# HCPCS Crosswalk Document

The following are the global changes applied across the application:

1. 'DMEPOS' changed to 'Non-drug, Non-biological Item or Service'
2. 'Product' changed to 'Item or Service'

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| 1 | For the purpose of publication on CMS' request list and public meeting agenda on the HCPCS web site, please provide a concise summary of your request (not to exceed 300 words). CMS may edit your summary prior to publication, even if the summary does not exceed 300 words. Please organize the summary in the following sequence: | As Is | Request Info (The web application has been divided into tabs, for organization purposes, with related questions grouped in one tab) | For the purpose of publication on CMS' request list and public meeting agenda on the HCPCS web site, please provide a concise summary of your request<br><br>* CMS may edit your summary prior to publication<br><br>The summary should be arranged in the form of a cohesive paragraph in the mentioned sequence.<br><br>Your request to modify the HCPCS code set (e.g., | Instead of a 300 word limit the response has been updated to be 3000 characters on the web application.<br><br>Instruction to assist applicant answer the question in the correct format |

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| | A) your request to modify the HCPCS code set (e.g., number of new codes requested, including recommended language; or revisions to an existing code, including old language and recommended language; or discontinuation of a code);<br><br>B) the name and description of the product;<br><br>C) the function of the product; and<br><br>D) the reason why existing codes do not adequately describe | | | number of new codes requested, including recommended language; or revisions to an existing code, including old language and recommended language; or discontinuation of a code);<br>The name and description of the item or service;<br>The function of the product; and<br>The reason why existing codes do not adequately describe the item or service;<br><br>The following information is required for drugs and biologicals and as applicable for non-drug, non biological Items and Services:<br>Indications for use;<br>Action;<br>Dosage;<br>Route of administration; and<br>How packaged. | |

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| | the product. In addition, for drugs and biologics only, please also include the following:<br><br>E) indications for use;<br><br>F) action;<br><br>G) dosage;<br><br>H) route of administration; and<br><br>I) how packaged.<br><br>Note that text that exceeds the 300 word limit may be truncated and not appear on CMS' published summary. | | | | |

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| 2 | Identify the item (product or drug/biological) for which a HCPCS Level II code is being requested.<br><br>A) Trade or Brand Name:<br><br>B) General Product Name or Generic Drug Name (active ingredient):<br><br>C) FDA classification: | As Is | Item or Service Info | **Provide additional details of the item or service for which the code is being requested**<br><br>Response is mandatory for all drugs and biologicals and as applicable for all other items or services. Where not applicable, please type NA and explain your answer.<br><br>1. Trade or Brand name<br>2. FDA classification<br>3. General Item or Service Name or Generic Drug Name (active ingredient) | Existing instructions reworded and moved from general instruction section to the relevant places in the application to help applicants answer the questions accurately without having to refer to another document or another tab in the system while completing the online application. |
| 3 | Please check one HCPCS category from the following list, which in your estimation most accurately describes the item identified in | As Is | Item or Service Info | **Provide the details of the item or service for which the code is being requested**<br><br>CMS may move the request into another category, if deemed appropriate, after | Moving a request to the appropriate category by CMS is an existing practice |

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| | question #1:<br><br>A) Medical/Surgical Supplies<br><br>B) Dialysis Supplies and Equipment<br><br>C) Ostomy/Urological Supplies<br><br>D) Surgical Dressing<br><br>E) Prosthetic<br><br>F) Orthotic<br><br>G) Enteral/Parenteral Nutrition<br><br>H) Durable Medical Equipment | | | evaluation.<br><br>Please check one HCPCS category from the following list, which you believe most accurately describes the item or service identified as the subject of this request.<br><br>• Drugs or Biologicals<br>• Non-drug, Non-biological Item or Service<br><br>Drop down selection for HCPCS category for Drugs or Biologicals:<br><br>• Drugs<br>• Biologicals<br>• Radiopharmaceutical<br>• Blood or Blood Products<br>• Other | and applicants are aware of it<br><br>HCPCS category split to 'Drugs or Biologicals' and 'Non-drug, Non-biological Item or Service'<br><br>We are not collecting new information that the applicant would not have provided in the cover letter that was included with and applicant's paper application. Since there is no longer a cover letter, the format of this question was changed to accommodate the system's need to know what application cycle is appropriate for the application based on whether an item or service is a drug or biological (quarterly application cycle) or a non-drug, non-biological (bi-annual cycle). The corresponding drop down selections are the same as the selections in the paper application.<br><br>Instructions added for clarification. |

