Variability in Private Payer Medical Policies for Osteochondral Allograft Transplantation Demonstrates the Absence of Standardization in Medical Criteria Between Payers

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Purpose: To define the criteria for coverage for a cartilage restoration procedure and osteochondral allograft (OCA) transplantation and to investigate coverage for OCA procedures among private payer medical policies. **Methods:** A systematic search of private payer websites was conducted to identify publicly available 2018 OCA medical policies. Medical criteria related to patient demographics, defect characteristics, and previous treatment were analyzed. Trends in coverage for treatment of talus and patella and the extent of restrictiveness of medical policies were evaluated from 2016 to 2018. The extent of restrictiveness of a policy was defined by number of medical criteria established by payer policies. Policies with >5, 3-5, and <3 specified criteria for OCAs were considered strongly, moderately, and weakly restrictive, respectively. **Results:** In total, 49 private payer medical policies for OCA transplantation were identified. Extracted criteria varied greatly between medical policies. Ten different defect size ranges were reported across payer policies. Criteria for patient body mass index was specified in 63% of policies. Criteria for failed arthroscopic or traditional surgical procedure were identified in 20% of the policies. More than one half of policies (51%) specified knee defect location to load-bearing surfaces. Analysis of trends in positive coverage statements and restrictiveness showed an increase from 4.7% in 2016 to 39.5% for talus, 4.7% to 7.0% for patella, and a slight shift (4.7% of payers) toward weakly restrictive medical policies. **Conclusions:** This study demonstrates wide variability and inconsistencies in published criteria among OCA medical policies. **Clinical Relevance:** This study informs clinicians of the current state of coverage for OCA transplantation, providing insights into the variability of payer policies and potential impact.

Osteochondral allograft (OCA) transplantation is well established for treating large chondral and osteochondral defects for various patient indications of the knee joint.[1-7] The most common site for treating chondral lesions with OCAs includes the femoral condyles. However, a growing body of evidence supports the treatment of osteochondral lesions with OCAs in sites besides the femoral condyles, including the talus, patella, and trochlea. Although there is now widely published outcome evidence[2-4,8] and consensus

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among the clinical community for treating osteochondral lesions with OCAs for the femoral condyles, talus, patella and trochlea, little is known about the current status of insurance payer coverage for OCA transplantation in the knee and its impact on health care providers and treating patients indicated for cartilage restoration surgery.

In the field of sports medicine, a large number of patients treated for osteochondral defects are reimbursed through commercial private payers (e.g., Blue Cross Blue Shield [BCBS], Aetna, UnitedHealthCare, etc.). Surgical care, including cartilage restoration techniques, can be influenced by the medical policies that payers establish. These policies typically define the most common clinical presentation, which can lead to controversy and restrictions for treating patients who fall outside the general criteria.[9] For OCA transplantation specifically, insurance coverage is defined by the medical policy criteria established by payers. To determine whether the patient meets the medical criteria for OCA transplantation, most private payers require prior authorization: a process to verify if the service/procedure/product is covered on the particular patient's plan and the criteria for medical necessity is met.[10] If prior authorization is denied, the provider has the opportunity to overturn the denial through an appeals process.[10] Both the prior authorization and appeals process can be time-consuming for providers and delay treatment for the patients.[11] Inconsistencies between payer policies further complicates the process and can lead to confusion and frustration among patients and providers. To understand trends and inconsistencies in coverage, several studies have evaluated payer medical policies to provide insights into restrictiveness and variability in coverage for a product/procedure in other fields of medicine.[12-15] The extent of medical insurance coverage for sports medicine procedures has not been investigated. The first phase of this study was designed to evaluate variability in medical criteria defining patient demographics, defect characteristics, and previous treatments. The second phase of this study evaluated private payer trends in coverage of OCAs for treatment of locations besides the condylar portion of the knee (patella) and other joints (talus), and the extent of restrictiveness of medical policies across private payers.

The purposes of this study were to define the criteria for coverage for a cartilage restoration procedure and OCA transplantation and to investigate coverage for OCA procedures among private payer medical policies. We hypothesized that the established medical criteria influencing coverage of OCA transplantation would be inconsistent across private payers.

