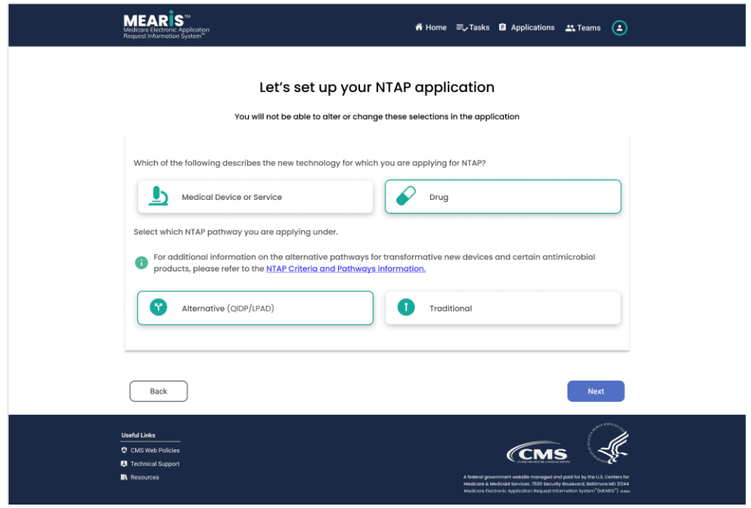
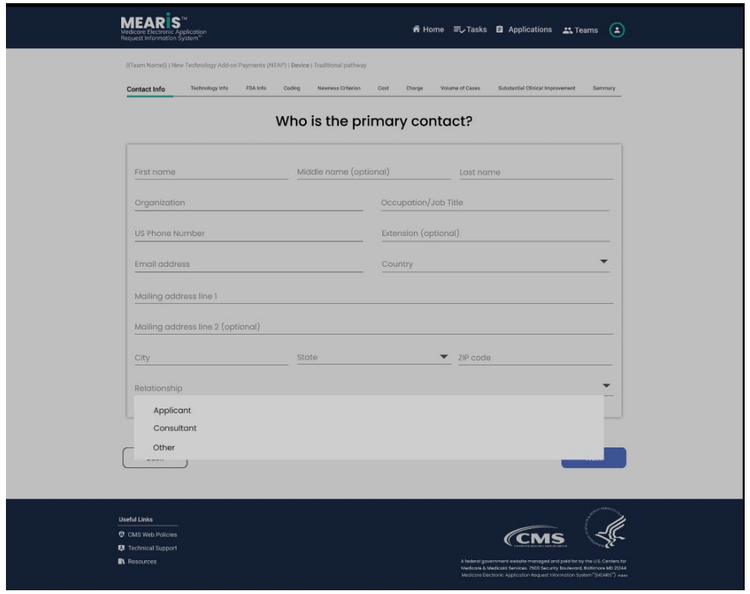
NTAP Crosswalk-2023

Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
Throughout paper application.	Currently the pathway questions are split across the paper application	Applicants need to include this information in the current paper application narrative, but we have consolidated on this screen to create the skip patterns that allow the system to only display the relevant questions to the specific pathway chosen.	No substantive change or burden	

1	Name, address, telephone, and email address of primary and backup contact for the application. If using a consultant, provide a contact from the manufacturer in addition to the consultant's contact information.	AS IS	No substantive change or burden	 **Alternative Screen**

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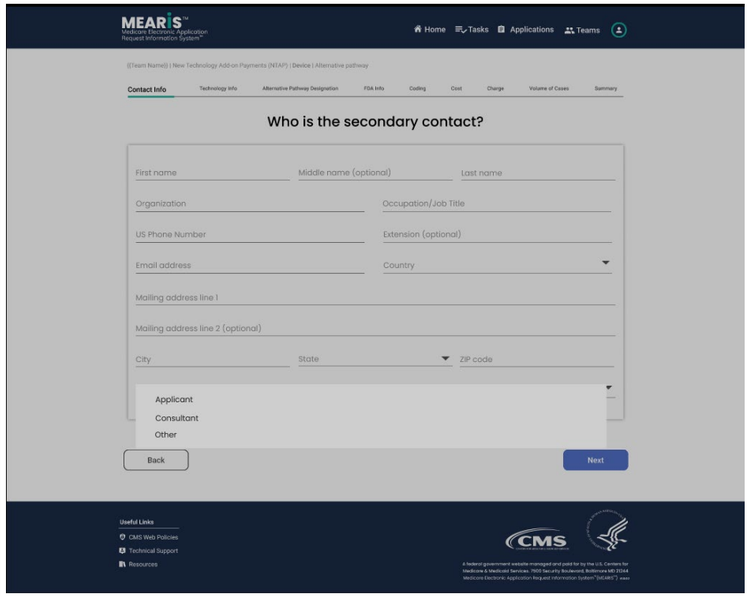
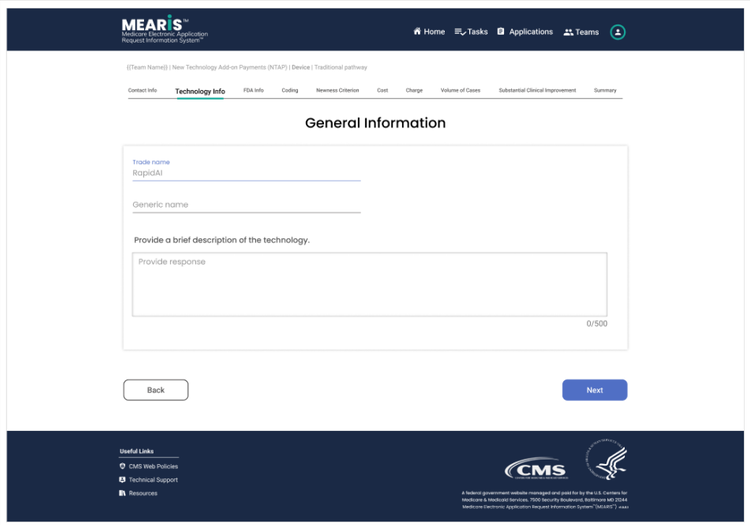
				
2, 3	Trade/brand name of the new technology. Describe the technology in general terminology.	AS IS	No substantive change or burden	

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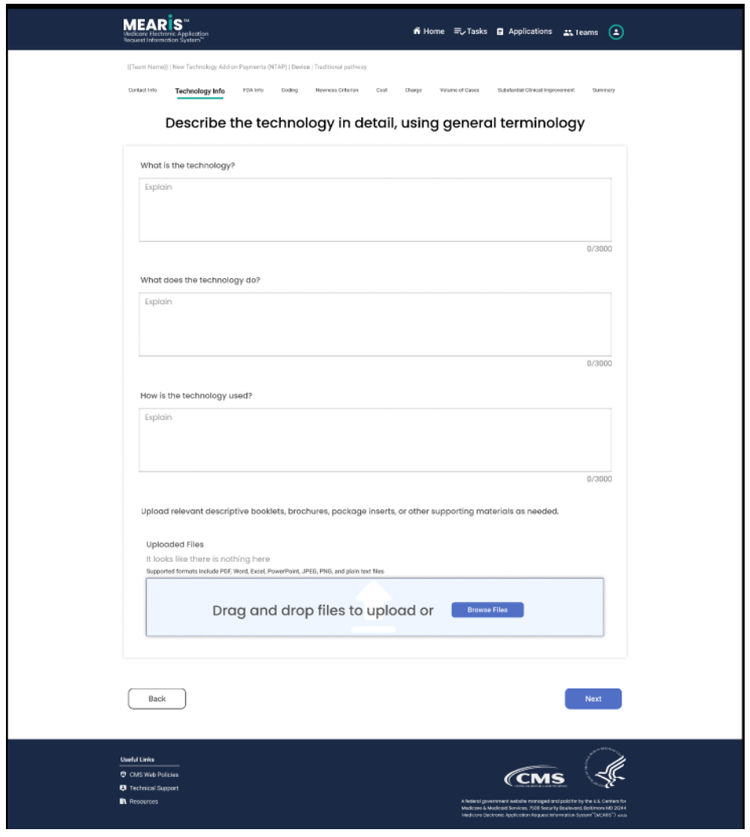
3	Describe the technology in general terminology. - What is it? What does it do? How is it used? - Also, submit relevant descriptive booklets, brochures, package inserts, as well as copies of published peer-reviewed articles relevant to the new medical services and technologies.)	AS IS	No substantive change or burden	

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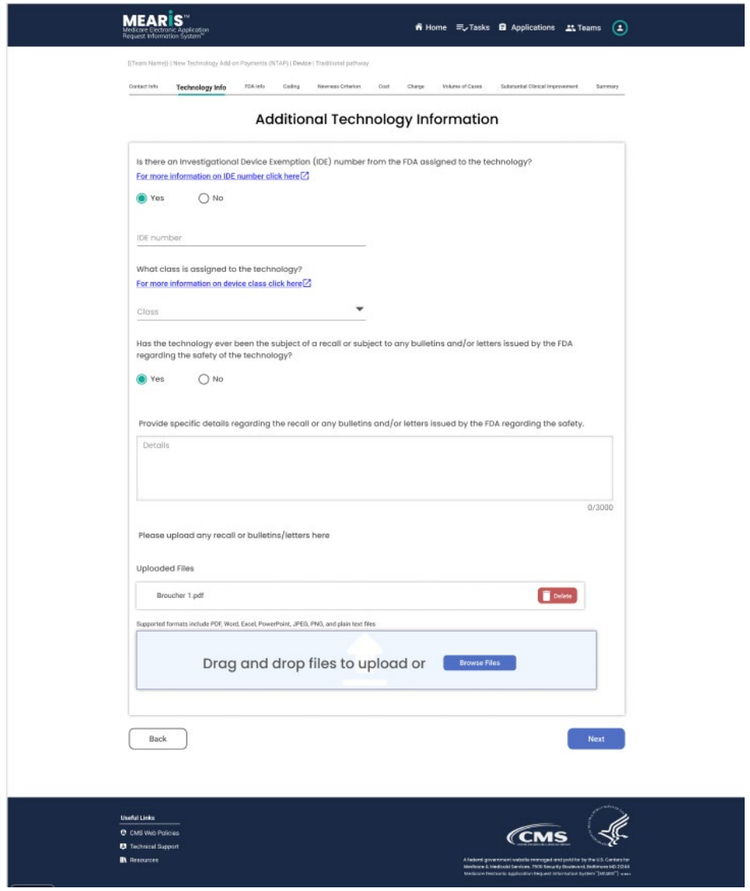
15	**Devices:** If the technology is a device, is there an investigational device exemption (IDE) number from the FDA assigned to the device? If yes, please provide this code. Refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051480.htm for more details.	AS IS Whether the technology has 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 has been added to this question set to ensure applicants do not forget to tell CMS about this. Currently, it is required to be included in the narrative, and the vast majority of applicants do include this information in their application. If they do not include it, CMS currently asks the applicant to provide the information during the review of the application.	No substantive change or burden	
16	**Devices:** If the technology is a device, what class (I, II, or III) was/is assigned to the device? Refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/overview/default.htm for more details.			

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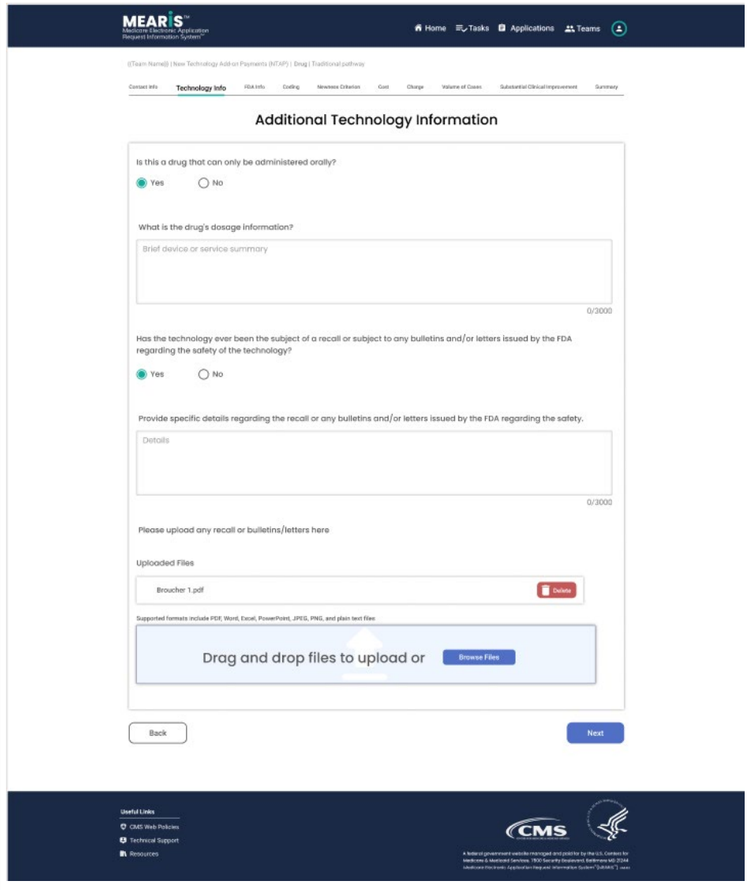
13 14	**Drugs:** If the technology is a drug, is this a drug that can only be administered orally? **Drugs:** If the technology is a drug, provide complete dosage information.	AS IS Whether the technology has ever been the subject of a recall or subject to any bulletins and/or letters issued by the FDA regarding the safety of the technology has been added to this question set to ensure applicants do not forget to tell CMS about this. Currently, it is required to be included in the narrative, and the vast majority of applicants do include this information in their application. If they do not include it, CMS currently asks the applicant to provide the information during the review of the application.	No substantive change or burden	

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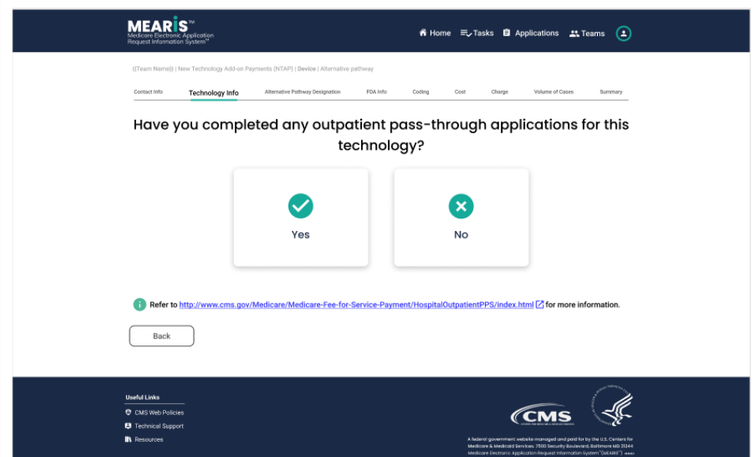
4	Have you submitted an outpatient application for pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. Refer to http://www.cms.gov/Medicare/MedicareFee-for-Service-Payment/HospitalOutpatientPPS/index.html for more information.	AS IS	No substantive change or burden	

