

Application for New Medical Services and Technologies Seeking to Qualify for Add-On Payments Under the Hospital Inpatient Prospective Payment System for FY 2024

MEARIS™
Medicare Electronic Application Request Information System™

Home Tasks Applications Teams

Let's set up your NTAP application

You will not be able to alter or change these selections in the application

Which of the following describes the new technology for which you are applying for NTAP?

Medical Device or Service

Drug

Select which NTAP pathway you are applying under.

i For additional information on the alternative pathways for transformative new devices and certain antimicrobial products, please refer to the [NTAP Criteria and Pathways information](#).

Alternative (QIDP/LPAD)

Traditional

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{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway

Contact Info Technology Info FDA Info Coding Newness Criterion Cost Charge Volume of Cases Substantial Clinical Improvement Summary

Who is the primary contact?

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 		
<div style="border: 1px solid #ccc; padding: 5px; background-color: #f9f9f9;"><p>Applicant</p><p>Consultant</p><p>Other</p></div>		

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Who is the secondary contact?

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
		

- Applicant
- Consultant
- Other

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Contact Info **Technology Info** FDA Info Coding Newness Criterion Cost Charge Volume of Cases Substantial Clinical Improvement Summary

General Information

Trade name

RapidAI

Generic name

Provide a brief description of the technology.

Provide response

0/500

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Describe the technology in detail, using general terminology

What is the technology?

Explain

0/3000

What does the technology do?

Explain

0/3000

How is the technology used?

Explain

0/3000

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

Uploaded Files

It looks like there is nothing here

Supported formats include PDF, Word, Excel, PowerPoint, JPEG, PNG, and plain text files

Drag and drop files to upload or

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Additional Technology Information

Is there an Investigational Device Exemption (IDE) number from the FDA assigned to the technology?
[For more information on IDE number click here](#)

Yes No

IDE number _____

What class is assigned to the technology?
[For more information on device class click here](#)

Class _____

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

Provide specific details regarding the recall or any bulletins and/or letters issued by the FDA regarding the safety.

Details _____

0/3000

Please upload any recall or bulletins/letters here

Uploaded Files

Broucher 1.pdf Delete

Supported formats include PDF, Word, Excel, PowerPoint, JPEG, PNG, and plain text files

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Additional Technology Information

Is this a drug that can only be administered orally?

Yes No

What is the drug's dosage information?

Brief device or service summary

0/3000

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

Provide specific details regarding the recall or any bulletins and/or letters issued by the FDA regarding the safety.

Details

0/3000

Please upload any recall or bulletins/letters here

Uploaded Files

Broucher 1.pdf

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Contact Info **Technology Info** Alternative Pathway Designation FDA Info Coding Cost Charge Volume of Cases Summary

Have you completed any outpatient pass-through applications for this technology?



Yes



No

 Refer to <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html> for more information.

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Provide information about your previous pass-through applications

Was this application submitted using MEARIS™?

Yes No

Application Type ▼

Application Confirmation Number 🔍 Application Date
This field will auto-populate based on Confirmation Number

Description

Add Application

Previous application list

Submitted using MEARIS™ : {{Yes}}	Application Date : {{mm/dd/yyyy}}	
{{application Type}}		Remove
Confirmation Number:{{ Application Confirmation Number}}		
Description:{{application description}}		
Submitted using MEARIS™ : {{No}}	Application Date : {{mm/dd/yyyy}}	
{{application Type}}		Remove
Tracking Number:{{ Application Confirmation Number}}		
Description:{{application description}}		

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Contact Info Technology Info **Alternative Pathway Designation** FDA Info Coding Cost Charge Volume of Cases Summary

Has the technology received a Breakthrough Device designation from FDA?



Yes



No

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Alternative Pathway Designation

i For additional information on the alternative pathways for transformative new devices and certain antimicrobial products, please refer to the [NTAP Criteria and Pathways Information](#).

When was the technology granted the Breakthrough Device designation?

