

Highmark Reimbursement Policy Bulletin



HISTORY VERSION

Bulletin Number: RP-061

Subject: Implants and Implant Components

Effective Date: September 28, 2020

End Date:

Issue Date: June 30, 2025

Revised Date: June 2025

Date Reviewed: March 2025

Source: Reimbursement Policy

Applicable Commercial Market

PA ☒ WV ☒ DE ☒ NY ☒

Applicable Medicare Advantage Market

PA ☒ WV ☒ DE ☒ NY ☒

Applicable Claim Type

UB ☒ 1500 ☐

➔ A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

This policy position applies to all commercial and/or Medicare Advantage lines of business as indicated above. Reimbursement policies are intended only to establish general guidelines for reimbursement. The Plan retains the right to review and update its reimbursement policy guidelines at its sole discretion.

PURPOSE:

This policy provides the Plan's direction as it pertains to medical implants and implant devices. The Food and Drug Administration (FDA) defines a medical implant as 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 thirty (30) days or more. 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, and types of autografts.

REIMBURSEMENT GUIDELINES:

Billed charges for items with revenue codes, including but not limited to, 0275 through 0279, require a vendor's invoice to validate and support implants used that correlate with services rendered.

Note: The Plan reserves the right to audit any claim submissions paid or payable for implants and implant components, in particular those that do not itemize a Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code for Revenue code(s) 0275 through 0279. This is not an all-inclusive list.

The Plan will utilize a National Invoice Average amount according to the national pricing program. If a provider disagrees with the invoice amount assigned by the Plan, the provider may submit actual invoices to substantiate implant costs.

The submitted claim and vendor invoice must clearly indicate the units that apply to the claim. If there is discrepancy in units indicated, charges for revenue codes 0275 through 0279 will be denied. Purchased units in bulk require specific identification to the claim (i.e. member specific) and must be noted on the invoice.

Administrative storage and delivery costs for providers or vendors will not be reimbursed.

The surgical rate charge should encompass all items and/or services. Unless allowed under the terms of the member's health benefit plan, the member should not be responsible for these charges or services.

Supplies used as part of implant procedures follow the same facility routine supplies and services reimbursement guidelines and are not separately reimbursable (See RP-040 Facility Routine Supplies and Services).

If a supply or instrument placed in the body is removed or discarded during the same inpatient/outpatient procedure or single episode of care, it is considered integral to the procedure and it is not considered an implant. Implant and implant components considered integral to the procedure will not be eligible for reimbursement.

External fixation is considered temporary and therefore will not be separately reimbursable.

Supplies, implants, and/or services considered experimental, investigational, or unproven, per Plan policy, will not be reimbursed.

Indications for non-coverage of implants and implant components include, but are not limited to:

Note: This is not an all-inclusive list.

- Implants, implant components opened and then found to be incorrect and not used
- Contaminated/Unused/Wasted implant and implant supplies
- Implants or implant components implanted then removed (i.e., implant screw removed and replaced when the wrong length of screw is used on a plate)
- Implants or implant components malfunction and are replaced during implantation
- Implants or implant components integral to the procedure (i.e. staples, sutures, clips, etc.)
- Provisional or temporary implants removed during the operative session
- Change of mind by the surgeon to use an item for the patient
- Equipment failure/technical difficulties
- Surgical case cancellation
- Materials 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
- If the underlying surgical procedure is deemed ineligible, implants, other associated supplies, drugs and services ancillary to the surgery or invasive procedure will be denied

RELATED POLICIES:

Refer to the following Reimbursement Policies for additional information:

- RP-029: Surgical Techniques, Procedures and Related Services
- RP-035: Correct Coding Guidelines
- RP-040: Facility Routine Supplies and Services
- RP-042: Global Surgery and Subsequent Services

ADDITIONAL BILLING INFORMATION AND GUIDELINES:

- Medicare Claims Processing Manual, Chapter 14, Ambulatory Surgical Centers
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c14.pdf>
- CFR-Code of Federal regulations, Title 21
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=860.3>
- Department of Health and Human Services, Centers for Medicare and Medicaid Services, Federal Register, November 24, 2006; pg. 67,989-67,990
https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/Federal_Register_Notice_Final_Rule.pdf
- Centers For Medicare and Medicaid Services, Department of Health and Human Services; Subchapter B-Medicare Program; Part 419-Prospective Payment System for Hospital Outpatient Department Services; Subpart G-Transitional Pass-Through Payments
<https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol3/xml/CFR-2019-title42-vol3-sec419-66.xml>