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| | I) Blood/Blood Products<br><br>J) Drug/Biological<br><br>K) Radiopharmaceutical<br><br>L) Vision<br><br>M) Hearing<br><br>N) Other (please indicate/provide category) | | | Drop down selection for HCPCS category for Non-drug, Non-biological Item or Service:<br><br>• Medical/Surgical Supplies<br>• Dialysis Supplies and Equipment<br>• Ostomy/Urological Supplies<br>• Surgical Dressing<br>• Prosthetic<br>• Orthotic<br>• Enteral/Parenteral Nutrition<br>• Durable Medical Equipment<br>• Vison<br>• Hearing<br>• Other | |
| 4 | Describe the item fully in general | As Is | Item or Service | **Describe the item or service** | Instructions for clarification of question in order to assist the applicants formulate |

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| | terminology. What is it? What does it do? How is it used? Describe the patient population for whom the product is clinically indicated. Descriptive booklets, brochures, package inserts, as well as copies of published peer- reviewed articles on the item may be included in the information packet submitted for review, but they do not replace the requirement to fully respond to this question and fully describe the item.<br><br>Responses for drugs and biologicals must include: | | Info | **fully in general terminology**<br><br>Responses must include Mechanism of action, Indications for use, Dosage, Route of administration for all drugs and biologicals and as applicable for all other items or services. Where not applicable, please type NA and explain your answer.<br><br>1. What is the item or service?<br>2. What does the item or service do and how? (Function and mechanism of action)<br>3. How is the item or service used? (Indications for use, dosage, route of administration) | accurate responses.<br><br>The questions in the first paragraph are separated out to individual form fields and terms “items or service” used to avoid any confusion. |

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| | A) indications for use; B) action;<br><br>C) dosage and route of administration; D) package insert; E) how supplied; F) National Drug Code (NDC), if one exists. | | | | |
| | | As Is | Item or Service Info | **Describe the item or service fully in general terminology**<br><br>Responses must include Mechanism of action, Indications for use, Dosage, Route of administration for all drugs and biologicals and as applicable for all other items or services. Where not applicable, please type NA and explain your answer.<br><br>1. How is the item or service supplied? (How packaged) | Package insert is also required in the FDA section hence, removed from here to avoid duplication of effort. |

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| | | | | 2. Describe the patient population for whom the item or service is clinically indicated<br>3. Does the item have a National Drug Code? Responses available, Yes, or No<br>4. National Drug Code | |
| 5 | Describe how the product is primarily and customarily used to serve a medical purpose. | As Is | Item or Service Info | How is the item or service primarily and customarily used to serve a medical purpose? | |
| 6 | A) Is the item durable? If so, explain how it can withstand repeated use. Specify whether the entire item or only certain components of the item can withstand repeated use. | Minor | Item or Service Info | **Provide durability information**<br><br>Where not applicable, please type NA and explain your answer<br><br>In order to help us determine whether the item can be considered Durable Medical | Existing instructions moved to the section to assist the applicants.<br><br>The questions are separated out to individual form fields for durability and warranty.<br><br>No substantive change in the durability section, however, in the electronic application we ask direct questions that speak to durability instead of directly |

