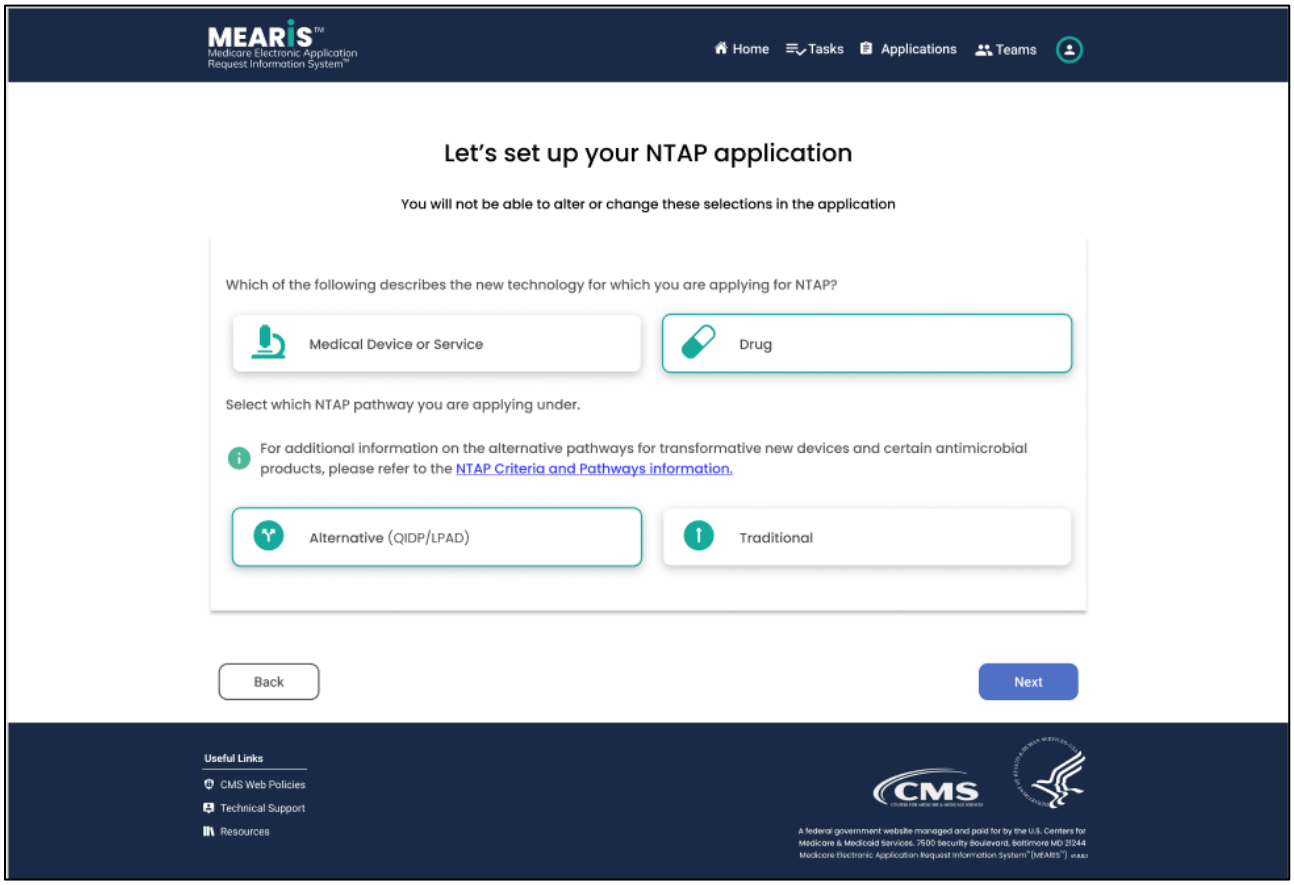
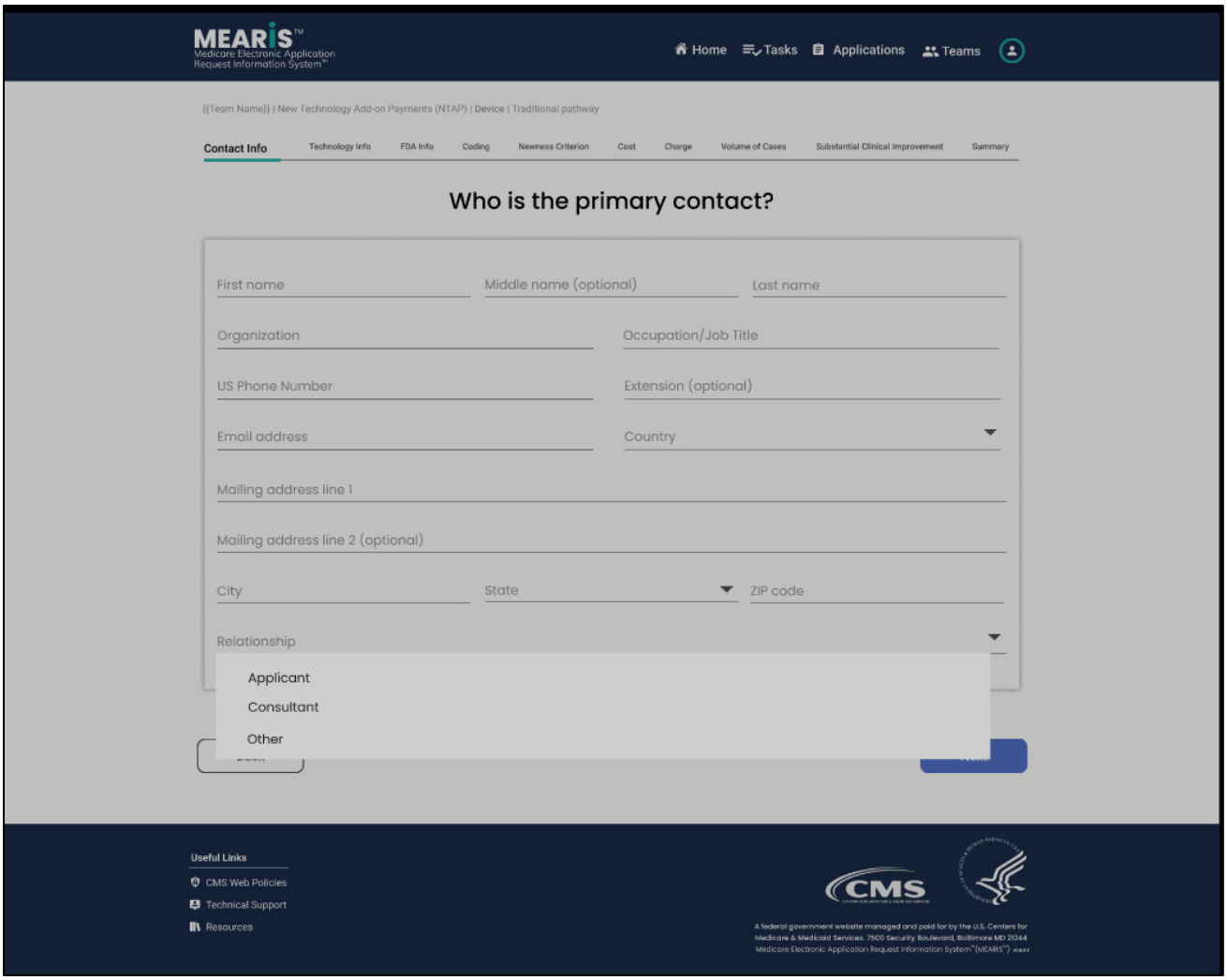
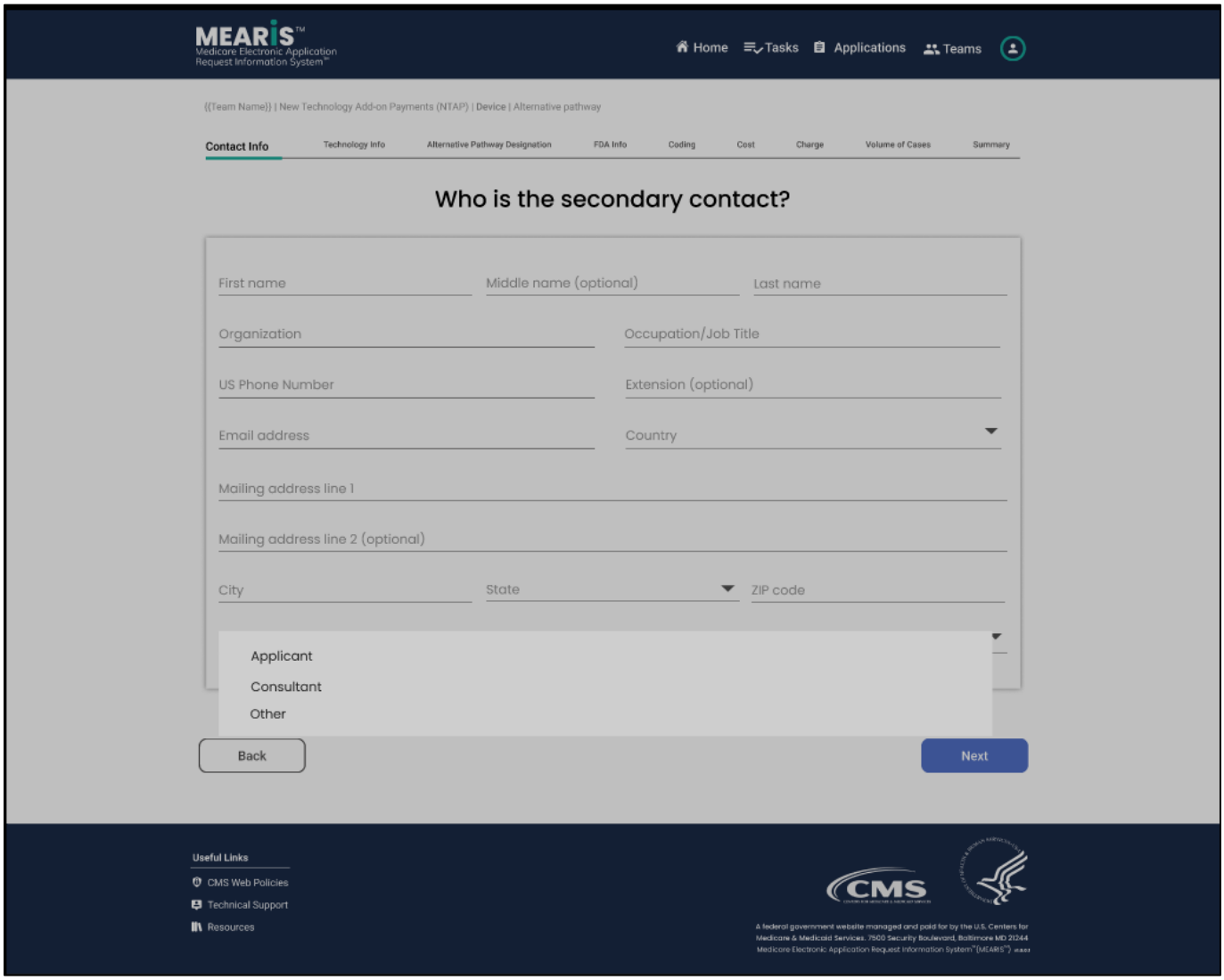
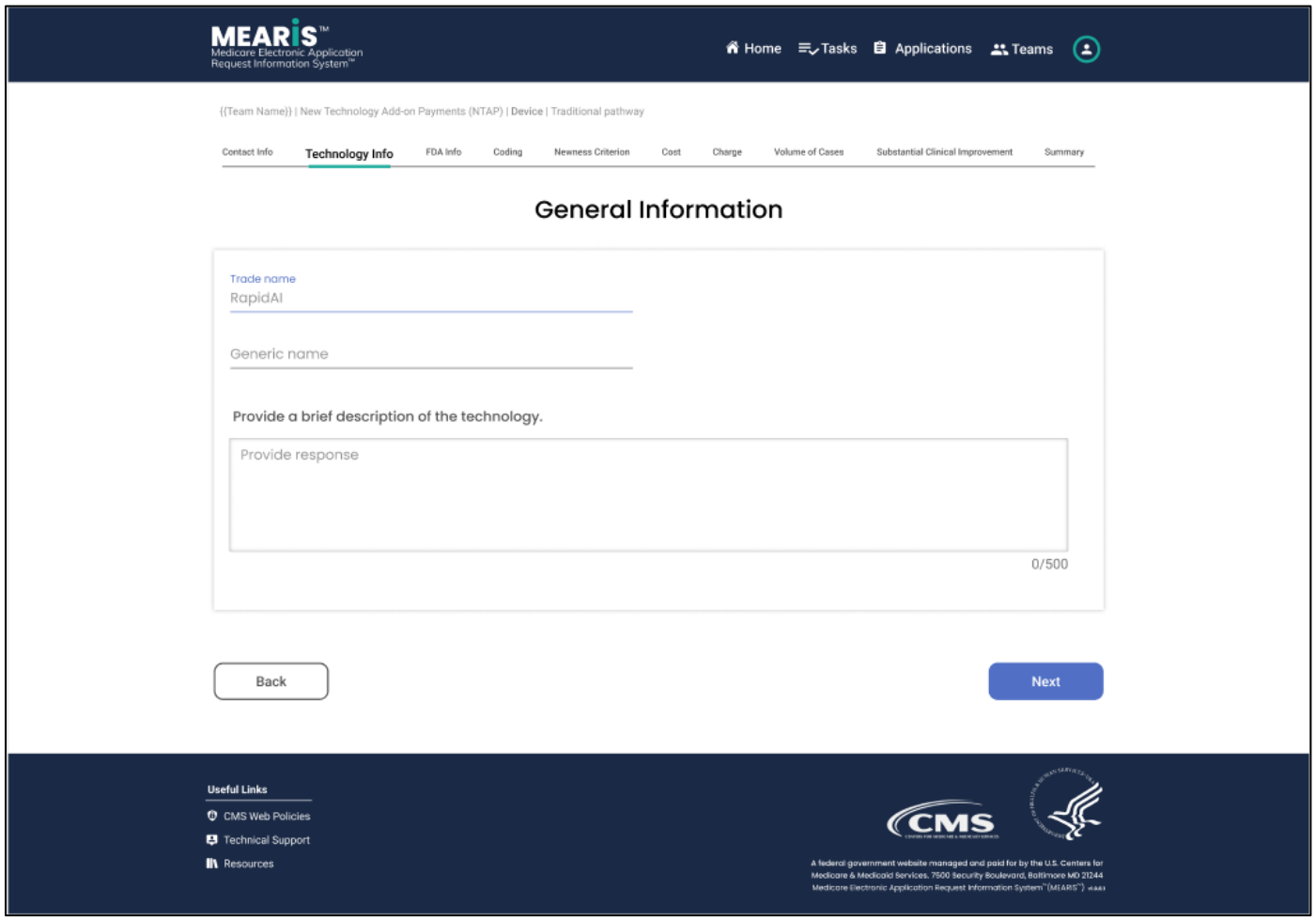
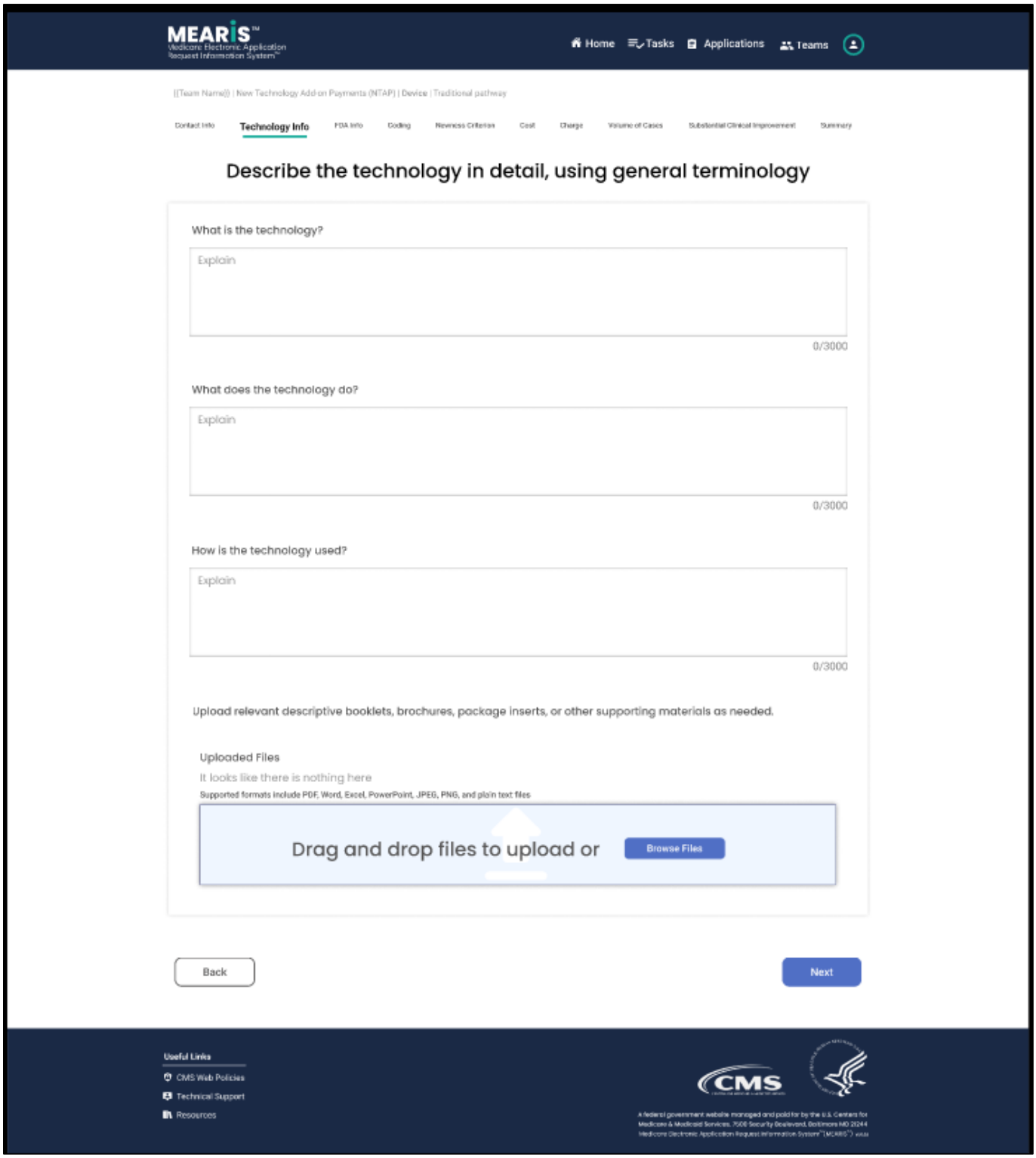
Application for New Medical Services and Technologies Seeking to Qualify for Add-On Payments Under the Hospital Inpatient Prospective Payment System for FY 2024




MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{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
Applicant
Consultant
Other
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services. 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Alternative pathway
Contact Info
Technology Info
Alternative Pathway Designation
FDA Info
Coding
Cost
Charge
Volume of Cases
Summary
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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services. 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{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
General Information
Trade name
RapidAI
Generic name
Provide a brief description of the technology.
Provide response
0/500
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
[[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
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
Browse Files
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS

MEARIS™
Medicare Electronic Application Request Information System™

Home | Tasks | Applications | Teams

{{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

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

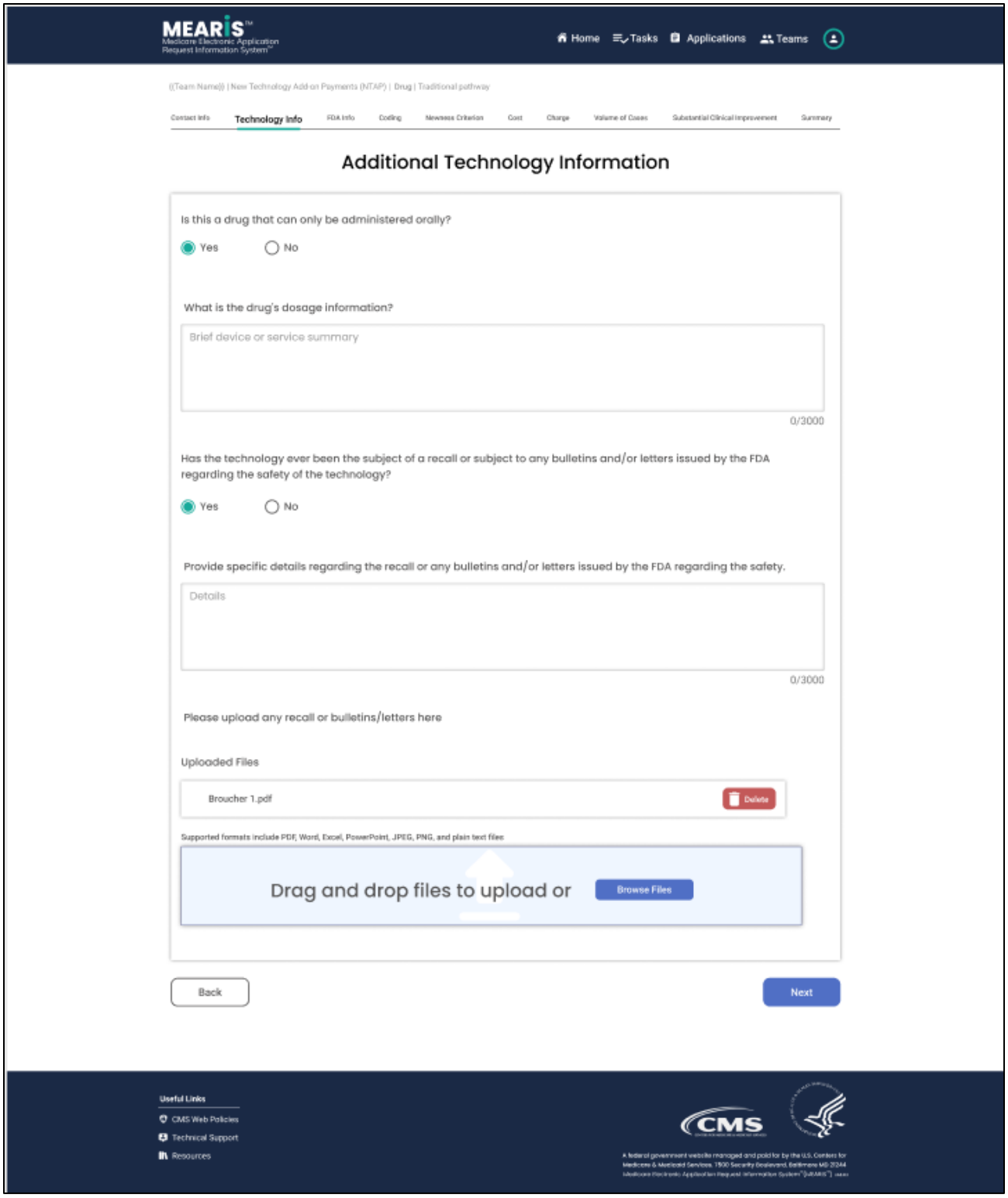
Drag and drop files to upload or Browse Files

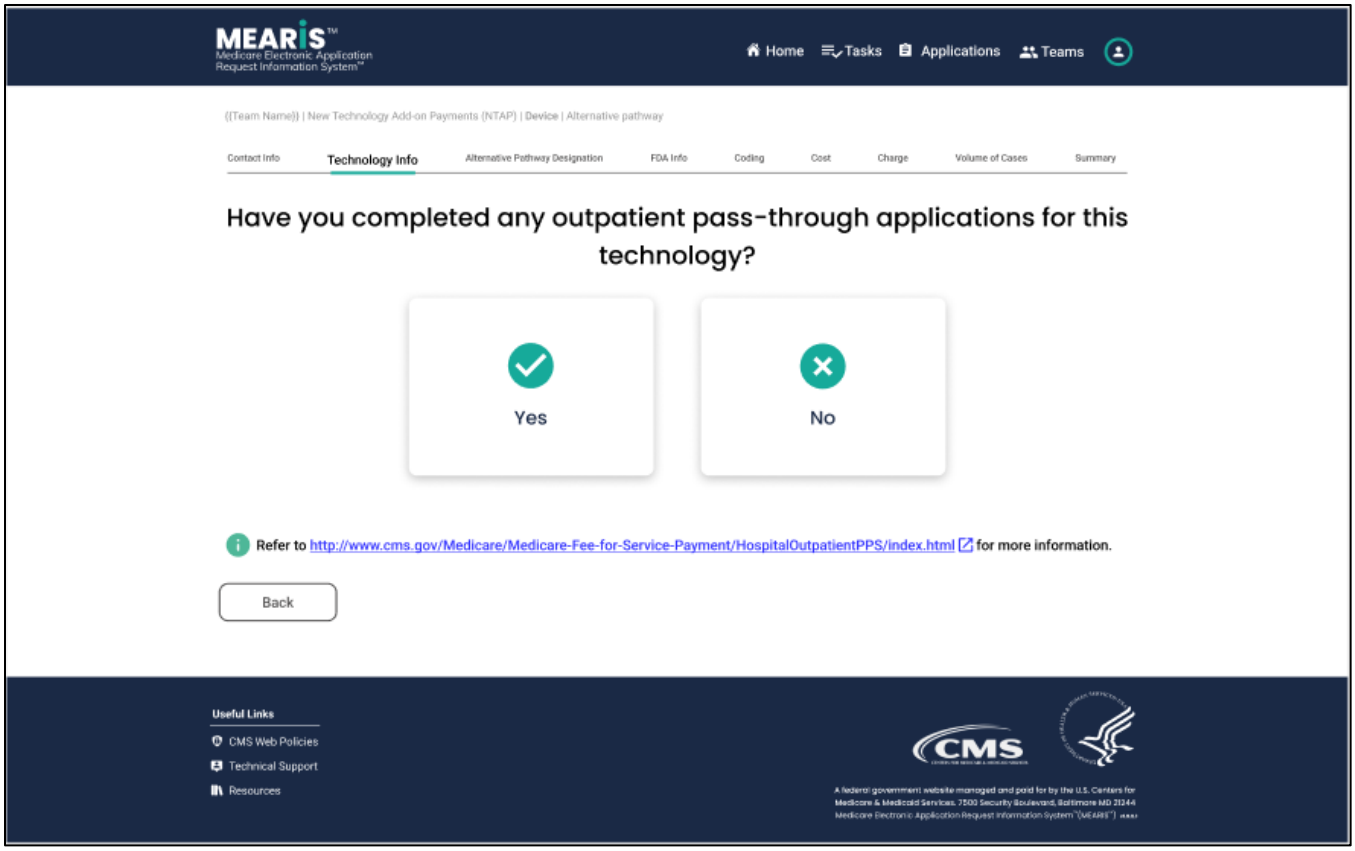
Back Next

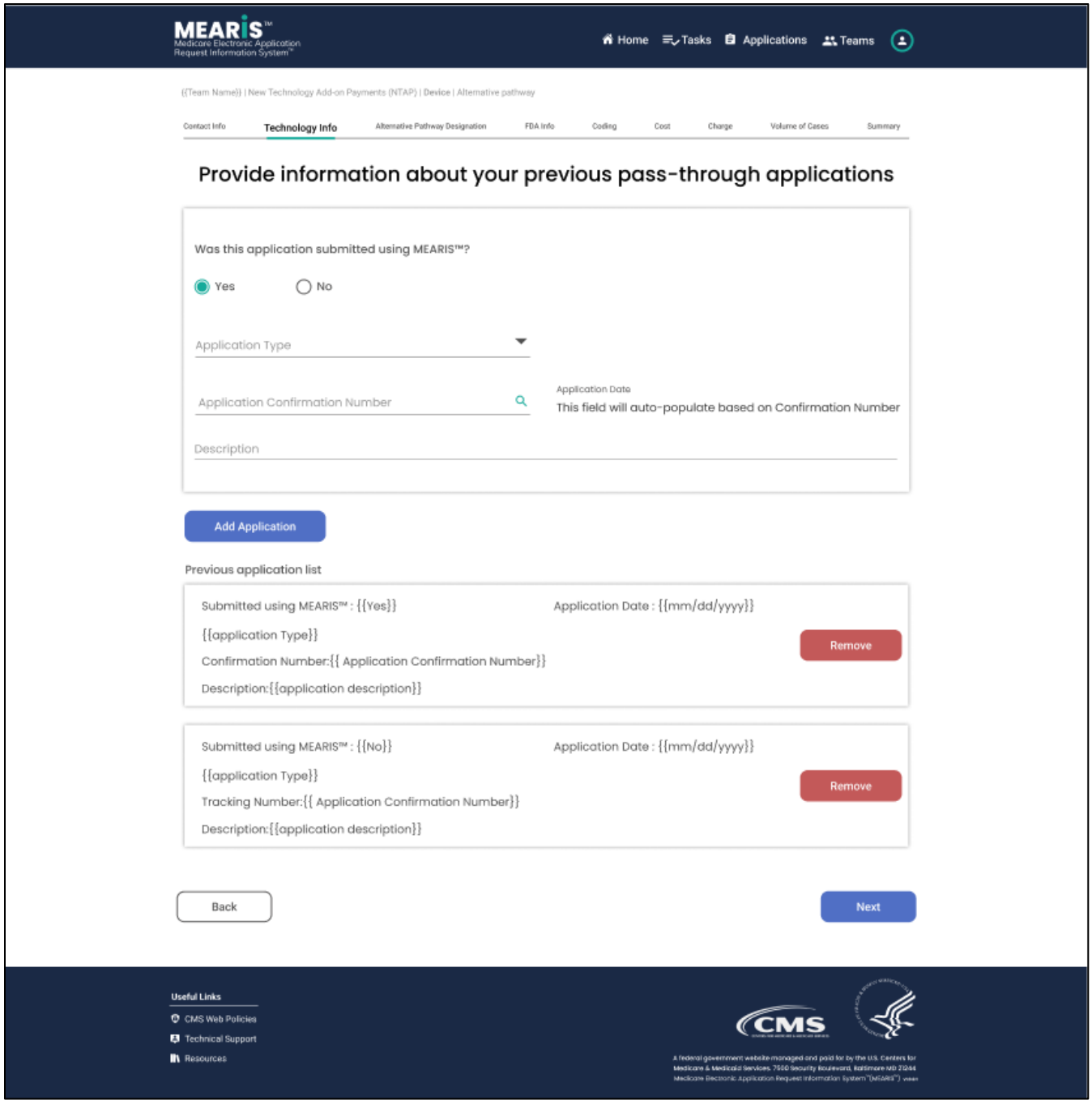
Useful Links
- CMS Web Policies
- Technical Support
- Resources

