High Level Device PTP Crosswalk

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DeviceCategoryPTP_Application (006).pdf

Previous documentation on application fields and content - Screen and Workflow Tracker - Device PTP

Question #	Paper Application Language (Exact copied text from application, page number from the paper application)	Modification	Web Application Content (Title of page in MEARIS, specific question language, any/all options from dropdowns or check boxes, field type)	Comments
A.	Proposed name or description for the additional category. Page 5	Minor	What is the name or description and additional details of the proposed device category? • Category name/ description • Ambulatory Payment classification (APC)assignment (optional)	Additional question added: Ambulatory Payment classification (APC)assignment(optional)

B.	Trade/brand names of any known devices fitting the proposed additional category. (Applications must include the name and description of at least one marketed medical device, or device with a Category B investigational device exemption, that would be placed in the proposed additional category.)
	Page 5
		Minor	Provide information about a device nominated to fit the proposed additional category.
			• Device Trade/ Brand Name (Text field)
			• Device type (dropdown)
			  • Implantable Device
			  • Implantable Biological
			  • Device and Drug/Biological Combination
			  • Skin Substitute
			  • Other Device	

C.	A list of all established device categories used presently or previously for pass-through payment that describe related or similar products. For each established device category, provide a detailed explanation as to why that category does not encompass the nominated device(s). Page 5	As Is	Are there any established device categories used presently or previously for pass-through payment that describe related or similar products? Yes/No If yes: Describe the established device category(s) and provide a detailed explanation as to why that category does not encompass the nominated device. (Text area, Maximum character limit: 2000)	
D.	Detailed description of the clinical use(s) of each nominated device requiring an additional category. Describe each nominated device fully: Page 5	Dropped		This text is not displayed in the application MEARIS requires a single application for each device. A user cannot list multiple devices on one form. The questions for D1 through D9 are broken out separately and listed in a different order in MEARIS.
D1.	What is it? Provide a complete physical description of the device including its components, e.g., hardware, software, reservoir, tubing, its composition, coating, or covering. Page 5	Minor	Provide information about a device nominated to fit the proposed additional category. • What is the device? what does it do? what is it used for? and how is it used? (Text area, Maximum character limit: 2000) • Provide a complete physical description of the device including its components, e.g., hardware, software, reservoir, tubing, its composition, coating, or covering. (Text area, Maximum character limit: 2000)	D1, D2, and D3 are combined into one single question. Physical description part of D1 is separated in another question.
D2.	What does it do? Page 5	Dropped	See D1	D1, D2, and D3 are combined into one single question.
D3.	How is it used? Page 5	Dropped	See D1	D1, D2, and D3 are combined into one single question.

D5.	What are its clinical characteristics, e.g., is it used for diagnosis or treatment, what is its life span, what are the complications associated with its use, for what disease processes and patient populations is it used?
	Page 5
		Minor	Provide information about a device nominated to fit the proposed additional category.
			1. Is the device used for diagnosis or treatment? (Radio button)
			  • Diagnosis
			  • Treatment
			  • Both
			2. For what disease processes and patient populations is the device used? (Text area, max character limit: 2000)
			3. What are the complications associated with the device's use? (Text area, max character limit: 2000)
			4. What is the device's life span? (Text area, max character limit: 2000)
				Separated into multiple questions and in the order listed here.

