Transcript Details

This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/medical-industry-feature/get-the-facts-about-reimbursement-for-a-secondary-hyperparathyroidism-treatment-option/12390/

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Get the Facts About Reimbursement for a Secondary Hyperparathyroidism Treatment Option

Announcer:
You're listening to ReachMD. This medical industry feature, titled "Get the Facts About Reimbursement for a Secondary Hyperparathyroidism Treatment Option" is sponsored by Amgen.

Before we begin, let's review some important information for Parsabiv® (etelcalcetide) injection.

Parsabiv® (etelcalcetide) is indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.

Parsabiv® has not been studied in adult patients with parathyroid carcinoma, primary hyperparathyroidism, or with CKD who are not on hemodialysis and is not recommended for use in these populations.

Parsabiv® is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients. Hypersensitivity reactions, including face edema and anaphylactic reaction, have occurred.

Stay tuned for additional Important Safety Information for Parsabiv® later in this podcast. This program is intended for healthcare professionals only.

Dr. Russell:
Welcome to today's program on ReachMD. I'm Dr John Russell. Today on the program I have the opportunity to talk with experts in the field of nephrology about updated 2021 Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for renal dialysis services.

This is an important topic for dialysis centers around the country, so I am excited to be joined by three guests who I am sure will help all of us understand the implications of the recent changes by the CMS. First up is Dr Kevin Griffiths, a nephrologist from Washington, DC. Dr Griffiths, I appreciate you being here!

Dr. Griffiths:
Happy to talk to you, Dr Russell.

Dr. Russell:
We are also excited to talk to Linda Roberto, a renal dietitian from Philadelphia, Pennsylvania. Thank you for being with us, Linda.

Ms. Roberto:
It's my pleasure, thank you.

Dr. Russell:
Also joining us is Colleen Guffee, a renal dietitian from Columbia, South Carolina. Thank you for being with us, Colleen.

Ms. Guffee:
Good to be here, thank you.

Dr. Russell:
Okay, our topic is Medicare's reimbursement system for dialysis care, including some new wrinkles to this year's policies. This issue really does impact everyone who works on a dialysis care team. Dr Griffiths, can you please tell us, what is the end-stage renal disease

(ESRD) bundle?

Dr. Griffiths:
Sure thing. Dialysis centers serve thousands and thousands of patients, a majority of whom end up on Medicare. Back in 2011, the CMS, the Centers for Medicare & Medicaid Services, were looking to evolve how they could continue paying for dialysis services and treatments. So, they landed on this idea of bundling together services and medications that were essential, and then reimbursing dialysis centers based on the value that they calculated for that bundle. All of this falls under the End-Stage Renal Disease Prospective Payer System, or ESRD PPS.[1]

Dr. Russell:
So that was a big change, you said back in 2011. Yet, it sounds like there are still many questions about the bundle?

Dr. Griffiths:
Yes, absolutely. Each year, it's become a question of what will the bundle hold this year? You know, what services and medications will be included? At what levels will they be reimbursed?

And it is evolving, which is a good thing. CMS has stated that they value bundled payments for ESRD to encourage non-wasteful, high-quality care.

Dr. Russell:
I get it, then, the bundle has many implications for the kind of care that patients receive.

Dr. Griffiths:
Yes, I think this year, especially, we are realizing how it can impact the management of patients with secondary hyperparathyroidism as facilities react to the new guidance around the bundle and reimbursement.

Dr. Russell:
I think this is a good time to get some perspective from our other two guests today who are patiently listening. Linda Roberto and Colleen Guffee, you are both renal dietitians, so obviously very hands on with the day-to-day realities of managing in this bundled world. So Linda, maybe I'll start with you what you are seeing and what's different.

Ms. Roberto:
Hi John. For me, and I'm sure every dietitian out there, it comes down to the patients. You don't want to see anything that could compromise the management of a patient whose lab values are being maintained in a good range.

Dr. Russell:
Do you have an example of what that might look like?

Ms. Roberto:
Yes, I think it's a matter of making sure we have more than one option because not every patient responds to treatment the same way.

For instance, I had a patient who had developed secondary hyperparathyroidism about 2 or 3 years ago. We started oral cinacalcet, which could be pretty effective for that condition when taken as prescribed. But I recognized that my patient was not responding to oral therapy. We switched him to Parsabiv® and he made strides as his PTH dropped about 30%, and phosphorus and calcium levels came back to the target range for our center.

Dr. Russell:
Prescribing options are definitely important. Colleen, are you noticing any changes this year that go back to the bundle question?

Ms. Guffee:
Well, hearing Linda made me think about a patient that I had on oral calcimimetic who was responding to therapy with oral calcimimetic, but then we started to see some changes in her lab values that indicated the treatment was not working and that lead us to try another option.

As for the bundle, I have heard that some dietitians and care teams are frustrated because Parsabiv® has been removed from their facility's algorithm as it's now part of the bundle and no longer reimbursed as an add-on.

Dr. Russell:
I can see why that might evoke some strong feelings. What's your sense of this Dr Griffiths?

