



## **Welcome to the New Technology Add-On Payments (NTAP)**

### **Application Overview**

*Please note that the intention of this document is to serve as an overview of the FY 2025 NTAP application, but it does not replace the NTAP application within MEARIS™. DNT only accepts applications submitted through MEARIS™ beginning with the FY 2024 cycle.*

*Please note that the MEARIS™ is only accessible from within the U.S.*

### **Section 1: Important Information**

#### **How the online application works**

##### ***Fields and Inputs***

All fields are required unless marked as optional. Applications must include a response to each question below unless otherwise specified. Information must be entered directly onto this form. Do not copy and paste questions and answers into a different document.

##### ***Saving***

The application saves automatically when you click 'Next' so you can continue where you left off.

##### ***Supplemental Information***

CMS may request additional information by sending a Request for Information (RFI), which will display in the applicant's home page as a Task. The applicant will be able to respond to the Task, supplying the information that CMS is requesting. Applicants who wish to update or supplement their application should send an email to the CMS NTAP mailbox, [NewTech@cms.hhs.gov](mailto:NewTech@cms.hhs.gov), requesting to open the application for updates.

CMS may also request to update an application by sending a Request for Revision, which will display in the applicant's Home page as a Task. The applicant will be able to view details on the requested updates and revise their application via the Task.

##### ***Documents***

You are able to upload documents intermittently when completing your application. Uploads must be supported with a brief description and pages that support the question's subject. If an uploaded document supports multiple questions you may add additional comments to that file.

#### **Application Guidance**

You will need the following information to complete this application:

- Contact Information
- Technology Information
- Alternative Pathway designation status (for alternative pathway applicants)
- FDA Information (including FDA review status and documentation of either FDA marketing authorization or FDA acceptance/filing of the marketing authorization request)
- Coding and Cost Information
- Newness Criterion (for traditional pathway applicants)
- Substantial Clinical Improvement evidence (for traditional pathway applicants)

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An application is considered complete when all of the information requested has been submitted by the application deadline and when questions related to such information have been answered by the applicant.

Applications must include a response to each question unless otherwise specified. CMS may request other information in order to evaluate specific requests.

A separate application is required for each distinct technology or service included in a request. For example, if an applicant requests add-on payments for two unique technologies or services, a separate application is required for each technology or service.

### **About the NTAP Criteria and Pathways**

#### ***NTAP Background***

Section 1886(d)(5)(K) authorizes the Secretary to establish a special payment methodology for new medical services and technologies used in inpatient procedures. In general, to qualify for additional payments under this provision, data reflecting the cost of a new technology must not yet be in the data used to recalibrate the Medicare severity diagnosis-related groups (MS-DRGs), the MS-DRG payment rate otherwise applicable to the new technology would be inadequate, and the new technology must represent a substantial clinical improvement over existing technologies (see 42 CFR 412.87(b)).

These three criteria are also referred to as the newness criterion, cost criterion, and substantial clinical improvement criterion.

#### ***Alternative Pathways***

Some new medical services and technologies may be eligible to apply under an alternative NTAP pathway:

- **Alternative Pathway for Certain Transformative New Devices** - for technologies with a Breakthrough Device designation from FDA
- **Alternative Pathway for Certain Antimicrobial Products** - for technologies with a Qualified Infectious Disease Product (QIDP) designation from FDA, or for technologies approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)

Technologies that apply under an alternative pathway are considered not substantially similar to existing technologies and are considered to be a substantial clinical improvement but must still be within the 2-3 year newness period (as described below) and meet the cost criterion. Additional information regarding the eligibility criteria for the alternative pathway for certain transformative new devices can be found in 42 CFR 412.87(c) and eligibility criteria for the alternative pathway for certain antimicrobial products can be found in 42 CFR 412.87(d).

#### ***Newness Period***

A technology, service or drug is only eligible to receive NTAP if it is within the 2-3 year newness period, usually beginning from the date of FDA marketing authorization.

Note: An EUA is not considered FDA marketing authorization for the purposes of NTAP. For additional information on this discussion, we refer applicants to the FY 2023 IPPS final rule (86 FR 45160).

