

## FAQs for AHFS Oncology Expert Committee Members

### 1. *What are the preferred qualifications for Committee members?*

Clinical oncology specialists, including representatives from the medical, pharmacy, and nursing disciplines, are identified and invited to serve on the AHFS Oncology Expert Committee. Candidates who express an interest are asked to provide a copy of their curriculum vitae for review and consideration by the American Hospital Formulary Service Drug Information (AHFS DI) staff.

#### **Qualifications (listed by specialty)**

##### *Medicine:*

- Board-Certified in Oncology; preference is given to those who have a board certification in both oncology and hematology.
- At least 5 years of clinical experience; preference is given to those who have direct involvement with clinical research.
- Demonstrated area of specialty, through clinical practice, research, or publications and/or presentations.

##### *Pharmacy:*

- Board-Certified in Oncology (BCOP) or completion of a specialty residency in oncology.
- At least 5 years of clinical experience; preference is given to those who have contributed to the medical literature or have given presentations on oncology-related topics or who have direct involvement with clinical research.
- Current ASHP member; preference is given to those who also are members of the Hematology/Oncology Pharmacy Association (HOPA).

##### *Nursing:*

- Oncology Certified Nurse (OCN).
- At least 5 years of clinical experience; preference is given to those who have contributed to the medical literature or have given presentations on oncology-related topics or who have direct involvement with clinical research.
- Preference is given to those who have served in a leadership capacity in national or local Oncology Nursing Society (ONS) chapters.

### 2. *How many members are appointed to the Committee and what is the composition of the Committee?*

Up to 15–20 Committee members, including physicians, pharmacists, and nurses, may be appointed. If a vacancy occurs during a term, a replacement appointment will be made. The number of Committee members is reviewed periodically to ensure that membership is adequate for the number of reviews being conducted. AHFS publishes a list of all Committee members on the AHFS website ([www.ahfsdruginformation.com](http://www.ahfsdruginformation.com)).

**3. *How long is the term of appointment? Do Committee members receive compensation?***

Committee members are appointed for 3-year terms. No compensation is provided to Committee members, but the American Society of Health-System Pharmacists (ASHP) is responsible for costs associated with conducting off-label use reviews.

**4. *How often are Committee members asked to participate in off-label use reviews?***

AHFS anticipates that Committee members will be asked to participate in a few off-label use reviews each year. Committee members are selected to participate in reviews on a rotating basis, although specific individuals may be selected based on their areas of expertise. If necessary, Committee membership can be expanded to accommodate a growing number of off-label use reviews.

**5. *What is the review process, specifically, what are the roles/responsibilities of the AHFS staff and the Committee members?***

Potential off-label uses are identified by AHFS staff through either an internal process (i.e., ongoing literature review, advice of the Committee) or an informal external request. Once a potential off-label oncology use is selected for review, AHFS staff review and evaluate the available evidence, draft an evidence table and narrative summary, and propose a Level of Evidence (strength of evidence). Committee members selected to participate in the off-label use review receive these materials, the primary supporting reference(s), and a ballot. The Committee members are asked to independently review the materials, vote on the proposed Level of Evidence, and select a Grade of Recommendation for the proposed off-label use from the 4 categories codified by AHFS. Committee members are encouraged to provide comments in support of their vote and recommendation. Once ballots are received, the results of the vote, all ballot comments, and a proposed consensus Grade of Recommendation are incorporated into a second ballot to establish a consensus recommendation. Rarely, the need for reballotting may occur. All comments provided on ballots and in support of recommendations are compiled and recorded in the Final Determination without attribution to specific individuals. Decisions resulting from balloted determinations made by the Committee cannot be overturned by AHFS staff.

The preferred method for handling deliberations and for communications is e-mail. In rare instances, a Committee member may be contacted directly via e-mail or phone to resolve a particular issue. Deliberations do not involve face-to-face meetings.

**6. *What else is required of Committee members?***

Upon appointment to the Committee, all individuals are required to complete a Confidentiality Agreement Form as well as Conflict of Interest Disclosure forms for themselves, their spouse, and any minor children. Conflict of interest disclosures must be updated at least every 3 years thereafter. In addition, prior to each off-label use review, Committee members selected to participate in the review are required to update this disclosure information.

