Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Device Pass-through Application Setup

Disclaimer

All content submitted as part of this application may be made public unless otherwise noted below. Please see the CY 2023 OPPS/ASC final rule (87 FR 71934 - 71938) for a full discussion of the policy to publicly post OPPS Device Pass-through applications.

Information that should not be made public is not taken into consideration when determining whether a technology meets the OPPS Device Pass-through payment criteria. Throughout this application, "made public" refers to either posting application materials publicly or including information from an application in our discussion in the Federal Register. If you would like to include information that should not be made public as part of your application, please refer to the "Additional Application Information - CONFIDENTIAL" section on the summary page at the end of the application. We also note that we will not make public any contact information included in the application.

Please note that any data provided in this application may become subject to disclosure where required by law. Where CMS has indicated that information won't be made public, CMS will attempt, to the extent allowed by law, to keep that information protected from public view.

☐ I certify that I have been duly authorized to submit this application on behalf of the applicant. I acknowledge and agree that I have read the Disclaimer and understand that all the information in this application may be made public, unless otherwise noted or included in the "Additional Application Information - CONFIDENTIAL" section.

Copyrighted Information:
For supporting evidence uploaded in the Substantial Clinical Improvement (SCI) section of the application you will be asked if the applicant does not have the appropriate license or right to release each document to the public. At the end of the SCI section, you will be asked to represent and warrant that the applicant owns the copyright or otherwise has the appropriate license to make any copyrighted material releasable to the public, with the exception of those materials for which the applicant indicates otherwise. Please be sure to select the appropriate checkboxes as you go through the SCI section to provide a representation of whether the files can be included in the public posting. You will also be asked to provide citations for the materials, and CMS will post those citations publicly. Documents that cannot be publicly posted will still be considered

Centers for Medicare & Medicaid Services
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by CMS and may be summarized in the proposed rule, and the summary information provided by the applicant will be posted publicly.

☐ I certify that I have been duly authorized by the applicant to sign this acknowledgement on behalf of the applicant. I acknowledge and agree that I have read this information regarding copyrighted information and understand that I will be required to represent and warrant that, except for studies for which I indicate otherwise, the applicant owns the copyright or otherwise has the appropriate license to make the studies included in the SCI section available to the public. I understand that CMS may post publicly any study for which I indicate that the applicant owns the copyright or otherwise has the appropriate license to make it public.

Device Pass-through Application

A. Contact Info

Info: The information in this section will not be made public, except the name of the party submitting the Device Pass-through application.

***Please note** that the MEARIS™ website can only be accessed by individuals who are located in the United States.*

1. **Who is the party submitting the Device Pass-through?** (e.g. the manufacturer, distributor, healthcare organization/entity)
   Provide contact information for the applicant.
   Info: The contact listed here will be included as a contact for this application.
   Applicant Information:
   - First name
   - Middle name (optional)
   - Last name
   - Organization
   - Occupation/Job Title
   - Email address
   - Country
   - US Phone Number
   - Extension (optional)
   - Mailing address line 1
   - Mailing address line 2 (optional)

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Centers for Medicare & Medicaid
Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850

- City
- State
- Zip code
- Applicant Type (selections):
    - Manufacturer, Other (explain)

2. Who is the primary contact?

Info: The information in this section will not be made public.

□ Select if this is the "Same as the Applicant Contact" and the fields will auto-populate with the Applicant Information provided in 1.

- First name
- Middle name (optional)
- Last name
- Organization
- Occupation/Job Title
- US Phone Number
- Extension (optional)
- Email address
- Country
- Mailing address line 1
- Mailing address line 2 (optional)
- City
- State
- Zip code
- Relationship (selections)
    - Manufacturer, Consultant, Other (explain)

3. Who is the secondary contact?

Info: The information in this section will not be made public.

□ Select if this is the "Same as the Applicant Contact" and the fields will auto-populate with the Applicant Information provided in 1.

