If a conflict arises between a Clinical Payment and Coding Policy ("CPCP") 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. BCBSIL may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSIL 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 ("HIPAA") approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing ("UB") Editor, American Medical Association ("AMA"), Current Procedural Terminology ("CPT®"), CPT® Assistant, Healthcare Common Procedure Coding System ("HCPCS"), ICD-10 CM and PCS, National Drug Codes ("NDC"), Diagnosis Related Group ("DRG") guidelines, Centers for Medicare and Medicaid Services ("CMS") National Correct Coding Initiative ("NCCI") 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: February 22, 2023

Plan Effective Date: February 22, 2023

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 must remain in the patient's body upon discharge from the inpatient stay or outpatient procedure. Implants may include but are not limited to: metal anchors artificial joints, pins, plates, radioactive seeds, metal screws, shunts, stents, types of allografts[1, 2], and types of autografts [1, 2].

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 (CSF) 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:

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 SEALANTS	TOPICAL ABSORBABLE HEMOSTATS (TAH) & TOPICAL THROMBINS	Instruments & Miscellaneous
Surgiflo	Duraseal	Surgicel	Bone Morphogenetic Proteins $(BMP)_1$
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 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 case but **not** used or implanted into the member;
- Items opened by mistake;
- Change of mind by the surgeon to use an item for the member;
- Equipment failure/technical difficulties; and
- Surgery case cancellation.
- Large packages of supplies 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.

The plan reserves the right to request supporting documentation. Failure to adhere to coding and billing policies may impact claims processing and reimbursement. Claims may be reviewed on a case-by-case basis.

[1] Allografts when mixed with viable stem cells are considered experimental, investigational, or unproven (EIU) and are not eligible for reimbursement.

[2] Implants differ from transplants. Transplants are composed of biomedical tissue.

Additional Resources:

Medical Policies:

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:

https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/

https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-definitions-and-acronyms

Clinical and Applied Thrombosis/Hemostasis 16(5) 497-514
https://journals.sagepub.com/doi/pdf/10.1177/1076029610363589

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