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| | B) If the entire item can withstand repeated use, please specify the length of the time that the item can withstand repeated use.<br><br>C) If only certain components of the device can withstand repeated use, please identify the individual components and the length of the time that the individual components can withstand repeated use. | | | Equipment under Medicare Part B, please answer the following questions:<br><br>Can the item be rented and used by successive patients?<br><br>Does the item have an expected lifetime of at least three years? | asking the applicant in their item is durable. The questions are worded to provide clarity as to what CMS needs to evaluate durability and to assist the applicants in formulating more targeted, concise and appropriate responses. The information we are collecting here is no different from the information we expected applicants to provide in the paper application. |
| | | As Is | Item or Service Info | **Provide warranty details**<br><br>Where not applicable, please type NA and explain your answer<br><br>Provide detailed information on the warranty of the device such as the parts included under the warranty, the length of the warranty, and the parts excluded from the warranty. In addition, please specify if the device includes any disposable components | There are no changes made to the warranty section. |

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| | D) Provide detailed information on the warranty of the device such as the parts included under the warranty, the length of the warranty, and the parts excluded from | | | and the expected life or the replacement frequency recommended for the disposable components. | |
| 7 | A) Identify similar items and their manufacturers. If the | As Is | Significant Therapeut | **Identify the similar products** | Separated out into individual questions<br><br>Question formatted as yes/no to |

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| | item is a drug, then list other drugs by trade name that are marketed under the same active ingredient category/generic name.<br><br>B) Identify significant differences between this item and other products listed above. Include differences in item cost; material; product design; how it is used; mechanism of operation, function/treatment provided to a patient; clinical indication; and clinical outcome.<br><br>C) Complete question 7c only if you are making a | | ic Distinction | 1. "Are there any items or services similar to this item or service?, Responses available, Yes, or No<br>2. Explain why there are no similar items or services<br><br>**Enter details of each similar item or service to the list**<br><br>1. If the item is a drug, then list other drugs by trade name that contain the same active ingredient . Item or service/Drug trade name Manufacturer<br><br>2. Identify significant differences between | accommodate skip pattern in the system<br><br>25 copies no longer required for the online application. |

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| | claim of significant therapeutic distinction. Claims of significant therapeutic distinction when compared to the use of other, similar items, must be described in detail. Articulate the clinical theory behind the claim, including differences in the product or its operation as it compares to other similar products. Specify how the product results in a significantly improved medical outcome or significantly superior clinical outcome. (Please refer to the | | | this item and your item or service. Include differences in item cost; material; item design; how it is used; mechanism of operation, function/treatment provided to a patient; clinical indication; and clinical outcome<br>3. Radio options for "Are you making a claim of significant therapeutic distinction?", Responses available, Yes, or No<br>4. Claims of significant therapeutic distinction when compared to the use of other, similar items, must be described in detail. Articulate the clinical theory behind the | |

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| | HCPCS decision tree for definitions and additional information.) Provide the best available information related to your claim. Include copies of all articles that result from your systematic analysis of the available literature. Information submitted should be as complete as possible. Unfavorable articles should also be provided with any appropriate rebuttal or explanation. It is acceptable to exceed the 40-page limit of this application only if the additional pages contain clinical information that | | | claim, including differences in the item or service or its operation as it compares to other similar items or services. Specify how the item or service results in a significantly improved medical outcome or significantly superior clinical outcome. Provide the best available information related to your claim.<br>5. Include copies of all articles that result from your systematic analysis of the available literature. Information submitted should be as complete as possible. Unfavorable articles should also be | |

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| | substantiate a claim of significant therapeutic distinction. When this occurs, the original application and all clinical documentation must be included in the original and each of 25 copies submitted to CMS. | | | provided with any appropriate rebuttal or explanation. Applicants are urged to mention/highlight the section or pages that contain information relevant to their request in the submitted articles or clinical studies to help CMS understand the applicants' claim of significant therapeutic distinction made in the request. Attach all clinical studies to support the Significant Therapeutic Distinction | |
| 8 | A) List any third party payers that pay for this product.<br><br>B) List any codes | As Is | Billing | **Provide billing information for this item or service**<br><br>1. List any third party payers that pay for | 4. |

