



GUIDELINES FOR PARTICIPATION IN 2022 SECOND BIANNUAL VIRTUAL HCPCS PUBLIC MEETINGS

The purpose of the virtual public meetings is to provide a forum for the public to present information regarding specific Healthcare Common Procedure Coding System (HCPCS) coding requests for items supplies and services, Medicare benefit Category, and Medicare payment determinations. The virtual public meetings also provide an opportunity for the Centers for Medicare & Medicaid Services (CMS) to obtain public reaction to CMS' preliminary coding, Medicare benefit category, and Medicare payment determination recommendations.

Occasionally CMS will establish temporary HCPCS codes ("K" codes) for supplies and other products for which a national code has not yet been developed. CMS is committed to migrating these codes, when appropriate, into permanent HCPCS code categories. Beginning with the First Biannual (B1) 2023 HCPCS Level II Coding Cycle, CMS will begin using the public meeting process promulgated through regulations to announce any plans it has to migrate K codes. The final rule outlining this process (86 FR 73902) is available at

<https://www.cms.gov/medicare/medicare-fee-for-service-payment/dmeposfeesched>.

Role of the Virtual Public Meetings for New Requests Relative to the Overall HCPCS Coding Process

The agenda for the virtual public meetings consists of summaries of HCPCS Level II coding requests for items, supplies and services submitted through the standard HCPCS coding review and recommendation process. CMS' preliminary recommendations, Medicare benefit category and Medicare payment determinations regarding coding requests, including specific items on the virtual public meeting agenda can be viewed in advance of the virtual public meeting

on CMS' HCPCS website at:

<https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings>.

The virtual public meetings are open to the public. The meetings typically have been attended by representatives of medical equipment manufacturers and suppliers; government relations, regulatory and compliance specialist personnel from various provider organizations; industry consultants; and CMS and other federal government staff. Applicants who submitted a HCPCS Level II code request for a product that appears on the public meeting agenda are welcome to attend; however, their attendance is not mandatory. CMS may reconsider its preliminary coding, Medicare benefit category, and Medicare payment recommendations in light of any new information presented at the public meetings and written comments submitted by the deadline. CMS maintains the HCPCS Level II code set and is the final decision-making authority concerning requests for HCPCS Level II codes. Medicare benefit category and Medicare payment determinations are not binding on non-Medicare payers.

The virtual public meetings are designed for applicants and others to present additional information, clarify issues, and offer supporting or opposing perspectives regarding CMS' preliminary recommendations. Final coding, Medicare benefit category, and Medicare payment decisions are not made at the public meetings. CMS reserves the right to change its preliminary decision following the public meeting. Final decisions may or may not model the preliminary recommendations. Please be aware that the assignment of a HCPCS code, Medicare benefit category, or Medicare payment amount does not guarantee or imply that a product or service is covered by any insurer. General information about the CMS' HCPCS coding process, including the standard HCPCS code request format and detailed instructions can be found on CMS' HCPCS Level II website at: www.cms.gov/medhcpcsgeninfo. The update of the HCPCS code system is

available as a Public Use File and can be downloaded at:

<https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS>.

All potential meeting participants and other stakeholders are advised to review the public meeting agendas at:

<https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings>.

Comments and inquiries will be accepted when emailed to HCPCS@cms.hhs.gov by 5:00 p.m. eastern time (ET), on the date of the virtual public meeting at which the request that is the subject of the comment appears on the agenda for discussion.

Virtual Meeting Dates: Tuesday, November 29, 2022, 9 a.m. to 5 p.m. ET, Wednesday, November 30, 2022, 9 a.m. to 5 p.m. ET, and Thursday, December 1, 2022, 9 a.m. to 5 p.m. ET

Virtual Meeting Location: The November 29-December 1, 2022 HCPCS public meetings will be held virtually and are available for remote attendance only via Zoom. Individuals who plan to attend one or more of the virtual public meetings and require special assistance must register and request special assistance services by 5 p.m., ET on Tuesday, November 22, 2022.