Methods

Systematic Medical Policy Search

A comprehensive systematic search of private payer medical policies (Appendix Fig 1, available at www.arthroscopyjournal.org) was conducted by a blinded investigator in October 2018 to identify established criteria for medical necessity for OCA transplantation. US private insurance payers were identified through health insurance market research literature.[16,17] Affiliated companies and licensees were further identified using each company's website. Payers' websites were further searched for 2018 effective medical or coverage policies pertaining to treatment of osteochondral and chondral defects with OCA transplantation. General search terms were used to identify most recent medical policy, including "osteochondral grafting" OR "cartilage restoration" OR "chondral defect" OR "cartilage defect" OR "allograft transplantation" OR "musculoskeletal." Previous medical policies with effective dates from 2017 and 2016, medical policy history, and notifications were searched on payer websites to identify criteria in medical policies from previous years. National payers, regional payers, and affiliates or licensees of private payers were all included in the search. Private payers without publicly available medical policies were not included in the study.

Data Extraction

To analyze the variability in established criteria for medical necessity, data were extracted from all medical policies effective in 2018 using a standardized data sheet. All coauthors, experienced orthopaedic surgeons and subject matter experts in cartilage restoration, reviewed the extracted and recorded data-included information related to the following categories—patient demographics, defect characteristics, and previous treatment for OCA treatment of the knee. Table 1 describes the specific data extracted from the medical policies for each category. Most private payer policies include coverage of the condylar portions of the knee but lack coverage for the patella and joints other than the knee (talus). To evaluate trends in coverage of the patella and talus, criteria specifying these locations were extracted and recorded from 2018 effective medical policies. Changes in criteria for patella and talus from 2016 and 2017 were measured by extracting criteria from earlier medical policies or reviewing policy history and payer policy updates. In addition, the restrictiveness of policies and trends in restrictiveness were measured by extracting the number of specified criteria from coverage policies to be considered medically necessary for treatment of the knee. The number of criteria specified by each medical policy was measured

Table 1. Specific Data Extracted From the Medical Policies for Each Category

Category	Data Extracted
Patient demographics	Duration of pain
	Age
	BMI
	Diagnosis
Defect characteristics	Defect size range
	Defect location
Previous treatment	Duration of conservative treatment
	Previous surgical procedure

BMI, body mass index.

directly from 2018 effective medical policies. To measure trends from 2016 to 2018, earlier publicly available policies or policy review history and payer policy updates were used to extract the number of criteria and changes in criteria over this time period.

Data Analysis

The first outcome measure evaluated the medically necessary criteria defined for patient demographics/history, previous treatment, and defect characteristics across payers. Descriptive statistics were used to characterize the various categories and determine the spectrum of criteria defined. For each category, the percentage of payers that reported the specified criteria was measured. The second outcome measure evaluated trends in coverage of OCA transplantation. The percentage of payers that defined criteria for talus and patella as medically necessary was measured over 2016 to 2018. In addition, the extent of restrictiveness of medical policies was measured over time. Restrictiveness was defined by the number of criteria specified in a medical policy to be considered medically necessary. Strongly restrictive was defined by having >5 specified criteria for patient demographics/history, previous treatment, and defect characteristics. Moderately restrictive and weakly restrictive were defined by 3-5 and <3 specified criteria respectively, for the various categories.

Results

Private Payer Medical Policy Selection

The search identified 49 commercial private payers that defined criteria for medical necessity for OCA transplantation in publicly available 2018 effective medical policies. All 49 effective medical policies were included in the first outcome measure. Six of the 49 payers were excluded in the second outcome due to limited publicly available information on 2017 and 2018 effective medical policies. More than 67% of the policies reviewed included Blue Cross Blue Shield (BCBS) licensees and regional companies

Table 2. Percentage of Payers With Specified Criteria for Patient Demographics

Category	Criteria Defined	Percentage of Payers (N = 49)
Duration of pain	Pain for >6 mo	12/49 (24%)
	Pain for >3 mo	1/49 (2%)
	Not reported	36/49 (73%)
Age	<49 years old	5/49 (10%)
	<50 years old	1/49 (2%)
	<55 years old	2/49 (4%)
	15-55 years old	1/49 (2%)
	18-55 years old	2/49 (4%)
	>15 years old	1/49 (2%)
	Adult (no range)	11/49 (22%)
	Skeletally mature adolescent	15/49 (31%)
	Skeletally immature	1/49 (2%)
	Not reported	26/49 (53%)
BMI	≤35	31/49 (63%)
	Not reported	18/49 (37%)
Diagnosis/cause	Avascular necrosis	1/49 (2%)
	Osteochondritis dissecans	2/49 (4%)
	Acute or repetitive trauma	36/49 (73%)
	Not reported	12/49 (24%)

BMI, body mass index.