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| | that are currently being billed to those payers for this product.<br><br>C) Explain why existing code categories are inadequate to describe the product. If a third party payer has an existing policy with regard to reporting this product on claims submitted to them, please include that policy. | | | this item or service.<br>2. List any codes that are currently being billed to those payers for this item or service.<br>3. Explain why existing code categories are inadequate to describe the item or service. If a third party payer has an existing policy with regard to reporting this item or service on claims submitted to them, please include that policy. | |
| 9 | A) Is this product prescribed by a health care professional?<br><br>B) If yes, who prescribes the | As Is | FDA Info | **Prescription Information**<br><br>1. Is this item or service prescribed by a health care professional? Responses available, Yes, or | Separated out into individual questions.<br><br>Yes/No options to accommodate skip patterns |

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| | product, and in what setting(s) is it prescribed? Please specify what the FDA label requires with regard to prescriber and setting. | | | No<br>2. For 'Yes"option:<br>1. As per the FDA label, who is this item or service prescribed by?<br>2. As per FDA label, in what setting(s) is this item or service prescribed?<br>3. For 'No' option:<br>1. The above 2 questions are disabled | |
| 10 | A) Is this product useful in the absence of an illness or injury?<br><br>B) Explain why or why not. | As Is | Item or Service Info | **Medical Use**<br><br>1. Is this item or service useful in the absence of an illness or injury? Responses available, Yes, or No | Yes/No options added |

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| | | | | 2. Explain why or why not ? | |
| 11 | A) Provide the date that the product was cleared for marketing by the FDA. If the product is exempt from FDA review and classification, please explain the basis for the exemption and provide proof of product establishment registration, such as HCT/P or other registration, as applicable.<br><br>B) Attach a copy of the cover sheet that was submitted to the FDA with the request for clearance. CMS does not accept | As Is | FDA Info | **Provide FDA Information**<br><br>1. Is the item or service exempt from FDA review and classification? Responses available, Yes, or No<br>2. For Yes option:<br>1. Please explain the basis for the FDA exemption.<br>2. Attach the applicable files:<br>1. Attach applicable files: 1) Provide proof of item | Question is broken down into two sections with a 'Yes' and 'No' response.<br><br>The information being asked is the same, the questions are reworded to accommodate the Yes/No questions for the skip pattern as well for further simplification of the questions to assist the applicant in providing more accurate answers.<br><br>Point (5) has been moved from “general instructions” section to the FDA section as it is FDA specific instruction and will help the applicants better answer the question. This is not new information.<br><br>Some instructions are slightly reworded for further clarification to aid applicants in providing appropriate information as required by CMS (including some example documents) |

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| | redacted copies.<br><br>C) Attach a copy of the final unredacted FDA approval letter, including the 510(k) summary for those items that are approved using the 510(k) process, and final FDA approved package insert. CMS does not accept redacted copies. Also, if an item is cleared using the 510(k) process, identify the predicate product(s) listed in the 510(k) submission as well as the HCPCS codes that describe the predicate product(s). Explain why the | | | or service establishment registration, such as HCT/P, verification of HCT/P subject to section 361 of the Public Health Service Act (PHS Act) and 21 CFR 1271 | |

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| | existing HCPCS codes for the predicate product(s) do not adequately describe the product that is the subject of this HCPCS application. In other words, if an item is listed as being substantially equivalent to another item(s) in an application for FDA marketing clearance, why is it not equivalent or comparable for coding purposes? | | | or other registration, if applicable. 2) Attach a copy of the final dated marketing authorization as published by the FDA. 3) Attach a copy of the cover | |

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| | | | | sheet that was submitted to the FDA with the request for marketing authorization. 4) Attach a copy of the final FDA approved package insert as publish | |

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| | | | | ed by the FDA. 5) If the item or service has been subject to an assessment by any other agency or recognized medical body, provide a copy of the results of that | |

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| | | | | assessment.<br>3. For 'No' option:<br>1. Provide the date that the item or service was cleared for marketing by the FDA.<br>2. Please specify the FDA marketing authorization pathway (e.g. 510 k, BLA, Breakthrough, DeNovo, NDA etc.)<br>3. Please identify the predicate product(s) as well as the HCPCS codes that describe the predicate product(s). Explain why | |

