NTAP Crosswalk-FY 2025 Program

Application Section	Application Language	Modifications	Burden	Revised Application Language
Application Setup	***Let's set up your NTAP application*** You will not be able to alter or change these selections in the application Which of the following describes the new technology for which you are applying for NTAP? • Medical Device or Service • Drug Select which NTAP pathway you are applying under. For additional information on the alternative pathways for transformative new devices and certain antimicrobial products, please refer to the *NTAP Criteria and Pathways* information above. • Alternative (QIDP/LPAD) or (Breakthrough Device) • Traditional	The question regarding drugs/devices will be removed, as we are moving from 4 application types (alternative drugs, alternative devices, traditional drugs, traditional devices) to just 1 for each pathway (traditional app, alternative app). The detail regarding type of Alternative application will also be removed for the same reason.	No change	***Let's set up your NTAP application*** You will not be able to change these selections in the application Select which NTAP pathway you are applying under. For additional information on the alternative pathways for transformative new devices and certain antimicrobial products, please refer to the *NTAP Criteria and Pathways* information above. • **Alternative** • **Traditional**

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Disclaimer	**<u>Disclaimer</u>** All content submitted as part of this application may be made public unless otherwise noted below. Please see the FY 2023 IPPS final rule (87 FR 48986-48990) for a discussion of the policy to publicly post NTAP applications. Information that should not be made public is not taken into consideration when determining whether a technology meets the NTAP criteria. Throughout this application, "made public" refers to either posting application materials publicly or including information from an application in our discussion in the Federal Register. If you would like to include information that should not be made public as part of your application, please refer to the "Additional Application Information - CONFIDENTIAL" section on the summary page at the end of the application. We also note that we will not make public any contact information or dates included in the "FDA Info" section related to FDA applications that are not yet approved or cleared, as indicated in the application. Please note that the following application sections are not included in the public application posting. However, some of the information submitted within the following sections may still be included in the proposed or final rules, as indicated: *Cost* • For traditional pathway applications, information in this section may be included in the proposed rule and final rules. However, the cost of the technology will only be included in the final rule (for technologies approved for NTAP). • For alternative pathway applications, information in this section may be included in the proposed and final rules. The cost of the technology will be included in the proposed and final rules. *Charge (Cost Analysis)* • The information in this section may be included in the proposed and final rules. Please note that the numerical value of any charges in this section will not be made public, with the exception of column S (Final Inflated Case Weighted Standardized Charge Per Case). *Volume* • The information in this section will only be included in the final rule (for technologies approved for NTAP). Please note that any data provided in this application may become subject to disclosure where required by law. Where CMS has indicated that information won't be made public, CMS will attempt, to the extent allowed by law, to keep that information protected from public view. Please also note that application tracking forms will be posted on the CMS website shortly after the application deadline. Please refer to the *NTAP Tracking Form Info* above for additional information. ☐ I certify that I have been duly authorized to submit this application on behalf of the applicant. I acknowledge and agree that I have read the Disclaimer and understand that all of the information in this application may be made public, unless otherwise noted or included in the "Additional Application Information - CONFIDENTIAL" section.	Minor text changes: The volume bullet was moved up to reflect the revised section order of the application, and the 'Charge (Cost Analysis)' header was revised to 'Cost Criterion' to match the new stepper name and bullet added for accuracy.	No change	**<u>Disclaimer</u>** All content submitted as part of this application may be made public unless otherwise noted below. Please see the FY 2023 IPPS final rule (87 FR 48986-48990) for a discussion of the policy to publicly post NTAP applications. Information that should not be made public is not taken into consideration when determining whether a technology meets the NTAP criteria. Throughout this application, "made public" refers to either posting application materials publicly or including information from an application in our discussion in the Federal Register. If you would like to include information that should not be made public as part of your application, please refer to the "Additional Application Information - CONFIDENTIAL" section on the summary page at the end of the application. We also note that we will not make public any contact information or dates included in the "FDA Info" section related to FDA applications that are not yet approved or cleared, as indicated in the application. Please note that the following application sections are not included in the public application posting. However, some of the information submitted within the following sections may still be included in the proposed or final rules, as indicated: *Cost* • For traditional pathway applications, information in this section may be included in the proposed rule and final rules. However, the cost of the technology will only be included in the final rule (for technologies approved for NTAP). • For alternative pathway applications, information in this section may be included in the proposed and final rules. The cost of the technology will be included in the proposed and final rules. *Volume* • The information in this section will only be included in the final rule (for technologies approved for NTAP). *Cost Criterion* • The NTAP Cost Criterion Codes and MS-DRGs worksheet will be publicly posted. • Other information in this section may be included in the proposed and final rules. Please note that the numerical value of any charges in this section will not be made public, with the exception of column S (Final Inflated Case Weighted Standardized Charge Per Case). Please note that any data provided in this application may become subject to disclosure where required by law. Where CMS has indicated that information won't be made public, CMS will attempt, to the extent allowed by law, to keep that information protected from public view. Please also note that application tracking forms will be posted on the CMS website shortly after the application deadline. Please refer to the *NTAP Tracking Form Info* above for additional information. ☐ I certify that I have been duly authorized to submit this application on behalf of the applicant. I acknowledge and agree that I have read the Disclaimer and understand that all of the information in this application may be made public, unless otherwise noted or included in the "Additional Application Information - CONFIDENTIAL" section.

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Disclaimer (only displays for traditional applications)	**Copyrighted Information:** For supporting evidence uploaded in the Substantial Clinical Improvement (SCI) section of the application, you will be asked if the applicant does not have the appropriate license or right to release each document to the public. At the end of the SCI section, you will be asked to represent and warrant that the applicant owns the copyright or otherwise has the appropriate license to make any copyrighted material releasable to the public, with the exception of those materials for which the applicant indicates otherwise. Please be sure to select the appropriate checkboxes as you go through the SCI section to provide a representation of whether the files can be included in the public posting. You will also be asked to provide citations for the materials, and CMS will post those citations publicly. Documents that cannot be publicly posted will still be considered by CMS and may be summarized in the proposed rule, and the summary information provided by the applicant will be posted publicly. ☐ I certify that I have been duly authorized by the applicant to sign this acknowledgement on behalf of the applicant. I acknowledge and agree that I have read this information regarding copyrighted information and understand that I will be required to represent and warrant that, except for studies for which I indicate otherwise, the applicant owns the copyright or otherwise has the appropriate license to make the studies included in the SCI section available to the public. I understand that CMS may post publicly any study for which I indicate that the applicant owns the copyright or otherwise has the appropriate license to make it public.	As is	No change	
Contact Information	*Info: The information in this section (A) will not be made public.* **Who is the primary contact?** • First Name • Middle Name (optional) • Last Name • US phone number • Organization • Occupation / Job Title • Extension (optional) • Email Address • Country • Mailing Address 1 • Mailing Address 2 (optional) • City • State • Zip • Relationship (selections): ○ Consultant, Manufacturer, Other (explain)	Question added to clarify that a contact from the applicant is required.	No change	*Info: The information in this section (A) will not be made public, <u>except the name of the party requesting the NTAP.</u> Please note that the MEARIS website can only be accessed by individuals who are located in the US.* <u>**Who is the party requesting the NTAP?** (e.g. manufacturer, distributor, healthcare organization/entity)</u> **<u>Provide a contact for the applicant.</u>** ***<u>Applicant Contact:</u>*** • First Name • Middle Name (optional) • Last Name • Phone number • Organization • Occupation / Job Title • Extension (optional) • Email Address • Country • Mailing Address 1 • Mailing Address 2 (optional) • City • State

