Open Meeting: External Infusion Pumps

Meeting Date & Time: August 27, 2025, 12:00 p.m. ET
Location: Virtual Meeting

JODY WHITTEN (0:00:04): Okay. Well, good afternoon, everyone. It is 12 noon Eastern time, and we will begin our open meeting. My name is Jody Whitten from the Noridian Medical Policy Team, and I'd like to thank everyone for taking the time to join us today to discuss the external infusion pump proposed LCD. We do have six stakeholders scheduled to present their comments today and have divided up the available time to speak by those six speakers, which will give each speaker 11 minutes to present their comments. We did check the speaker mics just a minute ago before starting, but as a reminder, once it's your turn to speak, we will send a note via the GoToMeeting app for you to unmute your line. If you are unable to unmute, we will move on to the next speaker, then after all the speakers have presented their comments, we will go back to anybody that may have been missed. Now, I would like to turn the meeting over to Dr. Smitha Ballyamanda for her opening remarks. So, Dr. Ballyamanda, please go ahead. Dr. Ballyamanda, we cannot hear you.

DR. BALLYAMANDA (0:01:27): Can you hear me now?

JODY WHITTEN (0:01:28): I sure can, perfect.

DR. BALLYAMANDA (0:01:3): Do you have an echo?

JODY WHITTEN (0:01:34): Yeah, a little bit.

DR. BALLYAMANDA (0:01:35): Okay, let me see if I can miss what I can do here. Give me a moment. How about now?

JODY WHITTEN (0:01:43): No.

DR. BALLYAMANDA (0:01:46): Wonderful. All right. Good afternoon, everyone and welcome to our virtual open meeting. Today, we will be soliciting comments regarding the proposed external infusion pump LCD, thus far known as EIP LCD. My name is Dr. Smitha Ballyamanda, and I'm with Noridian Healthcare Solutions, the Jurisdiction A, DME MAC. Also, from Noridian, here with me today is Dr. Angela Jenney from Jurisdiction D. And representing CGS Administrators are Dr. Sunil Lalla and Dr. Robert Hoover from Jurisdictions B and C, respectively.

We look forward to your comments regarding the EIP LCD updates. So please write these comments and send them to us via email at EIPLCDcomments@cgsadmin.com. So that's E-I-P-L-C-D-C-O-M-M-E-N-T-S-@-C-G-S-A-D-M-I-N-.-C-O-M. Please remember that we can only respond to written comments. These comments are due no later than Saturday, September 6, 2025 when the comment period closes. Also, we will record the meeting today, which will be posted on the DME MAC websites. You are giving your consent to use the use of your recorded voice and comments by signing into the meeting, and please be careful about sharing any personal health information in your verbal comments. We only allow register's commenters to speak at today's meeting, but anyone with submitted written comments to the email address I mentioned earlier we'll definitely address those comments. For our speakers today, we ask that you introduce yourself, the organization that you represent and any conflicts of interest that you may have with this topic. And for those listening, please mute your phone in line and computer, if applicable. Speakers should be prepared to begin their comments immediately after being called upon. And now I'll go ahead and discuss the overview.

So, a little bit about the proposed LCD. The DME MACs are proposing the reasonable and necessary coverage criteria for non-implanted infusion pump devices with an expansion in coverage for blinatumomab to include a new indication for the treatment of leukemia during the consolidation phase of chemotherapy for use in the home setting. Additionally, in agreement with the reconsideration request from AbbVie, the DME MACs are proposing the addition of coverage for foslevodopa and foscarbidopa for the treatment of advanced Parkinson's disease. And now I'll turn the mic back over to our wonderful moderator, Ms. Jody Whitten from Noridian. Thank you.

JODY WHITTEN (0:05:00): Thank you, Dr. Ballyamanda. Okay. Again, we do have six speakers with 11 minutes per speaker. So, our first speaker is Michelle Solano. We're going to be sending

you a little note to unmute your line.