Date

What is the Breakthrough Device designation for?

Note: The marketing authorization indication in the FDA section of this application must be the same as the Breakthrough Device designation.

Provide response

0/3000

Upload a copy of the Breakthrough Device designation letter.

Uploaded Files

It looks like there is nothing here

Supported formats include PDF, Word, Excel, PowerPoint, JPEG, PNG, and plain text files

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Alternative Pathway Designation

i For additional information on the alternative pathways for transformative new devices and certain antimicrobial products, please refer to the [NTAP Criteria and Pathways information](#).

Date of submission.

Date

Anticipated designation date.

Date

What is the proposed indication submitted for Breakthrough Device designation?

Note: The marketing authorization indication in the FDA section of this application must be the same as the Breakthrough Device designation.

Provide response

0/3000

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Has the technology received a QIDP designation or approval under the LPAD pathway from FDA?

QIDP Designation

LPAD Approval

Both QIDP Designation and LPAD Approval

Has not received a QIDP Designation or Approval under the LPAD pathway

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Alternative Pathway Designation

 For additional information on the alternative pathways for transformative new devices and certain antimicrobial products, please refer to the [NTAP Criteria and Pathways Information](#).

When was the technology granted the QIDP designation?

Date 

What is the QIDP designation for?

Note: The marketing authorization indication in the FDA section of this application must be the same as QIDP/LPAD indication.

Provide response

0/3000

Upload a copy of the QIDP letter

Uploaded Files

It looks like there is nothing here

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Contact Info Technology Info **FDA Info** Coding Newness Criterion Cost Charge Volume of Cases Substantial Clinical Improvement Summary

Has the technology received marketing authorization from the Food and Drug Administration (FDA) for the indication under which the applicant is applying for NTAP?

i To be considered for NTAP 2024 the technology will need to receive FDA approval or clearance by 07/01/2023.

 Approved	 Pending Approval	 Have Not Applied Yet
---	---	---

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NTAP Indication

What is the indication for the technology for which the applicant is submitting an NTAP application?

Details

0/3000

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)

Details

0/250

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Contact Info Technology Info **FDA Info** Coding Revenue Criteria Cost Charge Volume of Cases Substantial Clinical Improvement Summary

FDA Approval/Clearance Details

Select if this is a 510k FDA application

What is the type of the FDA application?

Provide response

0/3000

What is the date of FDA approval?

Approval date

Summarize the supporting information contained in the FDA approval letter.

Summary

0/3000

Upload FDA approval letter

Uploaded Files


It looks like there is nothing here

Supported formats include PDF, Word, Excel, PowerPoint, JPEG, PNG, and plain text files

Drag and drop files to upload or [Browse Files](#)

[Add FDA application to list](#)

FDA Application List

{{FDA Application Type}}	{{ Submission date}}	Remove
{{Summary}}		
 Attachment		

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Please provide additional information regarding the 510(k) clearance

List the predicate device(s) for the technology.

Predicate device

Describe any differences between the devices.

Differences

0/500

Add predicate to list

Predicate device list

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Calendar info Technology info Alternative pathway designation **FDA info** Coding Cost Charge Volume at Cases Summary

FDA Approval/Clearance Details

Select if this is a 510k FDA application

What is the type of the FDA application?

Provide response

0/3000

What is the date of FDA approval?

Approval date

Summarize the supporting information contained in the FDA approval letter.

Summary

0/3000

Upload FDA approval letter

Uploaded Files

It looks like there is nothing here

Supported formats include PDF, Word, Excel, PowerPoint, JPEG, PNG, and plain text files

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Add FDA application to list

FDA Application List

{{FDA Application Type}}

{{ Submission date}}

Remove

{{Summary}}

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CONTACT INFO TECHNOLOGY INFO **FDA Info** CODING BUSINESS CRITERIA COST CHANGE YOUNG AT RISK SUBSIDIZED Clinical Improvement Summary

FDA Approval/Clearance Details

What is the type of the FDA application?