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				• Zip • Applicant Type (selections): o Distributor, Manufacturer, Healthcare Organization, Other (explain) **Who is the primary contact?** *Note: this section will autopopulate if the contact is the same as the Applicant Contact* • First Name • Middle Name (optional) • Last Name • US phone number • Organization • Occupation / Job Title • Extension (optional) • Email Address • Country • Mailing Address 1 • Mailing Address 2 (optional) • City • State • Zip • Relationship (selections): o Consultant, Manufacturer, Other (explain)
Contact Information	**Who is the secondary contact?** • First Name • Middle Name (optional) • Last Name • US phone number • Organization • Occupation / Job Title • Extension (optional) • Email Address • Country • Mailing Address 1 • Mailing Address 2 (optional) • City • State • Zip • Relationship (selections): o Consultant, Manufacturer, Other (explain)	As is	No change	

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Technology Info	**General Information** a) Applicant b) Trade Name c) Generic Name d) Provide a brief description of the technology.	A note was added to clarify a name field can be left blank. Minor edit to clarify that a brief description is 1-2 sentences. The Applicant question will now autopopulate from the previously provided Applicant Contact Information.	No change	*Note: If one of the name fields do not apply or is TBD, please leave the field blank.* General Information o Applicant o Trade Name o Generic Name o Please provide a brief (1-2 sentence) description of the technology.
Technology Info	**Describe the technology in detail, using general terminology** • What is the technology? • What does the technology do? • How is the technology used? Upload relevant descriptive booklets, brochures, package inserts, or other supporting materials as needed (optional).	A note was added to clarify instructions for this section and uploader.	No change	**Describe the technology in detail, using general terminology** • What is the technology? • What does the technology do? • How is the technology used? Upload relevant descriptive booklets, brochures, package inserts, or other supporting materials as needed (optional). *Note: Please note that attachments uploaded in this section will not be included in the public posting. Please avoid referring to any attachments in the responses provided in this section. If using references, please use in-text citations rather than footnote numbering.*
Technology Info	**Additional Technology Information (Drug Flow)** • Is this a drug that can only be administered orally? (Yes/No) • What is the drug's dosage/administration information? • Has the technology ever been the subject of a recall or subject to any bulletins and/or letters issued by the FDA regarding the safety of the technology? (Yes*/No) o IF YES: Provide specific details regarding the recall, bulletins and/or letters issued by the FDA. o Please upload the recall, bulletins, or other documentation (REQUIRED IF YES IS SELECTED) **Additional Technology Information (Device Flow)** • Is there an Investigational Device Exemption (IDE) number from the FDA assigned to the technology? (Yes/No) o IF YES: IDE Number • What class is assigned to the technology? (Class I, II, III) • Has the technology ever been the subject of a recall or subject to any bulletins and/or letters issued by the FDA regarding the safety of the technology? (Yes*/No) o IF YES: Provide specific details regarding the recall, bulletins and/or letters issued by the FDA. o Please upload the recall, bulletins, or other documentation (REQUIRED IF YES IS SELECTED)	Minor revisions to existing question text to incorporate the transition from separate application flows for drugs and devices to one flow for both. All applications will now display the same questions for this section. Additional minor revisions to existing question text for accuracy and clarification.	No change	**Additional Technology Information** • Is there an Investigational Device Exemption (IDE) number from the FDA assigned to the technology? (Yes/No) o IF YES: IDE Number • If the technology is a device, what class is assigned to the technology? (Class I, II, III, unclassified, N/A) • If the technology is a drug, is this a drug that can only be administered orally? (Yes/No N/A) • If the technology is a drug, what is the drug's dosage/administration information when used in the inpatient setting? Please clearly indicate the average total dose per inpatient stay. • Has the technology ever been the subject of a recall or subject to any bulletins and/or letters issued by the FDA regarding the safety of the technology? (Yes*/No) o IF YES: Provide specific details regarding the recall, bulletins and/or letters issued by the FDA. o Please upload the recall, bulletins, or other documentation (REQUIRED IF YES IS SELECTED)

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Technology Info	**Have you completed any outpatient pass through applications for this technology? (Yes/No)** IF YES: *Additional Technology Information* **Was this application submitted using MEARIS™? (Yes/No)** **IF YES,** provide application type (Device OR Drug/Biological Pass through) ▪ Application Confirmation Number ▪ Provide Details (text box 3000 characters) **IF NO,** provide application type (Device OR Drug/Biological Pass through) ▪ Submission Date ▪ Provide Details	As is	No change	
Alternative Pathway	***(Alternative Drug flow)*** **Has the technology received a QIDP designation or approval under the LPAD pathway from FDA for the indication relevant to this application?** *Info: For additional information on the alternative pathways for transformative new devices and certain antimicrobial products, please refer to the NTAP Criteria and Pathways information above.* Choose 1: • QIDP designation (sequence 7a) • LPAD approval (sequence 7b) • Both QIDP and LPAD (sequence 7c) • Has not yet received a QIDP designation or LPAD approval (sequence 7d) Please answer the subsequent questions only for the sequence selected: **a: QIDP Designation Sequence** a) When was the technology granted the QIDP designation? Date: b) What is the QIDP designation for? *Note: The marketing authorization indication in the FDA section of this application must be the same as the QIDP/LPAD designation.* c) Upload a copy of the QIDP designation letter. **b: LPAD Approval Sequence** a) When was the technology granted the LPAD approval? Date: b) What is the LPAD indication for? *Note: The marketing authorization indication in the FDA section of this application must be the same as the QIDP/LPAD designation.* c) Upload a copy of the LPAD approval letter. **c. Both QIDP and LPAD Sequence** a) When was the technology granted the QIDP designation? Date: b) When was the technology granted the LPAD approval?	• Text from both Alternative application flows was combined to create one set of questions for all Alternative pathway applications. Questions were also simplified for the "YES" flow. 3 questions also were added; responses were previously expected to be provided within the application (under "What is the designation for"). Some applicants provided this information and others did not. Adding questions to ensure applicants provide the information to minimize follow-up.	No change	**Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? (YES/NO)** *Info: For additional information on the alternative pathways for transformative new devices and certain antimicrobial products, please refer to the NTAP Criteria and Pathways information above.* **IF YES:** **Alternative Pathway Designation** *Note: Only the marketing authorization indication in the FDA section of this application that corresponds to the Breakthrough Device/QIDP/LPAD designation is eligible for NTAP.* • Please provide details about the relevant designation/approval. Include the date received and the full Breakthrough Device/QIDP designation or approved LPAD indication on the FDA letter • Upload a copy of the Breakthrough Device/QIDP designation or LPAD approval letter. • If the indication in the FDA section of this application does not match the Breakthrough Device/QIDP/LPAD designation in the attached letter, please provide an explanation. • If the name of the technology in this application does not match the technology name in the attached letter, please provide an explanation. • If the technology was granted Breakthrough Device designation, please indicate if the device that is the subject of this application is the same device that was granted the Breakthrough Device designation: -Yes, this is the designated device (text box for optional explanation) -No, this is not the designated device (text box for required explanation) -Does not apply IF NO: **Alternative Pathway Designation** *Dates included in this response will not be made public.* Provide details regarding the Alternative Pathway designation and its status including the type (Breakthrough Device/QIDP/LPAD) and date of the designation request submission to FDA, the date of anticipated approval of the designation request, and the designation indication.