MICHELLE SOLANO (0:05:15): Thank you. Yes, this is Michelle Solano. I'm with CVS Specialty. I do not have a conflict of interest, but I do respond to audits and appeals for our organization for Part B medications and reviewing clinical documentation and providing that to various CMS entities upon request.

So, I do have a question as relates to the proposed criteria for VYALEV in the verbiage of the section I, criteria 2. It basically outlines that, you know, that the dosing interval of non-infusion-based Parkinson's disease therapy cannot be further optimized. So, this specific phrasing of non-infusion-based under criteria 2, we do request some clarity on this as we are not sure if this will leave a coverage gap for patients on DUOPA transitioning to VYALEV or vice versa. We want to understand the intent for patients already on infused therapy who are transitioning to another infused therapy, especially as this volume is, of course, anticipated to increase over time and what type of documentation would be looked at for non-infusion base. For example, if a patient started DUOPA years ago and is transitioning to VYALEV, is the intent that that pre-VYALEV/ pre- DUOPA documentation be provided from years ago? Is the intent that need to change from one to the other be summarized in a current progress note for the transition. We're trying to better understand this as we do understand that you know, there are, there may be a lot of patients over time that do transition between infused therapies and given the verbiage is non-infusion based being a requirement for coverage.

JODY WHITTEN (0:07:18): Is that the only comment you have, Michelle?

MICHELLE SOLANO (0:07:20): That is the comment that I am presenting, yes.

JODY WHITTEN (0:07:24): All right, and you will be submitting that in writing, correct?

MICHELLE SOLANO (0:07:28): Yes, I did take down that email and I will send it.

JODY WHITTEN (0:07:33): Okay, thank you so much.

Okay, our next presenter of comments is going to be Kelly Velasco. Kelly, we are sending you a note to unmute.

KELLY VELASCO (0:07:48): Perfect, can you hear me?

JODY WHITTEN (0:07:51): We sure can.

KELLY VELASCO (0:07:52): Great, thank you very much. Good morning, good afternoon, everyone and thank you for the opportunity to speak today. My name is Kelly Velasco and I'm a Senior Medical Director at Amgen and I'm in this role I'm serving as the U.S. Medical Lead for BLINCYTO for that program in acute lymphoblastic leukemia. On behalf of Amgen today, I wanted to provide briefly remarks related to the proposed external infusion pump LCD update specifically regarding BLINCYTO whose LCD is being updated at our request to align with the product's most recent FDA approved expanded indications for use. I'll be brief I won't take 11 minutes. I just wanted to quickly note three different you know points.

First, I'd like to thank the committee for their thorough review of the support of data and their thoughtful consideration of this important update. I think in totality, Amgen agrees with the draft updated policy as written, and we have no additional comments at this time. If there is any additional information the committee would require to finalize this update, please reach out. We will certainly prioritize your request. We do look forward to this policy being finalized as soon as possible to ensure that patients with ALL can continue to benefit from BLINCYTO. So again, thank you for the time and I'll have no further comments and I'll close there.

JODY WHITTEN (0:09:22): Thank you so much. Our next speaker is Sarah Hnath. Sarah, we are unmuting your line.

SARAH HNATH (0:09:30): Thank you very much. Good afternoon. I'm Sarah Hnath, the Director of Medical Payer Strategy in Neuroscience for AbbVie. And today I'll be speaking on behalf of AbbVie, manufacturer of VYALEV. First, I'd just like to thank the DME MACs for your thoughtful development of the proposed LCD language. We fully support the language as set forth and appreciate your efforts. We do kindly request that you review and finalize this LCD as quickly as possible to ensure timely access for people living with Parkinson's disease who rely on this technology. Thank you for your consideration and I'll yield back the rest of my time.

JODY WHITTEN (0:10:08): Thank you. And our next speaker is Bill Noyes. Bill, you have the floor.

