Priority Health	BILLING POLICY No. 033
SURGICAL IMPLANTS AND DEVICES	
Date of origin: Feb. 2024	**Review dates: 07/24, 02/25, 11/2025**

This policy describes Priority Health's guidelines for correct coding and appropriate reimbursement for:

- Implants and devices
- Rebated devices
- FDA recalled devices, supplies and drugs

DEFINITION

The FDA defines medical implants as devices or tissues that are placed inside or on the surface of the body. Many implants are prosthetics, intended to replace missing body parts. Other implants deliver medication, monitor body functions, or provide support to organs and tissues.
Implants may be:

- Permanent or temporary
- Comprised of various tissues or materials. Tissues may include skin, bone, or other defined tissues. Materials may include plastic, metal, or other materials.
- External fixation device(s) with components that remain in the body

Examples of implants include but aren't limited to stents, knee implants, screws, cages, ports and skin substitutes.

Anchor for Bone or Soft Tissue Fixation (C1713):
Implantable pins, screws, and related hardware secure soft tissue, tendon, or bone to bone. Screws achieve fixation by drilling into bone; pins are inserted for stabilization. This category includes orthopedic plates with washers and nuts, as well as synthetic bone substitutes used to fill defects from trauma or surgery.

Joint Device (C1776):
An implanted artificial joint that replaces a natural joint. Unlike anchors, it does not serve to fix soft tissue, tendon, or bone to bone, but functions as a substitute for the original joint.

Reference the Provider Manual for specific implant or device policies, including but not limited to (also see our medical policies for additional information):

- Arthroscopy and arthroscopically assisted knee, hip and shoulder surgery (91628)
- Autologous chondrocyte implant/meniscal allograft/osteochondral replacement (91443)
- Cardioverter defibrillators (91410)
- Carotid & intracranial artery stenting (91495)
- Drug Eluting Stents for ischemic heart disease (91580)
- Hearing augmentation (91544)
- Implantable heart failure monitors (91610)
- Implantable loop recorder (91618)
- Peripheral nerve stimulation (91634)
- Spinal cord column/dorsal root ganglion stimulation (91635)
- Spine Procedures (91581)
- Stimulation therapy & devices (91468)
- Titanium rib (91505)
- Total joint replacement: knee, hip, shoulder (91630)
- Transcatheter closure of septal defects (91528)

- Transcatheter heart valve procedures (91597)
- Ventricular assist devices artificial hearts (91509)

POLICY SPECIFIC INFORMATION

General guidelines

Priority Health follows industry coding requirements for correct claims submissions. Below are some examples:

- Revenue codes 0275, 0276 and 0278 must be billed with the applicable HCPCS code that represents the implant. These listed revenue codes align to specific anatomic devices by revenue code description. These revenue codes should *only* be used for devices that align to their description. In alignment with CMS, these are reported by facilities with the appropriate C code unless otherwise specified in policies.
- Implants must meet the FDA definition of an implant. Claim lines billed as implants that don't meet the implant definition will be denied.
- MUE values are not utilization guidelines and do not indicate units of service that can be reported without concern for medical review. MUEs are established using HCPCS/CPT code descriptors, coding instructions, anatomical factors, CMS policies, characteristics of the service or procedure, analyte or equipment type, prescribing information, and clinical judgment. Claims may still undergo medical review even when the reported units of service (UOS) are at or below the MUE value for a code.
- Supplies or instruments used but discarded during the same inpatient or outpatient procedure or single episode of care are not considered implants and should not be billed as such or billed as separately from primary procedure if inclusive.
- Facility claims should be coded with the appropriate C code that defines the implant used.
- HCPCS code C1776 – joint device should only be reported as multiple units if more than one joint parts are performed. Documentation must support the multiple joint parts used. For example, a total knee revision performed with a femoral and a tibia component would be billed as C1776 x 2 units.
- Devices, implants or brachytherapy sources with OCE Status Indicator H (pass-through device) or U (brachytherapy sources) will be denied if reported without a procedure with OCE Status J1, S or T on the same date of service and same claim.
- All applicable modifiers, condition codes, value codes, etc. must be reported to identify recall or rebated devices. Additional information is detailed below.
- Facility and supplier of implant device(s) won't be reimbursed for the same device. Identification of duplicate payment will result in recovery or denials.
- Absorbable materials or supplies integral to the implant or device procedure won't be reimbursed separately.
- We don't reimburse for implants, devices, supplies or drugs that weren't used due to contamination or waste or that weren't implanted for any reason.
- Storage for devices, implants, supplies and drugs isn't reimbursed.

Implants coded for inpatient services may be subject to documentation review to confirm the implant meets FDA requirements and adhere to correct coding guidelines.

Rebate or recall guidelines

This policy is applicable to durable medical equipment (DME), supplies, prosthetics, orthotics, drugs or vaccines for all Priority Health plans submitting claims for professional and facility claims in or out of network. In addition, this applies to medical devices as defined by the FDA.

- **Reimbursement will be made** for medically necessary services to remove and replace implanted recalled device.
- **Reimbursement isn't made** for repair or replacement of items associated with the medical recall.

- **Reimbursement will be reduced** when a facility receives a partial or full credit for a device when associated with a recall or rebate. The device credit will be reduced from payment amount.

We reserve the right to recoup or recover fees paid to the provider or facility when a full or partial credit is applied for a device or supply or when post pay review indicates repair or replacement is associated with recall.

Note: This is subject to provider contracts and state, federal or CMS requirements that may state otherwise. Priority Health policies are based on nationally accepted industry standards and correct coding principles.

