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Discoveries in Health Policy

Ideas for or from an evolving healthcare system

Saturday, October 17, 2020

My Video About the New CMS Colorectal Liquid Biopsy NCD

Here's my video and deck about Medicare's October 16, 2020, announcement of an all new approach to covering future liquid biopsy tests that screen for colorectal cancer.

The first six minutes explain what happened and why it's important. For those who want a deep dive, the next ten minutes provide that. The jump-point between the overview and the deep dive is clearly marked.

If you'd rather go straight to the deck alone, I provide the PowerPoint link below, as well as at the YouTube channel.

https://www.youtube.com/watch?v=241OWfeTf30

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INFORMAL TRANSCRIPT OF CMS NCD VIDEO BY QUINN

00:01

Hi, this is Bruce Quinn.

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I'm a physician and a full time Medicare policy expert. In this video, we're going to talk about a new and exciting Medicare coverage decision that was released on Friday, October 16, for screening tests with liquid biopsy for colorectal cancer.

The video will be divided in two parts. In the first part, we'll provide two or three minutes of overview of what happened and why it's important, enough to understand it, and we'll close Part One with some links to the original documents.

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Then in the second part for another seven or eight minutes, I'll talk about the background, the deep

dive where this came from, how it fits into existing Medicare law, and some other interesting ins and outs.

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All right, so let's start with **the title slide**. CMS proposes rolling coverage of future colorectal cancer screening tests by liquid biopsy. That means circulating free DNA or cfdna, circulating tumor DNA,

What happened, what's new and some background?

01:11

So what happens CMS released a proposed National Coverage Decision. It came out on Friday evening, October 16. It came out after markets closed. We'll see why that's important in a couple slides. It's a proposal, it's not final, it could be adjusted.

CMS has a 30 day comment period till November 15. And they have several months to come to a final position. Now what exactly does it contain?

CMS proposes to cover liquid biopsy tests that screen for colorectal cancer,

if they have FDA approval, and if they have at least 74% sensitivity and 90% specificity.

Plus, additionally, they have to be endorsed by the US Public Services Task Force or by a major guideline or Association.

So that latter endorsement will probably be the gateway to the date when your coverage at Medicare is effective. Once you get covered for this new test, it will be priced by conventional means lab fee schedule, crosswalk gap gapfill or other methods for pricing a lab test.

There's a quirk here, the index liquid biopsy test for this NCD is the Epigenomics epi pro colon test, which itself does actually does not actually meet the CMS criteria that were proposed. Um, it's like if you were 24 years old, and you proposed a new voting law, and you got it, but it's for 25 year olds, and wouldn't include you.

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But it's a proposed decision. So it could change.

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There are major tests in the pipeline from big companies, exact sciences, garden health, these are companies with literally $10, $15 billion market caps. And they're doing FDA trials for about 10,000 patients

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with both the blood test, the new blood test and a colonoscopy gold standard test.

Here's an example of the exact sciences stock price shooting up from about $70 to $100. In September, that was a bump in market cap of about $5 billion.

And it's because on that day at a conference, they reported good data as they're introducing their interest developing their colon cancer screening test.

Now CMS usually does not cover new preventive tests willy nilly, they have to have FDA approval. So there are no lab developed tests. AND they have to have us Public Services Task Force endorsement,

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with an exception for colon cancer screening. So we're in a little exception pathway here. Then they have to get NCD review. And that's what Cologuard got in about 2014.

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And it's what's happening now again, for the second time, the NCD review can often take six to 12 months.

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So in short, there are a lot of hurdles from developing the test getting FDA approval, and to finally becoming a Medicare benefit.

Now –

This is to step back and give you the 20,000 foot view for just a few seconds. So in Medicare, you can have all kinds of tests, drugs, surgeries, procedures, therapies, and you ask are they for current symptoms of disease? If the answer is yes, then it's a regular coverage decision. It's treating a disease or diagnosing a disease that you think you have.

If the answer is no, it's not for current SIGNS AND SYMPTOMS of disease, then you are thrown into the preventive services pathway up here. And it's a whole different area of Medicare policy.

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There are three ways to get a preventive services benefit

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Number One a named legislative benefit passed in law by Congress signed by the president, that's where pap smears. PSA testing,

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mammography live here.

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These legal new benefits, it doesn't happen very often.

Number Two - Then there's a legislative option to go directly to an NCD for preventive benefit, but that's only possible for prostate two. technologies in colon cancer technologies.

Finally, Number Three, there is a wide but slow pathway, which is any service endorsed by the US Public Services Task Force plus also, CNS opens and completes an NCD. And each of those steps could take two years, and they occur sequentially. So that's why we call it a slow pathway

The new CMS pathway and the proposed decision on October 16, that's right in the middle of channel two.

As you as you probably realize, how do you get to these different pathways? Well, for the legislative benefit, you got to invoke patient groups, patient and disease associations, American Cancer Society, you got to get voters interested lobbyist action on the Hill senators, congressmen, get your legislative benefit.