Provide response

0/3000

What is the date of FDA approval?

Approval date

Summarize the supporting information contained in the FDA approval letter.

Summary

0/3000

Upload FDA approval letter

Uploaded Files

It looks like there is nothing here

Supported formats include PDF, Word, Excel, PowerPoint, JPEG, PNG, and plain text files

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Add FDA application to list

FDA Application List

{{FDA Application Type}}

{{ Submission date}}

Remove

{{Summary}}

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FDA Approval/Clearance Details

What is the type of the FDA application?

Placeholder text

0/3000

What is the date of the FDA submission?

Submission date

Have you received an action date from FDA?

Yes No

Action date from FDA

Provide additional information about your FDA application.

Summary

0/3000

Upload any FDA related documents (optional)

Uploaded Files

It looks like there is nothing here

Supported formats include PDF, Word, Excel, PowerPoint, JPEG, PNG, and plain text files

Drag and drop files to upload or [Browse Files](#)

[Add FDA application to list](#)

FDA Application List

[[FDA Application Type]]	[[Submission date]]
[[Action date/ anticipated approval date]]	
Attachment	

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FDA Submission Details

What is the type of the FDA application (i.e. PMA, De Novo Classification, 510(k) clearance)?

Provide response

0/3000

What is the FDA Submission date?

Submission date

Have you received an action date from FDA?

Yes No

Anticipated approval date

Provide additional information about your FDA application.

Summary

0/3000

Upload any FDA related documents (optional)

Uploaded Files

It looks like there is nothing here

Supported formats include PDF, word, excel, Powerpoint, JPEG, PNG, and plain text files

Drag and drop files to upload or

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Add FDA application to list

FDA Application List

[[FDA Application Type]]	[[Submission date]]	Remove
[[Action date/ anticipated approval date]]		
Attachment		

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Who is the FDA contact?

First name	Middle name (optional)	Last name
US Phone Number		
Email address		

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Was this technology available on the market immediately after FDA approval?

 Yes	 No
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Reason for the delay

Please describe the reason for the delay in market availability.

Explanation for the delay

0/3000

When did the technology become available for sale, or when do you anticipate the technology becoming available?

Date of market availability



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Additional FDA Information

i Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology has received multiple types of approvals from the FDA.

Please describe any previous US approvals/clearances for this technology.

Provide response

0/3000

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Contact Info Technology Info FDA Info **Coding** Newness Criterion Cost Charge Volume of Cases Substantial Clinical Improvement Summary

Coding Information

 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 NDC(s) or 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 code request. For more details, including the deadlines to submit code requests, refer to <https://www.cms.gov/Medicare/Coding/ICD10/newrevisedcodes> for procedure code requests and https://www.cdc.gov/nchs/icd/icd10_maintenance for diagnosis code requests.

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{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway

Contact Info Technology Info FDA Info **Coding** Newness Criterion Cost Charge Volume of Cases Substantial Clinical Improvement Summary

ICD-10-CM Diagnosis Codes

List the diagnosis codes that may currently be used to identify the indication/proposed indication relevant to the application under the ICD-10-CM coding system.

ICD-10-CM code	ICD-10-CM title
<p>Summarize the diagnosis code.</p> <p>Provide response</p> <p>0/200</p>	

Add codes to list

ICD-10-CM code list

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Contact Info Technology Info Alternative Pathway Designation FDA Info **Coding** Cost Charge Volume of Cases Summary

ICD-10-CM Diagnosis Codes

List the diagnosis codes that may currently be used to identify the indication/proposed indication relevant to the application under the ICD-10-CM coding system.

ICD-10-CM code	ICD-10-CM title
<p>Summarize the diagnosis code.</p> <p>Provide response</p> <p>0/200</p>	
<p>Is this diagnosis code specific to the indication listed under the Breakthrough Device designation?</p> <p>Provide response</p> <p>0/200</p>	

Add codes to list

ICD-10-CM code list

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ICD-10-PCS Procedure Codes

Do these codes uniquely identify your technology under the ICD-10-PCS coding system?