#### ***FDA Marketing Authorization Deadline***

Per § 412.87(f)(2) of the regulations, applicants for NTAP must receive FDA marketing authorization for their new medical service or technology by May 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective, except for QIDP/LPAD applicants. Per § 412.87(f)(3) of the regulations, a technology for which an application is submitted under the alternative pathway for certain antimicrobial products that does not receive FDA marketing authorization by July 1 prior to the particular fiscal year for which the applicant applied for new technology add-on payment may be conditionally approved for NTAP for a particular fiscal year, effective for discharges beginning in the first quarter after FDA marketing authorization is granted, provided that FDA marketing authorization is granted before July 1 of the fiscal year for which the applicant applied for new technology add-on payments. See the FY 2022 and FY 2024 IPPS final rule for additional details.

[Please refer to the NTAP webpage for additional details](#)

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### **NTAP Tracking Form Info**

Applicants will not be required to complete separate tracking forms when completing applications in MEARIS™. The tracking form information will be sourced from applicant responses to the following questions within this application, and posted on [CMS website](#) shortly after the application deadline:

1. Technology Name (trade and generic, as applicable)
2. Applicant Name
3. Application Pathway (traditional, alternative-QIDP/LPAD, or alternative-Breakthrough Device)
  - a. For alternative pathway applications, status of the designation (e.g., anticipated, already received)
4. Brief description of the technology

### **Annual New Technology Town Hall Meeting**

Section 1886(d)(5)(K)(viii) of the Act provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies, CMS holds an annual public town hall meeting at CMS Headquarters or virtually. Typically, traditional pathway applicants present at the meeting (to the public and to the clinical staff of CMS) regarding whether their technology represents a substantial clinical improvement. We anticipate holding a virtual town hall meeting for the FY 2025 application cycle.

The town hall meeting is announced annually in the Federal Register (sometime in September/October of each year). For FY 2025 applications, we expect this annual meeting to be held in December similar to last year. We expect the deadline to register to present at the town hall to occur in November similar to last year.

Applicants should monitor the [CMS website](#) for the announcement of the town hall in the Federal Register and registration deadline, as well as other relevant information including possible schedule changes.

**Application submission deadline: October 17, 2023**

**Supplemental information deadline to guarantee inclusion in the IPPS proposed rule: December 18, 2023.**

### **PRA Disclosure Statement**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1347 (Expires 11/30/2023). This is a required information collection. The time required to complete this information collection is estimated to average 27 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

### **CMS Disclosure**

Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact the CMS point of contact for this module using the form available at the bottom of the MEARIS™ Resource Page.

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## Section 2: NTAP Application Setup

### ***Let's set up your NTAP application***

You will not be able to change this selection.

Select which NTAP pathway you are applying under.

For additional information on the alternative pathways for transformative new devices and certain antimicrobial products, please refer to the *NTAP Criteria and Pathways* information above.

- Alternative
- **Traditional**

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## **Disclaimer**

All content submitted as part of this application may be made public unless otherwise noted below. Please see the FY 2023 IPPS final rule (87 FR 48986-48990) for a discussion of the policy to publicly post NTAP applications. Information that should not be made public is not taken into consideration when determining whether a technology meets the NTAP 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 or dates included in the “FDA Info” section related to FDA applications that are not yet approved or cleared, as indicated in the application.

Please note that the following application sections are not included in the public application posting. However, some of the information submitted within the following sections may still be included in the proposed or final rules, as indicated:

### *Cost*

- *For traditional pathway applications, information in this section may be included in the proposed and final rules. The cost of the technology will be only be included in the final rule (for technologies approved for NTAP).*

### *Volume*

- *The information in this section will only be included in the final rule (for technologies approved for NTAP).*

### *Cost Criterion*

- *The NTAP Cost Criterion Codes and MS-DRGs worksheet will be publicly posted.*
- *Other information in this section may be included in the proposed and final rules. Please note that the numerical value of any charges in this section will not be made public, with the exception of column S (Final Inflated Case Weighted Standardized Charge Per Case).*

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.

Please also note that application tracking forms will be posted on the CMS website shortly after the application deadline. Please refer to the *NTAP Tracking Form Info* above for additional information.

☐ 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 of 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 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

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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.

