

Urological Supplies  
Open Meeting  
January 28, 2020

DR. PETER GURK

Good afternoon, everyone. Um on behalf the DME Medical Directors, uh I'd like to welcome you to our final comment session uh this afternoon. Uh my name is Dr. Peter Gurk, I'm the Jurisdiction D Medical Director uh for Noridian Healthcare Solutions. Our final session today is to solicit comments regarding the proposed LCD for Urological Supplies. Uh the number on that is DL33803. A few reminders that as with our morning sessions today, uh we will be recording the meeting and will post that recording on our DME MAC websites. By signing into the meeting and registering as a speaker, you are giving your consent to the use of your vocal, or your verbal comments to be recorded and posted. We also ask that any comments made today also be submitted in writing to uh [UroRecon@noridian.com](mailto:UroRecon@noridian.com), right, Jody? Okay, I got it right this time. Thank you. Only registered commenters will be allowed to comment at today's meeting, but anyone interested in commenting may submit their comments also in writing uh to the email address that I just mentioned. Uh also, a reminder for those of you who are on the phone, we ask that you place your phone on mute if you are not speaking, and please do not uh use the mute button. We had issues earlier in one of the sessions with a lot of feedback, and it made it very difficult to hear the speaker.

The proposed LCD for Urological Supplies adds coverage for the inFlow™ device in the section, in the LCD entitled External Catheters and Urinary Collection Devices. Uh this is manufactured

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by the Vesiflo Company and is considered reasonable and necessary as an alternative to intermittent catheterization for beneficiaries with permanent urinary retention due to impaired detrusor contractility. There is also a section in the LCD that contains a summary of evidence and bibliography references. With that being said, let's begin with our registered speakers. We have four speakers registered for this session, uh your time will be divided equally amongst you all, and it will be ten minutes apiece. All right, so Mr. Connolly, go right ahead.

KEVIN CONNOLLY

Good afternoon. I am Kevin Connolly, I'm the founder and CEO of Vesiflo, manufacturer of the inFlow™. Thank you for giving me this opportunity to speak.

So, Medicare covers urinary catheters as prosthetic devices, what's defined as permanent urinary retention. In this presentation I'm going to refer to that as PUR for simplicity. PUR is often the result of life altering neurologic disease or injury. So, think advanced MS, stroke, spinal cord injury, uh multiple system atrophy, things of that nature. This is a difficult to treat population and these are among Medicare's most fragile beneficiaries. The problem is that many of the women with PUR are not being well served by the current medical options. The inFlow™ is an alternative to the urinary catheters that almost all of them use right now. And the inFlow™ can restore function and dignity for many women. It mimics normal urination as opposed to passively draining

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urine with a tube. It's a 29-day device, and its pivotal trial showed it to have a lower infection rate than the standard of care, while significantly improving quality of life.

So right now, most Medicare beneficiaries with PUR use one of two types of urinary catheters. Intermittent catheters, clean intermittent catheterization, CIC, is the standard of care. Um the standard of care requires inserting a tube into your bladder four to six times a day. The only alternative, for most patients, is an indwelling catheter, typically a Foley catheter. A Foley is a tube connected to a urine bag that remains in the bladder at all times. You are literally tied to a bag of your own urine. CIC is the standard of care because it has a far lower infection rate than indwelling catheters. But because CIC requires insertion of a tube into your bladder multiple times a day, it's usually only practical if a woman can self-catheterize. And the problem is that many of these patients can't perform this procedure. Their primary medical conditions might limit their manual dexterity, their visual acuity, their ability to position themselves; they simply can't perform it. Others who can perform it find that it's too demanding to maintain. And these are patients who are dealing with a lot, and it results in a long-term low compliance rate.

Patients who cannot or will not perform CIC typically end up with a Foley, despite the fact that we all know about the high rate of catheter associated urinary tract infection that results in CAUTI. But even many of these patients, even many of the uh patients who use Foley or suprapubic can instead use the inFlow, and it's likely to reduce their rate of CAUTI. And importantly, uh CAUTI

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reduction has been one of Medicare's highest healthcare priorities for over a decade. Um Medicare's financial incentives I think have been successful insofar as they've raised awareness of unnecessary Foley use, and to that extent cut down on Foley use. But really there has been no progress made when catheters have to be made in terms of improving infection resistance. And no matter what catheter is used, many patients find chronic catheterization to be psychologically devastating. And this is because the ability to void is a basic daily function, and when we lose this ability it erodes our self-image as independent adults. InFlow™ can improve this ADL function and improve quality of life for catheter users.

