

If a conflict arises between a Clinical Payment and Coding Policy and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. "Plan documents" include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. Blue Cross and Blue Shield of Illinois may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCSBIL has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing Editor, American Medical Association, Current Procedural Terminology, CPT® Assistant, Healthcare Common Procedure Coding System, ICD-10 CM and PCS, National Drug Codes, Diagnosis Related Group guidelines, Centers for Medicare and Medicaid Services National Correct Coding Initiative Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

# Implant, Device, and Tissue Policy

**Policy Number: CPCP007** 

Version: 1.0

**Enterprise Clinical Payment and Coding Policy Committee Approval Date: Oct.** 

13, 2025

Plan Effective Date: Jan. 19, 2026

# **Description**

The Food and Drug Administration (FDA) defines a medical implant as a device or tissue that is placed inside or on the surface of the body. An implant is a device that is placed into a surgically or naturally formed cavity of the human body and is intended to remain there for a period of 30 days or more. However, there may be instances where a device that remains in the body less than 30 days, could be considered as an implant, such as, implants which deliver medication, monitor body functions, or provide support to organs and tissues.

Implants may include but are not limited to: metal anchors artificial joints, pins, plates, radioactive seeds, metal screws, shunts, stents, types of allografts<sub>1</sub>, <sub>2</sub>, and types of autografts <sub>1</sub>, <sub>2</sub>.

#### **Definitions**

**Adhesives**-glues which are capable of bonding various tissues together including a variety of surfaces, such as, skin or muscle and are also capable of bonding blood vessels together.

Hemostats-effective for diffusing bleeding.

**Material** – Inorganic or biological substance(s) that cannot be dissolved, absorbed, resorbed, or remodeled.

**Sealants**-agents that can prevent the leakage of potentially nonclotting fluids from tissues, such as, cerebrospinal fluid from the central nervous system but may also be capable of preventing the leakage of blood from blood vessels. Sealants form a barrier preventing a flow of liquids.

**Topical Hemostats**-materials that stop bleeding by causing blood to clot and thus require blood to be present to satisfy their clotting function.

### **Reimbursement Information**

The Plan reserves the right to request supporting documentation. Failure to adhere to coding and billing policies may impact claims processing and reimbursement.

Autografts are not eligible for separate reimbursement as the cost for the harvest and preparation should be included in the procedure charge. Generally, materials, allografts (that are dissolved/absorbed/resorbed/remodeled), and liquids (such as sealants, hemostats, and topical hemostats) will not be reimbursed if billed as an implant unless there is an exception, such as, extended support of organs and tissues.

A supply or instrument is not an implant if it is purposed to be removed or

discarded during the same inpatient or outpatient procedure or single episode of care in which they are placed in the body.

Below are examples of supplies, instruments and miscellaneous items that will not be additionally reimbursed outside of the global fee:

| ADVANCED HEMOSTATS & SEALANTS | SYNTHETIC<br>SEALANTS | TOPICAL ABSORBABLE HEMOSTATS (TAH) & TOPICAL THROMBINS | Instruments & Miscellaneous                    |
|-------------------------------|-----------------------|--|--|
| Surgiflo                      | Duraseal              | Surgicel   | Bone<br>Morphogenetic<br>Proteins <sub>1</sub> |
| Evicel                        | Bioglue               | Instant Surgifoam                                      | Bone Putty                                     |
| Floseal                       | Progel                | Arista   | Endoscopes                                     |
| Tisseel                       | Coseal                | Avitene  | Catheters                                      |
| Seprafilm                     | Omnex                 | Gelfoam Plus   | Staples  |
|                               |                       | Evithrom   | Clips  |
|                               |                       | Thrombin-JMI   | Tubes  |
|                               |                       | Recothrom  | Temporary<br>Drains                            |
|                               |                       |  | Guide wires                                    |

#### Revenue Code 278 (Other Implants)

- If separately reimbursable, billed charges for revenue code 278 may require a vendor's invoice to support implants used that correspond to the services rendered, unless otherwise agreed upon.
- These units must be clearly indicated on the vendor invoices submitted with the claim. If the units do not match or are not noted, the revenue code 278 will be denied, unless otherwise agreed upon.
- If implants are purchased by the provider in bulk, the units that apply to the claim billed must be noted on the invoice or the revenue code 278 will be denied, unless otherwise agreed upon.

## **Contaminated/Unused/Wasted Implants or Supplies**

Providers will not be reimbursed for implants and supplies that are presumed

contaminated, considered a waste, and/or were not implanted in the member. The Plan urges providers and facilities to utilize implants and supplies in an efficient manner to prevent waste. Some **examples** are:

- Any items that were prepared or opened during a procedure or service but were **not** used or implanted into the member
- Items that were opened by mistake
- Changes-of-mind by the surgeon to use an item for the member
- Equipment failure and/or technical difficulties
- Surgery case cancellation
- Large packages of supplies and/or implants when more appropriate packaging can be purchased.

#### **Additional Reimbursement Information**

- Provider or vendor administrative storage and delivery costs will not be reimbursed.
- Items or services should be all encompassed under the surgical rate charge, and therefore, the member should not be responsible for these charges or services, unless allowed under the terms of their health benefit plan.
- <sub>1</sub> Allografts when mixed with viable stem cells are considered experimental, investigational, or unproven and are not eligible for reimbursement.
- <sub>2</sub> Implants differ from transplants. Transplants are composed of biomedical tissue.

## **Additional Resources**

### **Medical Policy**

SUR703.051 Orthopedic Applications of Stem Cell Therapy (Including Allografts and Bone Substitutes Used with Autologous Bone Marrow)

SUR705.038 Bone Morphogenetic Protein

SUR705.039 Use of i-Factor Peptide Enhanced Bone Graft During Spinal Surgery

# **References**

U.S. Food & Drug Administration, Implants and Prosthetics. Accessed 07/11/2025.

<u>U.S. Food & Drug Administration, IDE Definitions and Acronyms</u>. Accessed 07/11/2025.

National Uniform Billing Committee, Guidance on Other Implant RC0278. Accessed 07/11/2025.

Clinical and Applied Thrombosis/Hemostasis 16(5) 497-514. Accessed 07/11/2025.

# **Policy Update History**

| Approval Date | Description  |
|---------------|--|
| 07/25/2017    | New policy   |
| 06/11/2018    | Annual Review                                      |
| 11/07/2018    | Verbiage updates                                   |
| 04/01/2019    | Annual Review                                      |
| 07/06/2020    | Annual Review, Disclaimer Update, Verbiage Update  |
| 02/22/2023    | Annual Review                                      |
| 09/24/2024    | Annual Review                                      |
| 10/13/2025    | Annual Review; Grammatical and formatting updates; |
|               | References updated.                                |