Smith+Nephew

CARTIHEAL◊

AGILI-C◊ Cartilage Repair Implant

CARTIHEAL◇ AGILI-C◇ CARTILAGE REPAIR IMPLANT

COMPREHENSIVE REIMBURSEMENT RESOURCE GUIDE: 2025

The information on the subsequent pages in this section provides coding guidance for physicians and facilities submitting authorization requests and claims for knee repair procedures.

Information on reimbursement in the U.S. is provided as a courtesy. Due to the rapidly changing nature of the law and the Medicare payment policy, and reliance on information provided by outside sources, the information provided herein does not constitute a guarantee or warranty that reimbursement will be received or that the codes identified herein are or will remain applicable. This information is provided "AS IS" and without any other warranty or guarantee, expressed or implied, as to completeness or accuracy, or otherwise. This information has been compiled based on data gathered from many primary and secondary sources, including the American Medical Association, and certain Medicare contractors.

Providers must confirm or clarify coding and coverage from their respective payers, as each payer may have differing formal or informal coding and coverage policies or decisions. Providers are responsible for accurate documentation of patient conditions and for reporting of products in accordance with particular payer requirements.

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Technology Description

CARTIHEAL◇ AGILI-C◇ Cartilage Repair Implant is a cell-free, off-the-shelf implant for use in cartilage and osteochondral defects in traumatic knee joints. It is a porous, biocompatible, and resorbable bi-phasic scaffold consisting of interconnected natural inorganic calcium carbonate (aragonite).[1]

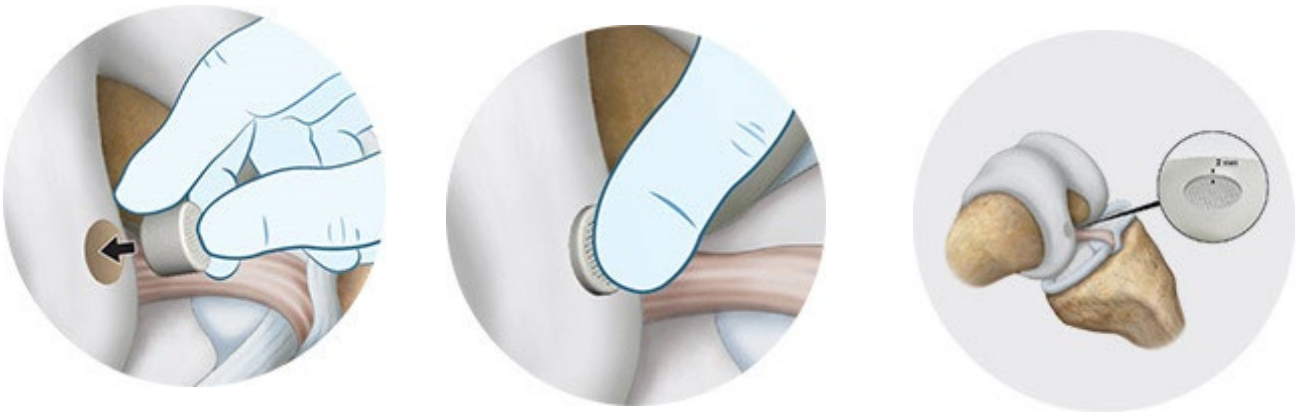
The CARTIHEAL AGILI-C scaffold is indicated for the treatment of an International Cartilage Repair Society grade III or above knee-joint surface lesion(s), with a total treatable surface area of 1-7cm^{2,} without severe osteoarthritis (Kellgren-Lawrence grade 0-3).[2]

The U.S. Food and Drug Administration (FDA) granted CARTIHEAL AGILI-C Breakthrough Device designation status in 2020 and Premarket Approval (PMA P210034), March 29, 2022.[3]

The FDA granted PMA approval based on the results of a two-year randomised controlled trial (N=251) that confirmed superiority of CARTIHEAL AGILI-C over current standard of care - microfracture and debridement for the treatment of knee joint surface lesions, chondral and osteochondral defects.

Implantation Procedure

The CARTIHEAL AGILI-C Cartilage Repair Implant is implanted using a designated surgical toolset. A hole is prepared to fit the CARTIHEAL AGILI-C implant. Multiple holes may be prepared in accordance with the size of the actual lesion with the implant size chosen. The implant is manually pressed into the hole until flush with the articular cartilage.

