EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES

I. Definition
The Academy employs an evidence based methodology for developing guidelines. Evidence-based guidelines are herein defined as documents that support clinical decision making and contain systematically developed recommendations based on a search and review of available literature.

The clinical questions addressed by the literature search will be indicated in the guideline, and the strength of evidence and specific references supporting clinical recommendations will be clearly indicated.

II. Funding of Guideline Development
Direct funding of evidence-based guideline production by medical and pharmaceutical industry is prohibited.

III. Conflict of Interest
Guidelines will be developed and approved in accordance with the conflict of interest policy outlined in Appendix A.

IV. Selection of Topics
The Clinical Guidelines and Research Committee proposes clinical areas for guideline development to the Council on Science and Research, and then the Board of Directors for approval. Selection of clinical areas for guideline development will be responsive to member needs, and the advocacy, policy, and educational concerns of the Academy.

Criteria to facilitate topic selection include, but are not limited to:
- Degree of public health importance (high prevalence, significant morbidity)
- Perceived or documented variation in practice patterns (impact on quality of care and patient safety)
- Potential for performance measure and MOC module development
- Timeliness of topic for informing and improving provider decision making
- Availability and strength/quality of evidence to produce clinical recommendations
- Area addresses multiple aspects of dermatology practice scope
- An area in which increased dermatologic attention and involvement would be helpful for the specialty
- Relevant to Medicare and Medicaid programs
Relevant to managed care programs
Availability of interventions with high societal or economic cost

V. Work Group Appointment and Activity
The clinical question(s) and clinical recommendations for Board-approved guideline topics are developed by an appointed Work Group. Academy staff develop draft technical report(s) that address the clinical question(s) and inform recommendations.

The Work Group is appointed by the Clinical Guidelines and Research Committee after a review of Academy conflict of interest full disclosure forms. The decision to allow or prohibit Work Group appointment is determined by deliberation over the nature of disclosed financial and non-financial conflicts of interest, relevancy, and potential impact to the guideline topic as a parallel to member’s clinical expertise and/or leadership.

A Work Group must minimally include 51% of experts without relevant financial conflict of interest. The Chair of the Work Group is prohibited from having any relevant financial conflict of interest, unless the expertise and leadership is deemed necessary by the Clinical Guidelines and Research Committee. In this instance, a co-chair with no relevant financial conflict of interest will be appointed. The chair or co-chair must also remain free of relevant conflict of interest for at least one year after guideline publication.

Academy staff and any contracted medical writer(s) supporting guideline development must provide full disclosure to the Work Group Chair prior to commencing guideline activity. Academy staff and the medical writer are prohibited from having any relevant financial conflicts of interest related to the guideline topic.

Work Group members for whom a relevant conflict has been identified will be required to recuse from discussions, drafting, and voting on clinical recommendations or guideline text related to the identified conflict, unless otherwise requested by the Work Group Chair. Disclosure updates will be obtained from all Work Group members, medical writer(s) and Academy staff at regular intervals throughout the development process. The guideline text will indicate the full disclosure and recusal history for all listed authors to include the Work Group, Clinical Guidelines and Research Committee Chair or named liaison, and affiliated staff.

The Clinical Guidelines and Research Committee may dismiss and/or appoint members to the Work Group to ensure the timely completion of a guideline, the integrity of the evidence based methodology and conflict of interest policy, and that all relevant areas of clinical expertise are reasonably addressed.

VI. Review Process

Expert Review
The Work Group produces a draft guideline which is submitted to the Clinical Guidelines and Research Committee for their approval, or if requested, further revision. This process may be repeated as necessary. Once approved by the Clinical Guidelines and Research Committee, the draft guideline is released to the membership for their review.
Membership Review
The draft guideline (marked ‘confidential’) is posted on the Academy Web site and may be accessed by member login only. Members will be given 10 business days to comment on the draft guideline, and are required to have a current disclosure statement with the Academy. Comments received in the absence of a current disclosure may be considered at the discretion of the Work Group Chair.

Comments are compiled in a standard format and sent to the Work Group Chair for review and response to accept, reject, modify or request further information. Receipt of, and action on individual member comments is conveyed to the member in writing.

Council on Science & Research Review
Following the member comment period and incorporation of modifications to the draft guideline, the guideline is presented to the Council on Science and Research for their review and approval. Once approved by the Council, the draft guideline may be sent to the Board of Directors for final approval.