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D6.	Submit relevant booklets, pamphlets, brochures, product catalogues, price lists, and/or package inserts that further describe and illuminate the nature of the nominated device. Page 5	Minor	Please upload all relevant booklets, pamphlets, brochures, product catalogs, price lists, and/or package inserts that further describe and illuminate the nature of the nominated device. Provide some details about the selected file: • Page number(s) (Text field) • Summarize the supporting information contained in this file (Text Area, max character limit: 500)	Allows multiple attachments each with metadata including page number and summary.
D7.	Using Healthcare Common Procedure Coding System (HCPCS) Level I and/or Level II code(s), list all of the specific procedure(s) and/or services with which the nominated device is used. HCPCS Level I is the American Medical Association's Current Procedural Terminology (CPT); HCPCS Level II National Codes are alpha- numeric codes that describe medical services and supplies not contained in CPT. Page 5	As Is	Using Healthcare Common Procedure Coding System (HCPCS) Level 1 and/or Level II code(s), list all of the specific procedure(s) and/or services with which the nominated device is used. • Enter HCPCS codes and titles (free text) Note: HCPCS General Info - link to https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo	
D8.	If a device replaces or improves upon an existing device, identify the trade/brand name of the existing device and any HCPCS Level I and/or Level II code(s) used to identify the existing device. Page 6	As Is	Does the device replace or improve upon an existing device? Yes/No If yes: List existing devices including trade/brand name and any HCPCS Level I and/or Level II code(s) used to identify the existing device. Enter device details to add them to the list. • Device Trade/ Brand Name (Text field) • Enter HCPCS codes titles (Text field)	
D9.	Identify by name and manufacturer similar devices that would also become eligible for transitional pass-through payment under the proposed additional category, insofar as this information is known to the applicant. Page 6	As Is	Are there similar devices that would also become eligible for transitional pass-through payment under the proposed additional category? Yes/No If yes: Identify by name and manufacturer similar devices that would also become eligible for transitional pass-through payment under the proposed additional category. (Text Area, max character limit: 2000)	
Substantial Clinical Improvement information: E	Provide a full discussion of the evidence supporting the proposition that the device for which an additional category is requested meets the substantial clinical improvement criterion. This discussion must include evidence to demonstrate that the device under consideration satisfies one or more of the measures of "substantial clinical improvement" that are listed above in this announcement. While we prefer published peer-reviewed clinical trials, we will consider all supporting evidence. For each claim of substantial clinical improvement over existing technologies, in table format (see sample table 1 below), list the claim of substantial clinical improvement and summarize the supporting information to include relevant clinical trial(s) or data. The application is incomplete without this table. Page 6	As Is	Substantial Clinical Improvement Claims Provide Substantial Clinical Improvement claims and supporting evidence. While we prefer published peer-reviewed clinical trials, we will consider all supporting evidence. Add a Substantial Clinical Improvement Claim • Short Title of the Substantial Clinical Improvement (Text field) Provide some details about the selected file • Study type (Text field) • Page number(s) (Text field) • Summarize the supporting information contained in this file (Text area, max character limit: 500)	
Sales and Marketing: F1	Sales and Marketing: Provide the following information for the device(s) for which an additional category is proposed: Date the device for which an additional category is requested was first marketed-- a. In the United States b. Outside the United States Page 6	As Is	Provide sales and marketing information about the nominated device. What date was the device first marketed in the United States and/or outside the United States? • US marketing date (date picker) • International marketing date (optional) (date picker)	
Sales and Marketing: F2	Date of sale of first unit of the device nominated for an additional category-- a. In the United States b. Outside the United States Page 6	As Is	Provide sales and marketing information about the nominated device. What date was the device's first sale in the United States and/or outside the United States? • US sale date (optional) (date picker) • International sale date (optional) (date picker)	

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Sales and Marketing: F3	Number of device(s) nominated for an additional category that have been sold up to the date of the application. Page 6	As Is	Provide volume data for the proposed device category. • How many units of the nominated device have been sold to date? (numeric entry)	
Sales and Marketing: F4	Number of facilities currently using the nominated device. Page 6	As Is	Provide details of the market availability delay. • How many facilities use the nominated device? (numeric entry)	
Sales and Marketing: F5	Projected total annual utilization for both the nominated device and for the proposed device category as a whole. Page 6	As Is	• Please outline the projected total annual utilization for both the nominated device and proposed device category as a whole. (Text area, max character limit: 2000)	
Sales and Marketing: F6	Indicate the annual projected utilization of the nominated device in connection with each HCPCS with which it is used. For example, projected utilization in connection with CPT code A equals 300 cases using 1 device per case; utilization in connection with CPT code B equals 1500 cases using 3 devices per case; utilization in connection with HCPCS code C equals 50 cases with 6 devices required per case. Page 6	Minor	For each HCPCS code associated with the device, provide an estimate annual utilization by the site of service. For example, HCPCS code XYZ has a projected utilization of: 200 hospital outpatient, 300 ambulatory surgical center, 10 hospital inpatient, 500 physician office. (Previously entered HCPCS codes automatically display here) • Hospital Outpatient (Text field) • Ambulatory Surgical Center (Text field) • Hospital Inpatient (Text field) • Physician Office (Text field) • Other (optional) (Text field) • Define what the "Other" utilization category is (Text field)	Combined F6 and F7 to capture annual utilization per each CPT code, and spread that utilization by site of service.
Sales and Marketing: F7	For each CPT code associated with a device, estimate annual utilization by site of service, that is, for HCPCS code A, projected utilization is 40% hospital outpatient, 30% ambulatory surgical center, 10% hospital inpatient, 20 % physician office. Page 6	As Is		MEARIS automatically calculates the percentage of estimated annual utilization based on the user's entries in F6.
Cost Info: G	Indicate the current cost of the device to hospitals, that is, the actual cost paid by hospitals for the device net of all discounts, rebates, and incentives in cash or in kind. In other words, submit the best and latest information available that provides evidence of the hospitals' actual cost for the nominated device. Page 6	As Is	What is the current cost of the entire device to hospitals? • Current Total Cost (numeric entry) Note: Current cost of the device to hospitals should be the actual cost paid by hospitals for the device net of all discounts, rebates, and incentives in cash or in kind.	
FDA Approval: H1	If the device requires approval or clearance by the Food and Drug Administration (FDA), submit a copy of the FDA approval/clearance letter. Page 7	Minor	Please upload all FDA supporting documents Items to include are the FDA decision letter, summary of safety and effectiveness, complete citation documentation, and guidance level documentation Select an existing or attach a new file. • (Drag and drop a file to upload or browse file) Provide some details about the selected file • Page number(s) (Text field) • Summarize the supporting information contained in this file (Text area, max character limit: 500)	H1, H2, H4, and H5 are listed on one page to be attached to the application.
FDA Approval: H2	Summary of Safety and Effectiveness Page 7	Dropped	See H1	
FDA Approval: H3	If the device has an investigational device exemption (IDE), submit the FDA approval letter and indicate whether it is a "Category B" IDE. Page 7	As Is	Provide details about your most recent FDA application for the nominated device. • Provide your Investigational Device Exemption (IDE) number (optional)	MEARIS does not state that the IDE approval letter must be attached to the application. MEARIS does not have a field specifically for the category of the IDE.
FDA Approval: H4	If the device is covered by a guidance document or is exempt from FDA approval or clearance, provide the complete citation of the guidance level regulation or exemption from approval or clearance. Page 7	Dropped	See H1	