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	Date: c) What is the QIDP designation/LPAD indication for? *Note: The marketing authorization indication in the FDA section of this application must be the same as the QIDP/LPAD designation.* d) Upload a copy of the QIDP/LPAD letter. **d. Has not yet received QIDP designation or LPAD approval sequence** a) Provide additional details regarding the QIDP designation or approval under the LPAD pathway from FDA and its status. *Note: The marketing authorization indication in the FDA section of this application must be the same as the QIDP/LPAD designation.* ***(Alternative Device flow)*** **Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? (YES/NO)** *Info: For additional information on the alternative pathways for transformative new devices and certain antimicrobial products, please refer to the NTAP Criteria and Pathways information above.* IF YES: **a: Alternative Pathway Designation** a) When was the technology granted the Breakthrough Device designation? Date: b) 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.* c) Upload a copy of the Breakthrough Device designation letter. IF NO: **b. Alternative Pathway Designation** Provide details regarding the Alternative Pathway designation and its status. *Note: The marketing authorization indication in the FDA section of this application must be the same as the Breakthrough Device designation.*			*Note: Only the marketing authorization indication in the FDA section of this application that corresponds to the Breakthrough Device/QIDP/LPAD designation is eligible for NTAP*
FDA Information	**Has the technology received marketing authorization from the Food and Drug Administration (FDA) for the indication relevant to this application?** *Info: To be considered for NTAP 2024 the technology will need to receive FDA approval or clearance before 07/01/2023.* Choose 1: • Approved (sequence 7a) • Pending Approval (sequence 7b) • Have not applied yet (sequence 7c)	2 existing questions will be moved up to before the skip pattern. Responses to create skip pattern were simplified from 3 to 2 options. Dates and "No" response modified to reflect recent finalized policy. There is slightly different language for applications under the alternative pathway to reflect different dates for	No change	**FDA Status** • What is the indication for the technology for which the applicant is submitting an NTAP application? • 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) **Has the technology already received marketing authorization from the Food and Drug Administration (FDA) for the indication relevant to this application?** *Info: To be considered for NTAP for FY 2025, the technology will need to receive FDA approval or clearance before 05/01/2024.* .

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		Breakthrough Devices and QIDP/LPADs under the recently finalized policy		Choose 1: • Yes • No, but the marketing authorization request has been accepted/filed by FDA and approval/ clearance is expected before the FDA deadline (May 1, 2024) For applications under the alternative pathway, this will read: **Has the technology already received marketing authorization from the Food and Drug Administration (FDA) for the indication relevant to this application?** *Info: To be considered for NTAP for FY 2025, alternative pathway devices (Breakthrough Devices) will need to receive FDA approval or clearance before 5/1/2024. Alternative pathway drugs (QIDP/LPAD) are eligible for conditional approval if they do not receive FDA marketing authorization before 7/1/2024. Technologies conditionally approved for FY 2025 under this pathway will need to receive FDA approval or clearance before 7/1/2025 in order to receive NTAP.* Choose 1: • Yes • No, but the marketing authorization request has been accepted/filed by FDA and approval/clearance is expected before the FDA deadline (May 1, 2024 for Breakthrough Devices / July 1, 2025 for QIDP/LPAD)
D. FDA Information	**Approved Sequence** **NTAP Indication** • What is the indication for the technology for which the applicant is submitting an NTAP application? • 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) **FDA Approval/ Clearance Details** ○ ◻ **Checkbox:** "Select if this is a 510(k) FDA application" • What is the type of the FDA application? Examples: New Drug Application (NDA), Biologic License Application (BLA) • What is the date of FDA approval? • Upload FDA approval letter (required) • Summarize the supporting information contained in the FDA approval letter. **IF CHECKBOX ABOVE IS SELECTED, answer the following question.** **Please provide additional information regarding the 510(k) clearance:** • List the predicate device(s) for the technology. • Describe any differences between the devices	The questions are re-ordered and additional detail added regarding FDA application examples	No change	**Yes Sequence** • **FDA Approval/ Clearance Details** What is the type of the FDA application? Examples: Premarket Notification 510(k), De Novo Classification, Premarket Approval Application (PMA), Humanitarian Device Exemption (HDE), New Drug Application (NDA), Biologic License Application (BLA) ◻ **Checkbox:** "Select if this is a 510(k) FDA application" o What is the date of FDA approval? o Upload FDA approval letter (required) *Note: Please note that attachments uploaded in this section will not be included in the public posting. Please avoid referring to any attachments in the responses provided in this section.* o Summarize the supporting information contained in the FDA approval letter. **IF 510(k) CHECKBOX ABOVE IS SELECTED, answer the following question:** • **Please provide additional information regarding the 510(k) clearance:** o List the predicate device(s) for the technology. o Describe any differences between the devices
D. FDA Information	**Who is the FDA Contact?** *This information will not be made public.* • First Name • Middle Name (optional) • Last Name • US Phone Number • Email Address	Note added to clarify who should be listed as the FDA contact	No change	**FDA Contact** *The information provided below will not be made public.* *Please provide contact information for the FDA reviewer most knowledgeable about your application.* • First Name • Middle Name (optional) • Last Name • US Phone Number

