Drug Pass Through Crosswalk

Paper Application Question #	Paper Application Language	Modifications	Web Application Content	Comments

1	The trade name and generic name of the product.
	Page: 2
		As Is	Provide information about the drug
			• Drug Trade Name
			• Generic Name
			• Drug Type (dropdown)
			  ○ Biological
			  ○ Radiopharmaceutical
			  ○ Viscosupplements
			  ○ Other	

2a.	A detailed description of the product including the following: Composition and clinical indication(s). Page: 2	As Is	Provide information about the drug What is the composition and clinical indication(s) of the drug? (Text area, max character length: 2000)	
2b.	The form in which it is supplied (e.g., solution, tablet, etc.). Page: 2	As Is	Provide information about the drug What is the drug's form? (radio button) • Solution • Tablet • Other If other: Describe other (free text)	
2c.	Method of administration (e.g., intramuscularly, intravenously, orally, subcutaneously, sublingually, etc.). Page: 2	As Is	Provide administration and dosage information about the drug Administration (dropdown) • Intramuscularly • Intravenously • Orally • Subcutaneously • Sublingually • Other If other: Describe "other"	
2d.	Manner of packaging (e.g., volume, dosages, concentrations per ml, per tablet, per mCi, etc.). Page: 2	As Is	Provide information about the drug What is the manner of packaging (e.g., volume, dosages, concentrations per ml, per tablet, per mCi, etc.)? (Text area, max character limit: 2000)	
2e.	The usual minimum dosage per administration for one patient. Page: 2	As Is	Provide administration and dosage information about the drug • Minimum dosage per patient (Text field)	

Paper Application Question #	Paper Application Language	Modifications	Web Application Content	Comments
2f.	The usual maximum dosage per administration for one patient Page: 2	As Is	Provide administration and dosage information about the drug • Maximum dosage per patient (Text field)	
2g.	The typical dosage per administration for a Medicare patient in the hospital outpatient department per one day. Specifically, based on a 70kg Medicare patient, what would be the typical dosage for this drug in the hospital outpatient setting for one day? Page: 2	As Is	Provide administration and dosage information about the drug • The typical dosage per administration for a Medicare patient in the hospital outpatient department per one day. Specifically, based on a 70kg Medicare patient, what would be the typical dosage for this drug in the hospital outpatient setting for one day? (Text area, max character limit: 2000)	
2h.	How dosages are measured. Page: 2	As Is	Provide administration and dosage information about the drug • How are dosages measured? (Text area, max character limit: 2000)	
3.	A copy of the most recently published AWP and Wholesale Acquisition Cost (WAC), including the date of publication and compendium where published (please include either RED BOOK™ or Medi-Span Price Rx among the compendium in which the price is published). Page: 2	As Is	Please upload a copy of the most recently published Average Wholesale Price (AWP) and Wholesale Acquisition Cost (WAC) • What date was publication? (Date picker) • What is the compendium where published? (please include either RED BOOKTM or Medi-Span Price Rx among the compendium in which the price is published) (Text field) 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)	
4.	Average Sales Price (ASP) for specified units of the drug. Page: 2	As Is	If available, what is the average sales price (ASP) for each unit of the drug? Enter unit cost details and click to add them to the list (optional) • Unit (Text field) • $ Current cost (numeric entry)	

Paper Application Question #	Paper Application Language	Modifications	Web Application Content	Comments
5.	The current cost of the drug, biological or radiopharmaceutical to hospitals, that is, the actual cost paid by hospitals 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 actual cost to hospitals for a specific product specified in terms of dosage and concentration. Page: 2	As Is	What is the current cost of the drug to hospitals? • Current total cost (numeric entry) • Minimum dosage cost (numeric entry) • Maximum dosage cost (numeric entry) • Typical dosage cost (numeric entry)	
6.	The date of commercial market availability or date of sale of first unit. Page: 3	As Is	Provide information about the drug What is the date of commercial market availability or date of sale of first unit? (Date picker)	
7.	List the Healthcare Common Procedure Coding System (HCPCS) code(s) associated with the product. a. CPT or Level II HCPCS code that reflects the drug administration procedure code(s) or other procedure code associated with the product. b. 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 OPPS 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. Page:3	As Is	List all Healthcare Common Procedure Coding System (HCPCS) code(s) or CPT codes associated with the drug • Enter HCPCS or CPT codes below (Text field)	

