External Infusion Pumps
Open Meeting
January 28, 2020

DR. STACEY BRENNAN

We are okay to go. All right, good afternoon, I'm Dr. Stacey Brennan, Jurisdiction B, DME MAC Medical Director, uh and I work for CGS Administrators. Welcome to the afternoon session. Uh this is the third of four comment sessions. Um with me today, I'll introduce again, if some of you were here earlier today, Dr. Robert Hoover from Jurisdiction C to my far right, Dr. Smitha Ballyamanda, and she's with Jurisdiction A, and Dr. Peter Gurk with Jurisdiction D.

Um we are now presenting um the proposed external infusion pump policy, or local coverage determination, about which we are soliciting comments. Um we will be recording the meeting today, which will be posted on the DME MAC websites. You are giving your consent to use, uh to the use of your recorded voice and comments by signing into this meeting today, whether it's done electronically or in person. Please be careful about sharing any personal health information in your verbal comments. We ask that any comments today be made on this topic in writing uh as well to the website which is EIPrecon@noridian.com. Details for submitting comments are also available on the uh DME MAC websites.

We do not have any commenters here in Dallas today, but we do have two commenters who preregistered to speak via conference call. Um we are only permitting registered commenters to uh speak at today's meeting, but anyone can submit written comments uh to that uh web address I

mentioned a moment ago. For those commenting we have 50 minutes for each person, so I'm sure that will be sufficient for each person to give their comments in hopefully their entirety. Um we ask for those on the phone who are listening, um or speaking, do not mute your line. Uh you may mute your line, but do not place it on hold in case we get background music. Uh speakers should be prepared to begin their comments immediately after we call for them.

Now a little bit about this uh proposed LCD. This uh provides coverage for uh Xembify®, which is immune globulin, subcutaneous human uh KLHW. This is manufactured by Grifols USA LLC. And this drug was approved by the Food and Drug Administration on July 3, 2019 and is assigned HCPCS code J7799. The proposed external infusion pump language posted on December 26, 2019 would add coverage language for this drug, which is an immune globulin, administered subcutaneously via a pump to Medicare beneficiaries within the home, for the treatment of primary immunodeficiency disorder. Please refer to the section in the proposed LCD called Coverage Indication Limitations and/or Medical Necessity for details. Also published within the proposed LCD near the end is the summary of evidence, which explains the scientific basis upon which we Medical Directors have proposed coverage for Xembify® for Medicare beneficiaries. So, I'll now turn this over to Jody. Thank you.

JODY WHITTEN

Thank you. Our first comment comes from an online registrant, Stephanie Hales. Stephanie, you can un-mute your line please. Stephanie, are you there? Okay, Stephanie, you are online, and you are un-muted, if you can un-mute your own line that would be helpful. Unfortunately, we cannot hear her. We will circle back. Um our next presenter is, or our next commenter is William Noyes. William, are you there?

WILLIAM NOYES

I am here. Can you hear me?

JODY WHITTEN

We can. Thank you very much.

WILLIAM NOYES

Okay. Well good afternoon. Um my name is Bill Noyes, I'm the Senior Vice President of Reimbursement Policy for the National Home Infusion Association, and I'm pleased to be making comments um regarding adding Xembify® to the external infusion pump and LCD on behalf of the association. Um I wish I could be in Dallas in person, but my schedule requires me to be in DC to meet with CMS um later this week.

Um a little bit about myself, prior to joining NHIA, the National Home Infusion Association, I worked in the home and specialty infusion industry for more than 20 years for a large multisite home infusion provider in New England. I am not a clinician; my focus has always been on operations and finance. And here at the association, as my title implies, Senior Vice President of Reimbursement Policy, my focus is on supporting and educating NHIA members on revenue cycle matters, claims submission, coding, audit process, all things reimbursement related. I also spend a fair amount of time advocating for viable reimbursement policies with both government and private payers. I'm a member of all four DME MAC jurisdiction advisory groups. Um a special hello to Dr. Hoover and Dr. Gurk, who attend many of those meetings.