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				• Email Address
D. FDA Information	**Was this technology available on the market immediately after FDA approval? (Yes/No)** IF NO: **Reason for the delay** • Please describe the reason for the delay in market availability. • When did the technology become available for sale, or when do you anticipate the technology becoming available?	As is	No change	
FDA Information	**Pending Approval Sequence** • **NTAP Indication** o What is the indication for the technology for which the applicant is submitting an NTAP application? o 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) • **FDA Submission Details** *Info: All of the FDA dates entered in this question (7b.b) will not be made public.* o What is the type of the FDA application? Examples: New Drug Application (NDA), Biologic License Application (BLA) What is the date of FDA submission? o Have you received an action date from FDA? **(Yes/No)** ▪ **IF YES: What is the action date from FDA?** ▪ **IF NO: What is the anticipated approval date?** o Provide additional information about your FDA application o Upload any FDA related documents (optional) • **Do you anticipate that this technology will be available on the market immediately after FDA approval? (Yes/No)** IF NO: Reason for the delay Please describe the reason for the delay in market availability and provide the anticipated release date. **Have Not Applied Yet Sequence** • **NTAP Indication** o What is the indication for the technology for which the applicant is submitting an NTAP application? o List if the technology has received any designations from FDA or if it is being considered under any particular pathways by FDA such as	The 'pending approval' and 'have not yet applied' sequences will be combined into one 'no' sequence. 'NTAP indication' questions were moved up to before the skip pattern. Some additional detail added to existing questions for clarity. Language modified to reflect recent finalized policy.	No change	**No Sequence** • **FDA Submission Details** *Info: All of the FDA dates entered in this question will not be made public.* o What is the date of FDA submission? o What is the type of the FDA application? Examples: Premarket Notification 510(k), De Novo Classification, Premarket Approval Application (PMA), Humanitarian Device Exemption (HDE), New Drug Application (NDA), Biologic License Application (BLA) □ **Checkbox:** "Select if this is a 510(k) FDA application" o What is the expected action date from FDA? (eg PDUFA date/MDUFA goal date) o Provide additional information about your FDA application. Include the review status of your application with FDA. For example, indicate whether it is accepted/filed and under review, on hold, denied, pending reapplication or submission of additional information, etc. ***Note:*** *As finalized in the FY 2024 IPPS final rule, technologies must be under active review by FDA at the time of NTAP application submission in order to be eligible for consideration. For additional information regarding this NTAP eligibility requirement, please see the regulations at § 412.87(e) and the FY 2024 IPPS final rule.* o Upload the FDA acceptance or filing letter for this submission. ***Note:*** *As finalized in the FY 2024 IPPS final rule, we are requiring the relevant acceptance letter (such as for 510k applications or De Novo Classification requests) or filing letter (such as for PMA, BLA, or NDA applications) from FDA which indicates that FDA has determined that the application is sufficiently complete to allow for substantive review by FDA.* • **Do you anticipate that this technology will be available on the market immediately after FDA approval? (Yes/No)** IF NO: **Reason for the delay** Please describe the reason for the delay in market availability and provide the anticipated release date.

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	Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review, etc. for this indication (optional) • **When do you plan to submit your FDA application?** *Info: Dates entered here will not be made public.* o Anticipated Submission date o Anticipated Approval date o Provide additional information about your FDA application o Upload any FDA related documents (optional)			
FDA Information	**Additional FDA Information** Include all types of approvals (e.g. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology received prior to submission of this application and/or is currently seeking. 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.	Existing question text reordered and slightly modified for clarity.	No change	**Additional FDA Information** Please describe any previous US approvals/clearances for this technology. Include any additional approvals (e.g. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology received prior to submission of this application and/or is currently seeking, including approvals for other indications or clearances for other versions of this technology. CMS recommends a timeline if the technology has received multiple types of approvals from the FDA.
Coding and MS-DRGs	**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 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 the New/Revised ICD-10-PCS Procedure Codes* *Requests and ICD-10 Coordination and Maintenance Committee for diagnosis code requests.*	Section name revised to describe existing questions as well as questions from a different section that were moved into this section; no other text changes	No change	**Coding and MS-DRGs** *If the technology/device utilized in the performance of a procedure/service or the administration of a drug/therapeutic agent were to receive add-on payment status approval, it would need to be distinctly identifiable by a unique code, such as ICD-10-PCS procedure code(s), with or without ICD-10-CM diagnosis codes, on the claim in order to receive the add-on payment. The ICD-10 Coordination and Maintenance (C&M) Committee is responsible for approving coding changes, developing errata, addenda, and other modifications. Requests for coding changes are submitted to the committee for discussion at either the Spring or Fall C&M meeting. If any coding changes are necessary to distinctly identify your technology by ICD-10-CM diagnosis and/or ICD-10-PCS procedure code(s), you MUST separately contact the ICD-10 C&M Committee to submit a code request. For more details, including the deadlines to submit code requests, refer to the New/Revised ICD-10-PCS Procedure Codes* *Requests and ICD-10 Coordination and Maintenance Committee for diagnosis code requests*
Coding and MS-DRGs	**Are there any diagnosis codes that may currently be used to identify the indication/proposed indication relevant to the application under the ICD-10-CM coding system? (Yes/No)** IF YES: **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: a) Provide ICD-10-CM codes and titles Explain why the diagnosis code(s) were included (and whether they are specific to the indication listed under the Breakthrough Device designation)	Question removed to avoid confusion; applicants should not be responding 'no' Note added, as current method of inserting codes and descriptors individually has been revised to a standard text box for simplification.	No change	**ICD-10-CM Diagnosis Codes** o List the ICD-10-CM diagnosis codes, with titles, that may currently be used to identify the indication/proposed indication relevant to the application under the ICD-10-CM coding system: *Note: Please use standard formatting for ICD-10-CM/PCS codes in your response. Standard formatting for ICD-10-CM/PCS codes has the descriptor following the code in parentheses, and capitalizes only the first letter of the descriptor. Example: I21.A1 (Myocardial infarction type 2)* (new textbox) Explain why these diagnosis code(s) were included (and whether they are specific to the indication listed under the Breakthrough Device/QIDP/LPAD designation.)