Yes No

Please Explain

Description

0/200

Have you submitted or will you be submitting an application for a unique ICD-10-PCS code?

Description

0/200

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Contact info Technology Info FDA info **Coding** Newness Criterion Cost Charge Volume of Cases Substantial Clinical Improvement Summary

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

Existing technologies using ICD-10-CM \ ICD-10-PCS or combinations.

Existing technologies

0/3000

Your ICD-10-CM codes:

{{CM code}}

Your ICD-10-PCS codes:

{{PCS code}}

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Contact Info Technology Info Alternative Pathway Designation FDA Info **Coding** Cost Charge Volume of Cases Summary

ICD-10 C&M Committee Request

Does this technology have an existing request pending with the ICD-10 C&M Committee for a new code?

Yes No

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.

Explanation

0/3000

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Current treatments for the disease or condition that this technology 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.

Provide response

0/3000

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Home Name: New Technology Add-on Payments (NTAP) | Device | Traditional | pdf view

Device Info Technology Info FDA Info Coding **Newness Criteria** Cost Charge Volume of Cases Substantial Clinical Improvement Summary

Substantial Similarity Criteria

- 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.)
- A technology can be considered "new" as long as one of the three criteria are NOT met

Does the technology use the same or a similar mechanism of action when compared to existing technology to achieve a therapeutic outcome?

Yes No

Explain why or why not?

Provide response

0/3000

Has the technology been assigned to the same MS-DRG when compared to an existing technology to achieve a therapeutic outcome?

Yes No

Explain why or why not?

Provide response

0/3000

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

Explain why or why not?

Provide response

0/3000

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Newness Criterion Summary

Please briefly summarize your responses to the previous slide regarding how the technology meets the newness criterion overall.

Provide response

0/500

Upload files related to the newness criterion or add comments to an existing file, as needed (optional)

Uploaded Files

It looks like there is nothing here

Supported formats include PDF, word, excel, powerpoint, JPEG, PNG, and plain text files

Drag and drop files to upload or

Browse Files

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Technology Cost

What is the current or anticipated cost of this technology to the hospital, per patient?

Provide response

0/500

How was the cost determined? (e.g., the average dosage or number of units per patient (ml/kg/hr); for technologies sold on a subscription basis, include an explanation of how the cost per case is calculated, including the list price of the technology and utilization across subscribers)

Note: You will be asked to provide a breakdown of the cost of each component in the next screen.

Cost determination e.g. the average dosage or number of units per patient (ml/kg/hr)

0/500

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Cost Breakdown

 Include a breakdown of the cost of all of the components used per patient, clearly showing which components are the "new" ones.

Provide a breakdown of how the cost of the technology is calculated and identify if any components are capital costs.

Name of the component	Capital or operating cost
Actual cost	
Is this component new?	
<input checked="" type="radio"/> Yes <input type="radio"/> No	

Add to list

Component list

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Cost Breakdown

i Include a breakdown of how the cost of the drug/therapeutic agent is calculated.

What is the (current and/or anticipated) cost of the drug/therapeutic agent to the hospital, per patient? Include the average dosage and number of vials (whole vials if single-use) and/or units per patient (ml/kg/hr)*

Explanation

0/3000

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

Files list

There are no files, please click the button below to add a supporting file.

Add/Edit File(s)

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MS-DRGs

Under the MS-DRG grouper for FY 2023, list all of the MS-DRGs that the technology currently maps to based on the indication (diagnosis) for which the technology has received or is seeking FDA approval.

MS-DRG	MS-DRG title
<input type="text"/>	<input type="text"/>

[Add to list](#)

MS-DRG code list

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MS-DRG mapping

Have you made a request to map to a new or different MS-DRG(s) for the upcoming Fiscal Year 2024?

Yes No

Comments.