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## **Section 3: Traditional Pathway Application**

### **A. Contact Information**

*Info: The information in this section (A) will not be made public, except the name of the party requesting the NTAP. Please note that the MEARIS website can only be accessed by individuals who are located in the US.*

- 1. Who is the party requesting the NTAP?** (e.g. manufacturer, distributor, healthcare organization/entity)

**Provide a contact for the applicant.**

***Applicant Contact:***

- First Name
- Middle Name (optional)
- Last Name
- Phone number
- Organization
- Occupation / Job Title
- Extension (optional)
- Email Address
- Country
- Mailing Address 1
- Mailing Address 2 (optional)
- City
- State
- Zip
- Applicant Type (selections):
  - Distributor, Manufacturer, Healthcare Organization, Other (explain)

- 2. Who is the primary contact?** ☐ Select if this is the same as the Applicant Contact and the fields will auto-populate.

- First Name
- Middle Name (optional)
- Last Name
- US phone number
- Organization
- Occupation / Job Title
- Extension (optional)
- Email Address
- Country: United States
- Mailing Address 1
- Mailing Address 2 (optional)
- City

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- State
- Zip
- Relationship (selections):
  - Consultant, Manufacturer, Other (explain)

### **3. Who is the secondary contact?**

- First Name
- Middle Name (optional)
- Last Name
- US phone number
- Organization
- Occupation / Job Title
- Extension (optional)
- Email Address
- Country
- Mailing Address 1
- Mailing Address 2 (optional)
- City
- State
- Zip
- Relationship (selections):
  - Consultant, Manufacturer, Other (explain)

## **B. Technology Info**

*Note: If one of the name fields do not apply or is TBD, please leave the field blank.*

### **4. General Information**

- a) Applicant (*auto-populates based on question 1 above*)
- b) Trade Name
- c) Generic Name
- d) Please provide a brief (1-2 sentence) description of the technology.

### **5. Describe the technology in detail, using general terminology**

- a) What is the technology?
- b) What does the technology do?
- c) How is the technology used?

Upload relevant descriptive booklets, brochures, package inserts, or other supporting materials as needed (optional). *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. If using references, please use in-text citations rather than footnote numbering.*

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## 6. Additional Technology Information

- a) Is there an Investigational Device Exemption (IDE) number from the FDA assigned to the technology? (Yes/No)  
IF YES: IDE Number
- b) If the technology is a device, what class is assigned to the technology? (Class I, II, III, unclassified, N/A)
- c) If the technology is a drug, is this a drug that can only be administered orally? (Yes/No N/A)
- d) If the technology is a drug, what is the drug's dosage/administration information when used in the inpatient setting? Please clearly indicate the average total dose per inpatient stay.
- e) Has the technology ever been the subject of a recall or subject to any bulletins and/or letters issued by the FDA regarding the safety of the technology? (Yes/No)
  - o IF YES: Provide specific details regarding the recall, bulletins and/or letters issued by the FDA.

Please upload the recall, bulletins, or other documentation (REQUIRED IF YES IS SELECTED)

## 7. Have you completed any outpatient pass through applications for this technology? (Yes/No)

IF NO, *skip to question 8*

IF YES:

### 7a. Additional Technology Information

Was this application submitted using MEARISTM? (Yes/No)

IF YES, provide application type (Device OR Drug/Biological Pass through)

- Application Confirmation Number
- Provide Details (text box 3000 characters)

IF NO, provide application type (Device OR Drug/Biological Pass through)

- Submission Date
- Provide Details

## C. FDA Information

### 8. FDA Status

- a) What is the indication for the technology for which the applicant is submitting an NTAP application?
- b) List if the technology has received any designations from FDA or if it is being considered under any particular pathways by FDA such as Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review, etc. for this indication (optional)

### 9. Has the technology already received marketing authorization from the Food and Drug Administration (FDA) for the indication relevant to this application?

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*Info: To be considered for NTAP for FY 2025, the technology will need to receive FDA approval or clearance before 05/01/2024.*

Choose 1:

- Yes (if selected, complete question 9a and skip 9b)
- No, but the marketing authorization request has been accepted/filed by FDA and approval/clearance is expected before the FDA deadline (May 1, 2024) (if selected, skip question 9a)

#### 9a. Yes Sequence

##### FDA Approval/Clearance Details

- What is the type of the FDA application?  
*Examples: Premarket Notification 510(k), De Novo Classification, Premarket Approval Application (PMA), Humanitarian Device Exemption (HDE), New Drug Application (NDA), Biologic License Application (BLA)*  
☐ **Checkbox:** “Select if this is a 510(k) FDA application”
- What is the date of FDA approval?
- Upload FDA approval letter (required). *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.*
- Summarize the supporting information contained in the FDA approval letter.