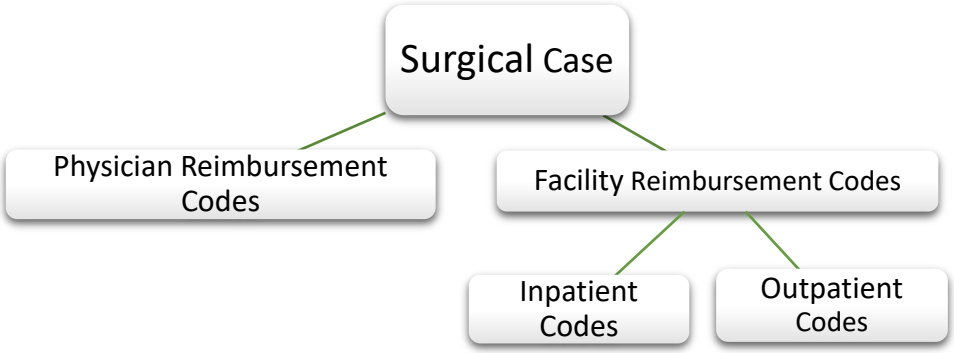


[1] https://www.accessdata.fda.gov/cdrh_docs/pdf21/P210034C.pdf. Accessed 12/17/2024.
[2] https://www.accessdata.fda.gov/cdrh_docs/pdf21/P210034B.pdf. Accessed 12/17/2024.
[3] https://www.accessdata.fda.gov/cdrh_docs/pdf21/P210034A.pdf. Accessed 12/17/2024.

Coding Basics

Coding assignment for new or existing procedures or technologies varies depending upon the reimbursement pathway. Coders assign distinct code sets to report various aspects of procedures, technologies or supplies for reimbursement depending on the entity billing the case.

Reimbursement pathways and appropriate code sets take two directions resulting in two separate reimbursements for a single patient encounter when performed in a facility. Physicians and the facility where physicians perform the procedure report their work or charges separately. This in turn creates unique coding pathways for each side of the equation that results in appropriate reimbursement from third party payers (Medicare or Commercial).



Physician Codes

Physicians use Current Procedural Terminology (CPT) codes to report services and surgical procedures. The American Medical Association (AMA) creates CPT codes through a process controlled by the AMA/CPT Editorial Panel. The AMA/CPT Editorial Panel approves new codes and code descriptions per a set of defined standards and review process criteria.[4]

Permanent (Category I) CPT Codes for both existing and newly created physician procedures and services have met the qualifications outlined by the AMA/CPT Editorial Panel. The Editorial Panel typically establishes Relative Value Unit (RVU) values. CMS and Commercial payers use RVUs to determine physician reimbursement.

Temporary (Category III) CPT "T" Codes for physician procedures and services, have met the qualifications outlined by the AMA/CPT Editorial Panel for temporary code status. AMA/CPT Editorial Panel will assign new technologies that have not yet qualified for a new permanent Category CPT code to a "T" code to provide a means of tracking procedures and collecting data essential to becoming a permanent CPT code. CAT III CPT codes provide a pathway to submit procedures to third party insurance companies. While there is no official valuation established by the AMA/CPT Panel or CMS for this type of code, some third-party carriers may reimburse for the reported procedure based on their specific coverage guidelines and fee schedules.

[4] American Medical Association Website. CPT-Current Procedural Terminology. Available at:https://www.ama-assn.org/amaone/cpt-current-procedural-terminology. Accessed 12/17/2024.

It is usually necessary for a physician to provide a "special report" letter to the third-party carrier that establishes the medical necessity of the procedure and a "crosswalk" code to determine the value or reimbursement rate for the procedure when submitting the billing form to the insurer.

Insurance carriers will review the claim and make reimbursement decisions based on their medical necessity guidelines. While this process requires additional work to obtain reimbursement, it also meets the needs of data collection relating to specific use of procedures reported with CAT III codes.

The AMA/CPT Editorial Panel established the CAT III code process to aid in data collection and the potential future valuation of new technologies and related procedures.

Outpatient Facility Codes

Physicians perform surgical procedures in the outpatient or inpatient setting of care. Physicians determine the setting of care based on individual medical necessity and according to payer policy. Each setting utilizes a different code set to report services to the payer for reimbursement. This is in addition to the surgeon, who reports his services separately with CPT codes. Payers may impose ***setting of care policies*** based on procedure type and clinical criteria to indicate whether the physician must perform an outpatient surgical procedure in an Ambulatory Service Center or the Hospital Outpatient Department.