Analysis of Private Payer Criteria for Patient Demographics

Medical criteria extracted from payer medical policies reported requirements for various patient factors and demographics (age, duration of pain, body mass index [BMI], diagnosis/cause) (Table 2) for treatment with OCA transplantation. The description of patient pain and duration of pain varied among payer policies. Most payer medical policies describe patient pain as debilitating, severe, function-limiting, localized, etc. A number of medical policies, 13 of 49 (26.5%), defined a specific duration of pain, 3 or 6 months, to be considered medically necessary. More than one half of the payers analyzed, 25 of 49 (51%), reported an age criterion for OCAs. Review of the policies identified 9 different age requirements spanning from skeletally immature to defined age ranges of 18 to 55 years old. The analysis identified younger than 49 years old as the most frequent age range considered medically necessary by payer policies. Specified requirements for adult or skeletally mature adolescents was defined in 15 of 49 medical policies (31%) and 1 policy covered skeletally immature patients. BMI was another patient criterion extracted from policies that was inconsistent between payers. More than one half of the payers, 31 of 49 (63%), specified patient criteria for BMI, whereas the remaining payer policies lack any criteria for this indication. Of the payers' medical policies that describe BMI criteria, the policies consistently require patients to have BMI less than or equal to 35. Payer criteria further defined requirements for diagnoses and a specific cause of a patient's chondral defect in 37 of the 49 (76%) medical policies analyzed. The specific diagnoses

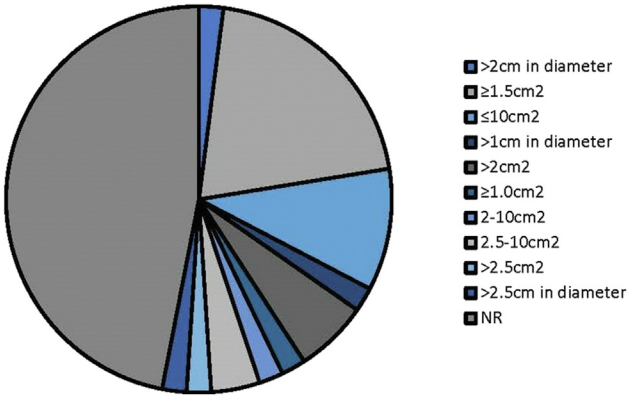

Fig 1. Reported defect size range by payers for osteochondral allograft treatment of chondral defects of the knee. (NR, not reported.)

extracted include avascular necrosis and osteochondral dissecans. Criteria indicating cause by repetitive or acute trauma were described in 36 of the 49 (73%) policies, showing some agreement between payers.

Analysis of Private Payer Criteria for Defect Characteristics

The majority of the payer medical policies analyzed for OCAs have established criteria for defect characteristics, including defect size, surrounding tissue, location, etc. Across the payer medical policies analyzed, 10 different defect sizes were defined as criteria for medical necessity (Fig 1). Furthermore, the measurements (area vs diameter) used by payers to define defect size were inconsistent between payers. The most frequent sizes included less than or equal to 10 cm^2 (10% of payers), greater than or equal to 1.5 cm^2 (20% of payer), and greater than 2 cm^2 (6% of payers).

The criteria for defect location of the knee and ankle joints were analyzed across payers (Table 3). Criteria for defect location of the knee joint varied by specific defined locations to a general description of the knee without any location specifications. Roughly one half of the payer policies, 24 of 49 (49%), included general nonspecific description of defects of the knee, and the remaining payers described location specifics, which included load-bearing or femoral articulation regions, the trochlea, and patella. Twenty-five of 49 payers (51%) established criteria that specifies defect on load-bearing surfaces or femoral articulation regions. Twenty-four of 49 payers (49%) specified coverage for OCAs of the trochlea. Although few payers included coverage for patella, 4 of 49 (8%), a greater number of payer policies defined criteria for the talus, 20 of 49 (41%). Any locations or joints not specified in criteria of the medical policies were consistently considered investigational or experimental across payers.