Deadline for Primary Speaker Registration and Presentation Materials: The deadline for primary speakers to register and submit any supporting PowerPoint presentations, as well as any relevant studies published after the date the applicant submitted its HCPCS code application, is 5 p.m. ET, Tuesday, November 22, 2022. All primary speakers must register by the registration deadline at: https://cms.zoomgov.com/webinar/register/WN_v9r9lfW_QZimHUNq_AXrg

Deadline for 5-Minute Speaker Registration: The deadline for 5-minute speakers to register for the meeting is 5 p.m. ET, Tuesday, November 22, 2022. All 5-minute speakers must register by the registration deadline at:

https://cms.zoomgov.com/webinar/register/WN_v9r9lfW_QZimHUNq_AXrg

Deadline for Registration for all Other Attendees: All individuals who plan to attend the virtual public meetings to listen, but do not plan to speak, must register to attend, using the link at: https://cms.zoomgov.com/webinar/register/WN_v9r9lfW_QZimHUNq_AXrg

Attendees can attend more than one meeting. The deadline to register for each public meeting is the date of that public meeting.

Deadline for all Registrants Requesting Special Accommodations: Individuals who plan to attend one or more days of the virtual public meetings and require special assistance must register and request special assistance services by 5 p.m. ET, Tuesday, November 22, 2022.

Deadline for Submission of Written Comments: In addition to the primary speaker presentation materials noted above, CMS will accept written comments from any stakeholder pertaining to a HCPCS code application or agenda item, including the preliminary Medicare benefit category and Medicare payment determinations, scheduled for discussion at the public meetings. The deadline for submission of written comments pertaining to a specific HCPCS code application or agenda item is 5 p.m. ET, on the day of the date of the virtual public meeting at which the applicable HCPCS code application or agenda item is scheduled for discussion.

Written comments are only accepted when emailed to: HCPCS@cms.hhs.gov.

Selecting Agenda Items for Public Meetings: Items are placed on the public meeting agenda for new requests if the application for the item was complete and submitted timely through CMS' HCPCS Level II application process in the current coding cycle or as identified by CMS for public consideration.

Virtual Public Meeting Registration Information: Prior to registering to attend a virtual public meeting, all potential participants and other stakeholders are advised to review the public meeting agendas at

<https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings> which identify our preliminary coding, Medicare benefit category, and Medicare payment determinations and the date each item will be discussed. All potential participants and other stakeholders are also encouraged to regularly check the HCPCS section of the CMS website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings> for publication of the draft agendas, including a summary of each HCPCS code application, our preliminary coding, Medicare benefit category, and Medicare payment determinations.

The HCPCS section of the CMS website also includes details regarding the public meeting process for new revisions to the HCPCS code set, including information on how to join the meeting remotely, and guidelines for an effective presentation. The HCPCS section of the CMS website also contains a document titled “Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures,” which is a description of the HCPCS coding process, including a detailed explanation of the procedures CMS uses to make HCPCS coding determinations.

When CMS refers to a HCPCS code or HCPCS coding application above, CMS may also be referring to circumstances when a HCPCS code has already been issued but a Medicare benefit category and/or payment has not been determined. At this meeting, CMS will provide preliminary Medicare benefit category and payment determinations for HCPCS codes that were effective October 1, 2022 or earlier, as well as for items that will be considered during this public meeting for coding actions, where applicable. CMS is working diligently to address Medicare benefit category and payment determinations for new items and services that may be DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or

splints, casts, and other devices used for reductions of fractures and dislocations under Medicare Part B. Please check the CMS website listed above for the final agenda.