Dr. Griffiths:

Yes, that is a pretty hot topic, as it does appear that Parsabiv® usage is being limited at some facilities.

You should know, John, this is a drug that came out a few years ago. I've used it. I've seen it work for patients, especially in cases like those that Linda and Colleen described. You have a patient who fails on orals or who had other concerns at the time of taking the oral therapy. I don't think it's beneficial for patients to have to go back to an oral medicine that didn't work for them because of a facility-specific algorithm that rules out a newer medicine such as Parsabiv®.

Dr. Russell:
So that's happening?

Dr. Griffiths:
Yes, you know, each dialysis center develops their own processes for managing conditions like sHPT. In the last several years, a new policy called TDAPA was set up to allow people on Medicare better access to newer products. Parsabiv® was the first product to go through TDAPA and set the precedence for future products that may go through TDAPA, providing a proven pathway for newer therapies in the future.2 As Parsabiv® was made available as an add-on to the bundle, facilities began adopting its use. That's what we did at our facility. We tried it and were impressed, so much so that we really began using it in earnest for those clinically-appropriate sHPT patients on hemodialysis.

During this TDAPA period, CMS collected the usage data for Parsabiv® and other newer treatments and actually factored that into the 2021 plan. So this year's bundle reflects that calcimimetics were used in approximately 30% of ESRD patients.[3] For that reason, the bundle base rate was increased by its largest amount in 10 years, resulting in an increase of $10.09 per session.[3-9] Therefore, every patient will receive $10.09 per dialysis session whether they are on a calcimimetic or not.[3]

Dr. Russell:
You're listening to ReachMD. I'm Dr John Russell and I'm joined by renal dietitians, Colleen Guffee and Linda Roberto, as well as Dr Kevin Griffiths. We're discussing the CMS bundle that shapes dialysis care for many patients with sHPT.

Before we continue, let's review some Important Safety Information for Parsabiv®.

Announcer:
Here's some additional important safety information for Parsabiv®. Parsabiv® lowers serum calcium and can lead to hypocalcemia, sometimes severe. Significant lowering of serum calcium can cause QT interval prolongation and ventricular arrhythmia. Patients with conditions that predispose to QT interval prolongation and ventricular arrhythmia may be at increased risk for QT interval prolongation and ventricular arrhythmias if they develop hypocalcemia due to Parsabiv®. Closely monitor corrected serum calcium and QT interval in patients at risk on Parsabiv®.

Dr. Russell:
Dr Griffiths, you were saying some facilities might be removing Parsabiv® from their algorithms. Is that temporary or permanent?

Dr. Griffiths:
It appears that some facilities are requiring some patients to try oral cinacalcet again, even those who failed orals earlier and were switched to Parsabiv®. So, I'd call it a reset of sorts. I'm not sure if this is temporary, but I hope so, and I'd encourage the people and committees involved with those decisions to really look again with the clinically-appropriate patients in mind.

Parsabiv® utilization nationally was approximately ~6% last year,[10*] so that gives you a sense of how many patients we're talking about. And we must act with those patients in mind, or I'm concerned for what that means for our patients' sHPT labs over time. I think these patients are certainly worth putting in the effort to make sure they get what they need.

Dr. Russell:
Again, I turn to you, Colleen and Linda. Your peers are out there making treatment decisions. What are their options if they don't have Parsabiv® available for the patients that were previously switched from oral cinacalcet to Parsabiv®?

Ms. Guffee:
I wish I had a good solution. It's very challenging to manage sHPT. We're trying every day to help them manage their lab results to a good place. Parsabiv®, which is an IV calcimimetic, offers control over administration.

It has to be very difficult to explain to a patient why they may have to go back to something that didn't work, for whatever reason. I imagine, for care providers in that situation, it's not a good feeling to be told that you are not able to access an important medication to

help the right patients.

Ms. Roberto:
If I understand the policy correctly, the bundle rate was structured so that every eligible dialysis patient is reimbursed as though they are all receiving Parsabiv®. But we know that not every patient with sHPT gets or needs Parsabiv®.

Dr. Russell:
Right, Dr Griffiths mentioned that 2021-based rate is based on the Parsabiv® national utilization of ~6%.[10*]

Ms. Roberto:
It just seems to me that centers are being reimbursed for all patients even though only a small percentage need it, so it's not clear to me why it wouldn't be available for those patients that do need it. There should be appropriate steps built into the algorithm that would allow a patient to progress, if needed, to Parsabiv®. That's how we've done it the past few years, and it seemed to work fine. It's just a shame that we followed a similar protocol of switching patients to Parsabiv® after they failed oral calcimimetics and some facilities are having to repeat that step again.

Dr. Russell:
Great points. Dr Griffiths, any final thoughts you want us to ponder?

Dr. Griffiths:
Yes, as CMS has stated, their intent with bundling services was to encourage non-wasteful, high-quality care.

With the knowledge that an extra ten dollars is provided in the bundle for calcimimetics for each and every dialysis session,[3] we should feel confident in prescribing Parsabiv® for those who are clinically appropriate.

