External Infusion Pumps
Open Meeting
May 19, 2020

JODY WHITTEN

Thank you, and good morning, everybody. And welcome to our Virtual Open Meeting regarding the proposed External Infusion Pump LCD, the DL33794. We apologize for our late start and for our technical difficulties. This is our first Virtual Open Meeting. Um my name, again, is Jody Whitten, and I'm with Noridian Healthcare Solutions, and I'll be the moderator for this meeting. We certainly do appreciate you taking the time to join us today and hope all are staying healthy and safe. This meeting is being recorded and the audio as well as the written transcript will be posted to our websites, both CGS and Noridian. All lines are currently muted by our system and will remain muted throughout the Open Meeting. Only registered commenters will be allowed to speak at today's, um today's meeting.

Now this is for the registered commenters. Each um of you will be allotted 20 minutes to make comments. Your line will be open when it's your turn to speak. We do want to make sure you are not on mute within your own system, otherwise we are not going to be able to hear your comments. You should be prepared to begin your comments immediately when called upon. And I'll make sure I let you know; I'll give you a one-minute warning to let you know your time is almost running out. Also, by signing in today, you are giving consent um to the use of your recorded voice and your comments. Please be mindful to not share any protected health information or personal health information um in your verbal comments. And we ask that any comments made today also be submitted in writing. We will provide the information on submitting those written comments at

the end of today's meeting. Also, while only registered speakers will be commenting today, anyone in attendance may submit their comments, and we'll have that um email address and address um at the end of the presentations. So, with that being said, I would like to um turn the meeting over to Dr. Ballyamanda for an overview of the proposed LCD. Dr. Ballyamanda, are you there?

DR. SMITHA BALLYAMANDA

Yes. Can everybody hear me? Can everybody hear me?

JODY WHITTEN

Yes, we can.

DR. SMITHA BALLYAMANDA

Okay. Good morning. Uh good morning, and welcome to our first Virtual Open Meeting. Uh this meeting is regarding the External Infusion Pumps Local Coverage Determination. Um my name is Dr. Smitha Ballyamanda from Jurisdiction A, DME MAC Medical Director. I work for Noridian Healthcare Solutions. With me today from CGS is Dr. Stacey Brennan from Jurisdiction B, and hopefully Dr. Robert Hoover from Jurisdiction C, as well as Dr. Peter Gurk from Jurisdiction D, who is also from Noridian Healthcare Solutions.

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We are looking forward to hearing your comments today regarding the External Infusion Pump LCD. Please put these comments in writing and send them to us via the email at EIPRecon@noridian.com. Again, that's EIPRecon@noridian.com. Details for submitting comments are also available on the DME MAC website. Uh please remember that we can only respond to written comments. Uh these comments are due by the close of business on Monday, June 15, 2020. And again, just to reiterate what Jody said, uh we will be recording the meeting today, which will be posted on the DME MAC websites. And you are giving your consent to the use of your recorded voice and any comments by signing into this meeting, so please be careful about sharing any personal health information in your verbal comments. We have three commenters who have preregistered to speak. We are only permitting registered commenters, again, to speak at today's meeting. So, anyone can submit written comments to the email address I mentioned earlier, however, only preregistered commenters will speak today. And each person will have approximately 13 minutes to speak. For those on the phone who are listening, again, please just mute your line or your computer. Um we ask that you do not place this call on hold because then we'll all be forced to listen to background music. No matter how good it is, we'd rather listen to the speakers. Uh so speakers should be prepared to begin their comments immediately after we call on them.

And now, just a little bit about this proposed uh policy. This is an EIP LCD policy again. This provides coverage for Cutaquig, which is an immune globulin subcutaneous solution. It was

manufactured, it is manufactured by Octapharma. This drug was approved by the Food and Drug Administration on December 12, 2018 and is assigned the not otherwise classified (NOC) HCPCS code of J7799. The proposed external infusion pump language posted on April 30th of 2020 would be to add coverage language for this particular drug. It is administered subcutaneously via an external infusion pump and to Medicare beneficiaries within the home for the treatment of primary immuno deficiency disorder. So, at this point I'm going to turn it back to Jody, and I look forward to hearing everybody's comments today. Thank you.

