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Recorded Webinar: Glucose Monitors & Supplies

Contract	DME MAC Jurisdictions B & C
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Good afternoon. Welcome to the glucose monitors and supplies webinar. My name is Tasha Duncan. I am a senior provider outreach analyst with the CGS DME provider outreach and education team. As you may already know, CGS is the DME MAC for Jurisdictions B and C.

During our presentation today, we will discuss the basic coverage criteria for home blood glucose monitors and continuous glucose monitors.

We will also discuss coding and billing, documentation requirements, and then we'll go over some resources that we have available to you.

You may find the LCD, the policy article, and the standard documentation requirements article on our website by looking to the left of your jurisdiction's landing page and clicking on the tab for local coverage determinations. This slide shows direct links for these documents. Please remember that you will not be able to click on these links from the Zoom screen. If you have downloaded the PDF and are following along, you may click on the link within your PDF.

Okay, so now we're going to get into that coverage criteria.

The first and the most basic requirement for coverage of a blood glucose monitor is that the beneficiary has diabetes. The second requirement is that the treating practitioner has concluded that the beneficiary is sufficiently trained in the use of the device prescribed. This may be shown just by the prescription of the appropriate supplies and the frequency of the blood glucose testing. Now if either one of these criteria is not met then the items will be denied as not reasonable and necessary.

This is an example of a medical record and a prescription that meet the basic coverage criteria. In the reason for the appointment, we have the mention of diabetes. This right here. And then we have the diagnosis that's repeated in the assessment down here. And then on the prescription form here we have the instructions for testing that have the, um, that have the frequency ff testing included.

These are the HCPCS codes and descriptions of covered glucose monitors. Blood glucose monitors or BGMs as well as the additional coverage criteria for the BGMs with special features.

You have your standard blood glucose monitor, which is the E0607 and of course that's just your basic coverage criteria. Those 2 special codes are the E2100 and the E2101. As you can see the E2100 requires that the treating practitioner certifies the beneficiary has a severe visual impairment, and by severe visual impairment, they mean the best corrected visual acuity of 20/200 or worse in both eyes.

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Now the E2101 is the BGM with the integrated Lansing blood sample. They can either have that best corrected visual acuity of 20/200 or worse in both eyes, or they can have that the treating practitioner certifies that they have a severe manual dexterity impairment. But as you can see, that's an either/or. It could be both, but coverage for that manual dexterity impairment is not dependent upon the visual impairment. So again, that one's an either/or.

When the blood glucose monitor is covered, most of the accessories and supplies are also covered. The reason I say most is because there are a few items that are not considered reasonable and necessary. We have 2 of those. That's the E0620 which is a skin piercing device. And then there's the related lens shield cartridge, which is the A4257. There are also some non-covered items that are listed in the policy article and that article member is A52464.

This slide outlines the usual utilization for the BGM supplies based on whether the beneficiary is insulin treated or not. Now suppliers must remember that beneficiaries who are insulin treated typically test 3 times a day whereas those for not insulin treated typically test less frequently. Whether they're insulin treated or not. only one spring powered device is covered every 6 months.

In the event that the physician has prescribed more than the typical number of supplies and frequency of testing, provision has been made.

More than usual amounts are covered when the basic coverage criteria has been met and the beneficiary has had an in-person visit with the treating practitioner within 6 months prior to the order, and the treating practitioner has evaluated the beneficiary's diabetes control, and the need for the specific quantity of supplies ordered and documented that the specific quantities of the supplies ordered are reasonable and necessary. But after that first prescription of the supplies that exceed the usual utilization, the treating practitioner must verify that the beneficiary's adhering to the high utilization testing. There must be documentation that the beneficiary is testing at a frequency that corroborates the quantity of supplies dispensed. Now, this can be done with a specific narrative statement adequately documenting the frequency at which beneficiary is testing, or they can have a copy of the beneficiary's testing log. Now these do have to be part of the medical record. The supplier may not directly collect the beneficiary testing information such as the logs. Now if these criteria are not met, the amount in excess will be denied is not reasonable and necessary.