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FDA Approval: H5	**Date of FDA approval or clearance**. If necessary, submit the date of U.S. market availability and documentation verifying delay between FDA approval and market availability. Page 7	As Is	Provide details about your most recent FDA application for the nominated device. • Provide the FDA decision date. (date picker) Note: The FDA decision date (or in certain documented cases U.S. market availability) must be within 3 years of the application date for transitional pass-through payment.	This question has been split between the FDA Info section and the Volume and Utilization section.
FDA Approval: H6	Date of FDA approval or clearance. **If necessary, submit the date of U.S. market availability and documentation verifying delay between FDA approval and market availability.** Page 7	As Is	Provide sales and marketing information about the nominated device. Was there a market availability delay for the device? Yes/No If yes: Provide details of the market availability delay. (Text area, max character limit: 2000)	This question has been split between the FDA Info section and the Volume and Utilization section.

Contact Information: I.	Contact Information: Name(s), address(es), e-mail address(es) 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 7
		Minor	For Primary and Secondary Contact Info:
			
			• First Name
			• Middle Name (Optional)
			• Last Name
			• phone number
			• email address
			• Address line 1
			• Address line 2
			• City, State (dropdown), Zip
			• Organization (Optional)
			• Relationship (dropdown)
			  • Consultant
			  • Manufacturer
			  • Other
			  • Describe "other" (Text field)	

D4.	What makes it different from similar products of the same type? Page 5	**Work in Progress**	List existing devices including trade/brand name and any HCPCS Level I and/or Level II code(s) used to identify the existing device. • What makes your device different?	This question is only presented if the user selects Yes in response to "Does the device replace or improve upon an existing device?" This question should be presented for all applicants without a skip pattern. There is no skip pattern on the paper form.
FDA Approval: H5	If a new category of devices is exempt from FDA approval or clearance, or the FDA has chosen an alternate regulatory scheme (e.g., guidance documentation during a defined period of time), then the applicant should so state, along with supporting references and citations. Page 7	**Work in Progress**	Not currently included in MEARIS	The DOC team is stating that this question should be included on the application as an optional question.
	This item is not included in the paper application.	**New**	Was there a market availability delay for the service? Yes/No If yes: Provide details of the market availability delay. (free text)	
	This item is not included in the paper application.	**New**	Have you completed other MEARIS 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)	

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	This item is not included in the paper application.	**New**	Provide the current cost of each individual component of the device to hospitals.
			Enter component details to add them to the list.
			• Item (Text field)
			• Current Cost (numeric entry)
			• Classification (dropdown)
			  • One Time Use
			  • Reusable
			  • Capital Equipment
			  • Other	

	This item is not included in the paper application.	**New**	If applicable, summarize any partial systems created by the components you listed. (optional) (Text area, max character limit: 2000)	
	How does CMS determine whether the cost of devices that would be included in an additional category is “not insignificant”? CMS considers the average cost of devices that would be included in an additional category and that are being marketed at the time the category is established to be “not insignificant” if the following conditions are met: 1. The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service associated with the category of devices. 2. The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the service associated with the category of devices by at least 25 percent. 3. The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determined to be associated with the device in the associated APC exceeds 10 percent of the total APC payment.	**New**	**Provide a detailed explanation for each cost subtest, including the calculations.** 1. Is the device cost at least 25% of the applicable APC payment rate to reach cost significance? (Highest Retail cost on application / Lowest APC rate available) x 100 = __ Percent (Text area, max character limit: 2000) 2. Is the device cost at least 125% of the offset amount (the device related portion of the APC found on the offset list)? (Highest Retail cost on application / Offset amount) X 100 = __ Percent (Text area, max character limit: 2000) 3. Is the device cost minus the APC offset amount divided by the APC payment amount at least 10% of the APC payment amount? (Highest Retail cost on application – Offset amount) / APC payment) X 100 = __ Percent (Text area, max character limit: 2000)	The paper application does not specifically ask the applicant to detail their explanation for each cost subset, but does provide explanation for how CMS determines whether the cost of devices included is "not significant". That explanation is used to prompt user to provide the detailed explanations of their calculations.

No labels

2 Comments

Daniel Standridge
@Unknown User (lv82) do you need any review from me following today's meeting? I have been busy all day on another meeting and have not been able to focus on anything else.

Unknown User (lv82)
No, we are good to go. You responded to the email with confirmation of your review. Thanks!