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ProChondrix

Osteochondral Allograft

Used in articular cartilage repair procedures

2018 Reimbursement Information

Articular Cartilage Repair Using **ProChondrix**

2018 Reimbursement Information

Stryker is committed to providing accurate coding and reimbursement information relating to ProChondrix, a cellular 3D osteochondral allograft for patients needing articular cartilage repair. This Reimbursement Information Guide has been developed specifically for healthcare providers and professionals responsible for coding and reporting provided services.

As with any new medical products, there are sometimes questions associated with coding and billing for services and devices. This Guide is not intended to serve as a substitute for payer specific billing and reimbursement policies. If you have any questions or need assistance, please contact our Reimbursement Support Program at 800-698-9985 or contact the specific payer directly.

The information in this Guide is shared for educational purposes only. The information is current as of December 1, 2017 and is based upon publicly available information. Reimbursement is dynamic. Codes, coverage and payment rates change, at minimum on an annual basis.

The provider is solely responsible for reporting the codes that accurately describe the services furnished to a particular patient as well as the patient's medical condition. Providers should follow payer specific billing and coding requirements and contact the payer if they have questions. Note, the existence of a code for a procedure does not guarantee coverage or payment. This guide includes Medicare national average payment rates rounded to the nearest dollar. Payment rates to individual providers will vary based on geographic location and other factors.

ProChondrix

ProChondrix is an osteochondral allograft that may be used in orthopedic reconstructive procedures to aid in the repair of articular cartilage. It is available in a range of sizes (15 mm, 17 mm, and 20 mm diameter discs) for surgical use. ProChondrix can be cut to fit the shape of the defect and may be secured with sutures, anchors or darts, as needed.

ProChondrix provides functional cells and other biological components that are needed for repair of damaged cartilage tissues. Viable chondrocytes in ProChondrix generate extracellular matrix proteins that help promote chondrogenesis. The presence of native growth factors help maintain healthy cartilage and facilitates chondrocyte functionality. In addition, the extracellular matrix helps support a structure for cellular migration and adhesion while preserving growth factors.[1]

FDA Regulatory Status

ProChondrix is regulated as a human cell, tissue, and cellular and tissue-based product or HCT/P by the Food and Drug Administration (FDA)'s Center for Biologics Evaluation and Research (CBER) under 21 CFR Part 1271. Stryker is a distributor for ProChondrix, which is prepared and processed by AlloSource, an FDA-registered tissue bank [registration number FEI:3000215346].

Coding and 2018 Medicare Payment Utilizing ProChondrix

Healthcare providers must submit properly completed claim forms with appropriate codes to the payor. Providers use various codes to describe patient conditions and diagnoses, services provided, procedures performed, and supplies/devices used to treat the patient. The various codes used to report services relating to implantation of ProChondrix are described in greater detail below.

ICD-10-CM Diagnosis Codes

Effective October 1, 2015, International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) replaced ICD-9-CM as the official coding system for describing diagnoses for patients in the United States. All healthcare providers are responsible for reporting the appropriate ICD-10-CM diagnosis code that describes the patient's condition and should consult with a current version of the ICD-10-CM code book.

Physician Services

Physician services are reported using Current Procedural Terminology (CPT®[2]) and Healthcare Common Procedure Coding System (HCPCS) codes and are paid by Medicare under the Medicare Physician Fee Schedule (PFS). Under the PFS, payment rates are based on relative weights, called relative value units (RVUs), which include physician work, practice expense, and malpractice insurance. Physician services are typically provided in either a facility (hospital, ambulatory surgery center) setting or a non-facility (office) setting. There may be different RVUs (and different payment rates) depending on the site of service where the service is provided, either in the physician office or a facility. Medicare payment is calculated for physician services using the RVUs for the procedure or service multiplied by a conversion factor[3], and adjusted based on geographic factors.

1. Delaney R, Barrett C, Stevens P. ProChondrix Cartilage Restoration Matrix Contains Growth Factors Necessary for Hyaline Cartilage Regeneration. AlloSource, Centennial, CO.

3. Annually updated by Medicare.

Hospital Outpatient

- **Ambulatory Payment Classifications (APCs)** — In the hospital outpatient setting, Medicare assigns procedures and services reported with CPT and HCPCS codes to APCs based on similar clinical characteristics and similar costs. Each APC has an assigned payment rate, and multiple different CPT codes and HCPCS codes may be assigned to the same APC. Within each APC, payment for dependent, ancillary, supportive, and adjunctive items and services is packaged into payment for the primary independent service. Separate payments are not made for packaged services, which are considered an integral part of another service. All hospital outpatient procedures are designated with a payment status indicator, which further defines payment policy for an APC.
- **Comprehensive Ambulatory Payment Classifications (C-APCs)** — CPT codes 27415 and 29867 are assigned the status indicator J1 which means that these codes are included in a comprehensive APC, or C-APC. C-APCs provide a single payment for the primary service and all adjunctive services, supplies, drugs, biologics, and tissue products reported on the same claim (similar to a Medicare Severity-Diagnosis Related Group (MS-DRG).
- **HCPCS® Codes** — Healthcare Common Procedure Coding System (HCPCS) Level II codes are used to identify drugs, devices, supplies, services, and some procedures that are not included in CPT. There is no separate HCPCS code that describes ProChondrix.
- **Device-Intensive Procedures** — CPT code 27415 and CPT code 29867 are designated as device-intensive procedures. Medicare requires that facilities submit a device HCPCS code when device intensive procedures are reported. When a device used in a device-intensive procedure does not have a specific HCPCS code, Medicare recommends that the following HCPCS code may be reported[4]:

HCPCS Code	Descriptor
C1889	Implantable/insertable device for device intensive procedure, not otherwise classified.

