Noridian Open Meeting Held on 9.20.23

0:00
Welcome everyone.

0:02
This open meeting as she mentioned is is concerning the molecular testing for solid organ allograph projection.

0:10
You wouldn't be on this meeting unless you and wanting to comment unless you were familiar with the policy.

0:16
But just to hit some of the highlights, this is a policy that has had some controversy and with this is an attempt to try to resolve some of that controversy based on policies that have preceded this one.

0:33
We have coverage guidelines and the guidelines are are contained with within that the definition that we use in the guidelines.

0:42
Where they will not be any confusion Medicare is going or Medicare in this contractor will provide them to coverage for molecular diagnostic test using the evaluation and management of patients who have undergone the solid organ transportation test.

0:57
Your informed decision making along with standard clinical assessment of the patient.

1:01
They'll be ordered by qualified position considering the diagnosis of a key rejection helping to rule out this condition When assessing the need results of a diagnostic biopsy, they are considered not as a item themselves but to be used and considered along with clinical evaluation results.

1:19
Collective tests that are test as transplant allograft for rejected status are covered and there is a list of 6 bullet points that are intended use and the test must be about one of the two following clinical status determination and that is acute rejection or cellular antibody mediated rejection.

1:41
The policy is list also non covered items are not items, but under conditions of which items are not to be or not be covered.

1:52
Those are all listed to several bullet points in here.

1:55
That summary of the evidence is likewise listed in the policy at where we came to the conclusion that we did come to and the contractors advisory committee.

2:07
We had two one on the heart and lung and a second one was conducted on additional organs.

2:22
Purpose of this meeting is to allow, and this is been truly a purpose, to try to gather information on objection to the test.

2:34
Not only do we want your feelings, but we also need for you to provide documentation and the documentation needs to be hopefully in the form of of clinical trials to our articles.

2:51
This policy we know is controversial.

2:57
We know it's going to take some explanation and that's what we are when we have this notice and comment period.

3:06
The notice.

3:07
Is 45 days long and it will be in the.

3:12
The.

3:12
The comment period is 45 days long and will end on the 23rd of this month.

3:18
So you need to get the information if you haven't already into us by the 23rd.

3:24
We then have a minimum of 45 days to respond and our comments and and response to comments will be published.

3:32
The reasons for our comments likewise will be published and the changes that will come out will then be afforded a additional 45 day notice period prior to its initiation.

3:50

With that introduction would like to begin with our presentation Doctor Jeffrey Tootenberg, you are up to bat the the three issues I wanted to bring up today and the proposed decision was the first of the use of molecular diagnostic testing being restricted to the the frequency that senders use biopsies.

4:12
The 2nd is the molecular testing should not be used concomitantly with a biopsy.

4:17
And the third is that for any given patient encounter only one molecular test can be used.

4:21
Next slide, excuse me just one minute I I failed to mention that the question that come up the the question of how long does each speaker have.

4:33
We typically ask that we limit these to 8 minutes, but there's no no set ironclad in stone rule we would try to keep it that short if you can.

4:46
If you cannot and get your you do cannot get all you want to talk to, that's fine.

4:49
We're not going to be limiting to that, but but if others are have already presented the point that you're trying to make you can you can just say issue that you know you agree and the same data it it would be much appreciated.

5:04
So that there is no particular limit.

5:08
We do have hopefully a a A2 hour window if we can go over that if we need be, but hopefully it's not in repetitive items.

5:17
So if you will keep that in mind, I would certainly appreciate it.

5:21
And I'm sorry to interrupt you if you please go ahead, not a problem.

5:24
Thanks so much.

5:26
So we certainly seen with our use clinically of molecular surveillance that it's definitely critical for the use for the management of patients outside of where we typically do a surveillance biopsy.

5:37
And specifically it's really used to help make transplant medicine and heart transplant medicine in particular in this case much more like precision medicine, focusing in on that particular patient and making sure we're managing that particular patient as precisely as we possibly can.

5:53
Next slide.

5:57
And to kind of give this some context.

5:59
So for most of our patients, there's a small proportion of them that are higher risk and they're typically younger.

6:04
And unfortunately many of those are young women.

6:06
And those patients we need to maybe have higher degrees of immunosuppression and we may need to keep a little bit closer eye on them.

6:13
And doing that with biopsy alone is impractical For the vast majority of the rest of the patients they tend to be lower risk.

6:19
And for our patients particularly those who are older who are more likely to have toxicities of chronic immunosuppression, it's really important that we establish their their being low risk and that allows us to back off on immune suppression and hopefully mitigate many of those adverse events from the chronic immune suppression.

6:36
Next slide and the other thing that molecular testing allows us to do is to catch things early and we like to catch up before there's histologic evidence of rejection or donor specific antibodies and certainly before patients develop left ventricular or by ventricular dysfunction and heart failure symptoms.

6:55
Next slide.

6:58
And we've seen that with some of our large national databases, this is data from shore, our large national database of heart transplant patients being managed with non invasive molecular testing.

7:08

And these are a couple of dozen patients who have biopsy proven rejection and we can see elevations of their cell free DNA starting a couple of months prior to rejection and that's important because we can interrupt that inflammatory and immune cascade before it gets out of control and more difficult to manage.

7:23
Next slide.

7:27
And that's important because when you look at patients who have rejection, those who have rejection without hemodynamic compromise do better over time sort of overall survival, not to mention many of the downstream effects of graft dysfunction and vasculopathy.

7:40
Next slide and rejection is still a problem throughout the lifetime of the graft, even though we sort of only have done our biopsies early on.

7:49
That's the period of high risk, but it's not the period of only risk.

7:53
And patients still get rejection throughout the lifetime of their grafts and that can result in adverse events and hospitalization and cost as well as mortality.

8:03
Next slide, the new guidelines I think sort of capture the spirit of although they came out to, I think a little bit too late to be included in the bibliography.

8:13
But you know, they do mention that routine tests and clinical visits are crucial for the success of heart transplantation and that's a class one recommendation.

8:21
And if you hit the button again, you know and the reassurance of these negative surveillance results with noninvasive testing outside the biopsy window are really, really critical to us having the ability to reduce toxic immunosuppression and manage our high risk patients as well.

8:39
News next slide.

8:43
You know the other things the biopsies are can be harmful.

8:45
We know from a lot of studies over many years that you can develop severe TR anywhere from maybe 10 to up to 25% of patients and that results in graft dysfunction and symptoms and can often lead to things like valve surgery to correct it.

8:59
Next slide, We also know the biopsies are inaccurate not only because they only sample a very limited area of the myocardium and we know rejection can be throughout the myocardium and often patchy.

9:11
But when you have local pathologists compare the results to central pathologist, you can see that from this slide when they grade is over to our rejection something that we would normally augment their immune suppression for about 40% of the time, the central pathologists actually disagree with those readings.

9:27
And so those patients potentially could have avoided that augmented immunosuppression.

9:32
In the flip side of things, only about about 7% of the time it's still reasonably common.

9:38
The local pathologist don't think the rejection is there, there is rejection and the central pathologist do.

9:43
And so those patients may have benefited from more immunosuppression, but don't get it because of the disagreement and pathology.

9:51
Next slide and long term biopsy is just impractical and not really patient centric and we'd like to try and move away from that.

10:00
When you look at 2019 and the distance of recipients from the heart transplant centers, over 20% of them are over 100 miles from the transplant center.

10:08
So it's just not practical for patients in terms of being able to get rides and affording it and gas and parking and not to mention things like pain and discomfort and anxiety from the procedure itself.

10:19
Next slide.

10:23
So molecular testing is clearly a suitable candidate to replace most surveillance biopsies in our program.

10:28
About 95% of our routine surveillance doesn't result in a biopsy because of the use of molecular

testing, but they should also be used to in areas where we don't use biopsies because they're either impractical or too risky.

10:42
Next slide.

10:45
And specifically I think extending the surveillance out over the years with molecular testing is reasonable both to detect rejection, but also again to specifically help us mitigate some of the chronic downstream negative effects of chronic immunosuppression.

11:00
Next slide, the 2nd is a molecular testing shouldn't be performed in conjunction with a biopsy.

11:07
We often see patients who present with graft dysfunction and often the biopsies are one difficult to get.

11:12
And if we do get them, they're often bland in relationship to sort of how much graft dysfunction we see.

11:17
And so it's often useful to get a molecular test to see if there's active rejection happening.

11:23
Maybe this process started just a couple of weeks ago and the patient would benefit from more immune suppression or maybe it happened six months ago and you just haven't seen them in six months and they wouldn't benefit from that those toxic immunosuppressive drugs.

11:36
Next slide and we're already using multi modality testing.

11:41
Our patients get antibodies tested, they get an echocardiogram, they get a biopsy, often times they get an angiogram as well.

11:48
And so these molecular tests just are part of the picture to help us better take care of our patients.

11:53
Next slide and we can also use it to determine this the the success of treating rejection.

12:02
We see that cell free DNA goes up with rejection whether antibody or cellular mediated and comes down after treatment.

12:08
And many of our patients can't come back for a two week biopsy.

12:11
It's too difficult for them to get back or their initial biopsy was sort of bland in the face of graft dysfunction.

12:16
And so it's hard to know whether a treatment worked or not and noninvasive testing is really a boon to being able to determine the adequacy of treatment.

12:24
Next slide.

12:28
And lastly, we're already doing multi modality testing and so limiting to only one molecular test per visit doesn't seem to make a lot of sense.

12:37
For acute cellular rejection, we're using gene expression profiling and cell free DNA.

12:42
For a Mr.

12:42
we're using things like antibodies and cell free DNA and hopefully we can start to use some of these tests to look at some of the more difficult chronic problems like Cav and allograph dysfunction.

12:52
Next slide.

12:55
So in summary, again thank you for the opportunity to present today and just some considerations for changes to the the language.

13:02
So in terms of the test frequency, we would suggest that molecular surveillance is really critical for patient management and shouldn't be limited to instances where surveillance biopsy wouldn't have been performed.