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Coding and MS-DRGs	**ICD-10-PCS Procedure Codes -** List the procedure codes that may currently be used to identify your technology under the ICD-10-PCS coding system. • Provide ICD-10-PCS codes and titles • Do these codes uniquely identify your technology under the ICD-10-PCS coding system? (Yes/No) Please explain. o IF NO: Have you submitted or will you be submitting an application for a unique ICD-10-PCS code?	Note added, as current method of inserting codes and descriptors individually has been revised to a standard text box for simplification.	No change	**ICD-10-PCS Procedure Codes** o List the procedure codes that may currently be used to identify your technology under the ICD-10-PCS coding system. *Note: Please use standard formatting for ICD-10-CM/PCS codes in your response. Standard formatting for ICD-10-CM/PCS codes has the descriptor following the code in parentheses, and capitalizes only the first letter of the descriptor. Example: I21.A1 (Myocardial infarction type 2)* (new textbox) o Do these codes uniquely identify your technology under the ICD-10-PCS coding system? (Yes/No) Please explain. • IF NO: Have you submitted or will you be submitting an application for a unique ICD-10-PCS code?
Coding and MS-DRGs	**Existing technologies using ICD-10-CM/ICD-10-PCS** - List existing technologies that use the same ICD-10-PCS codes or combination of the ICD-10-CM/PCS codes. **ICD-10 C&M Committee Request** o Does this technology have an existing request pending with the ICD-10 C&M Committee for a new code? (Yes/No) o 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.	As is	No change	
Coding and MS-DRGs	**(Existing application includes these questions under the 'Charge' section)** **MS-DRGs** Under the MS-DRG grouper, 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. *Note: Please refer to the latest* *version of the ICD-10 MS-DRGs list on the MS-DRG Webpage for the current list of MS-DRGs and titles.* o List MS-DRGs and titles o Comments related to the MS-DRGs listed above (optional) o Have you made a request to map to a new or different MS-DRG(s) for the upcoming Fiscal Year 2024? (Yes/No) i. IF YES, please provide details.	Questions moved up from current 'Charge' section (which is now renamed as 'Cost Criterion'section). Minor text modifications for clarity. Note added, as current method of inserting MS-DRGs and titles individually has been revised to a standard text box for simplification.	No change	**MS-DRGs** o Under the MS-DRG grouper, list all of the MS-DRGs that the technology would currently map to based on the indication (diagnosis) that is the subject of this NTAP application. *Note: Please refer to the latest version of the ICD-10 MS-DRGs list on the MS-DRG Webpage for the current list of MS-DRGs and titles.* *Note: Please use standard formatting for MS-DRGs in your response. Standard formatting for MS-DRGs has the descriptor following the MS-DRG number in parentheses, and capitalizes the first letter of each word, except for common words like "and, "with," etc. Example: 004 (Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face Mouth and Neck without Major O.R. Procedures).* [TEXT BOX] • Comments related to the MS-DRGs listed above (optional) o Have you made, or do you anticipate making, a request to map to a new or different MS-DRG(s) for the upcoming Fiscal Year 2025? (Yes/No) IF YES, please provide details.
Newness Criterion *(only displays for traditional applications)*	o 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. o Substantial Similarity Criteria *Info: To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the*	As is	No change	

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	Medicare-Severity Diagnosis Related Groups (MS-DRGs). CMS has established three substantial similarity criteria to determine if a technology is similar to an existing technology. (Refer to 70 FR 47351 through 47352 and 74 FR 43813 through 43814 for additional details.)
	
	Note: A technology can be considered "new" as long as one of the three criteria are NOT met.
	• 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?
	• 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?
	• 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?
	
	o Newness Criterion Summary: Please briefly summarize your previous responses regarding how the technology meets the newness criterion overall.
	
	o Upload files related to the newness criterion as needed (optional)			

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Cost and Volume	**Cost**	This section has been revised to incorporate the existing 'Volume' section; section title revised to describe all questions now within the section	No change	**Cost and Volume**
Cost and Volume	**Technology Cost** *(device flow)* • What is the current or anticipated cost of this technology to the hospital, per patient? *Note: The cost of the technology will be included in the proposed and final rules.* • How was the cost determined? (e.g., the number of units per patient; 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 question.* **Technology Cost** *(drug flow)* • What is the current or anticipated cost of this technology to the hospital, per patient? *Note: The cost of the technology will be included in the proposed and final rules.* • How was the cost determined? *Note: Include the average dosage and number of vials per patient (whole vials if single-use) and/or units per patient (ml/kg/hr). Please provide specific details about how that average was determined (e.g., how the drug is sold (such as x vials per box), variables in the Medicare population that effects the dosage administration (body weight, disease progression, etc.), whether and how the average is weighted based on those variables, etc.).*	Examples/notes revised to incorporate into one set of questions (as the separate drug/device flows were eliminated) Minor text revisions to existing questions for clarity. Skip pattern question added for the existing devices-only related question since the different flows were eliminated	No change	**Technology Cost** ○ What is the current or anticipated cost of this technology to the hospital per inpatient stay? *Note: The cost of the technology will be included in the proposed and final rules.* ○ How was the total cost per inpatient stay determined? Please include all relevant details and calculations to explain how the cost was determined. *Note: **For devices,** include the cost per unit and the average number of units per inpatient stay or for technologies sold on a subscription basis, an explanation of how the cost per case is calculated, including the list price of the technology and utilization across subscribers. **For drugs,** include the cost per unit/vial as well as the average dosage and number of vials per inpatient stay (whole vials if single-use) and/or units per patient (ml/kg/hr). Please provide specific details about how that average was determined (e.g., how the drug is sold (such as x vials per box), variables in the Medicare population that effects the dosage administration (body weight, disease progression, etc.), whether and how the average is weighted based on those variables, etc.).* • Indicate if this is a device: Yes/No *If this is a device, you will be asked to provide a breakdown of the cost of each component in the next question.* ○ Upload files or materials that support the cost of the technology and how it was calculated (optional)

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	• Upload files or materials that support the cost of the technology and how it was calculated (optional)			
Cost and Volume	**Cost Breakdown** *(for devices)* *Info: Include a breakdown of the cost of all of the components used per patient, clearly showing which components are the "new" ones.* a) Provide a breakdown of how the cost of the technology is calculated and identify if any components are capital costs. For each component, include the following: • Name of Component • Type of Cost (capital vs operating) • Component Cost • Is this component new? (Yes/No) ○ Upload files or materials that support the cost of the technology and how it was calculated (optional)	Minor text revisions for clarification	No change	IF YES: **Cost Breakdown** *(for devices)* *Info: Include a breakdown of the cost of the device components used in the per inpatient stay calculation (ie, relevant to the NTAP payment amount), clearly showing which components are the "new" ones.* ***Note:** Capital costs are not included in new technology add-on payments under the IPPS. (Refer to 72 FR 47307-47308 for further details.)* ○ Provide a breakdown of how the cost of the technology is calculated and identify if any components are capital costs. For each component, include the following: • Name of Component • Type of Cost (capital vs operating) • Component Cost • Is this component new? (Yes/No) ○ You may provide comments regarding the cost breakdown here (optional)