WILLIAM NOYES (0:10:17): All right. Thank you very much. My name is Bill Noyes. I'm the Senior Vice President of Reimbursement Policy for the National Home Infusion Association. I want to thank you for the opportunity to comment on the proposed external infusion pump local

coverage determination. I'm going to focus my comments on BLINCYTO in the expansion of coverage for newly approved FDA indications. Well, I understand that BLINCYTO may technically qualify for coverage according to the criteria laid out for DME infused drugs. The concern I wish to speak to is the lack of sufficient appreciation for the extensive pharmacy services that are required to ensure safe access to this drug in the home setting. No infusion drug can be administered successfully at home without access to necessary pharmacy and nursing services, and BLINCYTO is no exception. And because BLINCYTO must be treated as a hazardous drug, it requires a significant investment in specialized facilities, staff expertise, procedures that few home infusion pharmacies offer today due to the extraordinary expense for managing such facilities in compliance with the United States Pharmacopeia, chapter 800 standards. Those are the standards that mandate handling and processing of hazardous drugs. Unfortunately, the home infusion therapy services benefit in Part B lacks any payment for the extensive services provided by the DME pharmacy. These services include time spent performing patient assessment, care coordination, and developing plan of care, monitoring drug preparation, and compounding. Because it's the external infusion pump coverage that triggers HIT services, we believe that the DME MAC should consider whether these essential services are sufficient and accessible when evaluating new drugs for the DMEPOS benefit. NHIA generally supports expanding BLINCYTO for the indication for the newly approved FDA indication of CD19 positive Philadelphia chromosome negative B cell precursor acute lymphoblastic leukemias and believe a primary result of this may be to improve access to state Medicaid programs which often follow Medicare guidelines. I mention Medicaid because the highest incident of diagnosis is in those age one to four years old. NHIA does, however, remain seriously concerned that a decision to add new drug or new conditions are made independent of the consideration for patient access due to the fragmentation between the DME infused drug benefit and the home infusion therapy services benefit. Particularly lack of sufficient coverage of pharmacy services under the Part B home infusion therapy services benefit. CMS published data reflects significant beneficiary access issues to DME infused drugs. Looking to the most recent CMS DME utilization data files for 2023, there are, there were 407 pharmacies suppliers that dispensed HIZENTRA, which is the highest utilized subcutaneous infused Category 2 drug. There were 283 suppliers that dispensed milrinone, which is the highest utilized Category 1 drug. And just 64 pharmacies that dispense fluorouracil, the highest utilized chemotherapy, highly complex Category 3 drug. And for BLINCYTO specifically, there were 48 pharmacies that dispense that Category 3 drug. There's a correlation here. The more complex that involved the pharmacy services, the lower the number of dispensing pharmacies. Data in the February 2025 CMS Home Infusion Therapy Monitoring Report further highlights access challenges related to low supplier utilization or low supplier participation in the program and eroding patient access to many DME infused drugs that require significant pharmacy services, especially Category 1 and Category 3 drugs. The number of Category 1 drug recipients decreased by 20% over the 27 months Q1-2022 to Q2-2024 that the report reflects, while the number of Category 1 HIT service visits, those are the home infusion therapy service visits, decreased by over 40% during that same time period. Recipients of Category 3 HIT drugs, which BLINCYTO was a part of, decreased by 33%, while the number of Category 3 visits decreased by 25.5%. So, utilization of the drug and utilization of the visits are both on a very steep decline over that short 27-month period that's reflected in the report. The number of HIT service providers billing for visits during that same timeframe is low and declining, hovering around 60. Seven of the HIT supplier organizations provided 55% of all HIT services with 35 organizations providing fewer than 100 visits. That same CMS February 2025 HIT Monitoring Report also points to large geographic disparities for HIT services, especially for Category 3, where services are concentrated in the Mid-Atlantic states. Home infusion pharmacies often pay more than Medicare reimburses for Part B drugs, which are reimbursed at ASP plus 6% minus sequestration. Drug manufacturer discounts and rebates are typically not offered to home infusion pharmacies due to their class of trade used by manufacturers to categorize purchases. Payment for equipment and supplies is inadequate to support the physical and clinical infrastructure needed to respond to and provide BLINCYTO in the home. Due to the significant time involved with transitions of care from hospital to home, care coordination, high-risk compounding, BLINCYTO is handled as a hazardous drug per NIOSH recommendations and requires USP 800 compliant cleanroom, which requires significant capital and substantial administrative ongoing costs for pharmacies in order to provide the product. The need for backup equipment, 24-7 on-call availability of pharmacists and nurses, clinical implications for patients if the infusion is interrupted for more than four hours, the pharmacy investment far exceeds the reimbursement. As HIT services only recognize nursing services provided in the home, that's a face-to-face provision in the home, there is a substantial gap in the Medicare benefit in paying for the extensive pharmacy services required to offer BLINCYTO to patients in the home. Without a sufficient benefit for pharmacy services, patients needing BLINCYTO under Medicare, as well as other payers that follow Medicare guidelines, may find it difficult to find access, as it is currently limited and may become more limited as to the number of pharmacies that provide that service. NHIA strongly believes the DME MACs