This is the FDA Indication for Use Statement, and you'll see that they characterize um the inFlow™ in the Statement as a urinary prosthesis. Now, a prosthesis by definition is a device that replaces a missing body part or function. These women lack body function, bladder function, they can't spontaneously urinate. InFlow™ replaces their bladder function by pumping the urine out at a near normal flow rate. This means that they can use a toilet or a commode in a more typical and far more dignified way. I'd compare catheterizing versus using the inFlow™ to the difference between IV feeding and eating. They both supply nutrition, but they go about it very differently. Now you can put a needle or a tube in anybody. The catheters are tubes that passively drain urine. InFlow™ is an active device that mimics normal urination. It's hard to overstate the importance of this, but normalizing urination can have profound psychological benefits as well as medical benefits.

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And this is a short video to show you how the inFlow™ works. I suppose it needs stating, but um this problem is particularly bad for women. Men at least have condom catheters; they have prostatic stents; they have prostate interventions of one sort or another. Women have very little except the two kinds of catheters we are talking about. So, preparation is similar to a urinary catheter, but it's deployed by pushing that plunger mechanism that engages soft silicone fins that hold it at the bladder neck. And at the other end it's anchored by the anal tab. So, to void a patient would sit on a toilet or commode and push the button on the remote control. There is a large magnet in this remote control; pushing the button spins it at 10,000 rpm. It couples with a small magnet in the bladder (inaudible...) are two rotors. So, when this assembly rotates at 10,000 rpm it forms a turbine pump, and it provides turbulent evacuation of all of the urine in the bladder. When you let go of the button, the magnet counter-spins and it engages a valve automatically, so they don't leak in between voids. Unlike a Foley, the inFlow™ can be easily and safely removed at any time and by patients, uh but it should be replaced once a month.

Uh I'm not going to belabor the uh evidence. It's well described in the proposed LCD; just a couple of the high points. The FDA classified the inFlow™ as a Class III device, because there was nothing like it. And they required a prospective multicenter pivotal trial that compared inFlow™ to the standard of care, the CIC. After a lengthy review, and changes in the FDA review process,

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uh the FDA down-classified the inFlow™ to a Class II device and it became one of the agency's first de novo approvals, and it established a new FDA device type.

Uh the FDA found the inFlow™ to be highly effective in emptying the bladder, and that it did this with a higher quality of life. Uh the safety profile was very positive; there were no serious or long-lasting adverse events associated with device use. And the blue part is a quote from the FDA's News Release on approval. The most potentially significant adverse event, UTI, appears lower with the inFlow™ device than with CIC, was stable with time and was easily managed with antibiotics.

Including the uh pivotal, there were seven clinical studies published in peer review journals with an aggregate end of over 500 subjects. Uh three were long term studies of one to four years. Uh the studies concerned similar populations and showed similar results, despite the fact that they were conducted by different investigators in different countries, even, over a period of years. All the studies have reported UTI rates reported at very low rates. So, inFlow™ has been sold outside the U.S. for 20 years, it was a CE marked device. And uh again, per isolated complaint files, there have been no recalls and no reports of serious long-lasting adverse events. Um U.S. use, as you might expect, was uh severely curtailed by the noncoverage decision, but there are some patients who have been on device for three years. We did a post-market survey, and they reported high levels of satisfaction and significantly lower UTI rates than when they were on catheters. Um this

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study, and actually a description of their uh catheters that they used before uh is being published in the Urology journal in March.

Uh and the inFlow™ has undergone literally hundreds of laboratory and biocompatibility tests. Uh there have been uh implantation tests, incrustation tests, safety tests, EMC tests, usability tests and biocompatibility. Uh inFlow™ complies with the most recent ISO10993 biocompatibility standards for its product type. Uh again, the proposed LCD uh makes mention of the support that inFlow™ has uh in both the physician and patient communities. The American Urological Association uh has written twice to CMS requesting that a unique code be issued. Uh our company has contact information based on personal conversations with over 1200 urologists who would like to prescribe the inFlow™. Over 800 of them are at least in the U.S. Uh 12 leading experts uh in urology reviewed the clinical evidence for the inFlow™ according to American Urological Association Guidelines for Evidence Based Review, and they concluded that the inFlow™ should be a recommended medical option for women with UR.

Um many of the national uh patient advocacy groups have also requested coverage. I think all of the national MS groups have written in, and a few of the spinal cord injury groups. And individual beneficiaries have stated over and over uh the importance of this. Two of them are here today to tell you about their experience, including uh this patient, Mrs. Steinbach, who previously testified at a CMS public meeting.

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So, bottom line, um we think this is a consensus that there are new medical options needed for this patient population. They have very few alternatives, and we believe that inFlow™ will be a valuable addition to the clinical armamentarium. Thank you.

JODY WHITTEN

Thank you. Our next speaker is Laurie Steinbach. Is this Judith? Okay, I'm sorry, Judith Olson, come on up. Thank you.

