Device, Implant, and Skin Substitute Policy, Facility

IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare reimbursement policies may use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS) or other coding guidelines. References to CPT or other sources are for definitional purposes only and do not imply any right to reimbursement.*

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms. Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design, and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general reference resource regarding UnitedHealthcare's reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to legislative mandates, the physician or other provider contracts, the enrollee's benefit coverage documents and/or other reimbursement, medical or drug policies. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations. UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

Application

This reimbursement policy applies to services reported using the UB04 claim form or its electronic equivalent or its successor form. This policy applies to all products and all network and non-network outpatient facility claims, Ambulatory Surgical Centers (ASC), Outpatient Surgical Centers (OSC), including, but not limited to, non-network authorized, and percent of charge contract facilities.

United Healthcare Commercial
This Reimbursement Policy applies to all UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange
This Reimbursement Policy applies to all Individual Exchange benefit plans.

Policy

Overview

For outpatient hospital services, this policy describes the coding guidelines associated with reporting devices, implants, and skin substitutes with their associated procedures. The policy also describes required coding associated with devices or implants obtained by the provider at no cost or at a reduced cost.

For inpatient and outpatient hospital services, this policy describes appropriate revenue coding for devices based on the US Food and Drug Administration (FDA) product classification definition for an implant.

Device, Implant, and Skin Substitutes with Associated Procedures

These coding guidelines will be applied to outpatient hospital services using the CMS criteria for devices, implants, and skin substitutes within the Center for Medicare and Medicaid Services (CMS) Integrated Outpatient Claims Editor (OCE).

https://www.cms.gov/medicare/coding-billing/outpatient-code-editor

Device or Implant Dependent Procedures

When the use of a device or implant is necessary in the performance of certain procedures, the device or implant must be submitted with the same date of service and on the same claim as the procedure. A device or implant dependent procedure will be denied if reported without an applicable device or implant on the same claim and date of service. A submission of the procedure code without a device or implant would only be considered for reimbursement when the service was discontinued prior to the placement of the device or implant and appended with an appropriate modifier indicating it was a discontinued procedure. The applicable codes are defined in the OCE HCPCS data file.

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.

Skin Substitute Application

When a skin substitute application or replacement procedure is reported, the associated skin substitute product must be submitted on the same claim and for the same date of service. Skin substitutes are assigned two categories specific to low cost and high cost. The applicable codes are defined in the OCE HCPCS data file.

- Skin substitute application or replacement procedures identified in the OCE as low cost will be denied when a skin substitute product identified as low cost on the OCE is not submitted for the same date of service and on the same claim.
- Skin substitute application or replacement procedures identified in the OCE as high cost will be denied when a skin substitute product identified as high cost on the OCE is not submitted for the same date of service and on the same claim.

Skin Substitute Low Procedures

C5271	C5272	C5273	C5274	C5275	C5276	C5277	C5278

Skin Substitute High Procedures

15271	15272	15273	15274	15275	15276	15277	15278	15777

Device Credit

When a device or implant was obtained by the provider at no cost or a reduced cost, it must be submitted with the appropriate condition code, value code, and modifier.

Condition codes applicable to device or implant credit:

- Condition code 49: Product Replacement within Product Lifecycle--Replacement of a product earlier than the anticipated lifecycle.
- Condition code 50: Product Replacement for Known Recall of a Product--Manufacturer or FDA has identified the product for recall and therefore replacement.
- Condition code 53: Initial placement of a medical device provided as part of a clinical trial or free sample--Code is for outpatient claims that have received a device credit upon initial medical device placement in a clinical trial or a free sample.

Value Code applicable to device or implant credit:

- Value Code FD: Credit Received from the Manufacturer for a Medical Device

Modifiers applicable to device or implant credit:

- Modifier FB: Items without cost to provider, supplier, or practitioner, or full credit received for replaced device (examples, but not limited to, covered under warranty, replaced due to defect, free examples).
- Modifier FC: Partial credit for replaced device.

FDA Product Classification for Implants

The following FDA product classification guidelines will be applied to inpatient and outpatient hospital services.

The FDA has defined "Implant" to mean a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more unless the Commissioner determines otherwise in order to protect human health.

When a revenue code representing implants is submitted, a HCPCS code which meets the FDA definition of an implant must be reported for outpatient services. If a HCPCS code is not submitted or if the HCPCS code submitted does not match the FDA definition of an implant, the claim line with the implant revenue code will not be reimbursed.

When a revenue code representing implants is submitted for an inpatient service, medical records may be requested to verify that the implant meets the FDA definition. If it does not meet the FDA definition of an implant, the claim line with the implant revenue code will not be reimbursed.