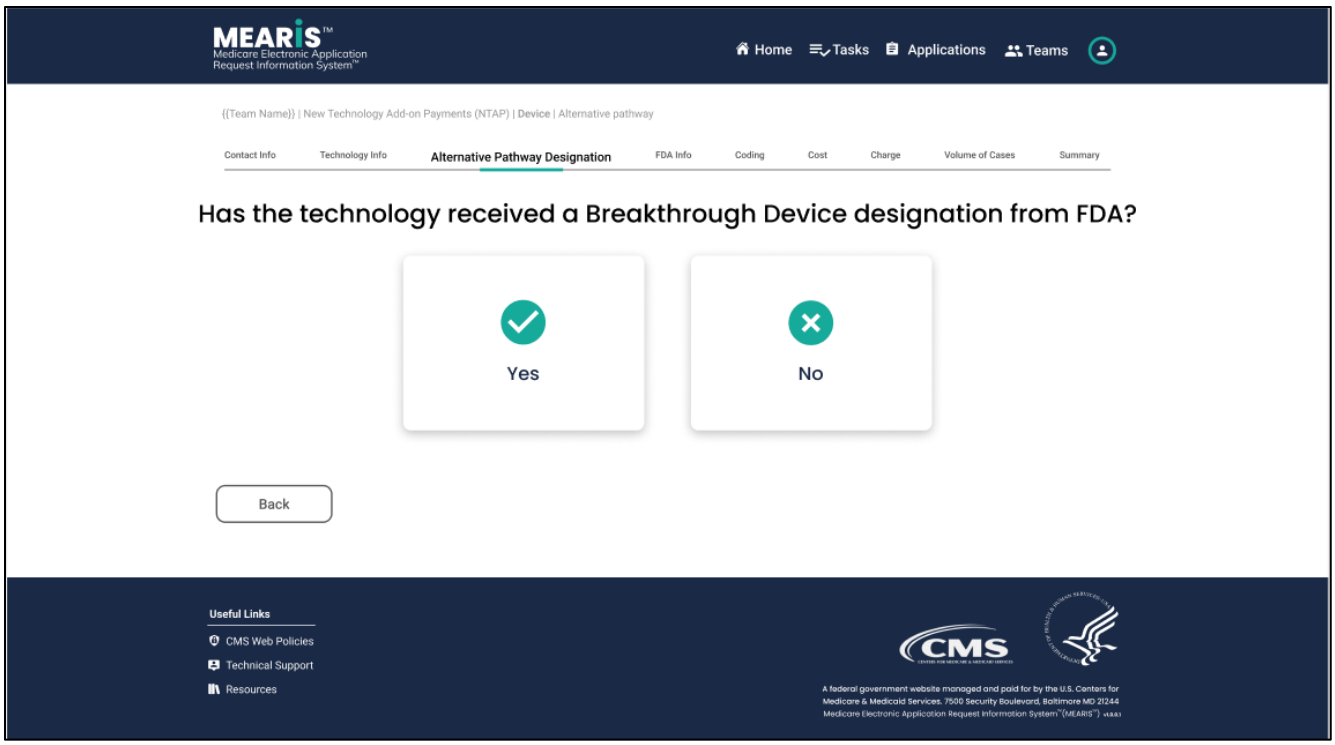
CMS

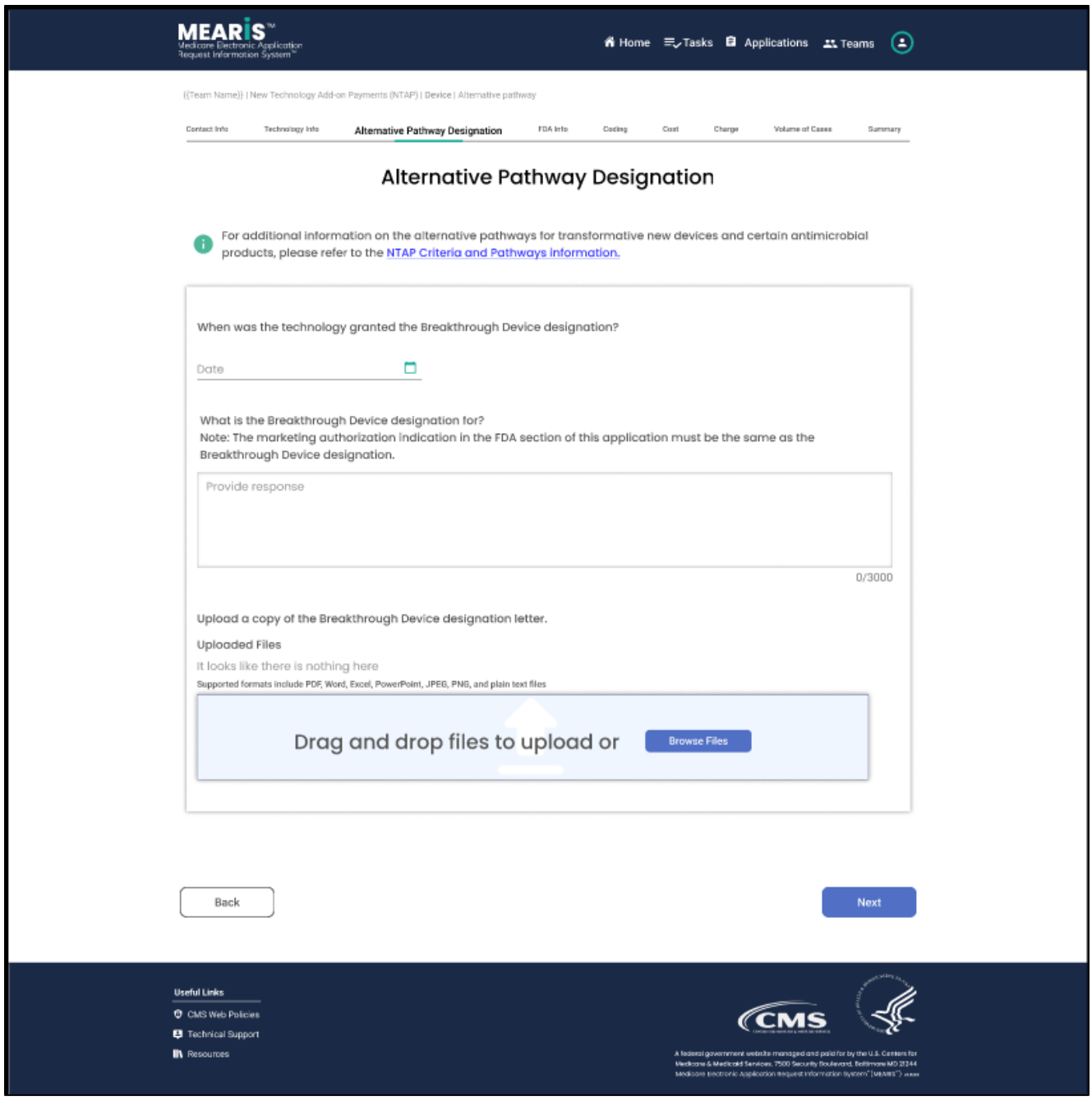
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
((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
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
Delete
Supported formats include PDF, Word, Excel, PowerPoint, JPEG, PNG, and plain text files
Drag and drop files to upload or
Browse Files
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Alternative pathway
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.
Back
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ ("MEARIS™")


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Alternative pathway
Contact Info
Technology Info
Alternative Pathway Designation
FDA Info
Coding
Cost
Charge
Volume of Cases
Summary
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}}
Confirmation Number:{{ Application Confirmation Number}}
Description:{{application description}}
Remove
Submitted using MEARIS™ : {{No}}
Application Date : {{mm/dd/yyyy}}
{{application Type}}
Tracking Number:{{ Application Confirmation Number}}
Description:{{application description}}
Remove
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™(MEARIS™) v1.0.0


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Alternative pathway
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
Back
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Alternative pathway
Contact Info
Technology Info
Alternative Pathway Designation
FDA Info
Coding
Cost
Charge
Volume of Cases
Summary
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 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
Drag and drop files to upload or
Browse Files
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)

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.

Date of submission.

Date

Anticipated designation date.

Date

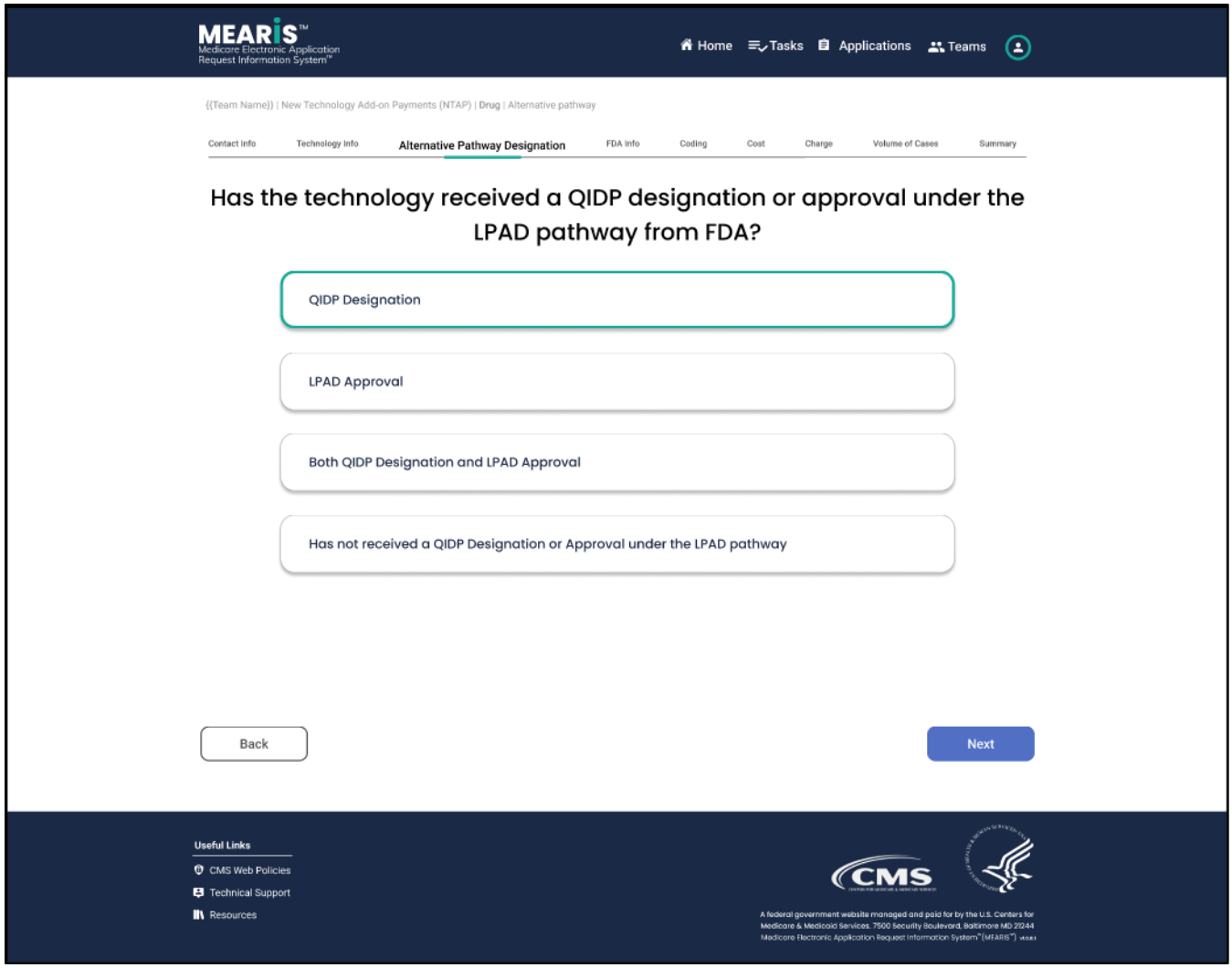
What is the proposed indication submitted for Breakthrough Device designation?
Note: The marketing authorization indication in the FDA section of this application must be the same as the Breakthrough Device designation.