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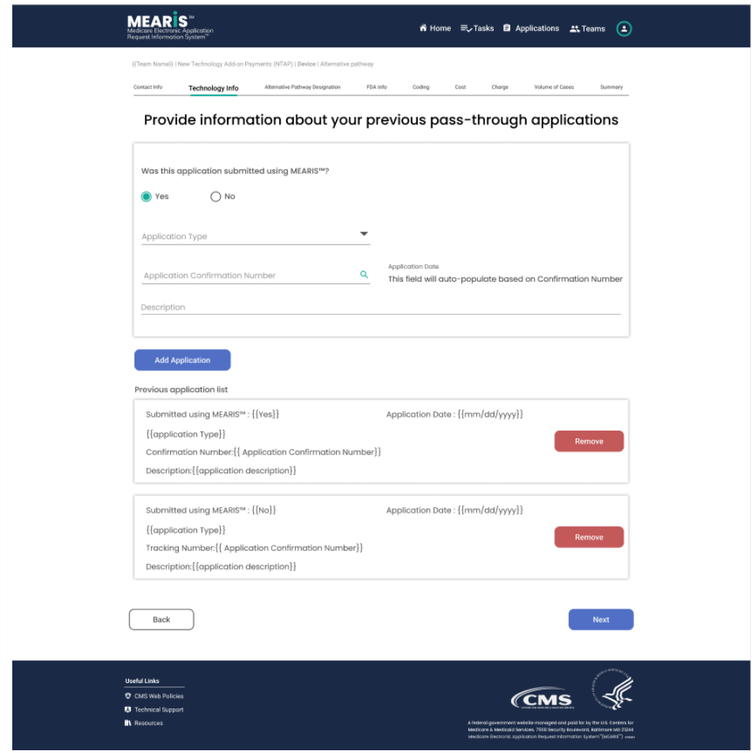
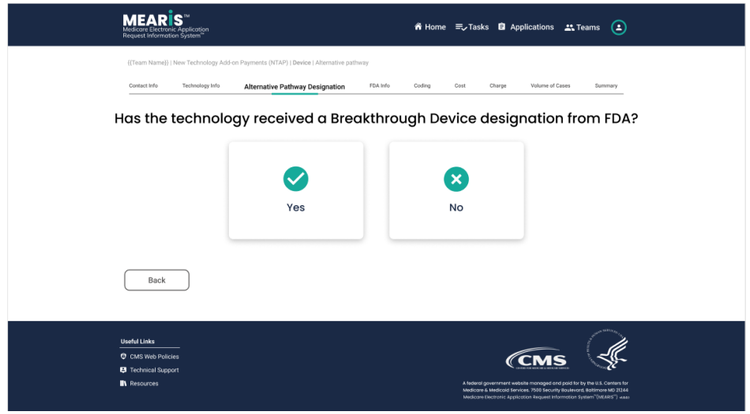
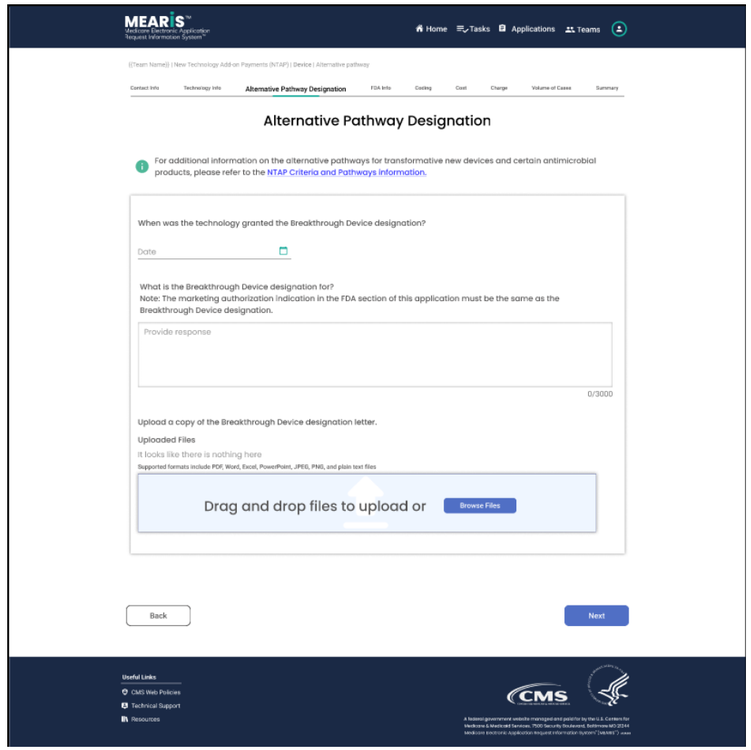
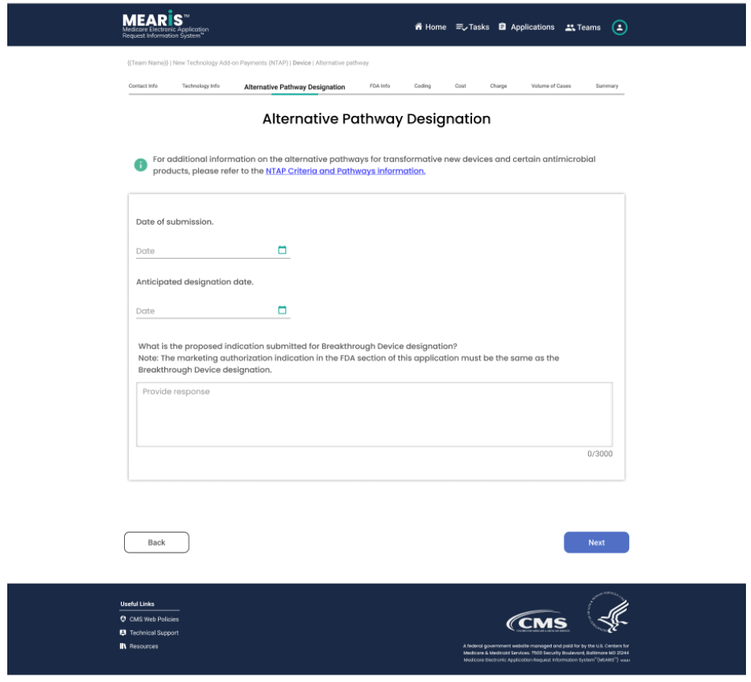
4	Question 4 (Continued) Have you submitted an outpatient application for pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. Refer to http://www.cms.gov/Medicare/MedicareFee-for-Service-Payment/HospitalOutpatientPPS/index.html for more information.	AS IS	No substantive change or burden	

Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
5	**Alternative New Technology Pathway for Transformative New Devices** Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? If yes, skip questions 6 through 21 (newness) and 34-36 (substantial clinical improvement) and proceed to question 22 - 33 (cost criterion). For additional details on the Alternative Pathway we refer applicants to 84 FR xxxxx – xxxxx for additional details.	AS IS	No substantive change or burden	

5,8	**Alternative New Technology Pathway for Transformative New Devices** Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? If yes, skip questions 6 through 21 (newness) and 34-36 (substantial clinical improvement) and proceed to question 22 - 33 (cost criterion). For additional details on the Alternative Pathway we refer applicants to 84 FR xxxxx – xxxxx for additional details. Date of Food and Drug Administration (FDA) (or expected) approval for the technology, service, or drug. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. Note: Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology, service, or drug has received multiple types of approvals from the FDA. Per § 412.87(c) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA approval or clearance for its new medical service or technology by July 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective (for FY 2021, not later than July 1, 2020).	Components of this question are now specified, that would have been required to be included in the narrative response previously. Applicants also currently provide this information in the FDA approval letter.	No substantive change or burden	

5,8	**Question 5 (Continued)** **Alternative New Technology Pathway for Transformative New Devices** Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? If yes, skip questions 6 through 21 (newness) and 34-36 (substantial clinical improvement) and proceed to question 22 - 33 (cost criterion). For additional details on the Alternative Pathway we refer applicants to 84 FR xxxxx – xxxxx for additional details. Date of Food and Drug Administration (FDA) (or expected) approval for the technology, service, or drug. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. Note: Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology, service, or drug has received multiple types of approvals from the FDA. Per § 412.87(c) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA approval or clearance for its new medical service or technology by July 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective (for FY 2021, not later than July 1, 2020).	Components of this question are now specified, that would have been required to be included in the narrative response previously. This information is also included in the FDA approval letter.	No substantive change or burden	

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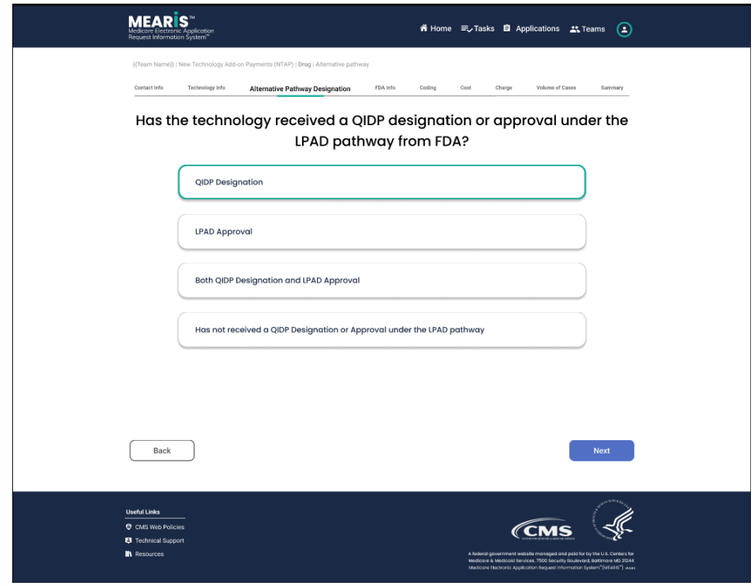
5,8	Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? Date of Food and Drug Administration (FDA) (or expected) approval for the technology, service, or drug. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. Note: Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology, service, or drug has received multiple types of approvals from the FDA. Per § 412.87(c) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA approval or clearance for its new medical service or technology by July 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective (for FY 2021, not later than July 1, 2020).	We have further broken out the breakthrough device designation to include these subcategories, so that applicants can skip questions that are not relevant. This information is included in the FDA approval letter.	No substantive change or burden	

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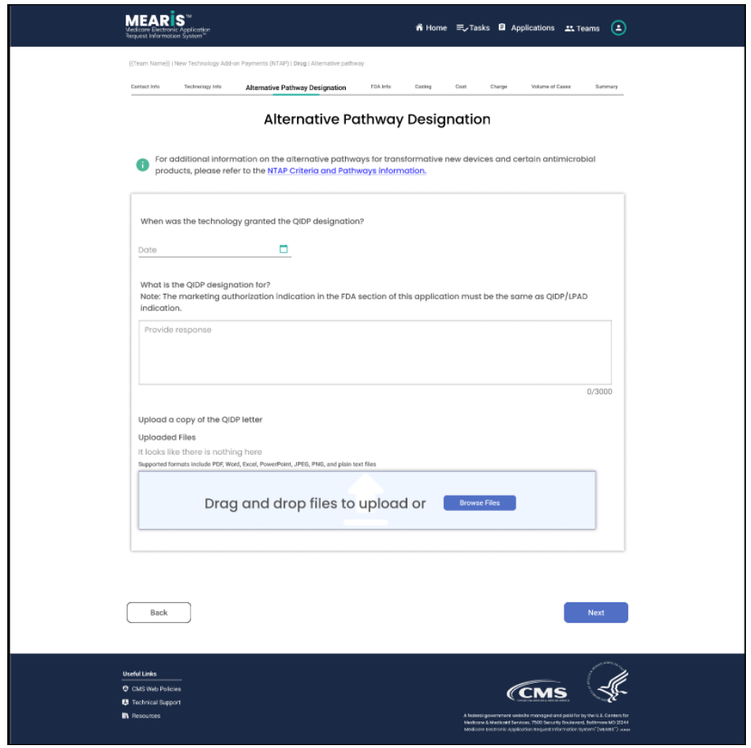
5, 8	Based on: Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? Date of Food and Drug Administration (FDA) (or expected) approval for the technology, service, or drug. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. Note: Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology, service, or drug has received multiple types of approvals from the FDA. Per § 412.87(c) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA approval or clearance for its new medical service or technology by July 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective (for FY 2021, not later than July 1, 2020).	Components of this question are now specified for applicants that receive a special designation from the FDA only. Applicants are currently required to provide this information to CMS in the narrative response in the paper application. This information is included in the FDA approval letter.	No substantive change or burden	

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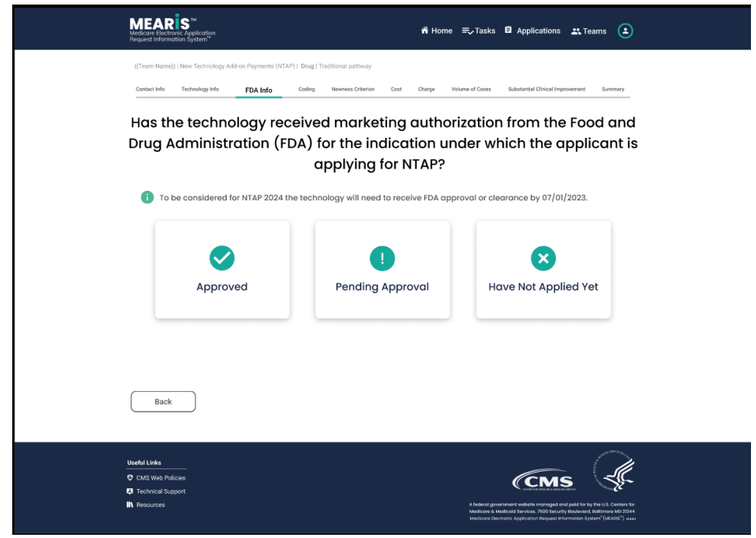
8	Date of Food and Drug Administration (FDA) (or expected) approval for the technology, service, or drug. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. Note: Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology, service, or drug has received multiple types of approvals from the FDA. Per § 412.87(c) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA approval or clearance for its new medical service or technology by July 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective (for FY 2021, not later than July 1, 2020).	AS IS - This question is broken down throughout the FDA section.	No substantive change or burden	

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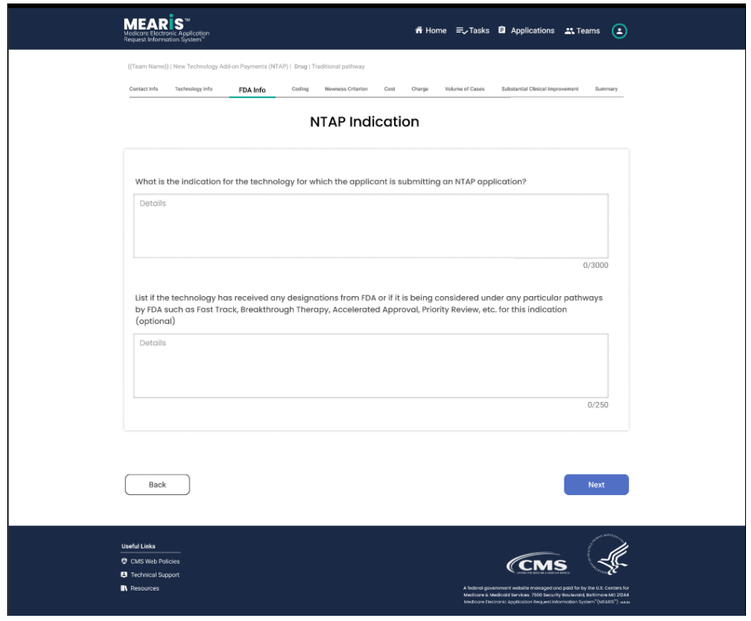
8,12	Date of Food and Drug Administration (FDA) (or expected) approval for the technology, service, or drug. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. Note: Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology, service, or drug has received multiple types of approvals from the FDA. Per § 412.87(c) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA approval or clearance for its new medical service or technology by July 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective (for FY 2021, not later than July 1, 2020). If the technology is a drug, was/is your FDA application considered under Fast Track, Breakthrough Therapy, Accelerated Approval, or Priority Review? Refer to http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantne wtherapies/ucm128291.htm for more details.	Request for indication has been added to this question set to ensure applicants do not forget to include this detail. Currently, it is required to be included in the narrative, and the vast majority of applicants include this. If an applicant does not provide the information, CMS will obtain the information from the applicant.	No substantive change or burden	

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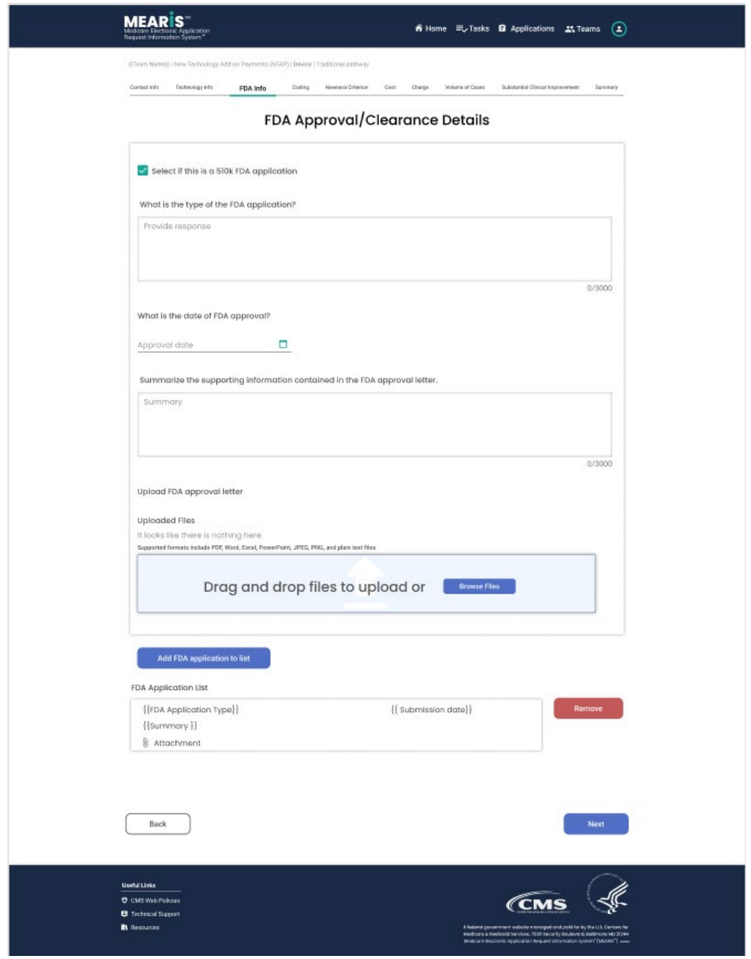
8	Date of Food and Drug Administration (FDA) (or expected) approval for the technology, service, or drug. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. Note: Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology, service, or drug has received multiple types of approvals from the FDA. Per § 412.87(c) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA approval or clearance for its new medical service or technology by July 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective (for FY 2021, not later than July 1, 2020).	AS IS - This question is broken down throughout the FDA section.	No substantive change or burden	