#### 9b. No Sequence

##### FDA Submission Details

*Info: All of the FDA dates entered in this question (9b) will not be made public.*

- What is the date of FDA submission?
- What is the type of the FDA application?  
*Examples: Premarket Notification 510(k), De Novo Classification, Premarket Approval Application (PMA), Humanitarian Device Exemption (HDE), New Drug Application (NDA), Biologic License Application (BLA)*  
☐ **Checkbox:** “Select if this is a 510(k) FDA application”
- What is the expected action date from FDA? (eg PDUFA date/MDUFA goal date)
- Provide additional information about your FDA application. Include the review status of your application with FDA. For example, indicate whether it is accepted/filed and under review, on hold, denied, pending reapplication or submission of additional information, etc. ***Note:** As finalized in the FY 2024 IPPS final rule, technologies must be under active review by FDA at the time of NTAP application submission in order to be eligible for consideration. For additional information regarding this NTAP eligibility requirement, please see the regulations at § 412.87(e) and the FY 2024 IPPS final rule.*
- Upload the FDA acceptance or filing letter for this submission.  
***Note:** As finalized in the FY 2024 IPPS final rule, we are requiring the relevant acceptance letter (such as for 510k applications or De Novo Classification requests) or filing letter (such as for PMA, BLA, or NDA applications) from FDA which indicates that*

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*FDA has determined that the application is sufficiently complete to allow for substantive review by FDA.*

**IF 510(k) CHECKBOX IS SELECTED, answer the following question. If not, skip to question 11.**

**Please provide additional information regarding the 510(k) clearance**

- List the predicate device(s) for the technology.
- Describe any differences between the devices.

**10. FDA Contact** *The information in this question (10) will not be made public.*

Please provide contact information for the FDA reviewer most knowledgeable about your application.

- First Name
- Middle Name (optional)
- Last Name
- US Phone Number
- Email Address

**11. Market Availability**

Was this technology available on the market immediately after FDA approval **OR** if not yet approved, do you anticipate that it will be available immediately after FDA approval? (Yes/No)

IF YES, *skip to question 12.*

IF NO:

- a) Please describe the reason for the delay in market availability.
- b) When did the technology become available for sale, or when do you anticipate the technology becoming available?

**12. Additional FDA Information**

Please describe any previous US approvals/clearances for this technology. Include any additional approvals (e.g. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology received prior to submission of this application and/or is currently seeking, including approvals for other indications or clearances for other versions of this technology. CMS recommends a timeline if the technology has received multiple types of approvals from the FDA.

**D. Coding and MS-DRGs**

*If the technology/device utilized in the performance of a procedure/service or the administration of a drug/therapeutic agent were to receive add-on payment status approval, it would need to be distinctly identifiable by a unique code, such as ICD-10-PCS procedure code(s), with or without ICD-10-CM diagnosis codes, on the claim in order to receive the add-on payment. The ICD-10 Coordination and Maintenance (C&M) Committee is responsible for approving coding changes, developing errata, addenda, and other modifications. Requests for coding changes are submitted to the committee for discussion at either the Spring or Fall C&M meeting. If any coding changes are necessary to distinctly identify your technology by ICD-10-CM diagnosis and/or ICD-10-PCS procedure code(s), you **MUST** separately contact the ICD-10 C&M Committee to submit a*

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code request. For more details, including the deadlines to submit code requests, refer to the [New/Revised ICD-10-PCS Procedure Codes Requests](#) and [ICD-10 Coordination and Maintenance Committee](#) for diagnosis code requests.

### 13. ICD-10-CM Diagnosis Codes

- a) List the ICD-10-CM diagnosis codes, with titles, that may currently be used to identify the indication/proposed indication relevant to the application under the ICD-10-CM coding system:

***Note: Please use standard formatting for ICD-10-CM/PCS codes in your response. Standard formatting for ICD-10-CM/PCS codes has the descriptor following the code in parentheses, and capitalizes only the first letter of the descriptor. Example: I21.A1 (Myocardial infarction type 2)***

- b) Explain why these diagnosis code(s) were included.

### 14. ICD-10-PCS Procedure Codes

- a) List the ICD-10-PCS procedure codes, with titles, that may currently be used to identify your technology under the ICD-10-PCS coding system.