- First name
- Middle name (optional)
- Last name
- Organization
- Occupation/Job Title

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Centers for Medicare & Medicaid
Services
Center for Medicare Management
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- US Phone Number
- Extension (optional)
- Email address
- Country
- Mailing address line 1
- Mailing address line 2 (optional)
- City
- State
- Zip code
- Relationship (selections)
    - Consultant, Manufacturer, Other (explain)

B. Device Info

4. Provide the name or descriptor and additional details for the proposed device category.

- Device Category Descriptor
- Ambulatory Payment Classification (APC) assignment (optional)

Info: Click to see device category requirements

Device Category Requirements

The device to be included in a proposed new category is not appropriately described by any of the existing (either currently active or expired) categories established for transitional device pass-through payments. A complete list of established device categories used presently or previously for pass-through payment is found on the OPPS website, in the CMS Internet Only Manual (IOM), Chapter 4, Section 60.4 of the Medicare Claim Processing Manual (PDF) currently under https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c04.pdf. *A category of devices does not appropriately describe the new device if the applicant adequately demonstrates that the candidate device is not similar to devices (including related predicate devices) included in an existing category. In addition, when required, the applicant must demonstrate substantial clinical improvement, discussed below, as described in the November 10, 2005 OPPS final rule (70 FR 68630-68631). The device to be included in the category was not being paid for as an outpatient service as of December 31, 1996.*

APC Information (Addendum A)

Addendum A and Addendum B Updates

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Centers for Medicare & Medicaid
Services
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5. General Information

a. Device Trade/Brand Name
b. Device type (selections):
- Implantable Device
- Implantable Biological
- Device and Drug/Biological Combination
- Skin Substitute
- Other Device

c. Please provide a brief (1-2 sentence) description of the technology.

6. Describe the device in detail, using general terminology

a. What is the device?
b. What does the device do?
c. How is the device used?
d. Provide a complete physical description of the device including its components, e.g., hardware, software, reservoir, tubing, its composition, coating, or covering.
e. For what disease processes and patient populations is the device used?
f. What are the complications associated with the device's use?
g. What is the device's life span?

Upload relevant descriptive booklets, brochures, package inserts, or other supporting materials as needed (optional).

7. Current treatments for the disease or condition the device treats or diagnoses:

- Are there any other treatments for the disease or condition that this technology treats or diagnoses? Yes/No
- Briefly describe current treatments for the disease or condition.

8. Does the device meet the following criteria?

a. Device is integral to the service provided: Yes/No
b. Device is used for one patient only: Yes/No
c. Device comes into contact with human tissue: Yes/No
d. Device is surgically implanted or inserted or applied in or on a wound or other skin lesion: Yes/No
e. Device is NOT equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-10: Yes/No
f. Device is NOT a material or supply furnished incident to a service (for example,

Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850

a suture, customized surgical kit, scalpel, or clip, other than radiological site marker); Yes/No

Note: The device description provided should clearly address how the nominated device meets or does not meet the eligibility criteria.

9. Using Healthcare Common Procedure Coding System (HCPCS) Level I and/or Level II code(s), list all of the specific procedure(s) and/or services with which the nominated device is used. (users must enter in at least one existing device)

- **Enter HCPCS code**
- **Long Descriptor**

Info:* *HCPCS General Info

10. Are there any established device categories used presently or previously for device pass-through payment that describe the nominated device or products similar to the nominated device? (Yes/No)

Info: In accordance with § 419.66(c)(1), to be eligible for device pass-through payment status, the device must not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996.

View established device categories

If "No", *skip to 11*
If "Yes":

Describe the established device category(s) and provide a detailed explanation why the applicant believes the nominated device is not appropriately described by the established device category(s).

11. List existing devices including trade/brand name and any HCPCS Level I and/or Level II code(s) used to identify the existing device.

Enter device details to add them to the list.

- Device Trade/Brand Name

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Centers for Medicare & Medicaid
Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850

- HCPCS code
- Long Descriptor
- What makes the nominated device different?

12. Are there similar devices that would also become eligible for transitional pass-through payment status under the proposed additional category? (Yes/No)

If "No", *skip to 13*
If "Yes":

a. Provide the device names and manufacturer for all devices that could be eligible for transitional pass-through payments under the proposed device category.

13. Please upload all relevant booklets, pamphlets, brochures, product catalogs, price lists, and/or package inserts that further describe and illuminate the nature of the nominated device.

