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| 11-0258 AMA electronic-chgo_lh | **DRAFT****AMA Guides® Editorial Change Proposal*** Text Revision, Correction, or Update
* Table Change
* New Content
* Clarifications
 |

**Proposal Submission Requirements**

All AMA Guides® Editorial Change Proposals are reviewed and evaluated by AMA Guides® staff and the AMA Guides® Editorial Panel. Strict conformance with the following is required for review of an editorial change application:

* Submission of a complete application, including all necessary supporting documents;
* Adherence to all deadlines; and
* Cooperation with requests from AMA Guides staff and/or Editorial Panel members for clarification and information.

**General Criteria for Guides Editorial Changes**

All editorial change proposals must satisfy each of the following criteria:

* The proposed editorial change is carefully drafted and conforms to the prevailing style of the A*MA Guides*;
* The terminology and the analytical frameworks used in the proposal are consistent with the World Health Organization’s International Classification of Functioning, Disability, and Health (ICF);
* The structure and content of the proposed editorial change ensures that impairment ratings are transparent, clearly stated, and reproducible, to insure physician interrater reliability;
* The clinical soundness of the proposed editorial change is demonstrated with the best available evidence (described below) except in the case of minor editorial changes (described below).

The following two Proposal Acceptance Criteria are valid through March 2021, unless renewed by the AMA Guides® Editorial Panel.

* + Any proposed methodologies conform to the diagnosis-based grid construct of the *AMA Guides Sixth*; where such grid exists.
	+ The proposed editorial change does not deviate from the unified template of the diagnosis-based grid that is common to each organ system and chapter of the *AMA Guides Sixth,* where such grid exists.

**Evidentiary Requirements**

A proposal for an editorial change must be supported by an evidence-based foundation when possible. When evidence-based medicine is not available, consensus-based medicine developed in a structured Delphi approach may be substituted.

In order of preference, one of the following is required to support each proposed editorial change.

1. Evidence-based medicine documented in peer reviewed articles published in medical journals indexed in PubMed, Web of Science, SCOPUS, or Google Scholar that are classified as Level of Evidence I-IV in the Oxford Centre for Evidence Based Medicine Level of Evidence Table (Appendix A); or
2. Outcomes-based Real-World Evidence (RWE), meaning observational data generated during routine clinical practice and stored in EHRs, medical claims or billing databases, and registries with evidence determined to be of High or Moderate quality using the WHO’s GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) framework (Appendix B); or
3. Other peer-reviewed sources such as specialty society guidelines developed in accordance with the Institute of Medicine standards[[1]](#footnote-1); or
4. Consensus-based decisions developed in a Delphi process[[2]](#footnote-2) endorsed or overseen by a relevant stakeholder professional association or society.

In some cases, evidence may take the form of data or case law that demonstrates inconsistent application of the AMA Guides or a need for clarification of some element. In these cases, evidence of the need to enhance the AMA Guides may include judicial outcomes such as:

1. State-based workers’ compensation impairment rating data that is categorized by CPT code or injury code;
2. Industrial Commissioner (or similar) data on litigated case outcomes when impairment ratings are an issue;
3. Judicial opinions or law journal articles that identify a specific issue of wide and inconsistent impairment ratings for similar conditions.

While this evidence may demonstrate a need for change, it does not necessarily reflect what change is required (i.e., the medicine). In these cases, the AMA Guides Editorial Panel may elect to provide more precise guidance, or may determine that it is necessary to engage a specialty society or other expert advisors to propose specific editorial changes.

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| 11-0258 AMA electronic-chgo_lh |  |
| *Cover Sheet for AMA Guides® Editorial Change Proposal* |
| It is recommended that applicants consult with national medical specialties and/or other relevant stakeholder professional organizations in the development of this application to obtain comments on the implications of the proposed change With recognition of scheduling needs of the specialty societies and other professional organizations, when assistance will be sought, it is highly recommended that the applicant plan for enough time for scheduling such discussions in advance of the application deadline to avoid violation of the AMA Lobbying Policy.  |
| **Date:** |  |  |
| **Change Requested by:** |
| **Name(s):** |  |  |
| **Organization­:** |  |  |
| **Address:** |  |  |
| **City:** |  | **State:** |  | **Zip Code:** |  |  |
| **Telephone:** |  |  |
| **­Email:** |  |  |
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***Please include this cover sheet with your application.***

**Guides® Editorial Change Proposal**

Please complete the following questions as part of your content proposal submission. If more space is required than allotted within this document, please feel free to attach additional documents as required.