Um a little bit about the association. Um the National Home Infusion Association is a trade association representing home infusion therapy providers, suppliers, equipment manufacturers, distributors, drug manufacturers and other key industry stakeholders. As the name suggests, infusion therapy is the administration of intravenous and/or subcutaneous drugs in the home site of care. Home infusion therapies treat both acute and chronic conditions. Some examples include IV antibiotics, chemotherapy, inotropic therapy, parenteral nutrition, hydration, immunotherapies as well as a host of other drug therapies to treat a variety of conditions. Some of these drugs are continuously administered, 24/7 without interruption. Others are administered daily or multiple times a day, and yet others are administered intermittently, um once a week, every two weeks,

once a month, maybe even once every six weeks, um as is the case with Xembify®. This is a drug therapy that is um administered intermittently.

Home infusion therapy services are centered around the pharmacy, which plays the leading role in care coordination for the patient. Typically, the first step in enrolling a patient in home infusion therapy is for the pharmacist to work closely with the referring physician and/or discharge planner to develop a transition plan, facilitate nursing services, to initiate patient and caregiver education. Beyond that point, the pharmacist maintains responsibility for case management, customizing the medication plan, sterile drug preparation, including clean room operations, clinical assessment, monitoring, coordination with the patient and other healthcare providers, provision of equipment and supplies and 24/7 patient support. Meanwhile a nurse will conduct periodic in-person visits to educate the patient, provide physical assessments, maintain vascular access device, among other services.

One of the key efficiencies created by the home infusion model is that many infusion services are provided without a face-to-face interaction between the patient and the provider. In the commercial sector, home infusion is typically reimbursed through three mechanisms. One, the payment for medication, which is tied to either average wholesale price or average sales price; two, a fixed daily rate, often known as a per diem, for each day of infusion, whether a nurse is present or not, that covers the pharmacy-related professional services I mentioned, as well as the

equipment and supplies; and three, thirdly, a separate nursing charge. So, nursing visits are paid for separately outside of the per diem in the commercial payment model. Still, even with this reimbursement model, uh reimbursing for the full spectrum of home infusion services and supplies, private payers consistently find home infusion to be a cost-effective alternative to other sites of care, including institutional settings in the hospital outpatient departments. In fact, they often deploy what they call site of care optimization programs that incent patients to receive their care in the home. There is no comparable benefit to home infusion services under the Medicare program. Coverage is fractured across many parts of Medicare, so I'll keep my comments focused on Part B coverage, um Part B DMEPOS, specifically the external infusion pump policy. The external infusion pump policy covers about 35 drugs, a small minority of the drugs commonly infused 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 drugs 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 LCD specifies coverage for subcutaneous IG under Section 5H. The policy currently covers a number of subcutaneous IG products. We have reviewed the proposed changes, and NHIA does not object to Xembify® being added to the list of subcutaneous IG products covered under this policy.

We do, however, have two concerns we would like to voice directly related to the DMEPOS program. First, the length of time it takes to modify policy to cover newly approved drugs, mainly the process we are involved in today, the LCD reconsideration process. While we understand the need for transparency, I would like to urge CMS to consider a swifter process for consideration of noncontroversial changes to policies like the one we are commenting on here today, adding a newly FDA-approved drug to existing coverage policy. This is important in terms of patient access, especially for drugs that have been subject to shortage issues as IG has. The second concern I would like to voice is regarding recent payment 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 that a drug is infused, CMS's current implementation of the statutory required reimbursement for home infusion therapy is inaccurate and is threatening patient access to this vital service. Historically, Medicare Part B infused drugs were tied to AWP with the expectation that the difference would be sufficient to offset the cost of expensive professional services needed to administer drugs.