- Drag and drop a file to upload or "Browse File"
  Provide some details about the selected file
  - Page Number(s)
  - Summarize the supporting information contained in this file

14. Have you completed other MEARIS™ applications for this device? (Yes/No)

If "No", *skip to 15*
If "Yes":

h. **Provide information about your previous applications**
(users are required to add at least one application)
- Application type (selections):
  - New Technology Add-on Payments (NTAP)
  - Device Pass-through
  - Drug and Biological Pass-through
  - New Technology Ambulatory Payment Classification (APC)
  - Healthcare Common Procedure Coding System (HCPCS) Level II
  - International Classification of Diseases Request (ICD-10-PCS)
- Application status (optional) (selections):
  - Approved
  - Pending

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Centers for Medicare & Medicaid
Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850

- Denied
- Withdrawn

- Description
- Submission date (Optional)

C. FDA Info/Newness

15. Provide the information for the most recent FDA Marketing Authorization for the nominated device.

a. Select the type of FDA Marketing Authorization (selections):
- Premarket Notification 510(k)
- Premarket Approval (PMA)
- De Novo Classification
- Other

b. Provide the complete FDA Marketing Authorization indication.
c. Provide the date the FDA Marketing Authorization was received.
d. Upload a copy of the FDA Marketing Authorization approval letter(s). (required) .

Please note that attachments uploaded in this section will not be included in the public posting. Please avoid referring to any attachments in the responses provided in this section

Info: The FDA decision date (or in certain documented cases U.S. market availability) must be within 3 years of the application date for transitional pass-through payment.

16. Has the device received FDA Breakthrough Device designation? Yes/No

If “No” Skip to 17
If "Yes”:

a. Provide the complete FDA Breakthrough Device designation indication.
b. Provide the date the FDA Breakthrough Device was granted.
c. Upload a copy of the FDA Breakthrough Device designation approval letter. *Note:*
d. If the indication in the FDA section of this application does not match the Breakthrough Device designation in the attached letter, please provide an explanation.
e. If the device was granted FDA Breakthrough Device designation, please indicate if the device that is the subject of this application is the same device that was granted the Breakthrough Device designation: **(select one)**

-Yes, this is the designated device (explanation optional)

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Centers for Medicare & Medicaid
Services
Center for Medicare Management
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-No, this is not the designated device (explanation required)
-Does not apply

Please note that attachments uploaded in this section will not be included in the public posting. Please avoid referring to any attachments in the responses provided in this section.

Note: To be considered under the alternative pathway, the device must be part of FDA's Breakthrough Devices Program and have received marketing authorization for the indication covered by the Breakthrough Device designation.

17. Do you have a Category B Investigational Device Exemption (IDE) number? Yes/No Selecting "No" makes the "Provide your Investigational Device Exemption (IDE) number." field disabled.

a. Provide your Investigational Device Exemption (IDE) number
b. Provide the FDA decision date.
c. Upload a copy of the FDA IDE approval letter.
d. Provide the class assigned to the device (Class I, II, III, unclassified, N/A)
e. Provide additional information regarding your alternate regulatory pathway, providing the complete citation of the guidance level documentation.

Note: Please note that attachments uploaded in this section will not be included in the public posting. Please avoid referring to any attachments in the responses provided in this section.

18. Please upload any other relevant FDA supporting documents

- Drag and drop a file to upload or "Browse File"
- Page Number(s)
- Summarize the supporting information contained in this file
- If the name of the device in this application does not match the technology name in the attached letter(s), please provide an explanation.

Info: Please note that attachments uploaded in this section will not be included in the public posting. Please avoid referring to any attachments in the responses provided in this section.

D. <u>Cost Info</u>

19. What is the current cost of the entire nominated device to hospitals?

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Centers for Medicare & Medicaid Services
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Info: Current cost of the device to hospitals should be the actual cost paid by hospitals for the device net of all discounts, rebates, and incentives in cash or in kind.

20. Provide a breakdown of the current cost to the hospital for each individual component of the nominated device.

Enter component details to add them to the list.

- Item/Name of Component
- Current Cost
- Classification (selections):
    - One Time Use
    - Reusable
    - Capital Equipment
    - Other

21. Provide all relevant details and calculations to explain how cost of the device was determined including the cost per unit and average number of units per procedure.