Outpatient APC Codes are based on CPT codes reported by physicians that map to a second code set called APC Codes. Ambulatory Payment Classification (APC) codes combine CPT procedures into groupings utilizing similar resources in the outpatient setting. Facility payments are based on established rates for the APC. Facilities report APC codes that result in payment for individual or groups of procedures determined by payer guidelines. Government payers and some private payers use this system, but reimbursement guidelines can differ depending on contracted agreements. Medicare reimbursement rates are determined by the Outpatient Prospective Payment System (OPPS) published semi-annually.[5]

HCPCS Level II Codes Outpatient reporting also requires that implantable devices and biologics used in procedures be coded separately using the Healthcare Common Procedure Coding System (HCPCS) Level II Codes. This code set allows line-item reporting of products used in procedures **that are not already included within the reimbursement rate for the reported APC**. This system differs for government payors where a pass-through payment code must be adopted and valued by CMS, and private payors, who use the HCPCS code to determine contracted rates with more generalized codes.

CPT Code Modifiers It is sometimes necessary to submit a CPT code with a modifier. Modifiers indicate a service has been altered by a specific circumstance but that the CPT code description has not changed. Complete lists are available in the AMA/CPT book and online on the Medicare website.

[5] Centers for Medicare & Medicaid Services Medicare Learning Network. Hospital Outpatient Prospective Payment System. Available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/html/medicare-payment-systems.html#Hospital (Accessed December 17, 2024).

Coding Pathways by Place of Service

Coding pathway information is intended for provider guidance and allows the physician to consider his or her reporting pathways on a case-by-case basis. Final decision-making regarding coding guidelines for specific third-party payers remains in the hands of the provider. The provider has a better understanding of the coding pathways available and how to use them appropriately in the outpatient and inpatient facility settings of care.

Physician Services

Physicians performing services in a facility, such as a hospital outpatient department or ambulatory surgery center, may submit a claim to the payer for his/her professional component of the service separate from the facility claim. Under Medicare, physicians are paid based on the Medicare Physician Fee Schedule (MPFS). Payments for CPT codes are determined by the review of the Relative Value Update Committee (RUC) and valuation by the Centers for Medicare and Medicaid Services (CMS). Medicare does not establish payment rates for Category III CPT codes such as 0737T on the MPFS. Individual Medicare Administrative Contractors (MAC) may establish their own payment rates.

Commercial payers use a variety of reimbursement methodologies and guidelines to reimburse physician services. Payment methods include established fee schedules, such as the Medicare Physician Fee Schedule (MPFS), charge-related basis (i.e., percentage of billed charges), or other arrangements. Payments for CPT codes under the MPFS are based on the Relative Value Update Committee (RUC) and valuation by the Centers for Medicare and Medicaid Services (CMS).

Payment methodologies vary among payers and the above are only a few examples of how payment is determined for a claim. Providers should contact the specific payer in question with any payment-related inquiries. Payers have fee schedules for established and covered procedures which are usually accessible by calling the payer or through the payer's online provider portal.

Facilities

Private payers may refer to Medicare's payment rates and policies for hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs). Under Medicare, HOPDs are paid based on the Outpatient Prospective Payment System (OPPS). Under OPPS, services are assigned to payment categories called Ambulatory Payment Classifications (APCs). Ambulatory surgical centers (ASCs) are paid based on the Ambulatory Surgical Center (ASC) Payment System.

Commercial payers can use a variety of reimbursement methodologies and guidelines to reimburse for outpatient department services. Methods include setting reimbursement rates which follow the Medicare APC grouping model and assign the service to an established fixed payment group, or payment based on a charge-related basis (such as a set percentage of the billed charges), in addition to others.

Contracts

Commercial payers will have specific contracts negotiated with participating network physicians or surgical facilities. A contract may contain language specific to a type of procedure or a CPT code or language that applies to Category III codes in general. For example, a contract may state that the provider agrees to accept a specific percent of billed charges for a specific code, or that they will accept the payer's rate for reasonable and customary charges for a code. Commercial payers typically have a specific provider relations contact assigned to physician's office or the surgical facility, who can discuss the provider's specific contract in detail if there are any questions about what it does and does not cover, or specific payment terms.

