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#	Form	Change	Current Location
1		Altered the introduction 1st and 2nd paragraphs.	1
2		Added the following headers: references, timeline for submissions,	1
3		Added an additional regulation reference: Refer to the interim final rule with comment period in the November 13 2015, Federal Register (80 FR 70416) for modifications to the pass through process and the addition of a newness criterion. These rules can currently be found at http://www.cms.gov/HospitalOutpatientPPS.	1
4		Added an additional regulation reference: Refer to the November 10, 2015 Federal Register (79 FR 66885) for modifications to the pass-through process for skin substitutes. When referring to the device application process and information requirements in this document, implantable biologicals and skin substitutes are also included.	1
5		Changed headers for the timeline for submission chart	1
6		Deleted: PLEASE NOTE: Pass-through status may or may not be effective on earliest possible effective date as described above. A longer evaluation period may be required if an application is incomplete, if further information is required, if a more extensive evaluation is required in order to determine eligibility, or due to other factors. An application is not considered complete until— • All required information has been submitted, AND • All questions related to such information have been answered. We can act only on applications that fully address the criteria and requirements set forth in this announcement.	1

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#	Form	Change	Current Location
7		Added: Beginning in CY 2016, all device pass-through applications will go through the OPPS annual rulemaking process in addition to being evaluated on a quarterly basis. Applications approved during the quarterly process will receive a pass-through effective date at the start of the next quarter after approval, and subsequently we would either finalize device pass-through payment status or discontinue pass-through payment status in the final rule. In the unusual case in which an applicant is approved during the quarterly process and then a decision is made in rulemaking to reverse the approval, the applicant could reapply with new information, in advance of the following year's proposed rule, as long as the device is still new (i.e., reapplication is within 3 years of initial FDA approval or clearance). For applications not approved during the quarterly review process, through rulemaking we would either approve device pass-through payment or deny the application for pass-through payment in the applicable final rule. Applicants who are not approved during the quarterly review process may withdraw their applications if they do not wish to go through the rulemaking process. If such a decision is made, the application will be considered to be denied. Because CMS intends to make application information available to the public for analysis and comment, applicants are advised that any information submitted, such as research findings and financial data, is subject to disclosure and publication through annual rulemaking. If you are providing data or information that is proprietary or otherwise protected from disclosure under the Trade Secrets Act or Exemption 4 under the Freedom of Information Act, please mark this information as such. CMS will attempt, to the extent allowed by Federal law, to keep this information protected from public view	1
8		Deleted "or", added "skin substitute" and deleted "hospitals".	2
9		Added "biological component" and " our determination of the key component is typically consistent with FDA's primary mode of action determination", and removed . For example, if the key component of the candidate pass-through product is a biological and that biological is only "implanted" because it is administered through an implanted delivery system for the biological (that is, the biological itself is not functioning as an implantable device), then we would evaluate the product under the drug and biological pass-through process. Conversely, if the key component of the candidate pass-through product is a biological and that biological is functioning as an implantable device or the key component of the product is the implantable delivery system for the biological, then we would evaluate the product under the device pass-through process."	2
10		added "skin substitute"	2, 4, 5

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#	Form	Change	Current Location
11		Removed "2. The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Social Security Act. However, the application process does not result in a coverage determination. Neither assignment of a HCPCS code nor approval of a device for transitional pass-through payment implies coverage of the device. Furthermore, each use of a qualified device is subject to medical review for determination of whether its use was reasonable and necessary in that particular case."	2
12		Removed "Are there any exceptions to the “not insignificant” cost test? The following medical devices are exempt from the “not insignificant” cost requirements if payment for the device was being made as an outpatient service on August 1, 2000: (1) A device of brachytherapy. (2) A device of temperature-monitored cryoablation.""	2
13		Deleted, "What has to be in an application for an additional transitional pass-through category for new medical devices?"	2
14		Added "template for application submission"	2
15		Renumbered the application submission template	2