JODY WHITTEN

Thank you, Dr. Ballyamanda. Now, just as an update, today we only have two individuals who will be giving oral comments, um one of them did dropout. So, because of that we do have to speak uh, split our time equally, so we will have 20 minutes per commenter. Um because we are in a virtual meeting today there are no, obviously no personal presenters. Um, again, 40 minutes for oral comments split by two is going to be 20 minutes each. Um I will give a one-minute notice as your time limit comes to an end, and then once your time expires, I will let you know, and we will move on to the next presenter. Although 20 minutes is a pretty long time, so hopefully we can get through everything. Also, please be sure if you haven't already done so, to make sure even the commenters today that are going to be speaking, you need to make sure you submit your comments in writing. And as Dr. Ballyamanda had mentioned, uh the email address is EIPRecon@noridian.com. That will be given at the end of the meeting today as well as um an

actual address to send your comments to. Also, all comments are due by June 15th at 5:00 p.m. Eastern Daylight Savings Time. So, with that being said, we are going to go ahead and go to our first presenter today. And I apologize if I mispronounce your name, I have Huub Kreuwel. Mr. Kreuwel, I see you have a presentation and um I will be advancing those slides for you. So, with that said, please let me know when you are ready to um, to go to the next slide. I have the first slide from the Cutaquig up right now. So, Mr. uh Kreuwel, are you on?

HUUB KREUWEL

Yes. Can you hear me?

JODY WHITTEN

Yes, we can, thank you.

HUUB KREUWEL

Perfect. And thank you so much for the introduction, we appreciate it. It's a great pleasure and many thanks for allowing us the opportunity to speak today. My name is Dr. Huub Kreuwel, I'm the VP of Medical for Octapharma U.S.. We are uh very excited to add our Cutaquig product to the LCD, especially considering these challenging times of COVID, and I certainly hope all of you are safe. Um we kept the presentation very, very brief, we only have ten slides. So, if you could go to the next slide?

Um Octapharma submitted a Local Coverage Determination to have our FDA approved product called Cutaquig added to this LCD. Uh we really appreciate the proposal that you've written so far, um and we are very excited to add coverage of Cutaquig to it. Uh we have two small requested um modifications. The first one is to authorize the coverage with both codes um 779 and 781. And then as well as in the corresponding local coverage article uh we propose to utilize a unit of service of 100 mg for Cutaquig instead of the 165. If you can go to the next slide.

So, what is Cutaquig? Real quick, it's an immunoglobulin solution for subQ um uh treatment of patients who suffer from primary immuno deficiency, also this is called PI or PID or sometimes PIDD. Uh the solution is 16.5%, and it is made from human plasma donors from the U.S. And then we use the same manufacturing as our IGIV product called Octagam. And so, the only difference is that this is a higher concentration than the Octagam, which is 5 or 10%.

And the way to calculate it is then um, if you could, sorry, go back one more slide. If you calculate it, you basically multiply the IGIV dose times 1.4 and then divide it by the weeks between the IGIV doses. So, if you were on an every three weeks IV dose, then um you can calculate and divide it by three and then you'll get to a weekly dose. You can go to the next slide then.

Um the product um is used with uh infusion pumps, and some examples are shown on this slide. So, there are two groups basically. Mechanical ones, these are the FREEDOM 60, FREEDOM EDGE, as well as the EMED pump. And then you also have electronic or battery operated uh infusion pumps, and CRONO is an example of that. Um the mechanical pumps, the FREEDOM and the EMED, that is in code 779 currently as well as the CRONO pump, that's in the other code in 781. And we've used um the different pumps both in our clinical trials as well as outside of the clinical trials now in practice, and a lot has to do with the patient preference or nurse preference what kind of pump that ideally you want to use the drug with. And go to the next slide. Thank you.

Um we in the reconsideration request we explain that Cutaquig meets the criteria of the LCD. It's a pooled plasma derivative, as I mentioned, it's FDA-approved for PIDD, so primary immuno deficiency. It's used for patients diagnosed with PIDD and then it's used with both the mechanical pump 779 as well as battery operated or electrical pump 781. Um and we ask for coverage in the LCD similar to other approved um subQ immunoglobulin products that are already on the market identified in the LCD. We go to the next slide.

So, the proposed LCD would add coverage of this product. Um based on a review of clinical evidence, the proposal concludes that Cutaquig is safe and efficacious as shown also in our clinical trial, and improves health outcomes for beneficiaries, with patients who have PIDD and thus

reasonable and necessary. Um currently under the proposal with Cutaquig only an infusion pump reported with 779 would be covered, but we weren't quite sure, and there was no explanation offered why um another product, Xembify, had both pumps. Um in the accompanying draft article, the unit of service designated for Cutaquig is 165 milligram, and we propose similar to other subQ products that it should be um 100 milligram. We go to the next slide.