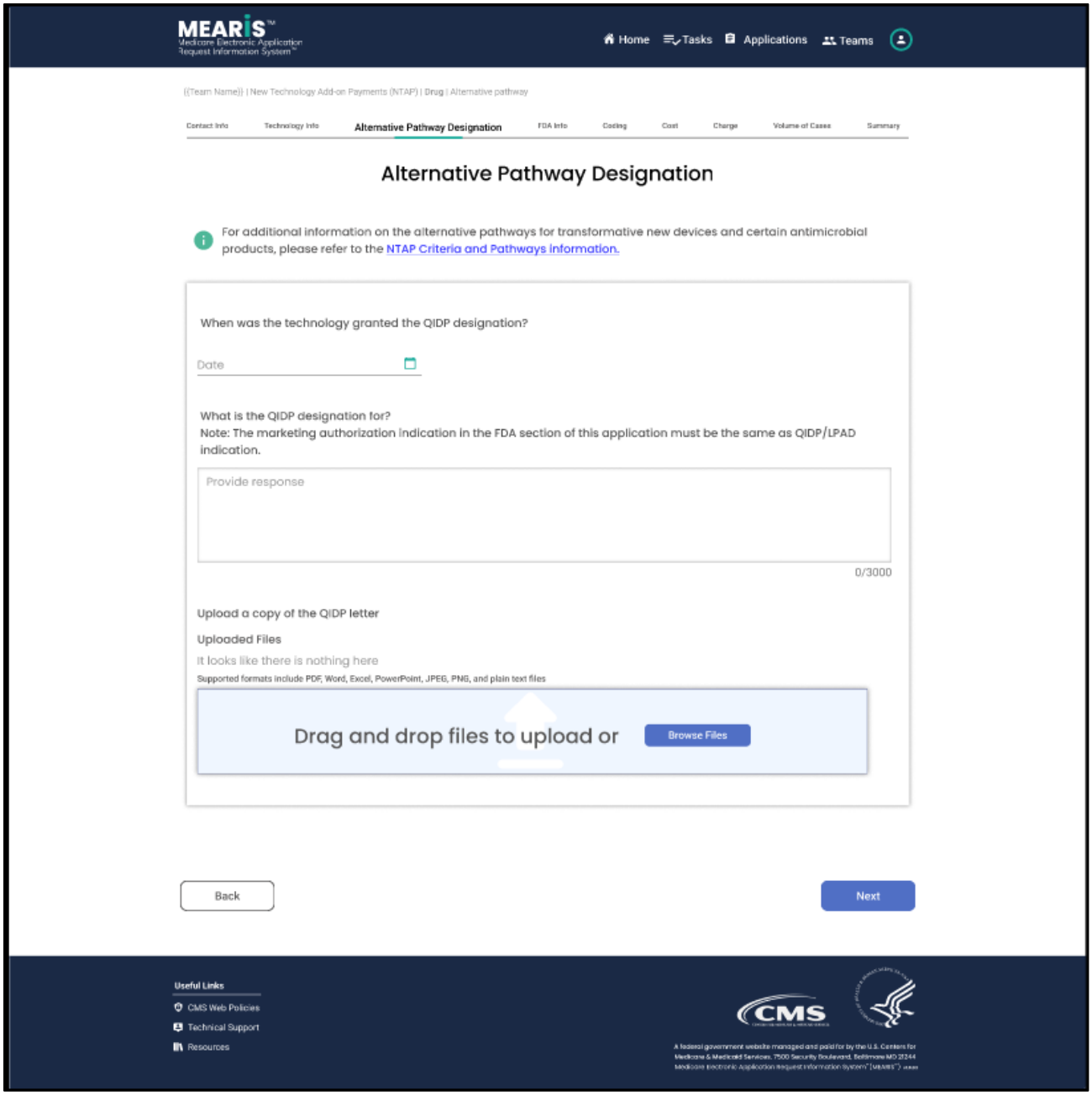
Provide response

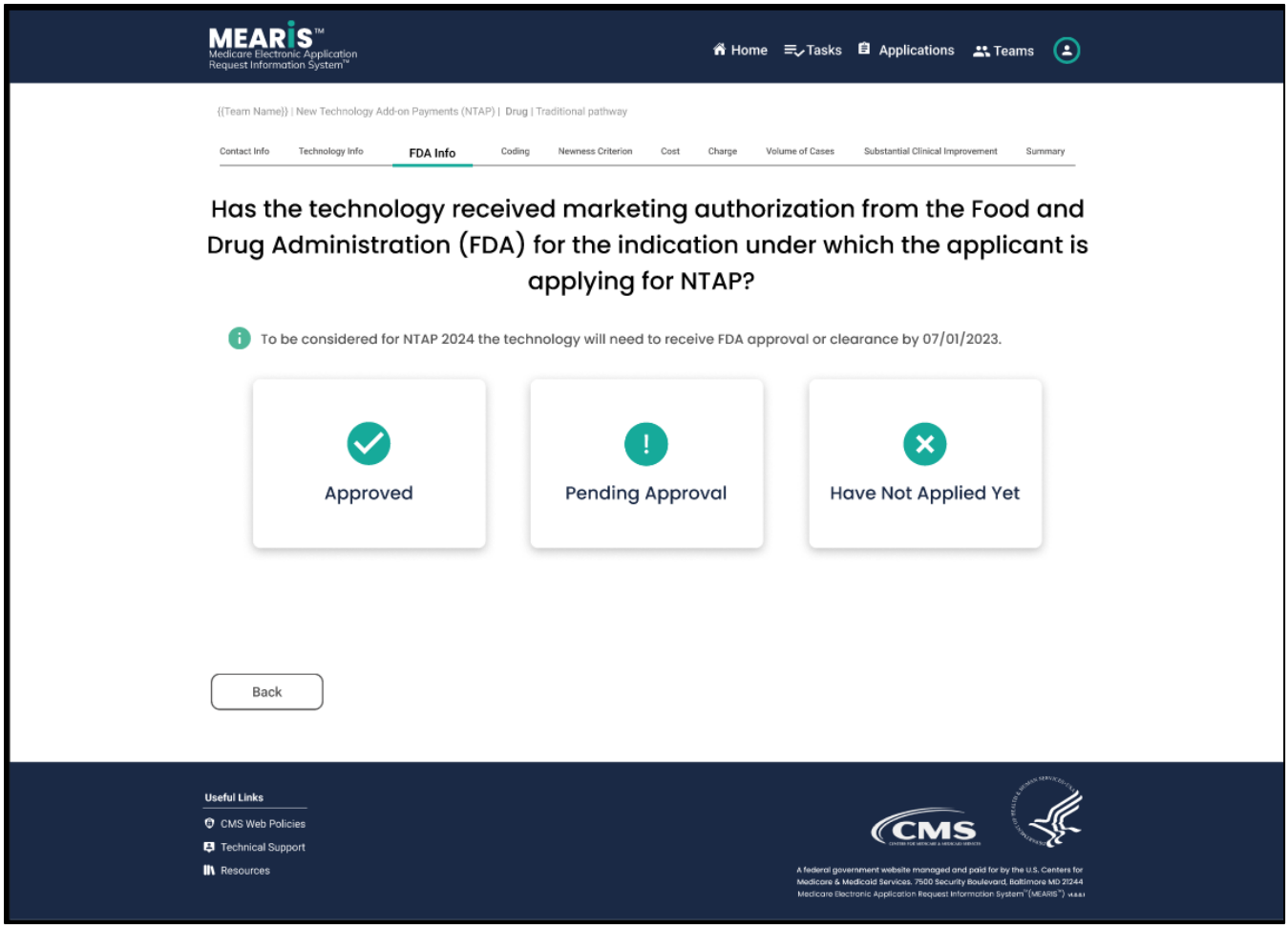
0/3000

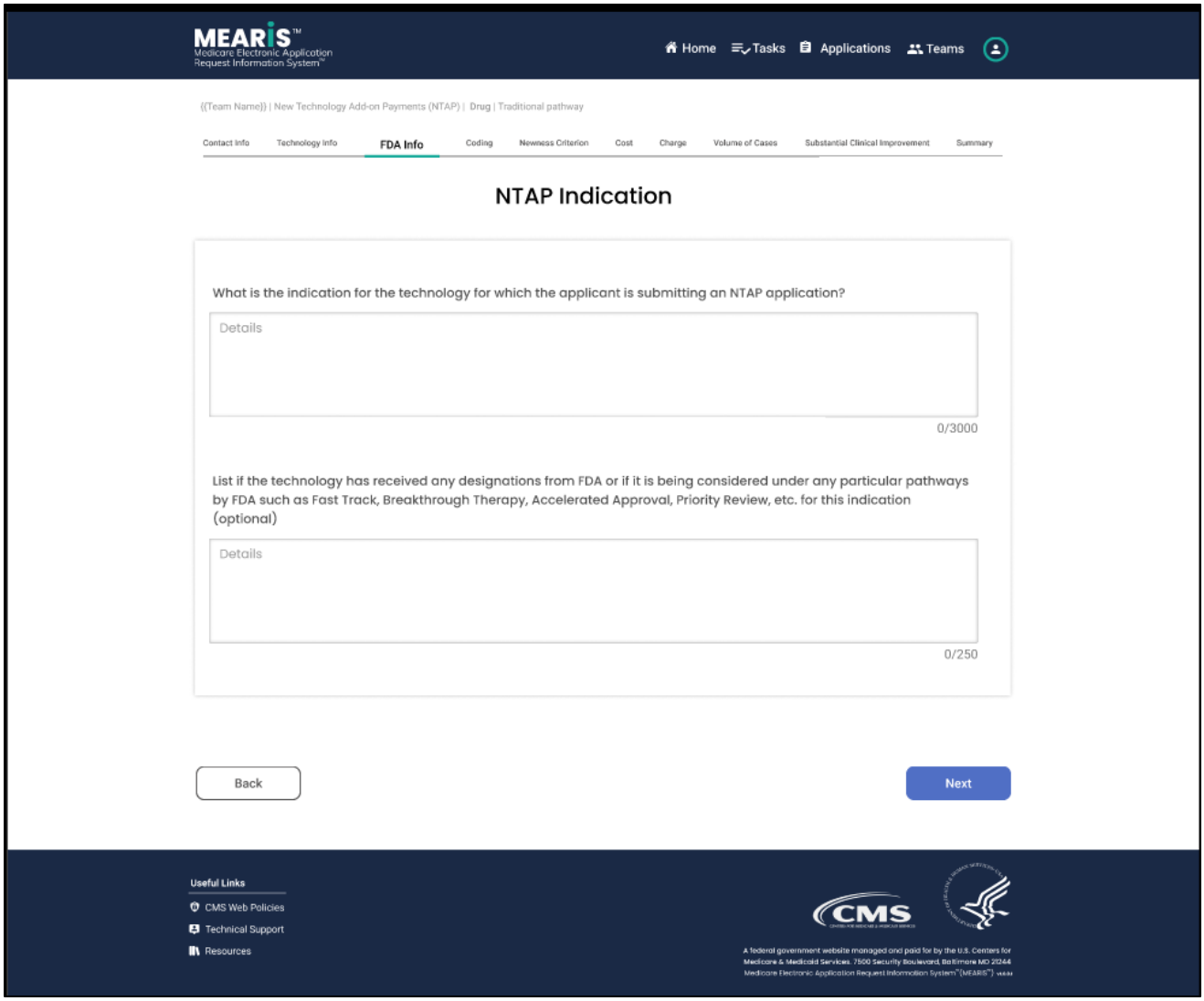
Back

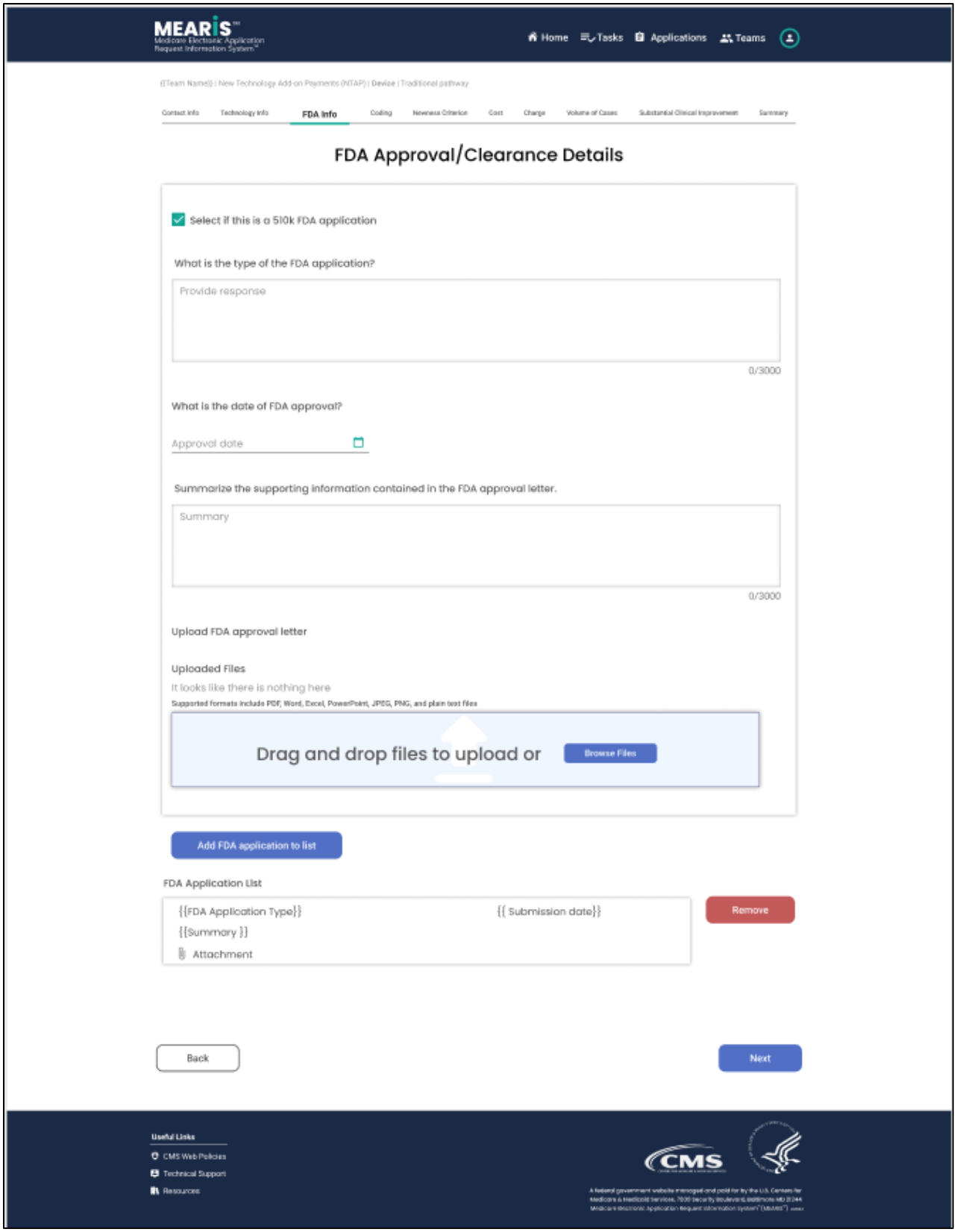
Next

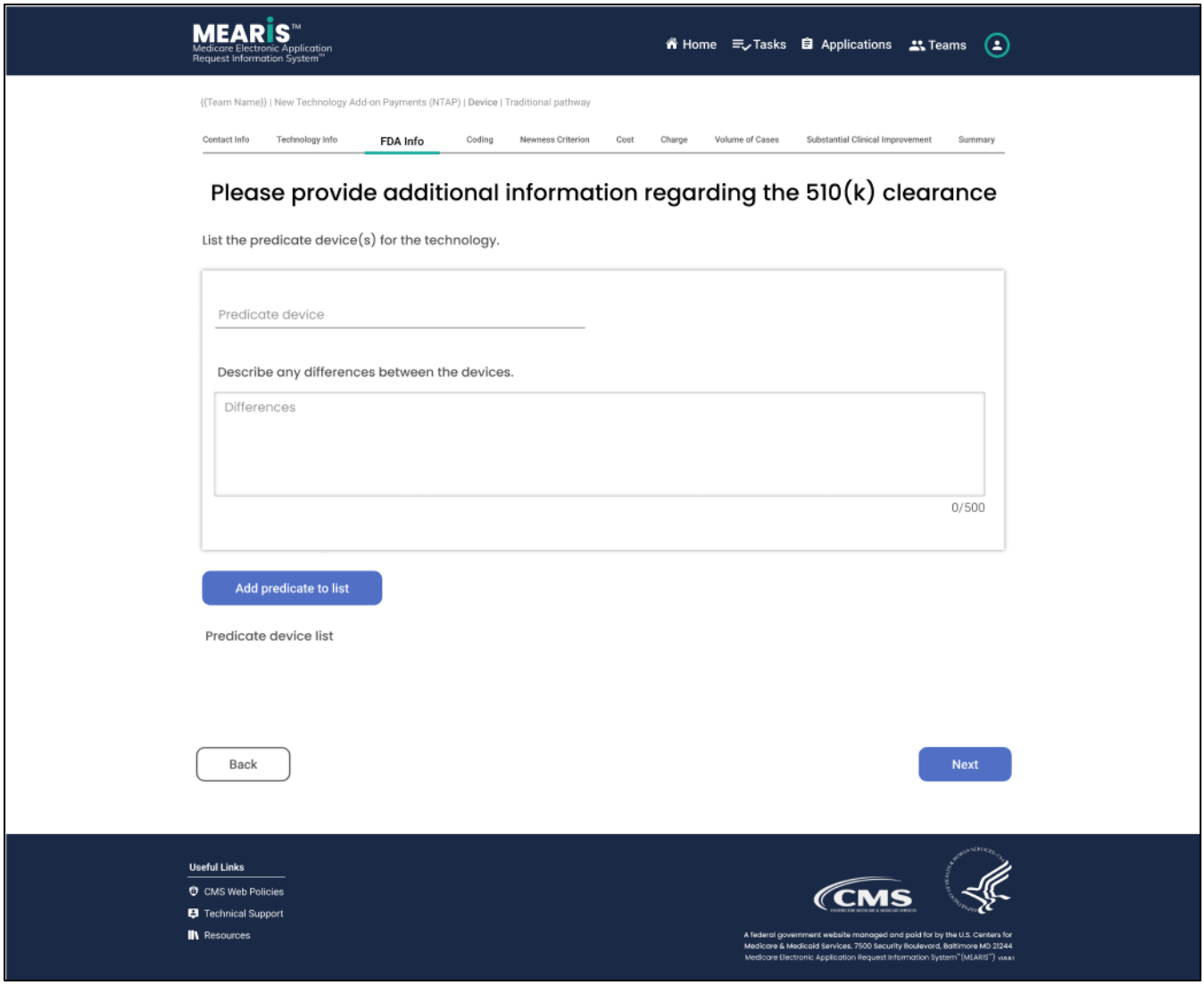

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Drug | Alternative pathway
Contact Info
Technology Info
Alternative Pathway Designation
FDA Info
Coding
Cost
Charge
Volume of Cases
Summary
Has the 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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)

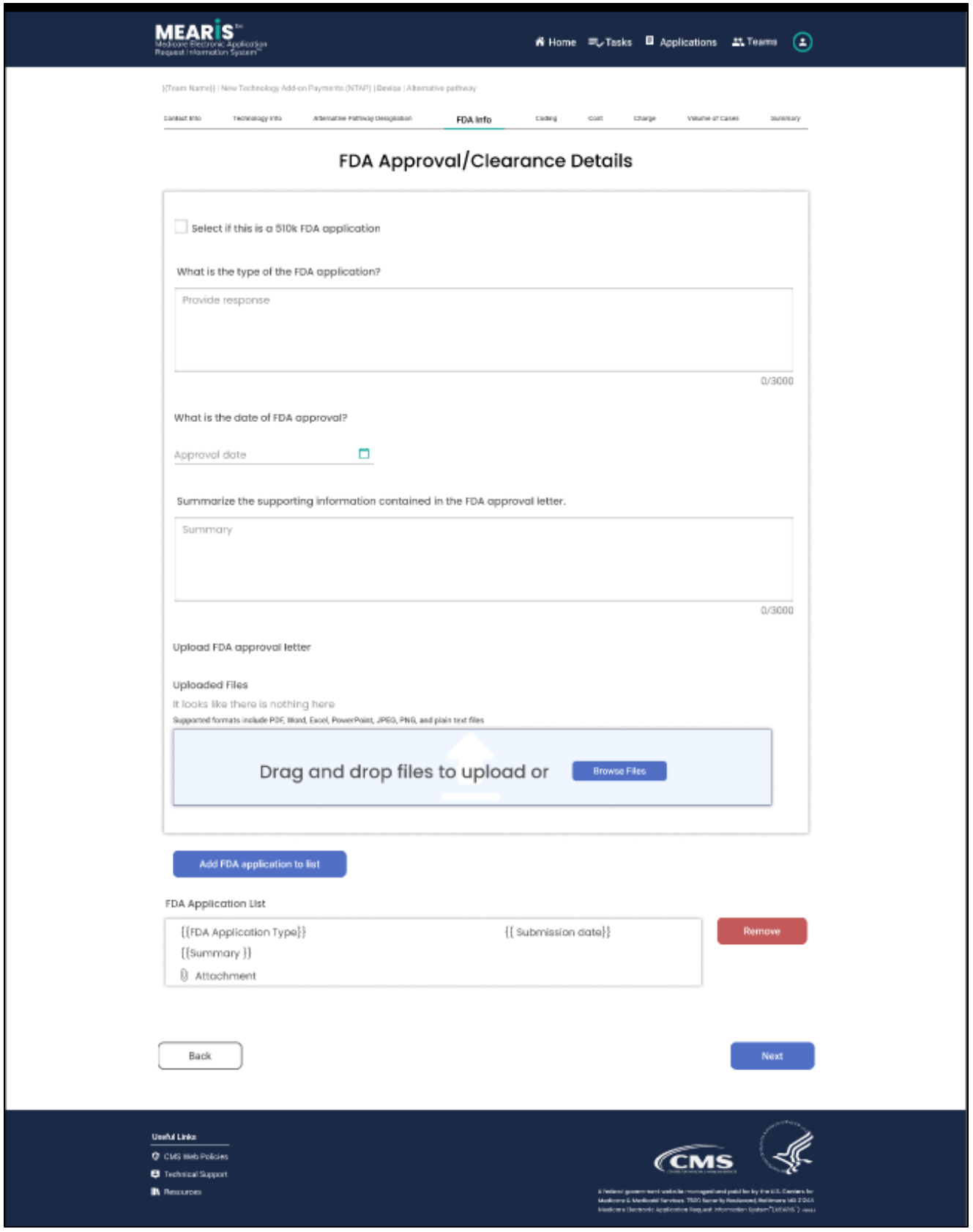

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Drug | Alternative pathway
Contact Info
Technology Info
Alternative Pathway Designation
FDA Info
Coding
Cost
Charge
Volume of Cases
Summary
Alternative 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
Supported formats include PDF, Word, Excel, PowerPoint, JPEG, PNG, and plain text files
Drag and drop files to upload or
Browse Files
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)

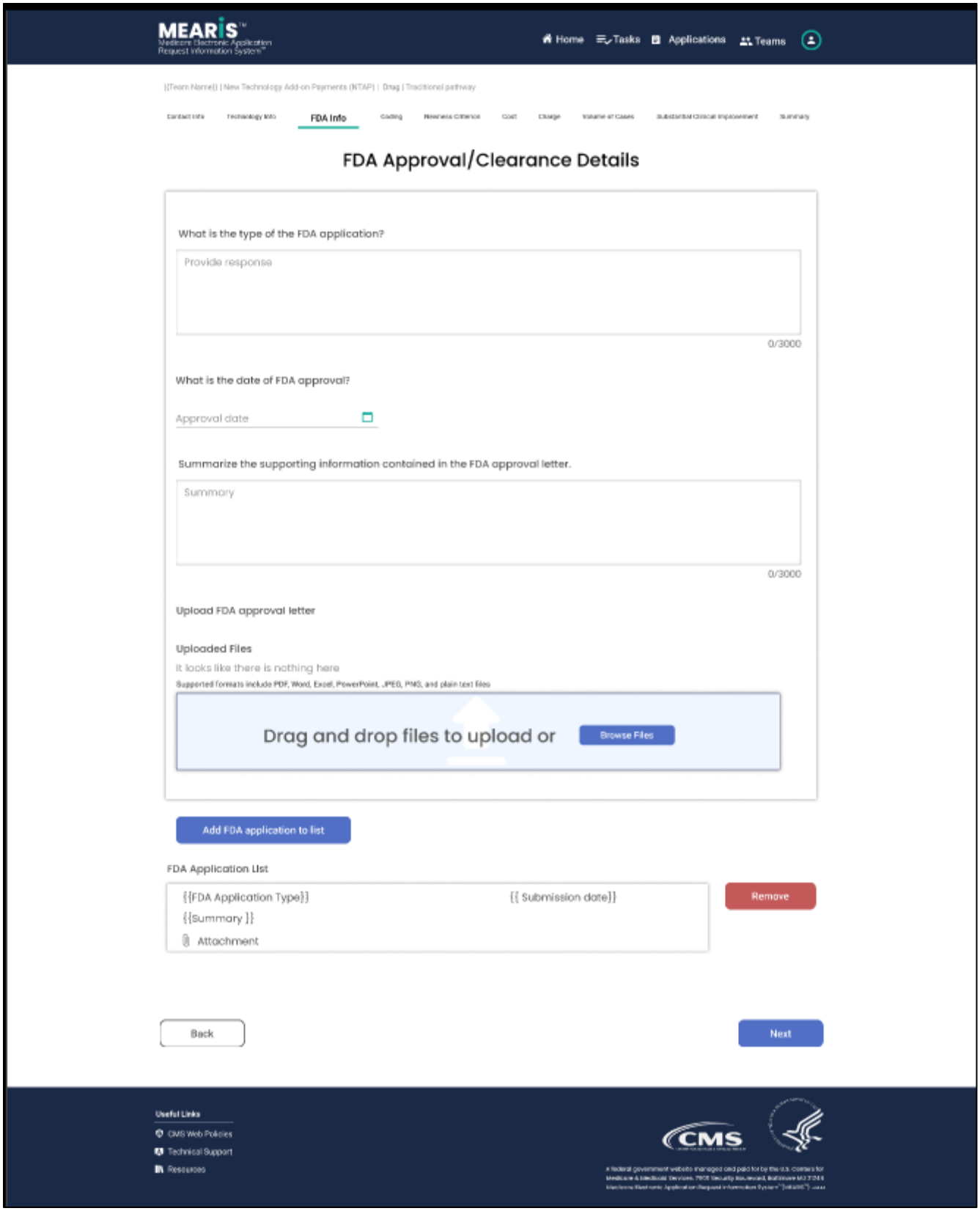

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Drug | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
Has the technology received marketing authorization from the Food and Drug Administration (FDA) for the indication under which the applicant is applying for NTAP?
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
Back
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)

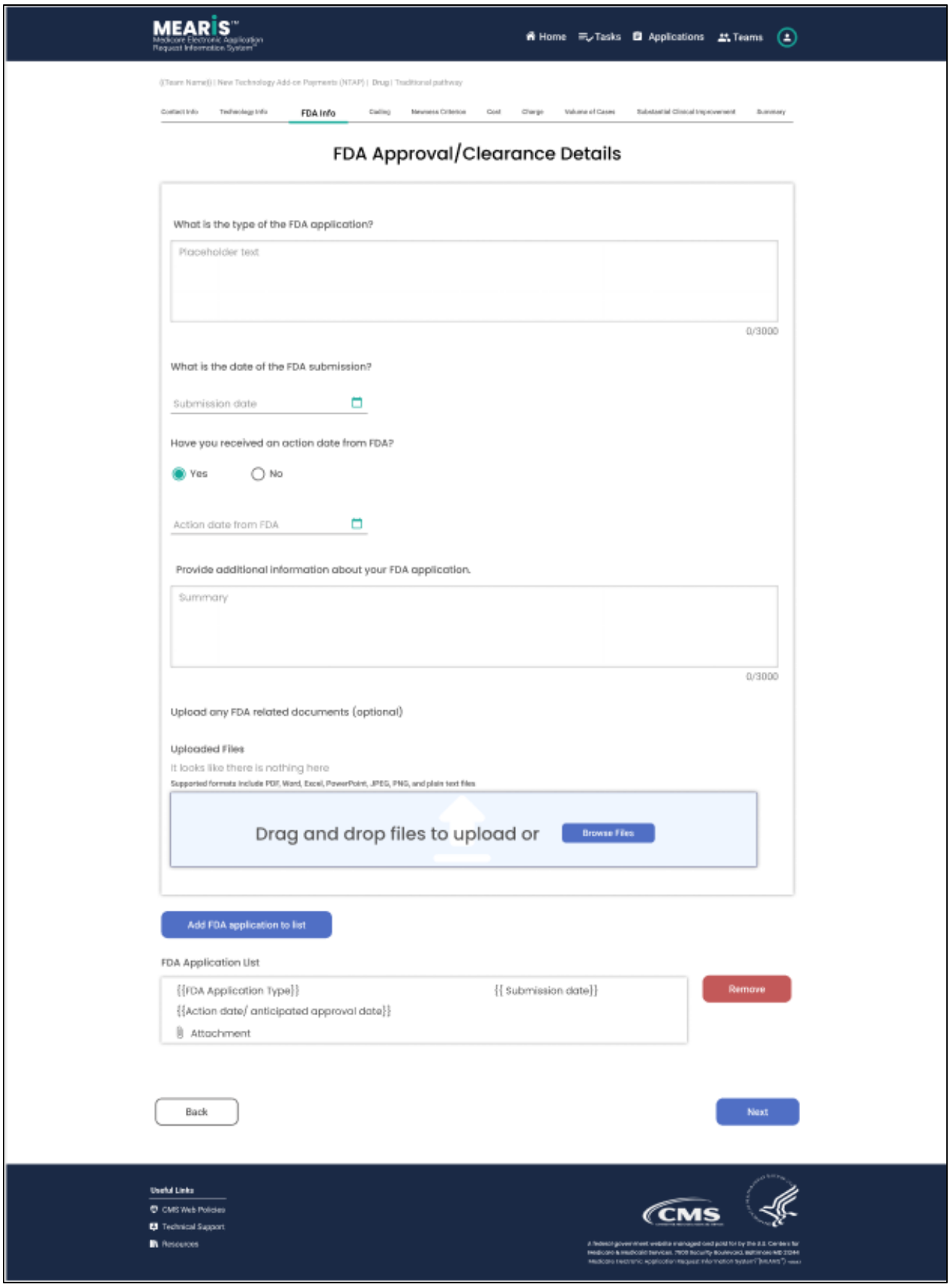

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Drug | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™) v1.0.0

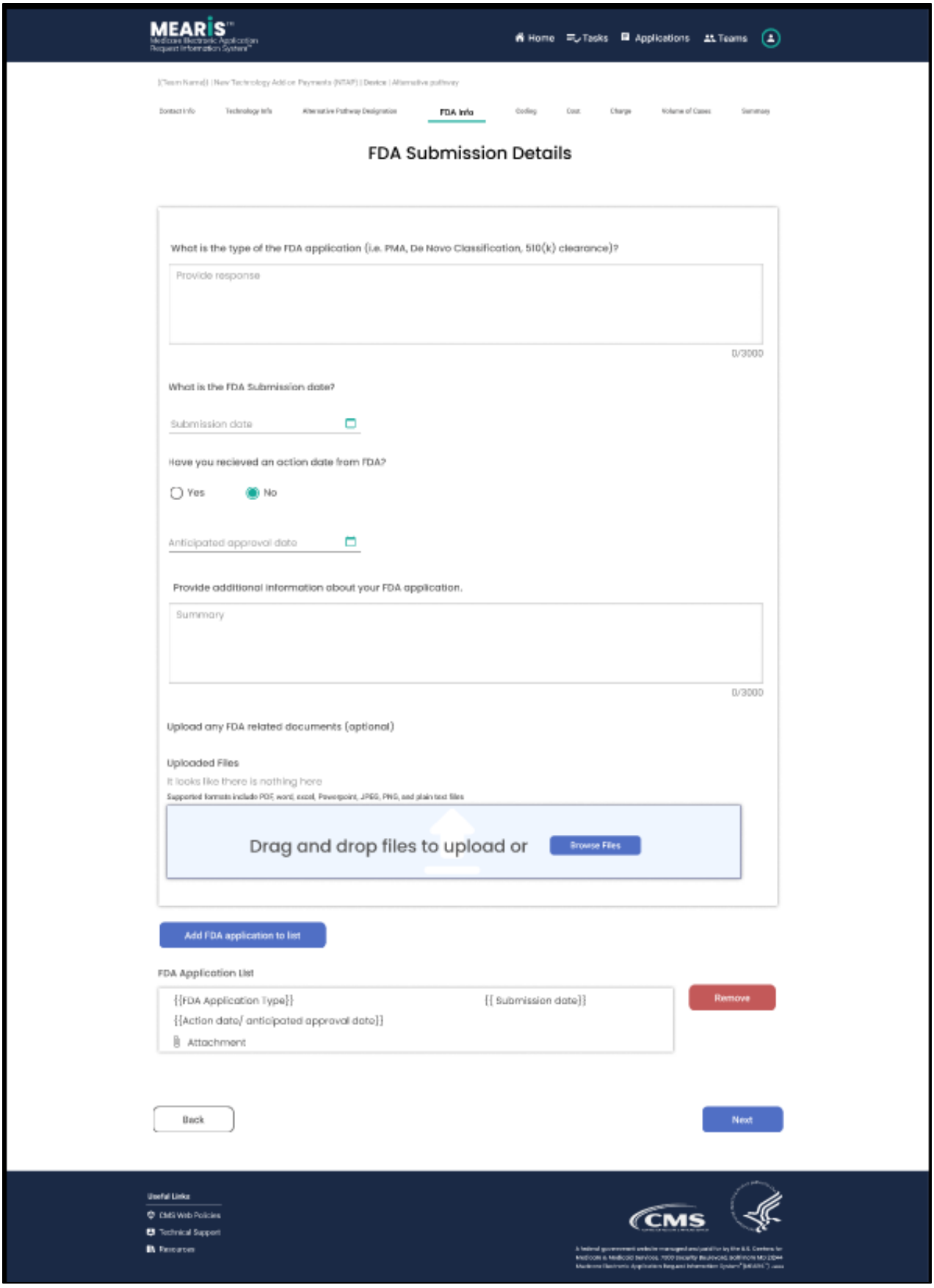

MEARIS
Medicare Electronic Application Request Information System
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
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}}
{{Summary }}
Attachment
Remove
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS

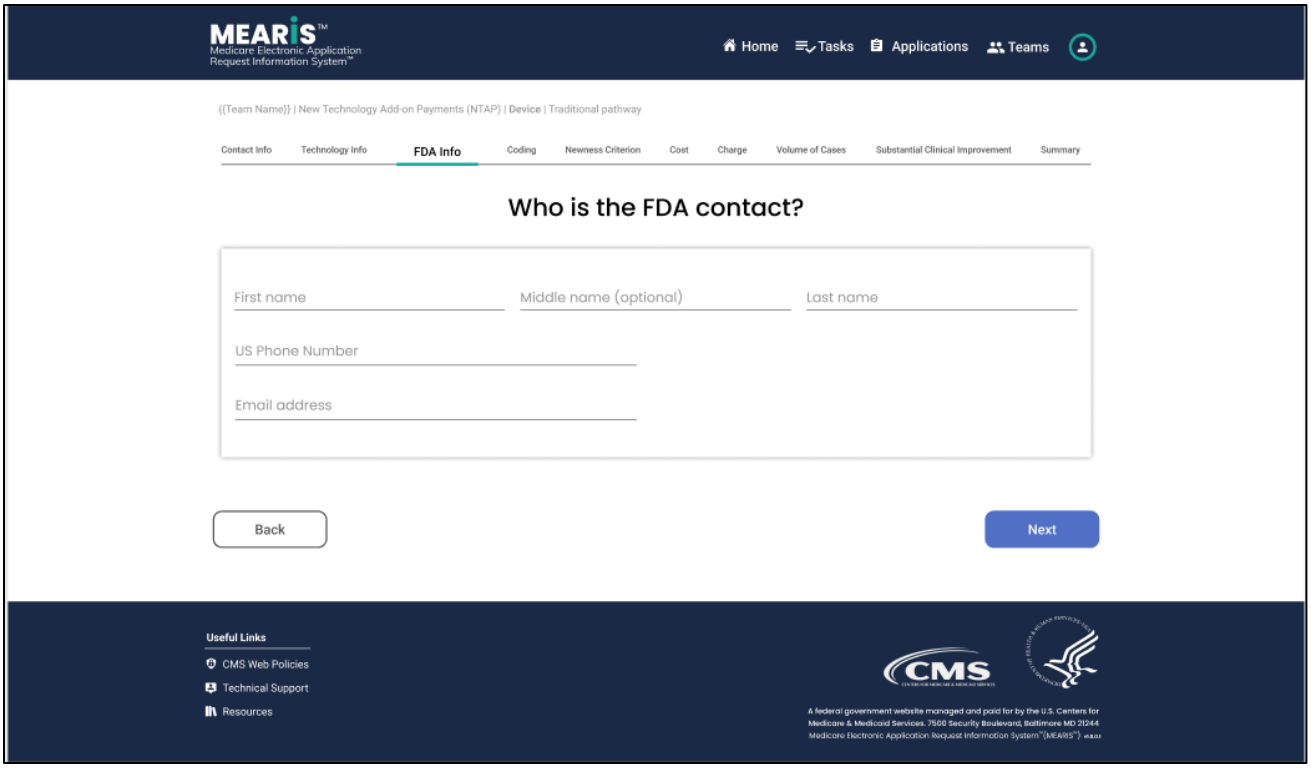

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)