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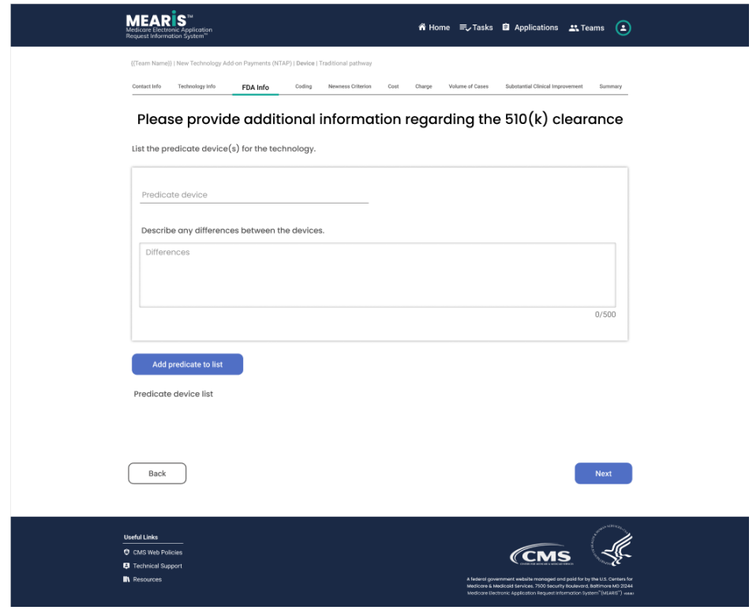
8	Date of Food and Drug Administration (FDA) (or expected) approval for the technology, service, or drug. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. Note: Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology, service, or drug has received multiple types of approvals from the FDA. Per § 412.87(c) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA approval or clearance for its new medical service or technology by July 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective (for FY 2021, not later than July 1, 2020).	AS IS - This question is broken down throughout the FDA section.	No substantive change or burden	

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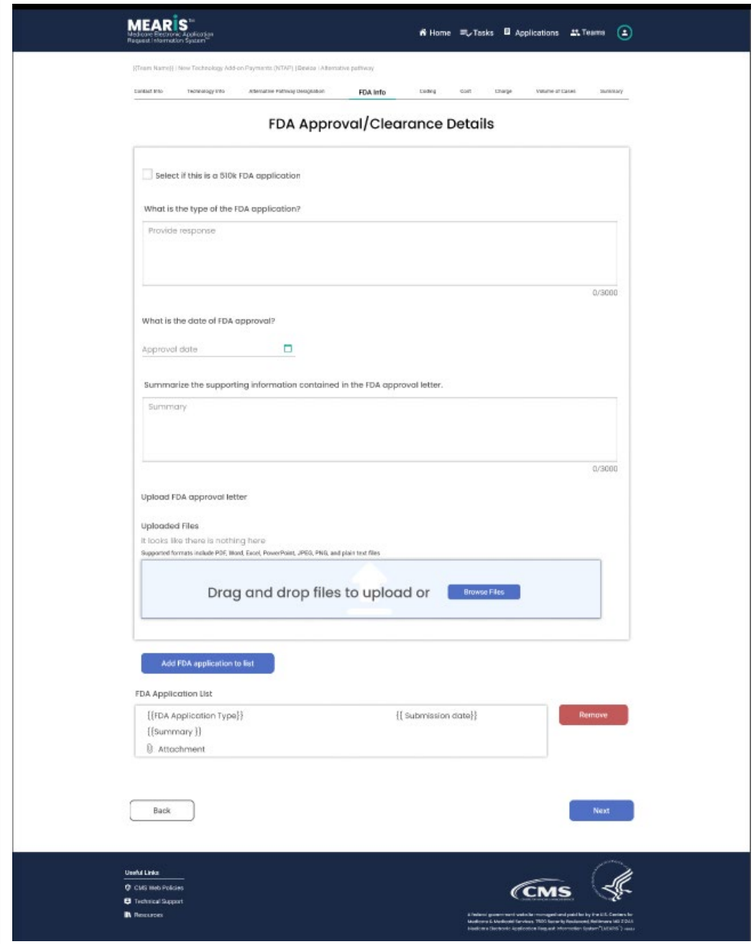
8	Date of Food and Drug Administration (FDA) (or expected) approval for the technology, service, or drug. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. Note: Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology, service, or drug has received multiple types of approvals from the FDA. Per § 412.87(c) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA approval or clearance for its new medical service or technology by July 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective (for FY 2021, not later than July 1, 2020).	AS IS - This question is broken down throughout the FDA section.	No substantive change or burden	

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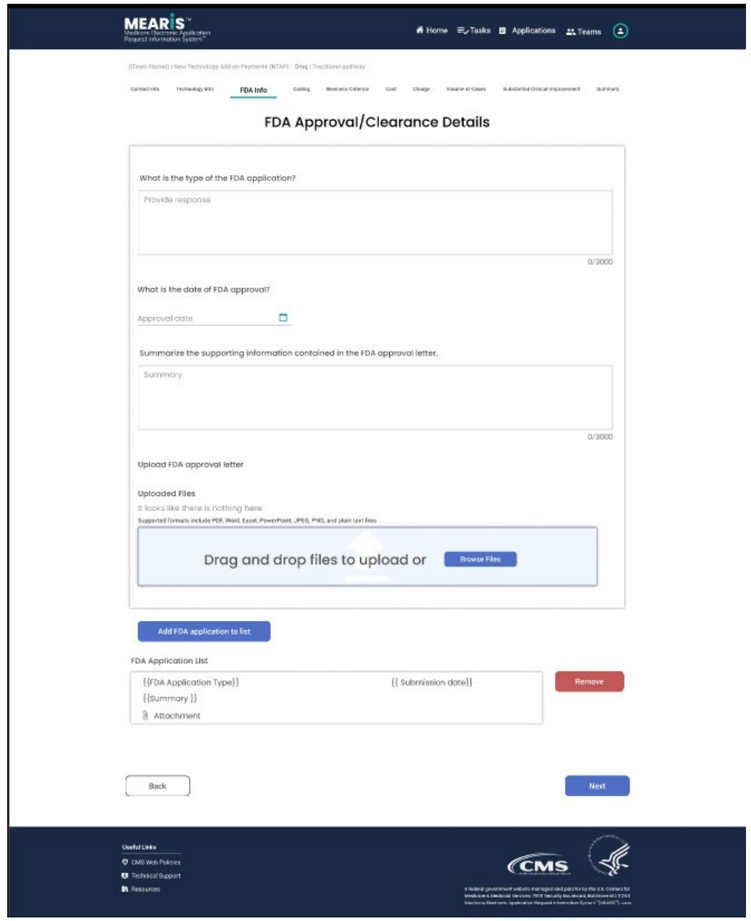
8	Date of Food and Drug Administration (FDA) (or expected) approval for the technology, service, or drug. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. Note: Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology, service, or drug has received multiple types of approvals from the FDA. Per § 412.87(c) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA approval or clearance for its new medical service or technology by July 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective (for FY 2021, not later than July 1, 2020).	AS IS - This question is broken down throughout the FDA section.	No substantive change or burden	

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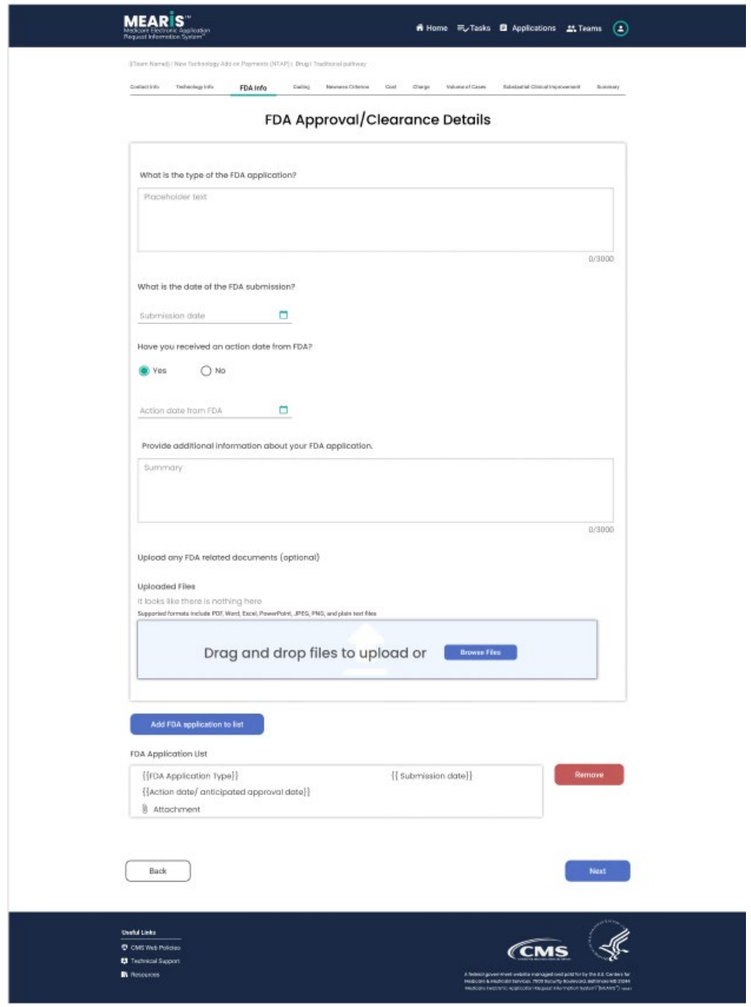
8	Date of Food and Drug Administration (FDA) (or expected) approval for the technology, service, or drug. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. Note: Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology, service, or drug has received multiple types of approvals from the FDA. Per § 412.87(c) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA approval or clearance for its new medical service or technology by July 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective (for FY 2021, not later than July 1, 2020).	AS IS - This question is broken down throughout the FDA section.	No substantive change or burden	

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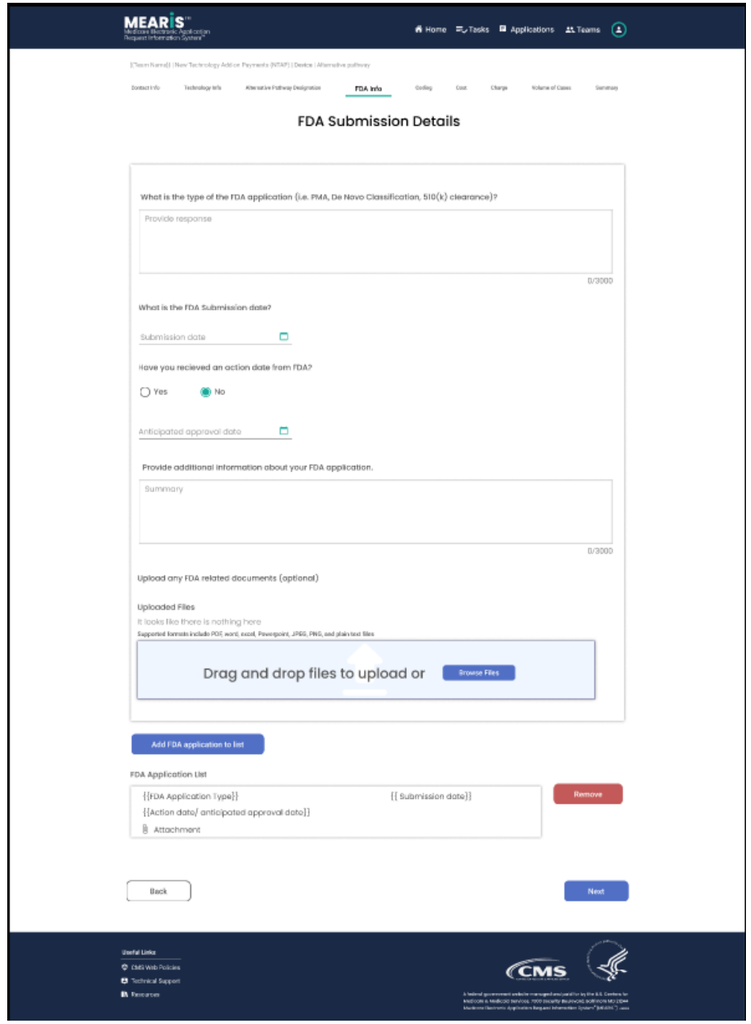
8	Date of Food and Drug Administration (FDA) (or expected) approval for the technology, service, or drug. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. Note: Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology, service, or drug has received multiple types of approvals from the FDA. Per § 412.87(c) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA approval or clearance for its new medical service or technology by July 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective (for FY 2021, not later than July 1, 2020).	AS IS - This question is broken down throughout the FDA section.	No substantive change or burden	

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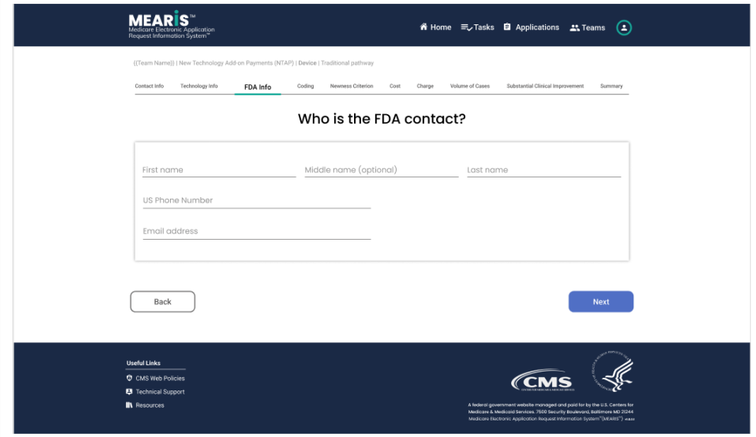
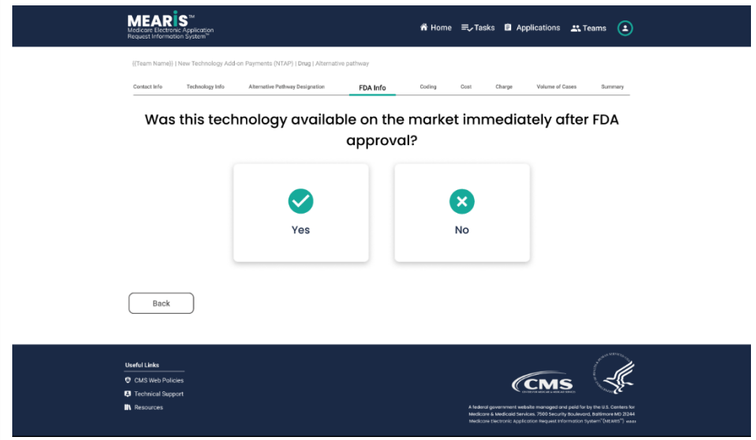
9	List the name and phone number of a contact at the FDA who is knowledgeable about the premarket approval request for the new technology listed	AS IS	No substantive change or burden	
11	Was the technology, service of drug available on the market immediately after FDA approval? If not, please provide the date that the medical service or technology came on the market (i.e. first sales or availability) and an explanation and documentation of any delay (i.e. manufacturing issues, shelf life concerns, or other reasons).	AS IS - This question is broken down throughout the FDA section.	No substantive change or burden	