13:12
The next is the concomitant use of biopsy and molecular testing.

13:15
We agree it shouldn't be used concomitantly all the time, but the simultaneous use of biopsies and molecular testing may improve the diagnosis in patients who present with graft dysfunction.

13:24
And last thing in terms of the number of molecular tests that you can use, I think we've seen the clinical evidence in our clinical experience of date has shown that these molecular assays are complementary to one another and provide data on various aspects of the L immune response and graft injury simultaneously that allows us to better take care of our patients.

13:43
Thank you so much.

13:47
Thank you, Sir.

13:48
Again, we've got your slide presentation, the articles, if you could get those in the and the language all of this in writing to us, it would certainly be appreciated.

14:00
Doctor Woodward will be our next speaker after this.

14:04
Doctor Oates is going to take over for me as far as the introducing the, the next speakers and participants in this meeting.

14:12
And Gary, thank you so much for doing that.

14:15
And but Doctor Woodward, please proceed if you're ready.

14:20
Thank you.

14:20
Thanks for the opportunity to present today.

14:22
As mentioned, I'm Robert Woodward, I'll be presenting on behalf of Care DX could move forward.

14:26
One more slide please.

14:29
At Care DX, we are 100% committed to transplantation with over 20 years of innovation and transplant patient care.

14:37

Our Medicare approval was in 2000, first Medicare was in 2006 for gene expression profiling of immune status and heart transplantation.

14:45
And we led the industry with the first approved coverage of donor Dr.

14:48
cell free DNA to major graft injury in kidney, heart and lung and then the first approved coverage for multimodality testing.

14:56
Next slide please.

14:59
I'll go through the next slide quickly.

15:01
This was in the previous presentation, but there's a significant need for these advanced molecular tests and transplantation which is a life saving treatment.

15:13
This transplant carries a lifelong risk of immune mediated rejection of the transplanted organ and rejection is currently diagnosed by histopathology from an invasive biopsy.

15:22
However, surveillance by biopsy is invasive and therefore undesired.

15:27
While surveillance through assessment of graph functioning is insufficient to identify rejection early enough, molecular tests have significantly reduced the dependence on biopsies, improved diagnostic capability and enabled noninvasive detection of subclinical rejection that occurs before function is impacted.

15:45
Next slide please.

15:50
These tests have proven so valuable that they have been quickly adopted.

15:53
Just those provided by Cardiacs are used in over 90% of heart centers, 75% of kidney centers and 65% of lung centers, the latter within just two years of launch.

16:05
Many consider these to be standard of care and in heart transplant where there are guidelines that exist, the clinicians society includes these tests in the guidelines.

16:14
Next slide please.

16:18
The proposed revisions to the LCD introduced changes in language that we view as changes to coverage.

16:25
These changes were initially improperly introduced in the associated billing article in March of this year, a concern also noted noted by physician professional societies.

16:34
Our first recommendation is that these changes be rescinded immediately until the full LCD process has completed.

16:42
That process including the comments today, the written comments that are due this week, and your complete evaluation until the LCD is finalized.

16:50
Next slide, please.

16:54
The proposed revised LCD changes coverage in three major ways.

16:58
First, it restricts surveillance use.

17:00
Second, it prohibits testing close to a biopsy, and 3rd it prohibits the use of multiple tests with unique contributions at the same encounter.

17:09
The LCD itself incorrectly states that these revisions are simply for clarity of coverage and are not changes to policy.

17:14
However, a question that should be asked is whether new evidence has emerged to support disturbing the longstanding coverage policy and has not.

17:22
The evidence supporting these established use of these tests has only increased in the past three years.

17:28
Next slide please.

17:32
So digging into each one of these, the first of these major changes that we'll comment on is the restriction on surveillance use as described in the box.

17:40
Since these the first LCD that covered ALASUR, which is our test for donor Dr.

17:45
Self free DNA.

17:46
The LCD's have always provided broad coverage for surveillance that is not tied to a biopsy.

17:51
In fact, on the first LCD, Iridian replied to a comment with an official statement that ALASUR may be performed at a frequency established for other noninvasive tests, for instance 4 to 6 times in the first year and two to four times in subsequent years.

18:07
More recently, the initial draft of the current foundational LCD included the language in lieu of biopsy, but that was subsequently removed after public comment and Molex and Meridian's response that they were not tying its use to the need for a biopsy.

18:22
The proposed LCD text, which is shown at the bottom in red, now states that for surveillance use, the testing frequency must be no more frequent than the center's surveillance biopsy schedule.

18:34
The accompanying billing article states that surveillance testing is only compliant if the patient would otherwise receive a surveillance biopsy.

18:42
Next slide please.

18:47
This change was made not based on evidence, but despite the evidence that these tests have demonstrated ability to identify subclinical rejection.

18:55
The early detection of rejection before the rejection impacts function allows earlier therapy and can lead to improved outcomes.

19:02
Kidney guidelines, which have not been updated since these tests have been available, recommend treating subclinical rejection despite not recommending an invasive surveillance biopsy.

19:13
As mentioned, the heart guidelines acknowledge the importance of surveillance with these tools, and in long surveillance, biopsies have been most have the most significant complication rates, further limiting use for surveillance.

19:25
Despite the great need, limiting the use of molecular tests to the biopsy frequency is flawed because the risk profile of a noninvasive blood test is fundamentally different from an invasive procedure.

19:37
We recommend maintaining coverage for surveillance use, possibly even memorializing its use consistent with prior official comments.

19:45
Next slide please.

19:49
The second major change is the restriction based on time of biopsy.

19:53
There are no limits in the current LCD in this regard.

19:56
However, the proposed LCD states that these tests are not covered by Medicare if the patient has undergone a recent biopsy with a definitive diagnosis, or has a planned upcoming biopsy.

20:07
The proposed billing article also states that molecular tests and biopsy cannot be performed simultaneously.

20:13
Next slide please.

20:19
Published evidence supports the use of these tests concurrent with biopsy for several reasons.

20:23
In kidney cell free DNA has been demonstrated to inform on outcomes in patients with biopsy diagnosed low grade T cell mediated rejection.

20:32
In both heart and kidney, there are publications demonstrating the ability to use cell free DNA to monitor treatment response.

20:39

This use requires comparison to the level of cell free DNA at the time of the biopsy confirmed rejection.

20:44
We recommend this new restriction be removed in favor of physician directed evidence based use of these tests alongside biopsy.

20:52
Next slide please.

20:57
The third major change is the prohibition of multimodality, that is, the use of use in the same visit of tests that offer complementary information.

21:05
This is enabled in the current LCD.

21:08
However, the proposed Lcd's strikes the phrase unless a second test is reasonable and necessary as a jump to the first.

21:15
This leaves the sentence to end with the phrase only one test may be performed.

21:21
The use of two complementary tests has been validated in both heart and kidney and has evolved to the standard of care and heart transplantation and is specifically mentioned in the latest guidelines.

21:31
Paired testing offers better diagnostic performance for active rejection.

21:35
We recommend the current language or similar be retained to enable physician's judgment to choose the appropriate test or tests for a given transplant recipient based on the evidence and the need.

21:47
There have been four other changes we will address in our written comments.

21:50
One comment regarding interpretation of surveillance use of biopsy without recognizing the originator of biopsy practice and the risk profiling biopsy 2 comments recommending definitions that incorporate language from the latest billing article for consistency.

22:05
And a fourth comment on the overspecific restriction on the comparative biopsy standard.

22:11
I won't go through these in detail today, so please advance three slides to the final slide.

22:21
Thank you.

22:23
So in summary, the proposed LCD changes coverage in ways that limit physician judgment and negatively impact care for organ transplant recipients that require lifelong monitoring to achieve longterm graphs or my revision to the LCD is the correct process to introduce such changes.

22:38
But this particular process is compromised by the earlier implementation of the same changes in a billing article, which does not and did not go through public comment.

22:48
We recommend rescinding the billing article changes until this current process is finished.

22:53
Ultimately, the longstanding coverage for these molecular tests should be maintained to allow physician judgment based on evidence and patient need for surveillance, for concurrent use for the biopsy, and for multimodality use of complementary tests.

23:08
The data support these changes covered by the existing policy.

23:12
I'm sorry the data support these uses that are covered by the existing policy, and no data supports the proposed changes.

23:19
Thank you for your time.

23:20
The evidence that I referenced today is listed here and we will submit this information in the form of a comment letter later this week as requested.

23:28
Thanks.

23:31
Thank you.

23:32
Doctor Woodard, Doctor Steven Carter, are you available?

23:38
Well, thank you very much for allowing me to speak during this public comment process.

23:44
I'm here representing the American side of transplant surgeons commenting on proposed revisions to molecular testing for solid organ allograph rejection and to Doctor White's appoint.

23:57
I have multiple references in this talk, but we also will be submitting expanded comments later this week through your pathway.

24:07
Next slide please.

24:10
So our societal disclosures Care, DX, Europeans and the Terra have provided financial support to a STS in the past.

24:18
Next slide.

24:24
So the local coverage determination review process is the proper process and venue for changes to coverage.

24:32
In March, ASTS requested delay of the revised billing article in favor of the LCD process, and we want to thank you for engaging in this LCD revision process and provide me attendant opportunity to give public comment.

24:47
The proposed LCD revisions were issued in August and while we are appreciative of the admission that a billing article was not the correct mechanism to introduce significant changes to the LCD, we are concerned that the billing article still in effect.

25:02
The fact that the revised billing article is still in effect despite an absence of public debate is at odds with both transparency and public process and with the comments you've received from the community.

25:15
Our comments today regard the proposed LCD and the existing constraints to optimal patient care imposed by the billing article.

25:23
Next slide please.

25:27
So the molecular diagnostic tests and questions are an emerging standard of care.

25:32
Some of the proposed LCD changes are inconsistent with the input provided by experts at the Clinical Advisory Committee or CAC meeting held in November of 2022.