POLICY UPDATE HISTORY INFORMATION:

9 / 2020	Implementation
11 / 2021	Added NY region applicable to the policy
1 / 2022	Added Delaware Medicare Advantage applicable to the policy
6 / 2023	Administrative policy review with no changes in policy direction
5 / 2025	Policy reformatted and National Invoice Average direction added for PA, DE, and WV
6 / 2025	Policy reformat and added direction for NIA applied in May 2025 now effective for NY

Highmark Reimbursement Policy Bulletin



HISTORY VERSION

Bulletin Number: RP-61

Subject: Implants and Implant Components

Effective Date: September 28, 2020

End Date:

Issue Date: June 12, 2023

Revised Date: June 2023

Date Reviewed: May 2023

Source: Reimbursement Policy

Applicable Commercial Market

PA ☒ WV ☒ DE ☒ NY ☒

Applicable Medicare Advantage Market

PA ☒ WV ☒ DE ☒ NY ☒

Applicable Claim Type

UB ☒ 1500 ☐

➔ A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

DEFINITIONS:

Term	Definition
Implant	An object, device or material inserted surgically, embedded via surgical or nonsurgical means, grafted into the body and remains in the body - either indefinitely for prosthetic and/or therapeutic purposes - or remains in the body for a temporary or provisional period of time for diagnostic and/or therapeutic purposes. An external fixation device is considered an implant only when a component of the fixation device is implanted and remains in the body.
Implant Components	Implant integral parts (i.e. screws, plates, rods) remaining in the body used in conjunction with the primary implant.
Implant Supplies	Elements (i.e., supplies and/or tools) of implant kits or implant systems used to place or remove implants, but do not remain in the body.
Medical and Surgical Supplies	Medical and/or Surgical supplies that are used as a part of a surgical procedure.
Provisional Implants	An implant which is intended to be placed temporarily or on a short-term basis; that is expected to be removed and replaced with a permanent implant.

COMMERCIAL REIMBURSEMENT GUIDELINES:

Indications for non-coverage of implants and implant components are as follows:

- Implants, implant components opened and then found to be incorrect and not used

- Implants, implant components inadvertently dropped from the sterile field and cannot be used again
- Implants or implant components implanted then removed (i.e., implant screw removed and replaced when the wrong length of screw is used on a plate)
- Implants or implant components malfunction and are replaced during implantation
- Provisional or temporary implants removed during the operative session
- Change of mind by the surgeon to use an item for the patient
- Equipment failure/technical difficulties
- Surgical case cancellation
- Implants may be eligible for payment meeting all of the above criteria, however, if the underlying surgical procedure is deemed ineligible, implants, other associated supplies, drugs and services ancillary to the surgery or invasive procedure may also be denied reimbursement.

Specific CMS criteria, (sources listed in the reference section of this policy) to determine whether or not reimbursement may be made including the use of NOC (Not otherwise classified CPT/HCPCS codes) is listed below.

1. **Eligibility.** A medical device must meet the following requirements:

- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness, injury, or to improve the functioning of a malformed body part.
- The device is an integral and subordinate part of the service furnished, is only used for a single patient, comes in contact with human tissue, and is surgically implanted/inserted whether or not it remains with the patient when the patient is discharged from the hospital.
- A supply or instrument purposed to be removed or discarded during the same inpatient or outpatient procedure in which they are placed in the body is not an implant. Liquids or materials absorbed or incorporated by the surrounding tissue will not be reimbursed if billed as an implant.

2. The device is **not** any of the following:

- Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined by CMS.
- A material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker).
- A material used to replace human skin (for example, a biological skin replacement material or synthetic skin replacement material).
- Endoscopes, tackers, staples/staplers and any reusable equipment whether or not such equipment is sterilized after each use.
- Items use in lieu of traditional surgical instruments such (but not limited to) as scalpels, cutters, kits composed of such items and those items designed to achieve closure or hemostasis.

3. Except for certain specified medical devices CMS determines the cost of the device is not insignificant as described below.