V. Final Approval and Publication
A final draft is approved by the Council on Science and Research and submitted for approval to the Board of Directors. Upon approval by the Board of Directors the guideline is posted on the Academy Web site and submitted to the editor of the Journal of the American Academy of Dermatology indicating the date of Board approval.

The first author is the Chair(s) of the Work Group, followed by the names of the other members of the Work Group and medical writer in an order determined by the Work Group Chair(s), the Chair of the Clinical Guidelines and Research Committee or named liaison, and staff as appropriate.

Board-approved guidelines will be submitted to the National Guideline Clearinghouse to support professional and public access.

VI. Review and Revision of Guidelines
Board approved evidence-based guidelines will be considered for reaffirmation, update, or sunset at least every 5 years based on a review of published literature since guideline publication. The Clinical Guidelines and Research Committee will determine if the revisions are of such substance to require the review of the entire membership. Final Board approval will be required for guideline modifications that are deemed substantive enough to prompt member review.

VII. Guideline Dissemination and Implementation
Board-approved guidelines may be further developed into clinical guideline derivative products. Guideline derivative products (GDP) are defined as tools used to promote awareness of Academy clinical guidelines, and aid dermatologists in the incorporation of evidence-based guideline recommendations into clinical practice. These tools may be produced in various formats including, but not limited to, print, electronic, web-based or multi-media. GDP may also include translation of the published clinical guideline into another language.
In so far as the development and distribution of these GDP may be financially supported by medical and/or pharmaceutical industry, activities related to GDP are governed by the AAD’s Administrative Regulation/Code for Interactions with Companies, and the Governance Policy on AAD Principles of Corporate Relationships. The AAD Principles stipulate that the Academy also follows the Standards for Commercial Support of Continuing Medical Education of the Accreditation Council for Continuing Medical Education (ACCME). In addition, the following principles are also to be understood with respect to industry support for GDP:

- Acceptance of support is not intended to convey Academy approval, endorsement, certification, acceptance or referral of any particular company or any product or service manufactured or distributed by a corporate supporter.

- The Academy will not accept funds from industry for the development of GDP until the primary clinical practice guideline has been developed, Board-approved, and accepted for publication. However, through acceptable channels outlined in the above Administrative Regulations and Governance Policies the Academy Development Department may engage in discussions with industry to develop a plan for future support of GDP activity concurrent with the development of the guideline. Industry communication with AAD Guideline staff and Work Group members and/or any exchange of unapproved guideline content are expressly prohibited. The preferred form of funding for GDP is an educational grant except for CME-certified activities in which an educational grant is required.

- The Academy will retain complete editorial control over GDP content, and such content must be free of commercial bias and company influence.

A written statement will be placed on all GDP acknowledging that the content of the GDP was developed solely by the Academy, independent of industry influence.
Appendix A: Conflict of Interest Management in Guideline Development

The following tables indicate the processes to evaluate and resolve identified conflicts of interest for guideline contributors following initial and periodic full disclosure during guideline development.

The review of full disclosure will include deliberation on the nature of each disclosed interest, and the relevancy and potential impact of each relationship relative to the guideline topic and the importance of the member’s expertise (and leadership in the case of Chair appointments). The relevancy of each interest will be determined by the reviewing body, but is generally defined as any financial or other incentive which can reasonably be perceived by an independent observer as a potential source of bias within the guideline scope.

Inquiries may be made by the evaluating body in order to determine if a prospective guideline contributor is willing to resolve certain conflicts prior to making a final decision. Periodic review of updated disclosure information will minimally occur prior to each meeting of the guideline contributor (conference call or in-person) where guideline materials for development or approval will be discussed.

If the primary reviewing group is unable to reach a decision based on the provided information, the decision may be referred to the next Academy governing level or to the Ethics Committee for a final determination.

Any implementation or change in the management of potential conflicts will be communicated to the member in writing and conveyed to the entirety of the Work Group, Clinical Guidelines and Research Committee (CGRC), Council on Science and Research, Board of Directors, and Ethics Committee as necessary. The management and resolution of conflicts will be documented in the summation reports for all meetings where activity related to guideline development or approval will be discussed. The disclosures and recusal history for all Work Group members, medical writer(s) and affiliated staff will be included in the draft guideline and published with the Board approved text.

