

# Drug PT Crosswalk-FY 2025 Program

Application Section	Application Language	Modifications	Burden	Revised Application Language																				
Welcome	What you will need to know:	The first line was modified to clarify this section provides basic key information for the application and process.	No change	Important Information																				
Welcome	Table for Application Process and Timeline <table border="1" data-bbox="406 620 1237 832"> <thead> <tr> <th>Applications submitted by</th> <th>Earliest effective date for drug pass-through status</th> </tr> </thead> <tbody> <tr> <td>March 1st</td> <td>July 1<sup>st</sup></td> </tr> <tr> <td>Jun 1st</td> <td>October 1st</td> </tr> <tr> <td>September 1st</td> <td>January 1<sup>st</sup></td> </tr> <tr> <td>December 1st</td> <td>April 1st</td> </tr> </tbody> </table>	Applications submitted by	Earliest effective date for drug pass-through status	March 1st	July 1 <sup>st</sup>	Jun 1st	October 1st	September 1st	January 1 <sup>st</sup>	December 1st	April 1st	Updated “Jun” to “June” to be consistent with spelling out all months.	No change	Table for Application Process and Timeline <table border="1" data-bbox="2026 620 2858 832"> <thead> <tr> <th>Applications submitted by</th> <th>Earliest effective date for drug pass-through status</th> </tr> </thead> <tbody> <tr> <td>March 1st</td> <td>July 1<sup>st</sup></td> </tr> <tr> <td>June 1st</td> <td>October 1st</td> </tr> <tr> <td>September 1st</td> <td>January 1<sup>st</sup></td> </tr> <tr> <td>December 1st</td> <td>April 1st</td> </tr> </tbody> </table>	Applications submitted by	Earliest effective date for drug pass-through status	March 1st	July 1 <sup>st</sup>	June 1st	October 1st	September 1st	January 1 <sup>st</sup>	December 1st	April 1st
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Welcome		Added PRA Disclosure Statement to provide information about this PRA, including contact information.	No change	PRA Disclosure Statement According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0802 (Expires: 01/31/2025). This is a required information collection. The time required to complete this information collection is estimated to average 16 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4- 26-05, Baltimore, Maryland 21244-1850.																				
Welcome		Added CMS Disclosure to clarify sensitive information should not be sent to the PRA Reports Clearance Office and to provide contact information for questions related to this application.	No change	CMS Disclosure Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact the CMS point of contact for this module using the form available at the bottom of the MEARIS™ Drug and Biological Pass-through <a href="#">resources page</a> .																				
Initial Information/ Contact Information	Initial Information	Section changed from “Initial Information” to “Contact Information” to more clearly specify the information contained in this section.	No change	Contact Information																				

<p>Initial Information/ Contact Information</p>	<p>1. Who is the primary contact?</p> <ul style="list-style-type: none"> <li>• First Name</li> <li>• Middle Name (optional)</li> <li>• Last Name</li> <li>• Phone Number</li> <li>• Email Address</li> <li>• Mailing Address Line 1</li> <li>• Mailing Address Line 2 (optional)</li> <li>• City</li> <li>• State</li> <li>• Zip Code</li> <li>• Organization (optional)</li> <li>• Relationship: <ul style="list-style-type: none"> <li>▪ Consultant</li> <li>▪ Manufacturer</li> <li>▪ Other (Describe “other”)</li> </ul> </li> </ul>	<p>Made minor updates to clarify the primary contact should have a US phone number and US address. Also, added an optional extension to allow for a more direct number to the applicant for better communication.</p>	<p>No change</p>	<p>1. Who is the primary contact?</p> <ul style="list-style-type: none"> <li>• First Name</li> <li>• Middle Name (optional)</li> <li>• Last Name</li> <li>• <b>US Phone Number</b></li> <li>• <b>Extension (optional)</b></li> <li>• Email Address</li> <li>• <b>Country: United States</b></li> <li>• Mailing Address Line 1</li> <li>• Mailing Address Line 2 (optional)</li> <li>• City</li> <li>• State</li> <li>• Zip Code</li> <li>• Organization (optional)</li> <li>• Relationship: <ul style="list-style-type: none"> <li>▪ Consultant</li> <li>▪ Manufacturer</li> <li>▪ Other (Describe “other”)</li> </ul> </li> </ul>
<p>Initial Information/ Contact Information</p>	<p>2. Who is the secondary contact?</p> <ul style="list-style-type: none"> <li>• First Name</li> <li>• Middle Name (optional)</li> <li>• Last Name</li> <li>• Phone Number</li> <li>• Email Address</li> <li>• Mailing Address Line 1</li> <li>• Mailing Address Line 2 (optional)</li> <li>• City</li> <li>• State</li> <li>• Zip Code</li> <li>• Organization (optional)</li> <li>• Relationship: <ul style="list-style-type: none"> <li>▪ Consultant</li> <li>▪ Manufacturer</li> <li>▪ Other (Describe “other”)</li> </ul> </li> </ul>	<p>Made minor updates to clarify the secondary contact should have a US phone number and to clarify the country for the contact’s address. Also, added an optional extension to allow for a more direct number to the applicant for better communication.</p>	<p>No change</p>	<p>2. Who is the secondary contact?</p> <ul style="list-style-type: none"> <li>• First Name</li> <li>• Middle Name (optional)</li> <li>• Last Name</li> <li>• <b>US Phone Number</b></li> <li>• <b>Extension (optional)</b></li> <li>• Email Address</li> <li>• <b>Country</b></li> <li>• Mailing Address Line 1</li> <li>• Mailing Address Line 2 (optional)</li> <li>• City</li> <li>• State</li> <li>• Zip Code</li> <li>• Organization (optional)</li> <li>• Relationship: <ul style="list-style-type: none"> <li>▪ Consultant</li> <li>▪ Manufacturer</li> <li>▪ Other (Describe “other”)</li> </ul> </li> </ul>