- **Cost criteria.** CMS considers the average cost of a category of devices to be not insignificant if it meets the following conditions:
 - The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices.

- The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent.

Implant Supplies are Not Eligible for Separate Reimbursement

Examples of non-reimbursable implant supplies include, but are not limited to:

- Specialized implant placement instruments (i.e. forceps, scissors, needle holder or other instruments)
- Specialized drill bits, saw blades and others

Implants and Implant Components Reimbursed via Vendors Invoice

Certain implants and implant components may be reimbursed via invoice if the following is applicable:

- Units indicated on vendor invoices must be present and match the associated claim line billed
- If units are purchased in bulk, specific identification to the claim billed (i.e. member specific) must be noted on the invoice unless otherwise agreed upon

Medical and Surgical Supplies for All Surgical Procedures

Please refer to Reimbursement Policy RP-040: Facility Routine Supplies and Services, which contains additional criteria for non-coverage of medical/surgical supplies that are used as part of surgical procedures. Supplies used as part of implant procedures follow the same facility routine supplies and services, and are not separately reimbursable.

Codes Related to the Billing of Implant and Implant Components

The Plan reserves the right to audit any claim submissions paid or payable for implants and implant components, in particular those that do not itemize a CPT or HCPCS codes for Revenue code(s) 0275 through 0279.

MEDICARE ADVANTAGE REIMBURSEMENT GUIDELINES:

The Plan follows and adheres to guidelines as directed by the Centers for Medicare and Medicaid Services (CMS) in relation to services associated with implants and implant components. See Medicare Benefit Policy Manual Claims Chapter 14 and other references linked in this policy.

Note: The list of references in this policy may not include all applicable CMS direction, but still apply.

RELATED HIGHMARK POLICIES:

Refer to the following Reimbursement Policies for additional information:

- RP-029: Surgical Techniques, Procedures and Related Services
- RP-035: Correct Coding Guidelines

- RP-040: Facility Routine Supplies and Services
- RP-042: Global Surgery and Subsequent Services

ADDITIONAL BILLING INFORMATION AND GUIDELINES:

- Medicare Claims Processing Manual, Chapter 14 – Ambulatory Surgical Centers
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c14.pdf>
- Department of Health and Human Services, Centers for Medicare and Medicaid Services, Federal Register, November 24, 2006; pg. 67,989-67,990.
https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/Federal_Register_Notice_Final_Rule.pdf
- Centers For Medicare and Medicaid Services, Department of Health and Human Services; Subchapter B-Medicare Program; Part 419-Prospective Payment System for Hospital Outpatient Department Services; Subpart G-Transitional Pass-Through Payments.
<https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol3/xml/CFR-2019-title42-vol3-sec419-66.xml>

POLICY UPDATE HISTORY INFORMATION:

9 / 2020	Implementation
11 / 2021	Added NY region applicable to the policy
1 / 2022	Added Delaware Medicare Advantage applicable to the policy
6 / 2023	Administrative policy review with no changes in policy direction

Highmark Reimbursement Policy Bulletin



HISTORY VERSION

Bulletin Number: RP-61
Subject: Implants and Implant Components
Effective Date: September 28, 2020 **End Date:**
Issue Date: January 3, 2022 **Revised Date:** January 2022
Date Reviewed: October 2021
Source: Reimbursement Policy

Applicable Commercial Market

PA ☒ WV ☒ DE ☒ NY ☒

Applicable Medicare Advantage Market

PA ☒ WV ☒ DE ☒ NY ☒

Applicable Claim Type

UB ☒ 1500 ☐

➔ A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

COMMERCIAL REIMBURSEMENT GUIDELINES:

Indications for non-coverage of implants and implant components are as follows:

- Implants, implant components opened and then found to be incorrect and not used
- Implants, implant components inadvertently dropped from the sterile field and cannot be used again
- Implants or implant components implanted then removed (i.e., implant screw removed and replaced when the wrong length of screw is used on a plate)
- Implants or implant components malfunction and are replaced during implantation
- Provisional or temporary implants removed during the operative session
- Change of mind by the surgeon to use an item for the patient
- Equipment failure/technical difficulties
- Surgical case cancellation
- Implants may be eligible for payment meeting all of the above criteria, however, if the underlying surgical procedure is deemed ineligible, implants, other associated supplies, drugs and services ancillary to the surgery or invasive procedure may also be denied reimbursement.