25:43
There is significant evidence of the clinical validity of these molecular tests.

25:48
There's widespread acceptance for utility and clinical decision making.

25:52
The cat supported expansion rather than limitation of Medicare coverage for these tests.

25:58
And these tests may provide the ability to improve patient and allograft survival, particularly longterm allograft survival, which has been an area of great concern to the transplant community and obviously to transplant recipients.

26:12
The proposed changes to the LCD substantively change coverage and the proposed coverage changes are not supported by evidence in the peer reviewed literature.

26:21
Next slide please.

26:26
So the proposed LCD would restrict surveillance, use of molecular testing to the direct replacement of existing surveillance biopsy protocols.

26:35
And I've quoted the language from your proposed LCD above.

26:39
Surveillance biopsy is used to detect kidney subclinical rejection, but surveillance biopsies are only performed by a small minority of centers.

26:47
Guidelines recommend treating subclinical rejection, recognizing its association with estimated GFR decline, chronic graft injury, and allograft loss.

26:59
There's strong correlation between the covered molecular test and kidney subclinical rejection and

there are no societal recommendations regarding surveillance biopsy to look for subclinical rejection, leaving us in a conundrum without reversion to the prior OF2021LCD.

27:20
Next slide please.

27:25
Heart transplant centers have reduced the frequency of surveillance biopsy dramatically by utilizing molecular testing and acknowledge the importance of rejection surveillance using molecular testing in their guidelines.

27:38
Molecular testing is not subject to interobserver variability or sampling errors as biopsy is and may actually have superior sensitivity and specificity in this difficult patient population than biopsy does.

27:52
The proposed LCD conflates to risk benefit calculations for a noninvasive blood test with an interventional procedure that can cause significant harm.

28:01
Molecular testing allows surveillance testing when biopsies were not typically performed due to a more favorable risk benefit ratio.

28:10
Transplant professional should retain the ability to determine the frequency of molecular surveillance testing in partnership with the patients under their care based on those patients immunologic risk and other risk factors that they face every day.

28:26
Next slide please.

28:30
The proposed LCD would restrict molecular testing based on timing relative to biopsy.

28:36
Again I've exerted the relevant language levels of DONOR Dr.

28:42
SELF RE DNA obtained concurrently with biopsies demonstrating low grade cellular rejection have shown significant prognostic utility improvement in DONOR Dr.

28:52
Self RE DNA after treating rejection is well documented in both kidney and heart recipient populations.

29:00
Therefore a DONOR Dr.

29:01
self reading a level obtained at the same time as a biopsy can evaluate the adequacy of response and preclude the need for follow up biopsy to document successful treatment.

29:11
Information from concurrent molecular and histologic testing can help clinicians make decisions about immunosuppression management, long term prognostication regarding allograph survival, individualization of immunosuppression for those patients and need for or timing of repeat biopsies.

29:29
Next slide please.

29:34
The proposed LCD would prohibit the concomitant use of multiple tests.

29:40
Definitive diagnosis of disease frequently requires comprehensive multimodal laboratory investigation.

29:47
Multimodal assessment utilizing donor Dr.

29:49
self free DNA and gene expression profiling in solid organ transplantation provides information on distinct biological processes.

29:58
In the case of donor Dr.

29:59
Self Re, DNA information is provided an allograft injury.

30:03
In the case of gene expression profiling, information about recipient immune activation is provided.

30:09
Paired testing demonstrates better diagnostic performance for active rejection diagnosis in both kidney and heart recipients than single technology platform testing alone.

30:21
The existing LCD includes language recognizing that quote combining both donor Dr.

30:27
self free DNA and gene expression profiling may further improve graph rejection determination.

30:32
End Quote and further states that quote.

30:35
These molecular tests have different strengths and weaknesses and can be leveraged for different populations.

30:40
End Quote The coverage criteria should allow providers latitude to determine the appropriate test or test for a given patient.

30:50
Next slide please.

30:54
So in conclusion, it's really all about patient care and patient survival.

31:00
Prior to molecular testing for allograft injury and immune activation, We in the transplant community have been performing organ surveillance in much the same way for several decades.

31:11
The results obtained with legacy surveillance techniques including urine protein assessment, serum creatinine and tissue biopsy were and continue to be suboptimal.

31:22
The failure to meaningfully improve longterm transplant survival despite massive improvements in shortterm patient and allograft survival remains one of the cardinal failures of the transplant endeavor.

31:34
Molecular diagnostic testing may help us unlock significant gains in longterm patient and allograft survival and are already widely used emerging standards of care in the management of our patients.

31:47
We urge you to support the utilization of these innovative tools with demonstrated clinical utility in the complex and vulnerable patients that we care for.

31:56
Thank you very much.

32:00
Thank you, Doctor Potter.

32:01
Appreciate the presentation.

32:04
Next up is Lorinda Gray Davis from the Transplant Recipients International Organization.

32:12
Yes, hi, this is Lorinda.

32:13
Thank you for listening to transplant patients and hearing our testimonies as evidence.

32:19
My name is Laurenda Gray Davis.

32:21
I'm the President of Transplant Recipients International Organization.

32:24
I am five years post liver transplant and heading towards a kidney transplant.

32:29
Due to the lack of innovation and post transplant medication, I'm concerned for the constituents of TRIO when it comes to the proposed coverage changes outlined in the proposed LCD.

32:42
The proposed changes limit patient access to innovative tests for surveillance and require patients to exhibit symptoms of rejection before being eligible for these tests.

32:53
This poses a significant threat to the well-being of transplant patients and the advancement of medical innovation.

33:01
Transplant patients are already dealing with complexities and challenges of organ transplantation when it comes to post transplant care.

33:09
This often means undergoing traditional invasive biopsies because they have because they've been no other options.

33:17
Biopsies are burdensome to patients, painful, expensive, and can come with complications and after often occur too late to successfully treat the issue.

33:27
Innovative tests for surveillance play a crucial role in the post transplant journey.

33:33
By providing early warning signs of rejection or other complications even before noticeable symptoms emerge.

33:41
Innovative tests have the potential to revolutionize how we monitor and manage transplant patients, making care more precise, efficient and ultimately improving patient outcomes.

33:53
They represent one of the most important advancements in this space in decades.

33:58
If access to these tests is restricted, researchers and developers may be discouraged from investing in further advancements in this area, resulting in a standstill in progress.

34:11
Now is the time.

34:11
Now is not the time to put patient access at risk.

34:15
In stifle innovation in the field of post transplant care.

34:19
It is essential that we maintain an environment that fosters innovation, supports early detection, and ensures the best possible care for transplant patients.

34:29
I respectfully request that you take into account the concerns raised by transplant patients, medical professionals, and advocates like me in making your final decision on this matter.

34:40
The health and wellbeing of transplant patients should remain at the forefront of any policy changes in this field.

34:48
Thank you for your attention.

34:50
I look forward to seeing the decision that prioritizes the need to transplant patients and encourages continued innovation and post transplant care.

35:00
And we will be submitting a written comment.

35:02
Thank you, thank you and thank you for presenting on behalf of the patients.

35:07
That's always very important.

35:11
Doctor Cush is not able to be with us.

35:15
Doctor Keller, are you available?

35:19
Yes, I am here.

35:20
My name is Brian Keller.

35:22
I'm an assistant professor of medicine at Harvard Medical School and the medical director for the lung transplant program at Massachusetts General Hospital.

35:29
First, I'd like to start by saying that I agree with and fully support all of the information presented by the previous speakers.

35:38
And while most of that information was focused on data from the heart and kidney transplant world, as a lung transplant pulmonologist, I'd like to highlight some of the differences in nuances that we face with lung transplant patients in monitoring their their allograft health.

35:55
So lung transplant patients face not only allograft rejection, but infection of the allograft.

36:01
Due to the exposure of the allograft directly to the environment, we utilize molecular tests such as cell free DNA to help us identify the health of the graft and to determine when the graft is not functioning as well as it should be.

36:14
However, unlike heart and and kidney bio kidney transplant patients, elevations in cell free DNA and lung transplant are not solely related to allograft rejection, but could represent infection.

36:29
And therefore the proposed LCD language that limits the use of molecular testing in place of a biopsy really does not help us because we're only detecting allograft injury in our patients and therefore use of a biopsy may be warranted, it may be complementary.

36:47

I'd also like to identify talk about a couple of unique situations that are lung transplant patients face in which use of cell free DNA is a complementary and and could potentially replace a biopsy.

37:01
Sometimes our patients are too sick to safely undergo an invasive transbronchial biopsy.

37:06
They can't tolerate the sedation.

37:08
The risk profile is too great for them to safely undergo the procedure and any situations.

37:13
We could in theory utilize self free DNA as a marker of allograft injury to help determine treatment and decision making.

37:23
Alternatively, when patients are diagnosed with acute cellular rejection or antibodymediator rejection, the use of self free DNA can be utilized to monitor response to treatment often times with acute cellular rejection.

37:40
Historically what we would do is we would treat acute cellular rejection and then follow that up with another invasive biopsy a short time later to determine response to treatment.

37:49
But as was previously described for heart transplant pathological readings, the same issues applied to lung transplant pathological readings pathological agreement.

38:00
The agreement between pathologists on biopsy grading varies quite dramatically.

38:05
Rejection can be spotty and patchy throughout the organ and it's possible to miss picking up rejection with biopsies.

38:12
And so the use of this molecular testing can allow us to more specifically monitor response to infection as the levels of self free DNA improve over time.

38:22
It can also tell us when our treatment is not working and we should maybe consider an alternative therapy or look for additional causes of allograft injury.

38:32
Finally, I'd like to kind of I'd like to point out that I view these molecular tests not so much as being

similar to biopsies in the utilization, but being more similar to other tests that we use for monitoring allograph function.

38:49
Every time we see a patient in clinic, we perform pulmonary function tests that we perform chest Xrays as well as routine lab work.