This slide gives an example of insufficient medical records for the high utilization. So here we have the order for testing 5 times a day. The reason for this testing is marked as uncontrolled blood sugar. The supplier did dispense supplies for testing 5, 5 times per day, excuse me. However, the accompanying medical record that we see here shows that the beneficiary's only testing 4 times a day and it also mentions that the beneficiary is not currently on any kind of a diet or exercise program and they're not having any problem with their current medication. So there is no mention of uncontrolled blood sugar or any other issue that may cause a need for testing more than 3 times a day. Therefore, this would be considered insufficient and the reasonable and necessary supplies would be paid and the rest of it would be denied.

Now we've covered the blood glucose monitors or the BGMs, we're going to discuss those Continuous Glucose Monitors or the CGMs.

As many of you know, the COVID-19 PHE ended on May 11th, 2023. Therefore, you would discontinue the use of the CR modifier and the COVID-19 narrative. For any claims with initial dates of service on or after May 12th, 2023. However, the CR modifier and the COVID-19 claim narrative may still be submitted for any rental items, supplies, and accessories for items that were initially provided under the waiver or non-enforcement. For more information on that, you can view the CGS COVID-19 resources page at the link listed on this slide.

Now here's a broader explanation of the information for that CR modifier. Now again, that that, PHE ended on May 11th of 2023. So any initial dates of service on or after May 12th of 2023, the waivers and non-enforcements are ended. Now if the item falls under the scope of a blanket waver or flexibility listed in the chart in the MLN Matters article, which is SE 2011, you may still append that CR modifier for those claims for dates of service, again for March 1st, 2020, through May 11th, 2023. And then claims for continued rental supplies or accessories for items provided during the PHE and under waver of non-enforcement, any dates of service on an after May 12th, 2023 again for this continued supplies and that the initial item was provided under the scope of that blanket waiver or flexibility that's listed in the chart in that MLN article matters article, excuse me, and that is again, MLN SE 2011 that is linked here on this slide. You can find that on our news and publication site. But since that is a, um, not super recent MLN it's easier to just use the link that you see on the slide.

These are 2 classifications of CGMs. There's the non-adjunctive CGM and that's used to make treatment decisions without a stand-alone BGM to confirm the testing results and this type of CGM has been classified as DME since 2017. The other type is the adjunctive CGM. An adjunctive CGM requires the user to verify their glucose levels, or their trends displayed on that CGM with a BGM prior to making any treatment decisions. Now this type of CGM has only been classified as DME since February 28th of 2022 and the only type of adjunctive CGM that meets the DME benefit is one that is incorporated into an insulin pump. There are currently no stand-alone adjunctive CGMs on the US market that meet the definition of DME.

The coverage requirements for CGMs changed as of April 15th, 2023, and became effective as you can see on April 16th, 2023. Now that first requirement is the same as for the blood glucose monitors, that the beneficiary has diabetes. The second requirement is again that the beneficiary's treating practitioner has concluded that the beneficiary or their caregiver has sufficient training in the use of that device, in this case the CGM. And again, a prescription for the item is evidence enough. The CGM must be prescribed in accordance with the FDA regulations for use. The beneficiary has to meet at least one of the requirements from the fourth criteria. Now this is where the policy really changed. Either the beneficiary is insulin treated or the beneficiary has a history of problematic hypoglycemia with documentation of either recurrent level 2 hypoglycemic events that persist despite mulpiple, excuse me, multiple attempts to adjust medications or modify the diabetes treatment plan, or the beneficiary has a history of one level 3 hypoglycemic event. These events are characterized by an altered mental or physical state that requires assistance from a third party for the treatment of hypoglycemia. And finally, for initial coverage, the beneficiary must have had an in person visit with the treating practitioner within 6 months prior to ordering the CGM to evaluate diabetes control and to determine that the first 4 criteria have been met. Then for continued coverage, the beneficiary must have an in person or approved telehealth visit with the treating practitioner every 6 months following the prescription of the CGM in order to document adherence to the CGM regimen and the diabetes treatment plan.

Now here we have the direct links for the Glucose Monitors LCD and the External Infusion Pumps LCD. An adjunctive CGM integrated into an, excuse me, an External Insulin Infusion Pump must meet the coverage requirements of both the CGM and the Insulin Infusion Pump. And again, the LCDs, both of these LCDs, may be accessed by going to our website, going to the left-hand side of the page and clicking on the LCD tab on that navigation menu.