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Cost and Volume	**(Existing application includes these questions under its own 'Volume' section)** **Volume of Cases** *Info: The information in this section (H) will not be included in the public posting but will be included in the final rule (for technologies approved for NTAP).* *Note: The volume estimates should be based on the actual or projected sales of your technology, not the total population eligible for the technology.* *Current Fiscal Year: (10/01/2022 - 09/30/2023) Upcoming Fiscal Year: (10/01/2023 - 09/30/2024)* • **What is the anticipated inpatient Medicare volume of this technology for the current and upcoming Fiscal Year?** a) Current Fiscal Year Anticipated Inpatient Medicare Volume ○ Please describe how you arrived at this estimate. b) Upcoming Fiscal Year Anticipated Inpatient Medicare Volume ○ Please describe how you arrived at this estimate. • **What is the anticipated inpatient non-Medicare volume of this technology for the current and upcoming Fiscal Year?** a) Current Fiscal Year Anticipated Inpatient Non-Medicare Volume ○ Please describe how you arrived at this estimate. b) Upcoming Fiscal Year Anticipated Inpatient Non-Medicare Volume	Existing questions moved out of the 'Volume' section to be included within the revised 'Cost and Volume' section. No modifications to the text except updated dates.	No change	**Volume** *Info: The information in this section will not be included in the public posting but will be included in the final rule (for technologies approved for NTAP).* *Note: The volume estimates should be based on the actual or projected sales of your technology, not the total population eligible for the technology.* *Current Fiscal Year: (10/01/2023 - 09/30/2024) Upcoming Fiscal Year: (10/01/2024 - 09/30/2025)* • **What is the anticipated inpatient Medicare volume of this technology for the current and upcoming Fiscal Year?** ○ Current Fiscal Year Anticipated Inpatient Medicare Volume ○ Please describe how you arrived at this estimate. ○ Upcoming Fiscal Year Anticipated Inpatient Medicare Volume ○ Please describe how you arrived at this estimate. • **What is the anticipated inpatient non-Medicare volume of this technology for the current and upcoming Fiscal Year?** ○ Current Fiscal Year Anticipated Inpatient Non-Medicare Volume ○ Please describe how you arrived at this estimate. ○ Upcoming Fiscal Year Anticipated Inpatient Non-Medicare Volume
Cost Criterion	**Charge** *Info: The information in this section (G) will not be included in the public posting but may be included in the proposed and final rules. Please note that the numerical value of any charges in this section will not be made public, with the exception of column S (Final Inflated Case Weighted Standardized Charge Per Case).* **MS-DRGs** Under the MS-DRG grouper, 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. *Note: Please refer to the latest version of the ICD-10 MS-DRGs list on the MS-DRG Webpage for the current list of MS-DRGs and titles.* a) List MS-DRGs and titles b) Comments related to the MS-DRGs listed above (optional) c) Have you made a request to map to a new or different MS-DRG(s) for the upcoming Fiscal Year 2024? (Yes/No) ii. IF YES, please provide details.	Section renamed 'Cost Criterion' MS-DRG questions moved up to another section ('Coding and MS-DRGs)	No change	**Cost Criterion** *Info: Information in this section (G) will not be included in the public posting, except for the NTAP Cost Criterion Codes and MS-DRGs worksheet. The information in this section may be included in the proposed and final rules. Please note that the numerical value of any charges in this section will not be made public, with the exception of column S (Final Inflated Case Weighted Standardized Charge Per Case).*

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Cost Criterion	**Cost Criterion** Click here for guidance about the cost criterion. Download Appendix A for an explanation of how to standardize charges per case if multiple MS-DRGs are affected by the technology. • Step 1: Download FY2024 New_Technology Cost Spreadsheet Example.xlsx *(available for download on the CMS webpage).* Using the table as demonstrated in the spreadsheet as a template, show how the standardized charge per case (if applicable, case weighted) exceeds the threshold for the cost criterion. In compliance with the CMS data use agreement, case volumes for MS-DRGs listed in the table must have a minimum value of 11; applicants should impute a value of 11 for those cells with a lower value. Please be sure the formulas are retained in the cells, when using the spreadsheet. You may add additional tabs for additional analyses or to provide supporting data. • Step 2: Upload the Completed Cost Analysis Spreadsheet. • Step 3: Does the final inflated average case-weighted standardized charge per case exceed the average case-weighted (if applicable) threshold for the cost criterion? (Yes/No) o Comments (optional)	Some text removed (and incorporated into a later question)	No change	**Cost Analysis** Click here for guidance about the cost criterion. *Download Appendix A for an explanation of how to standardize charges per case if multiple MS-DRGs are affected by the technology.* • Step 1: Download FY2025 NTAP Cost Analysis spreadsheet.xlsx Using the table as demonstrated in the spreadsheet as a template, show how the standardized charge per case (if applicable, case weighted) exceeds the threshold for the cost criterion. Please be sure the formulas are retained in the cells, when using the spreadsheet. You may add additional tabs for additional analyses or to provide supporting data. • Step 2: Upload the Completed Cost Analysis Spreadsheet. • Step 3: Does the final inflated average case-weighted standardized charge per case exceed the average case-weighted (if applicable) threshold for the cost criterion? (Yes/No) o Comments (optional)
Cost Criterion	**With regard to the cost analysis spreadsheet, please upload summary/aggregate data used to calculate charges and standardized charges per case involving the new technology.** You may include lists of ICD-10-PCS/CM codes (for identifying cases), and/or other data that was used in the development of the cost analysis spreadsheet**.** **In the box below, please list and briefly describe each upload, including information about the source and time periods of the data, any decision points in what data was used, and other relevant information.**	Questions and uploader reworked to separate the existing text into separate distinct questions for improved understanding. No new information is being requested.	No change	**Cost Analysis Methodology** o With regard to the cost analysis spreadsheet, please detail the ICD-10-PCS/CM codes and MS-DRGs used to identify cases in your cost analysis/analyses. • Step 1: Download the NTAP Cost Criterion Codes and MS-DRGs spreadsheet and complete the tables as demonstrated in the spreadsheet. • Step 2: Upload the completed "NTAP Cost Criterion Codes and MS-DRGs" spreadsheet. *This spreadsheet will be included in the public application posting, and information from this spreadsheet may be included in the proposed and final rules.* • Comments (optional) o Please provide the type of source data and year that was used to identify cases (such as "FY 2022 MedPAR" or "100% sample FY 2022 SAF"). If you did not use the most recently available claims data or if you used other types of source data, please also explain why. *Note: The most recent claims data for the upcoming application year would be 3 years prior (for example, for FY 2025 applications, the most recent claims data would be from FY 2022).*
Cost Criterion	**Cost Analysis Methodology** **For columns A to S of the cost analysis spreadsheet, as represented in the following questions A-S, list a step by step explanation for how the data and calculations were determined.** *Info: 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.*	Text revised to improve understanding of the question, info note removed	No change	**Cost Analysis Methodology** Use the following questions **A through S** (which correspond to columns A through S of the cost analysis spreadsheet) to explain in detail how each column was completed, step-by-step.
Cost Criterion	A. MS-DRG *Note: If you have not included cases in DRGs that CMS might expect to see cases*	Notes and examples added throughout this section to	No change	A. MS-DRG Explain how these MS-DRGs were determined, including any differences between multiple analyses if

