

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 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

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|---|----|-------------------------------------|------|-------------------------------------|----|-------------------------------------|----|-------------------------------------|
| Applicable Commercial Market | PA | <input checked="" type="checkbox"/> | WV | <input checked="" type="checkbox"/> | DE | <input checked="" type="checkbox"/> | NY | <input checked="" type="checkbox"/> |
| Applicable Medicare Advantage Market | PA | <input checked="" type="checkbox"/> | WV | <input checked="" type="checkbox"/> | DE | <input checked="" type="checkbox"/> | NY | <input checked="" type="checkbox"/> |
| Applicable Claim Type | UB | <input checked="" type="checkbox"/> | 1500 | <input type="checkbox"/> | | | | |

➔ 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 **End Date:**
Issue Date: November 1, 2021 **Revised Date:** July 2021
Date Reviewed: July 2021
Source: Reimbursement Policy

| | | | | | | | | |
|---|----|-------------------------------------|------|-------------------------------------|----|-------------------------------------|----|-------------------------------------|
| Applicable Commercial Market | PA | <input checked="" type="checkbox"/> | WV | <input checked="" type="checkbox"/> | DE | <input checked="" type="checkbox"/> | NY | <input checked="" type="checkbox"/> |
| Applicable Medicare Advantage Market | PA | <input checked="" type="checkbox"/> | WV | <input checked="" type="checkbox"/> | DE | <input type="checkbox"/> | NY | <input checked="" type="checkbox"/> |
| Applicable Claim Type | 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:

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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>
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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 **End Date:**
Issue Date: August 31, 2020 **Revised Date:**
Date Reviewed: August 2020
Source: Reimbursement Policy

Applicable Commercial Market PA WV DE
Applicable Medicare Advantage Market PA WV
Applicable Claim Type UB 1500

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.

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Medical and Surgical Supplies for All Surgical Procedures

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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>

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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 |
|----------|----------------|