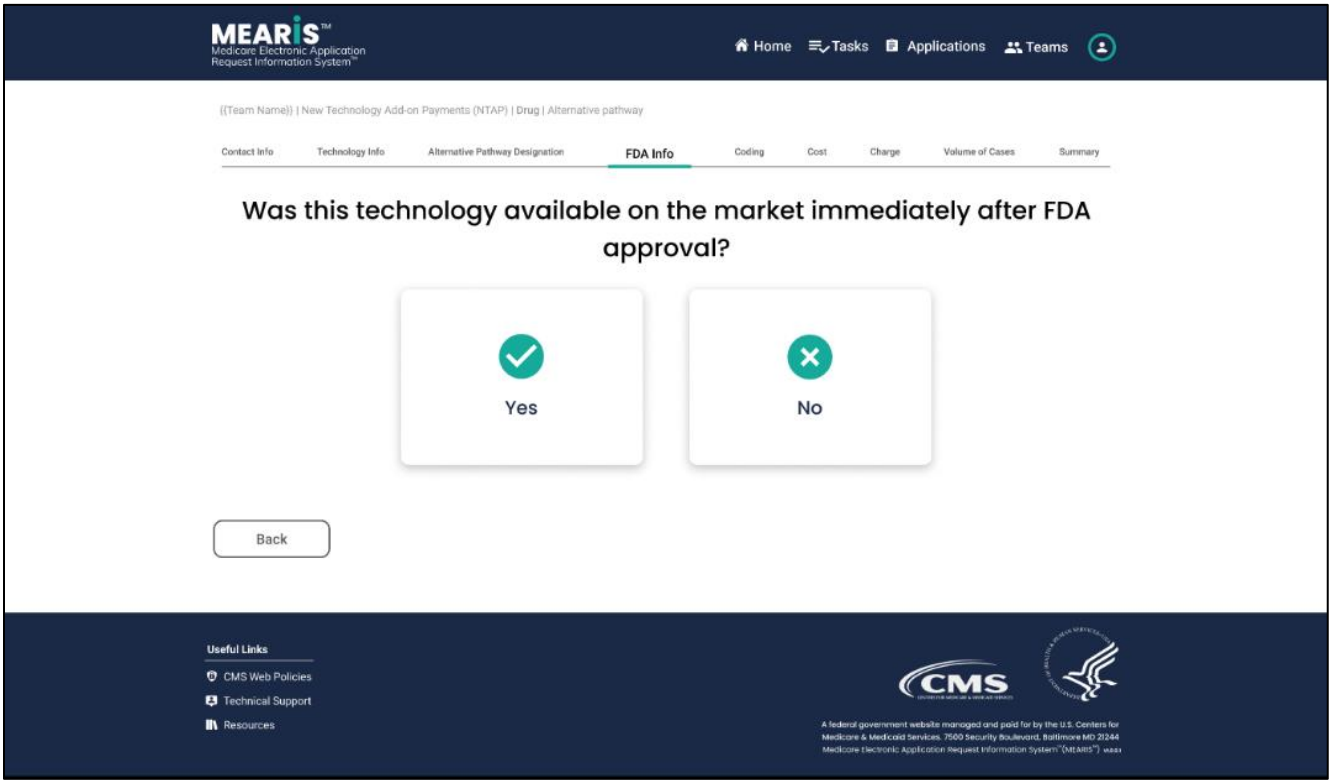

MEARIS
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Alternative pathway
Contact Info
Technology Info
Alternative Pathway Designation
FDA Info
Coding
Cost
Charge
Volume of Cases
Summary
FDA Approval/Clearance Details
Select if this is a 510k FDA application
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
Drag and drop files to upload or
Browse Files
Add FDA application to list
FDA Application List
{{FDA Application Type}}
{{ Submission date}}
{{Summary }}
Attachment
Remove
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS

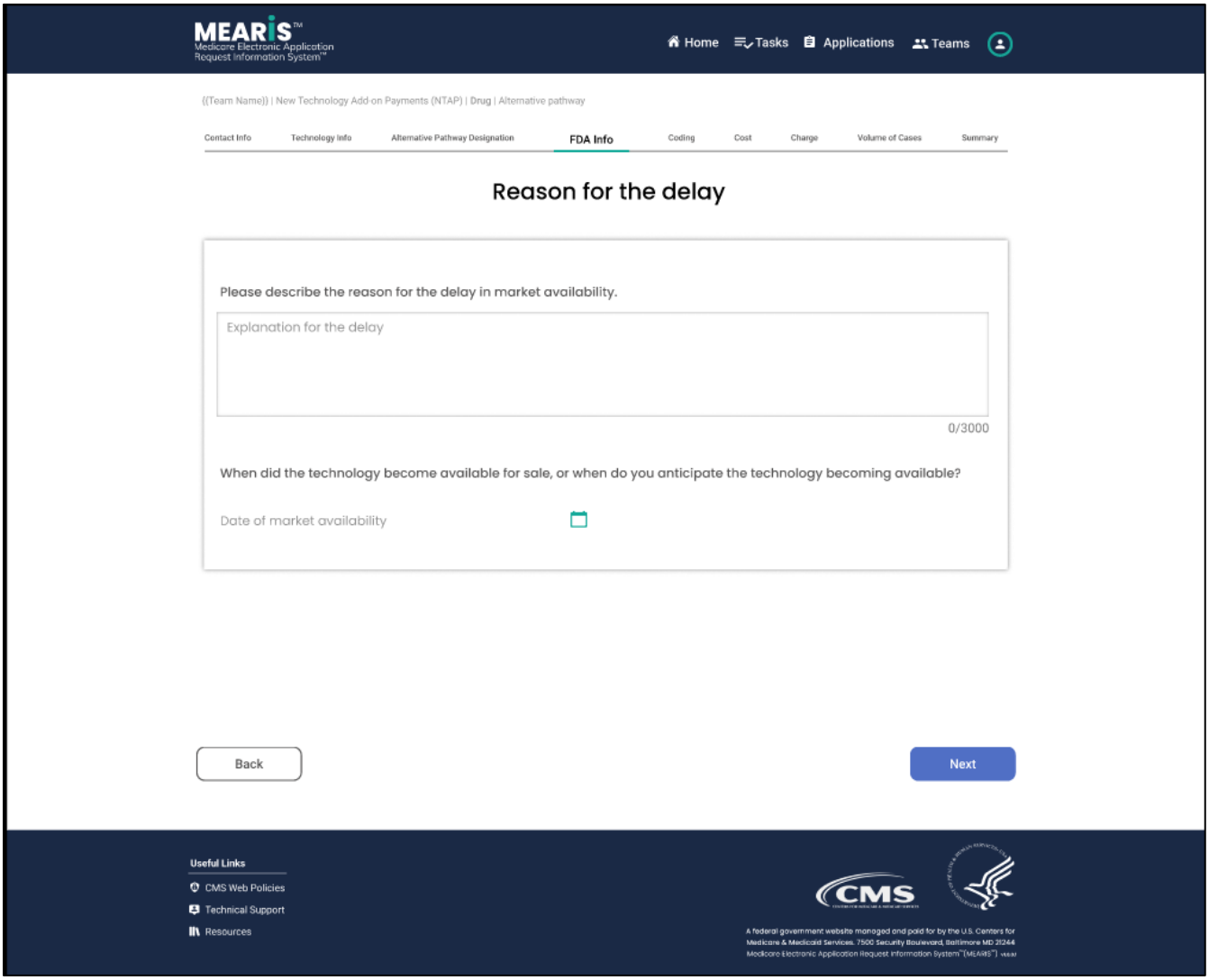

MEARIS
Medicare Electronic Application Request Information System
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Drug | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criteria
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
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
Drag and drop files to upload or
Browse Files
Add FDA application to list
FDA Application List
{{FDA Application Type}}
{{ Submission date}}
{{Summary }}
Attachment
Remove
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS

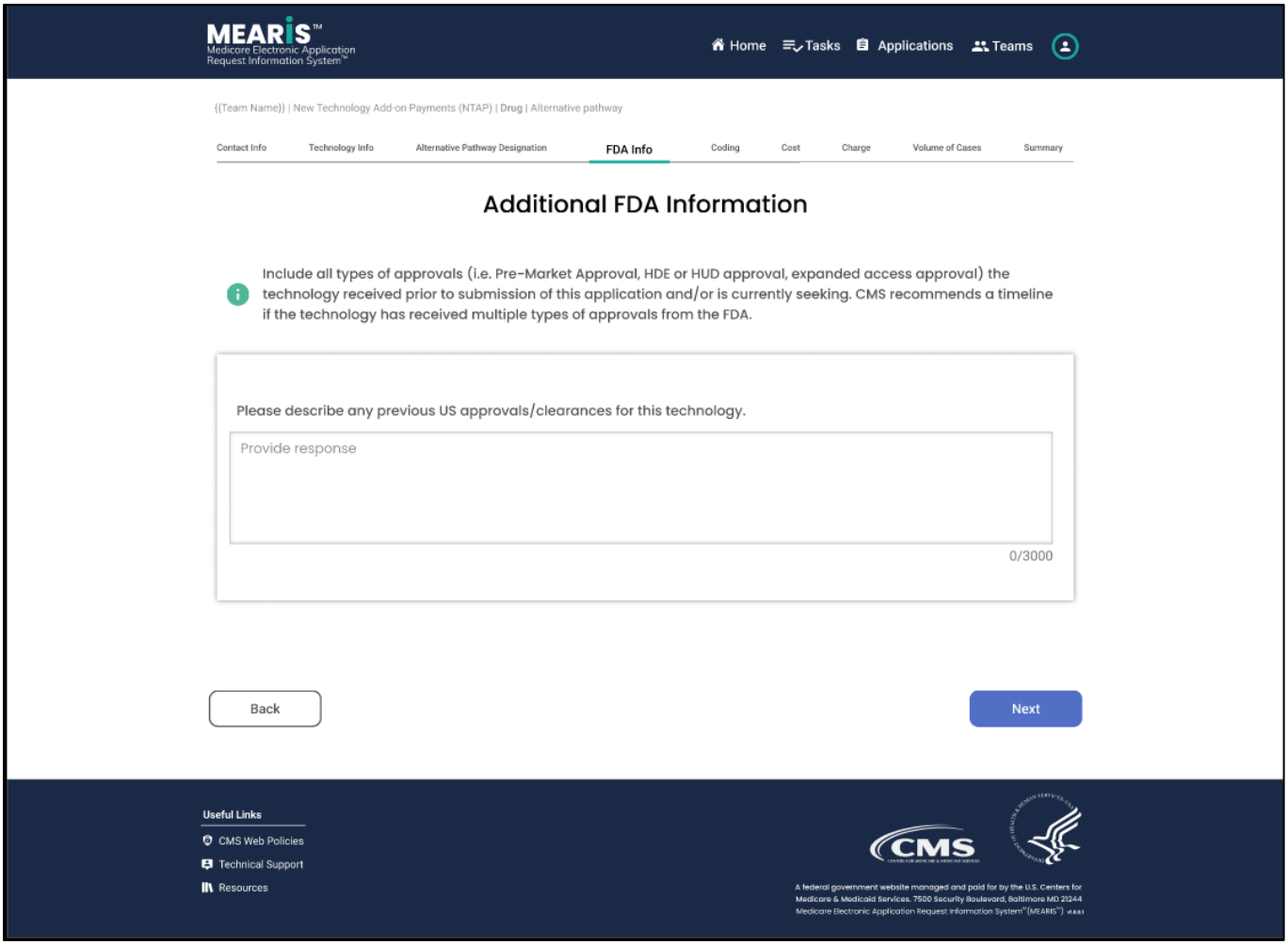

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
({Team Name}) | New Technology Add-on Payments (NTAP) | Drug | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
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
Remove
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS

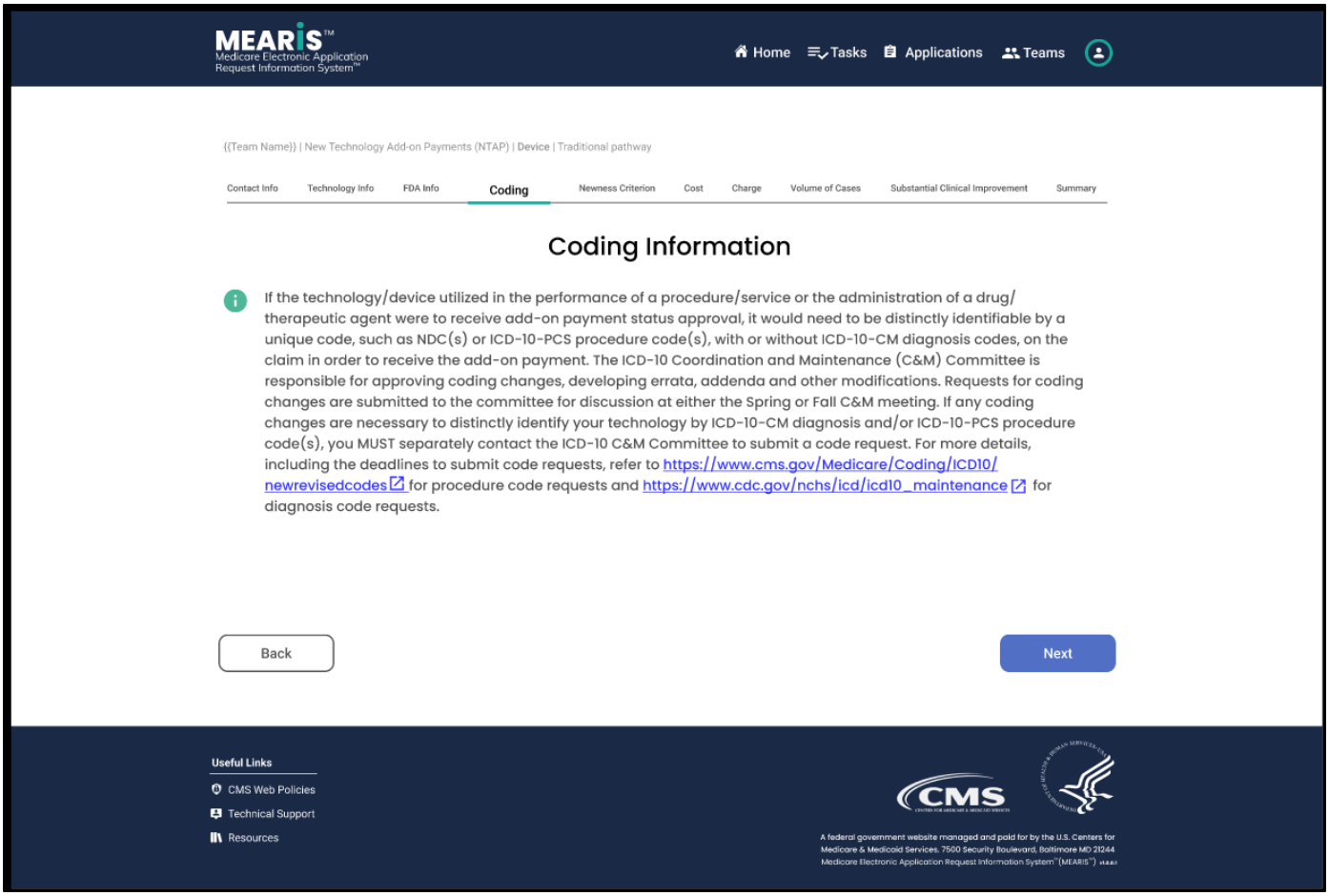

MEARIS
Medicare Electronic Application Request Information System
Home
Tasks
Applications
Teams
Contact Info
Technology Info
Alternative Pathway Designation
FDA Info
Coding
Cost
Charge
Volume of Cases
Summary
FDA Submission Details
What is the type of the FDA application (i.e. PMA, De Novo Classification, 510(k) clearance)?
Provide response
0/3000
What is the FDA Submission date?
Submission date
Have you recieved 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
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
Remove
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS

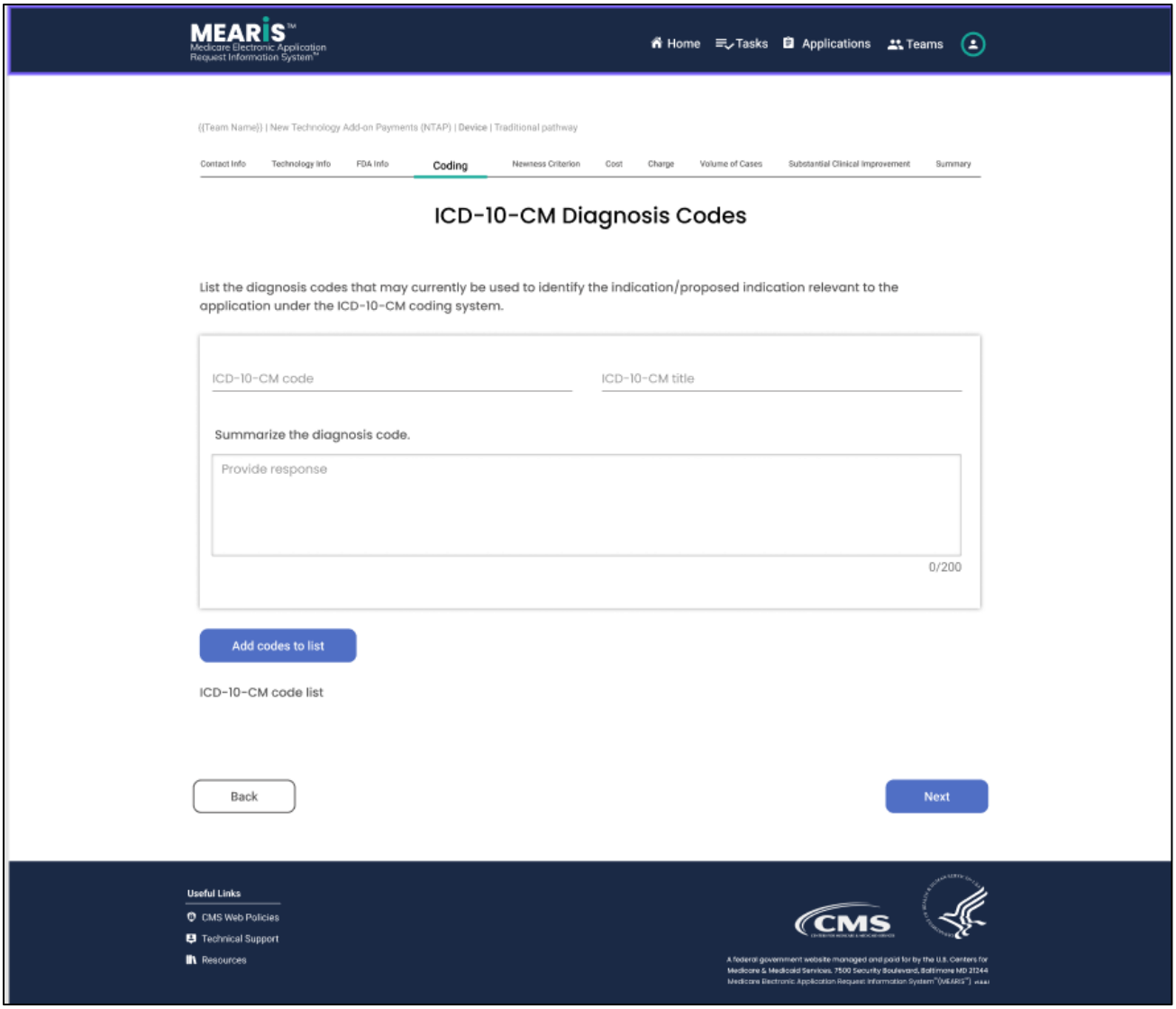

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
Who is the FDA contact?
First name
Middle name (optional)
Last name
US Phone Number
Email address
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)

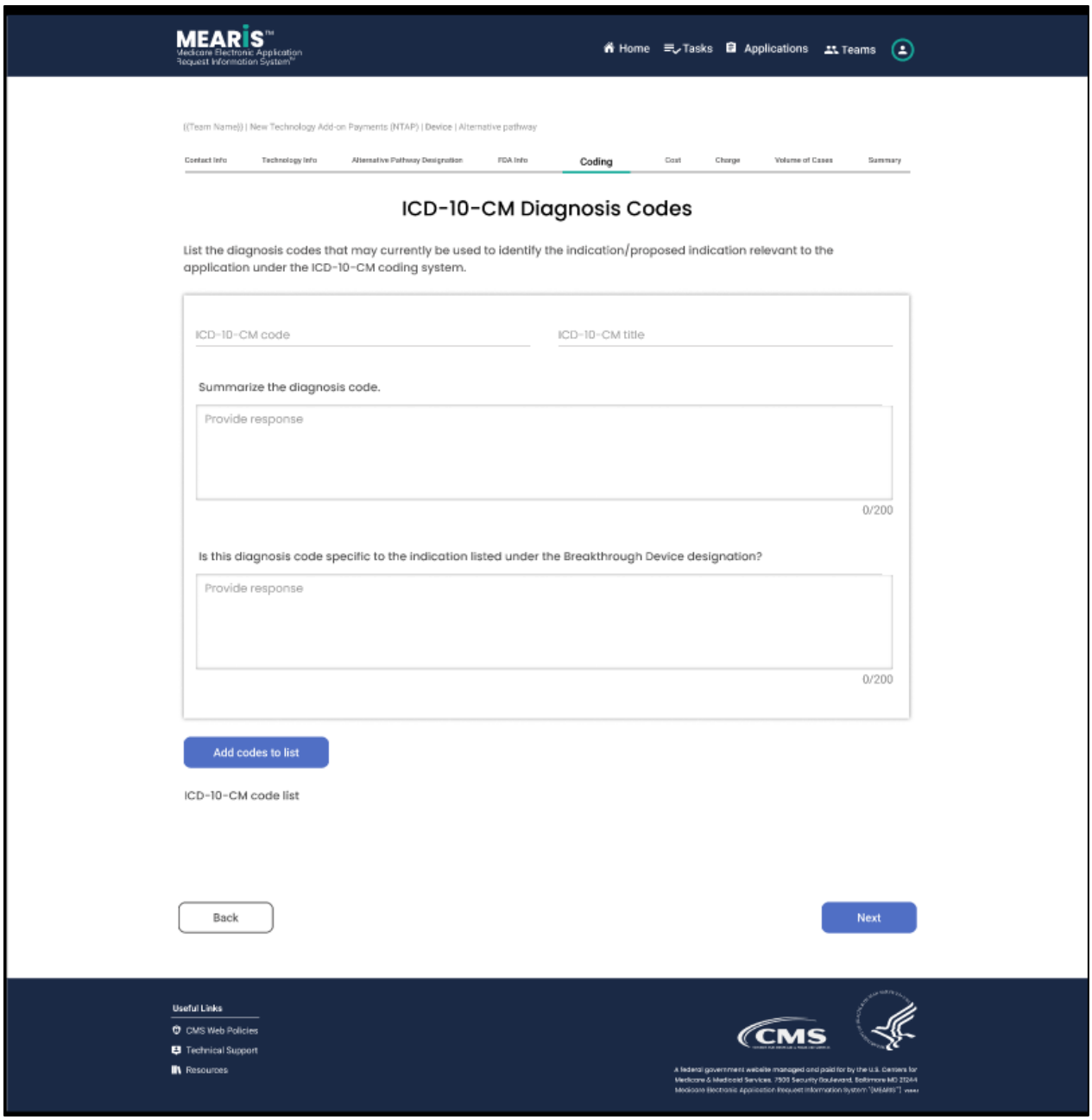

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Drug | Alternative pathway
Contact Info
Technology Info
Alternative Pathway Designation
FDA Info
Coding
Cost
Charge
Volume of Cases
Summary
Was this technology available on the market immediately after FDA approval?
Yes
No
Back
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)

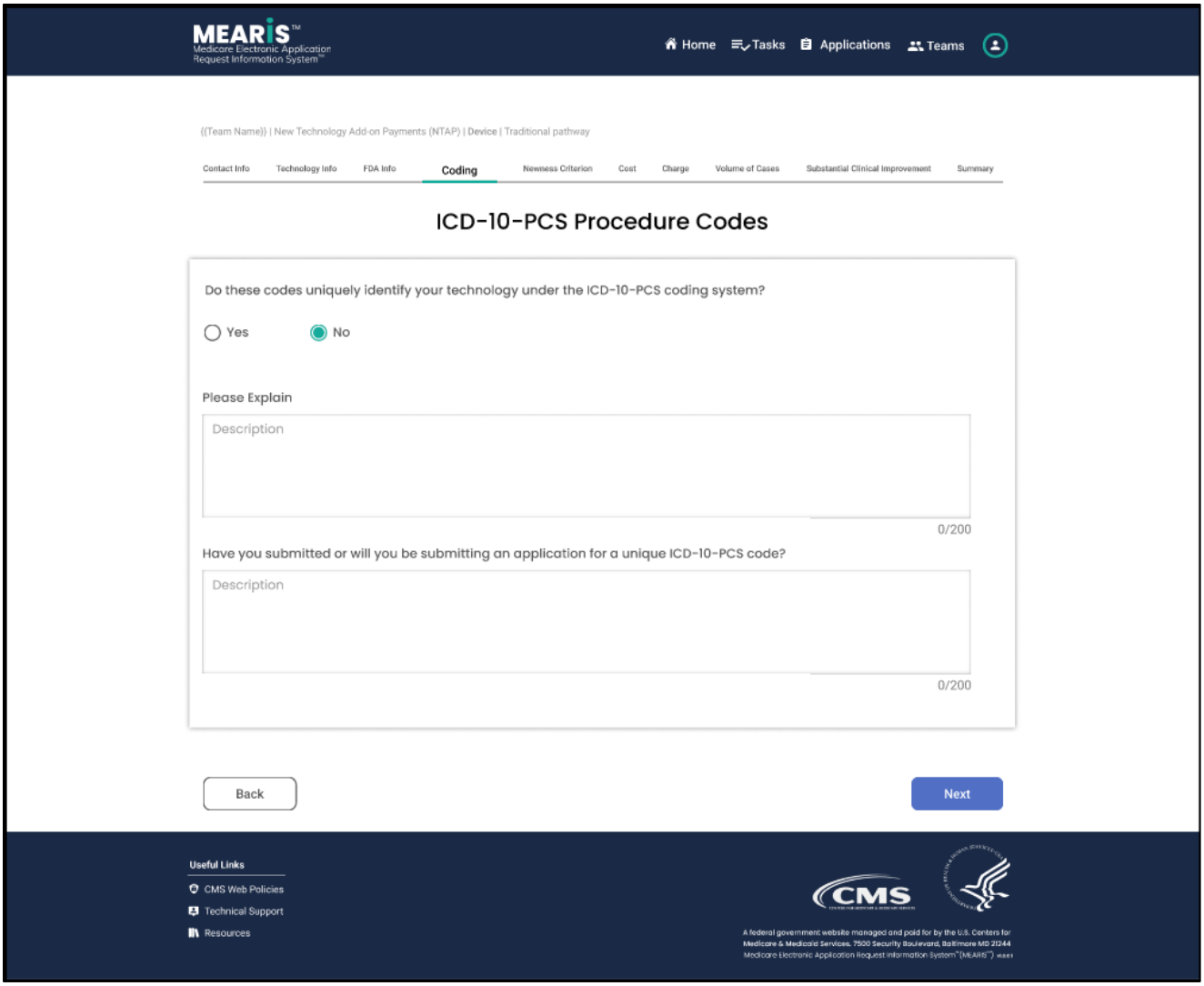

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Drug | Alternative pathway
Contact Info
Technology Info
Alternative Pathway Designation
FDA Info
Coding
Cost
Charge
Volume of Cases
Summary
Reason 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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services. 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)