There is no specific HCPCS code that describes ProChondrix. Therefore, providers may report C1889 in lieu of a specific HCPCS code for ProChondrix when the product is used in device-intensive procedures.

Private payors generally do not require hospital outpatient departments to report such HCPCS codes, but providers are encouraged to verify with their providers as to whether such a HCPCS code should be reported.

4. CMS OPPS and ASC Final Rule, Addendum AA and B (available on CMS website) 82 Fed. Reg. 217 (Nov. 13, 2017)

Ambulatory Surgery Center (ASC)

Osteochondral allograft implantation may be performed in an ASC, which can be either hospital owned or operated or privately owned by either physicians or other type of entity. Payment is primarily linked to the APC rates, and currently ASC payment is approximately 60% of hospital outpatient APC rates. Similar to the hospital outpatient setting, Medicare packages most ancillary items and services.

For Medicare payment purposes, CPT code 29867 is not included on Medicare's list of procedures that are payable in an ASC (Addenda AA). Private payors' policies may differ, and providers are encouraged to verify with the relevant payor to determine whether the payor will provide payment if the procedure is performed in an ASC.

CPT Codes and 2018 Medicare National Payment Rates[5]

Physicians, hospital outpatient departments and ASCs use CPT codes to report osteochondral allograft implantation procedures. There are two CPT codes that describe osteochondral allograft implantation. These CPT codes, along with the 2018 Medicare national payment rates for physician, hospital outpatient and ASC procedures are provided below:

CPT Code	Descriptor	Physician	Hospital Outpatient	ASC
27415	Osteochondral allograft, knee, open	$1,416	$10,122	$8,202
29867	Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)	$1,331	$10,122	N/A Not included on the ASC list of procedures

There are no specific osteochondral allograft implantation CPT codes for anatomic sites other than the knee. If providers are providing osteochondral allograft implants in other anatomic sites, providers may contact the payer for coding guidance or may report one of the unlisted CPT codes listed below:

CPT Code	Descriptor	Physician	Hospital Outpatient	ASC
23929	Unlisted procedure, shoulder	Contractor priced	$215	N/A Not included on the ASC list of procedures
24999	Unlisted procedure, humerus or elbow			
25999	Unlisted procedure, forearm or wrist			
27299	Unlisted procedure, pelvis or hip joint			
27899	Unlisted procedure, leg or ankle			
28899	Unlisted procedure, foot or toes			
29999	Unlisted procedure, arthroscopy			

5. 2018 CMS MPFS Final Rule, Addendum B (available on CMS website) 82 Fed. Reg. 219 (Nov. 15, 2017); CMS OPPS and ASC Final Rule, Addendum AA and B (available on CMS website) 82 Fed. Reg. 217 (Nov. 13, 2017).

Hospital Inpatient Coding and Medicare Payment

Hospital Inpatient

Medicare pays hospitals for inpatient services using a grouping system referred to as Medicare Severity Diagnosis-Related Groups or MS-DRGs. Each hospital stay is categorized into an MS-DRG which has a relative payment weight that reflects the average resources used to treat Medicare patients in that MS-DRG. MS-DRGs are assigned using the patient's discharge diagnoses (principal ICD-10 diagnosis code and additional diagnoses), the principal procedure (ICD-10-PCS procedure code) and additional procedures.

ICD-10-PCS Codes

Effective October 1, 2015, International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) replaced ICD-9 procedure codes as the official system of assigning codes to hospital inpatient procedures in the United States. There are many ICD-10-PCS codes that could be billed for inpatient osteochondral allograft implant procedures. Listed below are some of the osteochondral allograft procedures in the knee that may include ProChondrix:

ICD-10-PCS Code	Descriptor
0SUC0KZ	Supplement Right Knee Joint with Nonautologous Tissue Substitute, Open Approach
0SUC3KZ	Supplement Right Knee Joint with Nonautologous Tissue Substitute, Percutaneous Approach
0SUC4KZ	Supplement Right Knee Joint with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0SUD0KZ	Supplement Left Knee Joint with Nonautologous Tissue Substitute, Open Approach
0SUD3KZ	Supplement Left Knee Joint with Nonautologous Tissue Substitute, Percutaneous Approach
0SUD4KZ	Supplement Left Knee Joint with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach

If ProChondrix is used in allograft implantation procedures in the shoulder, hip or other anatomic sites, providers can locate the appropriate code in the ICD-10-PCS code book.