Required Information for Registration: The following information must be provided when registering online to attend:

- Name
- Organization/Company Name
- Email address
- Any special accommodation requests (which, as stated above, will be considered if the registration is submitted by 5:00 p.m., ET, Tuesday, November 22, 2022);
- Whether the registrant is a "primary speaker" or "5-minute speaker" for an agenda item, and if they have a PowerPoint presentation if they are a primary speaker for an agenda item.
- Primary speaker must be the applicant or designated by the entity that submitted the HCPCS coding request.

Additional Information:

1. Primary Speakers:

Each applicant that submitted a HCPCS code application(s) that will be discussed at the virtual public meetings is permitted to designate one primary speaker per agenda item. As stated above, CMS will accept PowerPoint presentations and relevant studies published after the date the applicant submitted its HCPCS code application if those materials are emailed to:

HCPCS@cms.hhs.gov by 5:00 p.m., ET, Tuesday, November 22, 2022. Due to the timeframe needed for the planning and coordination of the HCPCS virtual public meetings, materials that are not submitted in accordance with these deadlines cannot be accommodated.

All presentation materials should not exceed 10 pages/slides (each side of a page counts as 1 page). Relevant studies that were published after the date the applicant submitted the HCPCS code application are not subject to this page limit.

Fifteen minutes is the total time interval for each presentation. In establishing the public meeting agenda, we may group multiple, related requests under the same agenda item. Each agenda item may have one primary speaker.

The primary speaker must email a brief written summary (one paragraph) of their comments and conclusions to: HCPCS@cms.hhs.gov, by 5 p.m. ET, on the day of the date of the virtual public meeting at which the HCPCS code application or agenda item is scheduled for discussion.

Every primary speaker is required to disclose any financial ties to the manufacturer of the item that is the topic of the HCPCS code application or the agenda item, as well as any competitors of the manufacturers of the item, at the beginning of their presentation at the meeting and in their written summary. This includes any payment, salary, remuneration, or benefit provided to that speaker by the applicant.

2. 5-Minute Speakers:

As noted above, the deadline for registering to be a 5-minute speaker is 5:00 p.m., ET, Tuesday, November 22, 2022. The 5-minute speaker must email a brief written summary (one paragraph) of their comments and conclusions to: HCPCS@cms.hhs.gov, by 5 p.m. ET, on the day of the date of the virtual public meeting at which the HCPCS code application or agenda item is scheduled for discussion. CMS will not accept any other written materials from a 5-minute speaker. Due to time constraints and the desire to stay on schedule, CMS has the authority to limit the number of 5-minute speakers so that each agenda item does not exceed 30 minutes.

Every 5-minute speaker is required to disclose any financial ties to the manufacturer of the item that is the topic of the HCPCS code application or the agenda item, as well as any competitors of the manufacturers of the item, at the beginning of their presentation at the meeting and in their written summary. This includes any payment, salary, remuneration, or benefit provided to that speaker by the applicant.

3. Timeframes:

Because it is difficult to anticipate whether presenters will fill their allotted time period (e.g., 15 minutes for primary speakers; 5 minutes for 5-minute speakers), CMS cannot commit specific items to specific timeframes, but can only estimate the amount of time that may be needed. As a result, meetings may end earlier than the designated time.

Due to time constraints and the desire to stay on schedule, CMS has the authority to limit the number of 5-minute speakers so that each agenda item does not exceed 30 minutes.

4. Guidance to Speakers for an Effective Presentation:

Based on experience, CMS has established the following tips for an effective presentation:

A. Information Helpful to CMS:

React specifically to the individual coding, Medicare benefit category, and Medicare payment determination recommendations and state whether you support or disagree with it. If you disagree with the recommendation, please provide substantiating information and explanation and offer a recommendation for CMS to consider in the final determination. Focus on factual information and supporting documentation. The public meeting forum is an opportunity to provide additional information for CMS to fully evaluate its preliminary recommendation.

The focus of your presentation should be to explain to the audience why you agree or disagree with CMS' preliminary recommendation. For example, if the preliminary

recommendation is that the product that is the subject of your application is adequately described by existing HCPCS code categories, and you disagree, provide the reasons for why you disagree, along with substantiating information. It is also helpful to describe who would and would not benefit by the use of the product.