Initial Information/ Drug Information	<p>3. Have you completed other HAPG applications for this drug? (Yes/No)</p> <p>a) If Yes: Please provide information about your previous applications.</p> <ul style="list-style-type: none"> <li>• Application Type: <ul style="list-style-type: none"> <li>▪ New Technology Add-on Payments (NTAP)</li> <li>▪ Device Pass-through</li> <li>▪ Drug and Biological Pass-through</li> <li>▪ New Technology Ambulatory Payment Classification (APC)</li> <li>▪ Healthcare Common Procedure Coding System (HCPCS) Level II</li> <li>▪ International Classification of Diseases Request (ICD-10-PCS)</li> </ul> </li> <li>• Application Status (optional): <ul style="list-style-type: none"> <li>▪ Approved</li> <li>▪ Denied</li> <li>▪ Withdrawn</li> <li>▪ Pending</li> </ul> </li> <li>• Description</li> <li>• Submission Date</li> </ul> <p>b) If No: Continue to Drug Information.</p>	<p>Moved previous applications question from Initial Information section to Drug Information section for clarity when updated Initial Information section to Contact Information section. Updated application system to reflect current website. Added the submission date is optional.</p>	No change	<p>1. Have you completed other <b>MEARIS™</b> applications for this drug? (Yes/No)</p> <p>c) If Yes: Please provide information about your previous applications.</p> <ul style="list-style-type: none"> <li>• Application Type: <ul style="list-style-type: none"> <li>▪ New Technology Add-on Payments (NTAP)</li> <li>▪ Device Pass-through</li> <li>▪ Drug and Biological Pass-through</li> <li>▪ New Technology Ambulatory Payment Classification (APC)</li> <li>▪ Healthcare Common Procedure Coding System (HCPCS) Level II</li> <li>▪ International Classification of Diseases Request (ICD-10-PCS)</li> </ul> </li> <li>• Application Status (optional): <ul style="list-style-type: none"> <li>▪ Approved</li> <li>▪ Denied</li> <li>▪ Withdrawn</li> <li>▪ Pending</li> </ul> </li> <li>• Description</li> <li>• Submission Date (<b>optional</b>)</li> </ul> <p>d) If No: Continue to 2.</p>
Drug Information	<p>Minimum dosage per patient</p> <p>Maximum dosage per patient</p>	<p>Clarified to include the unit in the response so the dosage is clearer when submitting the application.</p>	No change	<p>Minimum dosage per patient (include unit)</p> <p>Maximum dosage per patient (include unit)</p>
Drug Information	<p>3. Have you applied for a Healthcare Common Procedure Coding System (HCPCS) code? (Yes/No)</p> <p>a) If Yes: What are the details of your HCPCS application?</p> <ul style="list-style-type: none"> <li>• Submission Date</li> <li>• What is the status? (<b>optional</b>) <ul style="list-style-type: none"> <li>▪ Approved</li> <li>▪ Pending</li> </ul> </li> </ul> <p>b) If No: Continue to 4.</p> <p>4. List all Healthcare Common Procedure Coding System (HCPCS) code(s) or CPT codes associated with the drug.</p>	<p>Minor updates to clarify HCPCS application status is now required and to clarify both HCPCS Level I and II codes should be submitted.</p>	No change	<p>4. Have you applied for a Healthcare Common Procedure Coding System (HCPCS) code? (Yes/No)</p> <p>c) If Yes: What are the details of your HCPCS application?</p> <ul style="list-style-type: none"> <li>• Submission Date</li> <li>• What is the status? <ul style="list-style-type: none"> <li>▪ Approved</li> <li>▪ Pending</li> </ul> </li> </ul> <p>d) If No: Continue to 5.</p> <p>5. Using Healthcare Common Procedure Coding System (HCPCS) Level I (CPT) and/or Level II code(s), list all of the specific procedure(s) and/or services with which the drug is used.</p>
Drug Information	<p>View HCPCS Codes (link)</p>	<p>Updated to provide additional information about HCPCS codes.</p>	No change	<p>HCPCS General Information (link)</p>