**7. *What are the requirements for disclosing potential conflicts of interest? How do potential conflicts affect participation on the Committee?***

All individuals (Committee members, AHFS staff, consultants) who substantively participate in the development, review, or disposition of an off-label oncology determination of medical acceptance are required to disclose direct and indirect financial interests that are relevant to matters considered by the Committee. These individuals are asked to provide financial information for themselves, their spouse, and any minor children as it relates to the following types of interests:

- Salary and other payments (employment, consultant, honoraria, advisor fees, and grants/contracts/CRADAS; teaching, speaking and writing activities; eye witness compensation).
- Equity interests (stocks, investments, or other ownership rights for which the member had direct control regarding the allocation of interests [excludes mutual funds, investment trusts]).
- Intellectual property rights (patents, copyrights, trademarks, and royalties).

Prior to each off-label use review, AHFS staff screens Committee members' current disclosure information and selects individuals with no direct or indirect conflicts of interest involving themselves, their spouse, or minor children that are relevant to the off-label use being reviewed. The nature, including amount, of any interest is considered, as outlined in the "AHFS Conflict of Issue and Disclosure Policy" posted on the AHFS website. In some cases, AHFS staff may grant a waiver permitting a Committee member to participate in an advisory capacity if their expertise is deemed necessary, but the Committee member is not permitted to participate in the review of clinical material or vote on the determination. Committee members may recuse themselves at any time during an off-label use review by notifying AHFS in writing of this decision.

**8. *Will my financial disclosure information be made public?***

Conflict of interest and disclosure policies for balloted determinations made by the Committee follow the definition of a publicly transparent process for identifying potential conflicts of interest as established in Section 414.930(a) of the Code of Federal Regulations (CFR). AHFS also has implemented enhancements to meet the desirable characteristics of compendia for use in determining medically accepted indications of drugs and biologics in anticancer therapy as recommended by Medicare Evidence Development and Coverage Advisory Committee (MedCAC).

Therefore, each published Final Determination identifies all individuals who participated substantively in the development, review, or disposition of that determination, and includes a statement summarizing the management of recognized conflicts of interest for these participants. All efforts are made prior to each review to select Committee members who do not have conflicts of interest that are relevant to the off-label use being reviewed. In the absence of any recognized relevant conflicts of interest, a statement in the Final Determination indicates that no conflicts of interest were identified for the determination. In the event that a Committee member is excused/recused during the review or voting stages of the determination or a waiver is granted allowing a Committee member to participate in an advisory

capacity, management of the recognized conflict of interest is described in the conflict of interest statement. Individual disclosures captured on the Conflict of Interest forms will *not* be made public unless so compelled by a government or regulatory body.

**9. *What information is included in a final determination of medical acceptance? Where is the determination published?***

AHFS DI has implemented policies and procedures to comply with the conflict of interest and transparency requirements for compendia as established by amended CFR section 414.930(a). In compliance with these requirements, Final Determinations are posted on the AHFS website ([www.ahfsdruginformation.com](http://www.ahfsdruginformation.com)) and include the following information:

- Criteria used to select the off-label use for review
- Name of the drug or drug combination
- Off-label use, to include specific patient population and disease information
- Strength of Evidence, using composite score of strength of supporting literature and strength of end point
- Grade of Recommendation
- Narrative summary of the off-label use, including a description of the regimen, to facilitate consistent interpretation of the off-label recommendation
- Listing of references used as part of the off-label review
- Voting records
- Comments provided by the Committee members
- Listing of all individuals who substantively participated in the development, review, or disposition of the determination
- A statement summarizing the management of recognized conflicts of interest for individuals who participated substantively in the determination process
- AHFS publication date

Comments provided by committee members in support of their votes and recommendations are compiled and recorded in the Final Determination without attribution to specific individuals. Voting results are reported without attribution to specific individuals.

Records pertaining to the publication of a Final Determination made on or after January 1, 2010, are maintained and available for not less than 5 years in accordance with Centers for Medicare and Medicaid Services (CMS) regulations. Such records will remain and be accessible on the AHFS website for a period of not less than 3 years, after which retention of the relevant information will be maintained for an additional 2 years by ASHP, thereby enabling public access to the material upon request.