Finally, I'd say let's keep in mind that the manner in which we care for patients today may be a basis for future programs. So as we try to achieve new quality initiatives in terms of outcomes, I think there's a strong case to be made for equipping dialysis care teams with the options they need to help patients who are dealing with something as challenging as sHPT and everything else they are dealing with.

Dr. Russell:
Well said, Dr Griffiths. I thank you for being here today and shedding light on this important aspect of dialysis care!

Dr. Griffiths:
My honor, thank you for having me!

Dr. Russell:
Colleen Guffee, thank you for joining us!

Ms. Guffee:
It's my pleasure, thank you!

Dr. Russell:
And Linda Roberto, I appreciated your perspective. Thank you!

Ms. Roberto:
Thank you, Dr Russell.

Dr. Russell:
Thank you for listening to what was a very enlightening discussion. I want to thank renal dietitians Colleen Guffee and Linda Roberto, and Dr. Kevin Griffiths for their time and insights in helping us understand more about the management of secondary hyperparathyroidism.

Announcer:
And, now here's the Important Safety Information for Parsabiv®.

Hypocalcemia: Significant reductions in corrected serum calcium may lower the threshold for seizures. Patients with a history of seizure disorder may be at increased risk for seizures if they develop hypocalcemia due to Parsabiv®. Monitor corrected serum calcium in patients with seizure disorders on Parsabiv®.

Concurrent administration of Parsabiv® with another oral calcimimetic could result in severe, life-threatening hypocalcemia. Patients

switching from cinacalcet to Parsabiv® should discontinue cinacalcet for at least 7 days prior to initiating Parsabiv®. Closely monitor corrected serum calcium in patients receiving Parsabiv® and concomitant therapies known to lower serum calcium.

Measure corrected serum calcium prior to initiation of Parsabiv®. Do not initiate in patients if the corrected serum calcium is less than the lower limit of normal. Monitor corrected serum calcium within 1 week after initiation or dose adjustment and every 4 weeks during treatment with Parsabiv®. Measure PTH 4 weeks after initiation or dose adjustment of Parsabiv®. Once the maintenance dose has been established, measure PTH per clinical practice.

Worsening Heart Failure: In Parsabiv® clinical studies, cases of hypotension, congestive heart failure, and decreased myocardial performance have been reported. Closely monitor patients treated with Parsabiv® for worsening signs and symptoms of heart failure.

Upper Gastrointestinal Bleeding: In clinical studies, 2 patients treated with Parsabiv® in 1253 patient years of exposure had upper gastrointestinal (GI) bleeding at the time of death. The exact cause of GI bleeding in these patients is unknown and there were too few cases to determine whether these cases were related to Parsabiv®.

Patients with risk factors for upper GI bleeding, such as known gastritis, esophagitis, ulcers or severe vomiting, may be at increased risk for GI bleeding with Parsabiv®.

Monitor patients for worsening of common Parsabiv® GI adverse reactions and for signs and symptoms of GI bleeding and ulcerations during Parsabiv® therapy.

Adynamic Bone: Adynamic bone may develop if PTH levels are chronically suppressed.

Adverse Reactions: In clinical trials of patients with secondary HPT comparing Parsabiv® to placebo, the most common adverse reactions were blood calcium decreased (64% vs. 10%), muscle spasms (12% vs. 7%), diarrhea (11% vs. 9%), nausea (11% vs. 6%), vomiting (9% vs. 5%), headache (8% vs. 6%), hypocalcemia (7% vs. 0.2%), and paresthesia (6% vs. 1%).

Please visit ParsabivHCP.com for the Parsabiv® full prescribing information. This Medical Industry Feature was sponsored by Amgen. To learn more about Amgen, please visit Amgen.com. And, if you missed any part of this discussion, please visit Reachmd.com/Parsabiv. This is ReachMD. Be Part of the Knowledge.

References:

1. CMS. 42 CFR Part 413. Medicare program; ESRD PPS, payment for renal dialysis services furnished to individuals with acute kidney injury, and ESRD QIP. Final rule.
2. CMS. Implementation of the Transitional Drug Add on Payment Adjustment. Transmittal R1999OTN. https://www.cms.gov/Regulations-and- Guidance/Guidance/Transmittals/2018Downloads/R1999OTN.pdf. Accessed March 11, 2021.
3. CMS. 42 CFR Part 413 CMS-1732-F. 2020.
4. DHHS. CMS. MLN Matters. 2011.
5. DHHS. CMS. MLN Matters. 2012.
6. CMS finalizes policies and payment rates for end-stage renal disease prospective payment system for CY2014.
7. CMS updates to policies and payment rates for end-stage renal disease facilities for CY2016 and changes to the ESRD QIP; 2015.
8. CMS updates to policies and payment rates for end-stage renal disease prospective payment system (CMS 1651-F); 2016.
9. CY19 ESRD DME NPRM (CMS-1691-F) and DMEPOS competitive bidding program temporary gap period announcement; 2018.
10. Data on file, Amgen; [Parsabiv and Cinacalcet Usage, 2020].