Specific CMS criteria, (sources listed in the reference section of this policy) to determine whether or not reimbursement may be made including the use of NOC (Not otherwise classified CPT/HCPCS codes) is listed below.

1. **Eligibility.** A medical device must meet the following requirements:

- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness, injury, or to improve the functioning of a malformed body part.
- The device is an integral and subordinate part of the service furnished, is only used for a single patient, comes in contact with human tissue, and is surgically implanted/inserted whether or not it remains with the patient when the patient is discharged from the hospital.
- A supply or instrument purposed to be removed or discarded during the same inpatient or outpatient procedure in which they are placed in the body is not an implant. Liquids or materials absorbed or incorporated by the surrounding tissue will not be reimbursed if billed as an implant.

2. The device is **not** any of the following:

- Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined by CMS.
- A material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker).
- A material used to replace human skin (for example, a biological skin replacement material or synthetic skin replacement material).
- Endoscopes, tackers, staples/staplers and any reusable equipment whether or not such equipment is sterilized after each use.
- Items use in lieu of traditional surgical instruments such (but not limited to) as scalpels, cutters, kits composed of such items and those items designed to achieve closure or hemostasis.

3. Except for certain specified medical devices CMS determines the cost of the device is not insignificant as described below.

- **Cost criteria.** CMS considers the average cost of a category of devices to be not insignificant if it meets the following conditions:
 - The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices.
 - The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent.

Implant Supplies are Not Eligible for Separate Reimbursement

Examples of non-reimbursable implant supplies include, but are not limited to:

- Specialized implant placement instruments (i.e. forceps, scissors, needle holder or other instruments)
- Specialized drill bits, saw blades and others

Implants and Implant Components Reimbursed via Vendors Invoice

Certain implants and implant components may be reimbursed via invoice if the following is applicable:

- Units indicated on vendor invoices must be present and match the associated claim line billed

- If units are purchased in bulk, specific identification to the claim billed (i.e. member specific) must be noted on the invoice unless otherwise agreed upon

Medical and Surgical Supplies for All Surgical Procedures

Please refer to Reimbursement Policy RP-040: Facility Routine Supplies and Services, which contains additional criteria for non-coverage of medical/surgical supplies that are used as part of surgical procedures. Supplies used as part of implant procedures follow the same facility routine supplies and services, and are not separately reimbursable.

Codes Related to the Billing of Implant and Implant Components

The Plan reserves the right to audit any claim submissions paid or payable for implants and implant components, in particular those that do not itemize a CPT or HCPCS codes for Revenue code(s) 0275 through 0279.

MEDICARE ADVANTAGE REIMBURSEMENT GUIDELINES:

The Plan follows and adheres to guidelines as directed by the Centers for Medicare and Medicaid Services (CMS) in relation to services associated with implants and implant components. See Medicare Benefit Policy Manual Claims Chapter 14 and other references linked in this policy.

Note: The list of references in this policy may not include all applicable CMS direction, but still apply.

DEFINITIONS:

Implant: An object, device or material inserted surgically, embedded via surgical or nonsurgical means, grafted into the body and remains in the body - either indefinitely for prosthetic and/or therapeutic purposes - or remains in the body for a temporary or provisional period of time for diagnostic and/or therapeutic purposes. An external fixation device is considered an implant only when a component of the fixation device is implanted and remains in the body.

Implant Components: Implant integral parts (i.e. screws, plates, rods) remaining in the body used in conjunction with the primary implant.

Implant Supplies: Elements (i.e., supplies and/or tools) of implant kits or implant systems used to place or remove implants, but do not remain in the body.

Medical and Surgical Supplies: Medical and/or Surgical supplies that are used as a part of a surgical procedure.

Provisional Implants: An implant which is intended to be placed temporarily or on a short-term basis; that is expected to be removed and replaced with a permanent implant.