Published guidelines will also contain the following standard conflict of interest statement to promote transparency:

The American Academy of Dermatology (AAD) strives to produce clinical guidelines that reflect the best available evidence supplemented with the judgment of expert clinicians. Significant efforts are taken to minimize the potential for conflicts of interest to influence guideline content. Funding of guideline production by medical or pharmaceutical entities is prohibited, full disclosure is obtained and evaluated for all guideline contributors, and recusal is used to manage identified relationships. The AAD conflict of interest policy summary may be viewed at www.aad.org.
<table>
<thead>
<tr>
<th>Guideline Contributor</th>
<th>Disclosure</th>
<th>Evaluation</th>
<th>Initial Management</th>
<th>Monitoring</th>
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</table>
| Work group chair(s)   | Required prior to appointment | By the entire CGRC;  
- The Chair and/or Co-Chair may not have relevant financial relationships. |  
- **Work Group chair appointment permitted**: no relationships disclosed, or disclosed information is not a possible source of bias.  
- **Work Group chair appointment prohibited**: relevant relationships are unacceptable and could lead to inappropriate bias.  
- **Work Group chair appointment permitted with exception**: relevant relationships are noted, but the need for expertise and leadership outweighs potential conflicts; a co-chair with no relevant financial interest is appointed. Chair responsibilities are permitted with recusal required for discussions and the formation of clinical recommendations relevant to the possible bias.  
- **Referred for further review and decision** |  
- **Chair responsibilities permitted**: no relationships are disclosed or disclosed information is not a possible source of bias.  
- **Chair responsibilities prohibited**: relevant relationships are unacceptable and could lead to inappropriate bias even with presence of co-chair. Member may be requested to step down to work group member or have appointment withdrawn at CGRC’s discretion. Another work group member is asked to serve as chair/co-chair at the discretion of the CGRC.  
- **Chair responsibilities permitted with exception**: relevant relationships are noted, but the need for expertise and leadership outweighs the potential conflicts, and will be mitigated by the co-chair. Chair responsibilities are permitted with recusal required for discussions and the formation of clinical recommendations relevant to the possible bias.  
- **Referred for further review and decision** |
| Work group members    | Required prior to appointment | By the CGRC in consultation with the work group chair(s) at the CGRC’s discretion.  
- The work group must be minimally comprised (>51%) of members with no relevant financial relationships. |  
- **Work Group appointment permitted**: no relationships are disclosed or disclosed information is not a possible source of bias.  
- **Work Group appointment prohibited**: relevant relationships are unacceptable and could lead to inappropriate bias.  
- **Work Group appointment permitted with exception**: relevant relationships are noted, but the need for expertise outweighs potential conflicts. Work group responsibilities are permitted with recusal required for discussions and the formation of clinical recommendations relevant to the possible bias.  
- **Referred for further review and decision** |  
- **Work group responsibilities permitted**: no relationships are disclosed, or disclosed information is not a possible source of bias.  
- **Work group responsibilities prohibited**: relevant relationships are unacceptable and could lead to inappropriate bias; appointment to work group rescinded.  
- **Work group responsibilities permitted with exception**: relevant relationships are noted, but the need for expertise outweighs the potential conflicts. Work Group responsibilities are permitted with recusal required for discussions, and formation of clinical recommendations relevant to the possible bias.  
- **Referred for further review and decision** |
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| CGRC Chair            | Required prior to appointment | By Chair, Council on Science and Research | • CGRC chair appointment recommended; no relationships are disclosed or disclosed information is not a possible source of bias.  
• CGRC chair appointment not recommended; relevant relationships are deemed unacceptable and could lead to inappropriate bias for significant portions of CGRC agenda.  
• CGRC chair appointment recommended with exception; relevant relationships are noted, but the need for expertise and leadership outweighs the potential conflicts. Chair responsibilities are permitted with recusal required for discussions and the approval of guidelines relevant to the possible bias; another CGRC member serves as temporary chair at the discretion of the Council chair.  
• Referred for further review and decision | • Chair responsibilities permitted; no relationships are disclosed, or disclosed information is not a possible source of bias.  
• Chair responsibilities prohibited; relevant relationships are unacceptable and could lead to inappropriate bias for significant portions of the CGRC agenda. Council chair may make recommendation that chair appointment be rescinded.  
• Chair responsibilities permitted with exception; relevant relationships are noted, but the need for expertise and leadership outweighs the potential conflicts. Chair responsibilities are permitted with recusal required only in areas relevant to the possible bias; another CGRC member serves as temporary chair at the discretion of the Council chair.  
• Referred for further review and decision |
| CGRC Members          | Required prior to appointment | By the Council on Science and Research; | • CGRC appointment recommended; no financial relationships are disclosed or disclosed information is not a possible source of bias.  
• CGRC appointment not recommended; relevant relationships are unacceptable and could lead to inappropriate bias.  
• CGRC appointment recommended with exception; relevant financial or other relationships are noted, but the need for expertise outweighs the potential conflicts. CGRC responsibilities are permitted with recusal required for discussions and the approval of guidelines relevant to the possible bias.  
• Referred for further review and decision | • CGRC responsibilities permitted; no relationships are disclosed or disclosed information is not a possible source of bias.  
• CGRC responsibilities prohibited; relevant relationships are unacceptable and could lead to inappropriate bias; full recusal required. Council chair may make recommendation that appointment be rescinded if relationships may significantly interfere with CGRC activity.  
• CGRC responsibilities permitted with exception; relevant relationships are noted, but the need for expertise outweighs potential conflicts. CGRC responsibilities are permitted with recusal required only in areas relevant to the possible bias.  
• Referred for further review and decision |
| Staff                 | Required prior to commencing literature identification and review. | By Work Group Chair  
• Staff may not have any relevant financial relationships. | • Staff responsibilities permitted; no financial relationships are disclosed or disclosed information is not a possible source of bias.  
• Staff responsibilities prohibited; relevant relationships are unacceptable; alternative staff member used for guideline. | • Staff responsibilities permitted; no relationships are disclosed or disclosed information is not a possible source of bias.  
• Staff responsibilities prohibited; relevant relationships are unacceptable; alternative staff member assumes literature review. |
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<td>Medical Writer (MW)</td>
<td>Required prior to appointment</td>
<td>By entire Work Group</td>
<td>MW appointment permitted: no financial relationships are disclosed or disclosed information is not a possible source of bias.</td>
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<td>The MW may not have any relevant financial relationships.</td>
<td>MW appointment prohibited: relevant relationships are unacceptable and could lead to inappropriate bias.</td>
<td>MW responsibilities prohibited: relevant relationships are unacceptable; contract is terminated.</td>
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<td>Members</td>
<td>Upon desire to comment on a draft guideline</td>
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<td>Council on Science and Research</td>
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Appendix B- Acceptance of Externally-Produced Guidelines