need to take into consideration whether or not the services needed to support patients on drugs added to the external infusion pump LCD, are readily available to ensure safe and effective treatment in the home. Since many health plans follow Medicare policies, the implication of Medicare decisions will carry over to the private sector, including Medicare Advantage. Drugs like BLINCYTO, particularly for pediatric populations, require hours of time to coordinate and ensure a smooth and safe transition. This coordination is initiated by a home infusion pharmacy and is ongoing once the patient starts on service and cycles through drug dosing schedules. NHIA asks the DME MACs and CMS to reevaluate the home infusion benefit under the Medicare program and implement changes to ensure decisions to add drugs take into account consideration of the extensive pharmacy services required and whether the associated HIT services are sufficiently available to patients as all DME infused drugs require pharmacy and nursing services to support home administration. NHIA appreciates the opportunity to provide public comment and we will be submitting written comment. So, thank you.

JODY WHITTEN (0:20:34) Thank you.

WILLIAM NOYES (0:20:35) Hopefully, I can got that within the 11 minutes allowance.

JODY WHITTEN (0:20:37) You did. You did great. Thank you. All righty. Our next speaker is Bridget Davies. Bridget, we're going to send you a note to unmute your line. If you could please do that and we can check to make sure we're able to hear you.

BRIDGET DAVIES (0:20:53) Good morning. Hopefully, you can hear me.

JODY WHITTEN (0:20:56) We certainly can. Thank you.

BRIDGET DAVIES (0:20:57) My name is Bridget Davies. I'm the director of pharmacy and I oversee pharmacy operations at two Option Care sites and I just wanted to expand actually upon what Bill had just gone over about the complexity of providing BLINCYTO treatment within the home. I currently have no conflicts of interest to disclose. We at Option Care provide BLINCYTO treatment to patients in the home for both adult patients and the pediatric patient population. And our patient's journey begins sometimes before they're hospitalized, if not, while they're hospitalized for that initial cycle of treatment for BLINCYTO. Cycles one and two typically require hospitalization for two to nine days to make sure that they're receiving that therapy appropriately and that they are reacting to it without having any adverse effects. Though the exact duration depends on each individual patient and how they're reacting to their medication. During that hospitalization period, and many times even before they start their hospitalization, our infusion team is in contact with the case managers and the navigators preparing for that patient's transition into the home environment to receive that complex therapy from their home. Once that patient has been identified and BLINCYTO is initiated in the hospital, then it typically takes several days for us to prepare and set that patient up for their first home delivery of drug. And sometimes we actually deliver straight to the hospital for the patient to be hooked up in the hospital before they transition to their home. This transition involves lots of conversations to coordinate a seamless transition and then a safe process for making sure that patient is getting from hospital to the home in a safe and timely manner. BLINCYTO is typically administered via continuous IV infusion using an infusion pump. Patient receives therapy for 28 days, which means that proper setup and coordination is absolutely essential for the success of a patient going home on BLINCYTO. Every patient needs somewhere between four and nine deliveries for their 28 days of therapy and includes a combination sometimes, depending on when they're started on their therapy of different length bags. So, 24, 48, 96 hour bags, up to seven-day bags at a time to administer the drug. Every time we deliver an infusion bag and there's a change in how long we're infusing, we're sending the patient new pumps to their home. There are several key responsibilities that we participate in. So, nurses and pharmacists will work closely together to help manage delivery timing, appropriate setup for deliveries for that patient calendar, ensuring that there's a nurse in the home to help that patient do their BLINCYTO change, lab draws, and obviously the nurse visit for ensuring appropriate line care. And since patients cannot be disconnected for more than four hours, there's always a backup pump that is sent to the patient as a contingency plan to ensure continuous and safe care. Between the treatment cycles, a clinician is also assigned to continue to monitor the patient's progress throughout their therapy to make sure that they're tolerating the therapy and providing another chemotherapy drug between each cycle of their BLINCYTO. With each dispensing cycle, the pharmacist is also responsible for reviewing and verifying physician orders, making sure all treatment orders are accurate and up to date. The pharmacist will coordinate the care plan and create a patient's treatment calendar. And a lot of times the pharmacist is also involved in making sure that authorization is set up so that patient doesn't get an out-of-pocket bill sent to them. Because this is considered a hazardous medication, a pharmacist with expertise in overseeing sterile compounding of hazardous drugs must be in place to ensure that USP 800 standards are being appropriately followed for receiving of BLINCYTO, handling BLINCYTO, compounding BLINCYTO, safe transportation of BLINCYTO from the pharmacy to the patient's