***Note: Please use standard formatting for ICD-10-CM/PCS codes in your response. Standard formatting for ICD-10-CM/PCS codes has the descriptor following the code in parentheses, and capitalizes only the first letter of the descriptor. Example: 047KOZZ (Dilation of right femoral artery, open approach)***

- b) Do these codes uniquely identify your technology under the ICD-10-PCS coding system? (Yes/No) Please explain.
  - **IF NO:** Have you submitted or will you be submitting an application for a unique ICD-10-PCS code?

### 15. Existing technologies using ICD-10-CM/ICD-10-PCS

List existing technologies that use the same ICD-10-PCS codes or a combination of the ICD-10-CM/PCS codes.

### 16. ICD-10 C&M Committee Request

- a) Does this technology have an existing request pending with the ICD-10 C&M Committee for a new code? (Yes/No)
- b) Explain the reason for your answer above, and any details you have about status of requests with the ICD-10 C&M Committee, if applicable.

### 17. MS-DRGs

- a) Under the MS-DRG grouper, list all of the MS-DRGs that the technology would currently map to based on the indication (diagnosis) that is the subject of this NTAP application.

***Note: Please refer to the latest version of the ICD-10 MS-DRGs list on the [MS-DRG Webpage](#) for the current list of MS-DRGs and titles.***

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***Note: Please use standard formatting for MS-DRGs in your response. Standard formatting for MS-DRGs has the descriptor following the MS-DRG number in parentheses, and capitalizes the first letter of each word, except for common words like “and,” “with,” etc. Example: 004 (Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face Mouth and Neck without Major O.R. Procedures).***

- Comments related to the MS-DRGs listed above (optional)
- b) Have you made, or do you anticipate making, a request to map to a new or different MS-DRG(s) for the upcoming Fiscal Year 2025? (Yes/No)  
IF YES, please provide details.

## **E. Newness Criterion**

### **18. Current treatments for the disease or condition that this technology treats or diagnoses**

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

### **19. Substantial Similarity Criteria**

*Info: To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the Medicare-Severity Diagnosis Related Groups (MS-DRGs). CMS has established three substantial similarity criteria to determine if a technology is similar to an existing technology. (Refer to 70 FR 47351 through 47352 and 74 FR 43813 through 43814 for additional details.)*

*Note: A technology can be considered “new” as long as one of the three criteria are NOT met.*

- a) Does the technology use the same or a similar mechanism of action when compared to existing technology to achieve a therapeutic outcome? (Yes/No)
  - i. Explain why or why not?
- b) Has the technology been assigned to the same MS-DRG when compared to an existing technology to achieve a therapeutic outcome? (Yes/No)
  - i. Explain why or why not?
- c) Does the use of the technology involve treatment of the same or similar type of disease and patient population when compared to an existing technology? (Yes/No)
  - i. Explain why or why not?

### **20. Newness Criterion Summary**

- a) Please briefly summarize your responses to the previous slide regarding how the technology meets the newness criterion overall.
- b) Upload files related to the newness criterion as needed (optional)

## **F. Cost and Volume**

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*Info: The information in this section (F) will not be included in the public posting but may be included in the proposed and final rules.*

## **21. Technology Cost**

- a) What is the current or anticipated cost of this technology to the hospital, per inpatient stay?

*Note: The cost of the technology will **only** be included in the final rule (for applications approved for NTAP).*

- b) How was the total cost per inpatient stay determined? Please include all relevant details and calculations to explain how the cost was determined.

*Note: **For devices**, include the cost per unit and the average number of units per inpatient stay or for technologies sold on a subscription basis, an explanation of how the cost per case is calculated, including the list price of the technology and utilization across subscribers. **For drugs**, include the cost per unit/vial as well as the average dosage and number of vials per inpatient stay (whole vials if single-use) and/or units per patient (ml/kg/hr). Please provide specific details about how that average was determined (e.g., how the drug is sold (such as x vials per box), variables in the Medicare population that effects the dosage administration (body weight, disease progression, etc.), whether and how the average is weighted based on those variables, etc.).*

- Indicate if this is a device: **Yes/No**

*If YES, you will be asked to provide a breakdown of the cost of each component in the next question. If NO, skip to question 23.*

- c) Upload files or materials that support the cost of the technology and how it was calculated (optional)

## **22. Cost Breakdown (for devices)**

*Info: Include a breakdown of the cost of the device components used in the per inpatient stay calculation (ie, relevant to the NTAP payment amount), clearly showing which components are the "new" ones. **Note:** Capital costs are not included in new technology add-on payments under the IPPS. (Refer to 72 FR 47307-47308 for further details.)*