Table 3. Private Payer Coverage for Defect Locations of the Knee and Ankle Joint

Joint	Criteria Defining Specific Joint Locations	Percentage of Payers (N = 49)
Knee	Load-bearing or femoral articulation	25/49 (51%)
	Trochlear	24/49 (49%)
	Patella	4/49 (8%)
	No specifications (knee)	24/49 (49%)
Ankle	Talus	20/49 (40%)

Analysis of Private Payer Criteria for Previous Treatment

Private payer policies varied in their criteria describing requirements for completion of conservative treatment, previous surgical treatment, and consideration of other surgical treatments (Fig 2). Approximately 16% of payer policies describe criteria for failed conservative management for at least 6 weeks or 3 months. The remaining payers who require failed conservative treatment (27%) do not specify a duration. One-fifth of the medical policies have established criteria that requires a failed arthroscopic or traditional surgical procedure for OCA transplantation to be considered medically necessary. Twenty-four of the 49 payer policies consider OCAs medically necessary when other cartilage-repair techniques (e.g., microfracture, osteochondral autografting, or autologous chondrocyte implantation) would be inadequate due to size, location, or depth of lesion. A number of policies also include guidelines for marrow-stimulation techniques that should be considered before an OCA. In cases in which debridement is the only previous surgical treatment, 20% of payer policies describe considering marrow-stimulating techniques before an OCA is performed.

Trends in Criteria for Medical Policies

The percentage of private payers with defined criteria for talus or patella was measured from 2016 to 2018 (Fig 3). A small increase in coverage for treating patella lesions with OCAs was observed from 2016 (4.7% of payers) to 2018 (7.0% of payers). A substantial increase in coverage for talus was observed from 2016 (4.7% of payers) to 2018 (39.5% of payers). This increase is attributed to BCBS companies and licensees establishing medical criteria for treating lesions of the talus with OCAs. Only 1 of the non-BCBS—affiliated private payer medical policies included criteria for patella, and none of the non-BCBS private payers included coverage of talus. Overall, changes in coverage were observed for both patella and talus.

The extent of restrictiveness across payer policies was measured from 2016 to 2018 medical policies (Fig 4). Restrictiveness was defined as strongly (>5 criteria), moderately (3-5 criteria), or weakly (<3 criteria) restrictive. The analysis of restrictiveness from 2016

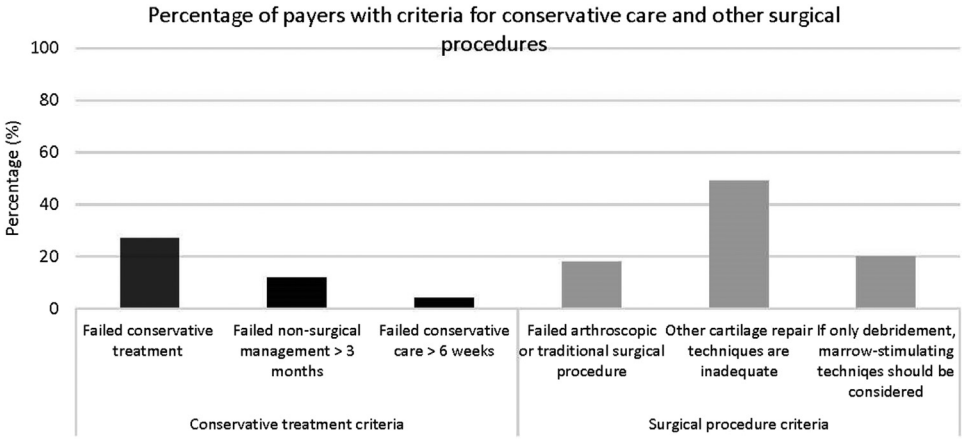

Fig 2. Criteria defined for patient prior treatment. Left, Percent of payers with various criteria describing conservative care. Right, Percent of payers with various criteria defining previous or other surgical procedures that should be considered.

medical policies showed a relative majority of private payer policies (48.8%) were strongly restrictive. The remaining payer policies were moderately (7.0%) or weakly restrictive (44.1%). The analysis of 2017 and 2018 medical policies showed a slight shift from moderate to weakly restrictive medical policies (48.8%). Interestingly, the majority of the BCBS-affiliated entities comprised the weakly restrictive medical policies and the remaining non—BCBS-affiliated payers comprised the strongly restrictive category.