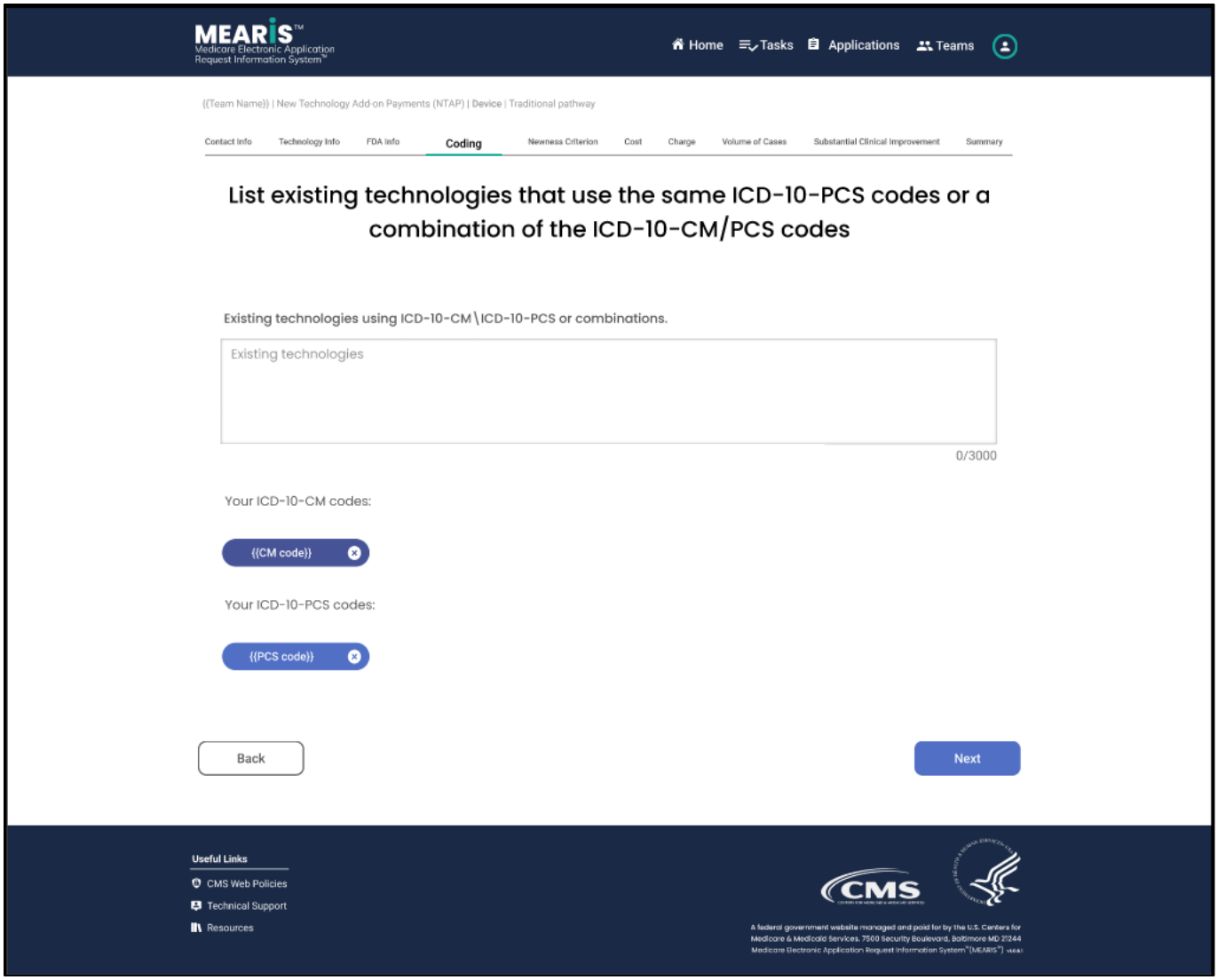

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Drug | Alternative pathway
Contact Info
Technology Info
Alternative Pathway Designation
FDA Info
Coding
Cost
Charge
Volume of Cases
Summary
Additional FDA Information
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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™(MEARIS™)

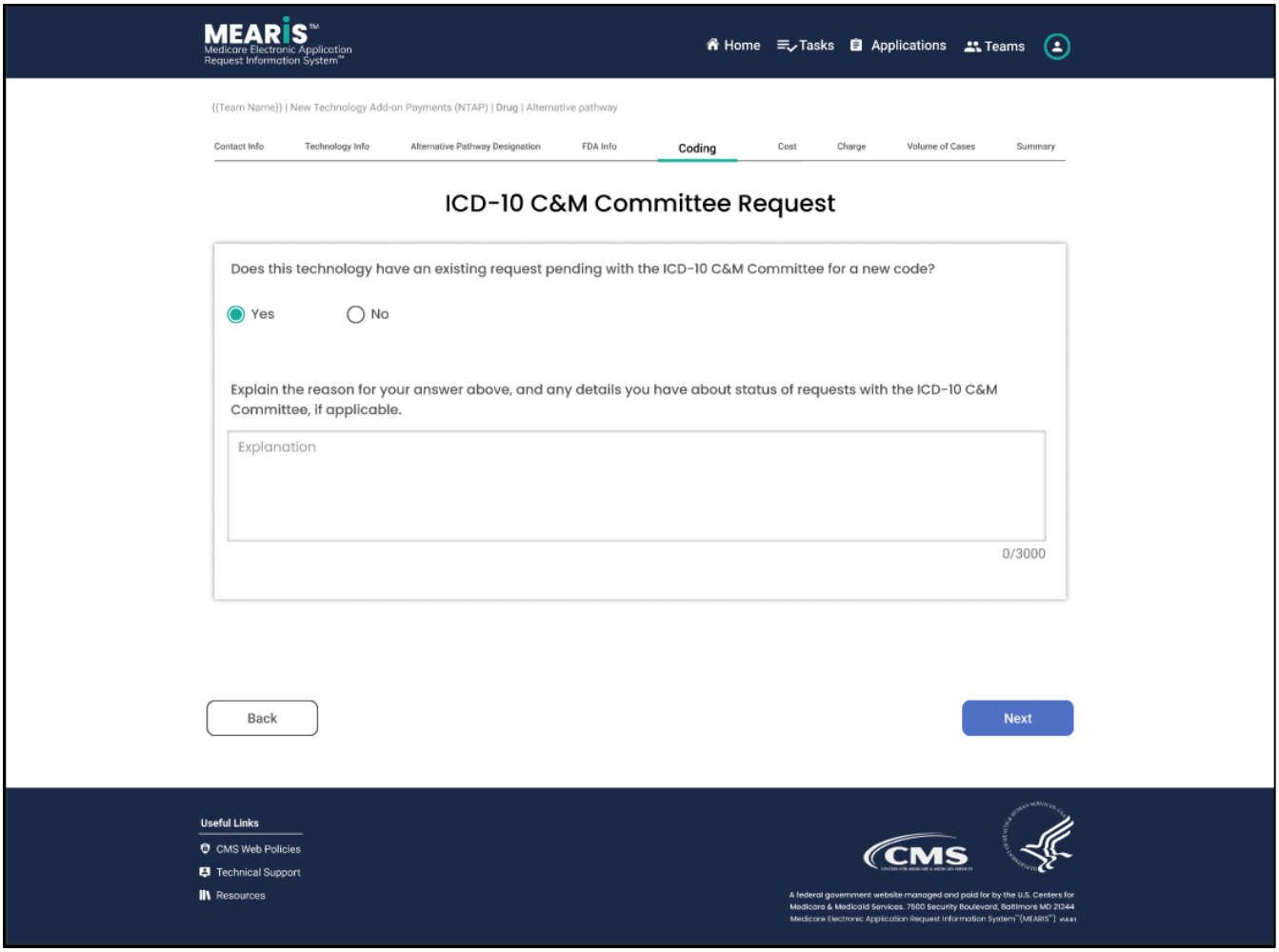

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
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.
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)

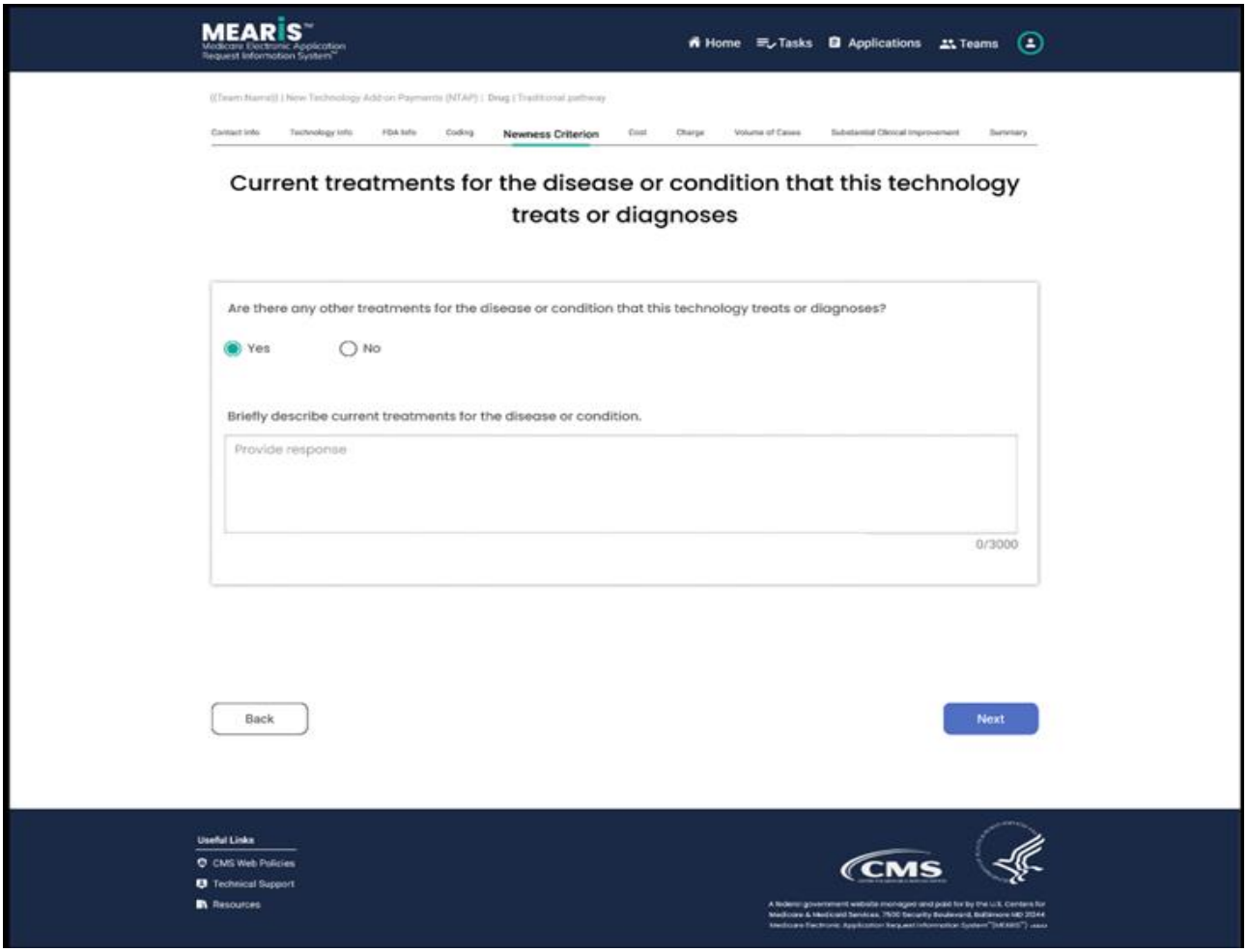

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
({Team Name}) | New Technology Add-on Payments (NTAP) | Device | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
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
Summarize the diagnosis code.
Provide response
0/200
Add codes to list
ICD-10-CM code list
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
((Team Name)) | New Technology Add-on Payments (NTAP) | Device | Alternative pathway
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
Summarize the diagnosis code.
Provide response
0/200
Is this diagnosis code specific to the indication listed under the Breakthrough Device designation?
Provide response
0/200
Add codes to list
ICD-10-CM code list
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System: ("MEARIS") ####


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{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-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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{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
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}}
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Drug | Alternative pathway
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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)


MEARIS
Medicare Electronic Application Request Information System
Home
Tasks
Applications
Teams
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS

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

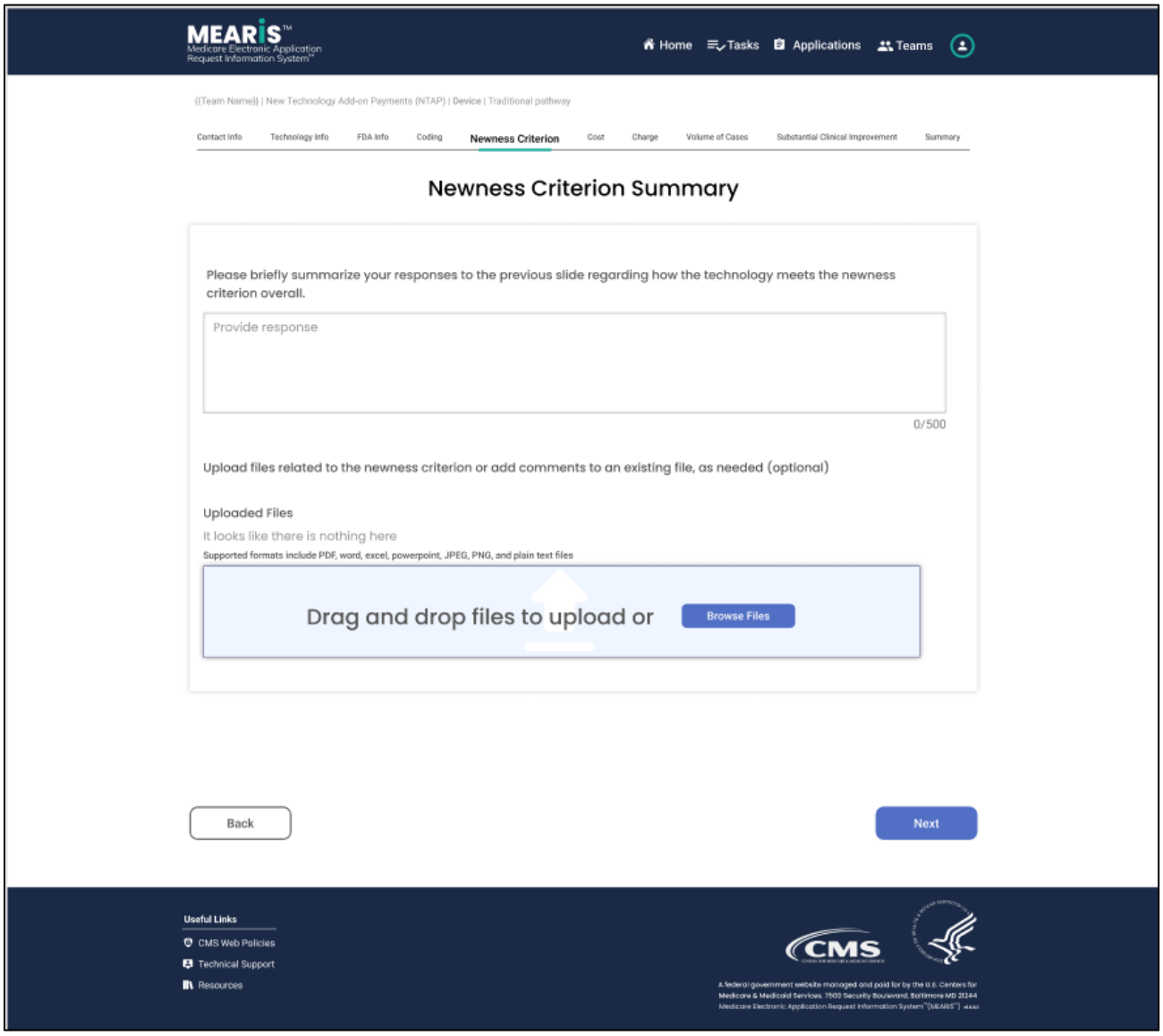
Explain why or why not?