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#	Form	Change	Current Location
16		Added "Beginning in CY 2016, all device pass-through applications will go through the OPPS annual rulemaking process in addition to being evaluated on a quarterly basis. Applications approved during the quarterly process will receive a pass-through effective date at the start of the next quarter after approval, and subsequently we would either finalize device pass-through payment status or discontinue pass-through payment status in the final rule. In the unusual case in which an applicant is approved during the quarterly process and then a decision is made in rulemaking to reverse the approval, the applicant could reapply with new information, in advance of the following year's proposed rule, as long as the device is still new (i.e., reapplication is within 3 years of initial FDA approval or clearance). For applications not approved during the quarterly review process, through rulemaking we would either approve device pass-through payment or deny the application for pass-through payment in the applicable final rule. Applicants who are not approved during the quarterly review process may withdraw their applications if they do not wish to go through the rulemaking process. If such a decision is made, the application will be considered to be denied. Because CMS intends to make application information available to the public for analysis and comment, applicants are advised that any information submitted, such as research findings and financial data, is subject to disclosure and publication through annual rulemaking. If you are providing data or information that is proprietary or otherwise protected from disclosure under the Trade Secrets Act or Exemption 4 under the Freedom of Information Act, please mark this information as such. CMS will attempt, to the extent allowed by Federal law, to keep this information protected from public view "	2
17		Our determination of the key component is typically consistent with FDA's primary mode of action determination.	2
18		Deleted "and subordinate "	3
19		Deleted "whether or not the device remains with the patient when the patient is released from the hospital"	3
20		Added "(either permanently or temporarily) or applied in or on a wound or other skin lesion."	3
21		Deleted "c. A material that may be used to replace human skin (for example, a biological or synthetic material)."	3
22		Added "1. Beginning with applications submitted on or after January 1, 2016, a device will only be eligible for transitional pass-through payment under the OPPS if, in cases where the device requires FDA approval or clearance, the device meets the newness criterion; that is, the date of original FDA approval or clearance (or in certain documented cases U.S. market availability) is within 3 years of the application date for transitional pass-through payment. Category B IDE devices that have not yet received FDA approval will be considered new."	3

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#	Form	Change	Current Location
23		Deleted "pass-through payments. A device for which a brand-specific application was made before December 1, 2000 that was determined to be eligible for transitional pass-through payment is not eligible to be placed in a new category. Such devices were placed in one of the initial categories that were effective April 1, 2001. " Added "device pass-through payments."	3
24		Deleted "whose costs are reflected in the OPPS claims data in the most recent OPPS update." Added "included in an existing category. "	3
25		Deleted "all" "treatments" "tests", Added "at least one other currently" " appropriate treatment" " test (ie. Considered a standard of care currently in use and utilized by the Medicare population)"	3
26		Deleted Are there any exceptions to the “not insignificant” cost test? The following medical devices are exempt from the “not insignificant” cost requirements if payment for the device was being made as an outpatient service on August 1, 2000: (1) A device of brachytherapy. (2) A device of temperature-monitored cryoablation.	4
27		Deleted "What has to be in an application for an additional transitional pass-through category for new medical devices?"	4
29		Substituted devices for products	5
30		Substituted "(typically, but not necessarily, in the form of published peer-reviewed clinical trials) " for "While we prefer published peer-reviewed clinical trials, we will consider all supporting evidence."	5
31		Added "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."	6
28		Deleted "(s) "	6
32		Added "2. Summary of Safety and Effectiveness"	7
33		Added "6. 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."	7
36		Deleted "five"	7
34		Substituted C4-04-25 for C4-05-17	7

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#	Form	Change	Current Location
35		Susbstituted 2007 for 2013	7
37		Added "Questions pertaining to the pass-through payment application process may also be sent via e-mail to the electronic mailbox noted above."	7
38			

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Reason
To provide more comprehensive guidance in light of stakeholder questions and feedback.
To allow for clearer organization and document flow.
The PRA was granted prior to the finalization of this rule.
The PRA was granted prior to the finalization of this rule.
Edited to allow for clearer meaning.
Sustituted this text for the below addition, to allow for comprehensive understanding of the background and resulting policies.

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Reason
Sustituted this text for the above deletion, to allow for comprehensive understanding of the background and resulting policies.
Edited to reflect changes in policy.
Edited this to reflect Agency level decisions and to reflect updated policy.
Edited to relect updated policy.

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Reason
Edited to relect updated policy.
Removed to eliminate confusion and to reflect udated policy.
Appeared redundant once we added the template for application submission.
Added to provide a more comprehensive guide and document flow.
Edited the numbering to reflect which questions are grouped together

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Reason
Added to explain a new policy change and resulting process.
Added to provide additional clarity.
Revised to reflect updated policy.
Revised to reflect updated policy.
Revised to reflect updated policy.
Revised to reflect updated policy.
Revised to reflect updated policy.

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Reason
Revised to streamline the information provided in the application.
streamline the information provided in the application.
Revised to reflect updated policy.
Revised to reflect updated policy.
Revised to reduce redundancy.
Revised to reflect updated policy.
Revised to provide policy clarity.
Revised to reflect updated policy.
Revised to relect updated policy.
Revised to relect updated policy.
Revised to reflect updated policy.
Revised to reduce redundancy.
To reflect logistic changes.

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Reason
To reflect logistic changes.
To reflect logistic changes.