On this slide, we have listed information on how to code CGMs and their supply allowance. So if you are billing a CGM device as an E2103, that device must have received a coding verification review by the Pricing, Data Analysis, and Coding contractor, or the PDAC, and it must be listed on the product classification list. Now the same became effective for CGMs billed as the E2102 on July, July 1st of 2022. The reason that we give you this chart is because we did have some changes in the code starting in January of 2023. So through December, 31st of 2022, if you happen to be billing a claim that was from the time period between April 1st, 2022, and December 31st, 2022, then you would bill with the codes that you see on the left side, and anything from January first going forward you would bill those codes on the right side. Of course, anything after August 9th at this point, 2023 would be, would be past timely because you only have a year to file.

So payment for the E2102 is only available for the CGM receiver function of a rented infusion pump if the beneficiary doesn't already own a CGM receiver or an insulin pump of any kind that is less than 5 years old. The beneficiary may switch from an insulin pump without a CGM receiver to an insulin pump with the CGM receiver feature. However, the switch does not result in an interruption in the period of continuous use for the insulin pump, nor does it justify the start of a new 13 month capped rental period for the insulin pump. There is more information about this in the Supplier Manual Chapter 5 and we've listed the links here on this slide.

The CGM monthly supply allowance for the adjunctive CGMs, that supply allowance is the A4238, includes the CGM sensors and the transmitters.

The supply allowance for the non-adjunctive CGMs, the A4239, includes the CGM sensor, the transmitter, and the home blood glucose monitor and related BGM supplies. The supplier must provide enough supplies to last for 30 days and monitor the usage of those supplies. Now in the event that the beneficiary exhausts the supplies prior to the 30 days being over, the supplier must provide additional supplies before the supply allowance is billed. The beneficiary may use a non-DME receiver in order to display their CGM glucose data, and these would be things such as their personal computer, their cell phone, sometimes they use a tablet.

They can use those devices. However, they must also use a DME receiver or Insulin Infusion Pump. If the beneficiary never uses the DME equipment to display CGM glucose data, then the supply allowance would not be covered by Medicare.

Beneficiaries are allowed to switch From a BGM to a CGM and back. However, BGMs and CGMs are considered same or similar equipment. Therefore the 5-year reasonable useful lifetime does apply. The BGM or CGM receiver may only be replaced in certain instances such as the item is lost, it's stolen or it's irreparably damaged in a specific incident. It may also be replaced if there is a change in the beneficiary's medical condition that necessitates that change. So in that case, it would be something like changing from the regular blood glucose monitor to one with the synthesizer for instance. The beneficiary may switch from the CGM supplies back to the BGM supplies without there being documentation for a change in equipment and the monitor will not be replaced unless one of the previous conditions applies. They must use a monitor that they already own, or they can purchase a new one out of pocket. There is an article that gives some information on switching between the CGM and the BGM supplies and that's available on our website, and we've provided the links on this slide.

On this slide, we have some information about pricing modifiers. It's class 3 devices, the E2102, E2103, and then their allowances, the A4238 and A4239. We'll need the KF modifier appended. Items that are inexpensive or routinely purchased such as the E0607, E2100, and the E2103 and the E2101 will need the NU, RR, and the UE, excuse me, or the UE modifier appended and the CGM billed with the external infusion pump will need that RR modifier appended because that's rental equipment still. Test strips need to be billed with the NU modifier. You may use the Advanced Modifier Engine or AME to determine which modifiers should be used in specific scenarios as well as what order the modifiers should appear on the claim line. We have included the links on this slide. However, you may also get to it by going to the left navigation bar on your jurisdiction's website and clicking on tools and calculators. The Advanced Modifier Engine or AME and other helpful tools are all listed on that page.

This is a slide that just gives information on the modifiers and which HCPCS codes that they apply to as well as giving a description of those modifiers. Now if you do run into any modifiers, and not just for glucose monitors, but for other policies as well; if you run into any modifiers that you don't know the definition for, or you don't understand the use for that, you may find that information by using the modifier description tool which is also available on that tools and calculators page I mentioned a minute ago.

