy into the overall product development plan to ensure that the available data most closely matches what payors are looking for.
- **Build relationships**—Work with relevant specialty societies, key opinion leaders within the provider community, and payors. Educate stakeholders, including payors, about the importance of the technology, its application, and how it can improve outcomes.
- **Execute the plan**—Proactive attention to potential pitfalls can make the difference between success and failure.

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ABOUT THE AUTHOR

Mr. Hunter has over ten years of experience helping biotechnology, drug, and device companies understand the complex and constantly changing world of healthcare coverage and reimbursement. Mr. Hunter leverages his professional work experiences with the federal government, a large international pharmaceutical and biotechnology company, a trade association lobbying the United States Congress, and as a consultant to help client companies develop unique and novel pathways to coverage and reimbursement. Mr. Hunter has a proven record of working with payors at the national and local levels to advocate for the adoption and appropriate coverage and reimbursement of new technologies.

Mr. Hunter comes to MCRA from Ortho Biotech, L.P., a subsidiary of Johnson & Johnson, where he was charged with understanding how federal Medicare and Medicaid policy changes impacted the company's portfolio of products, its

customers, and patient access. Prior to joining Johnson & Johnson, Mr. Hunter worked as a consultant with Covance Health Economics and Outcomes Services, where he led client companies through the intricacies of Medicare and Medicaid coverage, private health insurance coverage, new product development, and competitive marketing. Mr. Hunter also has held positions within the United States Department of Health and Human Services, where he was the lead analyst for the federal budgets of the Food and Drug Administration and Substance Abuse and Mental Health Services Administration, and the Biotechnology Industry Organization, the national trade association representing the biotechnology industry.

Mr. Hunter holds Bachelor of Arts degrees in Political Science and History and a Masters degree in Public Administration from the Maxwell School of Citizenship and Public Affairs at Syracuse University.



Musculoskeletal Clinical
Regulatory Advisers, LLC

1331 H Street, NW, 12th Floor
Washington, DC 20005
Phone (202) 552-5800
Fax (202) 552-5798

505 Park Avenue 14th Floor
New York, NY 10022
Phone (212) 583-0250
Fax (212) 750-2112

Email: info@mcra.com

www.MCRA.com

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