Coverage and Reimbursement Landscape CARTIHEAL◇ AGILI-C◇ Cartilage Repair Implant

Coverage Landscape

The CARTIHEAL AGILI-C Cartilage Repair Implant currently does not have an assigned Category I CPT Code describing the specific procedure for using the CARTIHEAL AGILI-C Implant. The AMA/CPT Editorial panel reviewed a code submission for CARTIHEAL AGILI-C Implant in September of 2021 (prior to FDA submission) and created a Category III CPT code 0737T Xenograft implantation into the articular surface.

For payers who do not have published coverage policies for the CARTIHEAL AGILI-C Implant, decisions may be made on a claim-by-claim basis.

Providers should verify commercial payer requirements regarding prior authorizations, keeping in mind some payers may not require prior authorization for codes describing the CARTIHEAL AGILI-C Cartilage Repair Implant, but may conduct a medical review at the time of claim processing. Providers should be prepared to furnish medical records and other relevant documents that support the medical necessity of the CARTIHEAL AGILI-C Implant procedure for the patient in question, for the claim to be processed.

Predeterminations and Prior Authorizations

Prior authorizations are sometimes required by commercial payers to determine medical necessity and coverage of a prescribed service for a specific patient. While obtaining an authorization does not guarantee payment of a claim, it can prevent administrative claim denials due to lack of authorization on file when one is required.

Prior authorization requirements can vary by payer, plan type (HMO vs PPO), and medical policies. Providers should check authorization requirements for a patient's plan in advance of the procedure to obtain any required authorizations. Surgical facilities should coordinate with the rendering physician's office to ensure that the place of service is represented correctly on any authorizations that are obtained by the physician's office.

Patient Access Program – MyKneeHealth

To support patient access, **S+N** has partnered with **JDL Access** to provide a patient access program, MyKneeHealth, customized to the CARTIHEAL AGILI-C Cartilage Repair Implant procedure and the needs of providers and patients/caregivers. **JDL Access** can perform electronic benefits verifications, pre-service authorizations and appeals, as well as manage post-claim denials through a cloud-based portal. Providers may engage with **JDL Access** at any step in the process for support by enrolling in the program with their patient's consent. For more information or to enroll call ***888-668-2608*** or email ***mykneehealth@jdlaccess.com*** to initiate this service at no charge to your practice.

Procedure Payment

Each payer establishes its own reimbursement methods and rates for procedures in physicians' offices and facilities. Private payers often follow Medicare's methodology, but final reimbursement may be informed by alternate data or provider contracts.

Coding Options and Guidelines

Relevant Code Summary

When coding claims for the CARTIHEAL◇ AGILI-C◇ Cartilage Repair Implant procedure, it is important to use the diagnosis and procedure codes that most accurately describe the patient's medical condition, the service or services performed, and medication administered to the patient.

For the CARTIHEAL AGILI-C Implant procedure to be considered medically necessary and eligible for coverage by payers, it must be performed and administered in accordance with the FDA approved indications for use. Individual payers and plans will vary on clinical coverage requirements.

Currently, 0737T is not assigned RVUs[6]. According to the AMA, a Category I code must be used in place of an unlisted code if the Category III code accurately identifies the service performed.

Applicable Diagnosis Codes (ICD-10-CM)

Health care providers are required to use ICD-10-CM diagnosis codes to describe a patient's medical condition and to justify medical necessity of items and services furnished to patients. Providers should always use ICD-10-CM diagnosis codes that most accurately reflect the patient's condition to the greatest degree of specificity possible.

Diagnosis codes for any particular claim will depend on the individual patient's presentation. Below is the list of potential diagnosis that may be applicable when performing the CARTIHEAL AGILI-C Cartilage Implant procedure. Providers must determine relevant and appropriate diagnosis coding applicable to the specific patient encounter. Not all of these diagnosis codes may be translated to on-label indications for CARTIHEAL AGILI-C Cartilage Implant, which is why it is important for providers to verify valid and billable diagnosis code/CPT code pairs with a patient's specific plan either by calling payers prior to the procedure taking place or obtaining a voluntary predetermination if no prior authorization is required.

ICD-10-CM Coding Options

ICD-10-CM	Code Description
M93.262	Osteochondritis dissecans, right knee
M93.261	Osteochondritis dissecans, left knee
M93.269	Osteochondritis dissecans, unspecified knee
M93.88	Other specified osteochondropathies other
M93.98	Osteochondropathy, unspecified other
M95.8	Other specified acquired deformities of musculoskeletal system
M99.86	Other biomechanical lesions of lower extremity
S83.3	Tear of articular cartilage of knee, current
M24.10	Other articular cartilage disorders
M23.9	Unspecified internal derangement of knee

[6] Total RVU (Relative Value Unit) – Total includes work RVU, Practice Expense RVU and Malpractice RVU.

