New Tech APC Crosswalk

Paper Application Question #	Paper Application Language	Modifications	Web Application Content	Comments
1.	The name by which the service is most commonly known. Page 5	As Is	Provide information about the service. Service Name (Text field)	
2.	A clinical vignette, including patient diagnoses that the service is intended to treat, the typical patient, and a description of what resources are used to furnish the service by both the facility and the physician. For example, for a surgical procedure this would include staff, operating room, and recovery room services, as well as equipment, supplies, and devices, etc. Page 5	As Is	Provide information about the service. 1) What diagnoses does the service intend to treat? (Text area, max character limit: 2000) 2) What are the resources used to furnish the service by both the facility and the physician? (Text area, max character limit: 2000)	This question is broken down into different fields for the applicant to describe the diagnoses and the resources separately.

3.	A list of any drugs or devices used as part of the service that require approval from the Food and Drug Administration (FDA) and information to document receipt of FDA approval/clearances and the date obtained, including a copy of the FDA approval or clearance letter. NOTE: Applicants are advised not to apply for a New Technology APC assignment until any required FDA approvals or clearances are received. An application is not complete without the required FDA information.
	Page 5
		As Is	Are there any drugs or devices used as part of the service that require approval from the Food and Drug Administration (FDA)? Yes/No
			If yes: List your devices and/or drugs that require FDA approval
			List of items used as part of the service:
			1) Item name (Text field)
			2) Select your most recent FDA Marketing Pathway (dropdown)
			  a) Premarket Notification 510 (k)
			  b) Premarket Approval (PMA)
			  c) De Novo Classification Request
			  d) HD Exemption
			  e) FDA Exemption
			  f) Other
			3) Enter the FDA decision date (date picker)
			4) Attach the FDA decision letter	

4.	A description of where the service is currently being performed (by location) and the approximate number of patients receiving the service in each location. Page: 5	As Is	Provide information about the service. Where is the service performed (by location) and how many patients receive the service in each location? (Text area, max character limit: 2000)	
5.	An estimate of the number of physicians who are furnishing the service nationally and the specialties they represent. Page: 5	As Is	Provide information about the service. How many physicians provide this service nationally and what are their specialties? (Text area, max character limit: 2000)	
6.	Information about the clinical use and efficacy of the service, such as peer-reviewed articles. Page: 5	As Is	CARIS does not have a field or screen specifically requesting this document. Peer reviewed articles are noted in the list of items to include on the Attachments page at the end of the application.	See Attachments field at the end of the crosswalk.

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7.	The CPT or HCPCS Level II code(s) that are currently being used to report the service and an explanation of why use of these HCPCS codes is inadequate to report the service under the OPPS Page: 5	As Is	List the Healthcare Common Procedure Coding System (HCPCS) code(s) and title(s) that are currently being used to report the service. • Enter HCPCS codes & titles (Text fields) • Why are the use of these HCPCS codes inadequate to report the service under the OPPS? (Text area, max character limit:2000)	
8.	A list of the CPT or HCPCS Level II codes for all items and procedures that are an integral part of the service. This list should include codes for all procedures and services that, if coded in addition to the code for the service under consideration for new technology status, would represent unbundling. Page: 5	As Is	List the CPT or HCPCS Level II codes for all items and procedures that are an integral part of the service. • Item / Procedure (Text field) • Enter CPT or HCPCS codes and titles (Text fields)	
9.	A list of all CPT and HCPCS Level II codes that would typically be reported in addition to the service Page: 5	As Is	List all CPT and HCPCS Level II codes that would typically be reported in addition to the service. • Enter CPT or HCPCS codes and titles:	
10.	A proposal for a new HCPCS code, including a descriptor and rationale for why the descriptor is appropriate. The proposal should include the reason why the service does not have a CPT or HCPCS Level II code, and why the CPT or HCPCS Level II code or codes currently used to describe the service are inadequate. Page: 5	As Is	What do you propose for a new HCPCS code, including a descriptor and rationale for why the descriptor is appropriate? Enter proposed code(s) and descriptor (Text fields) What is your rationale for the above? (Text area, max character limit: 2000)	
11.	An itemized list of the costs incurred by a hospital to furnish the new technology service, including labor, equipment, supplies, overhead, etc. Page: 5	As Is	List itemized costs incurred by a hospital to furnish the new service Enter cost details below and click to add them to the list Item (Text field) Cost (numeric entry)	

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12.	Name(s), address(es), e-mail addresses and telephone number(s) of the party or parties making the request and responsible for the information contained in the application. If different from the requester, give the name, address, e-mail address, and telephone number of the person that CMS should contact for any additional information that may be needed to evaluate the application.
	Page: 6
		As Is	Who is the primary contact? & Who is the secondary contact?
			1) First name (Text field)
			2) Middle Name (optional) (Text field)
			3) Last name (Text field)
			4) Phone number (Text field)
			5) Email address (Text field)
			6) Mailing Address line1 (Text field)
			7) Mailing address line2 (optional) (Text field)
			8) City (Text field)
			9) State (dropdown)
			10) Zip code (Text field)
			11) Organization (Text field)
			12) Relationship (dropdown)
			    a) Consultant
			    b) Manufacturer
			    c) Other
			       i) If other: Describe "other" (Text field)	

13.	Other information as CMS may require to evaluate specific requests or that the applicant believes CMS may need to evaluate the application.	Minor modification	List all referencing files and documents 1) Provide some details about the selected file 2) Page number(s) (Text field) Summarize the supporting information contained in this file (Text area, max character limit: 500) Note: Click to view important files and documents to include (opens in a pop up window) Items to Include Informative Materials • Booklets, pamphlets, and brochures • Peer Reviewed Articles • Clinical Vignettes • Case Studies FDA Documentation • FDA decision letter • FDA clearance letter Cost Documentation • Itemized cost lists • Manufacturing invoices • Pricing guides	Leveraging capability to add reference documents as attachments in addition to entered data
	This item is not included in the paper application.	**New in MEARIS**	Describe the service. (Text area, max character limit: 2000)	

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	This item is not included in the paper application.	**New in MEARIS**	Have you applied for a Healthcare Common Procedure Coding System (HCPCS) code? Yes/No If yes: What are the details of your HCPCS application? • Submission date (date picker) • What is the status (optional) (Radio button) ○ Approved ○ Pending	
	This item is not included in the paper application.	**New in MEARIS**	Have you completed other CARIS applications for this technology? Yes/No If yes: Please provide information about your previous applications Enter an application details below and click to add them to the list Application Type (dropdown list, options as follows) • NTAP • New & Revised Medicare Severity Diagnosis Related Groups • Device PTP • Drug PTP • WIA • New Tech APC • GME • HCPCS • HOP Nomination • HOP Presentations Application status (optional): • Approved • Pending • Denied • Withdrawn Description Submission Date (optional) (calendar picker)	