Provide response

0/500

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About Cost Criterion



To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of the thresholds established with the release of the most recent annual IPPS final rule (lesser of 75 percent of the standardized amount increased to reflect the difference between costs and charges or 75 percent of 1 standard deviation beyond the geometric mean standardized charge for all cases in the MS-DRGs to which the new technology is assigned). The most recent version of the thresholds can be downloaded at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>

Note: if the technology is proposed to be assigned to a proposed new MS-DRG in the upcoming annual IPPS proposed rule, then per the policy CMS finalized in the FY 2021 IPPS final rule, CMS uses the proposed threshold for the upcoming fiscal year for any proposed new MS-DRG to evaluate the cost criterion.

The inflation factor and cost center cost-to-charge ratios (CCRs) can be found in the "Cost Center CCR and Inflation Factor" tab in the cost spreadsheet. The factors in the spreadsheet come from the most recent final rule (for example, for FY 2023 applications, these factors can be found in the FY 2022 Final Rule or FY 2022 Correction Notice). If the thresholds, cost center CCRs and/or inflation factor are updated in a correction notice, those values must be used instead.

Applicants should monitor the most recent final rule home page for the release of the correction notice, which usually occurs in September. (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS>) and then click on the most recent final rule Fiscal Year home page on the left of the page; for example, FY 2023 Applications should click on the "FY 2022 IPPS Final Rule Home Page").

Ok

Cost Criterion Methodology

With regard to the cost analysis spreadsheet, please summarize the supporting data used to calculate charges and standardized charges per case involving the new technology (in electronic format). Examples include claims data, the ICD-10-CM/PCS codes used to identify cases, the provider-specific factors used to standardize charges, and assumptions behind removing charges for prior technology.

Provide response

0/3000

Upload all supporting files.

Uploaded Files

It looks like there is nothing here

Supported formats include PDF, word, excel, powerpoint, JPEG, PNG, and plain text files

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(Team Name) | New Technology Add-on Payments (NTAP) | Device | Traditional pathway

Contact Info Technology Info FDA Info Coding Medicare Criteria Cost **Charge** Volume of Cases Substantial Clinical Improvement Training

Cost Analysis Methodology (column A to E)

- For example, applicants must include the type of data used to calculate the average standardized charge (i.e. Medicare and/or non-Medicare, number of providers, time period from which data was collected) and/or the inflation factor used to inflate the charges etc. An application is NOT complete without a complete step by step explanation of the applicant's charge methodology.

For column A to E of the cost analysis spreadsheet, list a step by step explanation for how the data and calculations were determined.

A. MS-DRG

Provide response

0/3000

B. Cases

Provide response

0/3000

C. Case Weighted Amount

Provide response

0/3000

D. Threshold

Provide response

0/3000

E. Case Weighted Threshold

Provide response

0/3000

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Cost Analysis Methodology (column F to J)

i For example, applicants must include the type of data used to calculate the average standardized charge (i.e. Medicare and/or non-Medicare, number of providers, time period from which data was collected) and/or the inflation factor used to inflate the charges etc. An application is NOT complete without a complete step by step explanation of the applicant's charge methodology.

For column F to J of the cost analysis spreadsheet, list a step by step explanation for how the data and calculations were determined.

F. Average Charge Per Case (Unstandardized with No Case Weight)

Provide response

0/3000

G. Average Charge Per Case (Unstandardized with Case Weight)

Provide response

0/3000

H. Remove Charges for the Prior Technology or Technology Being Replaced

Provide response

0/3000

I. Remove Charges Related to the Prior Technology or Technology Being Replaced

Provide response

0/3000

J. Adjusted Average Charge Per Case (Unstandardized with No Case Weight)

Provide response

0/3000

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Cost Analysis Methodology (column K to O)

i For example, applicants must include the type of data used to calculate the average standardized charge (i.e. Medicare and/or non-Medicare, number of providers, time period from which data was collected) and/or the inflation factor used to inflate the charges etc. An application is NOT complete without a complete step by step explanation of the applicant's charge methodology.

