OMB: 0910-00756
Exp. Date: 5/31/2029

Early Payor Feedback Program Overview Request

**** Please be advised that this information will be shared with the payors you would like feedback from. Omit proprietary information that you wish to be kept confidential. Complete this document with 12 pt. Times New Roman font and provide 3-5 pages of information (no addendums, no attachments).*

The following information may be helpful to payors when evaluating your feedback request:

- Please list the company name, contact person, and device name.
- What is the device and how does it work?
- What condition is the device intended to treat or diagnose? What is the incidence and prevalence of the condition? How will the device be used in the continuum of care of patients? What are the proposed indications for use?
- What is the current FDA regulatory status and pathway for the device (e.g., PMA, 510(k), de novo, HDE, or IDE)? What is the FDA tracking number for submissions related to the device? If you have not submitted anything to FDA, please describe the conversations your company has already had with the agency about the device under consideration. What is the CE Mark status in Europe? What clinical experience, if any, has been obtained with the device?
- If interested in Medicare coverage, please state the benefit category that your device falls under.
- What is/are the current device/procedure/service this new device is intended to replace our augment in the US (or UK)? What are the alternative treatments, tests, or management strategies that are available?
- What comparative evidence to the current standard of care will be/has been generated as part of the development program for this device/procedure/service?

This section applies only to the requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The public reporting burden time for this collection of information is estimated to average 2 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Operations
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

- What is the current plan to gather supporting clinical evidence (e.g., a pivotal clinical trial and/or registry intended to gather data following FDA approval) including relevant information such as the study design, inclusion/exclusion criteria, clinical evaluations, proposed primary and secondary endpoints and associated timeframes, assumptions for power calculations, anticipated number of enrolled subjects, and total follow-up duration.
- In addition to the end-points that you will be measuring for FDA to demonstrate safety and efficacy, what additional health outcomes will you be measuring to support coverage?
- What, if any, previous interactions have occurred with payors/HTA(s)?
- What specific questions and topics would you like to address during the Pre-Submission meeting with FDA and payer/HTA(s)?
- What additional information do you feel the payer would like to have to provide constructive feedback about the medical device during a Pre-Submission meeting?
- When do you expect to submit your Pre-Submission to CDRH?