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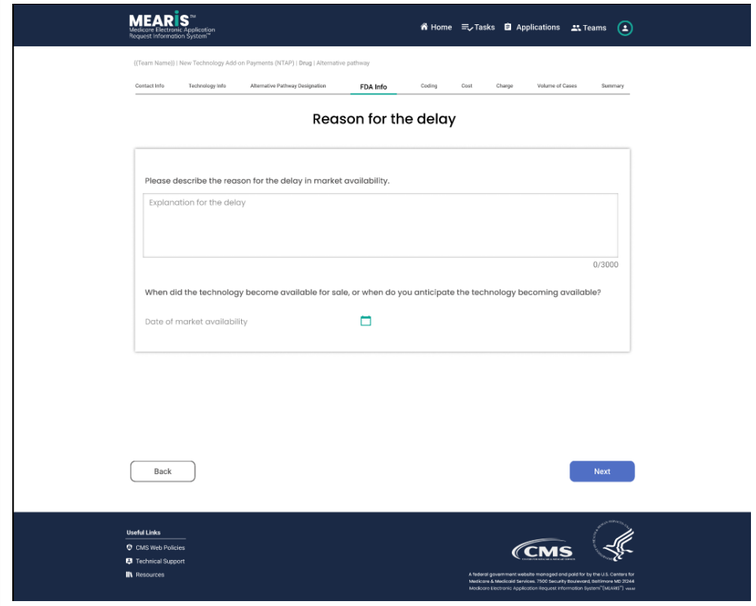
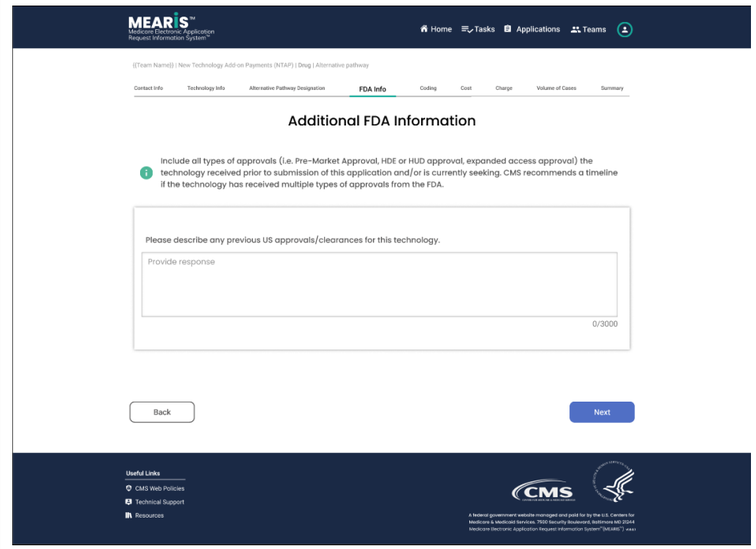
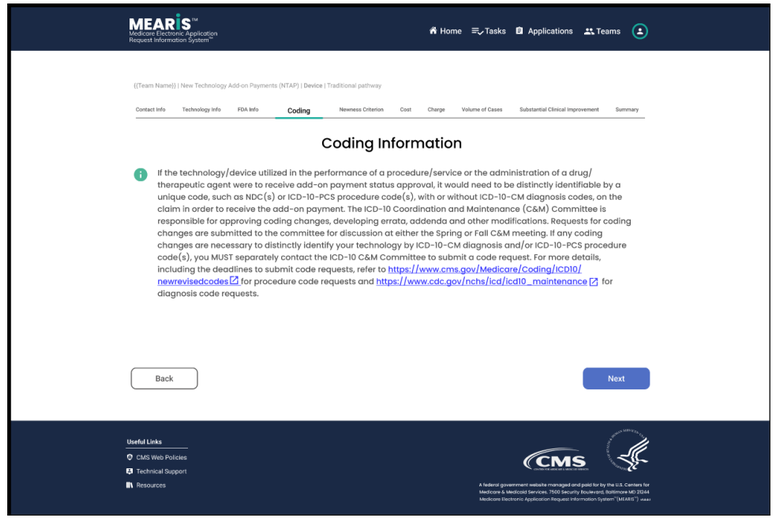
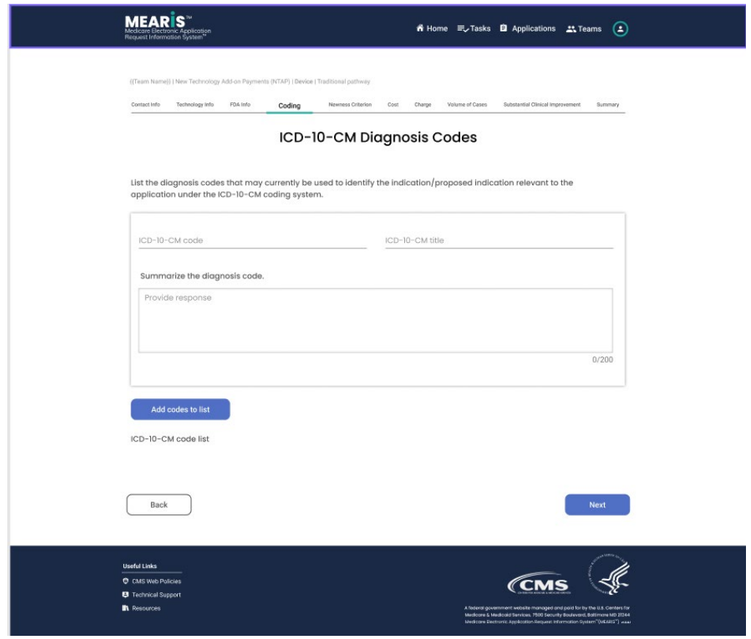
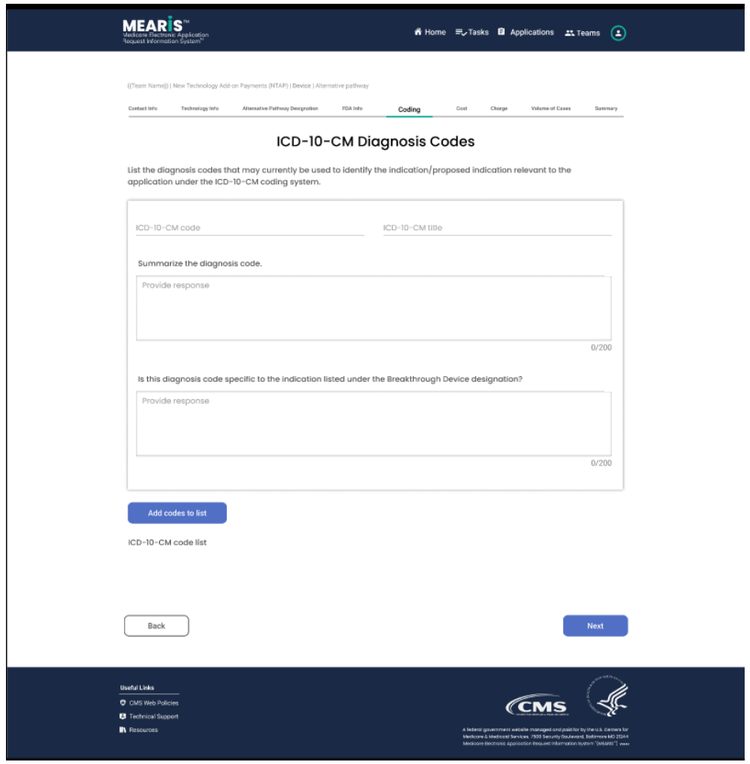
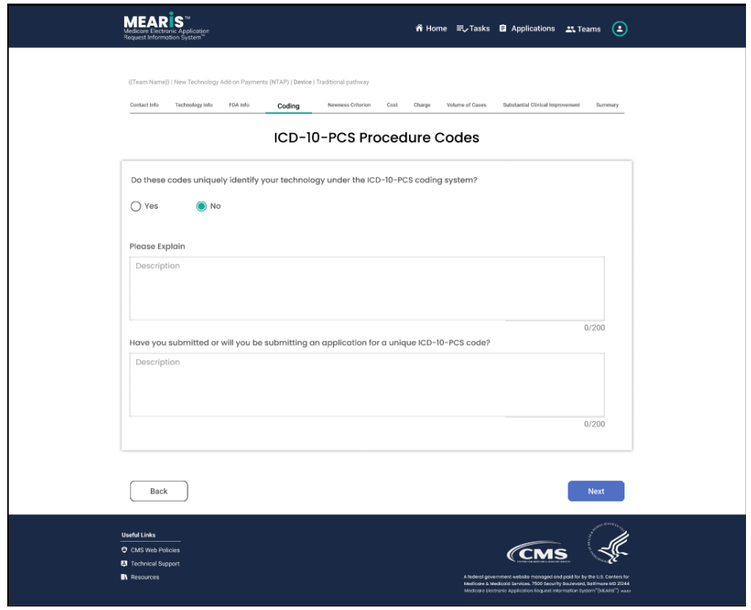
11	Was the technology, service of drug available on the market immediately after FDA approval? If not, please provide the date that the medical service or technology came on the market (i.e. first sales or availability) and an explanation and documentation of any delay (i.e. manufacturing issues, shelf life concerns, or other reasons).	AS IS - This question is broken down throughout the FDA section.	No substantive change or burden	

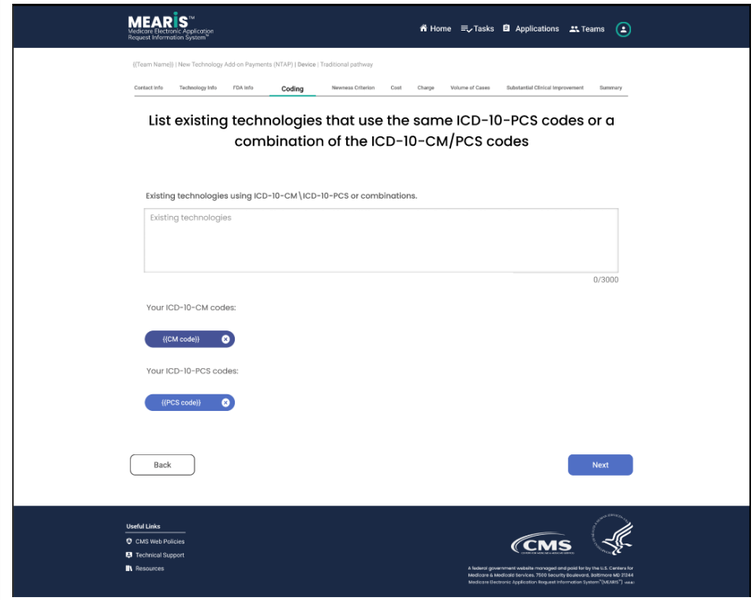
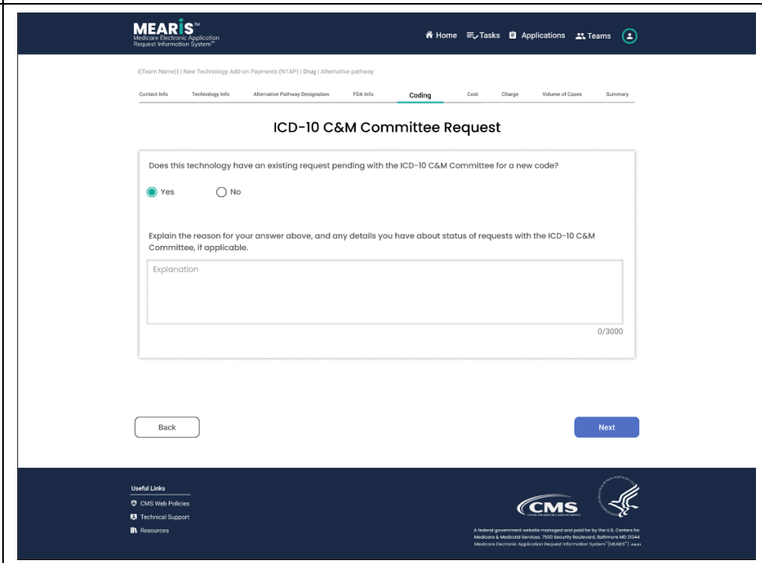
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
8 10	Date of Food and Drug Administration (FDA) (or expected) approval for the technology, service or drug. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. Note: Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology, service or drug has received multiple types of approvals from the FDA. Per § 412.87(c) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA approval or clearance for its new medical service or technology by July 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective (for FY 2021, not later than July 1, 2020). Please describe the (most recent, if applicable) type of application and approval the technology, service or drug has received or is seeking from the FDA (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval, New Drug Approval).	AS IS - This question is broken down throughout the FDA section.	No substantive change or burden	

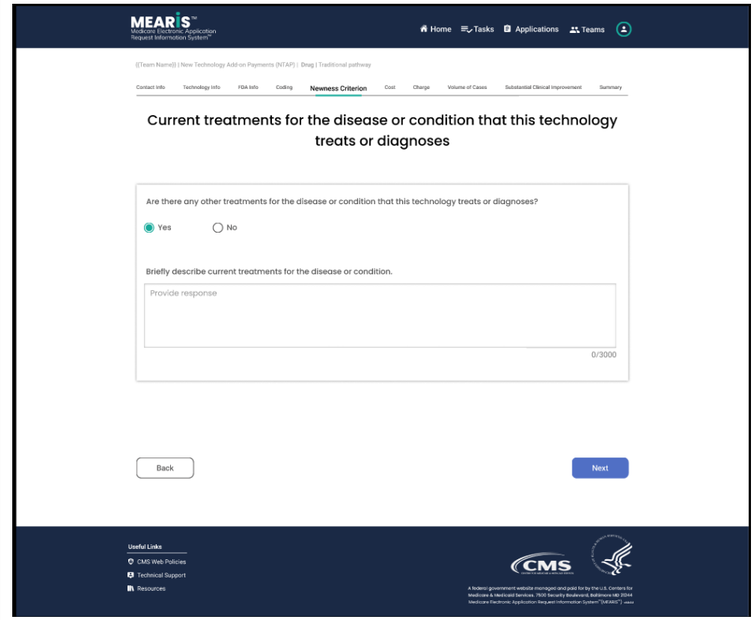
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
Coding Note	**Coding:** **Note:** If the technology, device, or drug (administered via procedure) were to receive add-on payment status approval, it would need to be distinctly identifiable by ICD-10-CM/PCS diagnosis and/or procedure code(s) 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/PCS diagnosis and or procedure code(s), you MUST separately contact the ICD-10 C&M Committee to submit a code request. Refer to https://www.cms.gov/Medicare/Coding/ICD10/newrevisedcodes.html for more details including deadline to submit code request.	AS IS	No substantive change or burden	

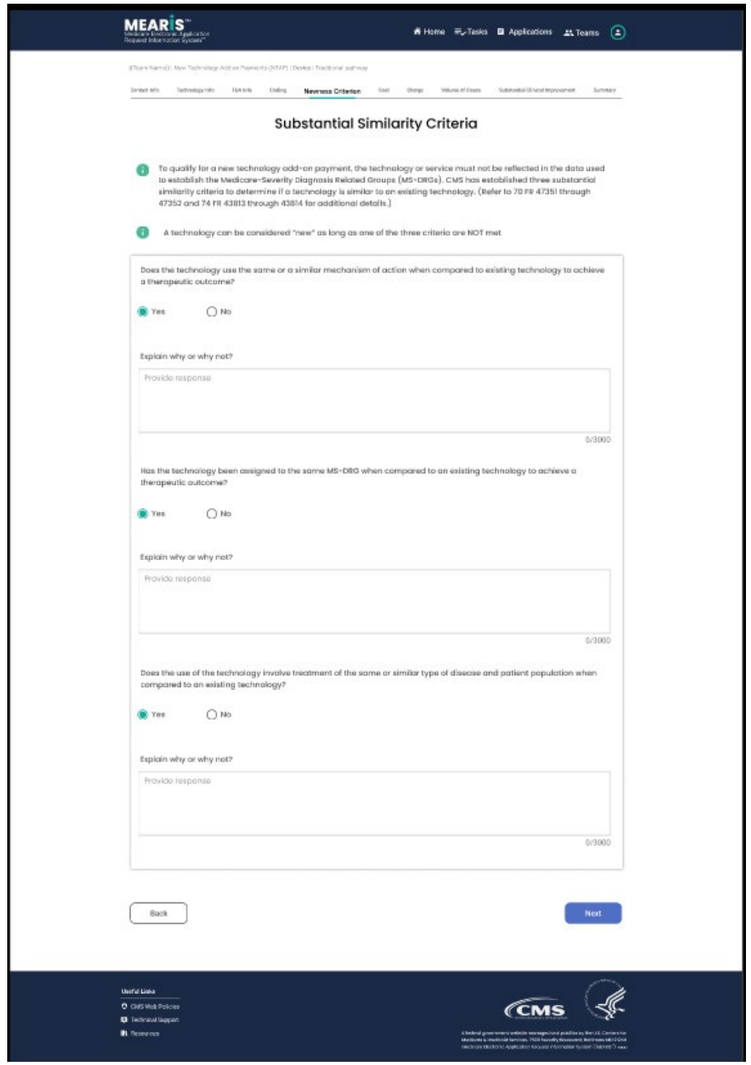
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
17	**Coding:** List the diagnosis and/or procedure codes that are currently or will be used to identify your technology under the ICD-10-CM/PCS coding system.	AS IS – this question has been broken down to separate code types	No substantive change or burden	