B. Information not Beneficial to CMS:

HCPCS codes identify categories of like items. The assignment of a HCPCS code does not guarantee or imply that an item or service is covered or separately payable by any insurer. HCPCS coding decisions and Medicare reasonable and necessary coverage determinations under Section 1862 of the Social Security Act (or other relevant statutory provisions) are completely separate processes.

Blanket dismissal of coding recommendation(s) or reiterating the original request without responding directly to the relevant preliminary coding recommendation, Medicare benefit category, and Medicare payment determinations and decision rationale reduces CMS understanding of a commenter's concerns about the recommendation or how/why it should be changed.

C. Timing of Presentations:

Speakers may not take more than the amount of time allotted (15 minutes for primary speakers, 5 minutes for 5-minute speakers). Speakers may not give away, assign, or yield unused time. Only the moderator may call speakers. In fairness to speakers, as well as other participants, the moderator will end all presentations at the end of their allotted time. Therefore, CMS recommends you rehearse and time your presentations to ensure that key points are made within the allotted time. Due to time constraints and the desire to stay on schedule, CMS has the authority to limit the number of 5-minute speakers so that each agenda item does not exceed 30 minutes.

D. Written Comments from Meeting Attendees Who are not Speakers:

Written comments from anyone who is not a primary speaker or 5-minute speaker will only be accepted when emailed to: HCPCS@cms.hhs.gov before 5 p.m., ET, on the date of the virtual public meeting at which the HCPCS code application that is the subject of the comments is discussed.

For Further Information: For further information, please reach out to the HCPCS team at HCPCS@cms.hhs.gov.

FAQs:

1. Who may attend the public meetings?

The public is invited to attend CMS' virtual public meetings.

2. Is attendance mandatory for applicants who have an item on the agenda?

No. Attendance is voluntary, and attendees are not required to present. Regardless, if an applicant attends the virtual public meeting, their agenda item(s) will be presented with a description of the request and the CMS preliminary recommendations including the Medicare benefit category and Medicare payment determinations published in the agenda on the official HCPCS website at

<https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings>, and public comments will be invited.

3. Are decisions made at the virtual public meetings?

No. CMS' virtual public meeting forum provides an opportunity for a requester to speak to CMS and the public, as well as an opportunity for CMS to hear from the requester and interested stakeholders. It is an opportunity for the public and competitors to participate in a discussion of new HCPCS coding requests, Medicare benefit category and Medicare payment determinations and to present their points of view.

Information provided at the virtual public meetings is considered by CMS when making its final decisions.

4. The agenda does not include times. How do participants know exactly when specific items will be discussed?

It is not possible to anticipate with precision whether presenters will fill their allotted time period (e.g., 15 minutes for primary speakers; 5 minutes for 5-minute speakers); therefore, CMS cannot commit specific items to specific time frames. CMS asks that speakers dial in to the meeting at least 10 minutes prior to the start time, plan on the meeting commencing promptly at the designated start time, and wait until it is their turn to speak. Meetings are typically scheduled to adjourn at a specified time; however, because CMS can only estimate the amount of meeting time that will be needed, meetings may adjourn earlier.

Zoom Webinar Joining Information: Virtual Public Meeting Zoom-link:

https://cms.zoomgov.com/webinar/register/WN_v9r9lfW_QZimHUNq_AXrg

After registering, you will get confirmation with instructions on how to join the meeting. Please join the meeting at least 10 minutes before the scheduled start time so you do not miss valuable information. For assistance, you can contact Marvelyn Davis at:

Marvelyn.Davis1@cms.hhs.gov.

Important Notice: Please note that this Zoom Meetings service allows audio and other information sent during the session to be recorded, which may be discoverable in a legal matter. By joining this session, you automatically consent to such recordings. If you do not consent to being recorded, discuss your concerns with the host or do not join the session.