And here we're looking at billing the CGM monthly supply allowance, and although you may provide a 90-day supply at one time, the supply allowance may only be billed 30 days or one month at a time. So no more than one unit of service for the supply allowances A4238 or A4239 is billable per 30 days. You do not need to bill a date span for the CGM supplies. We have an example of how that looks. We use January through March because there are often a lot of errors made during that time span. You provide 90 days' supply, the A4239, on January 1st of 2023. You would bill the from and to date as January first of 2023, 01 01 2023 the next date of service billed would be 01 31 2023 as that's 30 days later. Then the next date of service billed would actually be 03 02 2023 because February only has 28 days and 30 days from January 31st is March 2nd.

So where you have the date span not being required for the CGM supplies, it is required for the BGM testing supplies. You must use a separate date of service in the "from" and "to" columns. The "from" date is the date that the supplies are provided. The "to" date is the last date that the supplies are expected to be used. Now these supplies may be provided and billed 90 days at a time. Dispensing more than a 3-month quantity at a time, regardless of utilization, is not allowed. There's a chart available on our Guides and Charts page to help you with the span dates and narratives and we've provided the direct link on this slide.

When billing excess quantities of supplies that are not supported by documentation, and the supplier wants to collect from the beneficiary, you'll need to use upgrade modifiers. The excess quantity may be billed as an upgrade so make sure that there's a properly executed ABN or Advanced Beneficiary Notice for the excess quantity. You'll bill the total quantity dispensed on one line, on one claim line with the GA modifier, and then on the next line - the following claim line - you're going to bill the reasonable and necessary quantity that's allowed for the policy, and you'll use the GK modifier on that line. These supplies must be billed in the specific order. There is an article available about the use of upgrade modifiers. We provided the JB and JC links on this slide.

I mentioned the PDAC a little bit earlier. If you have a coding question, you'll need to call the PDAC. Again, that's the Pricing, Data Analysis, and Coding contractor. They maintain the durable medical equipment coding system, or DMECS and they have an interactive tool that can be used to search for HCPCS coding information applicable to claim submission, and for valid and invalid HCPCS and their effective and term dates. So DMECS is available, 24 hours a day and 7 days a week and as you can see here, there're some different views that they have available; the DMECS basic, the DMECS training, and the DMECS updated listing; and that is available at the links listed on this slide.

Now that we've discussed the coverage requirements and the coding and the billing, now we will discuss the documentation requirements.

The supplier must have a Standard Written Order for the item being billed prior to claim submission. The required elements of a Standard Written Order, or SWO, are the beneficiary's name or their Medicare beneficiary identifier or MBI; the date of the order; a general description of the item being provided; the quantity of the item if it's applicable; and the treating practitioner's name or NPI; and the treating practitioner's signature. For the general description of equipment, it can be as simple as glucose monitor test trips, or you can even just put the HHCPCS code or the HCPCS code narrative in there. But for supplies, you need to list those supplies separately. A statement of "and supplies" will not suffice. Again, each supply must be listed separately.

So this is a question that we receive a lot. When is a new order for glucose monitors and/or supplies required? A new order is required for all claims for purchases or initial rentals. If there's a change in the prescription, such as a change in the quantity to be dispensed or the frequency of use, then a new order will be needed. A new order is also needed when a monitor is replaced, and finally, a new order is needed when the supplier's unable to get, or to obtain a copy of, a valid Standard Written Order for the supplies from the transferring supplier.

Here we're talking about the documentation in the beneficiary's medical record, and supplier produced records are not considered part of the medical record. Also, neither supplier prepared statements nor physician or practitioner attestations by themselves are considered sufficient documentation of medical necessity even if they've been signed by the ordering physician or practitioner. Therefore, there should be information in the medical records themselves to substantiate the medical necessity for the item, the quantity ordered, and the frequency of use. And then medical, excuse me, the medical records, should include information such as the beneficiary's diagnosis, the duration of the condition, the clinical course of treatment, the prognosis, any functional limitations, and any past experience with related items. Now these are examples of information that should be included, but by no means is this an exhaustive list.

Another question that we get asked a lot is what's needed to prove continued need or continued use? For continued need and continued use there needs to be timely documentation in the beneficiary's medical record, and we define timely as within the preceding 12 month unless the policy dictates otherwise. Some acceptable examples for continued need are a recent order by the treating practitioner for refills, a recent change in the prescription or timely documentation, such as an office visit in the medical record, that shows that the beneficiary's using the items.