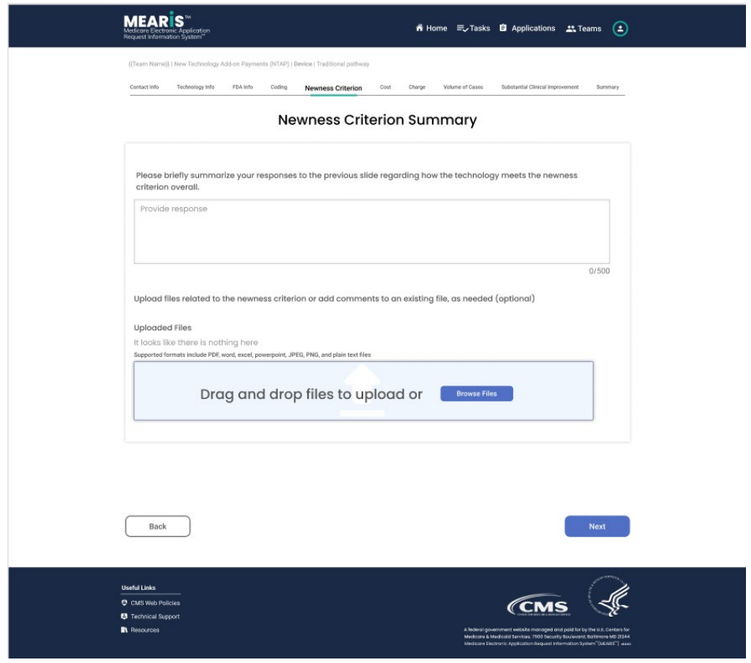
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
17-18	**Coding:** List the diagnosis and/or procedure codes that are currently or will be used to identify your technology under the ICD-10-CM/PCS coding system. Do the codes listed in question 17 distinctly identify your technology under the ICD-10-CM/PCS coding system? If not, please see the note above.	AS IS with one exception: Request now specific to indication to ensure clarity in applicants' responses. Currently, this detail is required to be included in the narrative.	No substantive change or burden	

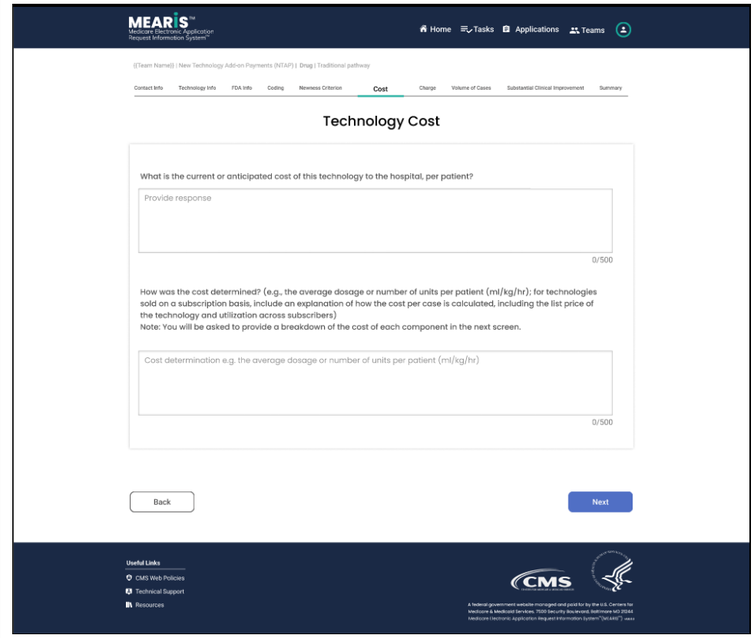
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
18 Preamble	**Coding:** Do the codes listed in question 17 distinctly identify your technology under the ICD-10-CM/PCS coding system? If not, please see the note above. REQUIRED INFORMATION Applications must include a response to each question below. Information must be entered directly onto this form. Do not copy and paste questions and answers into a different document. CMS may request other information in order to evaluate specific requests. Note: A separate application is required for each distinct technology or service included in a request. For example, if an applicant requests add-on payments for two **unique** technologies or services, a separate application is required for each technology or service. A completed tracking form. (A tracking form may be downloaded at http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/newtech.html.)	AS IS	No substantive change or burden	

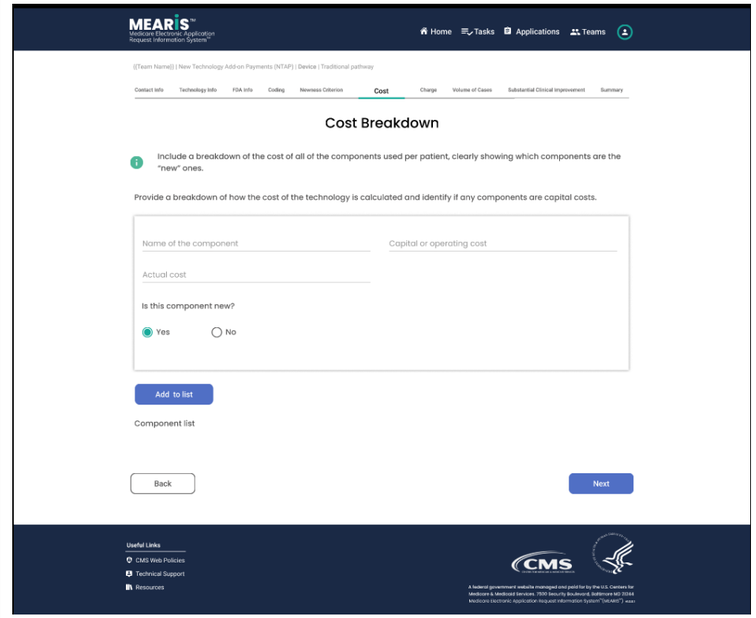
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
19	**Coding:** List any other technologies coded using the code(s) listed in question 17. For example, if you listed a single procedure code, what procedures use the code listed in question 17 aside from the procedure used for your technology? Similarly, if you listed a combination or multiple codes in question 17, what other procedures or technologies use the same combination of codes listed in question 17 aside from your technology?	AS IS	No substantive change or burden	
20	**Coding:** Does the service or technology have an existing request pending with the ICD-10 C&M Committee?	AS IS	No substantive change or burden	

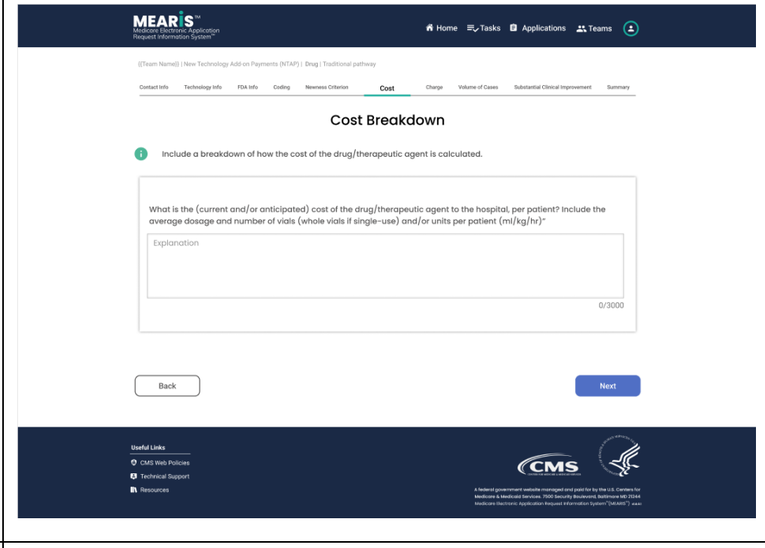
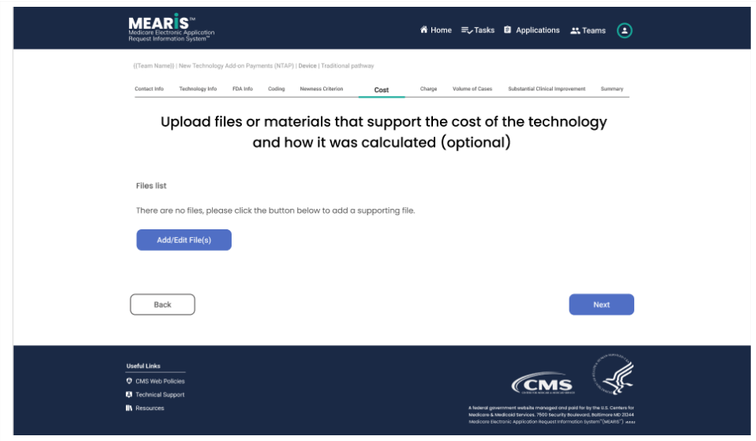
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
6	If applicable, briefly describe current and/or alternative treatments for the disease or condition that your technology treats or diagnoses.	AS IS	No substantive change or burden	

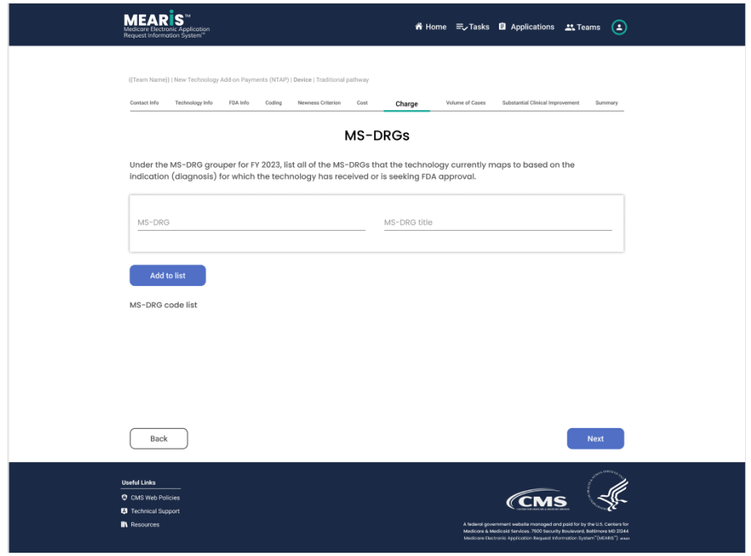
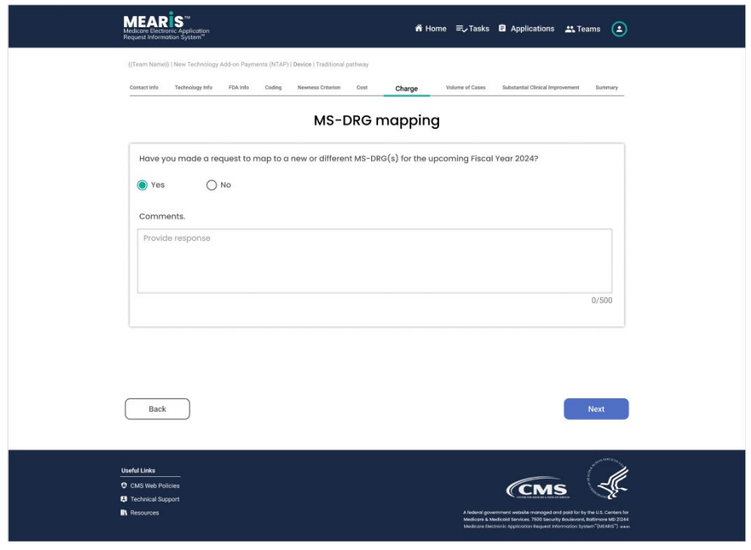
Newness Criterion **Note**	**Newness Criterion** **Note:** To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the Medicare-Severity Diagnosis Related Groups (MS-DRGs). As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 5 through 20 (newness criterion). CMS has established a 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 is not “new”, if it meets all three of the criteria below: a. If a product uses the same or a similar mechanism of action when compared to an existing technology to achieve a therapeutic outcome; and b. If a product is assigned to the same DRG when compared to an existing technology; and c. If the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology. **Applicants must explain why they do not meet the criteria above.**	AS IS	No substantive change or burden	
7		AS IS	No substantive change or burden	

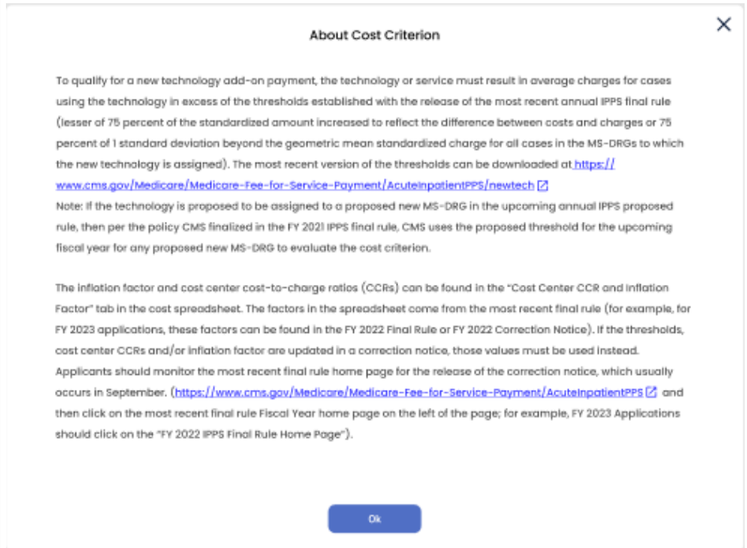
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
7	**Applicants must explain why they do not meet the criteria above.**	AS IS.	No substantive change or burden	

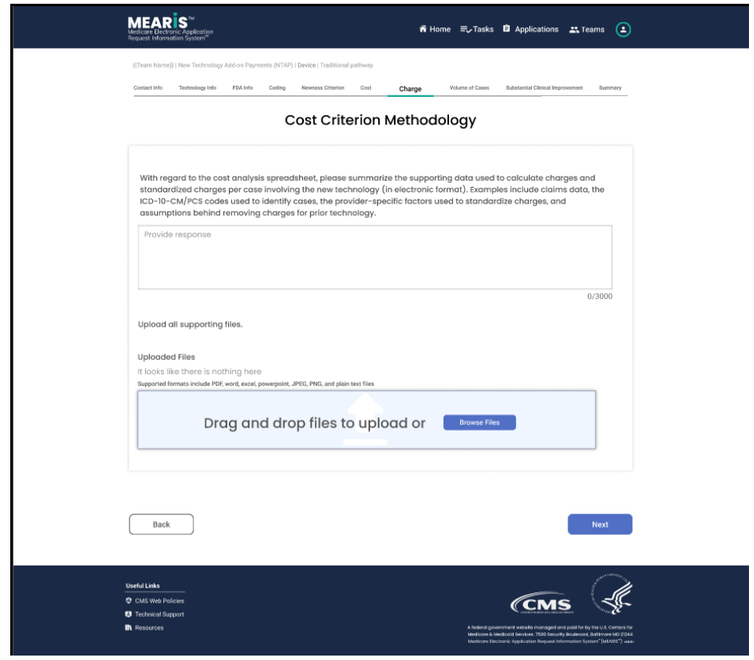
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
22	**Cost Information** What is the (current and/or anticipated) cost of the technology to the hospital, per patient?	AS IS	No substantive change or burden	

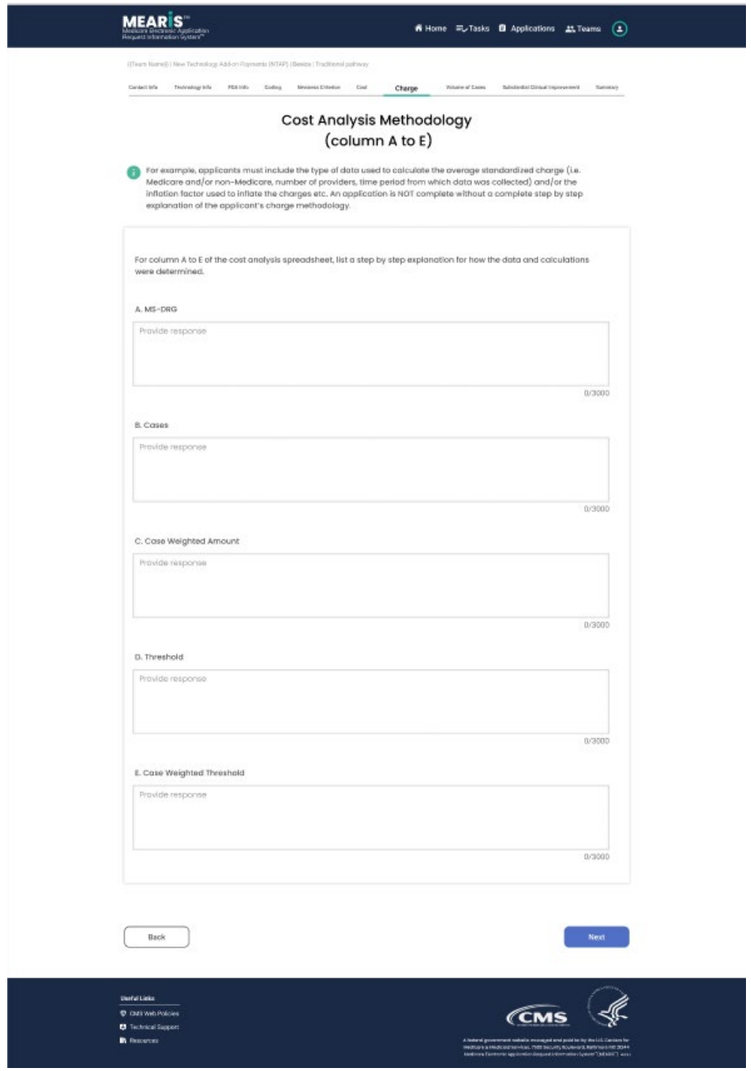
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
23	**Cost Information** Provide a breakdown of how the cost of the technology is calculated: (e.g. For drugs, the average dosage or number of units per patient (ml/kg/hr); For devices, a breakdown of the cost of all of the components used per patient, clearly showing which components are the “new” ones).	AS IS	No substantive change or burden	