1. Indicate the specific reasons why this editorial change is necessary (rationale). For example, “This proposal introduces a new diagnosis, not currently included in AMA Guides”. Or, “The AMA Guides cited an obsolete standard; this proposal updates the Guides to the latest standard”. Or, “New medical evidence suggests that outcomes for [a particular diagnosis] are less favorable than previously thought”.
2. Provide a citation for the text you propose to change in the form such as: 6th Ed, *page 407, Section 15.3c, second paragraph*. Or: *page 406, Table 15-6, Physical Examination row*. If you are proposing new text, please provide the new text and identify its placement relative to existing text, for example: *insert new paragraph on page 407, following the 4th paragraph, which ends with “may vary by region.”* Your submission is not required to be in final copy form.
3. For submissions where the content change is anticipated to be less than three (3) paragraphs, enter the content of the text or table you want to change as it currently appears in print. Then use Microsoft Word “track changes” functionality to show your proposed additions/changes/deletions in a red font. Do not use comments (balloons). Indicate deleted text via strikethrough rather than full deletion. If the change is longer than a single paragraph, and you wish to propose specific “redline” edits, please do so as described above in a separate document that accompanies your submission. If you wish to propose only a conceptual change at this stage, and to utilize AMA editorial resources to draft specific updates, please indicate so by checking the box that indicates “Concept Only” prior to providing your detailed answer. It should be noted that “Concept Only” submissions are subject to the same acceptance criteria as other proposals and will require panel approval of the concept as well as the final manuscript prior to final acceptance.

[ ]  Concept Only

Click here to enter text.

1. For all new and/or revised editorial content, describe the major differences from related editorial content already in AMA Guides.

Click here to enter text.

1. Describe the medical rationale for the proposed change.

Click here to enter text.

1. Describe the impact on relevant stakeholders from the proposed change.

Click here to enter text.

1. Has the clinical validity of the proposed editorial change been documented in literature provided with this application?

[ ]  Yes

[ ]  No (If no, please describe the scientific basis for your proposal in the below textbox. You may be contacted by the AMA Guides Staff to discuss the information that you believe warrants a change and how you will share that information with the Editorial Panel.)

Click here to enter text.

1. Provide a list of any other AMA Guides editorial content (e.g., introductory material) that would need to be revised were this proposal accepted.

Click here to enter text.

1. Please identify the medical specialty societies or other stakeholder organizations that will be affected by the proposed change. Indicate if you have consulted them.

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| ORGANIZATION | CONSULTED? (Y/N) |
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1. Are you aware of any clinical practice guidelines or policy statements that are pertinent to the proposed change?

[ ]  Yes Please provide a citation below.

 Click here to enter text.

[ ]  No

**Supporting Evidence**

Evidence-Based Proposals

If this proposal is evidence based rather than consensus based, the literature requirements set forth below specify the minimum requirements for AMA Guides Editorial Panel (“Panel”) consideration of the application. Panel members review the literature provided and each member makes an independent evaluation as to whether the literature submitted with the application satisfies the criteria for an editorial change. Applicants are urged to submit the strongest literature that supports the application. IMPORTANT: Meeting the minimum literature requirements does not guarantee that the Panel will determine that the proposed change has been adequately determined or supported in the submitted literature. The merit of the application is based on the totality of the information in the application and other relevant information brought to the attention of the Panel.

Minor Editorial Changes

Applicants who seek minor editorial changes (e.g., proposal seeks only editorial improvement of the existing text or a clarifying example), with no change to the impairment rating or its calculation are not obligated to meet the literature requirements. Panel members will review the suggested revision and each Panel member makes an independent evaluation of whether the request satisfies the criteria for “editorial change only” applications. If this request is an “Editorial Only” change, the requestors may choose to not submit literature. If the Editorial Panel determines that supporting evidence is required for the editorial change application, then this application will not be considered by the full Editorial Panel until the necessary evidence is submitted. Do you certify that this proposal constitutes a minor editorial change with no implications to rating changes?

