**AAO-HNS Anti-Lobbying Policy:**

Applicants and other interested parties must not engage in “lobbying” for or against new technology pathway applications, or any requests for coding changes made therein. “Lobbying” means unsolicited communications of any kind made at any time (including, except as permitted below, during meetings) for the purpose of attempting to improperly influence members of the AAO-HNS Physician Payment Policy (3P) Workgroup, other AAO-HNS Committee members, or Board of Directors. Any communication that can reasonably be interpreted as inducement, coercion, intimidation or harassment is strictly prohibited. Violation of the prohibition on lobbying may result in sanctions, such as the application being suspended or barred from further review for consideration of support by AAO-HNS. Information that accompanies a new technology pathway application, presentations or commentary during an in person or teleconference meeting with staff and 3P leaders, and responses to inquiries from AAO-HNS staff do not constitute “lobbying”.

1. Name of applying party and contact information.
2. Are you an AAO-HNS individual member? If so, please list any AAO-HNS subspecialty committees that are in support of the application.
3. Are you an industry representative? If so, are you a partner with the AAO-HNS? (Please include type of partnership.). Note: We request that industry partners submit this application prior to requesting formal support of other subspecialty societies, as any affected subspecialty societies will be represented during AAO-HNS review.
4. Names and affiliations of any consultant(s) you are currently working with on your new product/service.
5. Names of AAO-HNS members with whom you are currently working on your new product/service (e.g., physicians involved in clinical trial, publication of literature, assistance with strategy, etc.).
6. Are there members of other specialties which may also perform this procedure/service? If so, please list.
7. Name of service and brief description of procedure.
8. Please provide a proposed clinical vignette that describes the typical patient who would receive the procedure(s)/service(s), including diagnosis and relevant conditions. Also, please include the time you estimate the service to take (skin to skin time).
9. Is the service/procedure FDA approved for the specific use of applicable devices or drugs? If not currently FDA approved, please include the expected date of approval.
10. Reason for application/background information.
11. Is this a request for a revision of an existing code, request for revaluation of an existing code, request for a new code, or inquiry regarding proper coding for a new technology?
12. If the request is for a new CPT code, are you requesting a Category I or Category III code? If Category I, what existing CPT codes may be impacted or performed in conjunction with this service?
13. Is the service/procedure performed by many physicians/practitioners across the United States? If not widely practiced, provide names of individuals/centers providing this service.
14. What is the typical site of service (e.g., hospital outpatient, office, etc.) and population (e.g., adults, children under the age of 17 years, etc.) for each proposed NEW code(s)?
15. Is the service/procedure currently being reported by one or more existing codes? If so, which codes are being used?
16. Have you, or your organization, applied for a CPT code or HCPCS code previously? If so, what was the outcome of that request? Was the Academy apprised of the request and/or supportive to CMS or the CPT Editorial Panel in writing or otherwise?
17. **For Category III code requests, are the following AMA CPT Editorial Panel requirements met?**

* The procedure or service is currently or recently performed in humans; **AND at least one of the following additional criteria has been met:**
* The application is supported by at least one CPT or HCPAC advisor representing practitioners who would use this procedure or service; **OR**
* The actual or potential clinical efficacy of the specific procedure or service is supported by peer reviewed literature which is available in English for examination by the Editorial Panel; **OR**
* There is a) at least one Institutional Review Board approved a protocol of a study of the procedure or service being performed, b) a description of a current and ongoing United States trial outlining the efficacy of the procedure or service, or c) other evidence of evolving clinical utilization.

1. **For Category I code requests, are ALL of the following AMA CPT Editorial Panel requirements satisfied?**

* All devices and drugs necessary for performance of the procedure or service have received FDA clearance or approval when such is required for performance of the procedure or service.
* The procedure or service is performed by many physicians or other qualified health care professionals across the United States.
* The procedure or service is performed with frequency consistent with the intended clinical use (i.e., a service for a common condition should have high volume, whereas a service commonly performed for a rare condition may have low volume).
* The procedure or service is consistent with current medical practice.
* The clinical efficacy of the procedure or service is documented in literature that meets the requirements set forth in the CPT code change application.