38:56
And all of that is meant to measure the health of the allograft.

38:59
This is where molecular testing fits into lung transplant monitoring.

39:03
It is a measure of allograft health and a detection of allograft injury and provides insight as to when to proceed to a more invasive test.

39:13
It also allows us to monitor patients on a more frequent basis so that we can, as previously discussed detect allograft injury earlier and intervening before it becomes a threat to the longterm function of the graph.

39:28
So like to thank you for your time and the opportunity to present this information.

39:33
As it relates to lung transplantation, I hope you take into considerations all of the comments made today as well as the the idea that we really need to be putting patients 1st and allowing physicians and clinicians the bandwidth to make professional decisions that are in the best interest of the patient.

39:51
Thank you.

39:53
Thank you.

39:53
Doctor Keller, if I could get you to comment a little bit.

39:55
We've heard a lot about the heart and the kidney biopsies in conjunction with the test.

40:03
How often would you think that using this test would avoid a biopsy of the lung?

40:09
And when might you use it?

40:12
And I won't hold you to any of this is just helping educate us.

40:16
Yeah.

40:16
So first of all, I will say that light kidney transplant programs, the use of surveillance biopsies varies dramatically between lung transplant programs.

40:26
And so there's not a standard recommended frequency of of biopsies.

40:31
And so even within programs, there may be frequency differences in frequency of biopsy by transplant pulmonologist.

40:39
So I think it's hard to standardize it to that.

40:42
The way we utilize the test at our center is we test monthly during the first year which is the the time period where the patients are at highest risk for acute cellular rejection as well as antibody media rejection.

40:56
And it helps to guide us and if testing is shows an elevated level, we will proceed to biopsy sooner.

41:05
And if testing is consistently low and reassuring that the allograft injury is not occurring then we may utilize that information to forego a biopsy.

41:16
However, the present time, the testing, the experience with the testing is not sufficient enough to completely eliminate biopsies and for us to feel comfortable that we need to completely eliminate biopsies.

41:29
The other thing with lung transplantation is the bronchoscopy.

41:33
In addition to allowing us to do the biopsy also allows us to collect samples to test for infection, which is not specifically detected with these molecular tests at present.

41:44
It also allows us to evaluate the airway anastomosis and to evaluate for complications such as

bronchial stenosis, which are supplementary to detecting rejection but have important implications for patient health longterm.

42:01
Thank you Sir, it's very helpful.

42:03
Much appreciated.

42:06
Next on the list is Samuel Curtain.

42:09
Absolutely.

42:10
Thank you for the opportunity to be here and I feel like the previous speaker was the perfect segue for a lung transplant patient to offer a view that I hope you will take into due consideration.

42:23
My name is Samuel Curtin.

42:24
I live at Lake Anna which is near Mineral VA.

42:28
I was diagnosed with idiopathic pulmonary fibrosis on January 31st of 2017.

42:35
Radiopathic pulmonary fibrosis is a chronic progressive lung disease for which there are is no cure.

42:42
At the time there were two approved therapies which slow the progression of the disease.

42:48
There were only two possible outcomes.

42:51
First that is to be eligible for and receive a lung transplant.

42:55
The 2nd outcome, death, is far less desirable.

42:58
On July 10th of 2021, I received a bilateral lung transplant.

43:04
The lung transplant, as you know, is not a cure.

43:06
It is a commitment to a lifetime of medical surveillance.

43:10
Shortly following my transplant, my care team began the required surveillance to look for signs of projection using molecular diagnostics and a noninvasive blood test, specifically Care DX's Alasher Lung product.

43:24
I was among the first lung transplant patients to be monitored using Alasher Lung for the first year following my transplant.

43:31
These tests were monthly and beginning in the second year those labs were drawn on a quarterly basis.

43:38
The introduction of molecular diagnostics for post transplant surveillance provides my care team and me as the patient a noninvasive method to monitor the health of my transplant.

43:49
A A biopsy of my lung is an invasive assault on the very lungs which provide me the opportunity to extend my life.

43:58
During the last two years, a noninvasive blood test provided my care team with the opportunity to identify any early signs of projection of my donor lungs.

44:08
Each post transplant patient experience is unique and mine is not without exacerbations.

44:14
For ME3 separate exacerbations have benefited from this noninvasive blood test.

44:20
In the fall of 2022, I had pneumonia, followed by COVID in April of 23.

44:26
Between these two exacerbations, my care team discovered my left bronchial stem was closed up or narrowing despite several balloon dilations.

44:35
The decision was made to add a stent to my left bronchial stem when it narrowed to 3 millimeters.

44:40
Following each of these exacerbations, my care team could determined by a simple blood test whether I was at an increased risk of rejection.

44:50
My bilateral lung transplant was fully covered by Medicare and Tricare for Life, both federal government insurance programs.

44:57
It is confounding to me why Medicare would risk the health of my transplant by using or insisting on using an invasive biopsy when any risk of projection can be detected and dealt with earlier using a noninvasive blood test.

45:13
Is there any medical procedure where an invasive procedure or test is preferred over a noninvasive test?

45:20
Additionally, limiting the use of noninvasive predictive blood test until signs of rejection appear as the potential to further burden the Medicare and the healthcare system when more advanced projection requires hospitalization for treatment.

45:34
The use of molecular diagnostics is a medical decision based on a doctor's knowledge of their patient.

45:41
The transplant community is more susceptible to the potential risk of invasive testing.

45:46
What other predictive surveillance is at risk by this type of decision?

45:50
Mammograms, colon cancer screening?

45:53
This testing is vital to the health of the transplant community.

45:57
These comments will be submitted electronically as requested.

46:01
And I want to thank you for your time and the opportunity to share these comments with you this afternoon.

46:08
Thank you, Miss.

46:09
Mr.

46:09
Keller.

46:10
Excuse me, Mr.

46:11
Curtin.

46:11
Appreciate you taking time to come out and share it with us and best wishes as you move forward.

46:19
Next on the list is Tiffany Archibald from Community Kidney Care.

46:24
Tiffany, thank you for including me today and being able to share my testimony on this very important topic for all of our all of us transplant recipients.

46:37
My name is Tiffany Archibald and I'm a kidney transplant recipient, actually a three time kidney transplant recipient.

46:45
My journey started over 20 years ago as an active athlete with a healthy lifestyle.

46:50
All my life I never could imagine being in the position that I am now and the health challenges that I would experience after three kidney transplants and several traumatic biopsies.

47:03
I'm speaking now to shed light on the invaluable role that noninvasive molecular diagnostic testing plays for post transplant surveillance and the overall health of US transplant patients.

47:17
I believe access to this testing is a large part of the reason why I am here today, still strong, healthy and able to share my story.

47:27
I played collegiate level basketball MSC and after that I played for a few years overseas while undergoing a low risk procedure on my toe.

47:38

My purse surgical lab showed that my kidneys were only functioning at 25% and my only option was transplant.

47:46
That's where my transplant journey began.

47:48
In 2005, my mother was able to give me one of her kidneys.

47:52
She birthed me twice, and while I'm grateful for the second chance at life, it was during that time that I was exposed to the reality of a biopsy.

48:02
Biopsy are not just routine medical procedures, they are very traumatic and often times risky for US patients.

48:11
After 8 1/2 years with my first transplant, I required another transplant in 2013.

48:18
My husband was my donor at the time and that process moved very quickly.

48:22
I was fortunate up to that point that I did not have to undergo dialysis while waiting for a kidney.

48:28
My life as a transplant patient changed forever After another traumatic biopsy.

48:34
I then learned that there will be a better way moving forward to monitor my kidney for rejection.

48:42
Going into that biopsy, I was incredibly scared and traumatized.

48:45
From the first difficult experience, I learned that unfortunately the the biopsy that I had done did not successfully connect collect any of the kidney tissue, only medela, despite them invasively prodding and moving through my kidneys during the procedure.

49:02
It was ultrasound assisted.

49:04
There were several medical professionals in that room.

49:07
I was frustrated, scared, and confused.

49:10
I really get emotional talking about the discovery of noninvasive testing because I never could have imagined an option like this would exist for me.

49:19
After navigating those traumatic biopsies, I was given the option to start using the cell free DNA test Alice door.

49:29
After that unsuccessful biopsy, it amazes me that a simple blood draw, like many Routine labs I was doing anyway, could monitor my kidney health successfully and potentially detect signs of rejection.

49:42
I was fortunate that if I needed to, I had the resources and support to easily access inpatient medical care for surveillance and biopsies.

49:51
Not everyone has that luxury, though, and the convenience of a blood test at home is a game changer for every patient doing their best that their lives to preserve their transplant functioning to have a healthier lifestyle.

50:05
Fast forward to just five months ago, after receiving my third and my most recent kidney transplant, This was my first time that I had to endure dialysis, among other health challenges that caused me to be hospitalized.

50:19
Now that I'm on the other side of this third transplant, I continue to be grateful to have access to the noninvasive testing that monitors my transplant.

50:28
I couldn't imagine what it would be like to have restrictions on access to all my outshore tests, not knowing if I'm being tested frequently enough or if I would be able to shoulder the burden of the cost of that test.

50:41
I'm here sharing my story because I don't think it can be stated enough how much uncertainty transplant patients have to endure.

50:48
As you've heard for me now, it often times not just one transplant but two, but three and even 4 if we are lucky enough to receive the precious gift of donation.

51:00
The acting of non invasive testing is called a game changer and as I see it, it's one of the most important ways that some of the uncertainty of the post transplant journey can be alleviated for US patients.

51:13
It is essential for doctors and patients to be able to work together to set a care path that provides patients with access to the personalized noninvasive testing regimen that works best for them.

51:25
Any restrictions on access to these tests not only hinder much needed innovation in this space, but they also have the potential to put transplant patients at risk for rejection.

51:36
The stakes are just too high to risk any of that.

51:40
Thank you for considering my comments today.

