POL-020.4 Clinical Review Implant Payment Determination Policy

This policy applies to all NCA markets, all lines of business.

1.0 Business Policy

1.1 Payment Policy Statement

1.1.1 Kaiser Foundation Health Plan (KFHP) requires accurate and complete claims submissions that follow proper billing and submission guidelines according to industry standard Current Procedure Terminology (CPT) codes, Healthcare Common Procedure Coding System (HCPCS) codes and/or revenue codes. In addition, documentation (such as medical records, office notes etc.) must support services billed. KFHP may request additional supportive documentation to further validate billing, coding, and clinical accuracy of billed services prior to finalizing reimbursement on billed service(s). KFHP, in the interest of its members, reviews claims to ensure that KFHP pays the appropriate amounts on claims and does not overpay or pay for improper charges. While KFHP does not dictate to providers how to bill their claims, the industry recognizes that certain billing practices can lead to non-payable charges. If appropriate coding/billing guidelines or current reimbursement policies are not followed or documented in the records, KFHP may, depending on the circumstances: reduce or deny the claim or claim line, consider a claim line paid by virtue of payment of another claim line or the claim as a whole, or recover/recoup the claim processed for payment in error. Unless otherwise noted within the policy, KFHP's reimbursement policies apply to contracted and non-contracted professional providers and facilities.

1.1.2 KFHP payment policies are not intended to cover every claim situation. KFHP policies may be superseded by state, federal and/ or provider contractual requirements. KFHP will align with all applicable regulatory, state and federal guidelines. KFHP will employ clinical discretion and judgement, and coding expertise in its interpretation and application of the policy, and all KFHP payment policies are routinely updated.

1.1.3 Kaiser recognizes commonly accepted standards to help determine what items and/or services are eligible for separate reimbursement. Commonly accepted standards include but are not limited to the following:

- American Academy of Professional Coders (AAPC)
- American Medical Association (AMA)

- Associated Medical Societies (i.e.: American College of Obstetricians and Gynecologists (ACOG), American Academy of Family Physicians (AAFP), etc.)
- American Health Information Management Association (AHIMA)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- CMS Local Coverage and National Coverage Determinations (LCD NCD)
- CMS Manuals and Publications
- CPT Assistant
- CPT Manual, including code definitions and associated text
- Federal Register
- HCPCS Manual, including code definitions and associated text
- Integrated Outpatient Code Editor (I/OCE)
- International Classification of Diseases, 10th Revision (ICD-10-CM) official guidelines for coding and reporting
- Medically Unlikely Edits
- National Correct Coding Initiative Policy Manual for (NCCI)
- National Physician Fee Schedule Relative Value File
- National Uniform Billing Committee (NUBC)
- Professional and academic journals and publications

1.2 Scope

1.2.1 This policy provides an overview of Kaisers reimbursement guidelines for devices and implants. The policy applies to both contracted and non-contracted providers across all lines of business, unless otherwise specified.

2.0 Rules

2.1 Kaiser will not consider implants for reimbursement that do not meet the U.S. Food and Drug Administration (FDA) definition of implants. According to the FDA an implant is defined as:

2.1.1 "A device that is placed into a surgically or naturally formed cavity of the human body and is intended to remain implanted continuously for 30 days or more, unless otherwise determined by the FDA to protect human health."

2.2 Reimbursement Guidelines

2.2.1 Humanitarian Use Device (HUD)

2.2.1.1 KFHP Clinical Review evaluates the use of Humanitarian Use Devices (HUDs) to determine appropriate reimbursement. HUDs will not be reimbursed for investigational or off-label use. The following will be reviewed to determine the appropriate reimbursement.

2.2.1.2 Is the device approved by the FDA under a Humanitarian Device Exemption (HDE).

2.2.1.3 Was the device used strictly in accordance with FDA-approved indications.

2.2.1.4 Was the device administered in a non-research clinical setting with Institutional Review Board (IRB) approval.

2.2.1.5 Was the device deemed medically necessary, with no suitable alternative treatment available.

2.2.1.6 Was there comprehensive supporting documentation provided, including FDA approval, IRB approval, medical necessity justification, and patient consent.

2.2.2 Non-Covered Examples

2.2.2.1 (This is not an exhaustive list, nor is it intended to cover every claim scenario)

2.2.2.2 **Temporary items** Objects that do not remain in the member's body upon discharge are not considered implants.

2.2.2.2.1 Examples include, without limitation, the following: screws, clips, pins, wires, nails, and temporary drains.

2.2.2.3 **Disposable items** Single-use products not intended to remain in the body or be reused.