Paper Application Question #	Paper Application Language	Modifications	Web Application Content	Comments
8.	Usage: Projected units/volume by site of service that reflects one full year of utilization based on the drug's package size. Indicate the specific projected timeframe for the utilization (e.g., Jan 1–Dec 31, 2015, or April 1, 2015–March 30, 2016, etc.). If a drug is packaged in multiple sizes, list projections for every single package size. List projected units separately by the following categories for every single package size: a. Medicare Inpatient Hospital b. Medicare Outpatient Hospital c. Medicare Physician's Office d. Medicare Ambulatory Surgical Center e. Other sites of services (e.g., Federally Qualified Health Centers, Rural Health Clinics, Veterans Administration Hospitals, etc.). Page: 3	As Is	Identify all projected units/volume by site of service that reflects one full year of utilization based on the drug's package size. Indicate the specific projected timeframe for the utilization • Date (from) (Date picker) • Date (to) (Date picker) Packaging Size (units) (Text field) Hospital Outpatient - Amount (numeric entry) Hospital Inpatient - Amount (numeric entry) Ambulatory Surgical Center (ASC) - Amount (numeric entry) Physician Office - Amount (numeric entry) Other (optional) - Amount (numeric entry) • If user enters a value for other: Define what the "Other" utilization category is Explanation (Text field)	
9.	A copy of the FDA New Drug Application or Biologics License Application approval letter. Only for viscosupplements for osteoarthritis may a Premarket Approval (PMA) letter be submitted. Page: 3	As Is	Upload your FDA approval letter FDA approval letter Provide some details about the selected file • Page numbers(s) (Text field) • Summarize the supporting information contained in this file: (Text area, max character limit: 2000) What date was the FDA approval? Approval date (date picker)	
10.	A copy of the FDA label (package insert). Page: 3	As Is	- Not specifically listed in application. Users can attach documentation throughout the application. -	The applicant can attach this item in the Attachments section at the end of the application, but CARIS does not specifically ask for this document.

Paper Application Question #	Paper Application Language	Modifications	Web Application Content	Comments

11.	Applicant name(s), company name, 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 applicant name, company 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: 3
		As Is	Who is the primary contact? & Who is the secondary contact?
			• First name (Text field)
			• Middle Name (optional) (Text field)
			• Last name (Text field)
			• Phone number (Text field)
			• Email address (Text field)
			• Mailing Address line1 (Text field)
			• Mailing address line2 (optional) (Text field)
			• City (Text field)
			• State (dropdown)
			• Zip code (Text field)
			• Organization (Text field)
			• Relationship (dropdown)
			  ○ Consultant
			  ○ Manufacturer
			  ○ Other
			  ▪ If other: Describe "other" (Text field)	

12.	Other information as CMS may require or that the applicant believes CMS may need to evaluate the application. Page: 3		- Not specifically listed in application. Users can attach documentation throughout the application. -	

Paper Application Question #	Paper Application Language	Modifications	Web Application Content	Comments
			List all referencing files and documents • 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) Note: Click to view important files and documents to include (opens in a pop up window) Items to Include Marketing Materials • Booklets, pamphlets, and brochures • Product catalogs • Price lists and package inserts • Case Studies FDA Documentation • FDA decision letter • FDA New Drug application • Biologics License application approval letter • Premarket Approval (PMA) letter • FDA label • Package insert • Carton label Cost Documentation • Itemized cost lists • Manufacturing invoices • Pricing guides	

	This item is not included in the paper application.	**New in MEARIS**	Have you applied for a Healthcare Common Procedure Coding System (HCPCS) code?
			What are the details of your HCPCS application
			• Submission date (date picker)
			• What is the status (optional) (Radio button)
			  ○ Approved
			  ○ Pending	

Paper Application Question #	Paper Application Language	Modifications	Web Application Content	Comments
	This item is not included in the paper application.	**New in MEARIS**	Have you completed other CARIS 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)	