- a) Provide a breakdown of how the cost of the technology is calculated and identify if any components are capital costs. For each component, include the following:
- Name of Component
  - Type of Cost (capital vs operating)
  - Component Cost
  - Is this component new? (Yes/No)
- b) You may provide comments regarding the cost breakdown here (optional)

## **23. Volume**

*Info: The information in this question (#23) will not be included in the public posting but will be included in the final rule (for technologies approved for NTAP).*

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*Note: The volume estimates should be based on the actual or projected sales of your technology, not the total population eligible for the technology.*

*Current Fiscal Year: (10/01/2023 - 09/30/2024) Upcoming Fiscal Year: (10/01/2024 - 09/30/2025)*

**a) What is the anticipated inpatient Medicare volume of this technology for the current and upcoming Fiscal Year?**

- i. Current Fiscal Year Anticipated Inpatient Medicare Volume
  - Please describe how you arrived at this estimate.
- ii. Upcoming Fiscal Year Anticipated Inpatient Medicare Volume
  - Please describe how you arrived at this estimate.

**b) What is the anticipated inpatient non-Medicare volume of this technology for the current and upcoming Fiscal Year?**

- i. Current Fiscal Year Anticipated Inpatient Non-Medicare Volume
  - Please describe how you arrived at this estimate.
- ii. Upcoming Fiscal Year Anticipated Inpatient Non-Medicare Volume
  - Please describe how you arrived at this estimate.

## **G. Cost Criterion**

*Info: The information in this section (G) will not be included in the public posting except for the NTAP Cost Criterion Codes and MS-DRGs worksheet. The information in this section may be included in the proposed and final rules. Please note that the numerical value of any charges in this section will not be made public, with the exception of column S (Final Inflated Case Weighted Standardized Charge Per Case).*

### **24. Cost Criterion**

Click here for guidance about the cost criterion.

See Appendix A for an explanation of how to standardize charges per case if multiple MS-DRGs are affected by the technology.

- a) Step 1: Download the FY2025 NTAP Cost Analysis spreadsheet (*available for download on the CMS webpage*).  
Using the table as demonstrated in the spreadsheet as a template, show how the standardized charge per case (if applicable, case weighted) exceeds the threshold for the cost criterion. Please be sure the formulas are retained in the cells when using the spreadsheet. You may add additional tabs for additional analyses or to provide supporting data.
- b) Step 2: Upload the completed Cost Analysis Spreadsheet.
- c) Step 3: Does the final inflated average case-weighted standardized charge per case exceed the average case-weighted (if applicable) threshold for the cost criterion?  
(Yes/No)
  - o Comments (optional)

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### **Cost Analysis Methodology**

**25. With regard to the cost analysis spreadsheet, please detail the ICD-10-PCS/CM codes and MS-DRGs used to identify cases in your cost analysis/analyses.**

- a) Step 1: Download the NTAP Cost Criterion Codes and MS-DRGs spreadsheet and complete the tables as demonstrated in the spreadsheet.
- b) Step 2: Upload the completed “NTAP Cost Criterion Codes and MS-DRGs” spreadsheet.  
*Note: This spreadsheet will be included in the public application posting, and information from this spreadsheet may be included in the proposed and final rules.*
- c) Comments (optional)

**26. Please provide the type of source data and year that was used to identify cases (such as “FY 2022 MedPAR” or “100% sample FY 2022 SAF”).** If you did not use the most recently available claims data or if you used other types of source data, please also explain why. *Note: The most recent claims data for the upcoming application year would be 3 years prior (for example, for FY 2025 applications, the most recent claims data would be from FY 2022).*

**27. Use the following questions A through S (which correspond to columns A through S of the cost analysis spreadsheet) to explain in detail how each column was completed, step-by-step.**