Congress concluded, congress included provisions in 21st Century cures in the Bipartisan Budget Act of 2018 to lower the drug reimbursement rate from AWP to ASP-based payment, while also requiring CMS to create professional services benefits for Medicare Part B home infused drugs. While implementing this legislation, however, CMS issued regulations that limit reimbursement to days when a nurse is physically present in the patient's home per definition of infusion drug

administration calendar day, rather than each day the drug is actually infused into the patient. As congress pointed out in letters to the agency, this physical presence requirement contradicts the intent in drafting and enacting this legislation, and makes the reimbursement required by the Bill inadequate. In practice, the physical presence requirement only acknowledges face-to-face visits from a nurse, failing to take into account the extensive services provided remotely by a pharmacist. While CMS has suggested that this bundled payment is intended to cover all home infusion professional services, the current rate is barely enough to cover the cost of nursing, and not enough to cover even one hour of a pharmacist's time. For subcutaneous IG products, including Xembify®, once the initial patient training is complete, beneficiaries rarely, if ever, require a face-to-face nursing visit. So, there is no payment for these services, putting at risk the viability of the benefit.

This has had a direct impact on patient access and Medicare costs. CMS's current reimbursement policy has created a significant barrier to access by threatening the financial viability of home infusion therapy suppliers. Already the change in drug reimbursement from AWP to ASP has had a detrimental impact on access to infusion therapy in the Part B program. Based on review of the publicly available data, an alarming 20% fewer Medicare beneficiaries received DME-infused drugs in 2017 compared to 2016. Additionally, beginning in 2021 we are concerned that new requirements for accreditation and enrollment in the AB MAC Medicare administrative contractors 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 AB bank in order

to service the population that it currently services, with no financial up-side. Without robust access to home infusion, patients are often forced to remain in facilities, or travel to separate locations to receive their infusion treatments, sometimes multiple times a day. This may not be clinically warranted, and effectively restricts physicians' practice by not allowing them to refer patients to the most appropriate care setting, the home. Moreover, 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.

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 Xembify®. For DME drugs being added to the program we ask that CMS be mindful and monitor whether access is being hindered due to the current transitional home infusion services payment policy, and the soon to be implemented permanent home infusion services payment policy. I thank you for your time. I know I'm well short of the 50-minute allotment, um and I appreciate it. Thank you.

JODY WHITTEN

Thank you. Our next speaker is Stephanie Hales. Stephanie, I understand the problem is you can't have your speaker on your computer as well as your phone speaker on at the same time, so you'll

need to either have one off and the other on, or vice versa. Are you there, Stephanie? I think what you'll need to do is disconnect from your computer so that we can get you on the phone line.

STEPHANIE HALES

I am on the phone.

JODY WHITTEN

I hear background noise.

STEPHANIE HALES

I'm on, so. I'm on. Can you hear me?

JODY WHITTEN

Okay, you have to turn the mike off on your computer, Stephanie, and the speaker. And then just use your telephone. Um well you can certainly submit your, your comments in writing. We would appreciate that. Unfortunately, we can't seem to get through to Stephanie, Dr. Brennan, so if you'd like to close it out?

DR. STACEY BRENNAN

Sorry about that. So, um just to reiterate from earlier today, here is what will be happening next. Um the uh, as far as the LCD reconsideration process goes. We, as the DME MACs, will consider all of the comments, including um those presented today and any that come in in written form. Um, again, that email address is EIPrecon@noridian.com, if anyone would like to send any. They are due by February 10th, 2020 at 4:00 o'clock central time. So, once we have all of the comments, we will consider them, collate them, make any necessary changes to the policy as a result.

STEPHANIE HALES

Hello? This is Stephanie Hales, can you hear me?

DR. STACEY BRENNAN

Now hold on.

JODY WHITTEN

Stephanie, are you there?

STEPHANIE HALES

I am here, can you hear me?

JODY WHITTEN

We can.

DR. STACEY BRENNAN

Okay, so we are going to go ahead and let Stephanie speak.

STEPHANIE HALES

Thank you so much. I apologize for those technical difficulties. I was un-muting on my computer. I was doing all the things that um you were saying, and for some reason it wasn't working. But I tried calling on a different line and I really appreciate you bearing with me, so thank you. Are you still able to hear me?