Examples of HCPCS That Do Not Meet the FDA Definition of an Implant List

C1724	C1725	C1726	C1727	C1728	C1729	C1730	C1731	C1732	C1733
C1753	C1754	C1755	C1756	C1757	C1758	C1759	C1765	C1766	C1769
C1773	C1782	C1819	C1884	C1885	C1887	C1892	C1893	C1894	C2614
C2615	C2618	C2628	C2629	C2630					

Absorbable and Liquid Implants

- Absorbable material and liquids are considered part of the inpatient and outpatient hospital services provided. Liquids or other materials that are absorbed by the surrounding tissue will not be considered for reimbursement if billed as an implant because they are considered integral to the implant procedure. Liquids or absorbable materials include, but are not limited to: advanced hemostats and sealants, synthetic sealants, topical absorbable hemostats and topical thrombins, bone morphogenetic protein, bone putty or cement, catheters, staples, and clips.
- Additionally, a supply or instrument is not considered an implant and will not be considered for reimbursement 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.

Questions and Answers	
1	**Q:** May we submit a device dependent procedure code when the procedure was discontinued before the device could be implanted?

	A: Yes. If the procedure is a device dependent procedure and it was discontinued prior to completion, you may submit the code for the procedure with the appropriate modifier indicating it was a discontinued. You would not be required to submit a code for the device itself.
2	**Q:** May a low cost skin substitute product be reported along with a high cost skin substitute procedure? **A:** No. The low cost skin substitute products may only be reported with a low cost skin substitute procedure. Equally, the high cost skin substitute products may only be reported with a high cost skin substitute procedure.
3	**Q:** May we submit a code that is not an FDA approved implant under revenue code 0278 if it is reported with the appropriate procedure on the same claim and with the same date of service? **A:** No. An implant that does not meet the FDA product classification guidelines and definition for what is considered an implant may not be submitted under implant revenue code 0278.
4	Q: May we submit implant revenue code 0278 without an appropriate HCPCS code? A: No. A HCPCS code must be submitted with revenue code 0278 for outpatient claims. If an appropriate HCPCS code is not submitted, the line item will be denied. The HCPCS code submission requirement does not apply to inpatient claims.

Attachments	
Device Dependent Procedure List	Device Dependent Procedure List
Device Dependent Devices List	Device Dependent Devices List
Skin Substitute Low Product List	Skin Substitute Low Product List
Skin Substitute High Product List	Skin Substitute High Product List

Resources
Center for Medicare and Medicaid Services (CMS), Manual System and other CMS publications and services
Center for Medicare and Medicaid Services (CMS) Integrated Outpatient Code Edit (IOCE)
Center for Medicare and Medicaid Services (CMS) Hospital Outpatient Prospective Payment System (OPPS)
Code of Federal Register U.S Food and Drug Administration

History	
4/14/2024	Policy Version Change Updated application section Policy List Update: Device Dependent Procedure List, Device Dependent Devices List, Skin Substitute Low Product List Entries prior to 6/26/2022 archived

4/1/2024	**Template Update**
	• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans.
	• Updated Application section to indicate this Reimbursement Policy applies to:
	  ○ All UnitedHealthcare Commercial benefit plans
	  ○ All Individual Exchange benefit plans

2/11/2024	Policy Version Change Policy List Update: Device Dependent Procedure List
1/14/2024	Policy Version Change Policy List Update: Device Dependent Procedure List, Device Dependent Devices List, Skin Substitute Low Product List, Skin Substitute High Product List Entries prior to 4/7/2022 have been archived
9/24/2023	Policy Version Change Policy List Update: Skin Substitute Low Product List, Skin Substitute High Product List Entries prior to 11/1/2021 archived
6/25/2023	Policy Version Change Policy List Update: Device Dependent Procedure List, Skin Substitute Low Product List, Skin Substitute High Product List Logo update Entries prior to 7/10/2021 have been archived
3/1/2023	Policy Version Change FDA Product Classification for Implants section updated.
1/1/2023	Policy Version Change Policy List Update: Device Dependent Procedure List, Device Dependent Devices List Policy Lists Added: Skin Substitute Low Procedure List, Skin Substitute Low Product List, Skin Substitute High Procedure List, Skin Substitute High Product List
10/9/2022	Policy Version Change Policy List Update: Device Dependent Devices List
7/11/2022	Policy Version Change Policy List Added: Device Dependent Devices List
6/26/2022	Policy Version Change Policy List Change: Device Dependent Procedure List
1/1/2021	Policy implemented by UnitedHealthcare Employer & Individual
9/10/2020	Policy approved by Reimbursement Policy Oversight Committee