The Clinical Guidelines and Research Committee will consider review and acceptance of evidence-based clinical guidelines of care produced by other professional organizations when relevant and appropriate to the mission and interests of the American Academy of Dermatology (AAD). Acceptance of guidelines will be considered in selected circumstances when the Academy seeks to utilize another organization’s guideline in support of these interests in lieu of undertaking its own guideline on the same topic.

Considerations for Acceptance of Externally-Produced Evidence-Based Guidelines:

1. Only evidence-based guidelines, such as documents that have been accepted for inclusion in the National Guideline Clearinghouse to support clinical decision making will be considered.

2. The guideline should not duplicate an existing AAD guideline or a guideline that is in development.

3. Guidelines proposed for acceptance will be reviewed by the Clinical Guidelines and Research Committee and result in a recommendation and rationale for one of the following courses of action:
   - Accept entire guideline
   - Accept selected section(s) of the guideline
   - Do not accept guideline

   A companion document that details the outcome of this review process may be created by the Committee as necessary.

4. Recommended guidelines, as well any draft companion document, are posted on the Academy Web site and may be accessed by member login only. Members will be given 10 business days to comment on the candidate guideline/companion document, and are required to have a current disclosure statement with the Academy. Comments received in the absence of a current disclosure may be considered at the discretion of Committee Work Group Chair.

   Comments are compiled in a standard format and sent to the Work Group Chair for review and response to accept, reject, modify or request further information. Receipt of, and action on individual member comments is conveyed to the member in writing.

5. Guidelines recommended for acceptance, in whole or in part, along with any draft companion document, will be forwarded to the Council on Science and Research, and then the Board of Directors for consideration and approval.

6. Acceptance of such evidence-based guidelines will be reviewed periodically and extended if appropriate, or rescinded as necessary based on sunset of guidelines, withdrawal from National Guideline Clearinghouse, or revisions to guidelines that are not in alignment with available scientific literature or Academy interests.