Now remember that for a high utilization, there must be documentation that the beneficiary is using the quantity prescribed every 6 months and there must be documentation of an in-person visit with the treating practitioner every 6 months to assess adherence to the regimen and the treating plan, treatment plan, excuse me. For continued use, acceptable documentation would be the timely documentation in the medical record showing usage of the items, supplier records documenting, documenting requests for refill, and supplier records that document the beneficiary's confirmation of continued use of a rental item. So here, you know, we have where the supplier records are actually something that we're looking for because that would show that the beneficiary did request the refill or the replacement, and that they are continuing to use that, that item.

Requests for refills must be documented. So if the beneficiary obtains that refill in person, a signed delivery slip or a copy of the itemized sales receipt is enough to prove that they requested a, a refill.

So, remember that when the beneficiary picks up their items at your location. The delivery slip or receipt should have your address or the address of the store on it as where the item was, was obtained and that's very important because we have actually had to deny claims for that because it shows that the beneficiary picked something up in a store, but it would have the beneficiary's address on it as where the item was obtained. So do make sure that that has the address of that store, or wherever they actually received the equipment or supplies, on that receipt or delivery slip.

So whether the beneficiary sends a written request, the beneficiary calls, or the supplier calls the beneficiary, the documentation should include the beneficiary's name, or the name of their authorized representative and their relationship to the beneficiary; the date of the request; the description of each item that's requested; quantity or the condition; and/ or the condition of each item that the beneficiary has remaining. The contact may take place no sooner than 14 calendar days prior to shipping or delivery. And excuse me, the shipment or delivery may take place no sooner than 10 calendar days prior to the current supply exhausting.

Finally, we will discuss proof of delivery. When the equipment or supplies are delivered directly to the beneficiary, the proof of delivery must include the beneficiary's name and address; a

description of the item or items being delivered; the quantity that was delivered; the date it was delivered; and the signature of the beneficiary or the designee. When a shipping or delivery service is used, and that's going to be method 2, we're looking over here, the proof of delivery must include the beneficiary's name and address; a description of the item or the items being delivered; the quantity delivered; the documentation linking the supplier's delivery documents with the delivery services delivery documents - and that would be something such as a tracking number or a package ID. You'll also need the date delivered and the evidence of that delivery. And for that first method, the date of service would be the date of delivery. And for the second method, the date of service may be the date that the item was shipped, the date that the shipping label was created or the date of delivery. And those three dates should not be significantly different from each other.

Now we're just gonna get into some resources that CGS has available for you.

The first and the most useful resource that we have for you is our myCGS web portal. The myCGS, portal will save you time, money, and resources. There are so many things you can do in the portal. Among the things you can do are you can submit your redetermination and reopening requests, submit prior authorization requests, view and respond to additional documentation requests, and you can look up beneficiary eligibility information. If you aren't already registered for the portal, we have an easy registration guide available on our website and we also have a really great user guide that will walk you through any section of the portal that you need help with. We have provided the direct links on the slide, but you may also access these resources by going to our website and by clicking on my CGS on the left side navigation bar, and then from there you can click on the link on the myCGS landing page or under that navigation bar heading. As you can kind of see from here, these are not PDFs. These are actual web pages where you can click where you need to, which sections you need to go to, so no flipping of pages.

This is some information about our CGS Connect program. CGS Connect is a pre-review program offered by our Medical Review department. Again, this is a pre-review program so you may not use this program for a claim that has already been submitted, and in relation to glucose monitors and supplies, CGS Connect is available for the CGMs, the E2103, that CGM supply allowance, the A4239, and those glucose testing supplies, the A4253, A4256, A4258, and the A4259. This is a voluntary program so it's not something that you have to do. It's something that, really though, that you might want to do. It is a very good program and has prevented a lot of denials and has also prevented a lot of, a lot of, having to go back and do an appeal. You may request clinical review of your pre-claim documentation, again, and you'll be notified that your documentation is supported or unsupported. If the documentation review is being requested after you have already delivered that equipment, then CGS is going to respond in writing within 15 days. If it's being requested before the equipment has been delivered, then CGS will respond either in writing or by phone usually within 10 days. As a suggestion, you could gather your documentation according to the Glucose Monitors and Supplies documentation checklists and then you could submit your case to CGS Connect. Then after you received the supported or unsupported response, you could actually use the response as a training tool for your team members.