The clinical evidence that we've published now demonstrated that Cutaquig is reasonable and necessary for the treatment of patients with PIDD. Um in the clinical trial we showed um the occurrence of zero serious bacterial infection in adult patients. And the cutoff for any uh trial done in this uh patient population is 1 SB per year per patient. So, we were well below what the FDA uh demanded as the cutoff. Um the rate of other infections were 3.4, so infections still do occur, but they are fairly in line with what other products have shown. And most of the infections were mild or moderate. Uh the production of Cutaquig is derived from a proven manufacturing and pathogen safety measure, so this is the identical process that we are currently using for our Octagam product. In the trial then um the serum IG trough levels were constant and high during the study, which is usually a good sign that patients are protected from infections. And that is exactly what you need to see in a trial designed like that. Um also the evaluation of adverse events and infusion site reactions showed that subQ administration of Cutaquig was well tolerated and safe in the assessed clinical study patient population and that was published by Kobayashi and a second trial by Latysheva that has been published. You go to the next slide then?

In our LCD request we noted that Cutaquig is used um with infusion pumps reported with 779 and 781, and thus we seek coverage of both pump codes. Uh the proposed decision would cover only 779 currently with no reason for not including the 781, as was done with a similar product called Xembify recently. Uh Cutaquig can also be administered with a CRONO Super PID pump and other electronic pumps, and that product is listed as one of the products in the product classification list of 781. Um as a result, then, the final LCD should authorize coverage hopefully from both pumps, so 779 as well as the 781 with Cutaquig. We go to the next slide then.

Um, the other minor change we are requesting is according to the draft coverage article released with the proposed LCD, um the unit of service is equal to 165 milligrams , probably based on the concentration, the 16.5%. We are not quite sure where that figure comes from and why it's different from the 100 milligrams that was recently assigned to Xembify. Um then to maybe avoid confusion, we based this on the CMS average sales price, the ASP, not otherwise classified file, lists the Medicare payment rates for Cutaquig um as also 100 milligrams as it does for Xembify. So, the coverage article then likewise should state that one unit of service for Cutaquig is equal to 100 milligrams , to avoid the confusion and also to follow the model of other products including Xembify. We go to the next slide then.

So, it's very important that we can add this product for beneficiaries. Um more product options are important for patients um simply because some of these uh products are different. So, these um IVIG as well as subQ IG products they differ in how um all the manufacturers purify these products, and as well as the stabilized uh use. So, we use maltose, which is different from glycine or some of the other um uh stabilizers used. And some patients respond better to one versus the other, and it's hard to predict sometimes who responds best. Um also the product um has a lower viscosity, so it's a little easier to load the pump. Um there is definitely a need for another available immunoglobulin product currently to satisfy patient needs. Um currently in the U.S. um we have a supply issue. The products for IVIG and subQ IG are very limited, so it's nice to be able to offer another product that we can add to the list. Certainly COVID-19 has impacted patient access to IG therapies. Um of course, it might be better now that patients get treated at home with a subQ product rather than an IV product where um they might have to go into an infusion center or a hospital. Certainly, they can also use the IV product at home. Um we've also seen a decrease now in plasma center donations that we are working hard on, and so we'd like to make sure that we do have all the products available for these patients that really need these products. Then finalizing the proposed LCD with the two recommended small revisions I think is consistent with the clinical evidence and will increase patient access to needed therapy to treat this disease. I think that was it.

JODY WHITTEN

Yes, it is, and thank you, sir, for your comments. And our next up with be William Noyes. William, are you there?

WILLIAM NOYES

Yes. Can you hear me?

JODY WHITTEN

Awesome. Yes, we can.

WILLIAM NOYES

All right. Well good morning everyone. Um good morning to the Medical Directors and everyone on the call. My name is Bill Noyes, I'm the Senior Vice President of Reimbursement Policy for the National Home Infusion Association, and I appreciate the opportunity to provide comments in this virtual public meeting on behalf of the association. Uh the National Home Infusion Association is a trade association representing home infusion therapy providers, suppliers, equipment manufacturers, distributors, drug manufacturers and other industry stakeholders. As the name suggests, home infusion therapy is the administration of intravenous and subcutaneous drugs in the home site of care. Common home infusion therapies treat both chronic and acute conditions. Some examples include IV antibiotics, chemotherapy, parental nutrition, inotropic therapy, hydration, immunotherapies as well as a host of other drug therapies to treat a variety of

conditions. Some of these drug therapies are continuous 24/7 infusions, some are administered daily or multiple times a day; while others are intermittent, um administered once a week, every two weeks, once a month. Um Cutaquig would fall into this intermittent category.