- **A. MS-DRG**  
Explain how these MS-DRGs were determined, including any differences between multiple analyses if applicable. Please also discuss relevant decision points in choosing to include/exclude ICD-10-PCS/CM codes for identifying cases. If there are any other inclusion/exclusion criteria please describe them here as well.
- **B. Cases**  
*Note: In compliance with the CMS data use agreement, the aggregate amount of cases listed for each MS-DRG in the table must indicate a minimum of 11; applicants should impute a value of 11 for any MS-DRG included with a number under 11.*
- **C. Case Weighted Amount**
- **D. Threshold**  
*Note: Please confirm the thresholds used were from the prior year’s final rule/correction notice. For example: for FY 2025 applications, the thresholds from the FY 2024 final rule (or correction notice, if applicable) should be used.*
- **E. Case Weighted Threshold**
- **F. Average Charge Per Case (Unstandardized with No Case Weight)**
- **G. Average Charge Per Case (Unstandardized with Case Weight)**
- **H. Charges Removed for the Prior Technology or Technology Being Replaced**  
*Note: Please also discuss the assumptions behind removing (or not removing) charges for prior technologies. For example, if a technology is replacing the implantation of a different device, explain how the removal of charges for the previous device was determined; do not remove related charges such as operating room (OR) and/or intensive care unit (ICU) charges in this column.*

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- I. Related Charges Removed for the Prior Technology or Technology Being Replaced  
*Note: Please also discuss the assumptions behind removing (or not removing) related charges for prior technologies. For example, if the technology is replacing the implantation of a different device and requires less or more OR time and ICU days, explain how the removal of related charges such as OR/ICU charges were determined.*
- J. Adjusted Average Charge Per Case (Unstandardized with No Case Weight)
- K. Adjusted Average Charge Per Case (Unstandardized with Case Weight)
- L. Average Standardized Charge Per Case  
*Note: Please include sources for provider-specific factors used to standardize charges (for example, use of the FY 2022 final rule/correction notice impact file).*
- M. Average Standardized Charge Per Case with Case Weight
- N. Inflation Factor  
*Note: The inflation factor should be aligned with the year of claims data used, and the year for which the applicant is applying for NTAP. For example, when using FY 2022 MedPAR data and applying for FY 2025 NTAP, a three-year inflation factor would be appropriate.*
- O. Inflated Average Standardized Charges Per Case
- P. Charges Added for the New Technology  
Please explain how the current and/or anticipated charges for the technology by the hospital, per patient, were determined. Please confirm that the most recent national cost center CCRs (listed in the cost analysis spreadsheet) were used to convert cost to charges, if applicable. *Note: The charges here should be only based on direct costs of the drug/device itself, and not related costs such as OR/ICU charges.*
- Q. Related Charges Added to the New Technology  
*Note: The charges here should be only based on indirect costs related to use of the drug/device, such as OR/ICU charges. Please also discuss the assumptions behind adding (or not adding) related charges for the new technology.*
- R. Final Average Inflated Standardized Charge Per Case
- S. Final Inflated Case Weighted Standardized Charge Per Case

## **H. Substantial Clinical Improvement**

*Info: A summary on the substantial clinical improvement (SCI) criterion can be found in [Appendix B](#). Additional information on the SCI criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14), the FY 2010 IPPS Final Rule (74 FR 43808-43823) and the [FY 2020 IPPS Final Rule \(84 FR 42288-42292\)](#). Additionally, the annual IPPS final rule includes CMS' decision-making processes for each application.*

### ***Overview of the SCI Criterion***

*CMS uses the following in its evaluation of SCI for the purposes of the NTAP:*

1. *The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.*

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2. *The new medical service or technology 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 new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available.*

*A technology must demonstrate that it meets at least one of these three in order to be eligible for NTAP.*

### **Overview of the SCI Section**

*As you navigate through the Substantial Clinical Improvement section, you will be asked how the technology meets the SCI criterion. For each assertion made, you will be asked to explain why you believe the technology meets the SCI criterion. Each reason the technology meets the SCI criterion will need to be added as a separate claim, using supporting data as applicable.*

- *You will be able to enter one or more claims (i.e., reasons) for each assertion made.*
- *Each claim for an assertion must be added individually.*
- *If you have evidence to support a claim, you will be able to 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 Criterion 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 technology demonstrates a substantial clinical improvement over existing technologies.*

### **28. Does the new medical service or technology offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments? (Y/N)**

**IF NO,** *skip to question 29.*

**IF YES:**

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

Please provide an explanation for this assertion using supporting data. Add each reason as a separate claim.

- a) Add Claim - Claim Title
- b) Please provide a full explanation
- c) Add Supporting Evidence, if applicable

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- 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:
- ☐ The applicant **does not** 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.
  - Title of the supporting evidence
  - Data Source category (choose one)
    - Published, peer, reviewed studies using the technology
    - Unpublished studies, abstracts, or presentations using the technology
    - Other data submissions
    - Data submissions as background (does not directly assess the technology)
  - 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
  - Citation
  - 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
- Reason for inclusion/relevance to the claim
  - 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.
  - Provide the location of these results/outcomes (i.e. page number(s), paragraph, table number, etc., as applicable.)