51:42
I will be submitting a written comment and everyone have a wonderful day.

51:50
Thank you very much for taking time to join us here.

51:53
Doctor Rabald, are you able to join us from Advent Health?

51:58
Wonderful.

51:58
Thank you.

51:59
Thank you for allowing us or me to really give some comments.

52:04
One of my colleagues earlier, Doctor Tudiberg was probably getting very similar comments, but in the interest of time, I'm going to get started, you know, from a biopsy use and I did catch a little bit of the tail end of of the last presentation.

52:18
You know biopsy use is really declining with the use of gene expression profiling and donor Dr.

52:24
cell free DNA.

52:25
You know in the heart transplant patient the number one complaint we see post transplant is frankly the biopsy.

52:32
It could be you know obviously your nerve racking for the patient to go through it so many times etcetera.

52:39
There are other issues that we'll get into.

52:41
They can be.

52:42
So quality of biopsies as well.

52:45
You know we've seen the incidence of tricuspid valve abnormalities and the way we do this is actually go through the heart through the through the veins in the leg or in the neck and and go down through there and and and take pieces of of myocardium.

52:58
And you know we do get problems with tricuspid valve and even tricuspid registration sometimes necessitating even surgical fix of the valve.

53:08
You know we we went through all this trouble to put the heart in and now we're having to fix the heart because of biopsy.

53:15
One of the problems that patients who really have and our center is probably no different than any others.

53:19
But you know we're a relatively high volume center patients where they come from obviously the local Orlando area where I am and but even up to six hours away.

53:29
So you know that really starts to wear on people in terms of try travel time, fuel costs, lodging costs for example, wages lost because a lot of these patients are back to work and and gainfully employ.

53:41

And so those things really start to add up over time, you know and and and all the while the end of myocardial biopsy for heart transplant is an imperfect gold standard, but we still need something to detect rejection that has high sensitivity and high specificity.

54:00
So if you get to individual centers like us that have in health or other places BIOS schedules are variable all over the place.

54:08
So you know, there's not one particular way of taking care of these individuals, although I did say that probably on average that there's a bit of decline in all centers in terms of of the number of biopsies being done.

54:21
Certainly go, if you go above 2 years, it's extremely variable or not even not even at all, you know, codified at centers.

54:31
And so you know, you really can't biopsy these individuals forever, but you know it's important to surveil these patients even after two years, for example, because of late rejection.

54:41
One example might be a simple, one might be not adherence, patients may get a little complacent in their medication and and you know otherwise compliance around that two year mark.

54:53
And then actually there's a little bit of an inflection there where we might see some late rejection, but you know I'll give you another example, another type of rejection antibody immediate rejection starts to increase over that time period as well.

55:05
And the only way to to detect this is via a screening molecular diagnostic test, but then also a biopsy at the same time.

55:15
This is really the only way for us to formulate you know treatment correctly.

55:21
We may think it's something else and and immunosuppress them in a different way that may cause problems.

55:27
So we want to be judicious in what we do and and here is an example of where you might use a monthly diagnostics but also a biopsy at the same time in order to correctly treat the patient you know and follow up if that patient.

55:42
If you use our example of the antibody need a rejection, you treat these individuals in the correct way.

55:47
You know in the follow up we may be able to use some molecular diagnostic tests that we saw from before and see that reduced and that may obviate the biopsy later.

55:56
So we may not be able to, we may not need to do the end of myocardial biopsy in order to see hey that this, this individual has less graft damage and we are indeed treating this patient and we can forego the invasive biopsy as I mentioned.

56:10
Well, one other area that that we've been using it in, in, in our center is you know welcome to Florida.

56:16
You know this is a great state where patients really will age well.

56:20
People age well I would say and we see patients above the age of 65 and we transplant these people routinely, but we even see patients above the age of 70.

56:28
And those individuals you know are a selected select individuals and they they ought to do well.

56:33
But we also know that patients certainly above the age of 65 are really going to have problems with the immunosuppression itself.

56:41
You know the the nephrotoxicity of the of the medications of course and and also you know just over immunosuppression of the patients which you know we know that as patients age their immune system becomes a little less senescent or in other words a bit less active I would say.

57:00
And so we want to try and you know treat these individuals in a special way.

57:04
So we know it's susceptible to side effects in this suppression as they mentioned.

57:07
And so by using molecular diagnostics, we've been able to reduce them in the suppression levels sparing kidney function and other Endorgan function in these patients and also reducing the chance of infection, which is a little bit higher in this in this population.

57:24

Certainly that's the case above 2 years out and we still will you know adjust these patients based on molecular diagnostics.

57:32
One other good example of using a couple of diagnostics together is here.

57:38
This is a situation where we use gene expression profiling and so don't derive self free DNA.

57:44
We may have a positive gene expression profiling but a negative donor Dr.

57:49
software DNA and what that tells us is that there's not graph damage but something's going on right and and and what we may by using both of those we may be able to figure out that this person may have CMV.

58:02
So instead of biopsying this individual we may actually look for for CMV and and and in the presence of a normal graft function we may stop the biopsy because we don't need it.

58:13
We know they between those two tests done in one blood draw obviously that this is the case with the the patient's graft and the patient's overall health and and we'll treat the CMV rather than the biopsy or or immunosuppressing them inappropriately.

58:27
So you know you you use biopsy and and molecular diagnostics in certain cases, but you also use molecular diagnostics, a couple of types of molecular diagnostics together.

58:38
And the fact is that you know in peer reviewed literature when you use Jinx system profiling and donorized cell free DNA that actually is the the thing that gives us the best sensitivity and specificity for rejection.

58:53
You know it it's kind of like 2 + 2 = 5 really.

58:56
I mean both are OK individually, but when you use them together it's more powerful and more certain that sensitivity and specificity is actually better.

59:07
So using them together is something that we clinically do already frankly speaking and to use them sort of individually I think is relatively you know suboptimal for patients and we may be let down a different pathway.

59:22
You know in closing I'd say I disagree with kind of limits on concomitant testing whether it be an end of my cardio biopsy and and and molecular diagnostics or or even 2 two different molecular diagnostics at the same time.

59:38
I've given some good examples here.

59:39
I think where we use them already clinically, you know, we frankly don't get paid more to do molecular diagnostics as as clinicians, as physicians we are, we are taught to use data or use testing only when it's going to change our management.

59:59
Frankly speaking, I've got enough stuff to do and I've got a lot of data coming into me and my coordinators too.

1:00:04
It's a team effort here.

1:00:05
Transplant is a team sport.

1:00:07
And the fact is, is if we have extraneous data that we're not going to use, I I don't want it because that's that's data that we're not going to use it.

1:00:15
It sort of, you know, gives me more noise than signal.

1:00:18
But frankly speaking again.

1:00:20
See this is helpful to us and it is, it is very, very helpful for the patients and helps us to better understand how to you know care for them as well.

1:00:29
You know the other frank issue is and we we you know as as I was in my medical, you know medical education, you know we're cost conscious too frankly.

1:00:40
And you know we want to have you know direct costs that are as low as possible and have the best outcomes.

1:00:45

I mean I I can't, I don't want to be the, the the most expensive place to get a heart transplant whether it's Medicare or or private payer.

1:00:53
And and you know furthermore you know the the value proposition is what we really want here quality over cost right if we can improve the value.

1:01:03
I think that that's what we want to try and do and this goes for so many different places in medicine as you know you know keeping this in mind, I think it really should be our decision as physicians to use to molecular diagnostics together for the better of the patient or molecular diagnostics in tandem with end of myocardial biopsy.

1:01:26
Because I think that this is something that that is really clinically driven.

1:01:31
It's out of our data that we've done at these at these and some of these people are probably on the on the on the docket today for you to speak to.

1:01:39
But I think that this is this is important.

1:01:41
I think that to do otherwise is really, it's really sort of a travesty for the patient and will actually reduce our effectiveness in caring for these patients in a value laden manner.

1:01:56
And with that, I'm going to stop my comments there and I'm happy to take questions or I'm also really looking forward to getting a written, you know, written account of this I think because I may be able to embellish it a bit more.

1:02:15
Thank you very much for allowing me to give my comments and thank you Dr.

1:02:21
Braw.

1:02:21
Appreciate you taking time to come join us today.

1:02:24
My pleasure.

1:02:26
Next on the list was Doctor Gupta, but I understand he's not going to be able to be with us today.

1:02:30
So Paul Conway with the American Association of Kidney Patients.

1:02:35
Are you there, Sir?

1:02:37
I sure AM.

1:02:37
And I'd like to say thank you very much for the opportunity to appear and to speak to you.

1:02:42
I wear several different hats.

1:02:44
I serve as the Chair of Policy and Global Affairs and as a past President for the American Association of Kidney Patients, which is the largest and oldest kidney patient organization in the United States with the highest representation of kidney transplant patients in the USI also speak to you as a kidney patient of 46 years and one who specifically did three years on dialysis and has lived for 26 years with the gift of life from a young man who was cut down in the car accident but who was selfless in his gift of life to me.

1:03:17
And it is with him in mind, really, that I speak to you today.

1:03:22
Since I was transplanted in 1997, I've taken over 165,000 pills to maintain immunosuppression and to be responsible for my gift of life.

1:03:32
And I have worked with multiple transplant teams who always encouraged me to take my medicines, be on top of my game, reduce my exposure to infections, and in all areas, try to avoid situations where you would have to get a biopsy.

1:03:48
I had two when I was very young due to my kidney issues and in one of them I got sepsis.

1:03:56
And I will tell you this, a biopsy is not equivalent or substitute for molecular testing.

1:04:03
It simply isn't.

1:04:04
The burden on patients of the alternative is terrific and it's highly impactful upon their families.

1:04:12
But what I wanted to raise to you were a couple of points related to process and pertaining to the changes for clarity, quote UN quote, of the billing article and the deliberation around this, it was recognized at the outset of this phone call that it has been controversial.

1:04:31
And that's true.