MS-DRGs and 2018 MS-DRG Payment Rates[6]

As discussed above, Medicare makes a single payment for all hospital services provided to the patient during an inpatient stay, including the ProChondrix. The MS-DRGs listed below may be assigned for osteochondral allograft procedures. We include the associated 2018 Medicare national payment rates:

MS-DRG	Descriptor	2018 MS-DRG Payment
488	KNEE PROCEDURES W/O PDX OF INFECTION W CC/MCC	$12,035
489	KNEE PROCEDURES W/O PDX OF INFECTION W/O CC/MCC	$7,762
509	ARTHROSCOPY	$11,040

6. CMS IPPS Final Rule, Tables 1B, 1D and 5 (available on CMS website) 82 Fed. Reg. 155 (Aug. 14, 2017).

Additional Documentation Required When Submitting Claims with Unlisted CPT Codes

When billing a service or procedure, providers should select the CPT or HCPCS code that accurately identifies the service or procedure performed. If no such code exists, the service or procedure should be reported using the appropriate unlisted procedure code or Not Otherwise Classified (NOC) code. It is the responsibility of the provider to ensure all information required to process unlisted procedure codes or NOC codes is included on the CMS-1500 form or the electronic media claim (EMC) when the claim is submitted.

For Medicare claims, an unlisted procedure code or NOC must have a concise description of the services provided included in Item 19 on the CMS-1500 claim form or the electronic equivalent for Item 19 for EMC submissions. The electronic form will hold up to 80 characters.

If additional space is needed to describe the procedure, the provider will need to submit the claim with the appropriate "PWK" (paperwork) indicator included on the claim form followed by the appropriate documentation. Once the claim has been submitted with the PWK indicator, this signals the claims processing system to halt the claim. The provider has a certain amount of time to follow up with the appropriate Medicare contractor in order to submit the additional documentation. Medicare contractors may require that providers utilize special fax cover sheets specifically intended for the submission of additional PWK. Many Medicare contractors allow seven calendar days (if submitted by fax), or 10 calendar days (if submitted by mail). Providers should consult with the appropriate payor to determine the specific requirements for submitting additional documentation and be sure to use the appropriate fax coversheets where required.

UB Revenue Codes

Universal Bill (UB) revenue codes are used on hospital inpatient and hospital outpatient claims so that hospitals can categorize procedures, services, devices and supplies and allocate costs accordingly. The use of UB revenue codes also demonstrates to payers the department of the hospital that provided or furnished the item or service. In turn, the cost information is used by Medicare and other payors to establish payment rates for services and procedures. It is important that hospitals use the most appropriate revenue codes for reporting procedures and supplies. Select revenue codes are provided below:

UB Revenue Code	Descriptor
0272	Medical/Surgical Supplies and Devices, Sterile
0278	Medical/Surgical Supplies and Devices, Other Implants
0360	Operating Room Services

Charge Data Master (CDM)

Hospitals include all items, supplies, services, and procedures on a master list known as a charge data master or CDM. Hospitals are encouraged to update their CDM with the relevant cost and charge information associated with ProChondrix, so that it can be billed appropriately for osteochondral allograft implantation procedures.

Prior Authorization

Prior to scheduling any planned surgical procedure, healthcare providers are encouraged to contact the patient's healthcare plan to determine the availability of benefits and coverage. While Medicare does not provide for prior authorization of procedures, Medicare Advantage and other third-party payors do encourage providers to submit prior authorizations.

When submitting a prior authorization, it is very important to include both the primary surgeon and any assistant surgeon. A sample letter of medical necessity/prior authorization is included as Attachment A.

Appealing Denied Prior Authorizations and Denied Claims

There may be instances where the payor denies the claim. This could be due to a variety of reasons, including inaccurate coding, insufficient documentation, improper claims submission, or in some cases, a payer will deny based on medical necessity or coverage. It is very important to appeal denied claims. Appeals are often successful, and each successful appeal helps educate the claims staff and may smooth the path for reimbursement for the next claims. A sample appeal letter is included as Attachment B.

Physician Documentation

Accurately dictating and documenting all the steps performed in the osteochondral allograft implantation procedure is extremely important. This will enable professionals responsible for preparing and submitting claims to capture and report all appropriate charges.

Coverage

Coverage for any surgical procedure is dependent on a number of factors, including the patient's benefit package, the payor's medical policies, and whether the patient meets the indications or criteria for coverage. At this time, there are no published Medicare Local Coverage Determinations (LCDs) for osteochondral allograft transplantation procedures. Some private payors have developed such medical policies, while others have not. Providers are encouraged to review the relevant payor's websites for any medical policies and/or coverage criteria. If providers have any questions, they should consult the relevant payor.

Reimbursement Support

Stryker is committed to providing accurate coding and reimbursement information relating to ProChondrix. To support this commitment to our customers, we have a dedicated team of reimbursement professionals available to assist you. Stryker's Reimbursement Services can be reached at 800-698-9985.

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