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	present for your technology, please address this in detail (e.g., a CAR-T charge analysis that doesn't include cases from DRG-018). B. Cases *Note: Please discuss relevant decision points in choosing to include/exclude ICD-10-PCS/CM codes (for identifying cases).* C. Case Weighted Amount D. Threshold E. Case Weighted Threshold F. Average Charge Per Case (Unstandardized with No Case Weight) G. Average Charge Per Case (Unstandardized with Case Weight) H. Charges Removed for the Prior Technology or Technology Being Replaced *Note: Please discuss the assumptions behind removing (or not removing) charges for prior technologies.* I. Related Charges Removed for the Prior Technology or Technology Being Replaced J. Adjusted Average Charge Per Case (Unstandardized with No Case Weight) K. Adjusted Average Charge Per Case (Unstandardized with Case Weight) L. Average Standardized Charge Per Case *Note: Please include provider-specific factors used to standardize charges* M. Average Standardized Charge Per Case with Case Weight N. Inflation Factor O. Inflated Average Standardized Charges Per Case P. Charges Added for the New Technology Q. Related Charges Added for the New Technology R. Final Average Inflated Standardized Charge Per Case S. Final Inflated Case Weighted Standardized Charge Per Case	clarify the expected information to be provided, no new information is being requested		applicable. Please also discuss relevant decision points in choosing to include/exclude ICD-10-PCS/CM codes for identifying cases. If there are any other inclusion/exclusion criteria please describe them here as well. B. Cases *Note: In compliance with the CMS data use agreement, the aggregate amount of cases listed for each MS-DRG in the table must indicate a minimum of 11; applicants should impute a value of 11 for any MS-DRG included with a number under 11.* C. Case Weighted Amount D. Threshold *Note: Please confirm the thresholds used were from the prior year's final rule/correction notice. For example: for FY 2025 applications, the thresholds from the FY 2024 final rule (or correction notice, if applicable) should be used.* E. Case Weighted Threshold F. Average Charge Per Case (Unstandardized with No Case Weight) G. Average Charge Per Case (Unstandardized with Case Weight) H. Charges Removed for the Prior Technology or Technology Being Replaced *Note: Please also discuss the assumptions behind removing (or not removing) charges for prior technologies. For example, if a technology is replacing the implantation of a different device, explain how the removal of charges for the previous device was determined; do not remove related charges such as operating room (OR) and/or intensive care unit (ICU) charges in this column.* I. Related Charges Removed for the Prior Technology or Technology Being Replaced *Note: Please also discuss the assumptions behind removing (or not removing) related charges for prior technologies. For example, if the technology is replacing the implantation of a different device and requires less or more OR time and ICU days, explain how the removal of related charges such as OR/ICU charges were determined.* J. Adjusted Average Charge Per Case (Unstandardized with No Case Weight) K. Adjusted Average Charge Per Case (Unstandardized with Case Weight) L. Average Standardized Charge Per Case *Note: Please include sources for provider-specific factors used to standardize charges (for example, use of the FY 2022 final rule/correction notice impact file).* M. Average Standardized Charge Per Case with Case Weight N. Inflation Factor *Note: The inflation factor should be aligned with the year of claims data used, and the year for which the applicant is applying for NTAP. For example, when using FY 2022 MedPAR data and applying for FY 2025 NTAP, a three-year inflation factor would be appropriate.* O. Inflated Average Standardized Charges Per Case P. Charges Added for the New Technology Please explain how the current and/or anticipated charges for the technology by the hospital, per patient, were determined. Please confirm that the most recent national cost center CCRs (listed in the cost analysis spreadsheet) were used to convert cost to charges, if applicable. *Note: The charges here should be only based on direct costs of the drug/device itself, and not related costs such as OR/ICU charges.* Q. Related Charges Added for the New Technology *Note: The charges here should be only based on indirect costs related to use of the drug/device, such as OR/ICU charges. Please also discuss the assumptions behind adding (or not adding) related charges for the new technology.*

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				R. Final Average Inflated Standardized Charge Per Case S. Final Inflated Case Weighted Standardized Charge Per Case
Cost Criterion	**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.	Redundant question removed	No change	**N/A**
Substantial Clinical Improvement *(displays only for traditional applications)*	*Info: A summary on the substantial clinical improvement (SCI) criterion can be found in Appendix B. Additional information on the SCI criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14), the FY 2010 IPPS Final Rule (74 FR 43808-43823) and the FY 2020 IPPS Final Rule (84 FR 42288-42292) . Additionally, the annual IPPS final rule includes CMS' decision-making processes for each application.* ***Overview of the SCI Criterion*** *CMS uses the following criteria in its evaluation of SCI for the purposes of the NTAP:* *1. The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.* *2. The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that the use of the new medical service or technology to make a diagnosis affects the management of the patient.* *3. The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available.* *A technology must demonstrate that it meets at least one of these three SCI criteria in order to be eligible for NTAP.* ***Overview of the SCI Section*** *As you navigate through the Substantial Clinical Improvement section, you will be asked which of these 3 criteria the technology meets. For each criterion you assert that the technology meets, you will be asked to explain why you believe the technology meets that criterion, using supporting data as applicable. Each reason the technology meets a particular criterion will need to be added as a separate claim.* • *You will be able to enter one or more claims (i.e., reasons) for each criterion that you assert that the technology meets.* • *Each claim for a criterion must be added individually.* • *If you have evidence to support a claim, you will be able to provide one or more pieces of supporting evidence for each claim.* • *For each piece of evidence uploaded, you will be asked to describe the upload and summarize details related to the upload, such as the reason for inclusion/relevance to the claim, citation, summary of the data source, and results from the study that support the claim.*	Minor text revisions for accuracy and clarity	No change	*Info: A summary on the substantial clinical improvement (SCI) criterion can be found in Appendix B. Additional information on the SCI criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14), the FY 2010 IPPS Final Rule (74 FR 43808-43823) and the FY 2020 IPPS Final Rule (84 FR 42288-42292) . Additionally, the annual IPPS final rule includes CMS' decision-making processes for each application.* ***Overview of the SCI Criterion*** *CMS uses the following in its evaluation of SCI for the purposes of the NTAP:* *1. The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.* *2. The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that the use of the new medical service or technology to make a diagnosis affects the management of the patient.* *3. The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available.* *A technology must demonstrate that it meets at least one of these three in order to be eligible for NTAP.* ***Overview of the SCI Section*** *As you navigate through the Substantial Clinical Improvement section, you will be asked how the technology meets the SCI criterion. For each assertion made, you will be asked to explain why you believe the technology meets the SCI criterion. Each reason the technology meets the SCI criterion will need to be added as a separate claim, using supporting data as applicable.* • *You will be able to enter one or more claims (i.e., reasons) for each assertion made.* • *Each claim for an assertion must be added individually.* • *If you have evidence to support a claim, you will be able to provide one or more pieces of supporting evidence for each claim.* • *For each piece of evidence uploaded, you will be asked to describe the upload and summarize details related to the upload, such as the reason for inclusion/relevance to the claim, citation, summary of the data source, and results from the study that support the claim.* • *CMS may include attachments provided in this section as part of the public application posting. If any attachments are uploaded that cannot be made public due to copyright restrictions or other reasons, you must indicate that by selecting the checkbox under the upload.* *Once you provide responses for each of the SCI Criterion questions (including supporting evidence if applicable), you will be asked to provide a brief summary of these responses to explain overall why you believe the technology demonstrates a substantial clinical improvement over existing technologies.*

