WPS GHA

Moderator: Kettler, Dr. Robert

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4:00 PM CT (5:00 PM ET)

Operator: This is Conference # 6899204

Operator: Ladies and gentlemen, thank you for standing by and welcome to the J5 MAC Advisory Committee Meeting. At this time, all participants are in a listen-only mode. After the speaker's presentation, there will be a chance for a question-and-answer or comment session. To ask the question during the session, you'll need to press star one on your telephone. Please be advised that today's conference is being recorded.

If you require any further assistance, please press star zero. I would now like to turn the call over to your presenter today. Dr. Dr. Mark Brady, please go ahead.

Dr. Mark Brady: Good afternoon everybody. My name is Dr. Mark Brady and I'm an anesthesiologist here in the Kansas City area. I'd like to call this meeting to order. The first thing I'd like to do is allow the folks and WPS to introduce themselves. So that we all know who they are.

Dr. Bob Kettler: I am Dr. Bob Kettler, the Jurisdiction Five Contractor Medical Director.

Thom Ryan: Thom Ryan, Provider Outreach Education Representative.

Adam Anderson: Adam Anderson, I am the Data Analyst of GHA InSight.

Melissa Jacobs: Melissa Jacobs, Policy Development Coordinator.

Dr. Mark Brady: Alright. Thank you very much. We'll start off the meeting with discussion about the draft LCD or evidence discussion for LCD development. The first one is DL37228 Wound Care.

Dr. Bob Kettler: Dan, is Dr. Holzmacher on the line?

Dr. Bob Kettler: Okay. Dr. Holzmacher is the CMD responsible for this LCD. I didn't know if you might have some comments to make, but otherwise any comments from the CAC in terms of the evidence for this LCD. Seeing no comment on that LCD.

Dr. Bob Kettler: Going to the next one, DL35490 Category III Codes.

Dr. Bob Kettler: There are two Category III Codes that were the subject of the reconsideration just for the benefit of some background. Our Category III LCD will recognize certain codes as being eligible for coverage. If a code is not on the list, a reconsideration requests can be submitted, and those codes are considered. There are two codes that have been for which there has been a reconsideration request submitted.

The first is for CPT code 0254T, this is for an endovascular graft. And there is an analysis of the evidence that is available. Does anyone have any comments on this particular reconsideration?

See none. The second code is 0355T, this is for colon or for capsule colonoscopy. Again, the reconsideration request has a summary of the evidence. Is there any comment on the evidence that was submitted for this particular code?

Dr. Bob Kettler: Okay, that concludes the LCD portion.

Dr. Bob Kettler: All right. At this time, the public line should be disconnected.

Addendum

Dr. Bob Kettler: We're getting some feedback on the phone line. I don't know if somebody's trying to comment.

Dr. David Schroeder: Hi, can you hear me?

Dr. Bob Kettler: Yes.

Dr. David Schroeder: Hello.

Dr. Bob Kettler: Yes, could you please identify yourself?

Dr. David Schroeder:	Yeah, this is Dr. David Schroeder. I'm the CAC rep from Iowa and I was trying to punch numbers to get in, the star one, but it wasn't letting me in when you had brought up the Wound Care LCD reconsideration.
Dr. Bob Kettler:	Okay. Did you have a comment to make then?
Dr. David Schroeder:	Yeah. I do, I do have a number of comments. It's up to you, if you like to do that now or finish the current presentation and we can go back to it, and I'll leave that up to the chairman.
Dr. Bob Kettler	Why don't you go ahead?
Dr. David Schroeder:	Okay. So, as I said I am Dr. David Schroeder and I'm a podiatrist in Iowa. I am the CAC rep and I represent the Iowa Podiatric Medical Society and today I'm also representing the American Podiatric Medical Association. First of all, I'd like to thank Dr. Holzmacher and the other WPS medical directors and administrative staff for the opportunity to comment on the WPS wound care LCD. I think pretty much you're aware of our position and today I would just like to kind of hit on with some of our supporting evidence and perhaps offer a little bit of a new perspective on where we see this policy needs to be reconsidered and changed. As you know, our concern is that since the issuance of LCD, L37228 on wound care, effective April 2018, WPS no longer provides coverage of debridement, specifically for stage II pressure ulcers, diabetic foot ulcers without neuropathy or neuro-ischemia and chronic non-pressure ulcers with a tissue severity of limited to break down of skin. And we feel that WPS policies are inconsistent with the established standard of care for the treatment of wounds. The universally and widely accepted best practice for any wound exhibiting devitalized tissue is to debride that wound regardless of the type of wound or its cause. If there's devitalized tissue present, it needs to be removed. The standard of care for the treatment of wounds has always included debridement of devitalized tissue that would be-such as necrotic issues, slough-debridement, abnormal granulation tissue, infected tissue, etcetera. This devitalized tissue, when present, has been shown to harbor bacteria and to inhibit wound healing.

The standard of care is to establish a clean, healthy wound bed and optimize the wound environment to have the best chance of healing of the wound. This is based on the condition of the wound itself regardless of what medical conditions that patient has.

Additionally, WPS wound policy now sharply contrasts the policies of the majority of its MAC counterparts. Of the seven other MACs, 5 have LCDs that covered debridement and while all have requirements for coverage, none limit ulcer types other than WPS. WPS wound care policy now also sharply contrasts CMS policies that address standards of wound care. One example of this is the national coverage determination for Hyperbaric Oxygen Therapy contained in the internet only manual.

