GUIDELINES FOR PARTICIPATION

IN VIRTUAL HCPCS PUBLIC MEETINGS IN JUNE 2022

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 products, 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. The agenda for the first two days of the public meeting includes Medicare benefit category and Medicare payment determinations for items and services described by new HCPCS Level II codes established from 2020 to 2022 as well as additional items added by CMS to address Medicare benefit category or payment determinations. The agenda for the remaining days of the June meeting includes requests for new revisions to the HCPCS code set. The guidelines apply to agenda items found on all four days of the June meeting.

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 coding requests for products, 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 daylight time (e.d.t), 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, June 7, 2022, 9 a.m. to 5 p.m. e.d.t., Wednesday, June 8, 2022, 9 a.m. to 5 p.m. e.d.t., Thursday, June 9, 2022, 9 a.m. to 5 p.m. e.d.t. and Friday, June 10, 2022, 9 a.m. to 5 p.m. e.d.t.

Virtual Meeting Location: The June 7 – 10, 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., e.d.t. on Tuesday, May 24, 2022.

Deadline for Primary Speaker Registration and Presentation Materials: The deadline for primary speakers to register and submit any supporting PowerPoint presentation, as well as any relevant studies published after the date the applicant submitted its HCPCS code

application, is 5 p.m., e.d.t., Tuesday, May 24, 2022. All primary speakers must register

by the registration deadline at: https://cms.zoomgov.com/meeting/register/vJIsd-

mgpz4jEvObPtTKB0-BGiFBQ80CuHQ

Deadline for 5-Minute Speakers Registration: The deadline for registering to be a 5-

minute speaker is 5 p.m., e.d.t., Tuesday, May 24, 2022. All 5-minute speakers must

register by the registration deadline at: https://cms.zoomgov.com/meeting/register/vJIsd-

mgpz4jEvObPtTKB0-BGiFBQ80CuHQ

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/meeting/register/vJIsd-mgpz4jEvObPtTKB0-

BGiFBQ80CuHQ

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 of the virtual public meetings and require special assistance must

register and request special assistance services by 5 p.m., e.d.t., Tuesday, May 24, 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., e.d.t., on 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.

<u>Selecting Agenda Items for Public Meetings</u>

Items are placed on a 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.

<u>A. Required Information for Registration</u>

The following information must be provided when registering online to attend:

- Name

- Company name (if applicable)

- Direct-dial telephone

- Email address

- Any special accommodation requests (which, as stated above, will be considered if the registration is submitted by 5:00 p.m., e.d.t., Tuesday, May 24, 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.

<u>B. Additional Information</u>

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, we 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., e.d.t., Tuesday, May 24, 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 (each side of a page counts as 1 page). Relevant studies that were published after the date the applicant submitted its 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.

On the day of the virtual meeting that the primary speaker attends and speaks on a HCPCS code application, before 5 p.m., e.d.t., the primary speaker must email a brief written summary (one paragraph) of their comments and conclusions to: HCPCS@cms.hhs.gov.

Every primary speaker must also declare at the beginning of their presentation at the meeting, as well as in their written summary, whether they have any financial involvement with the manufacturer of the item that is the subject of the HCPCS code application that the primary speaker presented, or competitors of that manufacturer with

respect to the item. 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., e.d.t., Tuesday, May 24, 2022. On the day of the virtual meeting that the 5-minute speaker attends and speaks, on a HCPCS code application or agenda item, before 5 p.m., e.d.t., the 5-minute speaker must email a brief written summary (one paragraph) of their comments and conclusions to HCPCS@cms.hhs.gov. 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 must also declare at the beginning of their presentation at the meeting, as well as in their written summary, whether they have any financial involvement with the manufacturer of the item that is the subject of the HCPCS code application or agenda item that the 5-minute speaker presented, or any competitors of that manufacturer with respect to the item. This includes any payment, salary, remuneration, or benefit provided to that speaker by the applicant.

C. Additional Virtual 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 January 2020 through April 1, 2022 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.

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.

Guidance to Speakers for an Effective Presentation

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

1. Information that is 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.

2. <u>Information that is Not Beneficial to CMS</u>

HCPCS codes identify categories of like products. The assignment of a HCPCS code does not guarantee or imply that a product 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.

3. <u>Timing of presentations:</u>

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.

4. <u>Written Comments from Meeting Attendees Who are not Speakers</u>

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., e.d.t., 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, Contact:

Sundus Ashar, (410) 786 0750, Sundus.ashar1@cms.hhs.gov, or HCPCS@cms.hhs.gov.

FAQs

1. Who may attend the public meetings?

   The public 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. <u>The agenda does not include times. How do participants know exactly when specific items will be discussed?</u>

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.

<u>Join the Meeting Information</u>

Virtual Public Meeting Zoom-link:

https://cms.zoomgov.com/meeting/register/vJIsd-mgpz4jEvObPtTKB0-BGiFBQ80CuHQ

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.

<u>Important Notice</u>

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.