This slide actually shows some more resources that we have available and how to access them. Now, remember that navigation bar that I've been telling you about? Well, here's an image of it. It's right here and you'll see this on every jurisdiction page we have. Actually, it's even on the landing page, just shorter there.

So the Supplier Manual, either Jurisdiction B or Jurisdiction C, those are going to be in the News and Publications section. And the rest of the resources that you see on this slide are either going to be available under the Medical Review heading, actually they're usually available under both, excuse me. The Medical Review heading and the Forms Checklists and Guides heading.

Although CGS manages both Jurisdictions B and C, they are 2 separate entities. Now each jurisdiction has its own contact information. Therefore, be sure that you use Jurisdiction B information if you're looking for information on a beneficiary or claim in Jurisdiction B and Jurisdiction C information for a beneficiary or claim in Jurisdiction C. And these are, on this slide, these are the most commonly used resources for Jurisdiction B.

This slide includes our information for Jurisdiction C. Now these slides may be used as a reference, so you can print them out, put them on a desk, anything you want to do. But of course the information is available on our website. So just go to your correct jurisdiction on the website and click the contact information. That's available on that left hand side navigation bar. You could also click the "Contact Us" link at the top of the page or the "Contact Information" tab on, again, on the left side navigation bar and I believe it's also down in the bottom section of our web page.

Now these are the resources for other contractors. We spoke about the PDAC earlier. For any enrollment issues or questions about your NPI or PTAN, you'll need to contact your appropriate

NPE or National Provider Enrollment contractor. The Mississippi River is the dividing line. So NPE East is for suppliers that are east of the Mississippi River and NPE West is for suppliers that are west of the Mississippi River. Then for any issues that you have with electronic submission of claims, or to obtain easy to use software for claim submission, you'll need to contact the CEDI or the Common Electronic Data Interchange.

Now here we have some information that's going to be effective in just a little bit under 2 weeks. So effective on August, 21st of 2023 if you, um, you'll need to do an EFT authorization agreement. Those must be sent to the applicable National Provider Enrollment or NPE contractor for your physical location. The bank information must be applicable for all 4 jurisdictions. And we have that part 3 and financial institution information listed on the EFT agreement, and it must be the same for all jurisdictions. Any forms that are received by the DME MACS between August 21st and November 19th, 2023, will be forwarded to the correct NPE contractor. But on or after November 20th, 2023, the DME MAC is going to reject those forms and return them to the supplier. So remember, and we would hope actually that by the 20th, you remember, that those forms do need to be sent to the NPE contractor.

Now suppliers must contact that appropriate NPE contractor for all inquiries related to EFT, including any questions about EFT correspondence that's sent by the DME MACS or the NPE contractors, the status of your EFT requests or any changes in the EFT information, the DME MAC is not going to have that information, so you'll need to make sure that you do, again, contact your appropriate NPE contractor. There is some information available, and we have provided the link on this slide.

And now, we have information on that transition from the paper checks. And it's supported by, again, 42 code of Federal Regulations -Requirements for enrolling in Medicare. Suppliers must now agree to receive Medicare payment via EFT at the time of enrollment, any revalidation, any change of Medicare contractors, and the submission of an enrollment change request. Submit the CMS, 588 form to receive Medicare payment via EFT. The enrollment contractors will notify you when you must transition from paper checks to the, to EFT. So we have some links available on the slide, again, for that NPE and the NPE West contractor. And then we also have an article here with some information here that's CFR 424.510 that link is available here on this slide.

If you're not on the CGS Electronic Mailing List, you should sign up for it. CGS only sends one email a day through this list unless there is something that needs to be communicated urgently. It is the best way to stay up to date on DME MAC Jurisdiction B and C news. It's very easy to sign up for this list. Just use the link on the slide, or at the top of the web page, or at the bottom of the website, to reach the sign-up page. It doesn't matter which link you use; it's going to go to the same page.

You'll enter your name and business information and choose the contract that best fits your line of business. If you do bill both Jurisdictions B and C, we suggest that you sign up for both lists. You'll get an email from both each day. But there are times that information is relevant to one jurisdiction, but not to the other and that information is only going to be on that relevant email.

We've reached the end of our webinar today, and we thank you all for attending.