JUDITH OLSON

My name is Judith Olson. Um I had a fairly massive brain tumor removed in 1990, and the progressive development of scar tissue caused me to develop a neurogenic bladder. That meant that I couldn't void on my own and had to use catheters. I had many bladder infections a year, which meant extensive trips to the Emergency Room for lab tests, of course the doctor visits and the resulting prescriptions. One day I had a segment, uh I heard a segment on the local news about this miraculous thing that could replace catheters by spinning urine out of my bladder, or anybody's bladder by using a small pump and a magnet. I had no idea how it really worked, but I knew that I wanted one. I immediately called my urologist and talked to her about it. Amazingly, she knew about the development of the inFlow™ some years before, and she knew exactly what I was talking about.



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It took three months for me to get my device. Laurie was the company representative who measured my urethra and taught my urologist how to insert it. Then it was time for the big show, would it actually work? I invited everyone who was in that office to come into the bathroom to join me. I wasn't shy about such a momentous event. I pushed the button and urine came gushing out of me, and the whole room, men and women were laughing and crying. I think I was probably as happy as when I gave birth to my two children.

I had my urologist do the monthly device changes for the first six months, but it involved taking a ferry ride from my small town um close to Seattle, um and back. It took up half a day every time she taught my husband how to do it, or every time, so she taught my husband how to do it. That worked just fine for about a year until he got very sick and finally passed away. He was in a facility for a number of months, and I may be the only woman who ever had a device changed in a nursing home. We waited until his final care of the evening, and then I got everything that was needed uh to make the device change. He got out of bed, I got in and he changed it for me. We only did that once, and then I found a urologist who is just 20 minutes from where I live.

One of the main reasons that I wanted this device was because of the reoccurring infections. I found out, quite by accident, that I had significant kidney damage related to bladder infections. I had a fissure in the left ureter which was caused by an accident during surgery years ago. This

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helped enable bacteria to move from the infected bladder up into that kidney. Therefore, it's imperative that I do everything possible to reduce the chances of getting more bladder infections.

I have used the inFlow™ device for over three years and have had one or two infections in that time, which is a marked decrease from the number that I was getting while using catheters. My current urologist says that I have colonization of bacteria in my bladder from all of the previous infections, and once in a while that gets out of control, which accounts for those infections. I can't imagine why Medicare wouldn't approve coverage for inFlow™. It is a far better solution than catheters. It is so much easier and so much more dignified. I can't even begin to tell you how it feels to go into a stall in a public restroom and just urinate, just like the lady in the stall next to me, instead of washing my hands first, getting out all of the proper equipment, making sure I've washed my hands really well, opening the catheter and heaven help me if I've dropped it and it's my last one. Then of course, there are all of the aforementioned issues of what happens when you inevitably do get a bladder infection, plus the cost of the catheters. It's bad enough having to deal with a nonworking bladder. Please help all of the women out there with this condition by giving them access to this miraculous device. Thank you for having me here today.

JODY WHITTEN

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Thank you. Is Laurie Steinbach back yet? Okay, we are just going to wait a few minutes. She is in the hotel; we are just going to wait for her to show-up if that's okay. Hi, and this is Laurie? All righty, hi there. I have a mike for you.

STEPHEN STEINBACH

I'll probably end up holding it for her.

LAURIE STEINBACH

I'll be okay with it. Okay. Hi everybody. I'm a patient, I'm Laurie, and I'm a patient using the inFlow™ device, and I have no financial interests in the manufacturing. Due to MS and the damage it has done to my neurological system, I cannot empty my bladder. For the past four plus years, I have had to endure remittent self-catheterizations, approximately five times every day. Making this situation worse is the fact that I cannot do the catheterization myself, due to my MS. As such, I've had to depend upon my husband on a 24/7 basis to catheterize me. Up until four years ago, before I needed to be catheterized multiple times every day, I had two UTIs in my life. During the period during the multiple daily catheterizations, I had approximately 15 UTIs. Since starting inFlow™, I had only one. As you might imagine, this illness has taken a terrible toll on me and my family. The only positive thing that has happened to me over the last several years has been inFlow™, which I started using in January of 2016. inFlow™ has restored my independence and self-esteem in terms of being able to complete the simple process of urinization, urination, on

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my own. InFlow™ has significantly improved my quality of life. Thus, I believe that a billing code should be issued for this inFlow™ system. Thank you.

STEPHEN STEINBACH

Do you want me to continue?