For column K to O of the cost analysis spreadsheet, list a step by step explanation for how the data and calculations were determined.

K. Adjusted Average Charge Per Case (Unstandardized with Case Weight)

Provide response

0/3000

L. Average Standardized Charge Per Case

Provide response

0/3000

M. Average Standardized Charge Per Case with Case Weight

Provide response

0/3000

N. Inflation Factor

Provide response

0/3000

O. Inflated Average Standardized Charges Per Case

Provide response

0/3000

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- 🔗 Resources



[Team Name] | New Technology Add-on Payments (NTAP) | Device | Traditional pathway

Contact Info Technology Info FDA Info Coding Novelty Criteria Cost **Charge** Volume of Cases Substantial Clinical Improvement Summary

Cost Analysis Methodology (column P to S)

i For example, applicants must include the type of data used to calculate the average standardized charge (i.e. Medicare and/or non-Medicare, number of providers, time period from which data was collected) and/or the inflation factor used to inflate the charges etc. An application is NOT complete without a complete step by step explanation of the applicant's charge methodology.

For column P to S of the cost analysis spreadsheet, list a step by step explanation for how the data and calculations were determined.

P. Add Charges for the New Technology

Provide response

0/3000

Q. Add Charges Related to the New Technology

Provide response

0/3000

R. Final Average Inflated Standardized Charge Per case

Provide response

0/3000

S. Final Inflated Case Weighted Standardized Charge Per Case

Provide response

0/3000

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{{Team Name}} | New Technology Add-on Payments (NTAP) | Drug | Traditional pathway

Contact Info Technology Info FDA Info Coding Newness Criterion Cost **Charge** Volume of Cases Substantial Clinical Improvement Summary

Charge of the Technology

What is the current and/or anticipated charge of the technology by the hospital, per patient? Explain how this was determined.

Explanation

0/3000

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[[Team Name]] | New Technology Add-on Payments (NTAP) | Drug | Traditional pathway

Contact Info Technology Info FDA Info Coding Newsfeed Criterion Cost Charge **Volume of Cases** Substantial Clinical Improvement Summary

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

 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: (10/01/2022 - 09/30/2023) Upcoming Fiscal Year: (10/01/2023 - 09/30/2024)

Current Fiscal Year Anticipated Inpatient Medicare Volume

Please describe how you arrived at this estimate.

Determination details

0/3000

Upcoming Fiscal Year Anticipated Inpatient Medicare Volume

Please describe how you arrived at this estimate.

Determination details

0/3000

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{Team Name} | New Technology Add-on Payments (NTAP) | Drug | Traditional pathway

Contact Info Technology Info FDA Info Coding Newness Criterion Cost Charge **Volume of Cases** Substantial Clinical Improvement Summary

What is the anticipated inpatient Non-Medicare volume of this technology for the current and upcoming Fiscal Year?

i 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: (10/01/2022 - 09/30/2023) Upcoming Fiscal Year: (10/01/2023 - 09/30/2024)

Current Fiscal Year Anticipated Inpatient Non-Medicare Volume

Please describe how you arrived at this estimate.

Determination details

0/3000

Upcoming Fiscal Year Anticipated Inpatient Non-Medicare Volume

Please describe how you arrived at this estimate.

Determination details

0/3000

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Substantial Clinical Improvement Criterion

i A summary on the substantial clinical improvement criterion can be found in [Appendix B](#). Additional information on the substantial clinical improvement 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 process for each application.

Criterion 1

Does the new medical service or technology offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments?

Yes No

Please explain why the technology does or does not meet this criterion using supporting data.

Explanation

0/3000

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((Team Name)) | New Technology Add-on Payments (NTAP) | Device | Traditional pathway

Contact Info Technology Info FDA Info Coding Newness Criterion Cost Charge Volume of Cases **Substantial Clinical Improvement** Summary

Criterion 1 Claims

Provide the claims for Substantial Clinical Improvement and supporting evidence. While we prefer published peer-reviewed clinical trials, we will consider all supporting evidence.