home, storing the BLINCYTO and then with the nurse's help making sure that the patients are disposing of their therapy appropriately. This also includes operating a facility that has a negative pressure clean room that's separate from where the rest of our medications are typically prepared. Hazardous drugs also require separate storage areas and precautions to prevent accidental exposure during all steps of preparation delivery administration. And then each delivery, again, is coordinated with the nurse for discharge and delivery timing, which is critical for making sure that the patient receives continuous therapy. Before delivery, then the pharmacist will call, talk to a patient, talk to the nurse, make sure that they're verifying that the compounded drug, the supportive medications, and all the appropriate supplies are in place for that patient before, to make sure that do not have any interruption in their treatment. Nurses in the home also have a lot of responsibilities for BLINCYTO treatment including care coordination, communication, typically sometimes nurses are communicating with the pharmacy or the physician four to five times, also the patient to make sure that everything is going well for that patient. Nurses will also perform in-home visits for bag changes and lab draws, and each visit for those in-home visits are lasting one to two hours. And then the nurse is also monitoring the patient's response to treatment, ensuring the infusion is running smoothly, checking for any side effects or reaction, and making sure that the pharmacy is also aware of what's happening in the home. Administering BLINCYTO at home is highly coordinated and complex process that requires a full home infusion team and a lot of coordination amongst everyone from the hospital to the physician's office to ensure ongoing nursing visits are set up appropriately, pharmacist oversight, regular lab tests, processes to ensure safety and accuracy for that patient. And every step from the confirmation of discharge readiness to setting up the infusion schedule. Monitoring the patient's progress is carefully planned and coordinated to make sure that that patient is getting the optimal outcomes. So, this level of care requires a large team effort, clear communication, careful deep attention to detail, and ultimately to ensure that that patient's treatment is delivered in the most safe and efficient way as possible while they're able to stay in their home. Without sufficient payment for these services, patients in need of BLINCYTO may not be able to access their home infusion services, so we ask that this also be taken into consideration by the committee in determining the eligibility of the drugs applying for inclusion for DME. Thank you for your attention, and that's all the comments that I had for today.

JODY WHITTEN (0:28:48) Thank you. Our next speaker is Sabrina Yeamons. So, we will send you a note to unmute your line.