Hi, my name is Steve Steinbach and thank you for the opportunity to um hear us out, discuss how inFlow™ has impacted our lives. Um first of all you should be aware that, as you may have learned, I am a caregiver for a patient using inFlow™. Um and I don't have a financial interest in the manufacturer, but uh my interest is in finding an effective and efficient tool that will allow my wife to empty her bladder by herself, just like the rest of the population can do it on their own, naturally. Um and the second issue of my interest is to find a way that she can eliminate or reduce the risk of UTIs. Um my wife has been using inFlow™ approximately four and a half years, so when she uh or I speak about inFlow™ we speak with authority um and firsthand knowledge, um not hearsay, not someone said so but being there on the front line, actually using it, uh and so forth.

Um the inFlow™ device is a life altering technology, both from a quality of life perspective uh as well as a medical perspective. And let me explain why. Um from the medical perspective it's well known that failure to regularly empty your bladder can lead to an increased urinary tract infection, kidney damage and other issues. Um also, um from a more technical and medical perspective, um

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if you just use a Foley or self-catheterization the problem is that you may only empty part, which will also leave a lot of the sediment which can start a lot of the infections um that people see with these two other devices. Um but the inFlow™ device um really shines when you consider how it improves the quality of life. Um most people don't think about emptying their bladder until um you get the urge, and then you simply look for a toilet and use it.

Um it's not the case when you have neurological issues effecting emptying. Um but if you have a neurological problem, just to kind of explain, um it one, prevents natural urination that completely empties the bladder; two, it causes incontinent issues; and three, it causes the inability to self-catheterize due to dexterity issues. If you are familiar with MS um it can affect people in many different ways, there just isn't one simple set of um issues. It can cause blindness, temporary or otherwise, um it can cause gait and walking issues, it can cause dexterity issues. So, um in my wife's particular issue she has some dexterity issues. Um and so even um if she was able to self-catheterize, which she can't, we'd still have the problem of what are we going to do? And in fact, when I had to have knee replacement surgery, and I wouldn't be able to um catheterize her when we were doing self-catheterization, she actually had to have a Foley installed for a week. Um so having the inFlow™ device, if she had it back then, would have really made life a lot easier for everyone.

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Um so you can see why emptying your bladder becomes a major issue that can consume your entire life, and in fact um when she had to um do self-catheterization with me doing it, she really couldn't leave the house because of leakage issues, because you need a place to actually um be able to lie down and have the um catheter inserted. And uh I'm just thinking of a funny situation, we were in Paris about four years ago and um she needed to be emptied, and there was really no place to go. So, we went into a café and went into a single bathroom and um she was on the floor, and I was trying to do it, and the people were knocking on the door, what are you doing in there? Bla, bla, bla. And trying to explain, uh explain it in a foreign language, and I don't really speak much French, it would have been really difficult. Had she had the inFlow™ device she could have gone in by herself, used the device and we would have been in and out in two minutes, three minutes. Um so it really is a life changing technology that makes a big difference to people. And I don't, And I think that unless you actually have a person who has a disability, whatever it may be, you really don't understand all the issues that the person may be up against um with those particular situations.

Um and lastly, inFlow™ solves both bladder leakage and emptying issues, and provides a natural as possible solution for a neurologically impaired person. As I said, my wife has MS, but anyone who has had a stroke or other neurological issue um can have these issues. And um, just as a last thought, most people don't think about this, but when you go to empty your bladder there is a number of things that happen. You need to one, open up the sphincter which keeps the urine in

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the bladder, and at the same time you also have to close the muscles around the bladder to pump it out, push it out. So, it's very interesting, but uh if you don't have the right neurological messages um going down to the bladder in that area it becomes a real issue. Um and I think, in the words of my wife, um who has testified before this about this, it's what? Tell me. It's what? What is it? What's the inFlow™ device?

LAURIE STEINBACH

It's the best thing since sliced bread. And I'm not kidding. I mean I don't think I would be able to lead a really normal life without it because it could leak. I mean and leaking is not good at all for the person that has that issue. And I don't leak at all. I mean it's the best thing, like I said, since sliced bread. It's really the best thing. I mean I absolutely love it.

STEPHEN STEINBACH

Thank you. Thank you for spending a few minutes listening to us. And if there are any questions, I'd be happy to answer them, real happy, if you have any, you know, firsthand user questions. Thank you for your time.

JODY WHITTEN

Thank you.

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DR. PETER GURK

Well thank you all for attending. Um thank you all, we appreciate your comments. Um as a reminder to all, uh that all of the comment period will close on March 2nd, so if you have additional comments, other comments to make, please have them submitted by that deadline. Again, the email address is [UroRecon@noridian.com](mailto:UroRecon@noridian.com). Um we will consider your comments here today, uh as well as the final written comments that we received, and we'll post a final LCD along with a response to comments document on our website. Um with that uh being said, I think we are ready to adjourn for the day. Thanks.