[ ]  Yes

[ ]  No

Publication Details and Attributes (PDA) Grid

Please provide electronic, unrestricted (no digital rights management limitations) PDF or Word documents (and internet addresses, if available) of the peer-reviewed literature submitted to support your application in the “[Publication Details and Attributes Grid](#grid)” (PDA) that follows, specifying the Level of Evidence (LOE) as instructed.

Each item of submitted literature should be entered in the PDA grid as follows:

* 1. Author(s), title, journal, year, volume and page(s)
	2. Level of Evidence (Oxford or GRADE)
	3. Concise “relevance statement”.

**Provide up to 3 references, if references exist.**

Articles submitted with the designation of “Confidential” will not be accepted nor included in the supporting literature reviewed by the AMA Guides Editorial Panel. Abstracts, white papers, advertising, instructional manuals, and non-peer reviewed publications are not allowed to accompany application submissions and will not be accepted as substitutes for full-length journal articles.

Any “in press” manuscripts that are submitted will only be appropriate for consideration by the Panel if accompanied by the letter from the editor/publisher of the applicable journal informing the author that the manuscript has been accepted for publication in its final form, subject only to final copy editing. It is the responsibility of the submitter to ensure that such submission to AMA Guides (despite its very limited use by the Editorial Panel) does not jeopardize publication of the article being considered. Likewise it is the responsibility of the submitter to ensure that the final published study is available to the Panel without restriction.

Well-designed studies submitted for consideration should represent the most informative and compelling peer-reviewed publications that directly support the application. Therefore, applicants should submit studies that are well-designed and executed, ethical in nature, and directly support the editorial change request.

Book chapters and letters to the editor, whether peer-reviewed or not, are welcome to be submitted for review, in addition to the materials listed above.

For applications that request multiple changes, additional literature must be submitted to support all aspects of the requested changes.

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

**Use the following grid for each distinct editorial change requested.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Citation(author(s); title; journal; date; pages) | LOE from Oxford Centre | or | LOE from GRADE | Relevance of Article |
| #1 |  |  |  |  |
| #2 |  |  |  |  |
| #3 |  |  |  |  |

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| \* For each article cited, please provide a description of why the specific literature reference is relevant to the editorial change application (e.g., “this is the hallmark double blinded controlled study establishing the impact of the procedure/service” on function; or “this is a case report describing the appropriate measurement methodology in detail”, or “this is an opinion statement from a respected authority in the field”). |

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If you have you found any publications, in addition to those cited in this Editorial Change Application, which offer conflicting data or different opinions, and that you feel are important for Editorial Panel consideration in evaluating this editorial change application? If so, please provide the literature reference, level of evidence and reason that you consider the publication(s) relevant, and why you excluded them from the articles cited in the PDA Grid.

|  |  |  |
| --- | --- | --- |
| Reference (list Author, Title, Journal, Year, Volume, Pages) | Level of Evidence based on LOE Table | Brief description regarding relevance and why you excluded them. |
| Article #1 | Level # | Describe: |
| Article #2 | Level # | Describe: |
| Article #3 | Level # | Describe: |

Other Comments:

Click here to enter text.

­­­­­­­­­­­­­­ **Legal Requirements**

Notice of Potential Review by Interested Parties

Individuals or organizations that believe they may be affected by a decision of the AMA Guides Editorial Panel on your editorial change application may request review of your application in advance of the AMA Guides Editorial Panel meeting. To ensure transparency in the AMA Guides Editorial Panel process, if the AMA receives a request from an interested party (provided they can demonstrate a valid interest) to review this editorial change application, you will be notified of that request and the identity of the interested party. The complete Editorial Change Proposal (including supporting documentation) will be provided to the interested party for review.

[ ]  **I agree on behalf of myself and the submitting organization.**

### AMA Guides Confidentiality Agreement

In consideration of permission granted to me to participate in the AMA Guides® Editorial Development Process, including participation on the AMA Guides Editorial Panel meeting and ad hoc and standing workgroups/committees established by the Editorial Panel, I agree:

* I will maintain as confidential any and all materials and information I obtain in connection with my participation in the AMA Guides® Editorial Development Process including but not limited to the following, which shall collectively be considered “Confidential Information” and proprietary to the American Medical Association:
	+ AMA Guides Editorial Panel meeting agenda materials;
	+ pre-publication AMA Guides text editorial changes, changes to tables and guideline language, and all related materials;
	+ content scheduled for publication in AMA Guides Newsletter or other AMA Guides products; and
	+ any non-public information disclosed or discussed as part of the AMA Guides Editorial Panel meetings, including the content of editorial change applications and discussions about or evaluations of editorial change applications by the AMA Guides Editorial Panel and AMA Guides workgroups and committees.