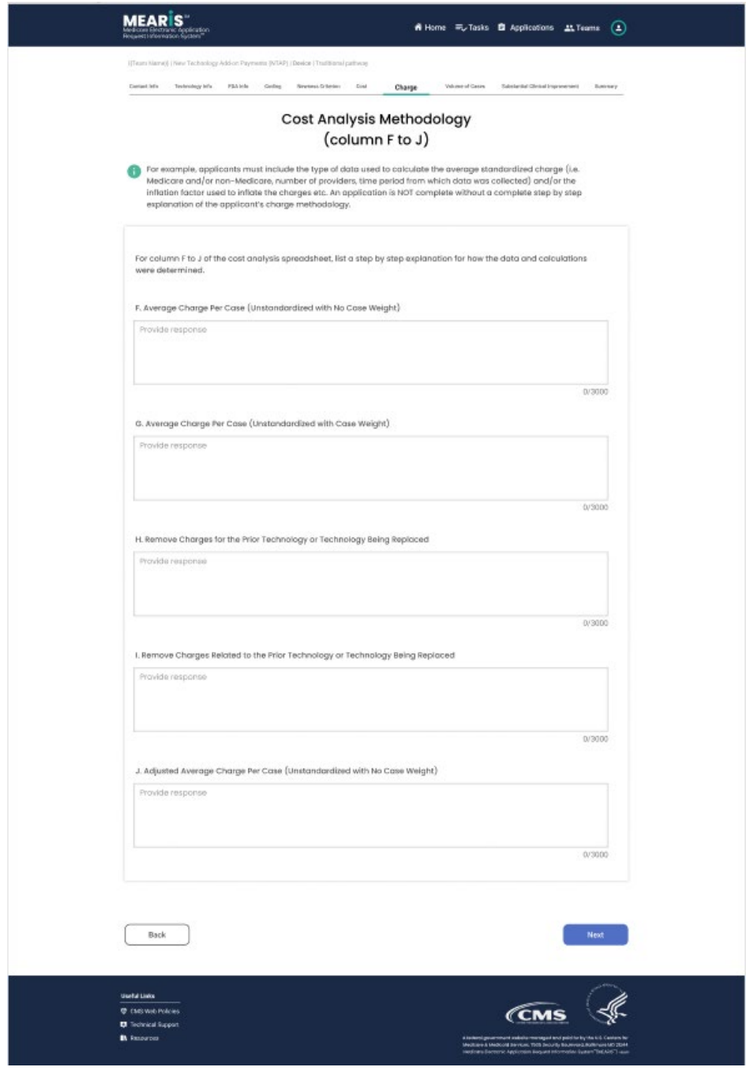
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
23	**Cost Information** Provide a breakdown of how the cost of the technology is calculated: (e.g. For drugs, the average dosage or number of units per patient (ml/kg/hr); For devices, a breakdown of the cost of all of the components used per patient, clearly showing which components are the “new” ones).	AS IS	No substantive change or burden	
		Optional upload. In the old application, they could upload anything they deemed relevant.	No substantive change or burden	

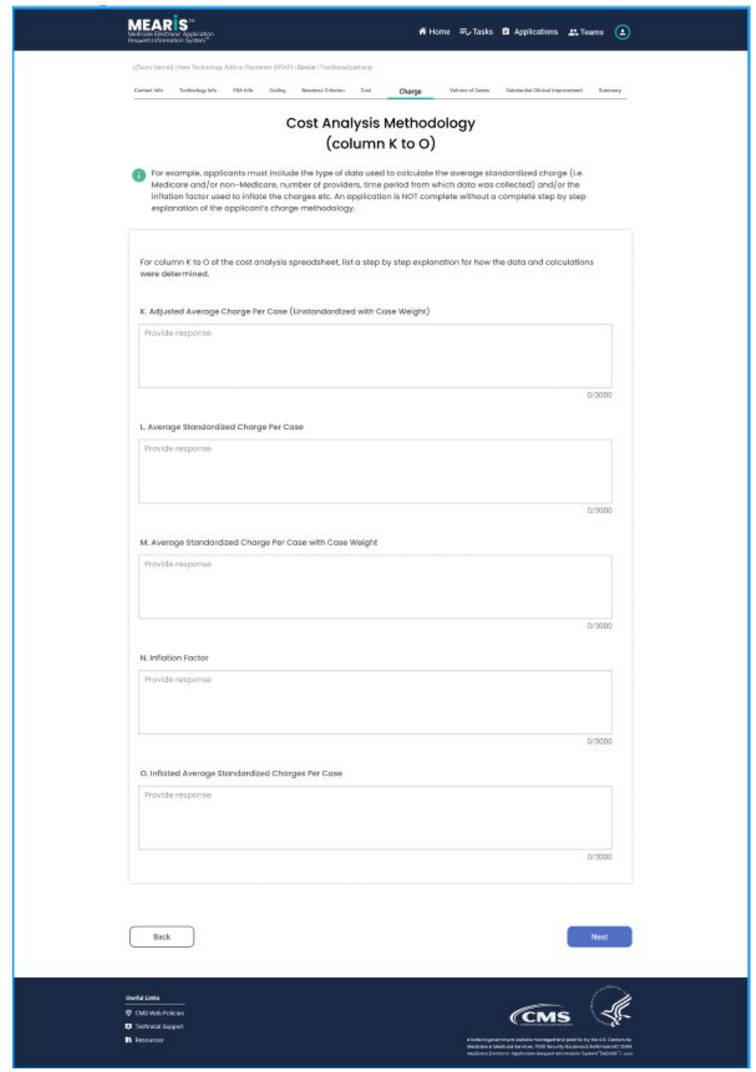
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
24	**Charge Information:** Under the MS-DRG grouper for FY 2020, list the MS-DRGs that the technology currently maps to?	AS IS	No substantive change or burden	
25	**Charge Information:** Has the applicant made a request for the new technology to map to a new or different MS-DRG(s) for the upcoming fiscal year (2021) other than the ones listed in question 24?	AS IS	No substantive change or burden	

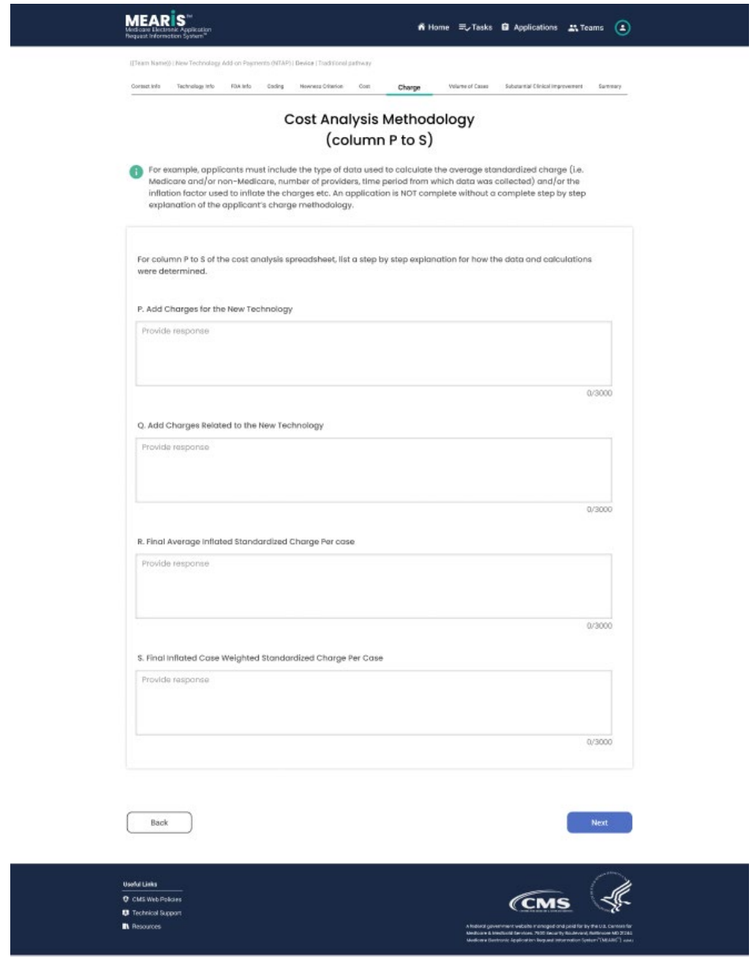
Cost Criterion Note	**Cost Criterion** **Note:** To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of the thresholds established for the FY (lesser of 75 percent of the standardized amount increased to reflect 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) of the annual IPPS final rule. The most recent version of the thresholds can be downloaded at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html	AS IS	No substantive change or burden	
26	**Charge Information:** (26) Using the table as demonstrated in the spreadsheet as a template, show how the standardized charge per case (if applicable, case weighted) exceeds the threshold for the cost criterion. **Note:** Refer to Appendix A for an explanation of how to standardize charges. Refer to the spreadsheet in the application packet how to case weight the average standardize charge per case if multiple MS-DRGs are affected by the technology.			

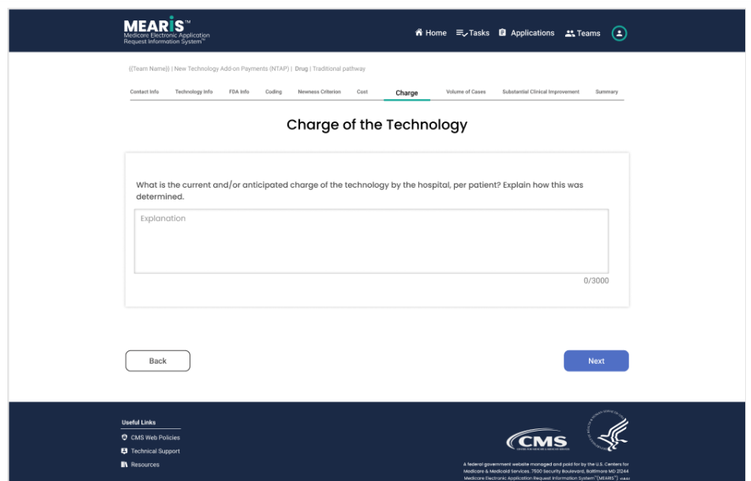
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
27	**Charge Information:** With regard to the spreadsheet in question 26, provide all supporting data used to calculate charges and standardized charges per case involving the new technology (in electronic format).	AS IS	No substantive change or burden	

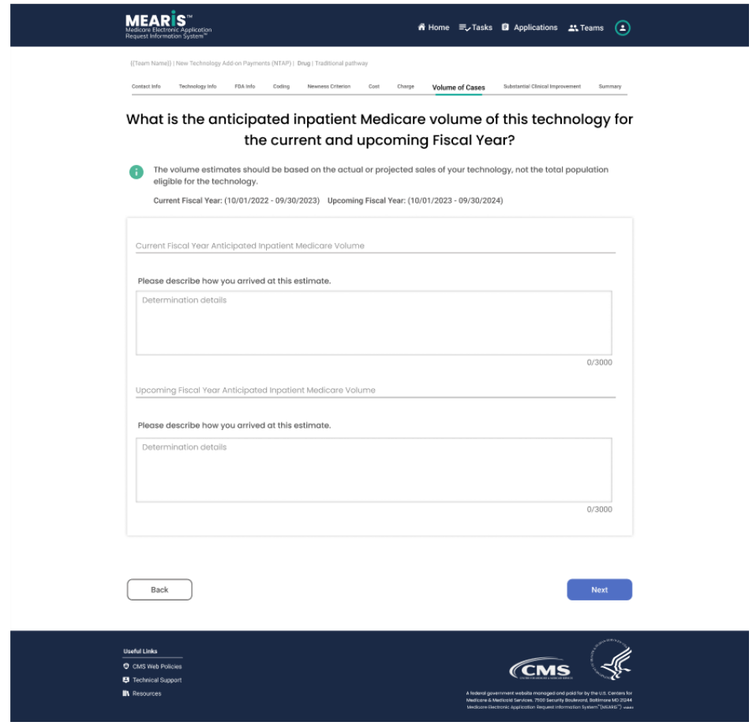
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
28	List a step by step explanation of how the data and calculations in each column of the spreadsheet were determined. For example, within the explanation applicants must include the type of data used to calculate the average standardized charge (i.e. Medicare and/or non[1]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.	This provides space for a column-by-column explanation instead of an open field to standardize applicant responses. Most applicants already used a column-by-column approach in their narrative response.	No substantive change or burden	

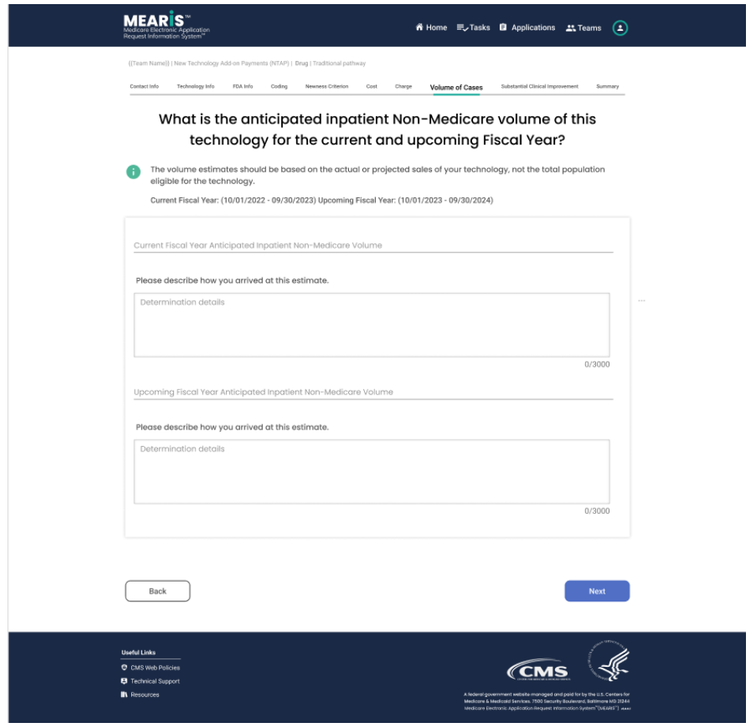
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
28	List a step by step explanation of how the data and calculations in each column of the spreadsheet were determined. For example, within the explanation applicants must include the type of data used to calculate the average standardized charge (i.e. Medicare and/or non[1]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.	This provides space for a column-by-column explanation instead of an open field to standardize applicant responses. Most applicants already used a column-by-column approach in their narrative response.	No substantive change or burden	

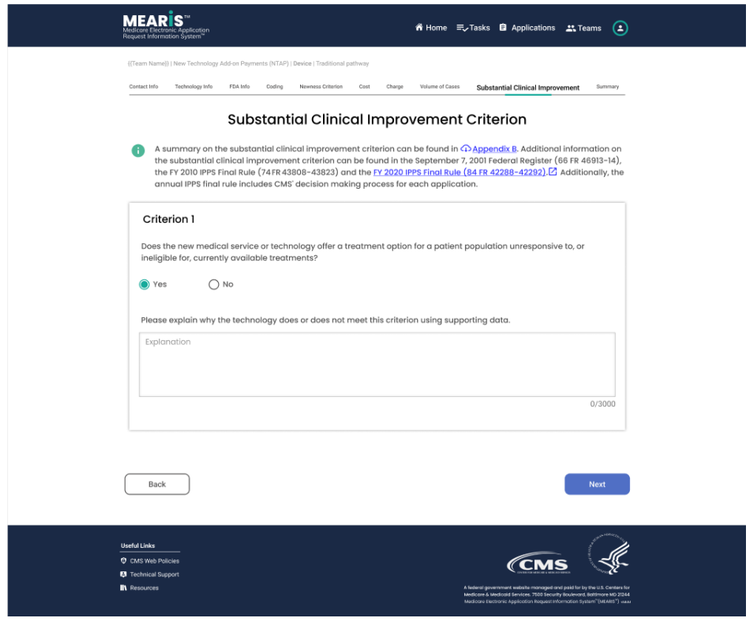
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
28	List a step by step explanation of how the data and calculations in each column of the spreadsheet were determined. For example, within the explanation applicants must include the type of data used to calculate the average standardized charge (i.e. Medicare and/or non[1]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.	This provides space for a column-by-column explanation instead of an open field to standardize applicant responses. Most applicants already used a column-by-column approach in their narrative response.	No substantive change or burden	

Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
28	List a step by step explanation of how the data and calculations in each column of the spreadsheet were determined. For example, within the explanation applicants must include the type of data used to calculate the average standardized charge (i.e. Medicare and/or non[1]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.	This provides space for a column-by-column explanation instead of an open field to standardize applicant responses. Most applicants already used a column-by-column approach in their narrative response.	No substantive change or burden	

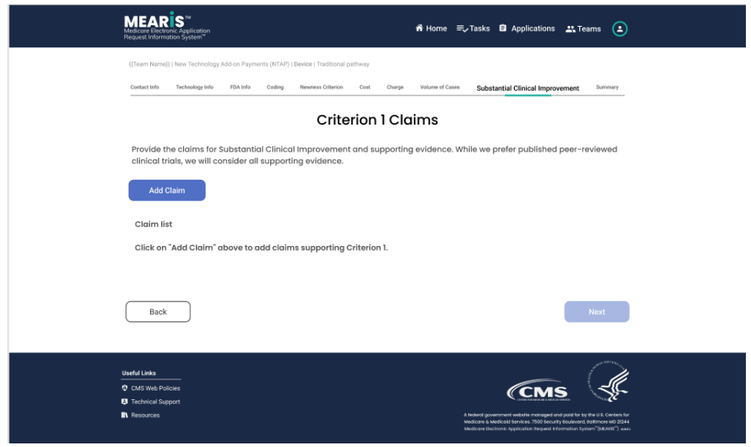
Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
29	**Charge Information:** What is the (current and/or anticipated) charge of the technology by the hospital, per patient? Explain how this was determined.	AS IS	No substantive change or burden	

Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
30 32	**Volume of Cases:** (30) What is the anticipated Medicare volume of this technology for FY 2020 (October 1, 2019 – September 30, 2020)? Please describe how you arrived at this estimate. This estimate should be based on the actual or projected sales of your technology, not the total population eligible for the technology. **Volume of Cases:** (32) What is the anticipated Medicare volume of this technology for FY 2021 (October 1, 2020 – September 30, 2021). Please describe how you arrived at this estimate. This estimate should be based on the actual or projected sales of your technology, not the total population eligible for the technology.	AS IS	No substantive change or burden	

Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
31	**Volume of Cases:** (31) What is the anticipated Non-Medicare volume of this technology for FY 2020 (October 1, 2019 – September 30, 2020). Please describe how you arrived at this estimate. This estimate should be based on the actual or projected sales of your technology, not the total population eligible for the technology.	AS IS	No substantive change or burden	
33	**Volume of Cases:** (33) What is the anticipated Non-Medicare volume of this technology for FY 2021 (October 1, 2020 – September 30, 2021). Please describe how you arrived at this estimate. This estimate should be based on the actual or projected sales of your technology, not the total population eligible for the technology.			

Substantial Clinical Improvement Criterion Note 34, 35, 36	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.** (34) Appendix B has descriptions of the substantial clinical improvement criteria, which are associated with treatments, diagnosis, and clinical outcomes. Using Appendix B, identify and describe how the technology meets the criteria for substantial clinical improvement over existing technologies. (35) Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology. In the annotation, please clearly summarize each article,	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	

Paper Application Question #	Paper Application Language	Modifications	Burden	Screenshot
	describe the purpose of the article, and the relevance to the technology. Please indicate all literature that is referenced in question #35 above. **Note:** Indicate if any peer-reviewed articles will be released after submission of this application. (36) For each claim of substantial clinical improvement over existing technologies, in table format (see Table 1 below), list the claim of substantial clinical improvement and summarize the supporting information to include relevant clinical trial(s) or data. See sample table below. (Application is incomplete without this table). Contact NewTech@cms.hhs.gov with questions concerning the table.			

Substantial Clinical Improvement Criterion Note 34, 35, 36	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.** (34) Appendix B has descriptions of the substantial clinical improvement criteria, which are associated with treatments, diagnosis, and clinical outcomes. Using Appendix B, identify and describe how the technology meets the criteria for substantial clinical improvement over existing technologies. (35) Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology. In the annotation, please clearly summarize each article,	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	

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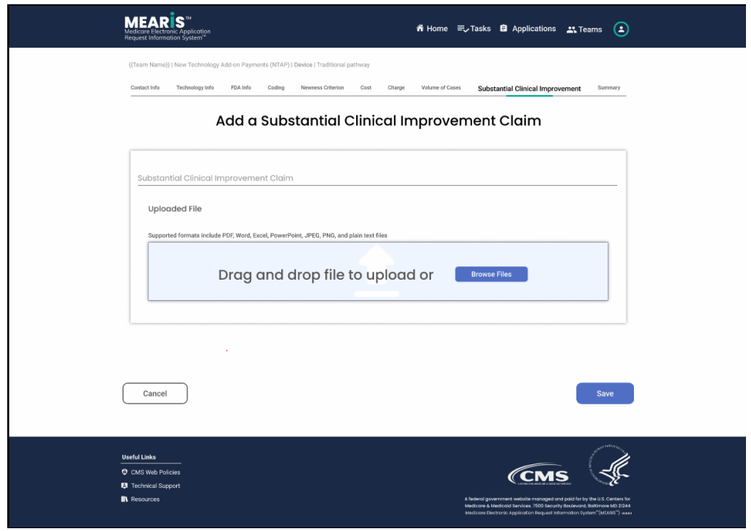
Substantial Clinical Improvement Criterion Note	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.**	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	
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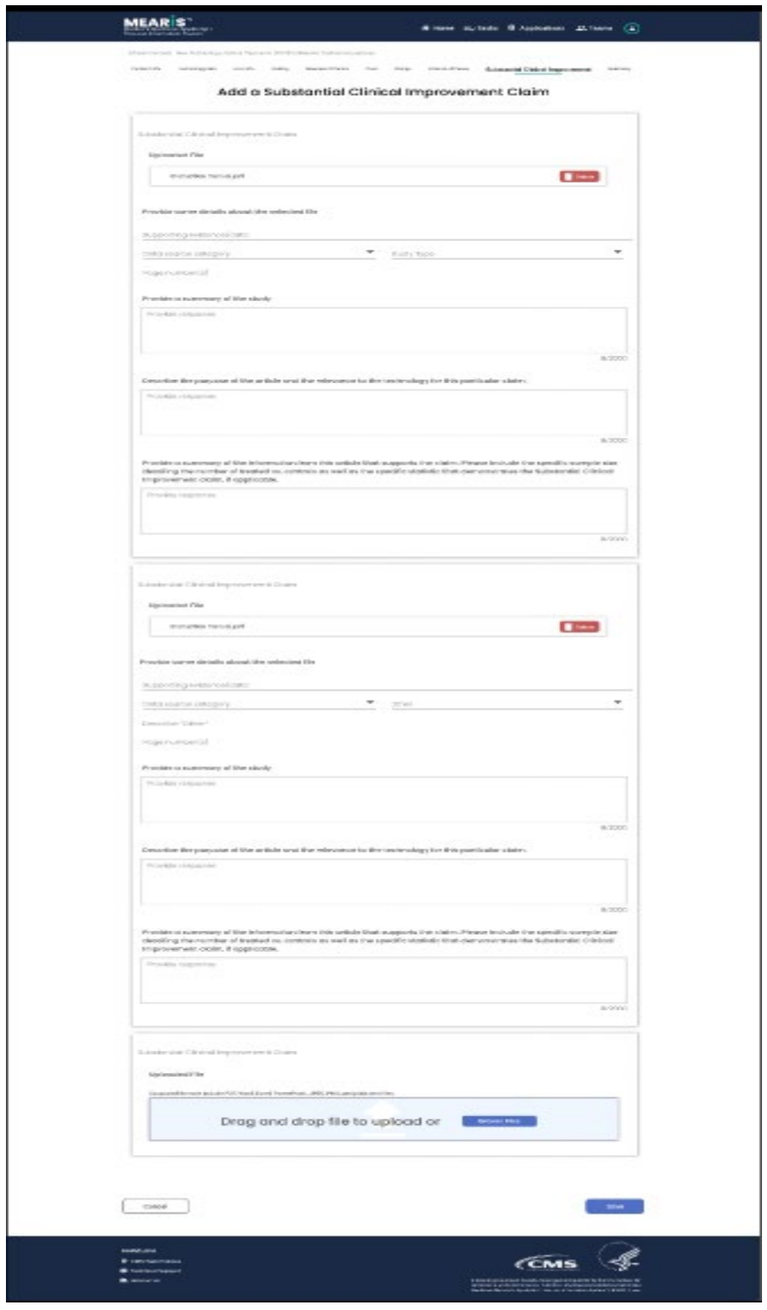
Substantial Clinical Improvement Criterion Note 34, 35, 36	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.** (34) Appendix B has descriptions of the substantial clinical improvement criteria, which are associated with treatments, diagnosis, and clinical outcomes. Using Appendix B, identify and describe how the technology meets the criteria for substantial clinical improvement over existing technologies. (35) Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology. In the annotation, please clearly summarize each article,	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	

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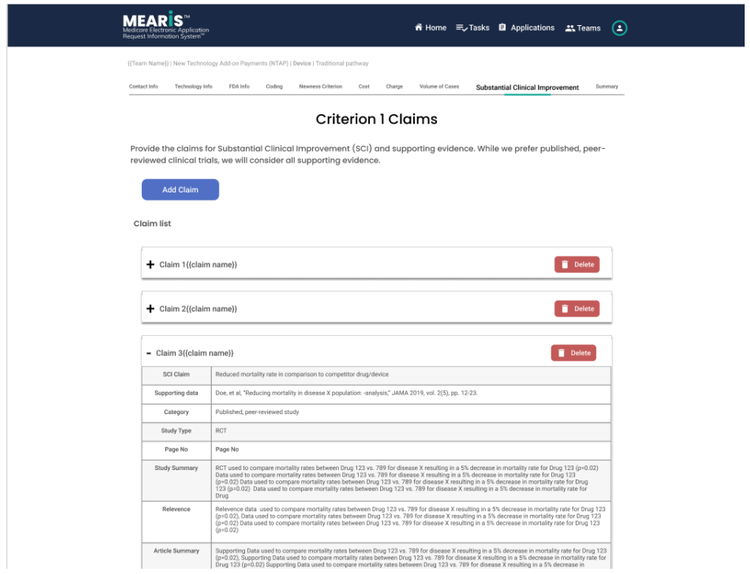
Substantial Clinical Improvement Criterion Note 34, 35, 36	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.** (34) Appendix B has descriptions of the substantial clinical improvement criteria, which are associated with treatments, diagnosis, and clinical outcomes. Using Appendix B, identify and describe how the technology meets the criteria for substantial clinical improvement over existing technologies. (35) Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology. In the annotation, please clearly summarize each article,	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	

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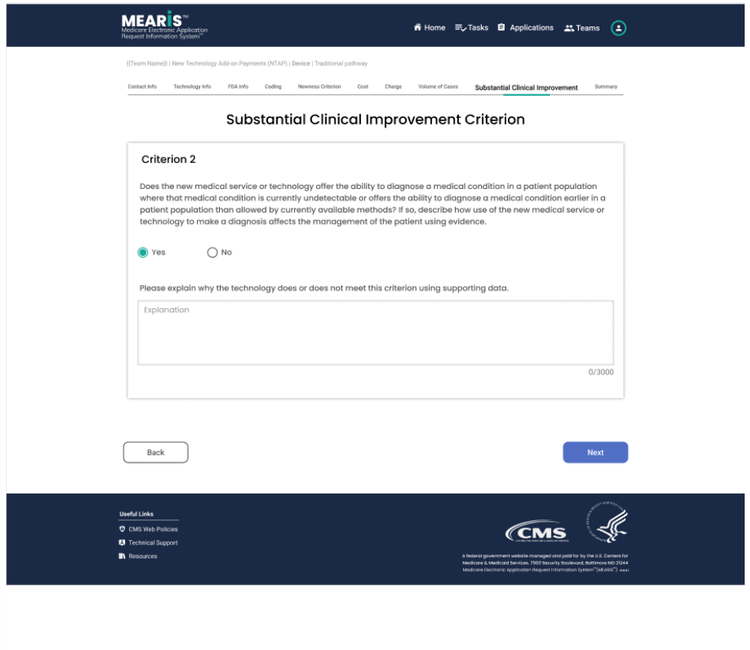
Substantial Clinical Improvement Criterion Note	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.**	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	
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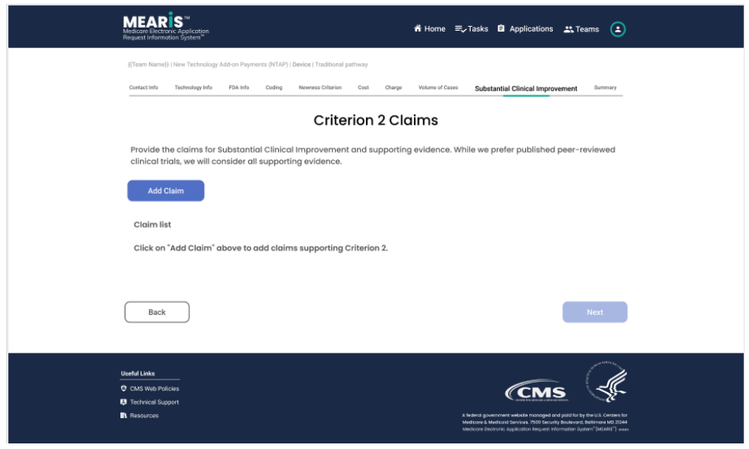
Substantial Clinical Improvement Criterion Note 34, 35, 36	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.** (34) Appendix B has descriptions of the substantial clinical improvement criteria, which are associated with treatments, diagnosis, and clinical outcomes. Using Appendix B, identify and describe how the technology meets the criteria for substantial clinical improvement over existing technologies. (35) Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology. In the annotation, please clearly summarize each article,	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	

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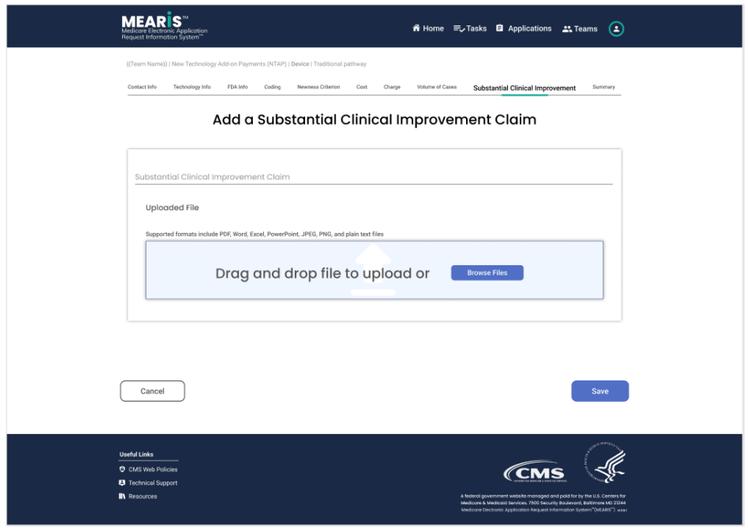
Substantial Clinical Improvement Criterion Note 34, 35, 36	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.** (34) Appendix B has descriptions of the substantial clinical improvement criteria, which are associated with treatments, diagnosis, and clinical outcomes. Using Appendix B, identify and describe how the technology meets the criteria for substantial clinical improvement over existing technologies. (35) Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology. In the annotation, please clearly summarize each article,	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	