**29. Does the new medical service or technology 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 new medical service or technology to make a diagnosis affects the management of the patient. (Y/N)**

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IF NO, skip to question 30.

IF YES: (complete the same questions as under SCI question 28 “YES” flow)

**30. Does the use of the new medical service or technology significantly improve clinical outcomes relative to services or technologies previously available? (Y/N)**

IF NO, skip to question 31. **NOTE: At least one of the responses to SCI questions 28, 29, or 30 must be a YES selection.**

IF YES: (complete the same questions as under SCI question 28 “YES” flow)

**31. SCI Criterion Summary and Attestation**

- a) Please briefly summarize your responses to this section (H) regarding how the technology 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.

**I. 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 NTAP 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 NTAP criteria and will not be made public. (Y/N)

IF YES:

- a) Select section and corresponding information below (add more than one if desired):  
(CHOOSE RELEVANT APPLICATION SECTIONS (INDICATED WITHIN THIS APPLICATION OVERVIEW AS HEADER TITLES A-H))
- 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)

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## **Appendix A: Standardizing Charges**

We standardize charges in order to compare charges equally amongst all hospitals. Standardized charges are charges per case after removing the wage index, indirect medical education (IME) and disproportionate share hospital (DSH). The formula below explains how to calculate standardized charges per case.

In order to standardize charges, you must obtain hospital specific operating cost-to-charge ratio (CCR), capital CCR, DSH (operating and capital), IME (operating and capital), Wage Index, GAF and COLA.

**Note:** Use all values (DSH, IME etc...) from the fiscal year that corresponds to the year that the claim(s) is/are being submitted from including the Labor and Non Labor share percentage. Also, different labor and non-labor percentages may apply for hospitals with a wage index over or under 1 depending on the fiscal year.

### **Formula to Standardize Charges:**

**Capital Charges:** The formula to calculate the Capital Standardized Charge is below.

1. Capital Standardized Charge = (((Capital CCR/(Capital CCR + Operating CCR)) \* Covered Charges) / (1 + Capital IME + Capital DSH)) / GAF) / (1 +(0.3152\*(COLA-1)))

**Operating Charges:** The formula to calculate the operating standardized charge is a two-step process; first you must calculate the Adjusted Operating Charge (AOC) then use the calculated AOC to compute the Operating Standardized Charge.

2. Adjusted Operating Charge (AOC) = ((Operating CCR / (Capital CCR + Operating CCR)) \* Covered Charges) / (1 + Operating IME + Operating DSH)
  - If wage index is greater than 1:
    - i) Operating Standardized Charge = ((AOC\* Labor Share %) / wage index) + ((AOC \* Non Labor Share %) / COLA)
  - If wage index is less than 1:
    - ii) Operating Standardized Charge = ((AOC \* .62) / wage index) + ((AOC \* .38) / COLA)

**Total Standardized Charges:** The formula to calculate Total Standardized Charges is below.

3. Standardize Charges = Capital Standardize Charges + Operating Standardized Charges

### **Definition Key**

-The Labor share percentages and Non Labor share percentages can be obtained from Table 1A of the annual IPPS final rule. 11 -COLA is always equal to 1, except for hospitals in Alaska and Hawaii. -Operating CCR, capital CCR, DSH (operating and capital), IME (operating and capital), Wage Index, GAF and COLA values by provider can be obtained by downloading the Public Use Files at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html> or <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-InpatientFiles-for-Download.html> or <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-ImpactFiles-for-FY-1994-through-Present.htm>

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## **Appendix B: SCI**

CMS uses the following aspects to evaluate Substantial Clinical Improvement for purposes of the add-on payment for a new technology (see 42 CFR 412.87(b)):

1. The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
2. A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means:
  - o The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
  - o The new medical service or technology 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.
  - o The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following:
    - A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication.
    - A decreased rate of at least one subsequent diagnostic or therapeutic intervention (for example, due to reduced rate of recurrence of the disease process).
    - A decreased number of future hospitalizations or physician visits.
    - A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time;
    - An improvement in one or more activities of daily living.
    - An improved quality of life;
    - A demonstrated greater medication adherence or compliance.
  - o The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
3. Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.
4. The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.
5. The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

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