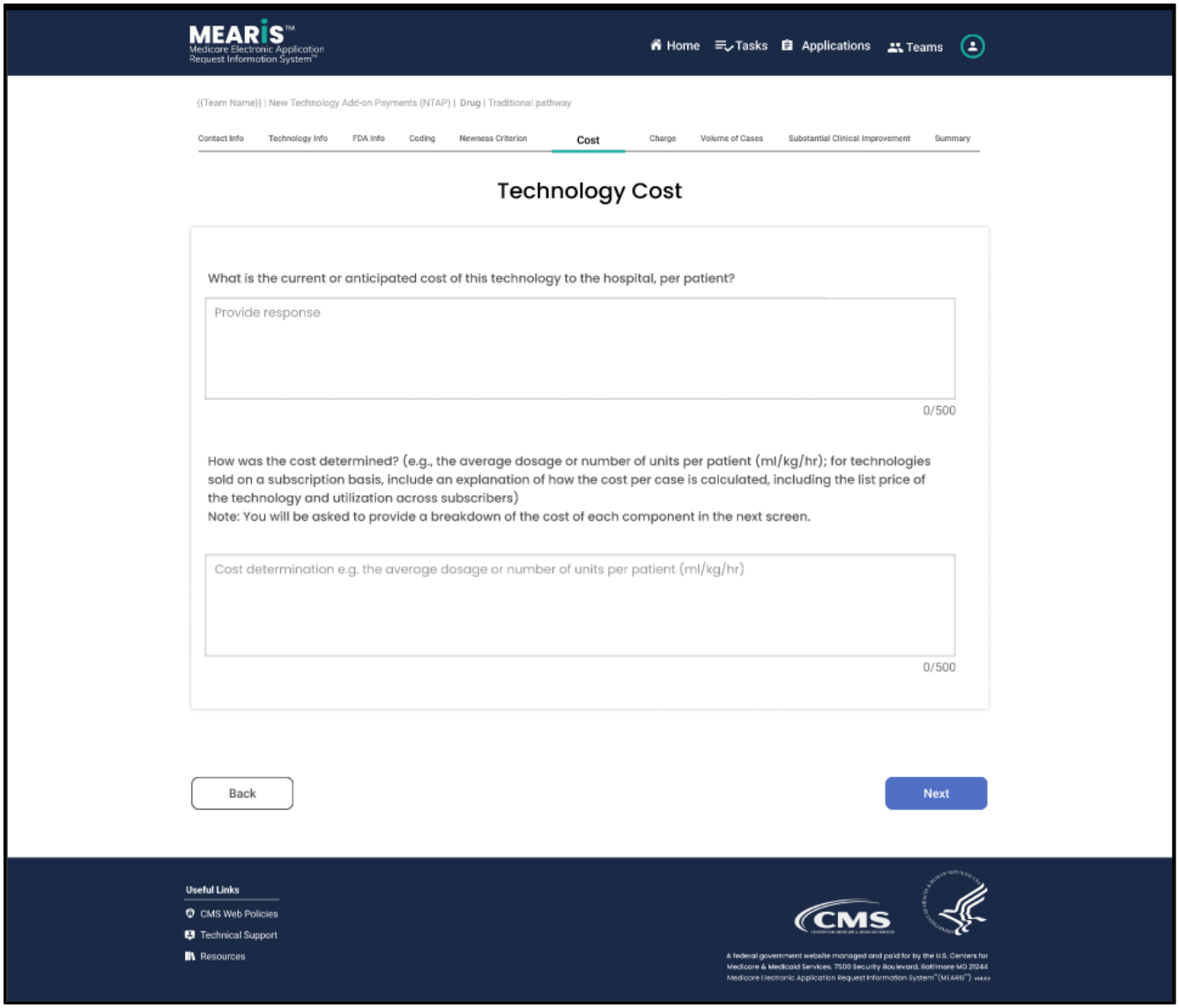
Provide response

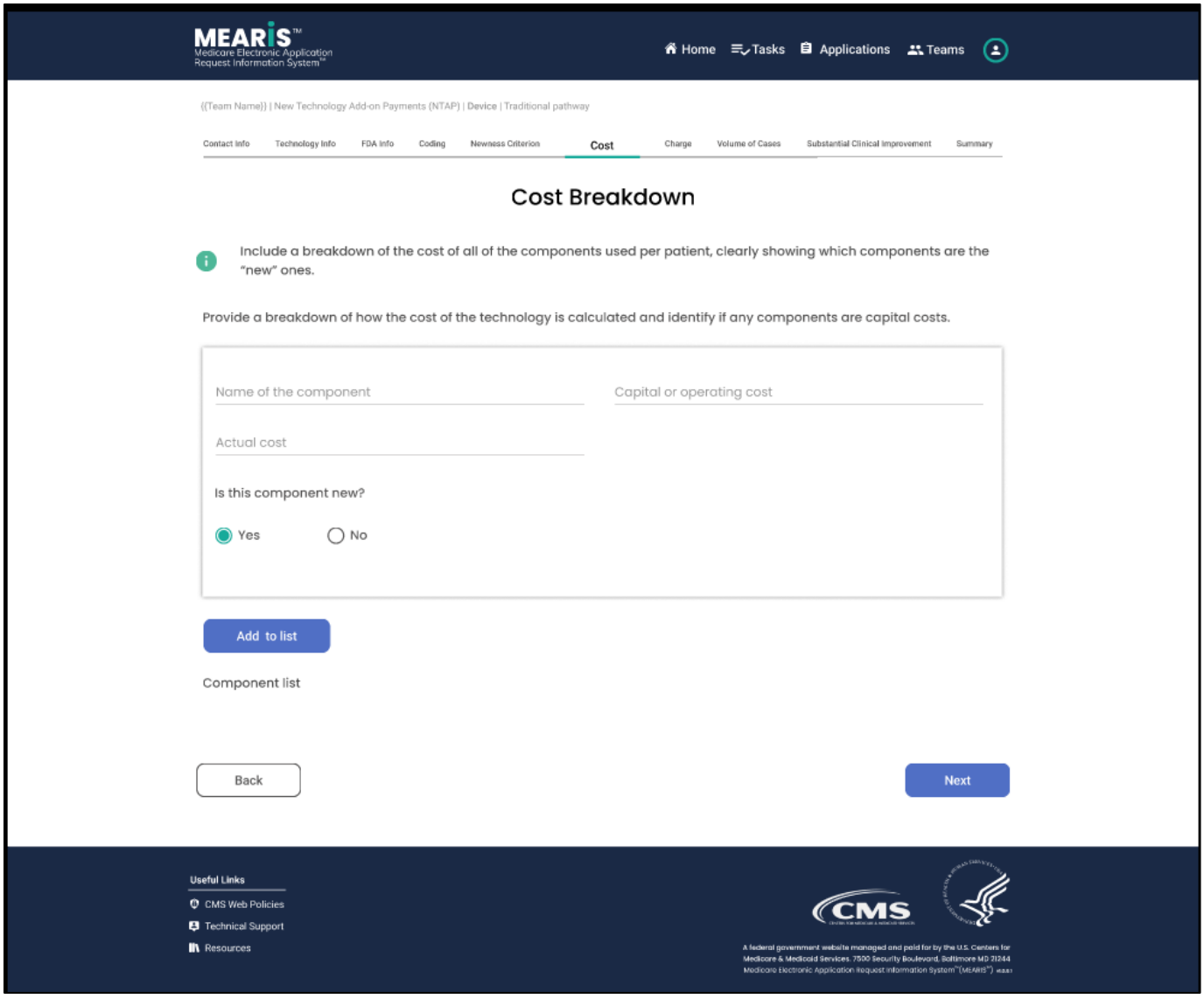
0/3000

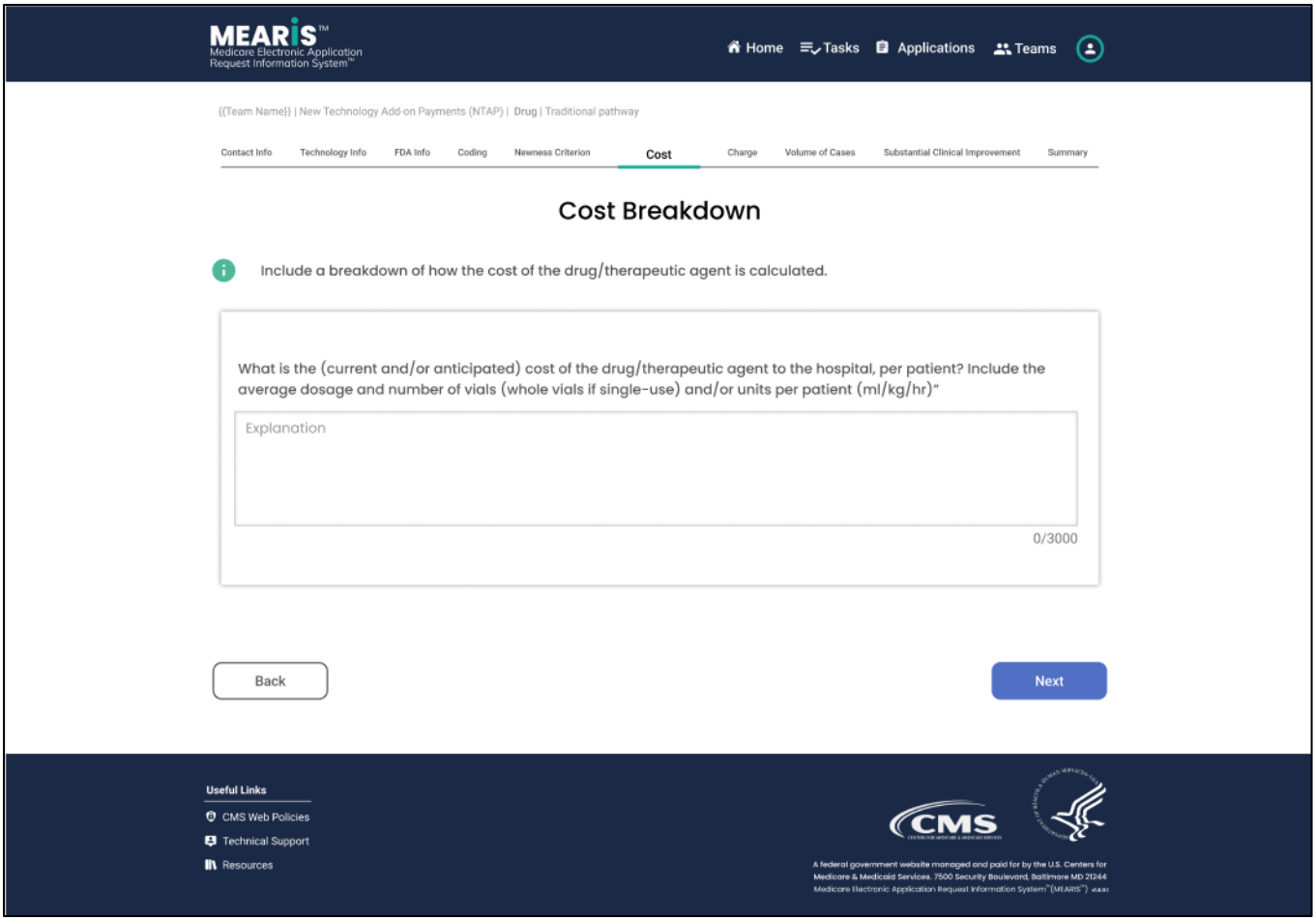
Back

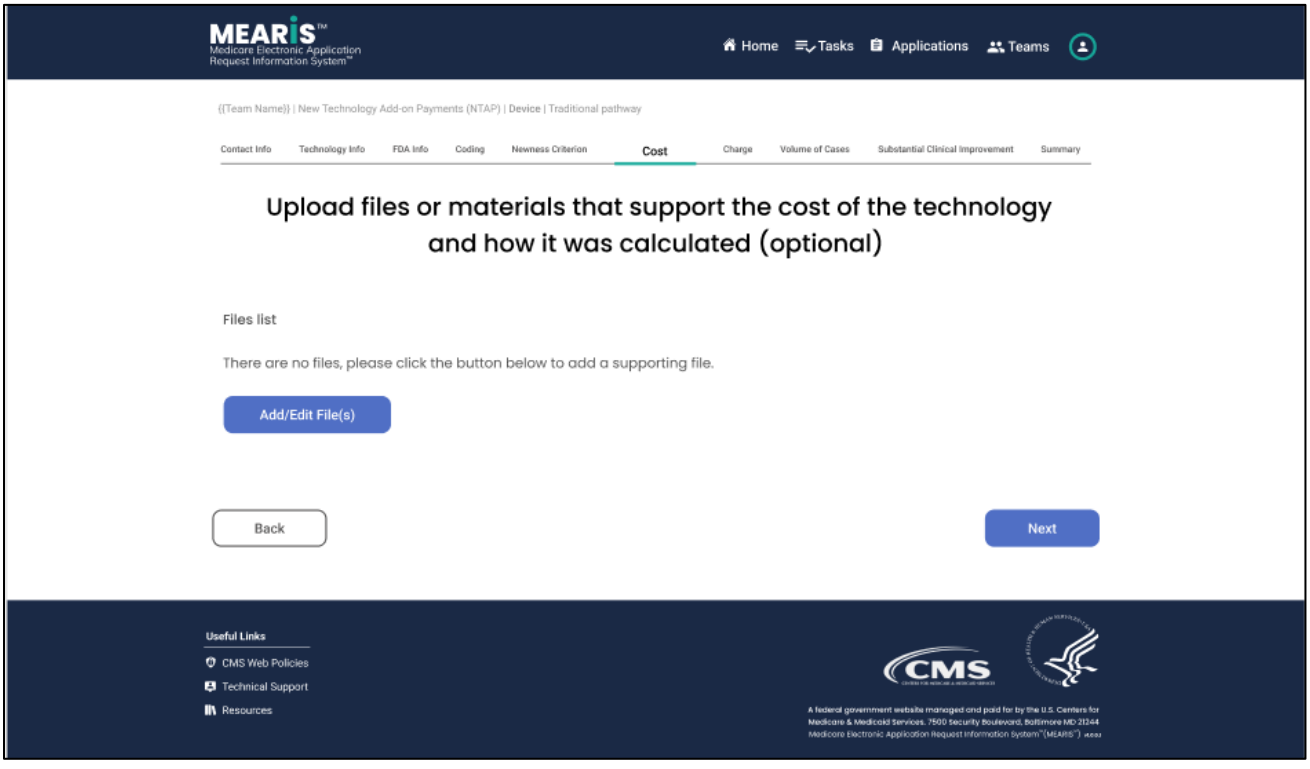
Next

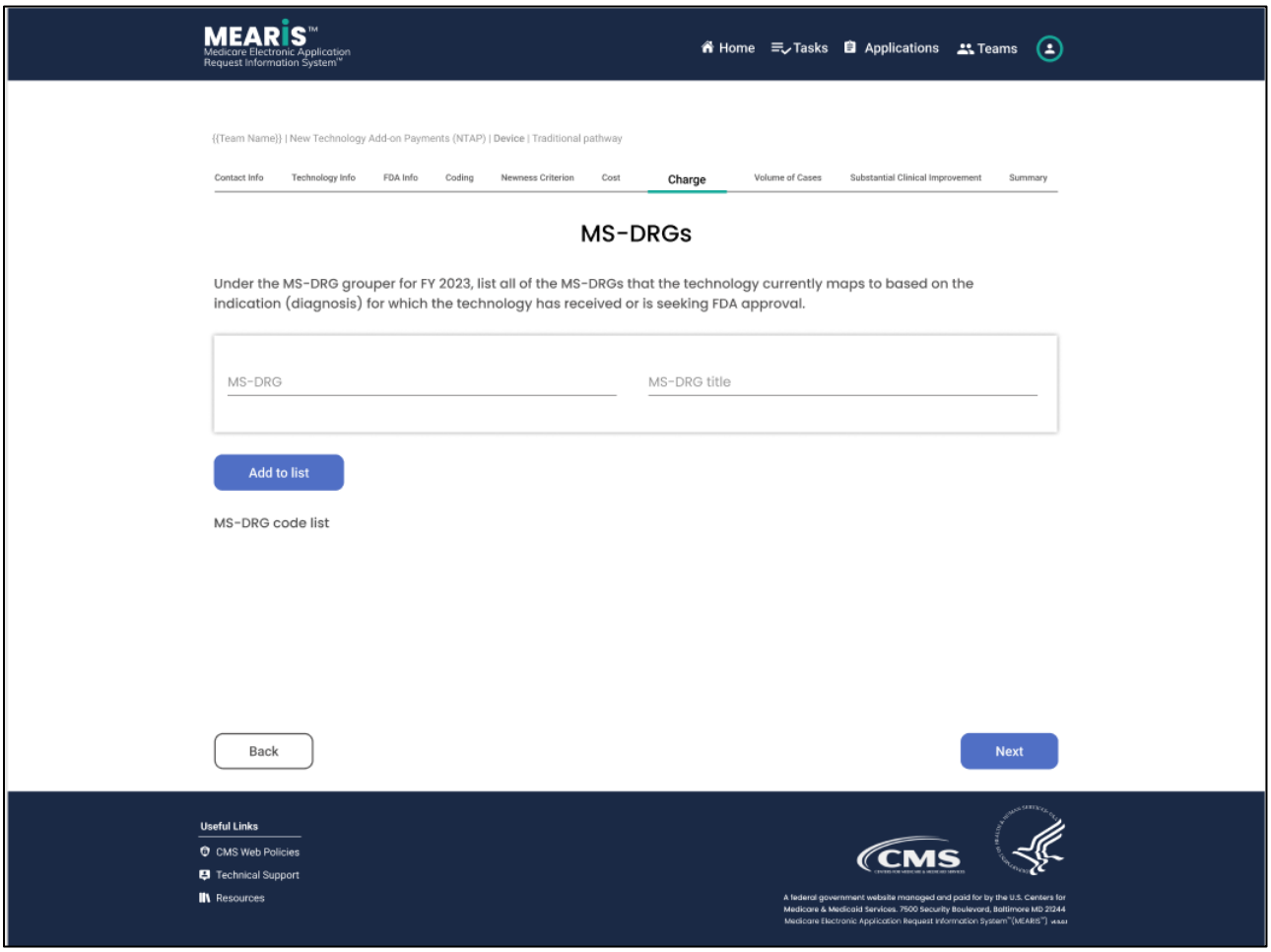

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services. 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ [MARIS™]

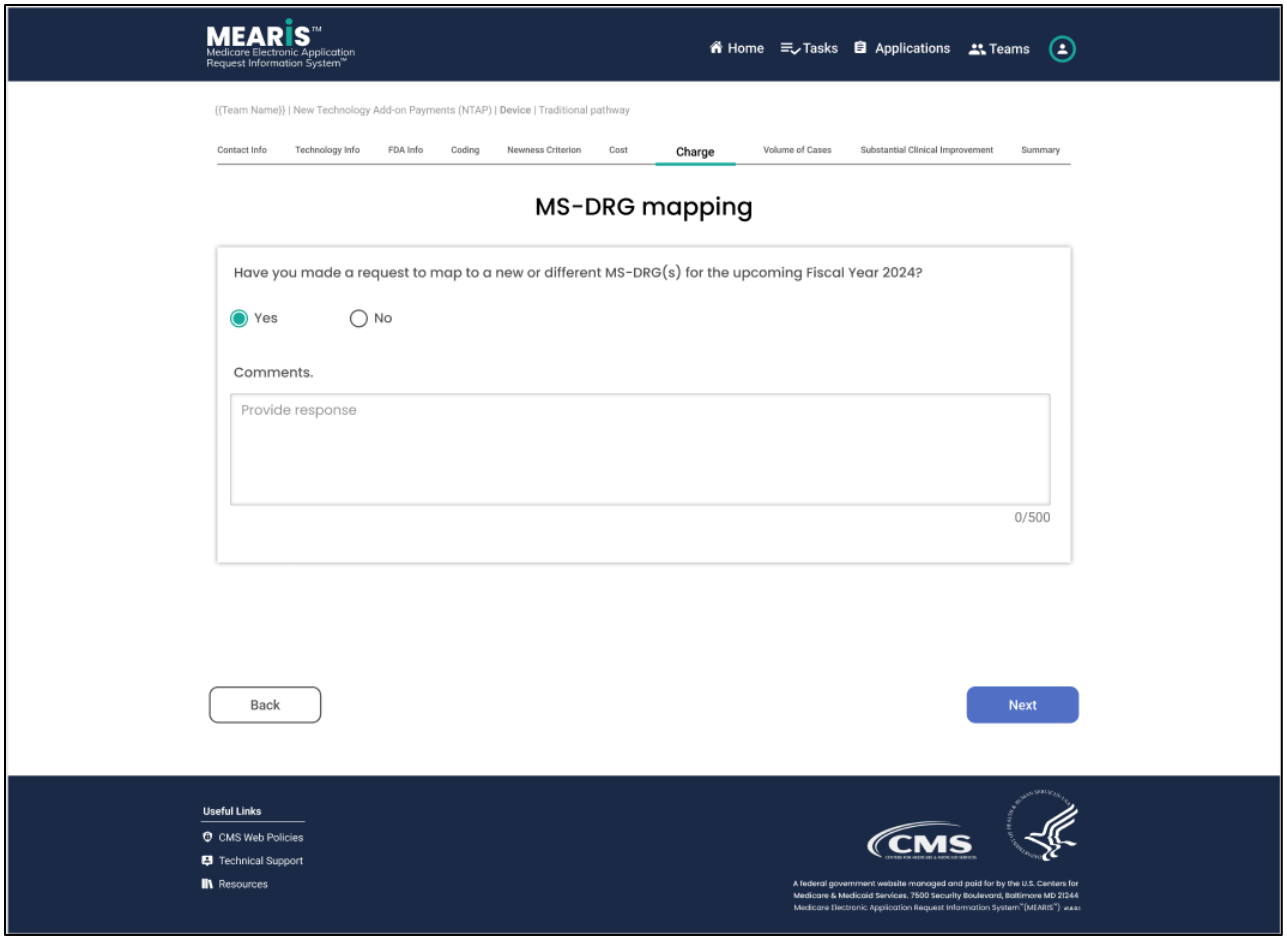

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Drug | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{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
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?
Yes
No
Add to list
Component list
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services. 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{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
Cost Breakdown
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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{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
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)
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{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
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
Add to list
MS-DRG code list
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services. 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™) v.x.x.x


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{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
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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services. 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)

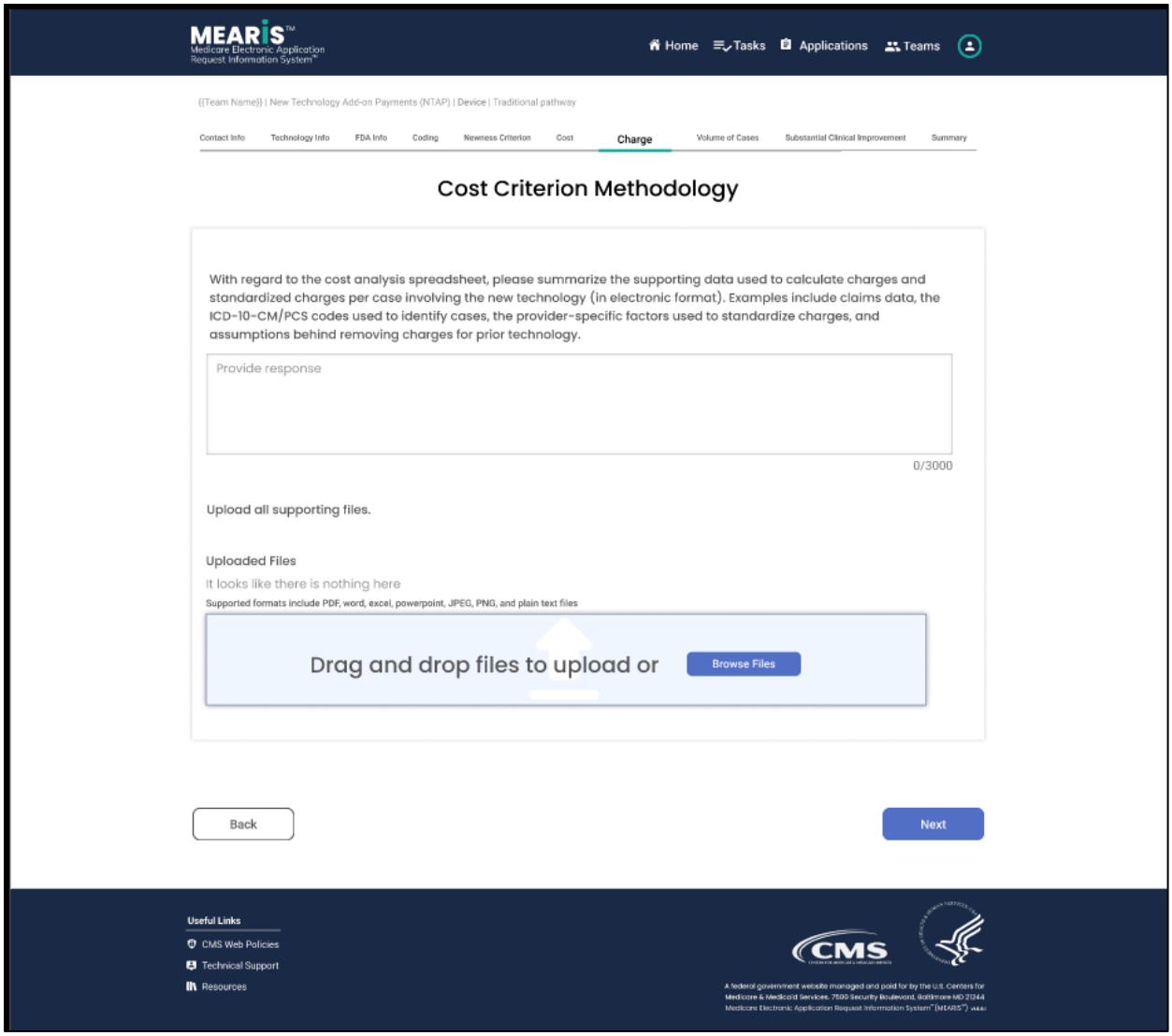
About Cost Criterion

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


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{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
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
Drag and drop files to upload or
Browse Files
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)

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

Back

Next

Cost Analysis Methodology (column F to J)

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

Back

Next

Cost Analysis Methodology (column K to O)

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

Back

Next

Cost Analysis Methodology (column P to S)

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

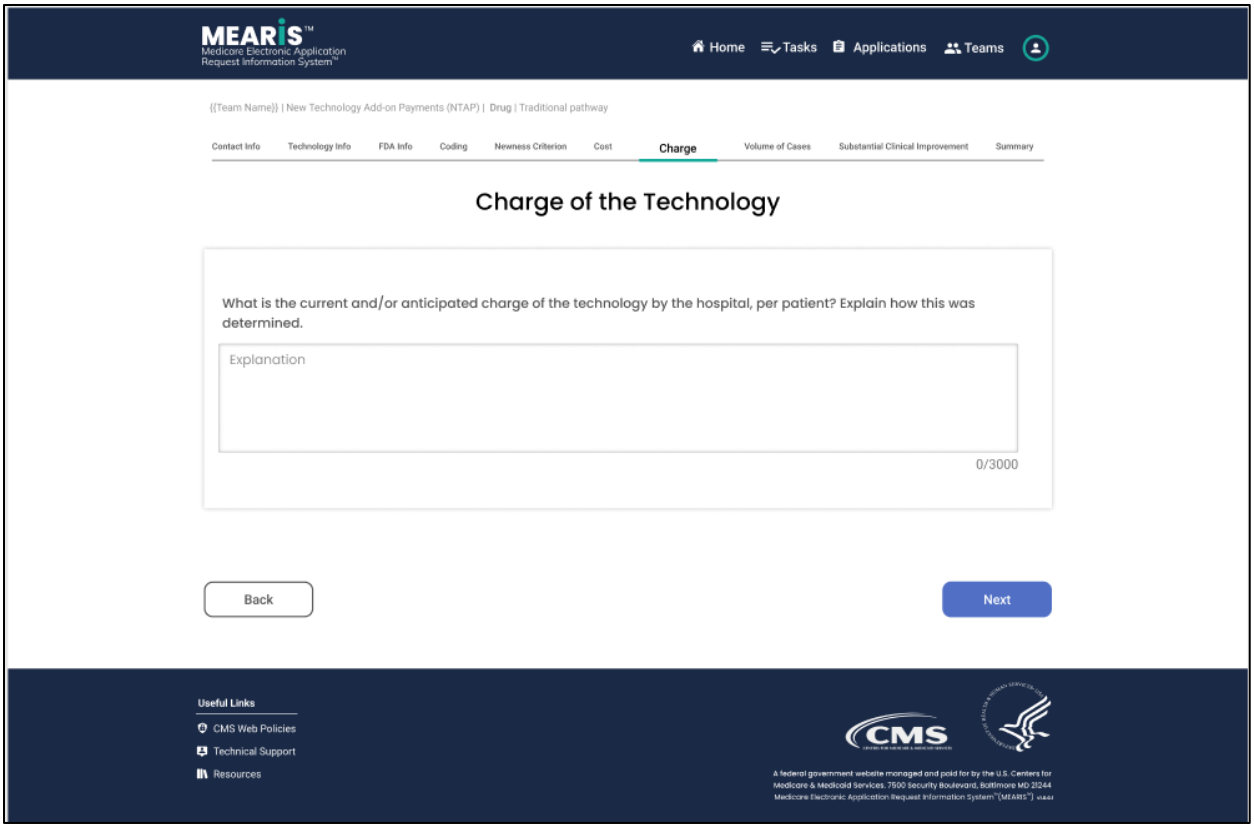
S. Final Inflated Case Weighted Standardized Charge Per Case

Provide response

0/3000

Back

Next


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)

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

Back

Next

What is the anticipated inpatient Non-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 Non-Medicare Volume

Please describe how you arrived at this estimate.

Determination details

0/3000

Upcoming Fiscal Year Anticipated Inpatient Non-Medicare Volume

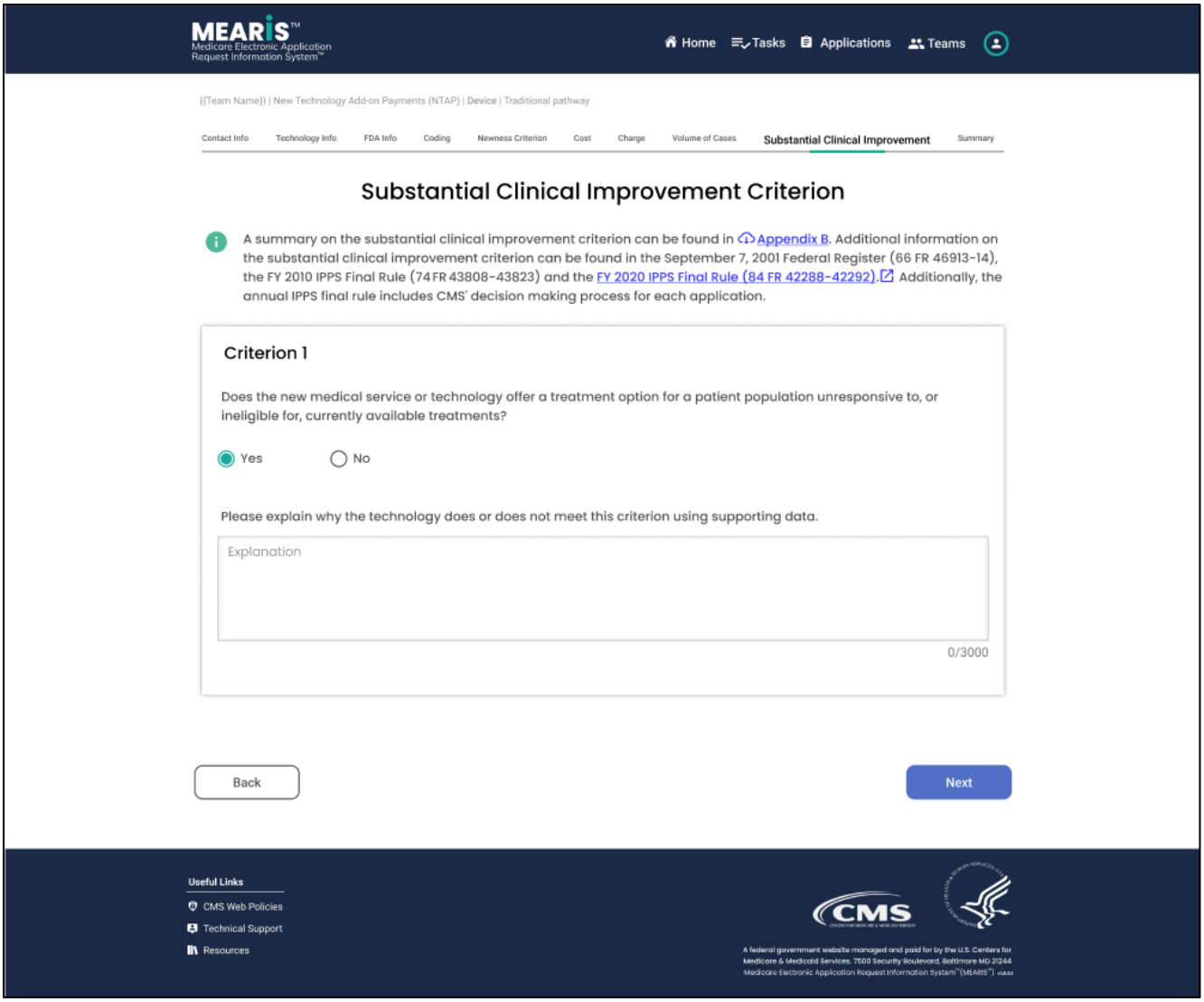
Please describe how you arrived at this estimate.