1:04:32
And there's a reason for that, because the process was flawed.

1:04:37
I have served under 4 presidents and proudly served under 4 governors in the state of Virginia.

1:04:41
I know government process quite well.

1:04:44
When I was on dialysis, I served as the Deputy Secretary of Health for the Commonwealth of Virginia, and I understand what cost control measures are.

1:04:52
I understand what it takes to do assessments for utilization, and I also understand what formularies are on the drug side.

1:05:04
I know her quite well, and I will say this quite directly.

1:05:08
The use of a billing article to articulate and change the practice of policy and medical practice was wrong.

1:05:16
Highly wrong.

1:05:18
And this recovery period that we're in, which is well meaning and appreciated to get patient comments and other provider comments on the record is important because as the USFDA shows patient insight data and lived experience data is evidence on par with studies and peer reviewed journals.

1:05:38
And I would encourage you to view the comments today and in the other literature and in newspapers as the same to get sideways with the American transplant communities, the American transplant societies, the leaders of the top universities in the United States, peer reviewed medical information and to earn yourself a place on the editorial page of the Wall Street Journal is pretty hard to do.

1:06:02
But it was achieved by a contractor for CMS.

1:06:06
We don't assume that the contractor owns all this responsibility.

1:06:09
Actually, we think it's the appointed leadership of CMS&HHS that owns this problem and needs to fix it.

1:06:16
And so let me lay out a couple important things here about why you're experiencing such a backlash on this issue.

1:06:23
We completely agree with the comments that have been offered by Doctor Potter of Georgetown and the American Society Transplant Surgeons and comments that have been offered by other surgeons here in lung, heart and kidney.

1:06:36
But one of the reasons why this is so sideways is this issue of this type of testing came about to address an unmet patient need that we articulated to the federal government and the industry.

1:06:52
These weren't random tests that came about for no reason.

1:06:55
They came about to address unmet patient need.

1:06:58
And I have been a leader in that field.

1:07:01
And So what you have here now is at least a decade of the United States government making it a priority, especially in the field of kidney medicine, that transplantation is the preferred policy.

1:07:13
Why?

1:07:14
It has better health outcomes for patients.

1:07:16
It reduces lifetime dependency on disability payments.

1:07:20
People can go back to work.

1:07:22
And the other thing that it does is it improves the ability of families to get out of simply the medical mindset and to rejoin society.

1:07:32
10 years of effort by the United States government, starting in 2013 with HIV to HIV transplant approvals through the US Congress In 2016.

1:07:42
A White House Summit on Organ transplantation.

1:07:45
In 2018, the US Department of Labor doing special waivers to extend the Family Medical Leave Act for living donors to increase transplantation.

1:07:54
2019 A United States Executive Order by the President of the United States capturing the prior six years of effort on transplantation.

1:08:02
The Executive Order on Advancing American Kidney Health prioritize transplantation.

1:08:07
In 2020, the United States Congress and the White House work together to extend immunosuppressive drug suppression.

1:08:14
So immunosuppressive drugs for the lifetime of the patient if they had insurance interruption.

1:08:19
And right now we're on Capitol Hill working diligently to get passage of living donor protections.

1:08:26
Why?

1:08:27
To increase living donations in the United States.

1:08:31
That is bipartisan consensus policy prioritization of transplantation.

1:08:37

And the only thing that is different about this national move towards transplant is when you have policies like this that jump up.

1:08:46
We call these the government determinants of health, GDH, and for a very good reason.

1:08:52
You've heard the medical experts, you've heard the research experts say why this is so astray from what they see as a new standard and how to manage patients.

1:09:01
Patients aren't managed as a class when you have a transplant.

1:09:05
Targeted medicine, precision medicine, and the ability of that doctor and the knowledge and skills they have about you as a patient and how they can tailor that through not just the medicines but the diagnostics, is critically important for you to remove.

1:09:21
That is not only contrary to policy, it's contrary to patientcentered medicine and valuebased medicine.

1:09:27
It makes absolutely zero sense to us.

1:09:31
It is one of the reasons why we have so heavily engaged, elected and appointed leaders and the media on this issue.

1:09:37
It is so fundamentally sideways with where this nation has progressed in the past 10 and 20 years on policy innovation and putting patients 1st.

1:09:47
And I have to tell you it's it's alarming that something like this can happen absent a process where the ultimate end users of this in the ultimate beneficiaries the patience, not a medical system, not a medical practice, but the patients are not listened to at the front end of executing policy.

1:10:09
Instead we're being pulled in on the back end of it.

1:10:12
We appreciate it, but that is not patient centric medicine and it is not consistent with the mission of CMS or the contractors that are charged to support it.

1:10:23
I appreciate you taking the time.

1:10:25
I encourage you to strongly look at Doctor Montgomery's presentation, Doctor Potter's presentation, and the presentation by the others that are here.

1:10:33
But most importantly, please listen to the patients who have offered their thoughts to you because their lived experience is legitimate evidence in this discussion and should have been included in the front end.

1:10:44
That's the point we've made to the Congress and we will keep making it.

1:10:47
Thank you.

1:10:49
Thank you, Mr.

1:10:50
Conway.

1:10:50
Greatly appreciate your comments.

1:10:53
Doctor Davis Quali from USC, are you available?

1:10:58
I am great.

1:11:01
Thank you for the opportunity to speak with all of you today on this very important topic.

1:11:06
I do echo the comments of all those who have spoken before me.

1:11:10
I'm a transplant cardiologist and the Medical Director of the Heart Failure and Transient program at the University of Southern California.

1:11:18
I've also served as guideline author on the guidelines steering committee for the International Society for Heart and Lung Transplantation guidelines for the care of the heart transplant recipient.

1:11:30

I am very supportive of the noninvasive tests for rejecting surveillance with gene expression profiling and cell free DNA, particularly their combined use.

1:11:40
And I have been a principal investigator or on the steering committee on the pivotal studies of OR D or and the shore registry.

1:11:48
These innovations have had a profound impact on our patients at our center.

1:11:53
We've reduced the number of biopsies during the first post transplant year to less than two or in other words only one surveillance biopsy.

1:12:01
Any biopsies beyond this point are for cause only and this is driven by these noninvasive tests.

1:12:08
So the loss of the concomitant approach will really adversely affect our patients.

1:12:14
With this approach our outcomes and patients quality of lives are excellent while eliminating unnecessary biopsy related complications which are not insignificant and can harm the new organ.

1:12:26
And these complications may include tamponade or blood surrounding the heart impacting heart's function which can be life threatening, can be damaged to the valves of the heart.

1:12:36
These are not insignificant complications, although they're rare.

1:12:42
You just need one of these to really adversely respect the life of the transplant recipient.

1:12:47
Our targeted approach enhances the yields into myocardial biopsies as the interpretation of the so-called gold standard of the antimocardial biopsy really is much to be desired.

1:12:58
The pathologists, when it comes to significant rejection, agree with themselves less than 2/3 of the time.

1:13:05
So as the gold standard, it really needs some room for improvements, and these noninvasive tests can certainly help.

1:13:13

The nontargeted approach can also result in variations in this interpretation that can really affect clinical decision making that can lead to over or under treatment to patients and put them put them at unnecessary risk.

1:13:25
For example, if you have a biopsy where you could go either way, the pathologist may be more likely to call that rejection, leading to unnecessary augmentation and immune suppression and the resulting infection and other complications that can come from the incorrect treatments.

1:13:43
And in this light, these tests will also enable the personalization of the care of the transmit recipient to optimize the transmit medications which may help prevent the long term consequences of these therapies.

1:13:54
As we have heard most vividly from A B Silverstein in our New York Times opinion piece before our untimely passing.

1:14:02
We've also used these tests as a useful tool for our center to extend our ability to care for our heart transplant recipients afar as we transplant patients who come from Nevada and Hawaii which are dumping up down the road from our center in Los Angeles.

1:14:17
Again, the use of these noninvasive testing commonly enhances the care of heart transplant patients.

1:14:23
These tests are supported by the heart transplant guidelines and additionally these tests together give a better assessment of the patients, reduce potentially unnecessary invasive testing and potential complications and the loss of these tests will adversely affect patient care.

1:14:38
I urge Medicare to continue coverage of these tests.

1:14:41
I want to thank you for your attention and happy answer any questions.

1:14:45
Thank you Sir and don't have any more right at the moment.

1:14:48
But I appreciate you joining us and sharing your your experience and your knowledge there with us.

1:14:56
Next up I show Alexandra Harrison, Flaxman.

1:14:59
Are you available please?

1:15:02
Yes, I am.

1:15:02
Thank you.

1:15:04
Good afternoon and thank you for allowing me the time to speak today.

1:15:08
I am here not just to share my own voice, but on behalf of the entire transplant patient community and particularly the voices of those patients who do not have the opportunity to be here today.

1:15:19
I feel very fortunate to be speaking alongside such esteemed members of the transplant community, especially the patients, many of which who are friends and colleagues.

1:15:28
As a two time kidney transplant recipient and patient advocate for over 2 decades, I believe the patient voice is powerful and should be present and heard in every room where decisions are being made that impact patient outcomes and access to care.

1:15:41
I was diagnosed with butter syndrome before birth, went through many years of reconstruction surgery including having one of my native kidneys removed, went on dialysis for the first time at only eight, and received my first kidney transplant at barely 11 from a deceased donor.

1:15:56
Unfortunately, at 18, I lost my first transplant and went back on in center hemodialysis for almost nine years.

1:16:03
In May of 2013, at 27, I finally received my second gift of life, also from a deceased donor.

1:16:10
It is because of access to noninvasive testing that I am in good enough health to be here sharing with you today.

1:16:16
The path to transplant is no easy journey, and for some patients it's a journey that they won't even have the opportunity to start.

1:16:23

As many of you know, with over 100,000 people currently waiting for an organ transplant in the US today, almost 90 thousand of those are specifically waiting for a kidney.