The CMS Hyperbaric Oxygen policy includes, and I quote, "…diabetic wounds of the lower extremities as a qualifying condition providing the patient has failed an adequate course of standard wound therapy." CMS further states in the policy that "standard wound care in patients with diabetic wounds includes debridement by any means to remove devitalized tissue and maintenance of a clean moist bed of granulation tissue with appropriate moist dressings."

WPS wound policy also ignores recommendations of the National Pressure Ulcer Advisory Panel (NPUAP. Their recommendations state "there is a strong informed clinical consensus to support the role of debridement and wound bed preparation. Despite epically understandable lack of randomized controlled trials, directly comparing debridement to no debridement in human subjects."

So, the concept of wound bed preparation has been around for over 3 decades. Studies have shown support for something called TIME, that stands for Tissue debridement, Infection control, Moisture balance and Epithelial or Edge advancement. The time framework consists of comprehensive strategies that can be applied to the management of different types of wounds to maximize the potential for wound healing. It promotes principles of wound bed preparation including that debridement is necessary to restore the wound base in cases where the tissue is nonviable or deficient. Currently, the TIME model is taught in allopathic and osteopathic medical school curriculum as well as podiatric medical schools including Temple University.

So, there is a broad clinical consensus regarding the need for and the benefit of debridement to remove the devitalized tissue in order to

improve visualization of the wound, to remove necrotic tissue or foreign bodies or reduce bacterial load and prepare the wound bed.

You see this in guidelines issued separately by the wound healing society, the international working group on the diabetic foot and the NPUAP. In addition to cross society guidelines issued by APMA in collaboration with counterparts focused on vascular medicine and surgery. Peer reviewed, clinical decision support tools like UpToDate also call for the removal of devitalized or necrotic tissue for proper wound care.

For example, the Wound Healing Society provides updated guidelines for treating diabetic foot ulcers. Guideline 3.1 directs providers to remove all necrotic tissue by surgical and somatic, mechanical, biological or autolytic debridement.

Another example is the International Working Group on the Diabetic Foot. They've addressed treatment of chronic diabetic foot ulcers noting that the majority of national guidelines emphasize that debridement is essential to good wound care. So I was looking, in the past couple of days, and the number of the articles and studies that WPS used to support their position, and it seems that, and in some cases, WPS selectively pulled out statements that support their position, but made no mention of the other statements and conclusions that did not support the position.

For instance, one example is in the publication The Management of the Diabetic Foot, a clinical practice guideline by the Society for Vascular Surgery in collaboration with the APMA and the Society for Vascular Medicine. Again, the APMA is the American Podiatric Medical Association.

This paper does not divide diabetic ulcers into groups based on depth, or neuropathy, or PAD (Peripheral Arterial Disease), but rather it refers to diabetic ulcers as a whole and states that the patient demographics related to diabetic foot ulceration are typically for patients with longstanding diabetes.

Risk factors for ulceration include neuropathy, peripheral arterial disease, deformity, limited ankle range of motion, high plantar foot pressures, minor trauma, previous ulceration or amputation and visual impairment. When WPS selectively chooses neuropathic ulcers and neuro-ischemic ulcers, it ignores the other risk factors making up the other 10 to 15% of diabetic ulcers. That is, those with the other risk

factors such as deformity, ankle equinus, high plantar pressure, et cetera.

So, in conclusion, prohibiting coverage for these types of ulcers place the patient at risk for worse outcomes and places providers in the position of having to choose between providing care that is inconsistent with their medical training, clinical guidelines, and the standard of care or forgoing reimbursement for medically necessary care that vulnerable patients need.

Prohibiting coverage of standard wound care for these wounds can also jeopardize the patient's ability to qualify for other advanced treatments such as hyperbaric oxygen, based on CMS policies. APMA and IPMS strongly urges WPS to reconsider and revise the proposed LCD and finalize updates that would provide for coverage of debridement services for stage II pressure ulcers, diabetic foot ulcers without neuropathy or neuro-ischemia and chronic non-pressure ulcers with severity limited to break down the skin when devitalized tissue is present.

Thank you, that's all I have. If you have any questions about this, I'd be happy to answer them or have further discussion.

Dr. Bob Kettler: Thank you, doctor. I don't have any questions right now. Could you please put a summary, maybe in bullet points, of what you said, send it to policycomments@wpsic.com. The reason for that is sometimes the transcript miss things and this way we would have your important points so that we can respond to that. But I appreciate your comments and I'm sorry you didn't get on the line earlier.

Dr. David Schroeder: No, no problem. I'm glad I was able to present that and thank you for the opportunity, and I think that the American Podiatric Medical Association will also be, I think, forwarding you some more information if they haven't already, but again, thank you.

Dr. Bob Kettler: You are welcome.

Dr. Ryan Holzmacher: Alright. Dr. Kettler, can you hear me?

Dr. David Schroeder: Yes.

Dr. Ryan Holzmacher: Hi, this is Dr. Holzmacher. I too was unable to get in earlier during your request for comments. I just wanted to say thank you to the physician who spoke there regarding the comments and just let you know that I am on the line.

Dr. David Schroeder: Okay, thank you.