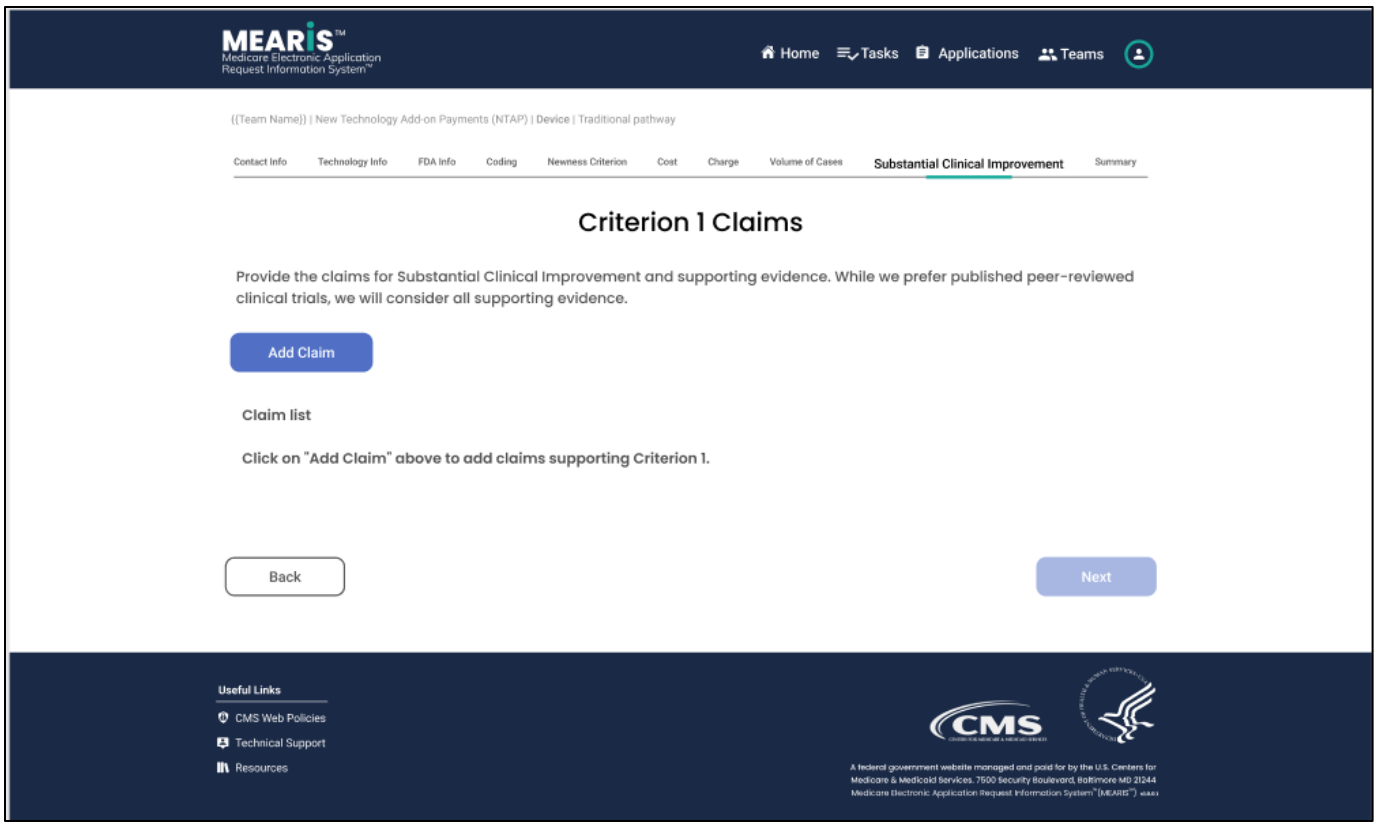
Determination details

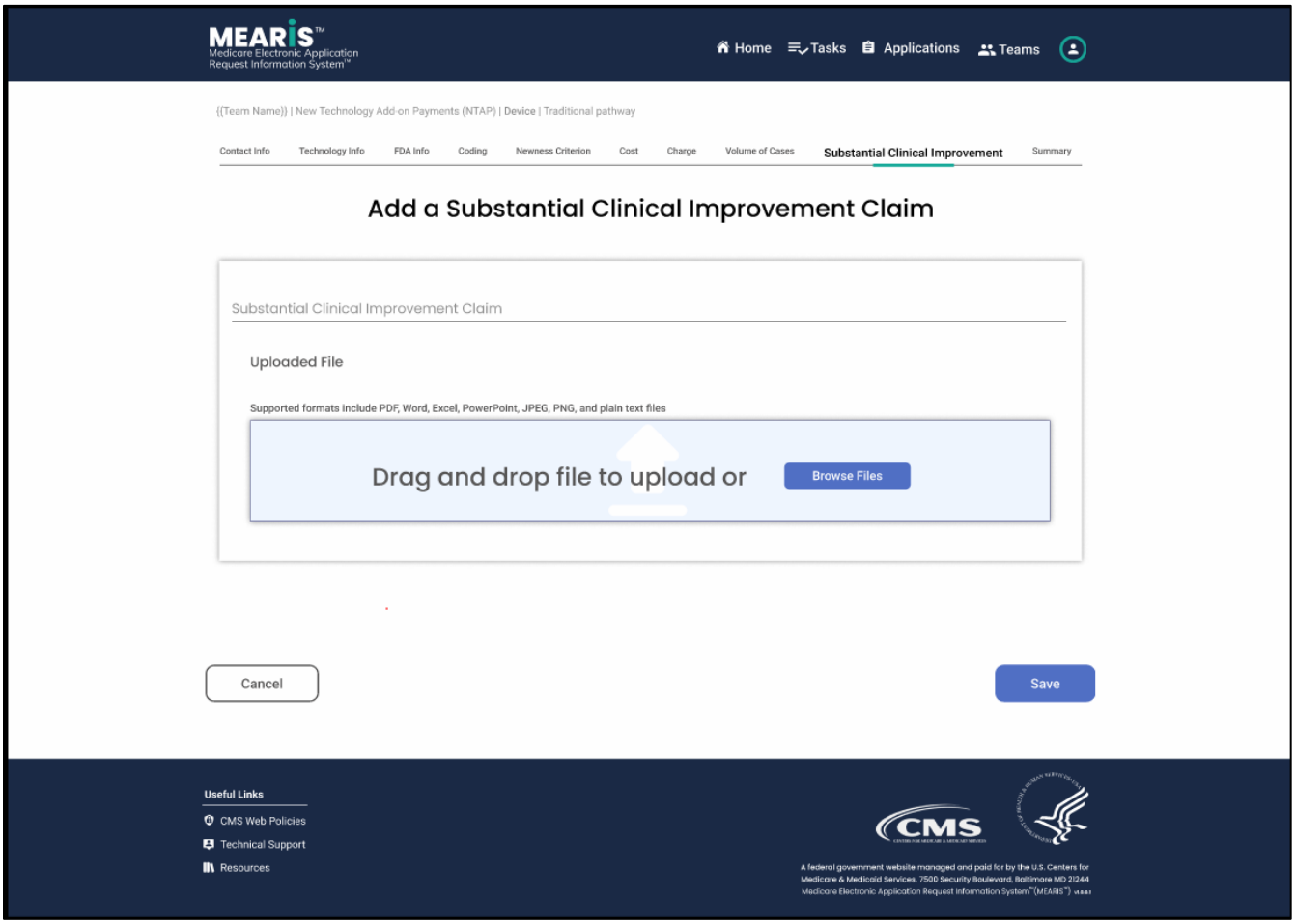
0/3000

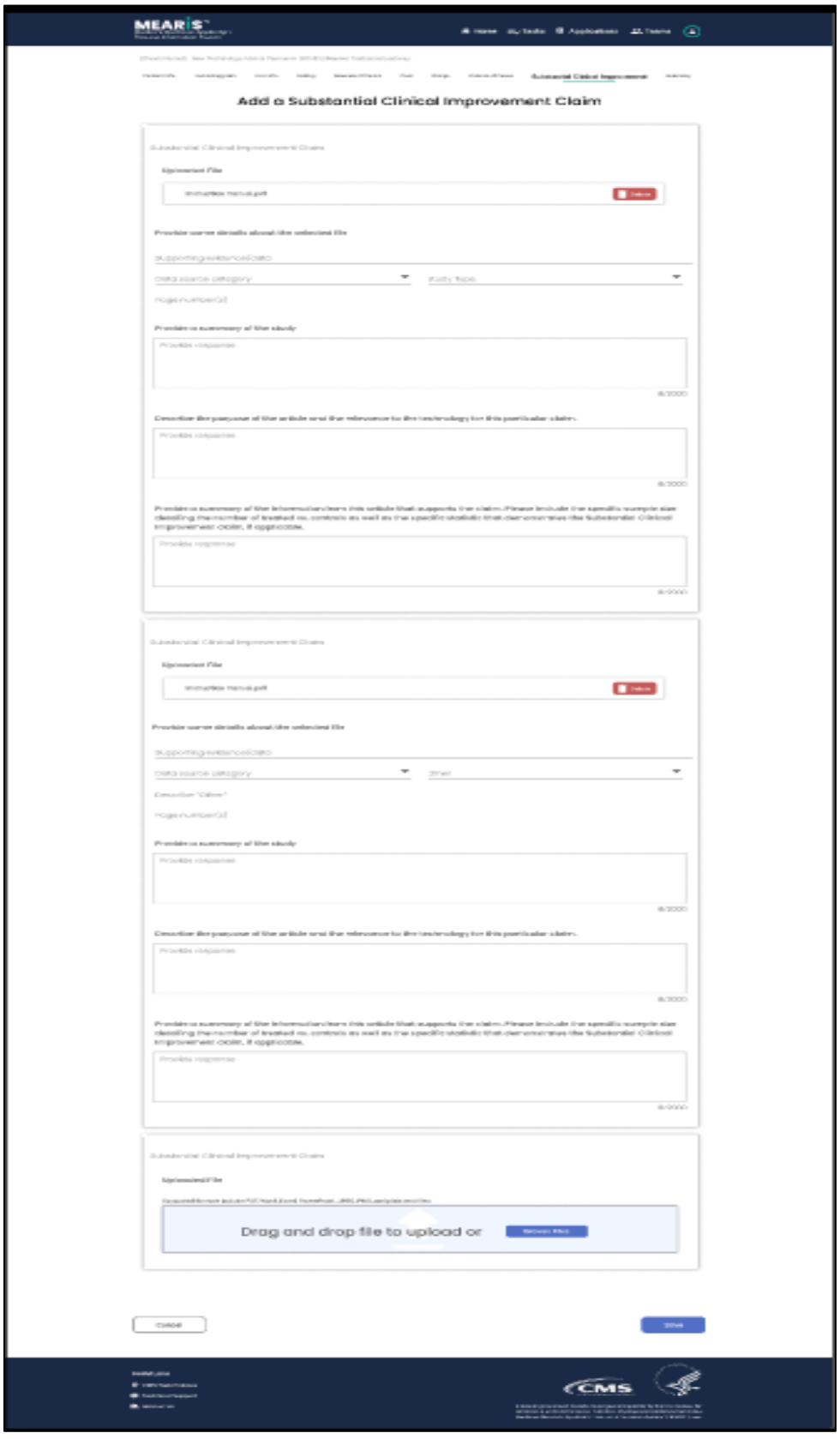
Back

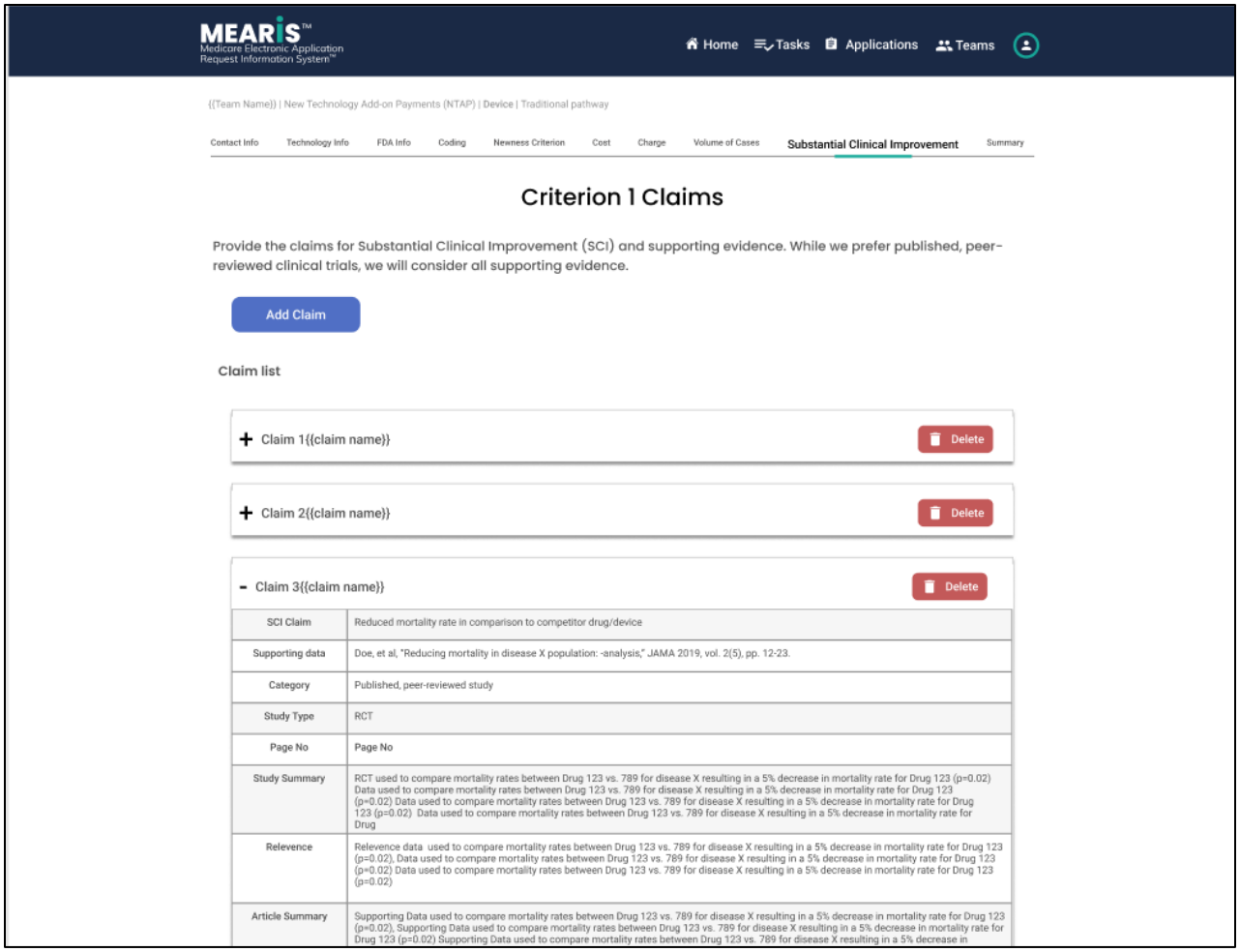
Next

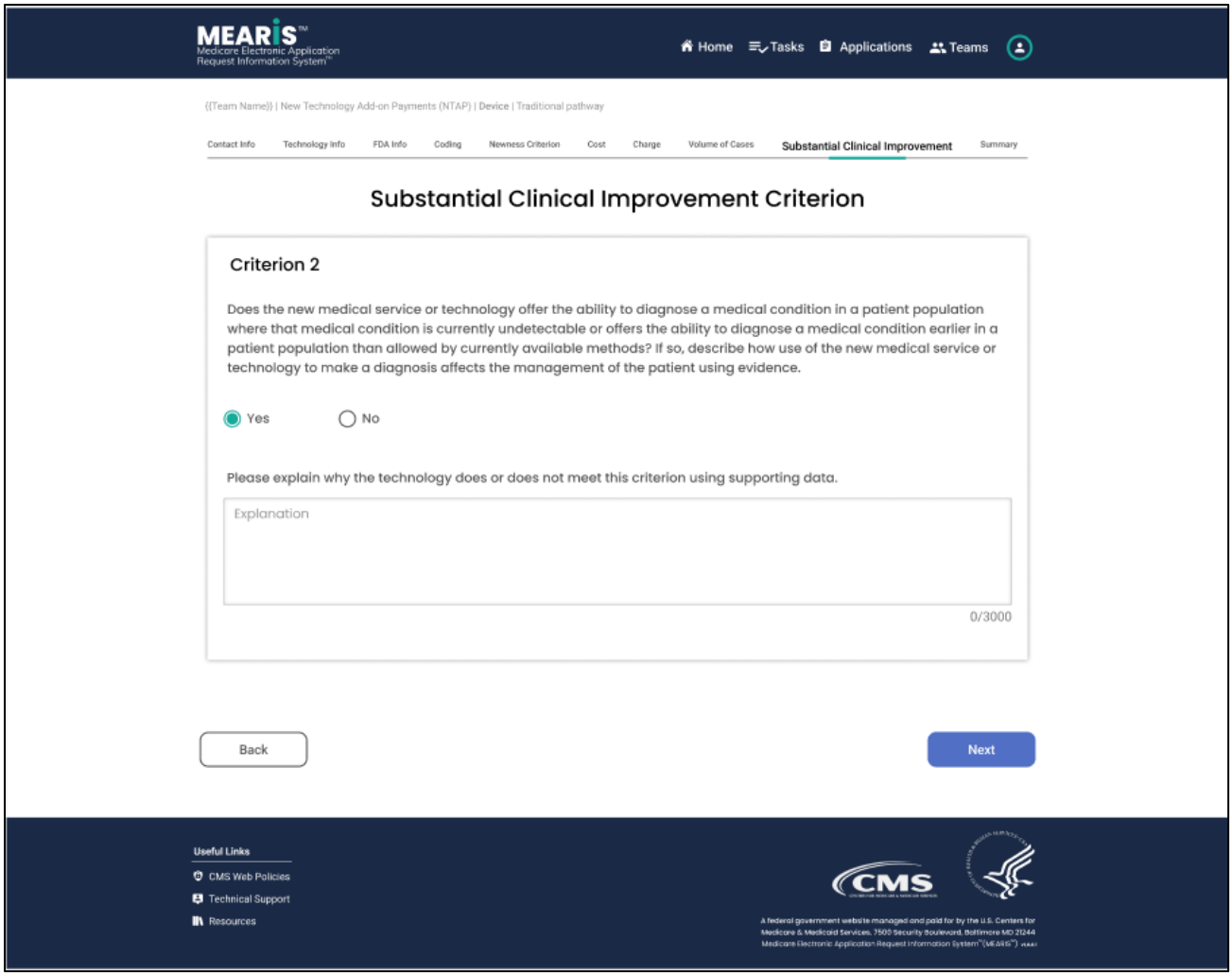

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
Substantial Clinical Improvement Criterion
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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™) v1.0.0

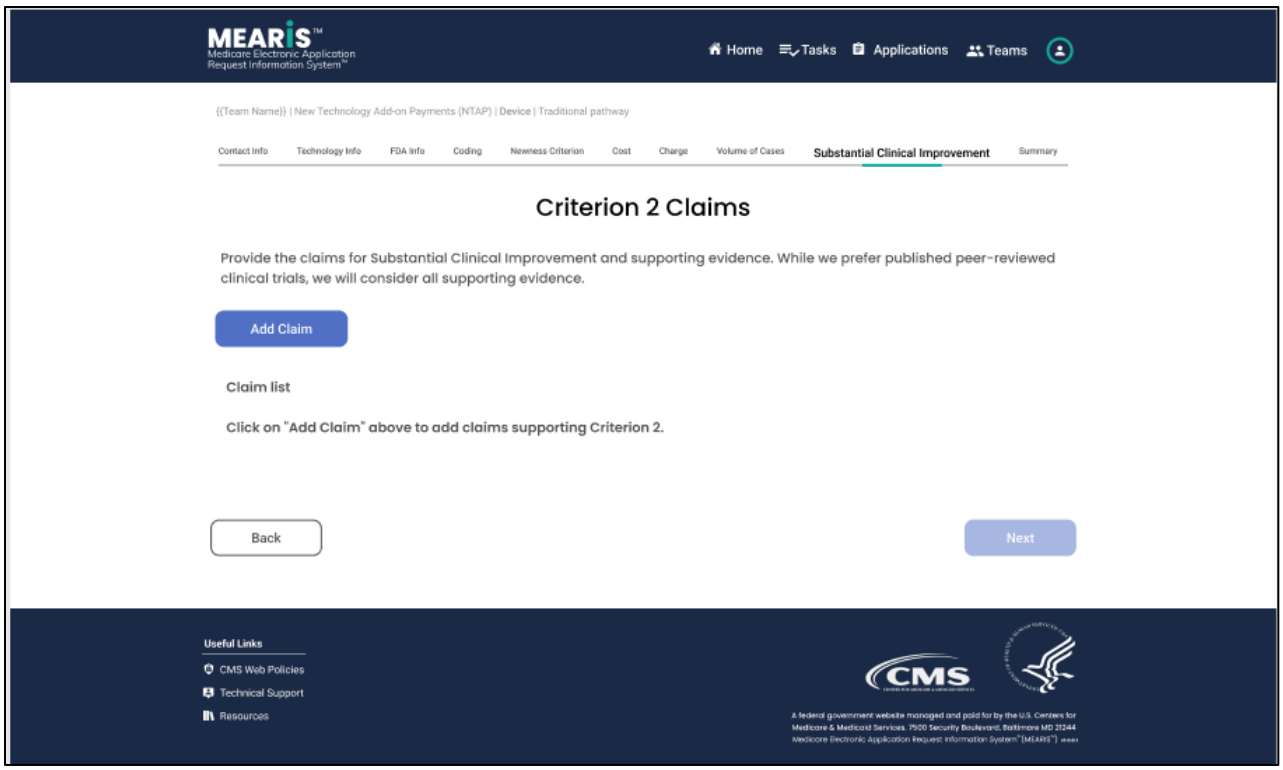

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
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.
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services. 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)

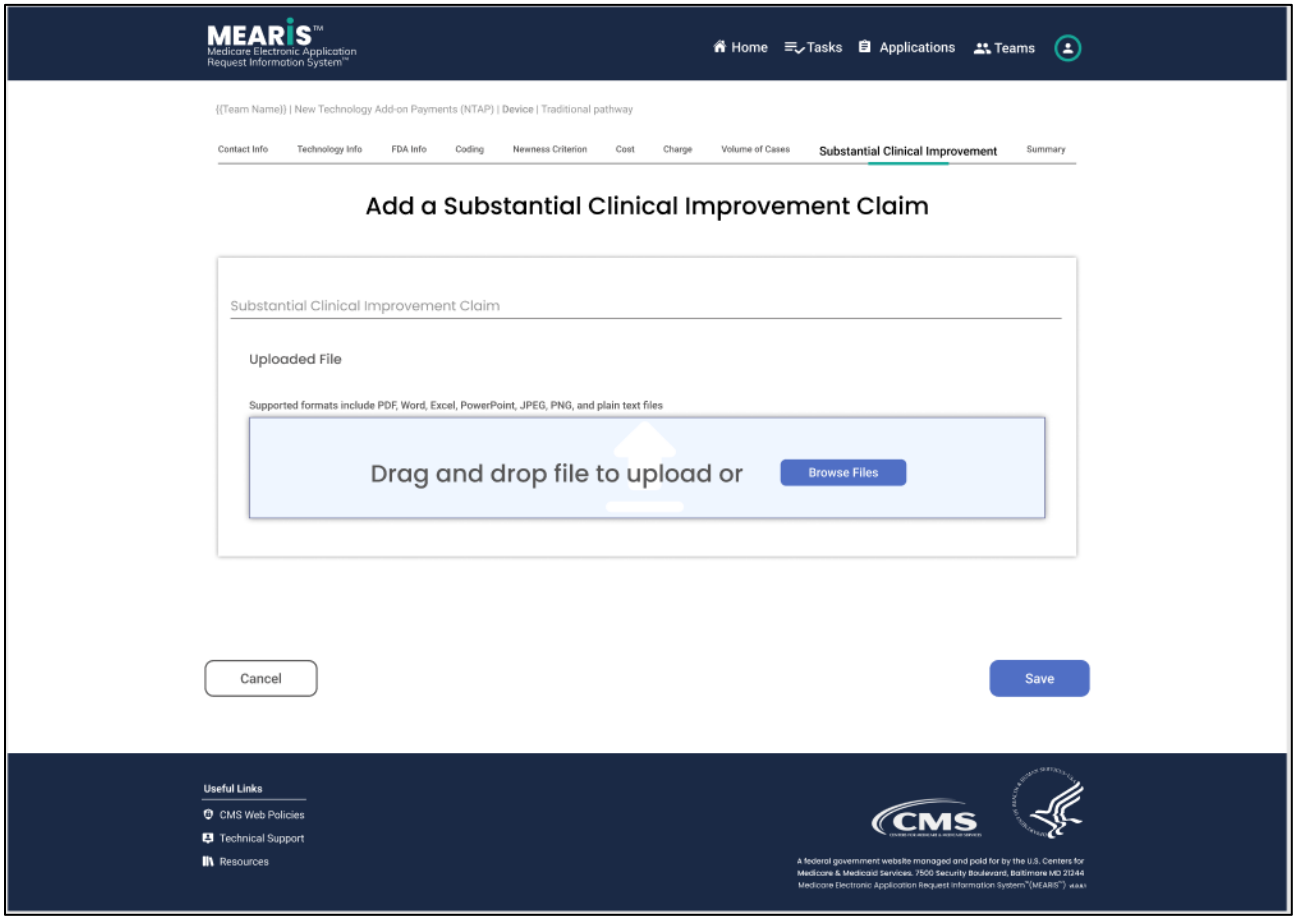

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
Add a Substantial Clinical Improvement Claim
Substantial Clinical Improvement Claim
Uploaded File
Supported formats include PDF, Word, Excel, PowerPoint, JPEG, PNG, and plain text files
Drag and drop file to upload or
Browse Files
Cancel
Save
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services. 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)

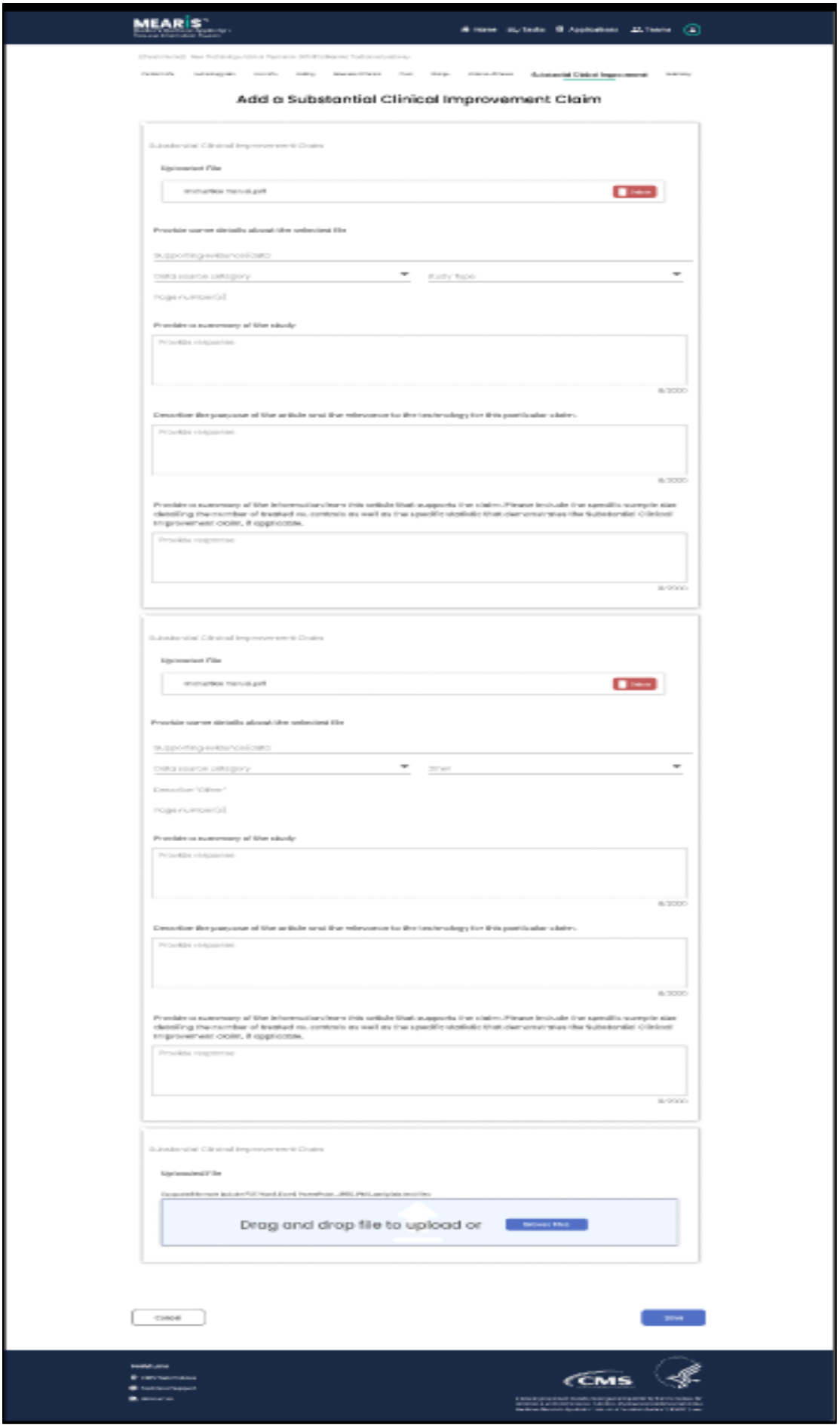

MEARIS
Add a Substantial Clinical Improvement Claim
Drag and drop file to upload or
CMS