RELATED HIGHMARK POLICIES:

Refer to the following Reimbursement Policies for additional information:

- RP-040: Facility Routine Supplies and Services
- RP-029: Surgical Techniques, Procedures and Related Services
- RP-042: Global Surgery and Subsequent Services

ADDITIONAL BILLING INFORMATION AND GUIDELINES:

- Medicare Claims Processing Manual, Chapter 14 – Ambulatory Surgical Centers
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c14.pdf>
- Department of Health and Human Services, Centers for Medicare and Medicaid Services, Federal Register, November 24, 2006; pg. 67,989-67,990.
https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/Federal_Register_Notice_Final_Rule.pdf
- Centers For Medicare and Medicaid Services, Department of Health and Human Services; Subchapter B-Medicare Program; Part 419-Prospective Payment System for Hospital Outpatient Department Services; Subpart G-Transitional Pass-Through Payments.
<https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol3/xml/CFR-2019-title42-vol3-sec419-66.xml>

POLICY UPDATE HISTORY INFORMATION:

9 / 2020	Implementation
11 / 2021	Added NY region applicable to the policy
1 / 2022	Added Delaware Medicare Advantage applicable to the policy

Highmark Reimbursement Policy Bulletin



HISTORY VERSION

Bulletin Number: RP-061
Subject: Implants and Implant Components
Effective Date: September 28, 2020
Issue Date: November 1, 2021
Date Reviewed: July 2021
Source: Reimbursement Policy

End Date:
Revised Date: July 2021

Applicable Commercial Market

Applicable Medicare Advantage Market

Applicable Claim Type

PA	<input checked="" type="checkbox"/>	WV	<input checked="" type="checkbox"/>	DE	<input checked="" type="checkbox"/>	NY	<input checked="" type="checkbox"/>
PA	<input checked="" type="checkbox"/>	WV	<input checked="" type="checkbox"/>	DE	<input type="checkbox"/>	NY	<input checked="" type="checkbox"/>
UB	<input checked="" type="checkbox"/>	1500	<input type="checkbox"/>				

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this Policy.

COMMERCIAL REIMBURSEMENT GUIDELINES:

Indications for non-coverage of implants and implant components are as follows:

- Implants, implant components opened and then found to be incorrect and not used
- Implants, implant components inadvertently dropped from the sterile field and cannot be used again
- Implants or implant components implanted then removed (i.e., implant screw removed and replaced when the wrong length of screw is used on a plate)
- Implants or implant components malfunction and are replaced during implantation
- Provisional or temporary implants removed during the operative session
- Change of mind by the surgeon to use an item for the patient
- Equipment failure/technical difficulties
- Surgical case cancellation
- Implants may be eligible for payment meeting all of the above criteria, however, if the underlying surgical procedure is deemed ineligible, implants, other associated supplies, drugs and services ancillary to the surgery or invasive procedure may also be denied reimbursement.

Specific CMS criteria, (sources listed in the reference section of this policy) to determine whether or not reimbursement may be made including the use of NOC (Not otherwise classified CPT/HCPCS codes) is listed below.

1. **Eligibility.** A medical device must meet the following requirements:

- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness, injury, or to improve the functioning of a malformed body part.
- The device is an integral and subordinate part of the service furnished, is only used for a single patient, comes in contact with human tissue, and is surgically implanted/inserted whether or not it remains with the patient when the patient is discharged from the hospital.
- A supply or instrument purposed to be removed or discarded during the same inpatient or outpatient procedure in which they are placed in the body is not an implant. Liquids or materials absorbed or incorporated by the surrounding tissue will not be reimbursed if billed as an implant.

2. The device is **not** any of the following:

- Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined by CMS.
- A material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker).
- A material used to replace human skin (for example, a biological skin replacement material or synthetic skin replacement material).
- Endoscopes, tackers, staples/staplers and any reusable equipment whether or not such equipment is sterilized after each use.
- Items use in lieu of traditional surgical instruments such (but not limited to) as scalpels, cutters, kits composed of such items and those items designed to achieve closure or hemostasis.

3. Except for certain specified medical devices CMS determines the cost of the device is not insignificant as described below.

- **Cost criteria.** CMS considers the average cost of a category of devices to be not insignificant if it meets the following conditions:
 - The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices.
 - The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent.