Information shall be considered Confidential Information no matter what format it is provided to or obtained by me including but not limited to verbally, electronically or in print media.

* I will use Confidential Information only in connection with my participation in the AMA Guides Editorial process. I will not disclose, distribute or publish Confidential Information to any party in any manner whatsoever without the prior written consent of the AMA; however, designated representatives of specialty societies and relevant stakeholder professional organizations, including their designated consultants and lawyers, may disseminate Confidential Information to their sponsoring organization for internal use within the organization, and only in connection with providing assistance to the organization and/or its Advisor in evaluating AMA Guides editorial change applications. I specifically acknowledge that I will not publish or authorize anyone else to publish Confidential Information in any Web posting, article, newsletter, press report and release, publication, or any other communication.
* I will not use any audio or video recording or photographic device in any manner to record or to copy any Confidential Information, including the meetings and proceedings of the AMA Guides Editorial Panel. I will not remove any notices of copyright, trademark, confidentiality or other conditions on materials obtained by me or take any other action to circumvent the purpose and intent of this Agreement.
* I will provide written and/or verbal disclosures as required prior to addressing any agenda item or issue as to which I, or an immediate family member, has a disclosable interest.
* The AMA Guides Editorial Panel can modify or eliminate language, table entries, or guidelines associated at any time up to the date of publication of an official release of the AMA Guides. AMA Guides Editorial Panel actions are not final until publication of the AMA Guides editorial update. I acknowledge that the early release of Confidential Information, including AMA Guides Editorial Panel actions and any related information, can cause significant problems for physicians, patients, payers, and third parties and could cause irreparable injury to the American Medical Association and others.
* Violators of this Agreement may be barred from participation in the AMA Guides editorial process.

### [ ]  **I acknowledge and agree on behalf of myself and the organization.**

Copyright Assignment

All copyright in and to any works such as text, grids, tables, report forms, descriptions, and guidelines, created by submission of this editorial change application and through the AMA Guides editorial process shall be owned by the American Medical Association. By checking below, I acknowledge the AMA’s copyright and I hereby assign to the AMA any right, title and interest in and to such copyrightable works on behalf of myself and the organization named below.

### [ ]  **I acknowledge and agree on behalf of myself and the organization.**

Statement of Compliance with the AMA Guides Conflict of Interest Policy

**For convenience, key elements of the Conflict of Interest Policy applicable for Presenters are summarized below. The Conflict of Interest Policy in its entirety is controlling (please refer to the** [**Conflict of Interest Policy**](https://www.ama-assn.org/sites/default/files/media-browser/public/physicians/cpt/cpt-conflict-of-interest-june-2017.pdf) **in its entirety):**

**Every applicant for an editorial change application or their designee(s) making a presentation (“Presenter”) to the AMA Guides Editorial Panel on an editorial change application shall disclose all individual and corporate disclosable interests held by the Presenter, or immediate family member, but without regard to financial limit. Verbal disclosures are required prior to addressing the Panel about any agenda item or issue as to which the Presenter, or immediate family member, has a disclosable interest. Any disclosable interest that is a material individual interest or a material corporate interest (“material” means a disclosable individual or corporate interest that exceeds $10,000 USD in the aggregate within the past two years and in the case of corporate interests, is reasonably expected to exceed $10,000 in the next two years) must be designated as such in the disclosure by checking the box next to the disclosable interest identified below.**

**NOTE: Disclosures of interests does not include [i] any interest that is limited to providing clinical services to patients (including the service for which an editorial change application has been submitted), or [ii] providing professional educational services or interpretative advice on proper use of the AMA Guides.**

**DISCLOSABLE INTERESTS INDICATE (“X”) IF MATERIAL:** [ ]

**If no disclosable interests, type and enter “NONE.”**

[ ] I affirm that I have read and understand the [AMA Guides Conflict of Interest Policy](#conflictofinterest). I have no individual or corporate disclosable interests at this time, except as disclosed above. I understand that I have a continuing obligation to comply with the AMA Guides Conflict of Interest Policy and will update this form, as needed, prior to submission or discussion of any editorial change application. Disclosure does not restrict or limit the ability of the presenter to support the applicant’s editorial change application