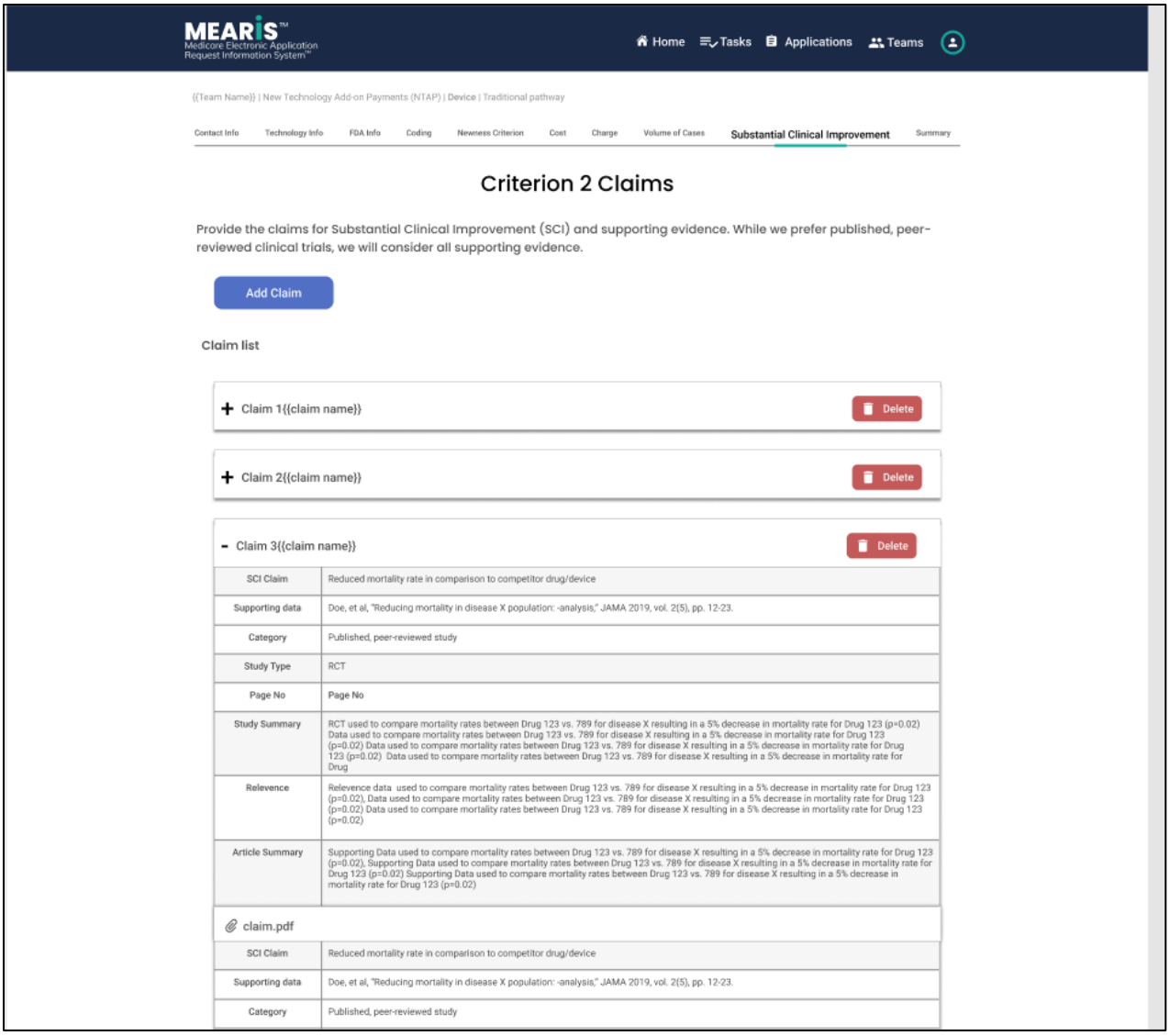

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
Criterion 1 Claims
Provide the claims for Substantial Clinical Improvement (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
Relevence
Relevence 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)
Article Summary
Supporting 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), Supporting 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) Supporting Data used to compare mortality rates between Drug 123 vs. 789 for disease X resulting in a 5% decrease in

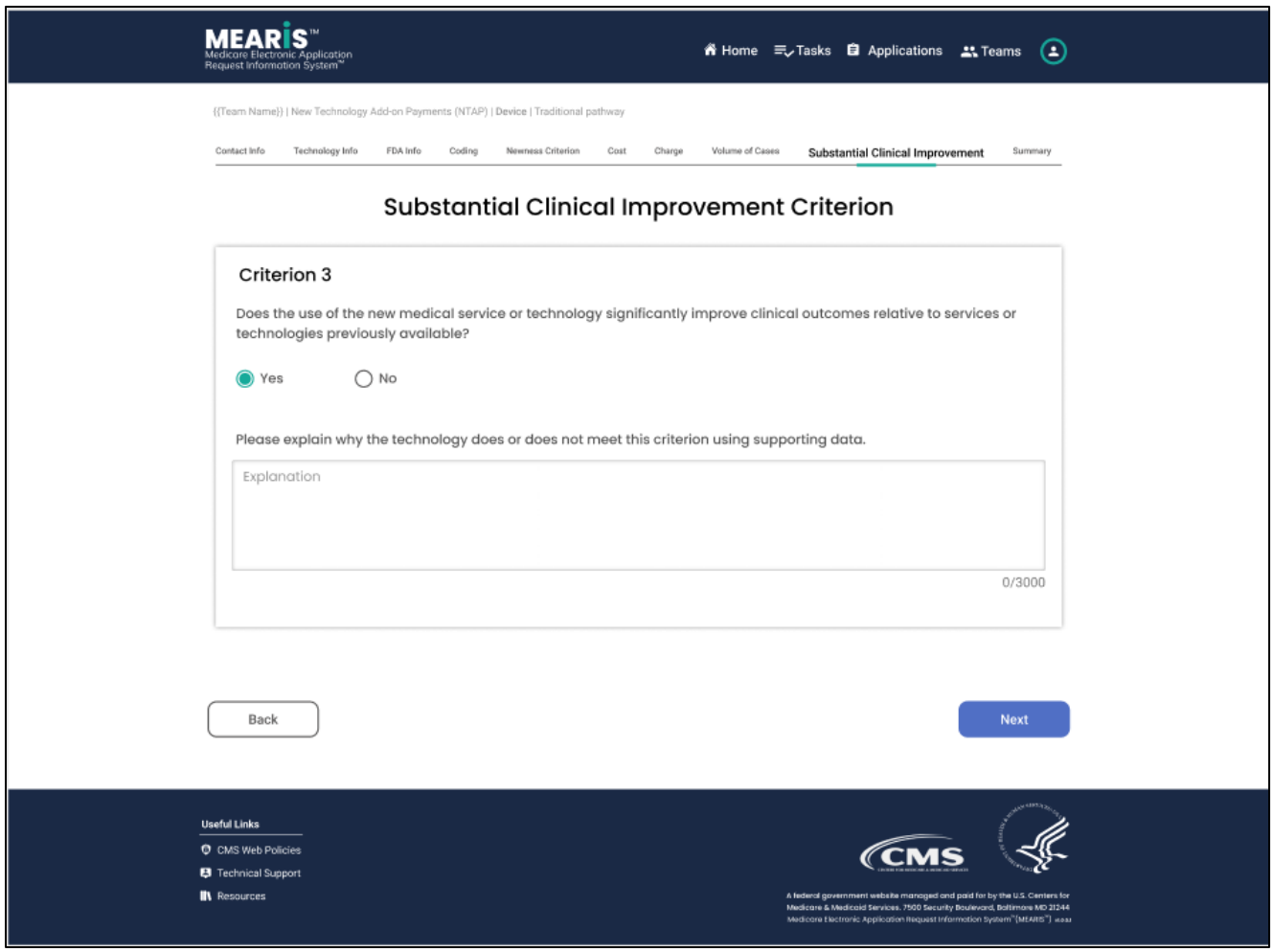

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)

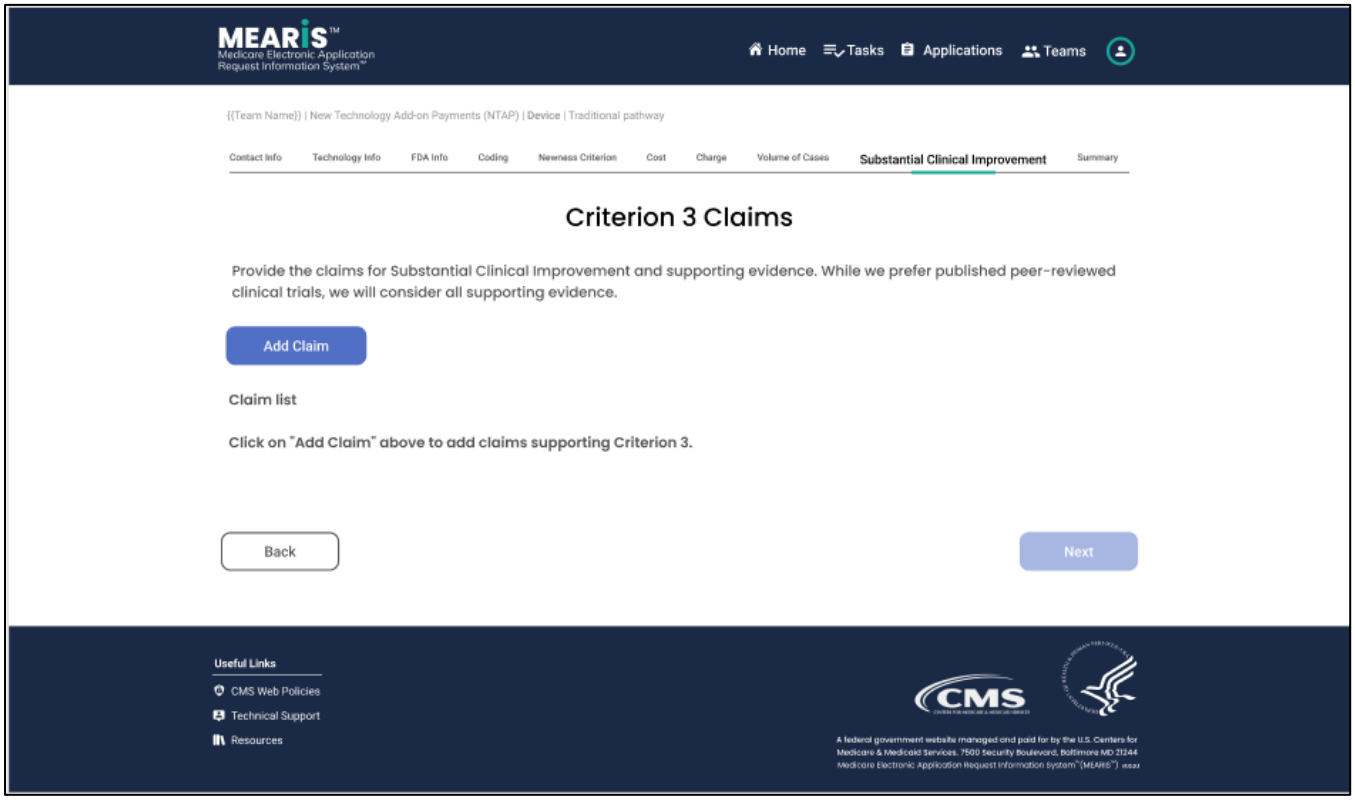

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
Criterion 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.
Add Claim
Claim list
Click on "Add Claim" above to add claims supporting Criterion 2.
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™(MEARIS™)

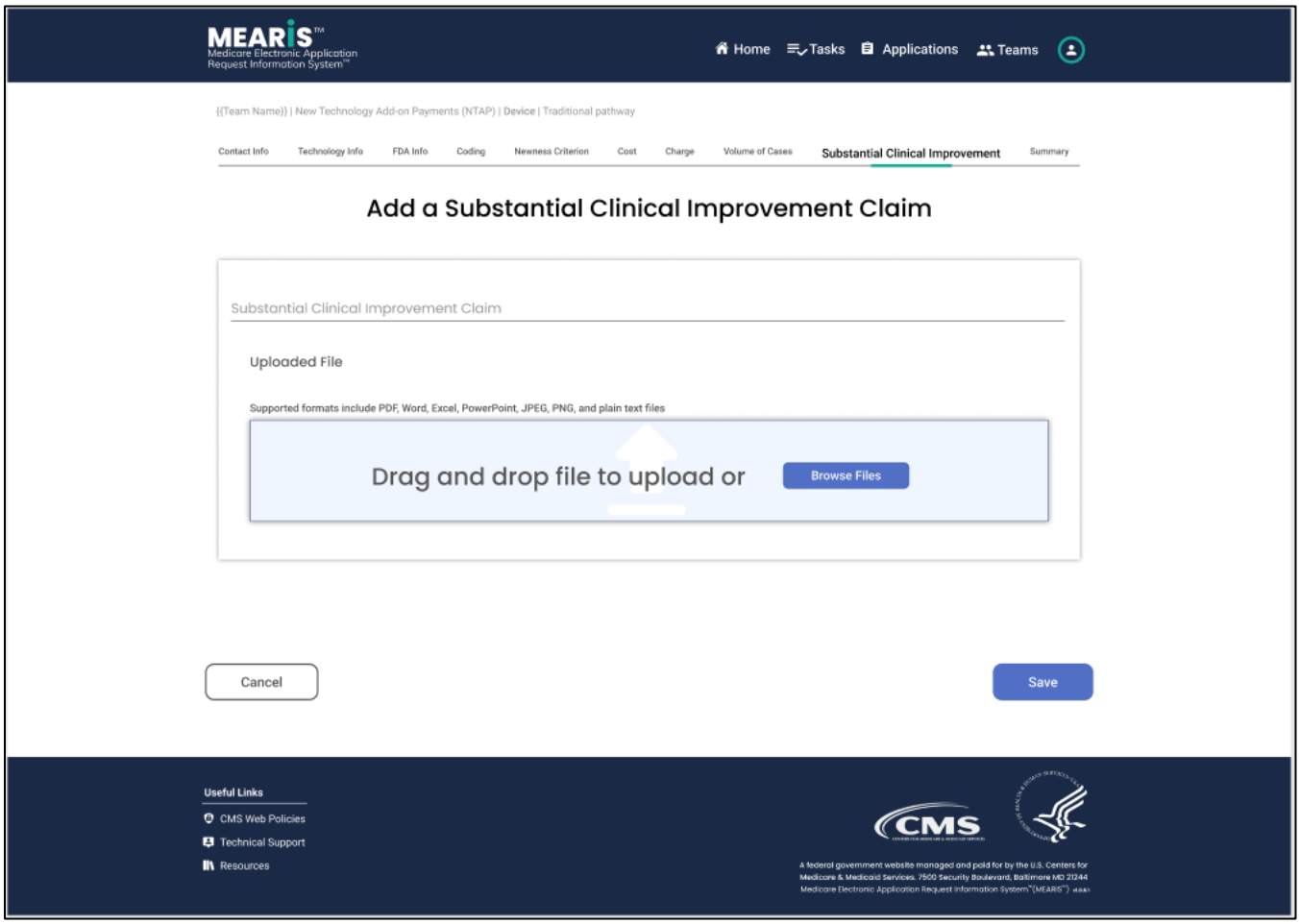

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
Add a Substantial Clinical Improvement Claim
Substantial Clinical Improvement Claim
Uploaded File
Supported formats include PDF, Word, Excel, PowerPoint, JPEG, PNG, and plain text files
Drag and drop file to upload or
Browse Files
Cancel
Save
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™(MEARIS™)

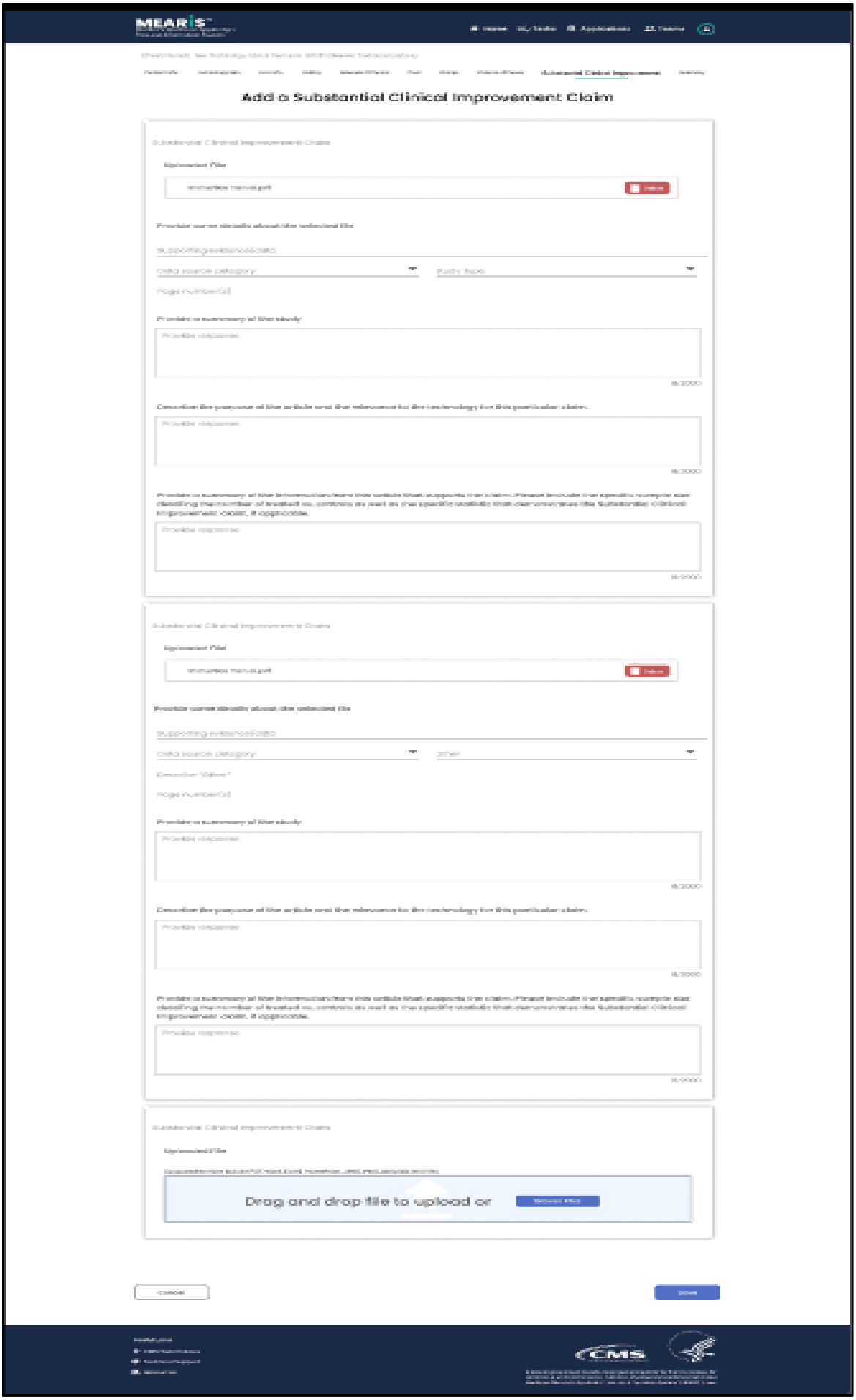

MEARIS
Add a Substantial Clinical Improvement Claim
Drag and drop file to upload or

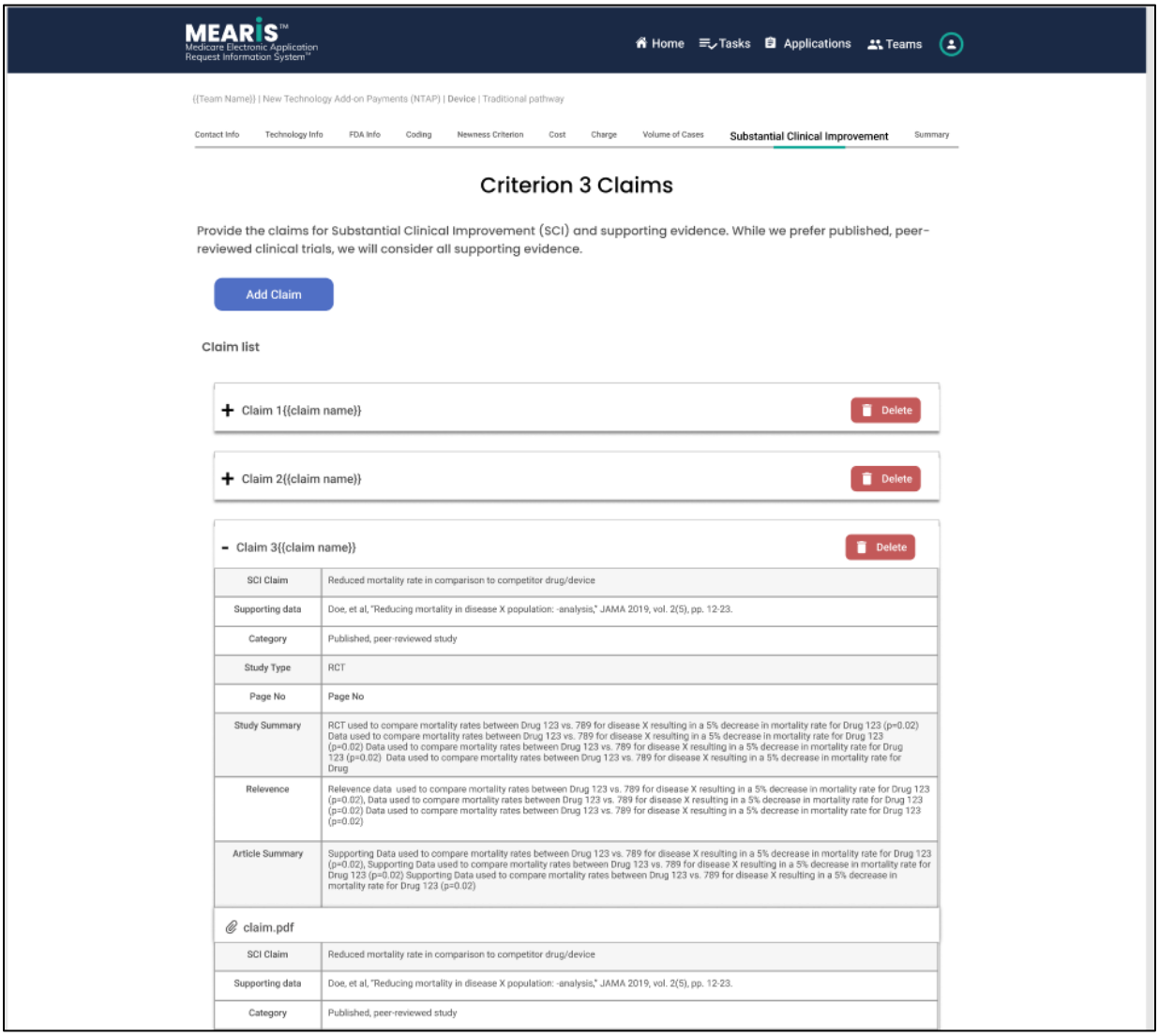

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
Criterion 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
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
Relevence
Relevence 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)
Article Summary
Supporting 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), Supporting 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) Supporting 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)
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

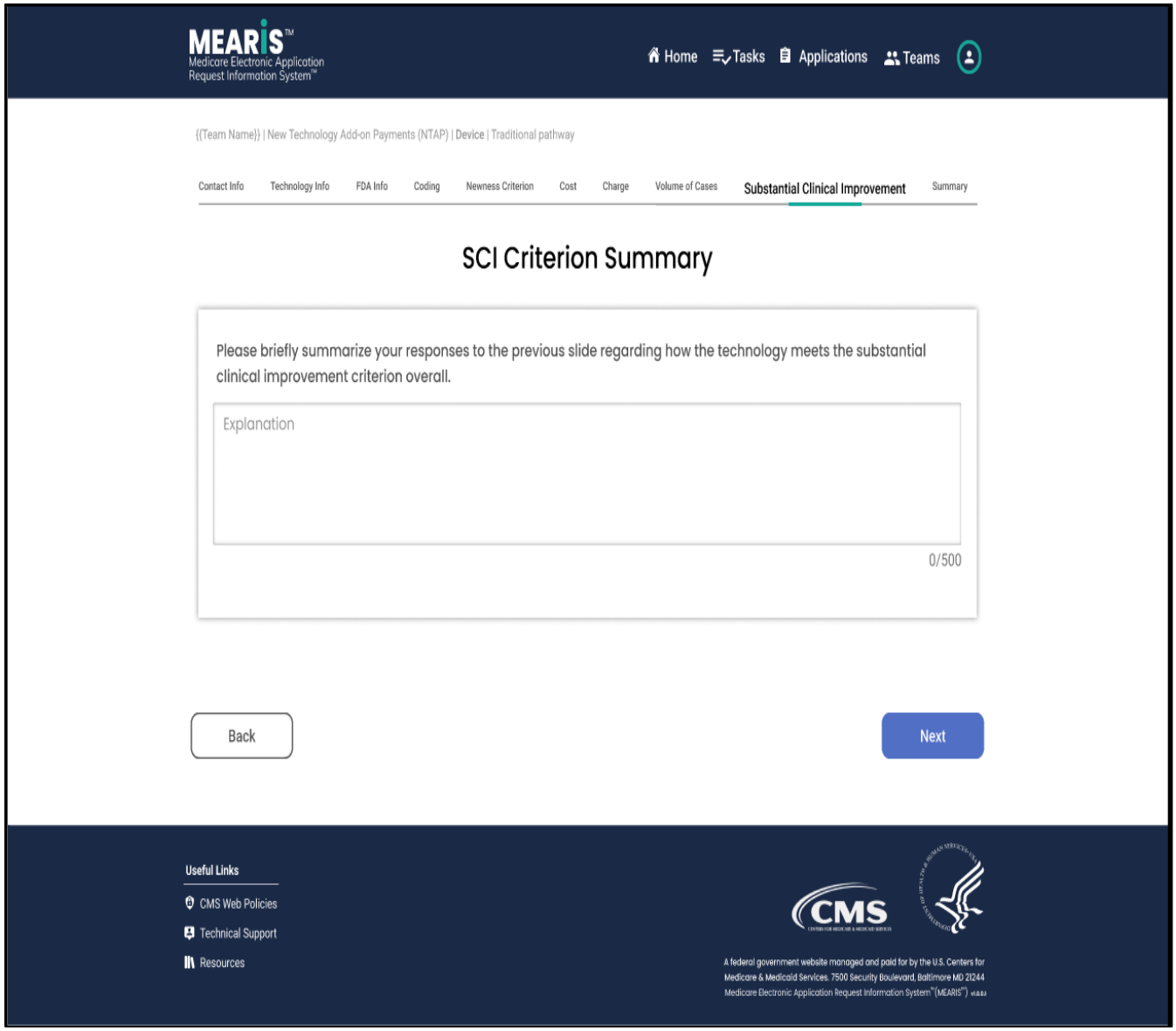

MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{Team Name}} | New Technology Add-on Payments (NTAP) | Device | Traditional pathway
Contact Info
Technology Info
FDA Info
Coding
Newness Criterion
Cost
Charge
Volume of Cases
Substantial Clinical Improvement
Summary
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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{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 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.
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{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
Uploaded File
Supported formats include PDF, Word, Excel, PowerPoint, JPEG, PNG, and plain text files
Drag and drop file to upload or
Browse Files
Cancel
Save
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™(MEARIS™)


Add a Substantial Clinical Improvement Claim
Drag and drop file to upload or


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{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 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
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
Relevence
Relevence 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)
Article Summary
Supporting 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), Supporting 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) Supporting 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)
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


MEARIS™
Medicare Electronic Application Request Information System™
Home
Tasks
Applications
Teams
{{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
Back
Next
Useful Links
CMS Web Policies
Technical Support
Resources
CMS
A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services. 7500 Security Boulevard, Baltimore MD 21244
Medicare Electronic Application Request Information System™ (MEARIS™)