Discussion

Our analysis found inconsistencies and wide variation in the medical criteria defined for OCA transplantation between the payer policies included in this study. One of the main findings of this study was the trend of increasing coverage for the talus and patella. Overall, the outcomes showed varying degrees in restrictiveness between payers and a slight shift toward less-restrictive policies, which supports the initial hypothesis that the established medical criteria influencing coverage of OCA transplantation will be inconsistent across private payers and will become less restrictive over time. The widest variation in medical criteria was observed for patient age and defect characteristics, which spanned 9 and 10 different requirements, respectively. Variation and inconsistencies between payer policies not only impact if the procedure is covered but can lead to administrative complexities and restrict the use of a treatment.[11,14] Therefore, it is important for providers to understand that when a patient falls outside of the defined criteria a coverage denial is possible and may influence patient care. Furthermore, even with appeals, coverage for the procedure may not be obtainable from the payer, even when medically indicated and consistent with the state-of-the-art understanding of this therapeutic. As such, it is essential to understand whether the defined criteria are consistent with the current available evidence, peer-reviewed clinical literature, and the clinical community standards of care.

Most insurance providers develop medical policies with criteria deemed medically necessary for a procedure through their interpretation of the published evidence and criteria established through medical specialty societies.[10] The wide variability in criteria for OCA treatment suggests that payer interpretation of the evidence also varies. For example, several clinical studies have evaluated the effect of patient age on outcomes. Wang et al[18] demonstrated clinically significant improvement in outcome scores across all patients ≥40 years of age, suggesting that OCAs may delay the need for arthroplasty and provide patients improved quality of life for several years. Findings from Frank et al[19] further demonstrated that the survival and reoperation rates in older patients ≥40 years were similar to younger patients aged <40 years, and this was further corroborated by Anderson et al,[20] who indicated remarkable improvements in quality of life and activity metrics, in patients ≥40 years of age. These findings appear to be inconsistent with the defined age ranges identified in this study. Although the evidence and literature used by private payers to develop criteria were not evaluated in this study, the variability suggests

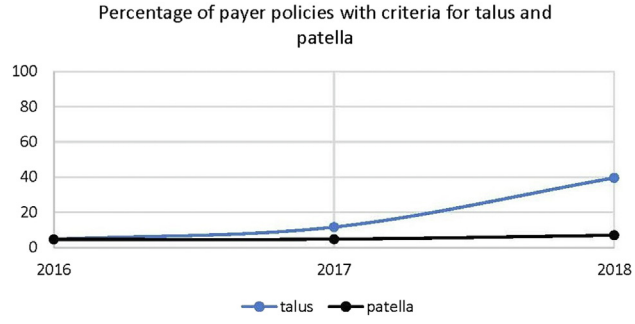

Fig 3. Change in medical criteria for coverage of talus and patella over 2016-2018 medical policies.

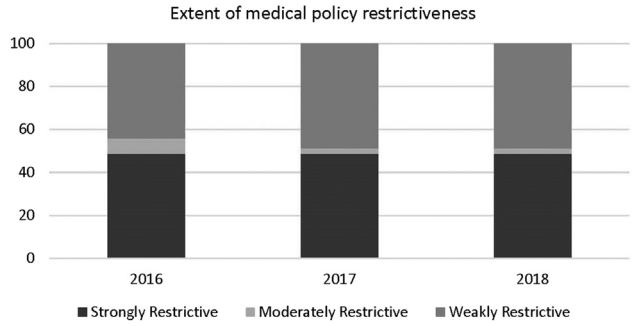

Fig 4. Percentage of payers with strongly (>5 criteria), moderately (3-5 criteria), or weakly (<3 criteria) restrictive medical policies for osteochondral allograft transplantation.