1:16:34
And sadly, 17 people will die each day still waiting for their gift of life.

1:16:38
And a new person is added to that wait list every 10 minutes.

1:16:42
With the national organ shortage crisis at an all time high now more than ever for those of us lucky enough to have a transplant, we want to have access to innovations that would allow us to keep our new kidney, heart or lungs healthy for as long as possible.

1:16:56
An innovation that not only can detect if there's a possible issue, but can can detect it sooner than standard post transplant testing, allowing for earlier intervention and treatment and potentially better outcomes.

1:17:09
Also providing A noninvasive option to the alternative invasive biopsy.

1:17:14
I've been fortunate enough to receive the gift of life not once but twice, and receiving a transplant is precious, and we as patients want to do everything within our power to ensure that that gift is cherished and well taken care of.

1:17:26
In February of 2020, right before the start of the COVID-19 pandemic, I had my first experience with a noninvasive blood test.

1:17:34
I just moved back to my home transplant center and was reestablishing care and while the rest of my standard labs like Serum Cratinen were the were within normal range for me due to not having been under their care for some time, they also wanted to perform a biopsy.

1:17:48
This terrified me because of my previous experiences with biopsies.

1:17:53
I had a biopsy done when I was younger and they accidentally nicked an artery causing me to bleed uncontrollably for almost 3 days.

1:18:00
My parents were told I was losing too much blood and needed a transfusion while hospital staff rotated holding bricks wrapped in towels on my abdomen trying to stop the bleeding.

1:18:10
Since then, the thought of biopsies gives me anxiety and PTSD to the point that I must be fully sedated in order to have one.

1:18:18
At the time that my team wanted to do another biopsy, I was aware of the fact that there were non invasive options we could use.

1:18:24
I advocated for this and my team ordered an Ala shirt to get a full picture of the health of my kidney.

1:18:30
A few days later, I got a call from my coordinator letting me know that my Ala shirt score had come back at 2.7, signaling that I was in fact in experiencing some sort of injury and more testing would later confirm antibody mediate rejection.

1:18:44
Mind you, the rest of my labs were still within range for me.

1:18:48
My team quickly went into action, putting together a treatment plan, starting me on multiple infusion therapies to help stabilize the A/B Mr.

1:18:55
Three months later, Alasure was performed, showing it come down to 2.3.

1:19:00
It wouldn't be for two more months that my creatinine would finally start to reflect that something was wrong.

1:19:05
Now, this might not seem like a significant amount of time to you, but as a two time kidney transplant recipient who lost her first kidney at 7 years and 10 months, this was my greatest fear to lose my kidney.

1:19:16
Around the same timeline that I was months from celebrating 7 years with my current transplant.

1:19:21
Over the next nine months of infusion therapy and immunosuppressant changes, my alosher would come down to .6.

1:19:27
And while the damage had already been done and I had entered into rejection because of my team having the opportunity to act quickly, they were able to stabilize me and the with the last three years keeping me off dialysis and working towards a preemptive living donor transplant.

1:19:43
I like to use the analogy of a house on fire, alosure being the smoke alarm saying hey, something is wrong, but it's not too late to try and fix it, and even though the damage could not be reversed because of alosure, I only lost a room and not the whole house because of access to noninvasive molecular diagnostic testing.

1:20:01
I celebrated 10 years on May 18th of this year, and while I am now on the road to my third transplant, I could be in much worse shape than I am now.

1:20:10
Only last week I found out that my husband has been approved and is moving forward as my nondirect living donor and I want to be sure that his donation, which will lead to me getting my new kidney, is not done in vain.

1:20:21
I am already fearful of what the future may bring, and whether I have access to noninvasive testing shouldn't have to be a part of that.

1:20:28
I share my story with you to demonstrate how much we as recipients go through to protect our gift of life, a gift that was given so selflessly and deserves to be honored.

1:20:38
Transplant patients need and deserve access to innovation in a space that has seen so little up over the last several decades.

1:20:45
It's important that transplant patients and their care teams be able to make informed decisions about their care without the worry of coverage.

1:20:52
What is best for a patient and their transplant is a decision that should be made between the patient and their care team.

1:20:58
Every transplant patient is unique and deserves individualized care and treatment.

1:21:03
The proposed changes to coverage of noninvasive testing would be detrimental to the transplant community, not only impacting patients and their transplants, but also the living donors and donor families who have given the gift of life.

1:21:15
This could also stifle future advancements that could be coming down the pipeline, limiting future innovation for our community.

1:21:22
I hope that you will consider all the remarks that you've heard today.

1:21:26
I will also be submitting a written comment.

1:21:28
Thank you for your time.

1:21:31
Thank you very much for taking time to come join us today and share your experiences.

1:21:37
Eddie Garcia is Next up.

1:21:39
Are you there?

1:21:40
Yes, thank you.

1:21:41
Good afternoon.

1:21:42
My name is Eddie Garcia.

1:21:44
Thank you for the time to share my thoughts on the March 2023 billing article regarding molecular testing for solid organ allograph rejection.

1:21:52
I received a heart transplant on April 16th, 2020.

1:21:56
During the summer of 2021, the noninvasive post transplant test most likely saved my life.

1:22:02
At a minimum, it saved me from pain, suffering, and additional financial stress.

1:22:08
My heart failure journey started on June 7th, 2010.

1:22:11

That day, a 100% occlusion in my left anterior descending artery, otherwise known as the widow maker, caused a massive heart attack.

1:22:20
I was 46 years old.

1:22:22
My wife and I had two young daughters and my career was on the rise.

1:22:26
10 days later.

1:22:27
Cardiac arrest caused my heart to stop beating and a rare form of lung failure required me to be on life support in the ICU.

1:22:35
My medical record on June 28th, 2010 simply stated that I was, quote, intubated, sedated, and paralyzed.

1:22:44
I remained in that state for six weeks as doctors worked on my lungs.

1:22:48
When I emerged from a medically induced coma and survived the lung failure, I still had a badly damaged heart.

1:22:55
For the next 10 years, I managed congestive heart failure with a strict diet, exercise, and medicine regimen.

1:23:02
My heart transplant in 2020 gave me a new lease on life.

1:23:06
A critical part of my post transplant management plan included noninvasive post transplant tests for surveillance purposes, as opposed to invasive, expensive, and, as we've heard, traumatizing biopsies.

1:23:18
The testing process was simple.

1:23:20
A phlebotomist came to my home to do a standard blood draw.

1:23:24
Within three days of each test, I had the results for the first four quarters.

1:23:28
Post transplant, my doctors called to confirm me that there were no signs of rejection.

1:23:32
All was well.

1:23:34
In late June 20, 2115 months post transplant, the noninvasive test detected that my body was rejecting my heart.

1:23:43
I had just completed a daily three mile walk with my doctor called.

1:23:46
I had no symptoms of rejection.

1:23:49
Nonetheless, her direction was urgent and to the point.

1:23:52
I checked into the hospital that day to undergo 11 days of treatments to address rejection.

1:23:58
In the hospital, doctors that administered plasmapheresis treatments.

1:24:02
It's a process that removes blood plasma from the body, separates it into plasma and cells, and transfuses the cells back into the bloodstream to remove antibodies that cause organ rejection.

1:24:14
After the 11 day treatment and six monthly outpatient treatments, my body was free of antibodies that were attacking my heart with minimal elograft damage.

1:24:24
The short story here is that the noninvasive post transplant test works.

1:24:29
It's the proverbial care Canary in a coal mine.

1:24:32
The noninvasive test is effective, efficient, and it saves lives and money without reservation.

1:24:39
I urge you and Medicare to continue covering noninvasive post transplant testing as was done pre March 2023.

1:24:49
On another note, the proposed coverage for these tests, as stated in the March 2023 billing article is too restrictive.

1:24:56
Limiting patient access to these tools for surveillance purposes and requiring patients to exhibit some sort of rejection before being able to use these tests is both costly and mostly draining, and usually too late to save lives.

1:25:11
Under the March 2023 order, I would not have had access to that test and that detected my rejection in 2021.

1:25:20
On that note, there's a good chance I wouldn't be here today.

1:25:22
Testifying before you.

1:25:25
Transplant surgery is a significant emotional and financial investment for patients, families, and insurance providers, not to mention doctors.

1:25:35
Regular noninvasive post transplant tests for surveillance purposes effectively and efficiently preserve the investment for all involved.

1:25:43
The March 2023 building article just doesn't make sense.

1:25:48
It's my heartfelt hope, my new heart heartfelt hope that you and Medicare reconsider the decision regarding the March 2023 Building article.

1:25:59
Once again, thanks for the opportunity to share my thoughts.

1:26:04
Thank you, Sir.

1:26:04
Much appreciated.

1:26:08
Next up is Tiffany Jones Smith from the State of Texas Kidney Foundation, but I'm honored to represent the Texas Kidney Foundation.

1:26:20
Our mission is clear to slow or stop the progression of kidney diseases.

1:26:26
Through genuine commitment and mutual respect, we have built a community engagement model that has earned us the honor of trusted agent.

1:26:34
We approach our mission and our position in the community with humility.

1:26:38
What brought us to this juncture?

1:26:40
Our unwavering belief in the intrinsic value of every individual and our commitment to treating each person with the dignity they inherently possess.

1:26:51
Our strategies are rooted in evidence based scientific paradigms, with our Community Empowerment models serving as a linchpin for all our initiatives across Texas.

1:27:02
We are not.

1:27:03
We are recognized not merely as a resource, but as a beacon of hope, particularly for the underserved.

1:27:11
Numerous churches, synagogues, mosques, and community centers place their trust in us, relying on our expertise and commitment through our endeavors.

1:27:19
We offer free early detection tests, vital education, and a pathway to preventative care.

1:27:26
We open the lines of communication between patients and practitioners.

1:27:31
We serve as an example of what can accomplish when, what can be accomplished when curiosity, mission, and commitment align.

