AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY

AAO-HNS New Technology Pathway Process Application

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 Workgroup (3P), 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. **Are there members of other specialties which may also perform this procedure/service? If so, please list.**

5. **Name of service and brief description of procedure**

6. **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).**

7. **Reason for application/background information**

8. **Is this 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?**

Please return information requested in this application to Jenna Kappel, Director of Health Policy, at JKappel@entnet.org.

9. **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?**

10. **Is the service/procedure FDA approved for the specific use of applicable devices or drugs?**

11. **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.**

12. **Is the service/procedure currently being reported by one or more existing codes? If so, which codes are being used?**

13. **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?**

14. **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 <u>at least one</u> 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.

15. **For Category I code requests, are <u>ALL</u> 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.

16. 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,a nd 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	Type of evidence (based on AHCPR 1992)
Ia	Evidence obtained from meta-analysis of randomized controlled trials
Ib	Evidence obtained from at least one randomized controlled trial
IIa	Evidence obtained from at least one well-designed controlled study without randomization
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study
III	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case control studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities
V	Evidence obtained from case reports or case series

References	Level of Evidence Based on LOE Table	U.S. or Foreign Peer Reviewed	U.S. or Foreign Population Studied	Prospective Study	Total Patients Studied
Article #1 (Author, Title, Journal, Year, Volume and Pages)	*Insert level #*	☐ U.S. ☐ Foreign	☐ U.S. ☐ Foreign ☐ Both	☐ Yes ☐ No	*Insert #*
Provide brief description regarding relevance to CCP*					
Article #2 (Author, Title, Journal, Year, Volume and Pages)	*Insert level #*	☐ U.S. ☐ Foreign	☐ U.S. ☐ Foreign ☐ Both	☐ Yes ☐ No	*Insert #*
Provide brief description regarding relevance to CCP*					
Article #3 (Author, Title, Journal, Year, Volume and Pages)	*Insert level #*	☐ U.S. ☐ Foreign	☐ U.S. ☐ Foreign ☐ Both	☐ Yes ☐ No	*Insert #*
Provide brief description regarding relevance to CCP*					
Article #4 (Author, Title, Journal, Year, Volume and Pages)	*Insert level #*	☐ U.S. ☐ Foreign	☐ U.S. ☐ Foreign ☐ Both	☐ Yes ☐ No	*Insert #*
Provide brief description regarding relevance to CCP*					
Article #5 (Author, Title, Journal, Year, Volume and Pages)	*Insert level #*	☐ U.S. ☐ Foreign	☐ U.S. ☐ Foreign ☐ Both	☐ Yes ☐ No	*Insert #*
Provide brief description regarding relevance to CCP*					

* For each article cited, please provide a brief description of why the specific literature reference is relevant to the CCP (e.g. "This is the hallmark double-blinded controlled study establishing the value of the procedure/service;" "This is a case report describing the procedure/service in detail;" or "This is an opinion statement from a respected authority in the field").