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| | | | | the existing HCPCS codes for the predicate product(s) do not adequately describe the item or service that is the subject of this HCPCS application. In other words, if an item is listed as being substantially equivalent to another item(s) in an application for FDA marketing clearance, why is it not equivalent or comparable for coding | |

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| | | | | purposes?<br>4. Attach the applicable files:<br>1. Attach applicable files: 1) Provide proof of item or service establishment registration, such as HCT/P, verification of HCT/P subject to | |

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| | | | | section 361 of the Public Health Service Act (PHS Act) and 21 CFR 1271 or other registration, if applicable. 2) Attach a copy of the final dated marketing | |

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| | | | | authorization as published by the FDA. 3) Attach a copy of the cover sheet that was submitted to the FDA with the request for marketing authorization. | |

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| | | | | 4) Attach a copy of the final FDA approved package insert as published by the FDA.<br>5) If the item or service has been subject to an assessment by any other | |

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| | | | | agency or recognized medical body, provide a copy of the results of that assessment. | |
| 12 | A) Is the product currently marketed and available for use and purchase in United States?<br><br>B) Date the product was first marketed in the United States. Note: for drugs and biologicals, the date | As Is | Item or Service Info | **Marketing Information**<br><br>Applications for non-drug, non-biological items that are not regulated by the FDA and also not yet available in the U.S. market will be considered incomplete and will not be processed. | Instructions to assist the applicants better understand the question requirements.<br><br>Yes/No options added for skip pattern in the system. |

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| | of first sale is also required. | | | 1. Is the item or service currently marketed and available for use and purchase in United States? Responses available, Yes, or No<br>2. For 'Yes' option:<br>    1. Provide the date the item or service was first marketed in the United States. (Date picker)<br>3. For 'No' option:<br>    1. The above question is disabled<br><br>Response mandatory for drugs and biologicals for the request to be considered | |

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| | | | | complete.<br><br>1. Date of first sale in the United States. (Date picker) | |
| 13 | Identify the percent of use of the item across the following settings. For drugs or biologicals, provide the percent of use for the setting in which the item is or would be administered.<br><br>1. Physician's Office:<br>2. Freestanding Ambulatory Care Clinics:<br>3. Patient's Home by patient:<br>4. Patient's Home by Health Care | As Is | Setting of Use | **Identify the percent of use**<br><br>Provide physical setting type and not ownership or insurer type.<br><br>Provide the percent of use for the setting in which the item or service is or would be used or administered.<br><br>1. Physician's Office:<br>2. Freestanding Ambulatory Care Clinics:<br>3. Patient's Home by patient:<br>4. Patient's Home by Health Care Provider:<br>5. Nursing | Instructions to assist the applicant better understand the requirements of the question being asked.<br><br>Information being asked is the same, the question is reworded for better understanding. |

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| | Provider:<br>5. Nursing Home/Skilled Nursing Facility:<br>6. Hospital Inpatient Facilities:<br>7. Hospital Outpatient Facility:<br>8. Other (identify):<br><br>TOTAL VOLUME OF USE ACROSS ALL SETTINGS SHOULD EQUAL 100% | | | Home/Skilled Nursing Facility:<br>6. Hospital Inpatient Facilities:<br>7. Hospital Outpatient Facility:<br>8. Other (identify):<br><br>TOTAL VOLUME OF USE ACROSS ALL SETTINGS SHOULD EQUAL 100% | |
| 14 | A) Please provide complete contact information for the applicant. Foreign applicants are encouraged to provide a U.S. primary contact with | Provide Manufacturer Contact details, if applicant is not a manufactur | Contact Info and Attestation | **Who is the primary contact?**<br><br>1. First Name<br>2. Middle name<br>3. Last name<br>4. Organization<br>5. Occupational/job title | Manufacturer attestation is no longer required in the electronic system which will ease the applicant burden. |