1:27:39
As President and CEO of the Texas Kidney Foundation, I've dedicated my life to championing the rights and needs of kidney transplant recipients across the great state of Texas, supporting early detection measures, innovations, and testing and connecting patients to the many options that exist within the transplant world.

1:27:59
As a part of our mission, my journey into this realm was not by choice but by a tragic personal circumstance.

1:28:07
I've grieved the loss of 15 beloved family members to kidney disease.

1:28:12
As I delve deeper to understand the silent killer behind these heart wrenching losses, I discovered as it was a genetic variant named APOL, one of which I carried to a little.

1:28:24
I quickly began to learn all that I could about the genetic variant.

1:28:28
Today I'm well aggressed as to what's going on with a Pol One and a published author for the Journal of American Society of Nephrology.

1:28:39
On a paper called Diagnosed Education and Care of Patients with a PO, L1I hold the conviction that those nearest to the issue are also nearest to its solution.

1:28:50
APOL One is a merely a scientific fact for me.

1:28:54
It's the fuel that Stokes the fire in my belly because it is a ticking clock, a stark reminder that the the very disease could manifest itself rapidly within me, just as it did in my brother in 2019, resulting in him receiving a preemptive transplant.

1:29:10
Three of my cherished family members have been blessed with transplants.

1:29:14
Where once the narrative was one of unending waiting, of lives fading away on dialysis, we now see a narrative of renewal, of second chances.

1:29:25
Non invasive molecular diagnostic tests are not merely medical tools, they are the life lines that assist my brother's care team and my two cousins care team.

1:29:36
All are high risk patients and all are healthy because of the gift of life being monitored by molecular diagnostic test.

1:29:45

Today I'm here asserting the the pressing need for unrestricted patient access to non invasive molecular diagnostic tests.

1:29:55
Our kidney transplant beneficiaries, under the guidance of their providers, recognize that these tests are essential components of their regular healthcare.

1:30:06
With precision medicine in play, we know that each patient is an individual.

1:30:12
They have to be seen as individuals and not as a singular class not regulated by policy.

1:30:21
Healthcare should never be regulated by policy.

1:30:26
Undergoing A biopsy isn't just physically taxing, it demands travel.

1:30:31
Logistical efforts and breaks from work are caregiving roles.

1:30:36
These challenges are notably magnified for our economically underserved members.

1:30:42
While the journey to achieving equitable access to care for marginalized black and brown communities is still in its early stages.

1:30:52
Trust, such a vital component to transparent patient practitioner dialogue, is jeopardized when choices are made to restrict access to non invasive tests in favor of costlier, invasive alternatives.

1:31:07
Transparency in policy making is important.

1:31:11
Let's be clear, for our trans, for our kidney transplant community, the repercussions of losing a transplant span beyond financial considerations.

1:31:21
It's an emotional upheaval marking a return to the demanding regimen of dialysis.

1:31:27
As you heard previous advocates state, it's really emotionally traumatizing to have a biopsy.

1:31:40
The simplicity of noninvasive diagnostic test, a straightforward blood draw possible within the the confines of one's home, ensures no patient faces barriers in accessing their rightful care.

1:31:55
Ensuring uninterrupted care is the bedrock for successful transplants and overall patient well-being.

1:32:03
I earnestly urge you, as you weigh the coverage for molecular diagnostic test under the proposed LCD to deeply consider my remarks.

1:32:13
As a representative of a trusted agency, I emphasize the paramount importance of ensuring all kidney transplant patients, along with the wider transplant community, have unrestricted access under their physician's guidance to the tests that are pivotal in preserving the invaluable gift of life they require through transplantation.

1:32:36
The trust our agency has built stands testament to the gravity of our advocacy.

1:32:42
Your attention and thoughtful consideration today is deeply appreciated.

1:32:47
Thank you.

1:32:49
Thank you very much.

1:32:51
Appreciated.

1:32:53
Next up is Melissa McQueen with Transplants Families.

1:32:58
Thank you so much for the opportunity to speak today.

1:33:02
I will not reiterate the wonderful commentary already made, but I will briefly share my experience.

1:33:07
My name is Melissa McQueen.

1:33:09

I'm the president of Transplant Families, a collaborative group that supports the pediatric transplant community and their families.

1:33:16
What brought me to transplant was the birth of my youngest son, Dylan.

1:33:19
He was born with cardiomyopathy and subsequently needed a transplant.

1:33:23
He received his gift of life at 8 months old.

1:33:26
We didn't have a transplant center near us when we needed it, so we traveled for care.

1:33:31
Much of the traveling we did for the first two years of his life was necessary for biopsies.

1:33:37
He had dozens of biopsies within that time period.

1:33:41
This is common for many recipient children.

1:33:44
As a now 15 year old, he has had a lifetime of biopsies reminding him that he will forever be a patient with all the side effects that go with that including but not limiting limited to missing school time, extreme difficulty with anesthesia, inpatient stays and intense anxiety.

1:34:02
The first time my son had access to Self Free DNA test, he was thrilled that he wouldn't have to be bedridden for days on end and he could finally participate in his state wrestling tournament, which he plays top four in.

1:34:14
As president of transplant families, I can attest that there is no topic spoken about more by families than biopsies.

1:34:20
This is a constant source of anxiety for them.

1:34:23
We urge you to reconsider restrictions to noninvasive testing.

1:34:26
Invasive biopsies are disruptive to children's lives and traumatizing to their psyches.

1:34:32
Children already have difficult access points and have so many invasive tests being transplant recipients.

1:34:38
Many of these happen in their first year alone.

1:34:41
Many families have to travel for these biopsies as well, bringing an unnecessary burden for those in rural areas.

1:34:47
This is not equitable for families that can't afford these tests, which rack up quickly to the 10s of thousands of dollars each time.

1:34:55
Please consider giving access to self free DNA test to help give these children a more normal childhood that they deserve and that their donor families intended.

1:35:05
Thank you so much for allowing me to speak today.

1:35:08
Thank you for a take of time to do so.

1:35:11
And last on the list for today that I show is Bill Ryan with Transplant Life Foundation.

1:35:18
Yeah, hi, good afternoon.

1:35:19
My name is Bill Ryan.

1:35:21
I am President and CEO of the Transplant Life Foundation of 501C3 nonprofit representing almost 10,000 transplant recipients and caregivers in the United States.

1:35:35
Along with producing the biennial Transplant Games of America, we also published Transplant Nation magazine, a full feature publication dedicated to the transplant community.

1:35:47
Our mission in supporting the transplant community has been directly affected by the recent decision to restrict access to noninvasive post transplant testing that provides early diagnosis of transplanted organ failure.

1:36:02
I'm here today to provide commentary on behalf of thousands of recipients and their families who view these changes as a step backwards in the care and treatment of transplant patients nationwide.

1:36:15
Post transplant patient care takes a significant toll on recipients and their families.

1:36:20
Non invasive testing provides a measure of relief at the same time provides critical diagnostic tool for their medical teams.

1:36:30
These tests provide an early warning system that suggests treatment options for organ preservation before significant rejection can occur.

1:36:39
Without the capability of early analysis, there's a possibility the organ may go into failure, resulting in either more intense treatment options or ultimately complete organ failure.

1:36:51
The development of noninvasive post transplant testing has been one of the most dramatic improvements for patient care in our community.

1:37:00
The decision to restrict or reduce coverage for noninvasive testing is the wrong message to send the companies.

1:37:07
We're seeking to design and implement new and innovative medical care for transplant patients.

1:37:14
The alternative to testing is the use of biopsies for analysis of organ damage.

1:37:19
Biopsies are invasive and invasive option that requires A surgical procedure and aside from the invasive nature of the biopsy of the patient and caregivers require time off of work for the procedure and endure unnecessary burden of increase travel related costs and extended recovery time frames.

1:37:40
These challenges often come with a loss of wages along with those travel costs.

1:37:46
These issues are exacerbated by our economically disadvantaged patients with and within our rural communities.

1:37:54

We are here today to advise you that our patient community needs these diagnostic diagnostic tools in order to maximize the health benefits that were provided in receiving the gift of a transplanted organ.

1:38:06
Our patients deserve better.

1:38:08
And on behalf of the thousands of patients and caregivers, we will also be submitting written comments later this week.

1:38:15
Thank you for listening.

1:38:18
Thank you.

1:38:18
Mr.

1:38:18
Ryan, any closing remarks before we end this session please thank none.

1:38:27
Please accept our gratitude for coming out, taking your valuable time to share your experiences and to share your knowledge.

1:38:37
We will take these comments very seriously.

1:38:40
They will all be published along with the policies and with the billing and coding article that attend to that.

1:38:49
And we will have responses to those that require a response.

1:38:54
The anyone may submit a written comment going forward until the 45 days ends and I'm going to turn that back to our admin team to help me with that.

1:39:09
All right, thank you Doctor Oakes.

1:39:11
In closing, we would like to communicate the next steps in the policy development process.

1:39:17
The comment period for the proposed LCD will remain open until September 23rd to 2023.

1:39:24
All comments to be considered by our medical directors for the proposed LCD must be submitted in writing.

1:39:32
Written comments can be emailed to policydraft@meridian.com or mailed to the address on your screen.

1:39:41
Comments information for our proposed LCD is located on our website at meridianmedicare.com.

1:39:49
Upon review of the comments, our medical directors will either finalize or retire the proposed LCD.

1:39:56
Responses to comments will be viewable in the Response to comments article.

1:40:01
Please monitor our website or register for listserv notifications to be informed of actions taken on our proposed LCD.

1:40:10
And with that, Doctor Oaks, do you have anything else you'd like to say before we end the meeting today?

1:40:15
I do not.

1:40:16
Just again, thanks for each of you coming out, share time with us.

1:40:20
Hope you have a good afternoon.

1:40:22
All right.

1:40:23
Yes, Thank you.

1:40:23
This concludes our meeting and thank you for attending the Meridian Open Public Meeting today.