1. **The clinical efficacy of the procedure or service must be documented in literature that meets the requirements set forth in the CPT code change application (new or revised), which includes the following:**

* Is the clinical efficacy of the service/procedure well established and documented in U.S. peer-reviewed literature? If so, please supply electronic copies of references and fill in reference grid below.
* Optimally, 5 references should be submitted, of which at least 3 report the procedure/service in US patient populations.
* At least 1 of the publications must meet or exceed the criteria for evidence level III (i.e., obtained from well-designed, non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies).
* At least 2 articles should report different patient populations or have different, non-overlapping authors. Foreign references are acceptable if published in English and relevant or applicable to US populations.
* Please assign level of evidence for each reference from the table below. Note that, for codes describing new procedures, at least one publication should meet or exceed the criteria for Level III.

**Level of Evidence Table – LOE**

|  |  |
| --- | --- |
| **Level** | **Short Description (based on Oxford Centre 2009)** |
| Ia | Evidence obtained from systematic review of randomized controlled trials |
| Ib | Evidence obtained from an individual randomized controlled trial |
|  | ***Randomized Controlled Trial(s):*** *An epidemiological experiment in which subjects in a population are randomly allocated into groups, usually called study and control groups, to receive or not receive an experimental preventive or therapeutic procedure, maneuver, or intervention. The results are assessed by rigorous comparison of rates of disease, death, recovery, or other appropriate outcome in the study and control groups.* |
| IIa | Evidence obtained from systematic review of cohort studies |
| IIb | Evidence obtained from an individual cohort study |
|  | ***Cohort study(ies):*** *The analytic method of epidemiologic study in which subsets of a defined population can be identified who are, have been, or in the future may be exposed or not exposed, or exposed in different degrees, to a factor or factors hypothesized to influence the probability of occurrence of a given disease or other outcome. The main feature of cohort study is observation of large numbers over a long period (commonly years) with comparison of incidence rates in groups that differ in exposure levels.* |
| IIIa | Evidence obtained from systematic review of case control studies |
| IIIb | Evidence obtained from a case control study |
|  | ***Case-control study(ies):*** *The observational epidemiologic study of persons with the disease (or other outcome variable) of interest and a suitable control (comparison, reference) group of persons without the disease. The relationship of an attribute to the disease is examined by comparing the diseased and non-diseased with regard to how frequently the attribute is present or, if quantitative, the levels of the attribute, in each of the groups.* |
| IV | Evidence obtained from case series |
|  | ***Case-series:*** *A group or series of case reports involving patients who were given similar treatment. Reports of case series usually contain detailed information about the individual patients. This includes demographic information (for example, age, gender, ethnic origin) and information on diagnosis, treatment, response to treatment, and follow-up after treatment.* |
| V | Evidence obtained from expert opinion without explicit critical appraisal |