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	• *CMS may include attachments provided in this section as part of the public application posting. If any attachments are uploaded that cannot be made public due to copyright restrictions or other reasons, you must indicate that by selecting the checkbox under the upload.* • *Once you provide responses for each of the SCI criteria questions (including supporting evidence if applicable), you will be asked to provide a brief summary of these responses to explain overall why you believe the technology demonstrates a substantial clinical improvement over existing technologies.*			
Substantial Clinical Improvement *(displays only for traditional applications)*	**Substantial Clinical Improvement 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? (Y/N) IF YES: a) Please provide a reason this technology meets this criterion using supporting data. Add each reason for meeting this criterion as a separate claim. i. Add claim – title of claim (add as many claims as desired) ii. Provide a full explanation as to why this technology meets Criterion 1	Minor text revisions for accuracy	No change	○ **Does the new medical service or technology offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments? (Y/N)** IF YES: Please provide an explanation for this assertion using supporting data. Add each reason as a separate claim. (i) Add Claim - Claim Title (ii) Please provide a full explanation
Substantial Clinical Improvement *(displays only for traditional applications)*	iii. Add Supporting Evidence, if applicable. (Add as many as desired for each claim) Upload file and answer the following questions related to each upload: ○ Title of the supporting evidence ○ Data Source category (choose one) ▪ Published, peer, reviewed studies using technology ▪ Unpublished studies, abstracts, or presentations using technology ▪ Other data submissions using technology ▪ Data submissions as backgrounds (does not directly assess the technology) ○ Evidence Type (eg meta-analysis, case report, RCT) ○ Uploaded File ▪ □ The applicant **does not** have the appropriate license or right to release this document to the public. If this box is checked, this document will not be included in the public posting. ▪ Page Number(s) ▪ Citation ▪ Reason for inclusion/relevance to the claim ▪ Study summary: *Please clearly summarize the study in full, to include (at minimum) the purpose of the study, number of patients treated, study arms, demographics, inclusion/exclusion criteria, endpoints tested, and outcomes (specify if statistically significant).* ▪ Results from the study that support this claim: Please provide the specific statistic(s)/outcome(s) from the study and the page/paragraph within the study where it can be found.	Existing questions reordered and minor text revisions for clarification; no new information is being requested	No change	(iii) Add Claim - Claim Title (iv) Please provide a full explanation (v) Add Supporting Evidence, if applicable ○ Select an existing file or upload a new one ○ Upload file and answer the following questions related to each upload: • □ The applicant **does not** have the appropriate license or right to release this document to the public. If this box is checked, this document will not be included in the public posting. • Title of the supporting evidence • Data Source category (choose one) ○ Published, peer, reviewed studies using technology ○ Unpublished studies, abstracts, or presentations using technology ○ Other data submissions using technology ○ Data submissions as background (does not directly assess the technology) • Evidence Type (choose one) ○ Case-control Study ○ Case Reports and Case Series ○ Cohort Study ○ Cross-sectional Study ○ Meta-Analysis ○ Randomized Controlled Trial ○ Systematic Review ○ Other • Citation • Study summary: *Please clearly summarize the study in full, to include (at minimum) the purpose of the study, number of patients treated, study arms, demographics, inclusion/exclusion criteria, endpoints tested, and outcomes (specify if statistically significant).* ○ Please explain why this uploaded file was provided in support of this claim • Reason for inclusion/relevance to claim • What are the results/outcomes from this study that support this claim? Please be sure to provide the specific statistic(s)/value(s) in your response.

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				Provide the location of these results/outcomes (i.e. page number(s), paragraph, table number, etc., as applicable.)
Substantial Clinical Improvement *(displays only for traditional applications)*	**Substantial Clinical Improvement 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?	Text added for accuracy to mirror the regulations	No change	Does the new medical service or technology offer the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods? There must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient.
Substantial Clinical Improvement *(displays only for traditional applications)*	**Substantial Clinical Improvement Criterion 3:** Does the use of the new medical service or technology significantly improve clinical outcomes relative to services or technologies previously available?	As is	No change	
Substantial Clinical Improvement *(displays only for traditional applications)*	**SCI Criterion Summary and Attestation** Please briefly summarize your responses to the previous slide regarding how the technology meets the substantial clinical improvement criterion overall. **□ I represent and warrant, on behalf of the applicant, that except for those documents for which I indicated otherwise, the applicant owns the copyright or otherwise has the appropriate license to make available all of the documents uploaded in this section to the public. I certify that I have been duly authorized to submit this representation on behalf of the applicant.**	Minor clarifying edit to change "the previous slide" to "this section"	No change	**SCI Criterion Summary and Attestation** Please briefly summarize your responses to this section regarding how the technology meets the substantial clinical improvement criterion overall. **□ I represent and warrant, on behalf of the applicant, that except for those documents for which I indicated otherwise, the applicant owns the copyright or otherwise has the appropriate license to make available all of the documents uploaded in this section to the public. I certify that I have been duly authorized to submit this representation on behalf of the applicant.**
Summary	*Info: If there is any information that you wish to provide with your application that should not be posted publicly, it must only be added in the "Additional Application Information - CONFIDENTIAL" section below. Please note that we generally do not consider any information that cannot be made public when determining whether a technology meets the NTAP criteria.* **Additional Application Information – CONFIDENTIAL** Do you have any information that you wish to provide as part of your application that should not be made public? Please note that the information in this section will not be considered when determining whether a technology meets the NTAP criteria and will not be made public. (Y/N) IF YES: a) Select section and corresponding information below (add more than one if desired): (CHOOSE RELEVANT APPLICATION SECTIONS b) Confidential information about this section: *Note: Data provided in this section may become subject to disclosure where required by law. CMS will attempt, to the extent allowed by law, to keep this information protected from public view.*	As is	No change	

Application Section	Application Language	Modifications	Burden	Revised Application Language
	c) Upload any relevant files (optional)			