Attestations

I hereby attest to each of the following:

1. I understand that my editorial change request will be evaluated by the AMA Guides Editorial Panel and AMA Guides staff. I will cooperate with requests from the AMA Guides Editorial Panel and AMA Guides staff for clarification and additional information.
2. I understand that it is recommended that I consult with national medical societies and other relevant stakeholder professional organizations to obtain comments on the proposal and its implications ***prior to the submission*** of this application.
3. I understand that this application is not complete until I and the other co-applicants (if applicable) named on this editorial change application have electronically completed the **AMA Guides Confidentiality Agreement**, the **Copyright Assignment** and an **AMA Guides Conflict of Interest Policy Compliance Statement**. Failure to submit a signed application or the requested documentation within the requested timeframe will prevent AMA Guides staff from processing my editorial change request. If the editorial change request is not submitted in time for the upcoming Panel meeting, I will need to resubmit an application for consideration by the Panel at a later date.
4. I understand that after I submit this editorial change request, I may withdraw this application up until the time that the AMA Guides Editorial Panel takes up the agenda item at a AMA Guides Editorial Panel meeting. At that time, the discussion falls under the authority of the Editorial Panel, and the application may not be withdrawn.

### [ ]  **I acknowledge and agree on behalf of myself and the organization.**

When submitting a request for multiple editorial changes, a response should be provided for each new editorial type. The applicant may need to create (copy/paste) additional lines and pages as needed. Once the application is completed, submit the form electronically to the AMA. (See information on submitting applications on the last page for [instructions on uploading](#Submission_instructions) applications, literature supplements and other documents.)

**If the AMA Guides Editorial Panel determines that additional information or evaluation is warranted, consideration of your application may be tabled until later during that meeting or postponed until time certain (a specific future AMA Guides meeting) or to time uncertain.**

**Final Attestations**

|  |
| --- |
| By signing below, I hereby attest to each of the following: |
| 1. the information provided in this application is true, correct and complete, and, to the best of my knowledge, accurately depicts current clinical and or surgical practice;
 |
| 1. I have read the AMA Statement on Lobbying, AMA Guides Code Proposal Instructions, and the AMA Guides Confidentiality Agreement, and have and will comply;
 |
| 1. I have authority to sign this application in both an individual and organizational capacity.
 |

|  |  |
| --- | --- |
| Signature |  |
| Print Name |  |
| Organization (if applicable) |  |
| Date |  |

If you have any questions concerning the requirements on the AMA Guides® Editorial Change Application, please consult with AMA staff prior to the submission of your application.  An incomplete application may delay processing of your request and may cause it to be returned.

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| **Appendix A****Level of Evidence (LOE) Table** <https://www.cebm.net/2009/06/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/>

|  |  |
| --- | --- |
| **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 |
| IIbIIc | Evidence obtained from an individual cohort studyEvidence obtained from outcomes research or ecological studies  |
|  | ***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 |

 |

**Appendix B**

**GRADE (Grading of Recommendations, Assessment, Development, and Evaluation)**



Gaitán-Duarte, Hernando Guillermo, Rodríguez-Hernández, Andrea Esperanza, Arévalo-Rodríguez, Ingrid, Angel-Müller, Edith, López-Ramos, Hugo Enrique, & Estrada-Mesa, Jesús Santiago. (2013). Clinical practice guideline for syndromic management of patients with sexually transmitted infections and other genital tract infections - 2013. *Revista Colombiana de Obstetricia y Ginecología*, *64*(2), 126-177. Retrieved August 15, 2019, from <http://www.scielo.org.co/scielo.php?script=sci_arttext&pid=S0034-74342013000200007&lng=en&tlng=en>.

**Instructions for Submitting your AMA Guides® Editorial Change Application**

**An online submission process will be forthcoming. In the interim:**

* Email the application and any signature pages to **guidesproposals@ama-assn.org**.
* **The AMA will contact you to collect your supporting evidence and other documentation.**
1. Institute of Medicine. 2011. *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/13058> [↑](#footnote-ref-1)
2. Helmer-Hirschberg, Olaf, Analysis of the Future: The Delphi Method. Santa Monica, CA: RAND Corporation, 1967. <https://www.rand.org/pubs/papers/P3558.html> [↑](#footnote-ref-2)