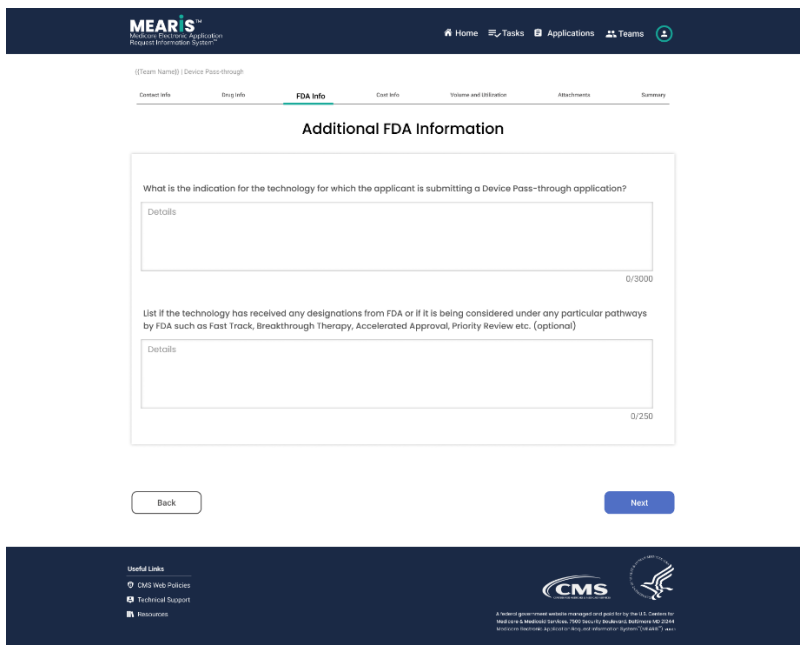
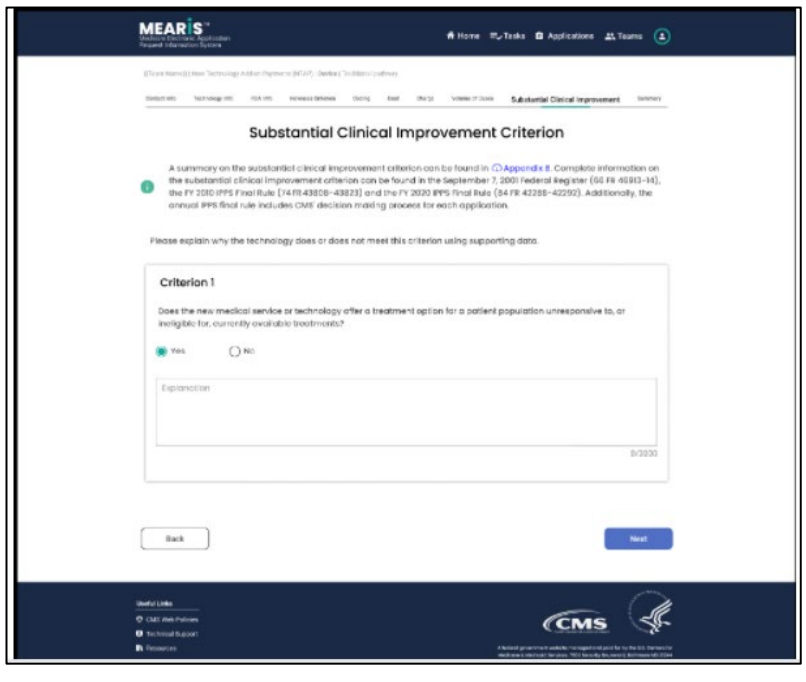
Device Pass-through Web Application Crosswalk

	Web Application Section	Web Application Content	Screenshot	Burden	Modification
15	FDA Info	Additional FDA Information from the already required FDA clearance documentation: **Note: Utilizing slide format but will tweak questions to read:** List the indication for which the Device Pass through is being submitted. If the device received a breakthrough indication from the FDA then list the indication for which the designation was received. (optional)		We do not anticipate any additional burden. The answers to these questions are in the FDA clearance documentation the applicant is required to attach to their application under the current process.	New
27	Substantial Clinical Improvements	Substantial Clinical Improvement Criterion Please Note: Utilizing slide format from NTAP application with modifications to the first paragraph to make it relevant for OPPS Device P-T purposes. CMS determines that a device to be included in the category will substantially improve the diagnosis or treatment of an illness or injury or improve the		None	Question added that was in the original paper application that was inadvertently not included in the MEARIS system when originally

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		functioning of a malformed body part compared to at least one other currently available and appropriate treatment or diagnostic test (ie. considered a standard of care, currently in use and utilized by the Medicare population). Whether a candidate device provides substantial clinical improvement is evaluated by one or more of the following: a. The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. Refer to the interim final rule with comment period in the November 2, 2001 Federal Register and the final rule with comment period in the November 1, 2002 Federal Register (67 FR 66781) and the modifications to certain criteria in the November 10, 2005 (70 FR 68628) final rule with comment period for a full discussion of the criteria for establishing additional pass-through			implemented.

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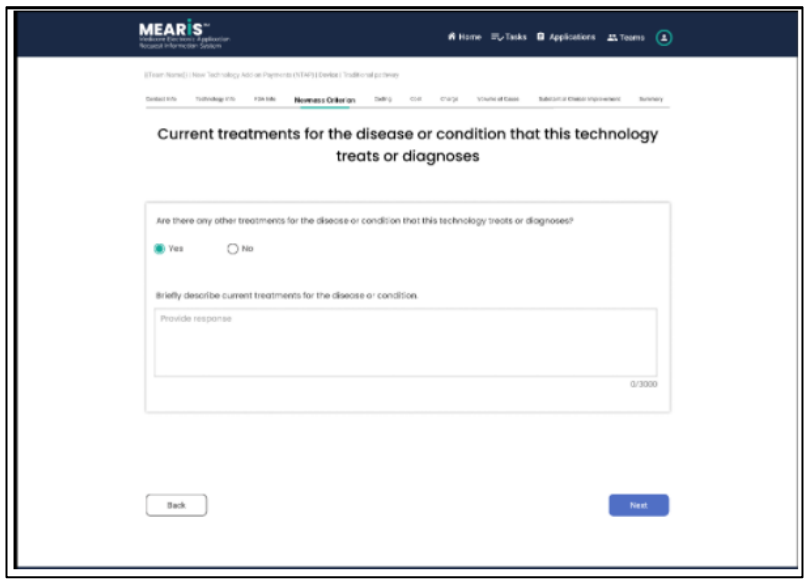
		categories for medical devices. • Does the new medical service or technology offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments? • Yes / No • Please explain why the technology does or does not meet this criterion using supporting data. • Text Box: Explanation 0/3000			
28	Newness Criterion	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? o Yes / No • Briefly describe current treatments for the disease or conditions o Text Box: Provide response 0/3000		None	Question added that was in the original paper application that was inadvertently not included in the MEARIS system when originally implemented.