Home infusion services are centered around the pharmacy, which plays the lead role in care coordination for the patient. Typically, the first step in enrolling a patient in home infusion is for the pharmacist to work closely with the referring physician or discharge planner to develop a transition plan, facilitate nursing services, initiate patient and caregiver education. Beyond that, the pharmacist maintains responsibility for case management, customizing medication plan, sterile drug preparation, lab tracking, clean room operations, clinical assessment and monitoring, um coordination with patient and other healthcare providers, provision of equipment and supplies, and 24/7 availability for patient support. Meanwhile, a nurse is to conduct periodic in-person visits to educate the patient, provide physical assessment and maintain the vascular access device, among other services. One of the key efficiencies created by the home infusion model is that many of the services are provided without a face-to-face interaction between the patient and provider.

In the commercial payment sector home infusion is typically reimbursed through three mechanisms. One, payment for medication, which is tied to either average wholesale price or average sales price. Um two, a fixed daily rate or per diem for each day the drug is infused, whether a nurse is present or not. This covers the pharmacy-related professional services as I

outlined earlier, equipment and supplies. And three, the/a separate charge for nursing. Still, even when reimbursed for the full spectrum of home infusion services and supplies private payers consistently find home infusion to be cost effective alternative to other sites of care, including institutional settings and hospital outpatient departments.

There is no comparable benefit for home infusion services under the Medicare program. Coverage is fractured across different parts of Medicare. I'll keep my comments focused on Medicare Part B, DMEPOS specifically, the external infusion pump policy that covers about 35 drugs, which is a small minority of the drugs commonly utilized in the home. Under the External Infusion Pump Local Coverage Determination, the durable medical equipment in this case, the infusion pump, must be deemed necessary to safely deliver the drug to the beneficiary in order for coverage to exist. The primary benefit here is for the infusion pump, and the drug is considered a supply necessary to make the pump therapeutic. The external infusion pump currently covers a number of subcutaneous IG products. We've reviewed the proposed LCD and NHIA does not object to Cutaquig being added to the list of subQ products covered under the policy.

As the previous speaker mentioned, I tend to agree with him regarding the billing unit. Um the billing unit should be consistent with that of other IG products, 100 milligrams . Um it is listed in the ASP not otherwise classified file, um consistent with other subQ IG products. And I think that it would cause great confusion from a billing standpoint, and the potential for inaccuracies if it was

to vary um and be inconsistent with other products. Uh I also tend to agree with the comment, the previous commenter, um that if the product has been tested with multiple um different types of pumps that it should be allowed the flexibility to utilize either J, I'm sorry E0779 or E078.

I do, however, have two concerns I'd like to voice directly related to the DME program as it exists today. Um one, the length of time it takes for policies to cover newly approved drugs, this process we are involved with today, the LCD reconsideration process. We understand the need for transparency, but would like to urge CMS to consider a swifter process for considerations um of noncontroversial changes to policy, like the one we are commenting on here today, adding a newly FDA-approved drug to existing coverage policy. Um this is important in terms of patient access, especially for drugs that have been subject to shortages as IG products have.

Second, I'd like to raise concern about the recent policy changes that are negatively effecting beneficiary access to Part B, DME infused drugs. Unlike the commercial sector where home infusion is generally paid for every day the drug is infused, CMS's current implementation of the statutory requirement for reimbursement of home infusion is inadequate and is threatening patient access to this vital service. Historically, Medicare Part B drugs were tied to ASP with the expectation that the difference would be sufficient to offset the cost extensive professional services needed to administer drugs. Congress um included provisions in the 21st Century CURES Act and Bipartisan Budget Act of 2018 to lower the drug reimbursement rate from an AWP-based rate

to an ASP-based rate, while also requiring CMS to create a professional services benefit for Medicare Part B home infusion drugs. The recognition of the need to pay for the services was directly tied to the reduction in drug reimbursement.