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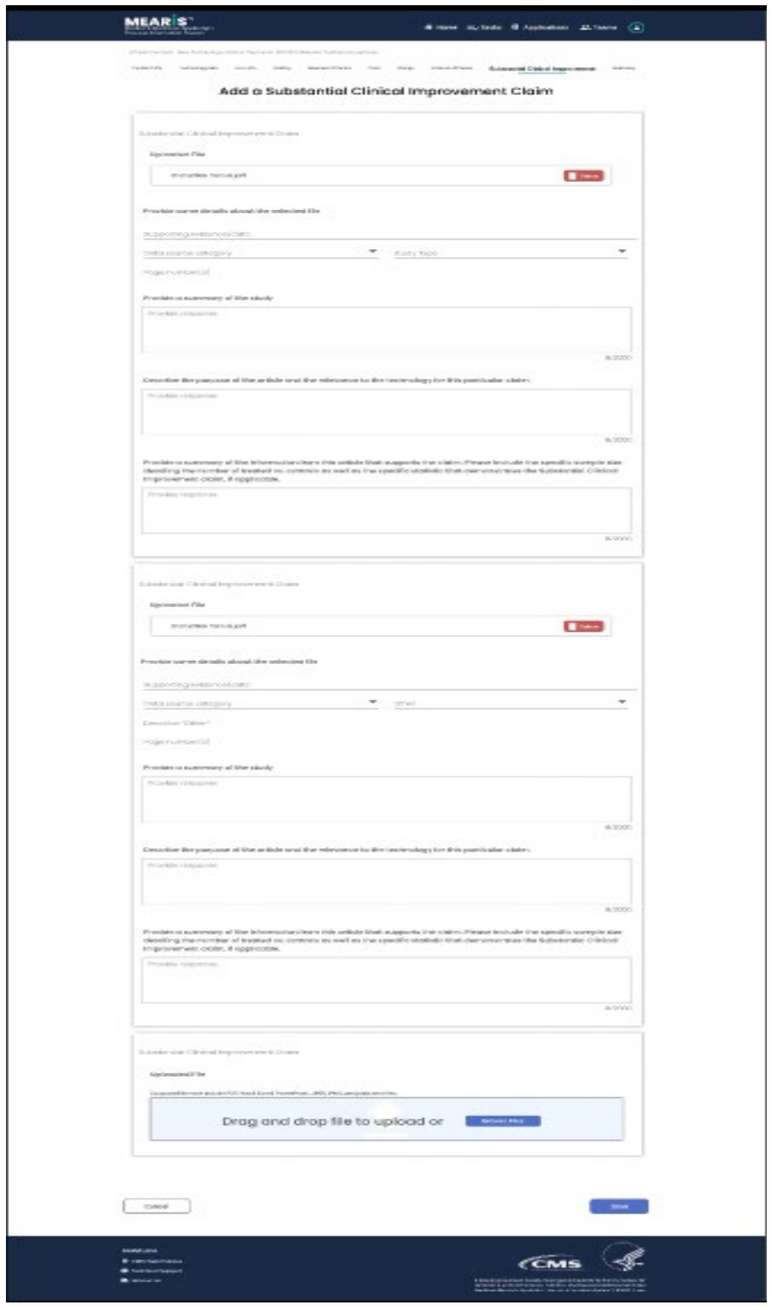
Substantial Clinical Improvement Criterion Note 34, 35, 36	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.** (34) Appendix B has descriptions of the substantial clinical improvement criteria, which are associated with treatments, diagnosis, and clinical outcomes. Using Appendix B, identify and describe how the technology meets the criteria for substantial clinical improvement over existing technologies. (35) Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology. In the annotation, please clearly summarize each article,	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	

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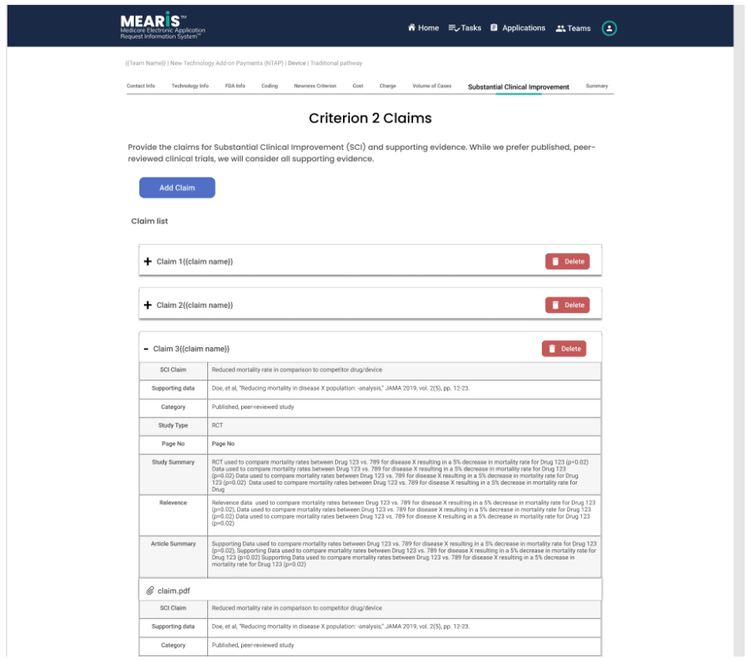
Substantial Clinical Improvement Criterion Note 34, 35, 36	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.** (34) Appendix B has descriptions of the substantial clinical improvement criteria, which are associated with treatments, diagnosis, and clinical outcomes. Using Appendix B, identify and describe how the technology meets the criteria for substantial clinical improvement over existing technologies. (35) Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology. In the annotation, please clearly summarize each article,	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	

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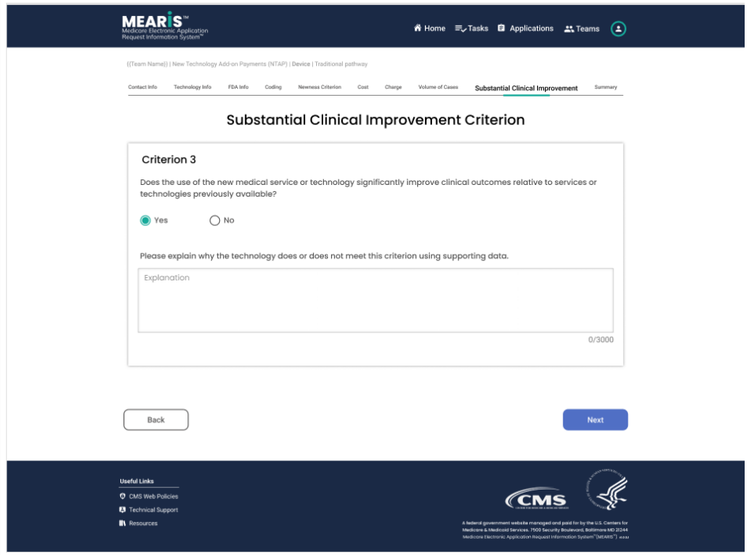
Substantial Clinical Improvement Criterion Note 34, 35, 36	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.** (34) Appendix B has descriptions of the substantial clinical improvement criteria, which are associated with treatments, diagnosis, and clinical outcomes. Using Appendix B, identify and describe how the technology meets the criteria for substantial clinical improvement over existing technologies. (35) Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology. In the annotation, please clearly summarize each article,	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	

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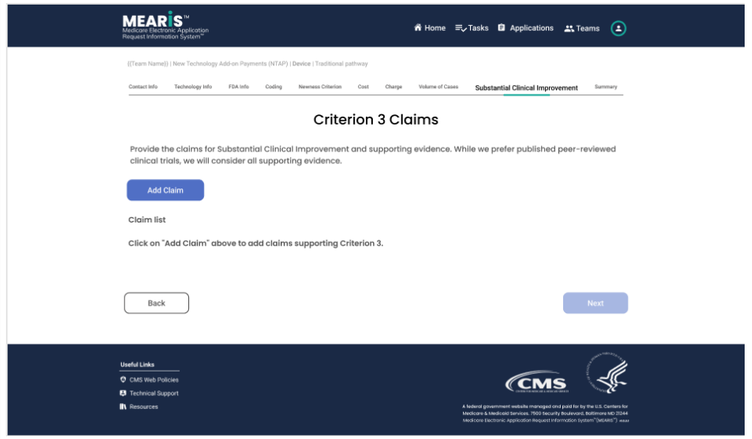
Substantial Clinical Improvement Criterion Note 34, 35, 36	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.** (34) Appendix B has descriptions of the substantial clinical improvement criteria, which are associated with treatments, diagnosis, and clinical outcomes. Using Appendix B, identify and describe how the technology meets the criteria for substantial clinical improvement over existing technologies. (35) Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology. In the annotation, please clearly summarize each article,	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	

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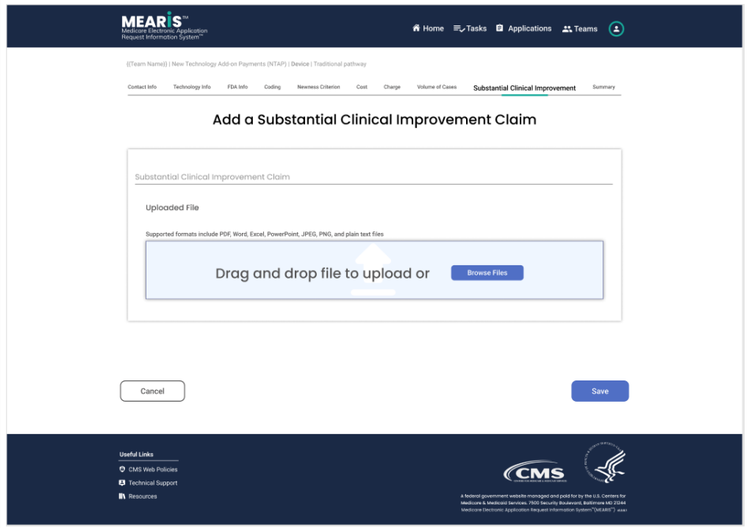
Substantial Clinical Improvement Criterion Note 34, 35, 36	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.** (34) Appendix B has descriptions of the substantial clinical improvement criteria, which are associated with treatments, diagnosis, and clinical outcomes. Using Appendix B, identify and describe how the technology meets the criteria for substantial clinical improvement over existing technologies. (35) Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology. In the annotation, please clearly summarize each article,	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	

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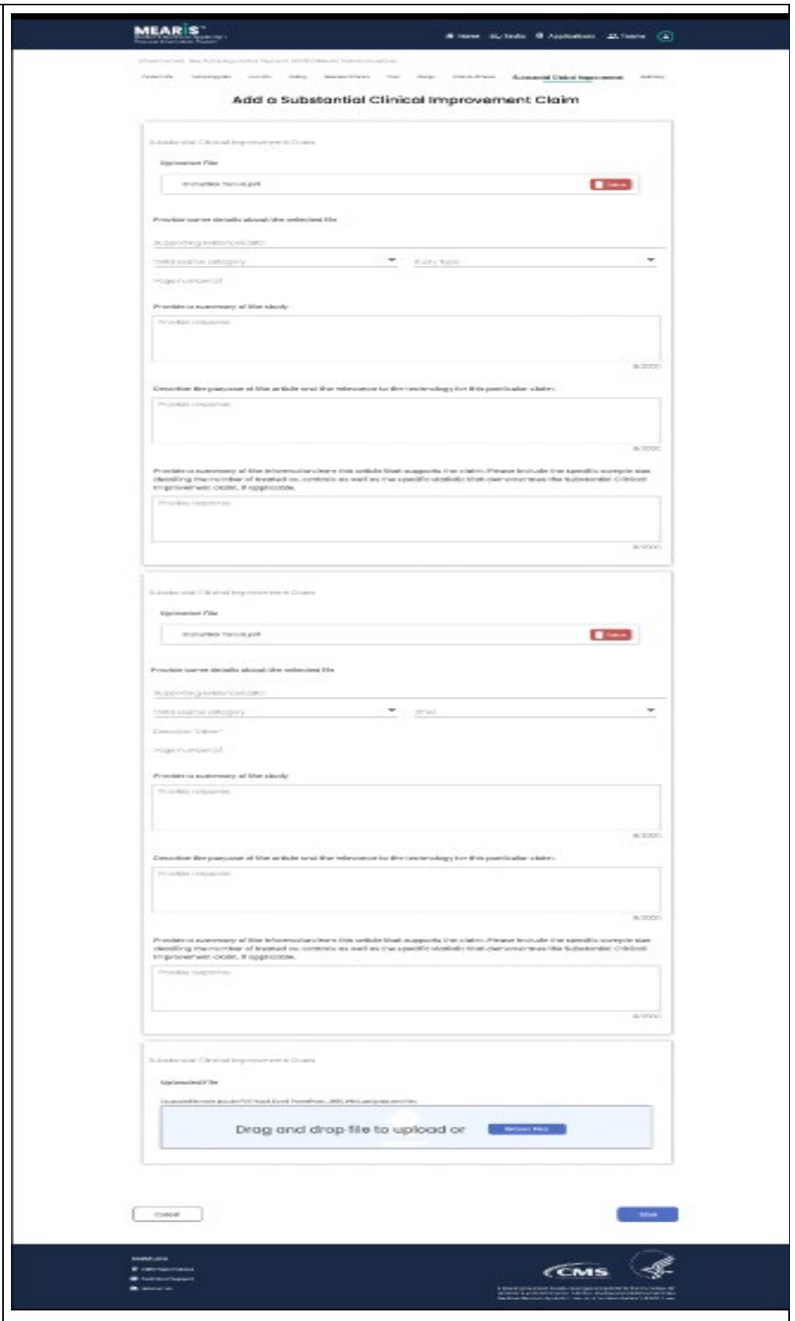
Substantial Clinical Improvement Criterion Note 34, 35, 36	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.** (34) Appendix B has descriptions of the substantial clinical improvement criteria, which are associated with treatments, diagnosis, and clinical outcomes. Using Appendix B, identify and describe how the technology meets the criteria for substantial clinical improvement over existing technologies. (35) Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology. In the annotation, please clearly summarize each article,	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	

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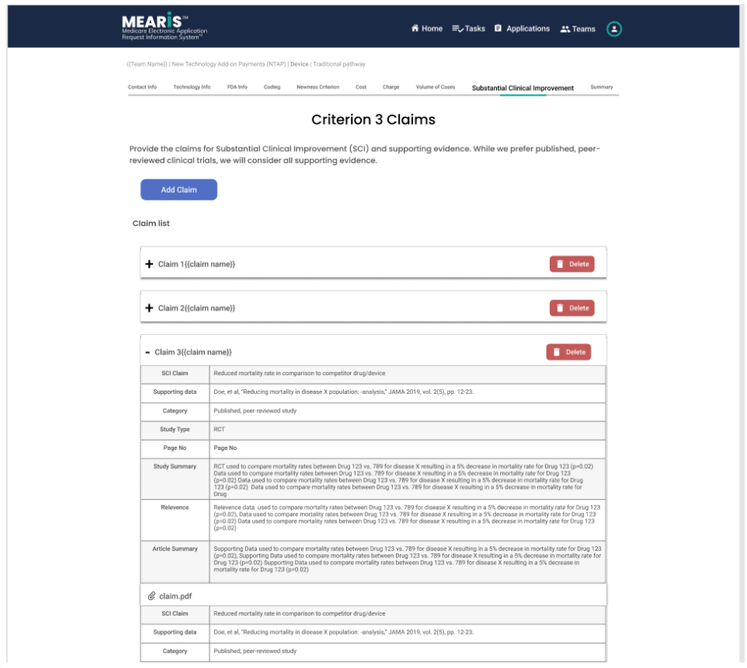
Substantial Clinical Improvement Criterion Note 34, 35, 36	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.** (34) Appendix B has descriptions of the substantial clinical improvement criteria, which are associated with treatments, diagnosis, and clinical outcomes. Using Appendix B, identify and describe how the technology meets the criteria for substantial clinical improvement over existing technologies. (35) Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology. In the annotation, please clearly summarize each article,	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	

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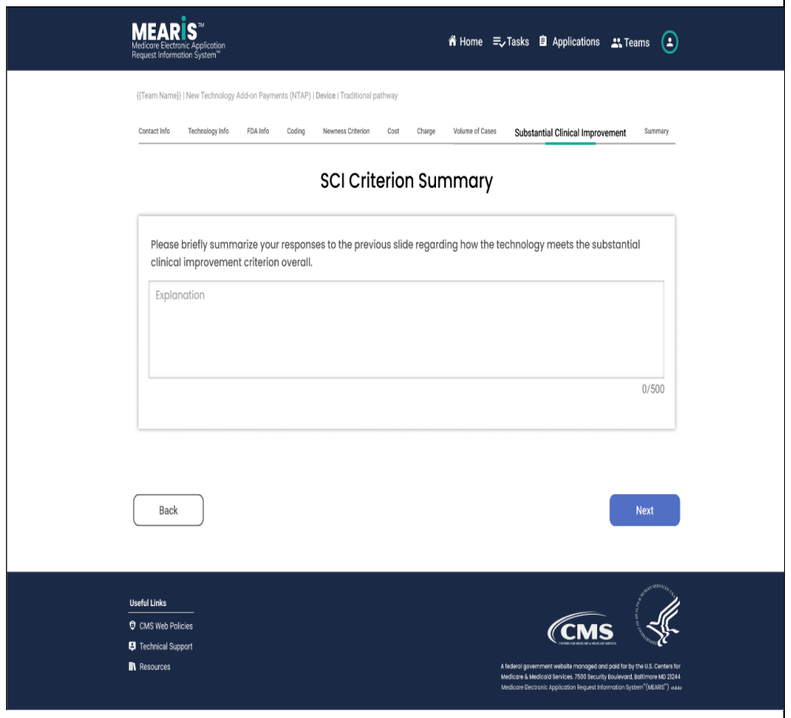
Substantial Clinical Improvement Criterion Note	**Substantial Clinical Improvement Criterion:** **Note:** A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion). **Convert posters to word documents or to provide a summary document of all posters.**	Reworded as individual questions to clarify for the applicant and allow for a more straightforward response. This also consolidates information that was required to be included in subsequent questions/tables. All information would have been included previously.	No substantive change or burden	
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