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

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.
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.
- Supplies or instruments used but discarded during the same inpatient or outpatient procedure or single episode of care aren't considered implants and shouldn't 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.
- 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

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