discrepancy in the interpretation of literature between payers and even within payers. These findings are not unique to OCA transplantation. A study by Chambers et al.[12] investigated coverage of rheumatoid arthritis drugs by private payers and the evidence reviewed to determine coverage. This study found variation in both the coverage determination and the evidence reviewed. Consensus on the defined criteria of medical policies in the clinical community and additional studies where evidence is lacking could help standardize the criteria. A recently published consensus statement on OCA transplantation of the ankle by a group of international cartilage repair experts reached strong agreement for treating talus lesions with OCA plugs in preference to autograft for various clinical scenarios.[21] Although there is consensus in the clinical community for treating talus lesions with OCA,[21] only 40% of payer policies have established coverage. Further work understanding the rationale of payer policies may provide insights into the discrepancies into anatomic locations covered and variability between payers.

Other important criteria analyzed were requirements regarding previous treatment. Variations were observed around nonsurgical (conservative) care and previous or other surgical treatments. These criteria can have significant implications for health care providers making decisions on patient care, as patients without a failed specified surgical treatment may not obtain coverage, even though the literature to support the requirement of a previous surgical procedure is lacking.[22] The ethical conundrum of requiring a failed surgery and/or a prolonged period of nonoperative treatment, to receive a properly indicated surgical procedure authorization seems self-evident and questionably necessary in many circumstances. This would be particularly true for large osteochondral articular defects, which are known to progress with time, potentially causing additional pathology during delays in definitive treatment.[23] These circumstances can render care more complex, while prolonging suffering and temporally increasing the socioeconomic impacts of disability in such patients.

The private payer policies included in this study consistently included coverage for treatment of the knee or load-bearing portions of the knee. The patella and joints besides the knee, including talus, are considered investigational by majority of payer policies. To understand trends in coverage of these locations, payer policy criteria for patella and talus was measured over 2016 to 2018. One of the main findings showed a trend towards increasing coverage of talus and patella, however a greater increase was observed with talus. This increase was solely attributed to BCBS affiliated payers; no other non-BCBS commercial payer considered criteria for talus as medically necessary. Similarly, trends in policy restrictiveness, defined by the number of criteria, were analyzed over the same time period. The outcomes showed varying degrees in restrictiveness between payers and a slight shift toward less-restrictive policies. The degree of restrictiveness may impede or facilitate coverage decisions; however, the direct effect of restrictiveness on prior authorization and coverage was not evaluated in this study.

Despite the growing body of literature and consensus among the clinical community for treatment of chondral lesions with OCAs, these findings depict inconsistent and at times absent coverage from payers. The variation in patient criteria across payers can pose a burden to health care providers, increasing the time and complexity for previous authorization. The variation in coverage can further influence provider decision-making and affect the delivery of patient care. Although other cartilage-repair procedures were not included in this analysis, future work will investigate the restrictiveness of coverage for other types of cartilage procedures and the impact on delivery of care.

Limitations

There are a number of limitations in this study. First, only private payer policies with publicly available medical policies for OCA transplantation were included in the study, which could lead to selection bias. A number of payer policies are not publicly available, making it difficult to capture comprehensive data and to generalize the data. Workers' compensation and government providers also were not included in the analysis. Furthermore, the policies identified were at a single point in time. Since this study was conducted in 2018, it is possible that the criteria for OCA transplantation have substantially changed in recent years. The medical policies are continuously revised and updated at various times throughout the year. This review did not measure the impact of the wide variability in coverage and restrictiveness of policies on health care providers or patient care. In addition, for purposes of clarify and coherence, the number of criteria depicted restrictiveness in this review. However, it should be noted, by further breaking down the criteria, for

instance patient experiencing symptoms for 3 months versus 6 months, a more direct indication of policy restrictiveness could be observed. Due to the heterogeneity of the payer criteria, we were unable to develop a consistent and objective restrictiveness measure for the specific type of medical criteria descriptions. Future investigations will explore the restrictiveness of specific criteria type versus the number of criteria per policy and the impact on delivery of care.

Conclusions

This study demonstrates wide variability and inconsistencies in published criteria among OCA medical policies.

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