22. If applicable, summarize any partial systems created by the components you listed.

*optional field

23. Provide a detailed explanation for each cost test, including the calculation.

- **1) Is the device cost at least 25% of the applicable APC payment rate to reach cost significance? Yes/No**
  (Highest Retail cost on application / Lowest APC rate available) x 100 = __ Percent
    - Calculation and Explanation
- **2) Does the device cost exceed the offset amount (the device related portion of the APC found on the offset list) by at least 25 percent? Yes/No**
  (Highest Retail cost on application / Offset amount) X 100 = __ Percent
    - Calculation and Explanation
- **3) Is the device cost minus the APC offset amount divided by the APC payment amount at least 10% of the APC payment amount? Yes/No**
  (Highest Retail cost on application – Offset amount) / APC payment) X 100 = __ Percent
    - Calculation and Explanation

24. Please upload all cost supporting documents (optional)

- Drag and drop a file to upload or “Browse File”
    - Page Number(s)

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Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850

- Summarize the supporting information contained in this file

E. Volume and Utilization

25. Provide sales and marketing information about the nominated device.

- What date was the nominated device first marketed in the United States and/or outside the United States?
  - US marketing date
  - International marketing date (optional)
- What date was the nominated device's first sale in the United States and/or outside the United States?
  - US sale date (optional)
  - International sale date (optional)
- Was there a market availability delay for the nominated device?
  - Yes
    - If "Yes", it makes the "Provide details of the market availability delay." field appear
  - No
    - If "No", it makes the "Provide details of the market availability delay." field disappear
- Provide details of the market availability delay.

26. Provide volume data for the proposed device category.

- How many units of the nominated device have been sold to date?
- How many facilities use the nominated device?
- Please outline the projected total annual utilization for both the nominated device and proposed device category as a whole. (required)

27. Please upload all volume and utilization supporting documents.

- Drag and drop a file to upload or "Browse File"
  - Page Number(s)
  - Summarize the supporting information contained in this file

F. Substantial Clinical Improvement

28. Do you have a Substantial Clinical Improvement claim? (Yes/No)

If "No", *skip to G*

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Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850

If “Yes”:

Info: Applicants are required to select 'Yes' unless the nominated device is part of FDA’s Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation in accordance with § 419.66(b)(1). Devices with FDA Breakthrough Device designation must have received marketing authorization for the indication covered by the Breakthrough Device designation to qualify for OPPS device pass-through payment on a quarterly or annual basis without demonstrating substantial clinical improvement.

Substantial Clinical Improvement Criterion

Info: A summary on the substantial clinical improvement (SCI) criterion can be found in the New Device Categories for Transitional Pass-through Payment Status under the Hospital Outpatient Prospective Payment System guidance. Additional information on the SCI criterion can be found in the November 10, 2005 OPPS final rule (70 FR 68630-68631). Additionally, the annual OPPS final rule includes CMS' decision making processes for each application.

Overview of SCI Criterion

The nominated device must demonstrate a substantial clinical improvement, that is, the device substantially improves the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

CMS uses the following in its evaluation of SCI for the purposes of device pass-through payment status applications:

1. *The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.*
2. *The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that the use of the new medical service or technology to make a diagnosis affects the management of the patient.*
3. *The use of the device significantly improves clinical outcomes relative to services or technologies previously available.*

The nominated device must demonstrate that it meets at least one of these three in order to be eligible for device pass-through payment status.

Instructions for the SCI Section

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Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Boulevard
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As you navigate through the Substantial Clinical Improvement section, you will be asked which of the sub-criteria you believe the device meets in order to demonstrate how the device meets the SCI criterion.

- *You will be able to enter one or more claims (i.e., reasons) under each sub-criterion.*
- *Each claim under a sub-criterion must be added individually.*
- *Provide one or more pieces of supporting evidence for each claim.*
- *For each piece of evidence uploaded, you will be asked to describe the upload and summarize details related to the upload, such as the reason for inclusion/relevance to the claim, citation, summary of the data source, and results from the study that support the claim.*
- *CMS may include attachments provided in this section as part of the public application posting. If any attachments are uploaded that cannot be made public due to copyright restrictions or other reasons, you must indicate that by selecting the checkbox under the upload.*
- *Once you provide responses for each of the SCI sub-criteria questions (including supporting evidence if applicable), you will be asked to provide a brief summary of these responses to explain overall why you believe the device demonstrates a substantial clinical improvement over existing technologies.*

Note: Responses to the questions should be limited to the text boxes provided and should not extend into supplemental attachments.