2.2.2.3.1 Examples include, without limitation, the following: surgical drapes, irrigation tubing, wedge positioning pads, accessory packs, needles and syringes.

2.2.2.4 **Supplies and instruments** Tools or materials used during procedures but not implanted.

2.2.2.4.1 Examples include, without limitation, the following: surgical instruments (e.g., forceps, scalpels), sterile drapes, tubes, guidewires, operating room kits, and diagnostic tools (e.g., endoscopes).

2.2.2.5 Unused or discarded items Devices or implants that are opened or prepared but not implanted for any reason. This includes surgical changes, complications, or handling errors. All of which are considered waste and are not reimbursable.

2.2.2.5.1 Examples include, without limitation, the following: implantable screw(s) not used due to a change in approach by the treating provider, biologic mesh discarded after plan change, pacemaker lead not implanted due to complications.

2.2.2.6 Absorbable materials and biological products not classified as implants by the FDA Includes tissue-based or absorbable products intended for temporary use that do not meet the FDA's definition of an implant.

2.2.2.6.1 Examples include, without limitation the following: absorbable hemostats, and topical thrombin's (e.g., Surgicel®).Temporary wound matrices (e.g., Integra®), amniotic membrane grafts, collagen-based scaffolds, skin substitutes used as temporary coverings, bone putty or cement, and absorbable sutures.

2.2.2.7 Off-label or non-indicated use Biological products used outside their FDA-approved purpose—such as absorbable scaffolds or tissue grafts used for structural support—are not covered.

2.2.2.8 Procedural tools and temporary devices Devices used during procedures but not intended to remain in the body.

2.2.2.8.1 Examples include, without limitation, the following:Catheter, transluminal atherectomy, rotational, Adhesion barrier, Intracardiac introducer/sheath (non-peel-away), Guide wire, Retrieval device (e.g., for fractured implants), Pulmonary sealant (liquid), and Cryoablation probe/needle.

3.0 Guidelines

N/A

4.0 Definitions

4.1 Biological Products Products derived from living organisms (such as human or animal tissue) that are used in the prevention, treatment, or cure of diseases. When not classified as implants by the FDA—such as absorbable or temporary tissue-based products—they are not considered reimbursable implants.

4.2 **Centers for Medicare & Medicaid Services (CMS)** A federal agency within the U.S. Department of Health and Human Services (HHS) that administers Medicare, Medicaid, and other health programs. CMS establishes national coverage policies and reimbursement methodologies, including those related to implantable devices.

4.3 **Disposable Medical Supplies** Single-use items utilized during a procedure that are not retained in the body after discharge. These are not considered implants and are typically not reimbursed separately.

4.4 **HCPCS Code** The Healthcare Common Procedure Coding System (HCPCS) is used to report medical procedures, services, and devices. A valid HCPCS code must be submitted for any implant billed on a claim.

4.5 **Humanitarian Use Device (HUD)** A medical device intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 8,000 individuals in the U.S. per year. HUDs must have FDA approval for the specific indication to be eligible for reimbursement.

4.6 **Implant** A device placed into a surgically or naturally formed cavity of the human body and intended to remain continuously for 30 days or more, as defined by the FDA.

4.7 **Skin Substitutes** Products used to temporarily or permanently replace the skin's structure and function. Only those intended for permanent implantation may be considered for reimbursement; temporary wound coverings or dressings are not reimbursed as implants.

5.0 References

5.1 Centers for Medicare & Medicaid Services (CMS). Medicare Claims Processing Manual, Chapter 4 – Part B Hospital (Including Inpatient Hospital Part B and OPPS)

5.2 U.S. Food and Drug Administration (FDA). Implants and Prosthetics Guidance https://www.fda.gov

5.3 U.S. Food and Drug Administration (FDA). IDE Definitions and Acronyms IDE Definitions and Acronyms | FDA

5.4 CPT® Manual and CPT® Assistant, published by the American Medical Association (AMA)

5.5 HCPCS Level II Manual, published by CMS

5.6 ICD-10-CM Official Guidelines for Coding and Reporting

6.0 Related Topics

POL-020.1 Clinical Review Itemized Bill Review Payment Determination Policy

POL-020.2 Clinical Review Medical Record Review Payment Determination Policy

POL-020.3 Clinical Review Coding Payment Determination Policy

POL-020.5 Clinical Review 30 Day Readmission Payment Determination Policy

POL-020.6 Clinical Review Intraoperative Neuromonitoring (IONM) Payment Determination Policy

(Updated: 09/08/2025)

Revision History

Approvals