Procedure Codes (CPT) Category III CPT Codes

The American Medical Association (AMA) advises that when billing CPT codes, providers should select the procedure or service that most accurately identifies the procedure that was performed, and not to select a CPT code that merely approximates the service provided, if a more specific code is available.

Category III CPT codes are temporary codes representing new and emerging technologies, procedures, and services. They typically do not have a national fee schedule payment amount. As such, payers typically will determine payment amounts for Category III CPT 0737T on a claim-by-claim basis, based on the description of the procedure, the provider's billed charges, the provider's contract with the payer, and any additional information associated with the claim that documents the time and complexity of the work associated with the service.

Modifiers

Modifiers are two-digit codes that are appended to a CPT or HCPCS code on a claim, to provide payers with additional information that may be necessary in order to process the claim. Providers should verify which modifiers are allowed by a payer beforehand, to avoid claim denials for the use of an inappropriate modifier.

Examples of modifiers that might be applicable:

CPT/HCPCS Modifier Options

Modifier[7]	Description
-22	Increased Procedural Service
-50	Bilateral Procedure
-51	Multiple Procedures
-58	Staged or Related Procedure or Service by Same Physician
-59	Distinct Procedural Service
-XE	Separate Encounter
-XS	Separate Structure
-XP	Separate Practitioner
-XU	Unusual Non-Overlapping Service

[7] The CPT codes listed are unilateral procedures. If performed bilaterally, some payors require that the service be reported twice with modifier 50 appended to the second code while others require identification of the service only once with modifier 50 appended. Check with individual payors.

CARTIHEAL™ AGILI-C™ Cartilage Repair Implant

2025 Coding Reimbursement Guide

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CARTIHEAL® AGILI-C® Cartilage Repair Implant

Category III CPT[1] Code

CPT[1] Code	Description	Total RVUs[2]	2025 Medicare National Average			APC[4]
			Physician[3]	HOPD[4]	ASC[5]	
0737T	Xenograft implantation into the articular surface	NA	NA	NA	NA	5115

Facility Medicare National Average Rates

CPT[1] Code	APC	APC Description	2025 Medicare National Average			
			HOPD[4]		ASC[5]	
			SI	RATE	PI	RATE
0737T	5115	Level 5 Musculoskeletal Procedures	J1[6]	$12,867	J8[7]	$9,339

Options for Category I CPT Crosswalk

CPT[1] Code	Description	Total RVUs	2025 Medicare National Average			APC[4]
			Physician[3]	HOPD[4]	ASC[5]	
27412	Autologous chondrocyte implantation, knee	49.98	$1,617	$7,144	$3,511	5114
27415	Osteochondral allograft, knee, open	41.75	$1,350	$12,867	$11,002	5115
27416	Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s])	29.92	$968	$7,144	$3,511	5114
27447	Arthroplasty, knee, condyle, and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)	38.88	$1,258	$12,867	$9,256	5115
29877	Arthroscopy, knee, surgical; debridement/shaving of articular cartilage (chondroplasty)	19.06	$617	$3,245	$1,579	5113
29879	Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture	20.30	$657	$3,245	$1,579	5113

Options for HCPCS[8] Level II Codes – Medicare Reporting

HCPCS[8] Codes	Description
C1889	Implantable/insertable device, not otherwise classified
L8699	Prosthetic implant, not otherwise classified
C1776	Joint device (implantable)
C1763	Connective tissue, nonhuman (includes synthetic)

Under Medicare's Outpatient Prospective Payment System, HCPCS codes are required to report devices used with outpatient procedures.

For commercial claims submissions, check with each individual payer for proper reporting.

Disclaimer

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[1] CPT is a registered trademark of the AMA. All rights reserved.
[2] Total RVU (Relative Value Unit) – Total includes work RVU, Practice Expense RVU and Malpractice RVU. MPFS, 2025 Final Rule. www.cms.gov
[3] Medicare Physician Fee Schedule, 2025, Final Rule. www.cms.gov
[4] Hospital Outpatient PPS, 2025 Final Rule, www.cms.gov
[5] Prospective Payment Systems, ASC Payment, Addenda, 2025, Final Rule. www.cms.gov
[6] Hospital Part B services paid through comprehensive APC, Hospital Outpatient PPS, 2025 Final Rule, www.cms.gov
[7] Device-intensive procedure; paid at adjusted rate, Prospective Payment Systems, ASC Payment, Addenda, 2025, Final Rule. www.cms.gov
[8] HCPCS Level II Expert, 2025, AAPC.