Add Claim

Claim list

Click on "Add Claim" above to add claims supporting Criterion 1.

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((Team Name)) | New Technology Add-on Payments (NTAP) | Device | Traditional pathway

Contact Info Technology Info FDA Info Coding Newness Criterion Cost Charge Volume of Cases **Substantial Clinical Improvement** Summary

Add a Substantial Clinical Improvement Claim

Substantial Clinical Improvement Claim

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Add a Substantial Clinical Improvement Claim

Substantial Clinical Improvement Claim

Supporting File

Supporting Evidence

Provide a summary of the study

Describe the purpose of the article and the relevance to the technology for this particular claim.

Provide a summary of the information from this article that supports the claim. Please include the specific sample size, including the number of treated vs. controls as well as the specific statistics that demonstrate the Substantial Clinical Improvement (SCI), if applicable.

Substantial Clinical Improvement Claim

Supporting File

Supporting Evidence

Provide a summary of the study

Describe the purpose of the article and the relevance to the technology for this particular claim.

Provide a summary of the information from this article that supports the claim. Please include the specific sample size, including the number of treated vs. controls as well as the specific statistics that demonstrate the Substantial Clinical Improvement (SCI), if applicable.

Substantial Clinical Improvement Claim

Supporting File

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Criterion 1 Claims

Provide the claims for Substantial Clinical Improvement (SCI) and supporting evidence. While we prefer published, peer-reviewed clinical trials, we will consider all supporting evidence.

[Add Claim](#)

Claim list

+ Claim 1{{claim name}} [Delete](#)

+ Claim 2{{claim name}} [Delete](#)

- Claim 3{{claim name}} [Delete](#)

SCI Claim	Reduced mortality rate in comparison to competitor drug/device
Supporting data	Doe, et al, "Reducing mortality in disease X population- analysis," JAMA 2019, vol. 2(5), pp. 12-23.
Category	Published, peer-reviewed study
Study Type	RCT
Page No	Page No
Study Summary	RCT used to compare mortality rates between Drug 123 vs. 789 for disease X resulting in a 5% decrease in mortality rate for Drug 123 (p=0.02) Data used to compare mortality rates between Drug 123 vs. 789 for disease X resulting in a 5% decrease in mortality rate for Drug 123 (p=0.02) Data used to compare mortality rates between Drug 123 vs. 789 for disease X resulting in a 5% decrease in mortality rate for Drug 123 (p=0.02) Data used to compare mortality rates between Drug 123 vs. 789 for disease X resulting in a 5% decrease in mortality rate for Drug 123 (p=0.02)
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Substantial Clinical Improvement Criterion

Criterion 2

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? If so, describe how use of the new medical service or technology to make a diagnosis affects the management of the patient using evidence.

Yes No

Please explain why the technology does or does not meet this criterion using supporting data.

Explanation

0/3000

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Criterion 2 Claims

Provide the claims for Substantial Clinical Improvement and supporting evidence. While we prefer published peer-reviewed clinical trials, we will consider all supporting evidence.

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Claim list

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Criterion 2 Claims

Provide the claims for Substantial Clinical Improvement (SCI) and supporting evidence. While we prefer published, peer-reviewed clinical trials, we will consider all supporting evidence.

Add Claim

Claim list

+ Claim 1{{claim name}} Delete

+ Claim 2{{claim name}} Delete

- Claim 3{{claim name}} Delete

SCI Claim	Reduced mortality rate in comparison to competitor drug/device
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Category	Published, peer-reviewed study
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Page No	Page No
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📎 claim.pdf	
SCI Claim	Reduced mortality rate in comparison to competitor drug/device
Supporting data	Doe, et al, "Reducing mortality in disease X population: -analysis," JAMA 2019, vol. 2(5), pp. 12-23.
Category	Published, peer-reviewed study

Substantial Clinical Improvement Criterion

Criterion 3

Does the use of the new medical service or technology significantly improve clinical outcomes relative to services or technologies previously available?