JODY WHITTEN

Yep, go ahead. We hear you. Thank you very much for calling back in.

STEPHANIE HALES

Perfect, thank you so much for your patience with me, I'm very appreciative. Well good afternoon, and thanks so much to everyone for the opportunity to provide these comments today on this proposed LCD, Draft LCD 33794, External Infusion Pumps, which pertains to the proposed coverage for Xembify®, as Dr. Brennan said, which is an immune globulin subcutaneous product, human KLHW 20% solution. My name is Stephanie Hales, I am a partner at Sidley Austin, LLP.

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I represent and am speaking today on behalf of Grifols USA LLC. Grifols is a biopharmaceutical company that specializes in producing therapies derived from human blood plasma to treat rare, chronic and life-threatening diseases. Grifols manufactures Xembify®, which received approval from the U.S. Food and Drug Administration on July 3, 2019, as Dr. Brennan noted. Uh and the indication is for treatment of primary immunodeficiencies, also known as primary immunodeficiency disease or PIDD. More specifically, as stated in the Xembify® prescribing information, Xembify® is indicated for treatment of primary humoral immunodeficiency in patients two years of age and older. Xembify® is for subcutaneous infusion through an infusion pump. We appreciate and support the DME MAC's proposed updates to LCD L33794, which would update the LCD to include coverage for Xembify® in Section 5H of the LCD, which relates to subcutaneous immune globulin when appropriate criteria are met as specified in the LCD. We believe it is important, appropriate and consistent with Medicare's coverage standards to update the LCD as proposed to include coverage of Xembify® as reasonable and necessary for the treatment of beneficiaries with a diagnosis of PIDD.

As reflected in the proposed LCD, Xembify® is administered through external infusion pumps described by either HCPCS E0779 or HCPCS E0781. We support the proposed LCD's addition of Xembify® under Section 5H of the LCD, including the proposal to cover Xembify® under the LCD when the specified criteria are met and when Xembify® is used with an external infusion pump described by HCPCS code E0779 or E0781. We also appreciate the LCD's discussion and

analysis of clinical literature and evidence demonstrating and supporting Xembify® safety, efficacy and satisfaction of Medicare's reasonable and necessary coverage standards for appropriate patients.

Xembify® has been shown through clinical trials, published clinical literature, FDA reviews and FDA positive approval decisions to be safe and effective and not experimental or investigational. We appreciate and support the DME MAC's conclusion as stated in the proposed LCD that based on the review of published clinical literature, evidence-based guidelines and professional society recommendations there is sufficient evidence that subcutaneous immune globulins, such as Xembify®, are safe and efficacious and improve health outcomes of beneficiaries with a diagnosis of PIDD.

We also support the proposed LCD's use of HCPCS code J7799 to identify Xembify® at this time. Xembify® currently does not have a product specific HCPCS code. Grifols has submitted an application for a product specific HCPCS code for Xembify® which is currently pending with the Centers for Medicare and Medicaid Services. We therefore agree with and support the proposed LCD's use of J7799 to identify Xembify® at this time. In summary, Grifols appreciates and supports the proposed LCD for external infusion pumps, see L33794, and supports finalization of this proposed LCD as has been proposed. We thank the DME MAC Medical Directors and staff for all of your work on this proposed LCD, and for the opportunity to provide these oral comments

at today's open meeting. We also will be submitting written comments by the February 10 deadline, and we are happy to address any questions that you may have. Thank you again very much.

JODY WHITTEN

Thank you, Stephanie.

DR. STACEY BRENNAN

Thank you. So just to pick up where I left off, I think we've finished with our two commenters. Um once we have considered and collated all of the comments, we will make any necessary changes to the proposed LCD, and then post a final LCD along with a response to comments document. So, I want to thank everyone for their participation this afternoon, and the next session will commence at 4:30 p.m. central time, on the uh last proposed policy, Urological Supplies. Thank you.