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| | U.S. contact information to ensure effective communication. CMS uses this information to contact applicants regarding upcoming meetings, ask questions regarding applications, and provide notifications of the status of applications. Applicants are CMS' primary contacts for any information pertaining to HCPCS code applications.<br><br>Applicant's Name and Title:<br><br>Name of Corporation/Organization: Mailing Address (street): | er.<br><br>Removing manufacturer's signature from the attestation | | 6. Phone Number<br>7. Email Address<br>8. Country<br>9. Mailing address<br>10. City<br>11. State<br>12. Zip/postal code<br>13. Relationship (consultant/ not applicable)<br><br>Who is the Secondary Contact?<br><br>1. First Name<br>2. Middle name<br>3. Last name<br>4. Organization<br>5. Occupational/job title<br>6. Phone Number<br>7. Email Address<br>8. Country<br>9. Mailing address<br>10. City<br>11. State<br>12. Zip/postal code<br>13. Relationship | |

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| | City, State, Zip<br><br>Direct Dial Telephone Number and Extension: FAX Number:<br><br>E-Mail Address:<br><br>I attest that the information provided in this HCPCS coding application is accurate and correct to the best of my knowledge.<br><br>Date:<br><br>Signature of Applicant<br><br>B) Is the applicant the manufacturer? Check one box below. | | | (consultant/ not applicable)<br><br>Are you the manufacturer?, Responses available, Yes, or No<br><br>1. Manufacturing Company<br>2. Representative Title<br>3. First name<br>4. Middle name (optional)<br>5. Last name<br>6. Manufacturer's Email address<br>7. Country<br>8. Manufacturer's Phone number<br>9. Extension (optional)<br>10. Mailing address line 1<br>11. Mailing address line 2 (optional)<br>12. City | |

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| | YES [ ]<br><br>NO [ ]*<br><br>C) *If the applicant is submitting this application on behalf of a manufacturer, the manufacturer must provide the requested contact information, sign, and date the attestation (below).<br><br>Name and Title of Manufacturer's Representative:<br><br>Name of Manufacturing Company:<br><br>Mailing Address | | | 13. State<br>14. ZIP/Postal Code | |

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| | (street):<br><br>City, State, Zip<br><br>Direct Dial Telephone Number and Extension:<br><br>FAX Number:<br><br>E-Mail Address:<br><br>I declare that the information in this application describing the product that is the subject of this application is true and accurate to the best of my knowledge.<br><br>Date:_____<br><br>Signature of | | | | |

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| | Manufacturer's Representative | | | | |
| | All the upload attachments for Items or Services | **Attachments** | Item or Service Info | **Upload descriptive booklets, brochures, package inserts, and other marketing materials pertaining to this item or service** | Instead of 25 printed copies of the information, the applicants will upload the relevant information in the system. |
| | This information is already provided in the current paper application as part of the cover letter. | **Minor** | Request Info | **Applications associated with this request**<br>1. Is this a repeat request, Responses available, Yes, or No<br>2. Prior application number (optional field)<br>3. Submission Year (optional)<br>4. Decision (required)<br>5. Why applicant disagrees with the decision (required) | This information is already recorded and provided by the applicant as part of the cover letter that is submitted with the application. In the web format, CMS will no longer require a cover letter and instead these questions are placed in the beginning of the web application. |

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| | | | | 6. New information/supporting information attachment (optional) | |
| | This question already exists in the current paper application as part of the summary question (question 1). | **Minor** | Request Info | HCPCS Code Request<br><br>1. Request New Code<br>2. Revise Existing Code<br>3. Delete Existing Code<br><br>HCPCS Code<br><br>Suggested language for this code (optional) | This information is already required and provided by the applicant in the paper application as part of question 1 (Summary) but is broken down as a separate question in the web application. This is due to the fact that the information is part of agenda and decision report templates and need to be in distinct fields in order for the program to pull it from the application.<br><br>Additionally, it will help the applicants to organize the information more efficiently. |