29. Does the device offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments? (Y/N)

IF NO, *skip to question 30.*

IF YES:

You stated that the device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

Please explain which patients have no other treatment options, and provide supporting data.

a) Add Claim - Claim Title
b) Please provide a full explanation
c) Add Supporting Evidence, if applicable
    i. Select an existing file or upload a new one
    Note: *Only one attachment may be entered at a time. You may select or upload additional supporting evidence for this claim after clicking "Save."*
    ii. Upload file and answer the following questions related to each upload:
        a. □ The applicant **<u>does not</u>** have the appropriate license or right to release this document to the public. If this box is checked, this document will not be included in the public posting.
        b. Title of the supporting evidence

Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850

c. Data Source category (choose one)
    - Published studies using the device
    - Unpublished studies using the device
    - Studies demonstrating outcomes for a comparator technology
    - Background/Contextual

d. Evidence Type (choose one)
    - Case-control Study
    - Case Reports and Case Series
    - Cohort Study
    - Cross-sectional Study
    - Meta-Analysis
    - Randomized Controlled Trial
    - Systematic Review
    - Other

e. Citation

f. Study summary: *Please clearly summarize the study in full, to include (at minimum) the purpose of the study, number of patients treated, study arms, demographics, inclusion/exclusion criteria, endpoints tested, and outcomes (specify if statistically significant).*

iii. Please explain why this uploaded file was provided in support of this claim

a. Reason for inclusion/relevance to the claim

b. What are the results/outcomes from this study that support this claim? Please be sure to provide the specific statistic(s)/value(s) in your response.

c. Provide the location of these results/outcomes (i.e. page number(s), paragraph, table number, etc., as applicable.)

30. Does the device offer the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods? There must also be evidence that use of the device to make a diagnosis affects the management of the patient. (Y/N)

IF NO, *skip to question 31.*

IF YES: (complete the same questions as under SCI question 29 "YES" flow)

You stated that the device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient.

Please include the medical condition and Medicare patient population relevant to this claim as well as the change in patient management in your explanation using supporting data. Add each reason as a separate claim.

Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850

31. Does the use of the device significantly improve clinical outcomes relative to services or technologies previously available? (Y/N)

IF NO, *skip to question 32.* ***NOTE: At least one of the responses to SCI questions 29, 30, or 31 must be a YES selection.***

IF YES: (complete the same questions as under SCI question 30 "YES" flow)

You stated that the device significantly improves clinical outcomes relative to services or technologies previously available.

Please explain how the device demonstrates improved outcomes compared to existing technologies using supporting data. Add each reason as a separate claim.

32. SCI Criterion Summary and Attestation

a) Please briefly summarize your responses to this section (H) regarding how the device meets the substantial clinical improvement criterion overall.

b) ☐ **I represent and warrant, on behalf of the applicant, that except for those documents for which I indicated otherwise, the applicant owns the copyright or otherwise has the appropriate license to make available all of the documents uploaded in this section to the public. I certify that I have been duly authorized to submit this representation on behalf of the applicant.**

G. Summary

Info: If there is any information that you wish to provide with your application that should not be posted publicly, it must only be added in the "Additional Application Information - CONFIDENTIAL" section below. Please note that we generally do not consider any information that cannot be made public when determining whether a technology meets the Device Pass-through criteria.

Additional Application Information – CONFIDENTIAL

Do you have any information that you wish to provide as part of your application that should not be made public? Please note that the information in this section will not be considered when determining whether a technology meets the OPPS Device Pass-through payment criteria, and will not be made public. (Yes/No)

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Centers for Medicare & Medicaid
Services
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If “Yes”:

a) Select section and corresponding information below: (selections)
    - Device Info
    - FDA Info/Newness
    - Cost Info
    - Volume and Utilization
    - Substantial Clinical Improvement
b) Confidential information about this section.
    Note: Data provided in this section may become subject to disclosure where required by law. CMS will attempt, to the extent allowed by law, to keep this information protected from public view.
c) Upload any relevant files (Optional).