**Publication Details and Attributes (PDA) Grid**

**Use the following grid for each distinct service requested**

**Applicable Proposed or Existing Code(s) # \_\_\_**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Article #1** | **Length**  **of Follow-up** | **Level of Evidence Based on LOE Table** | **U.S. or Foreign Peer Reviewed** | **Organization Sponsoring Journal** | **Impact Factor** | **U.S. or Foreign Population Studied**  **(REQUIRED)** | **Prospective Study?** | **Total Patients Studied** |
| **Publication Title:**  **Author(s) Name(s):** |  |  | **US**  **Foreign** |  |  | **US**  **Foreign**  **Both**  (If answered both: Provide specific  % of patients **OR** # of patients for both regions)  **Population %**   |  |  | | --- | --- | | **U.S.** | **Foreign** | | **%** | **%** | | **Yes**  **No** |  |
|  | **Population #**   |  |  | | --- | --- | | **U.S.** | **Foreign** | | **#** | **#** | |
| **Year of Publication:** |
| Provide brief description regarding relevance to code change application\* | | | | | | | | |
| **Article #2** | **Length of Follow-up** | **Level of Evidence Based on LOE Table** | **U.S. or Foreign Peer Reviewed** | **Organization Sponsoring Journal** | **Impact Factor** | **U.S. or Foreign Population Studied**  **(REQUIRED)** | **Prospective Study?** | **Total Patients Studied** |
| **Publication Title:**  **Author(s) Name(s):** |  |  | **US**  **Foreign** |  |  | **US**  **Foreign**  **Both**  (If answered both: Provide specific  % of patients **OR** # of patients for both regions)  **Population %**   |  |  | | --- | --- | | **U.S.** | **Foreign** | | **%** | **%** | | **Yes**  **No** |  |
|  | **Population #**   |  |  | | --- | --- | | **U.S.** | **Foreign** | | **#** | **#** | |
| **Year of Publication:** |
| Provide brief description regarding relevance to code change application\* | | | | | | | | |
| **Article #3** | **Length of Follow-up** | **Level of Evidence Based on LOE Table** | **U.S. or Foreign Peer Reviewed** | **Organization Sponsoring Journal** | **Impact Factor** | **U.S. or Foreign Population Studied**  **(REQUIRED)** | **Prospective Study?** | **Total Patients Studied** |
| **Publication Title:**  **Author(s) Name(s):** |  |  | **US**  **Foreign** |  |  | **US**  **Foreign**  **Both**  (If answered both: Provide specific  % of patients **OR** # of patients for both regions)  **Population %**   |  |  | | --- | --- | | **U.S.** | **Foreign** | | **%** | **%** | | **Yes**  **No** |  |
|  | **Population #**   |  |  | | --- | --- | | **U.S.** | **Foreign** | | **#** | **#** | |
| **Year of Publication:** |
| Provide brief description regarding relevance to code change application\* | | | | | | | | |
| **Article #4** | **Length of Follow-up** | **Level of Evidence Based on LOE Table** | **U.S. or Foreign Peer Reviewed** | **Organization Sponsoring Journal** | **Impact Factor** | **U.S. or Foreign Population Studied**  **(REQUIRED)** | **Prospective Study?** | **Total Patients Studied** |
| **Publication Title:**  **Author(s) Name(s):** |  |  | **US**  **Foreign** |  |  | **US**  **Foreign**  **Both**  (If answered both: Provide specific  % of patients **OR** # of patients for both regions)  **Population %**   |  |  | | --- | --- | | **U.S.** | **Foreign** | | **%** | **%** | | **Yes**  **No** |  |
|  | **Population #**   |  |  | | --- | --- | | **U.S.** | **Foreign** | | **#** | **#** | |
| **Year of Publication:** |
| Provide brief description regarding relevance to code change application\* | | | | | | | | |
| **Article #5** | **Length of Follow-up** | **Level of Evidence Based on LOE Table** | **U.S. or Foreign Peer Reviewed** | **Organization Sponsoring Journal** | **Impact Factor** | **U.S. or Foreign Population Studied**  **(REQUIRED)** | **Prospective Study?** | **Total Patients Studied** |
| **Publication Title:**  **Author(s) Name(s):** |  |  | **US**  **Foreign** |  |  | **US**  **Foreign**  **Both**  (If answered both: Provide specific  % of patients **OR** # of patients for both regions)  **Population %**   |  |  | | --- | --- | | **U.S.** | **Foreign** | | **%** | **%** | | **Yes**  **No** |  |
|  | **Population #**   |  |  | | --- | --- | | **U.S.** | **Foreign** | | **#** | **#** | |
| **Year of Publication:** |
| Provide brief description regarding relevance to code change application\* | | | | | | | | |