Implant Supplies are Not Eligible for Separate Reimbursement

Examples of non-reimbursable implant supplies include, but are not limited to:

- Specialized implant placement instruments (i.e. forceps, scissors, needle holder or other instruments)
- Specialized drill bits, saw blades and others

Implants and Implant Components Reimbursed via Vendors Invoice

Certain implants and implant components may be reimbursed via invoice if the following is applicable:

- Units indicated on vendor invoices must be present and match the associated claim line billed

- If units are purchased in bulk, specific identification to the claim billed (i.e. member specific) must be noted on the invoice unless otherwise agreed upon

Medical and Surgical Supplies for All Surgical Procedures

Please refer to Reimbursement Policy RP-040: Facility Routine Supplies and Services, which contains additional criteria for non-coverage of medical/surgical supplies that are used as part of surgical procedures. Supplies used as part of implant procedures follow the same facility routine supplies and services, and are not separately reimbursable.

Codes Related to the Billing of Implant and Implant Components

The Plan reserves the right to audit any claim submissions paid or payable for implants and implant components, in particular those that do not itemize a CPT or HCPCS codes for Revenue code(s) 0275 through 0279.

MEDICARE ADVANTAGE REIMBURSEMENT GUIDELINES:

The Plan follows and adheres to guidelines as directed by the Centers for Medicare and Medicaid Services (CMS) in relation to services associated with implants and implant components. See Medicare Benefit Policy Manual Claims Chapter 14 and other references linked in this policy.

Note: The list of references in this policy may not include all applicable CMS direction, but still apply.

DEFINITIONS:

Implant: An object, device or material inserted surgically, embedded via surgical or nonsurgical means, grafted into the body and remains in the body - either indefinitely for prosthetic and/or therapeutic purposes - or remains in the body for a temporary or provisional period of time for diagnostic and/or therapeutic purposes. An external fixation device is considered an implant only when a component of the fixation device is implanted and remains in the body.

Implant Components: Implant integral parts (i.e. screws, plates, rods) remaining in the body used in conjunction with the primary implant.

Implant Supplies: Elements (i.e., supplies and/or tools) of implant kits or implant systems used to place or remove implants, but do not remain in the body.

Medical and Surgical Supplies: Medical and/or Surgical supplies that are used as a part of a surgical procedure.

Provisional Implants: An implant which is intended to be placed temporarily or on a short-term basis; that is expected to be removed and replaced with a permanent implant.

RELATED HIGHMARK POLICIES:

Refer to the following Reimbursement Policies for additional information:

- RP-040: Facility Routine Supplies and Services
- RP-029: Surgical Techniques, Procedures and Related Services
- RP-042: Global Surgery and Subsequent Services

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https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/Federal_Register_Notice_Final_Rule.pdf
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<https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol3/xml/CFR-2019-title42-vol3-sec419-66.xml>

POLICY UPDATE HISTORY INFORMATION:

9 / 2020	Implementation
11 / 2021	Added NY region applicable to the policy

Highmark Reimbursement Policy Bulletin



Bulletin Number: RP-061
Subject: Implants and Implant Components
Effective Date: September 28, 2020
Issue Date: August 31, 2020
Date Reviewed: August 2020
Source: Reimbursement Policy

End Date:

Revised Date:

Applicable Commercial Market

Applicable Medicare Advantage Market

Applicable Claim Type

PA	<input checked="" type="checkbox"/>	WV	<input checked="" type="checkbox"/>	DE	<input checked="" type="checkbox"/>
PA	<input checked="" type="checkbox"/>	WV	<input checked="" type="checkbox"/>		
UB	<input checked="" type="checkbox"/>	1500	<input type="checkbox"/>		

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Provisional Implants: An implant which is intended to be placed temporarily or on a short-term basis; that is expected to be removed and replaced with a permanent implant.

COMMERCIAL REIMBURSEMENT GUIDELINES:

Indications for non-coverage of implants and implant components are as follows:

- Implants, implant components opened and then found to be incorrect and not used
- Implants, implant components inadvertently dropped from the sterile field and cannot be used again
- Implants or implant components implanted then removed (i.e., implant screw removed and replaced when the wrong length of screw is used on a plate)
- Implants or implant components malfunction and are replaced during implantation
- Provisional or temporary implants removed during the operative session
- Change of mind by the surgeon to use an item for the patient
- Equipment failure/technical difficulties
- Surgical case cancellation
- Implants may be eligible for payment meeting all of the above criteria, however, if the underlying surgical procedure is deemed ineligible, implants, other associated supplies, drugs and services ancillary to the surgery or invasive procedure may also be denied reimbursement.

