Device, Implant, and Skin Substitute Policy (CES)

Policy Number: ADMINISTRATIVE 283.1 T0
Effective Date: January 1, 2021

Instructions for Use

Table of Contents Page

Related Policies
None

Applicable Lines of Business/Products

This policy applies to Oxford Commercial plan membership.

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, all network and non-network physicians and other qualified health care professionals, including, but not limited to, non-network authorized and percent of charge contract physicians and other qualified health care professionals.

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.

Reimbursement Guidelines

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/OutpatientCodeEdit/

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.

Similarly, some devices and implants are required to be submitted with certain procedures. The procedure must be submitted with the same date of service and on the same claim as the device or implant. 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.

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.

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

These coding guidelines will be applied to inpatient and outpatient hospital services in alignment with the FDA product classification guidelines.

When submitting a revenue code representing implants is submitted a HCPCS code which meets the FDA definition of an implant must be reported. If a HCPCS is not submitted or if the HCPCS submitted does not match the FDA definition of an implant it will be denied. 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 t remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise in order to protect human health.

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.

References

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Reimbursement Policy Oversight Committee. [*2021R5019A*]

Center for Medicare and Medicaid Services (CMS) Hospital Outpatient Prospective Payment System (OPPS)

Code of Federal Register

Center for Medicare and Medicaid Services (CMS) Integrated Outpatient Code Edit (IOCE)

Center for Medicare and Medicaid Services (CMS), Manual System and other CMS publications and services

U.S Food and Drug Administration

Policy History/Revision Information

Date	Summary of Changes
05/01/2021	Template Update • Reformatted and reorganized policy; transferred content to new template
01/01/2021	• New Reimbursement Policy

Instructions for Use

The services described in Oxford policies are subject to the terms, conditions and limitations of the member's contract or certificate. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify policies as necessary without prior written notice unless otherwise required by Oxford's administrative procedures or applicable state law. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

Certain policies may not be applicable to Self-Funded members and certain insured products. Refer to the member specific benefit plan document or Certificate of Coverage to determine whether coverage is provided or if there are any exclusions or benefit limitations applicable to any of these policies. If there is a difference between any policy and the member specific benefit plan document or Certificate of Coverage, the member specific benefit plan document or Certificate of Coverage will govern.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.