Drug Information	<p><i>Notes for applicant:</i></p> <ul style="list-style-type: none"> <li>CPT or Level II HCPCS code that reflects the drug administration procedure code(s) or other procedure code associated with the product.</li> <li>Level II HCPCS code that currently identifies the product/item, including an unlisted HCPCS code (e.g., A, C, J, or Q code). Note: Approval of a drug, biological or radiopharmaceutical for a transitional pass-through payment under the hospital OPSS is not contingent on prior assignment of a national HCPCS code. If no HCPCS code is currently available, please specify the requested code descriptor, including dosage units.</li> </ul>	Updated to clarify a CPT code is required in the application and provided minor wording to clarify discussion of Level II HCPCS codes.	No change	<p><i>Notes for applicant:</i></p> <ul style="list-style-type: none"> <li>HCPCS Level I codes (also known as CPT codes) associated with the specific procedure(s) and/or services with which the drug is used are required to be submitted or the application will be considered incomplete.</li> <li>HCPCS Level II code that currently identifies the product/item, including an unlisted HCPCS Level II code (e.g., A, C, J, or Q code). Note: Approval of a drug, biological or radiopharmaceutical for a transitional pass-through payment under the hospital OPSS is not contingent on prior assignment of a national HCPCS Level II code. If no HCPCS Level II code is currently available, please specify the requested code descriptor, including dosage units.</li> </ul>
Cost Information	<p><i>Note for applicant: Current cost of the drug to hospitals should be the actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in kind.</i></p>	Provided an additional note for clarifying reporting of cost for select types of products to avoid confusion when submitting this information.	No change	<p><i>Notes for applicant:</i></p> <ul style="list-style-type: none"> <li>For products where the amount of drug product represented by an NDC varies (ie. Radiopharmaceuticals, clotting products), please report the cost per each unit (cost can be reported as WAC and/or AWP).</li> <li>Current cost of the drug to hospitals should be the actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in kind.</li> </ul>
Cost Information	<ul style="list-style-type: none"> <li>What is the compendium where published? (please include either REDBOOK™ or Medi-Span Price Rx among the compendium in which the price is published)</li> </ul>	Updated to proper names of listed compendia and clarified the two provided compendia are examples.	No change	<ul style="list-style-type: none"> <li>What is the compendium where published? (For example, RED BOOK™ or Medi-Span® Price Rx®.)</li> </ul>
Volume and Utilization	<ol style="list-style-type: none"> <li>Identify all projected units/volume by site of service that reflects one full year of utilization based on the drug's package size. <ul style="list-style-type: none"> <li>Indicate the specific projected timeframe for the utilization.</li> <li>Packaging Size</li> <li>Amount <ul style="list-style-type: none"> <li>Hospital Outpatient</li> <li>Ambulatory Surgical Center (ASC)</li> <li>Hospital Inpatient</li> <li>Physician Office</li> <li>Other (optional)</li> </ul> </li> </ul> </li> </ol>	Updated wording for clarity and to include percentage, in addition to volume, to understand the full picture of estimated utilization.	No change	<ol style="list-style-type: none"> <li>Identify all projected units/volume by site of service that reflects one full year of utilization based on the drug's package size. <ul style="list-style-type: none"> <li>Indicate the specific projected timeframe for the utilization.</li> <li>Packaging Size (include units)</li> <li>Site of Service in Volume and Percentage <ul style="list-style-type: none"> <li>Medicare Hospital Outpatient</li> <li>Medicare Ambulatory Surgical Center (ASC)</li> <li>Medicare Hospital Inpatient</li> <li>Medicare Physician Office</li> <li>Medicare Other Identify (optional)</li> <li>Total (Percentage should equal 100%)</li> </ul> </li> </ul> </li> </ol>
Attachments	Product catalogs	Updated to correct spelling.	No change	Product catalogs