Um in implementing the legislation, however, CMS issued regulations that limits reimbursement to days when a nurse is physically present in the patient's home per its definition of infusion drug administration calendar day, rather than each day that the drug is infused. As Congress has pointed out in letters to the agency, this physical presence requirement contradicts the intent of drafting and enacting this legislation and makes the reimbursement required by the Bill inadequate. In practice, the physical present requirement only acknowledges face-to-face visits from a nurse, failing to account for the extensive services provided remotely by a pharmacist. While CMS has suggested that this a bundle payment intended to cover all home infusion services, the current rate is barely enough to cover the cost of the nursing and not enough to cover even one hour of a pharmacist's time. For subQ IG products, including Cutaquig, once the initial patient training is complete beneficiaries rarely require a nursing visit, so there is no access or path to payment, putting at risk the viability of the benefit. This has had a direct impact on patient access for Medicare fee for service patients. CMS's current reimbursement policy has created a significant barrier to access by threatening the financial viability of home infusion therapy suppliers caring for Medicare beneficiaries under traditional Medicare fee for service. Already the change in

reimbursement from AWP to ASP has had a detrimental impact on access to infusion therapies in the Part B program.

Based on a review of the most recent publicly available data, uh 20% fewer Medicare beneficiaries received DME-infused drugs in 2017 compared to 2016. The change in drug reimbursement resulting um from the shift from AWP based to ASP based was over $200 million annually, while the home infusion service payment has been negligible, NHIA estimates that in 2019 the services payment totaled less than $10 million, or less than 5% of the reduction in the cuts to drug pricing reimbursement. With the permanent benefit beginning in 2021 NHIA is concerned that CMS will continue the policy of paying only when a nurse is in the home, and additionally we are concerned about the new requirements for accreditation and enrollment to the A/B MAC, um or the A/B Medicare administrative contractors that this will further negatively impact beneficiary access. This will require home infusion pharmacies, most of which are currently enrolled as DME suppliers, to also enroll with the A/B MACs in order to serve a population that currently offers little upside, little financial upside.

Without robust access to home infusion, patients are often forced to remain in facilities overnight or travel to a physician's office or hospital outpatient department to receive their infusion treatments. This may not be clinically warranted and effectively restricts physician practice by not allowing them to refer patients to the most appropriate care setting, the home. This problem is

even more acute in rural areas where patients may require treatment on a daily basis and live more than an hour from the closest infusion center. This is especially troubling during a public health emergency where many are asked to remain in their homes, creating additional barriers for access. The National Home Infusion Association and other stakeholders are working with CMS and legislators proposing solutions to create a viable benefit which will improve patient access to the home site of care for infused drugs such as Cutaquig. For DME infused drugs being added to the program we ask that CMS be mindful of and monitor whether access is being hindered due to current payment policies. Thank you for your time today and stay safe.

JODY WHITTEN

Thank you, sir. And um this concludes the registered speakers for today's Open Meeting. Again, the comment period for the proposed LCD will remain open until June 15th at 5:00 p.m. Eastern Daylight Savings Time. Um as noted earlier, all comments to be considered by our Medical Directors for the Proposed LCD must be submitted in writing. Please monitor our website or register for the ListServ notifications to be informed when actions are taken to implement or retire our Proposed LCD. I'd like to now turn it over to Dr. Ballyamanda for her final comments, please.

DR. SMITHA BALLYAMANDA

Thank you, Jody. Can everybody hear?

JODY WHITTEN

Yes, we can.

DR. SMITHA BALLAMANDA

Can you hear me? Perfect. Thank you, Jody. Uh I would like to again thank all members of the public and stakeholders for your thoughtful comments today. Uh once again, please remember to send your comments in writing. If you have any full text um peer-reviewed article to help support any of your comments, whether you spoke today or you are submitting comments in writing that have not been included in the bibliography, please send them along as well. As another reminder, the comment period, as Jody mentioned, is going to end on Monday, June 15, 2020. Once we have considered and collated all of the comments received during the Open Comment Period uh we will think about whether we are going to make any changes to the proposed language, and then we will post a final LCD along with a Response to Comments Document. Um for any updates please refer to the DME MAC website, that's where you will be receiving any updates or any postings that we will be making. So please just watch the DME MAC website for any updates. Again, I want to thank everyone for their participation today. We'll formally adjourn this meeting at this time. Thank you.

JODY WHITTEN

Thank you, everyone, and you now may disconnect.