Specific CMS criteria, (sources listed in the reference section of this policy) to determine whether or not reimbursement may be made including the use of NOC (Not otherwise classified CPT/HCPCS codes) is listed below.

1. **Eligibility.** A medical device must meet the following requirements:

- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness, injury, or to improve the functioning of a malformed body part.
- The device is an integral and subordinate part of the service furnished, is only used for a single patient, comes in contact with human tissue, and is surgically implanted/inserted whether or not it remains with the patient when the patient is discharged from the hospital.
- A supply or instrument purposed to be removed or discarded during the same inpatient or outpatient procedure in which they are placed in the body is not an implant. Liquids or materials absorbed or incorporated by the surrounding tissue will not be reimbursed if billed as an implant.

2. The device is **not** any of the following:

- Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined by CMS.
- A material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker).
- A material used to replace human skin (for example, a biological skin replacement material or synthetic skin replacement material).
- Endoscopes, tackers, staples/staplers and any reusable equipment whether or not such equipment is sterilized after each use.
- Items use in lieu of traditional surgical instruments such (but not limited to) as scalpels, cutters, kits composed of such items and those items designed to achieve closure or hemostasis.

3. Except for certain specified medical devices CMS determines the cost of the device is not insignificant as described below.

- **Cost criteria.** CMS considers the average cost of a category of devices to be not insignificant if it meets the following conditions:

- The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices.
- The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent.

Implant Supplies are Not Eligible for Separate Reimbursement

Examples of non-reimbursable implant supplies include, but are not limited to:

- Specialized implant placement instruments (i.e. forceps, scissors, needle holder or other instruments)
- Specialized drill bits, saw blades and others

Implants and Implant Components Reimbursed via Vendors Invoice

Certain implants and implant components may be reimbursed via invoice if the following is applicable:

- Units indicated on vendor invoices must be present and match the associated claim line billed
- If units are purchased in bulk, specific identification to the claim billed (i.e. member specific) must be noted on the invoice unless otherwise agreed upon

Medical and Surgical Supplies for All Surgical Procedures

Please refer to Reimbursement Policy RP-040: Facility Routine Supplies and Services, which contains additional criteria for non-coverage of medical/surgical supplies that are used as part of surgical procedures. Supplies used as part of implant procedures follow the same facility routine supplies and services, and are not separately reimbursable.

Codes Related to the Billing of Implant and Implant Components

The Plan reserves the right to audit any claim submissions paid or payable for implants and implant components, in particular those that do not itemize a CPT or HCPCS codes for Revenue code(s) 0275 through 0279.

RELATED HIGHMARK POLICIES:

Refer to the following Reimbursement Policies for additional information:

- RP-040: Facility Routine Supplies and Services
- RP-029: Surgical Techniques, Procedures and Related Services
- RP-042: Global Surgery and Subsequent Services

ADDITIONAL BILLING INFORMATION AND GUIDELINES:

- Medicare Claims Processing Manual, Chapter 14 – Ambulatory Surgical Centers
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c14.pdf>

- Department of Health and Human Services, Centers for Medicare and Medicaid Services, Federal Register, November 24, 2006; pg. 67,989-67,990.
https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/Federal_Register_Notice_Final_Rule.pdf
- Centers For Medicare and Medicaid Services, Department of Health and Human Services; Subchapter B-Medicare Program; Part 419-Prospective Payment System for Hospital Outpatient Department Services; Subpart G-Transitional Pass-Through Payments.
<https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol3/xml/CFR-2019-title42-vol3-sec419-66.xml>

MEDICARE ADVANTAGE REIMBURSEMENT GUIDELINES:

The Plan follows and adheres to guidelines as directed by the Centers for Medicare and Medicaid Services (CMS) in relation to services associated with implants and implant components. See Medicare Benefit Policy Manual Claims Chapter 14 and other references linked in this policy.

Note: The list of references in this policy may not include all applicable CMS direction, but still apply.

POLICY UPDATE HISTORY INFORMATION:

9 / 2020	Implementation
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