Documentation of the recall or rebate item should be detailed in the member's medical record. In addition, supporting documentation associated with recall or rebate can be submitted with the claim. This may include:

- Device brand name, model/catalog number, log/serial number, device invoice
- Manufacturer's contact information
- Description of event or corrective/removal actions
- Illness or injuries associated with use of device (if applicable)
- Support detailing actual rebate or replacement item supplied

The appropriate condition code, value code, modifier and diagnosis must be billed to identify the medically recalled device. Claims will be denied and returned to the provider when required information is missing.

You're responsible for monitoring the FDA notifications for FDA recalled devices. These can be monitored at the FDA's Medical Device Recalls webpage. Notifications may also be posted to *PriorityHealth.com*.

Billing for rebated services

- The appropriate HCPCS/procedural code, condition code, value code, modifier and diagnosis must be billed to identify the medically recalled device. Claims will be denied and returned to the provider when required information is missing.
- If the appropriate HCPCS code doesn't meet the definition of an implant, the service will be denied.

HCPCS or revenue code for items

Use the appropriate CPT or HCPCS code to describe the replacement device or service.
Revenue codes 0275, 0276 and 0278 must be reported with the applicable HCPCS code.
Use the appropriate diagnosis codes (when applicable) to describe mechanical complications
Examples:

- Mechanical complication of cardiac device, implant and graft – T81.110A- T82.191A
- Mechanical complication of other vascular or cardiac device, implant and graft – T82.310A-T82.898A
- Mechanical complication of genitourinary device, implant and graft – T83.498A, T83.011A-T83.091A, T83.31XA-T83.39XA
- Mechanical complication of internal orthopedic device, implant and graft – T84.498A, T84.0360A-T84.039A
- Mechanical complication of other specified prosthetic device, implant and graft – T85.318A-T86.841

Note: Not an all-inclusive list. Follow all appropriate ICD-10 coding guidelines for diagnosis coding.

Value code FD

The value code FD is required when reported claims indicate a credit has been received from the manufacture of a medical device.

Condition codes 49,50 and 53

- When reporting services for rebate or recall, the appropriate condition code is required: **Code 49**: Product replacement with product lifecycle. **Code 50**: Product replacement for known recall.

- **Code 53**: Initial placement of a medical device provided as part of a clinical trial or free sample (outpatient claims only)

REFERENCES

- CMS Manual System
- Annual Policy Files | CMS
- MLN909368 – Cardiac Device Credits: Medicare Billing (cms.gov)
- Recalls, Corrections and Removals (Devices) | FDA
- CMS049493 | CMS
- Medicare Claims Processing Manual Chapter 4 – Part B Hospital section 60.4.3
- Zimmer Biomet HCPCS Level II Coding Reference Guide
- Medicare NCCI FAQ Library | CMS
- AHA Coding Clinic 2016 Third Quarter, Volume 16, Number 3, Joint Device Q & A, page 3
-

DISCLAIMER

Priority Health's billing policies outline our guidelines to assist providers in accurate claim submissions and define reimbursement or coding requirements if the service is covered by a Priority Health member's benefit plan. The determination of visits, procedures, DME, supplies and other services or items for coverage under a member's benefit plan or authorization isn't being determined for reimbursement. Authorization requirements and medical necessity requirements appropriate to procedure, diagnosis and frequency are still required. We use Current Procedural Terminology (CPT), Centers for Medicare and Medicaid Services (CMS), Michigan Department of Health and Human Services (MDHHS) and other defined medical coding guidelines for coding accuracy.

An authorization isn't a guarantee of payment when proper billing and coding requirements or adherence to our policies aren't followed. Proper billing and submission guidelines must be followed. We require industry standard, compliant codes defined by CPT, HCPCS and revenue codes for all claim submissions. CPT, HCPCPS, revenue codes, etc., can be reported only when the service has been performed and fully documented in the medical record to the highest level of specificity. Failure to document for services rendered or items supplied will result in a denial. To validate billing and coding accuracy, payment integrity pre- or post-claim reviews may be performed to prevent fraud, waste and abuse. Unless otherwise detailed in the policy, our billing policies apply to both participating and non-participating providers and facilities.

If guidelines detailed in government program regulations, defined in policies and contractual requirements aren't followed, Priority Health may:

- Reject or deny the claim
- Recover or recoup claim payment

An authorization on file for an item or services doesn't supersede coding, billing or reimbursement requirements.

These policies may be superseded by mandates defined in provider contracts or state, federal or CMS contracts or requirements. We make every effort to update our policies in a timely manner to align to these requirements or contracts. If there's a delay in implementation of a policy or requirement defined by state or federal law, as well as contract language, we reserve the right to recoup and/or recover claim payments to the effective dates per our policy. We reserve the right to update policies when necessary. Our most current policy will be made available in our Provider Manual.

CHANGE / REVIEW HISTORY

Date	Update made

July 1, 2024	• Added revenue codes 0275 and 0276 as needing to be billed with applicable HCPCS code that represents the implant • Noted that revenue codes 0275, 0276 and 0278 align to specific anatomic devices and should only be used for devices that align to their descriptions • Updated supporting documentation for recalls or rebates to include device invoice • Removed note that modifiers appended incorrectly will be denied • Removed information on modifiers FB and FC
Feb. 13, 2025	Added “Disclaimer” section
Nov. 2025	• Added a definition for anchor for bone or soft tissue fixation and joint device • Added MUE information • Added coding specifics for HCPCS code C1776 • Added References: o Medicare Claims Processing Manual Chapter 4 – Part B Hospital section 60.4.3 o Zimmer Biomet HCPCS Level II Coding Reference Guide o Medicare NCCI FAQ Library | CMS o AHA Coding Clinic 2016 Third Quarter, Volume 16, Number 3, Joint Device Q & A, page 3