Prior Authorization and Denial Appeal Process Overview

Pre-Authorization

To facilitate coverage access for a procedure, the physician may request a pre-authorization from the patient's private insurance carrier. Health plans require pre-authorization for designated procedures. Requesting pre-authorization may only involve simple contact by the physician's office to verify benefits and acquire an approval number to submit with the claim. Alternatively, pre-authorization may require that the physician provide more substantive information about the case. **Each payer process varies**. The timeline for the payer to respond to prior authorization requests also varies.

To prepare a pre-authorization request that requires additional information beyond basic coding, the physician's staff must provide technical information about the procedure and the unique technology involved. The treating physician must also establish the medical necessity for the procedure, as it applies to the specific patient.

Typically, the pre-authorization process and/or appeal process may require submitting some or all of the following documentation:

- ✓ Patient clinical notes, including documentation of prior conservative care.
- ✓ Supporting technical information in the form of the FDA clearance letter, peer-reviewed clinical literature, and other available technical resources.
- ✓ Description of the technology and its use in this patient's case; and
- ✓ Description of medical necessity of the procedure for the specific patient.

Pre-Authorization Appeal Process

Benefit Verification and Initial Pre-Authorization

Peer-to-Peer review (optional) between treating and payer physician

1st Level Appeal – Expedited/standard opportunity to request second review from Medical Director that did not review initial request

2nd Level Appeal – Expedited/standard opportunity to request review from Medical Director that did not review initial request or peer-to-peer

External Review (IRO) – follows appeal denials at all internal levels

Post-Claim Denial

When a third-party health plan denies a procedure in accordance with their medical policy guidelines, there is a process available to appeal that decision. Insurance carriers provide this check and balance to allow for reconsideration of the decision per their plan provisions and applicable state regulations. The process will vary depending on the plan and regulatory requirements; however, there are basic steps that can assist the provider in appealing the initial denial.

To present an effective appeal, follow these steps:

1. Carefully review the denial reason and understand the specific health plan's policy.
2. Write an appeal letter clearly addressing the specific denial reasons.
3. Provide supporting information including product details and FDA approval; and
4. Submit the appeal on time.

The following additional considerations may be helpful:

1. If the health plan is self-funded (employer based), patients can contact their Human Resources (HR) department to assist in the patient's appeal of the decision. HR departments may have contacts within the health plan that can provide helpful support.
2. The patient can contact the health plan directly and is the policyholder with the ability to influence the decision.
3. There are multiple steps in the appeal process and providers and patients may exercise these rights according to their third-party payor and state guidelines.

Patient Access Program - MyKneeHealth

Smith+Nephew has engaged JDL Access to support patients and providers through the process of prior authorizations and appeals. Participation the program is voluntary and requires provider enrollment in order to access the cloud-based hub and patient consent.

Providers and patients may elect to engage at any stage of the process from benefit verification to prior authorization through to post-claim denial appeal. For further information on enrollment please contact mykneehealth@jdlaccess.com or call 888-668-2608.

Writing an Appeal Letter

When appealing a denial, whether it be at authorization or post-service, the first step is often composing a letter to the health plan that initially reviewed the case. This letter is submitted by the provider on behalf of the patient, with the patient's approval, and should outline the reasons the denial should be overturned.

Detailed information regarding the denial reason should be prepared utilizing the case specific information in the denial, as well as the more general technology specific information and supporting clinical literature.

First, collect all the information required to support the appeal:

- ✓ Denial letter
- ✓ Health plan contracts and provider agreements
- ✓ Applicable medical policy guidelines from the health plan (website access is often a good resource for general policy)
- ✓ Literature supporting the technology
- ✓ FDA Clearance or Approval letter
- ✓ Safety and effectiveness documentation
- ✓ Peer-reviewed literature references (when available)

In drafting an appeal letter, consider the following:

- ✓ Did the reviewer miss information about the technology?
- ✓ Did the reviewer overlook a case specific detail?
- ✓ Does the health plan clearly understand the procedure?
- ✓ Was the information provided about the case correctly submitted?
- ✓ Review the plan's official policy online for more detailed understanding of the denial reason

Be mindful of details, including:

- ✓ Patient's name
- ✓ Subscriber's name
- ✓ Policy number
- ✓ Description of exact service denied
- ✓ Date denied

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