Yes No

Please explain why the technology does or does not meet this criterion using supporting data.

Explanation

0/3000

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Criterion 3 Claims

Provide the claims for Substantial Clinical Improvement and supporting evidence. While we prefer published peer-reviewed clinical trials, we will consider all supporting evidence.

Add Claim

Claim list

Click on "Add Claim" above to add claims supporting Criterion 3.

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Add a Substantial Clinical Improvement Claim

Substantial Clinical Improvement Claim

Approved File

submitter-manuscript

Provide more details about the selected file

Supporting Evidence Code

DATA SOURCE CATEGORY

Page number(s)

Provide a summary of the study

Provide response
8,000

Describe the purpose of the article and the relevance to the technology for this particular claim.

Provide response
8,000

Provide a summary of the information from this article that supports the claim. Please include the specific sample size, detailing the number of treated vs. controls as well as the specific results that demonstrate the Substantial Clinical Improvement Code, if applicable.

Provide response
8,000

Substantial Clinical Improvement Claim

Approved File

submitter-manuscript

Provide more details about the selected file

Supporting Evidence Code

DATA SOURCE CATEGORY

Executive Order?

Page number(s)

Provide a summary of the study

Provide response
8,000

Describe the purpose of the article and the relevance to the technology for this particular claim.

Provide response
8,000

Provide a summary of the information from this article that supports the claim. Please include the specific sample size, detailing the number of treated vs. controls as well as the specific results that demonstrate the Substantial Clinical Improvement Code, if applicable.

Provide response
8,000

Substantial Clinical Improvement Claim

Approved File

Supporting Evidence Code

DATA SOURCE CATEGORY

Executive Order?

Page number(s)

Provide a summary of the study

Provide response
8,000

Describe the purpose of the article and the relevance to the technology for this particular claim.

Provide response
8,000

Provide a summary of the information from this article that supports the claim. Please include the specific sample size, detailing the number of treated vs. controls as well as the specific results that demonstrate the Substantial Clinical Improvement Code, if applicable.

Provide response
8,000

Cancel

Done

Criterion 3 Claims

Provide the claims for Substantial Clinical Improvement (SCI) and supporting evidence. While we prefer published, peer-reviewed clinical trials, we will consider all supporting evidence.

Add Claim

Claim list

+ Claim 1{{claim name}} Delete

+ Claim 2{{claim name}} Delete

- Claim 3{{claim name}} Delete

SCI Claim	Reduced mortality rate in comparison to competitor drug/device
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Category	Published, peer-reviewed study
Study Type	RCT
Page No	
Study Summary	RCT used to compare mortality rates between Drug 123 vs. 789 for disease X resulting in a 5% decrease in mortality rate for Drug 123 (p=0.02) Data used to compare mortality rates between Drug 123 vs. 789 for disease X resulting in a 5% decrease in mortality rate for Drug 123 (p=0.02) Data used to compare mortality rates between Drug 123 vs. 789 for disease X resulting in a 5% decrease in mortality rate for Drug 123 (p=0.02) Data used to compare mortality rates between Drug 123 vs. 789 for disease X resulting in a 5% decrease in mortality rate for Drug 123 (p=0.02)
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claim.pdf

SCI Claim	Reduced mortality rate in comparison to competitor drug/device
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Category	Published, peer-reviewed study

{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway

[Contact Info](#) [Technology Info](#) [FDA Info](#) [Coding](#) [Newness Criterion](#) [Cost](#) [Charge](#) [Volume of Cases](#) **[Substantial Clinical Improvement](#)** [Summary](#)

SCI Criterion Summary

Please briefly summarize your responses to the previous slide regarding how the technology meets the substantial clinical improvement criterion overall.

Explanation

0/500

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