SABRINA YEAMONS (0:29:03) Hi, good morning and good afternoon. My name is Sabrina Yeamons. I am the Director of Operations with Premier Infusion and Healthcare Services. I currently have no conflicts of interest to disclose. Thank you for the opportunity to comment on the proposed local coverage determination for blenotumomab, BLINCYTO, to expand coverage under the DMEPOS for additional indications. I agree with the previous speaker about the need for the local DME MACs need to consider the availability of professional services when evaluating new drugs for the DMEPOS benefit. While our organization has the capacity to provide this therapy, the lack of coverage under the Part B HIT benefit for pharmacy will make it difficult to serve patients without incurring financial losses. The financial investment required to build and operate a USP 800 compliant facility to prepare hazardous drugs is a major deterrent to providing BLINCYTO. Most home infusion pharmacies have stopped providing hazardous drugs for home use. In addition to the extensive services required to coordinate and deliver BLINCYTO at home, the infusion pharmacy invests hours of time prior to the first delivery of the pumps and drug and before any home visit takes place. At present, Medicare reimbursement is tied to whether a home nurse visit occurs on a given day and for the cost of a single pump and the catheter and administration supplies. As an example, the home infusion pharmacy must have a sophisticated intake department to assess each patient's appropriateness for home infusion and to verify the patient meets Medicare's coverage requirements. Additionally, many patients have secondary insurance or require copay assistance due to the high cost of the therapy. All of the payment information must be investigated and verified before the patient can receive services at home. For patients on BLINCYTO who are hospitalized before coming home, this process usually starts several days before home admission. The home infusion intake team, including pharmacists, nurses, and reimbursement experts, work collaboratively with the prescriber and hospital to coordinate the transition to home. It is common for this process to occur over many days with numerous hours of time from multiple staff to complete. Due to the need to avoid disruptions in the infusion, the plan must be prepared precisely to ensure the patient will not need to be re-hospitalized and undergo re-treatment. Another responsibility of the pharmacy is to secure qualified nursing services to train patients on the administration of BLINCYTO. Not all nurses are trained in handling hazardous drugs and very few have experience with pediatric patients. The pharmacy ensures the home nurse has the appropriate training and skills to administer the therapy being provided. The hospital and physician expect the pharmacy to arrange for the nursing care as a coordinated service with the DME and drug. These items and services are not coordinated

by the hospital in isolation of each other, as some have suggested. The nurse must be familiar with the equipment and pharmacy protocols related to the medication being delivered and thus the pharmacy is responsible for the nurses performing the home infusion regardless of the billing arrangement as a separate benefit. Every day of therapy involves intensive clinical management regardless of whether a nurse is physically present. None of this work is being reimbursed by Medicare currently. Our concern is that with so few pharmacies engaged in providing the Part B home infusion therapy service, there will not be enough pharmacies capable of serving these patients. I respectfully urge you to modify the HIT per diem language so that reimbursement applies daily whether or not a nurse visit occurs. This change will ensure patient safety, provider sustainability, and appropriate access for beneficiaries receiving this critical therapy. We thank you for your time and hope you will consider these aspects of the home infusion service when evaluating new drugs for the DMEPOS benefit. Thank you.

JODY WHITTEN (0:33:41) Thank you very much for your comments. I'm going to now turn it over to Dr. Ballyamanda for her closing remarks.

DR. BALLYAMANDA (0:33:53) Thank you, Jody. Just testing to make sure that everybody can hear me.

JODY WHITTEN (0:33:58) Yep, sounds great.

DR. BALLYAMANDA (0:34:01): Thank you. So, we want to just take a moment to thank you all for your thoughtful comments today. Once again, please remember to send your comments in, in writing to the appropriate email address and as another reminder, the comment period will end on Saturday, September 6th, 2025. Once we have considered and collated all of the comments received during the comment period, we'll consider any changes necessary as a result of the comments received and then post final LCD along with a response to comments document. The final LCD will take effect a minimum of 45 days following the posting of the final LCD and for any updates please refer to the DME MAC websites. Again, I want to thank everyone for participating today and we'll formally adjourn this meeting now. Thank you.

JODY WHITTEN (0:35:01) Thank you.