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If you want to get the prostate or colon cancer NCD for a specific new technology, outside stakeholders need to convince the CMS leadership that would be a good idea. Again, ColoGuard got that in about 2014. And that's what's happening now again.

And the third pathway, first, the service has to be approved and published and rise to the agenda of the US Public Services Task Force. USPSTF then has to actually do a report that takes a year or two or three, then stakeholders have to convince the CMS to look into this as a new Medicare benefit. And that could take a couple years.

06:27

We're closing out the introductory five minutes. LINKS.

So here you've got the tracking sheet, I'll link to this down below in the YouTube video, you've got the draft proposal, and it's got a comment box at the top, that comment box will be active for about a 30 days, you can see a little picture of that at the bottom.

And then there's my blog Discoveries in Health Policy, look at the October 16 date for the written article and these links again.

OK.

So if you've heard enough, you can step away if you want to stick around for seven or eight minutes, I'll give you the deep dive.

07:01

In the beginning, Medicare was signed by Lyndon Johnson in 1965. And it covered several categories of providers and to be a physician, a hospital, a clinical laboratory, you had to be something Medicare would recognize to get in the door. Then you had to provide a medical or other health service. And that's defined in a list. It's physician services, hospital services, ambulance services, diagnostic test services, therapy services, and so on.

Have to be what's called a benefit category, they're in the middle.

Then there are things that are not covered eyeglasses not covered hearing aids, dental care not covered by Medicare by law. And things that are not reasonable, unnecessary to treat a disease are not covered cannot be covered unless there's some other action.

They probably figured out early on that a pap smear could be run by a clinical laboratory - That's a Medicare provider. It's a diagnostic test. That's a Medicare coverage category and it could be the service of a physician. But it's not necessary to treat disease. A healthy woman gets a pap smear. She has no signs and symptoms of cervical cancer. So she does not have signs and symptoms of the disease. So it fails to be something to treat signs and symptoms of disease.

Signs and symptoms of disease does not occur in the Medicare statute. But they came to the idea pretty early on decades ago, that Medicare does not pay for preventive care, quote unquote. Although the statute does not say that point blank.

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Let's look at the history of mammography. It was introduced by legislation on the hill in 1991. This is expanded again annual screening with no co pays in 1997. in that era, 1997 he got other benefits like pap smears bonus density for osteoporosis, colorectal screening testing.

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All those came in in 1997.

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This is what the regulations look like for Medicare mammography. 42 Code of Federal Regulations…No don't look it up. It reads like tax law.

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Here's the statutory benefit for colorectal cancer screening tests. Colorectal cancer screening test is defined in law by Congress to be as fecal occult blood test or screening flexible sigmoidoscopy or screening colonoscopy, that's probably the most familiar or

· D other tests or procedures with frequency and payment limits, as the Secretary determines are appropriate in consultation with appropriate organizations.

This is the channel these new contests are going to it's a colon test, and it is determined by the Secretary to be appropriate in consultation with organizations.

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15 years ago Medicare did that for fecal immune testing. It was a new type of people in unit testing.

Then and about 2014 Medicare did it for the cola guard test, which is now a $250 million a year Medicare test. One of the largest tests in the Medicare system

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And it's looking at now for liquid biopsies.

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The other pathway, the broad and slow pathway is from Medicare Improvement Act of 2008. And this is any services any a 50 60 or 70 services that have a US public services A or B rating, and via a national coverage, determination, Medicare determines they're appropriate for the Medicare population. Oh, wrap up before we talk about some of the flies in the ointment.

You've got channel one services written in law by Congress enumerated in the statute, channel two, only for colon and prostate.

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Those are technologies that Medicare can directly do an NCD on number three, any kind of preventive service, maybe it's an test for ovarian cancer, pancreatic cancer, thyroid cancer, a preventive test not mentioned in statute, but you got to get a US Public Services Task Force committee interested in it, then you got to get an NCD wait for years. That's channel three

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Flies in the ointment.

11:04

So the US Public Services Task Force timeline, they only update their recommendations at four to 10 year intervals. That process can take two years I've watched it. There's no mechanism for quickly doing a review in a brand new category infecting a brand new categories, probably a bigger barrier to getting started. new categories are virtually unknown. Lung cancer screening is probably with the CT scan, that's probably one of the newest categories. But there are a few of them, then it's unclear what outcomes data and replications US public services taskforce would require to approve something that's truly new. And they may not know until they see it and talk about it and investigate it.

They may not know what their exactly standards are going to be. A US Public Services Task Force is unlikely to seriously reviewing non FDA approved tests and CMS nationally will not do so.

NCD. Now you have the NCD timeline.

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There's a variable consideration period before opening an NCD. And we just saw the Epigenomics company probably was starting to talk to CMS going back to its FDA approval

several years ago. The formal letter for this proposed NCD is dated February 2019, Medicare did not act on it until January of 2020. The proposed decision is now in the fall of 2020. And it won't get finalized until sometime in 2021. So the NCD process from the request to the final literally takes several years.

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There is something called parallel review where Medicare sort of collapses its process and lays it on top of the FDA process with there's some time savings. But it's only done that twice in five years, it's not easy to do that. If you have a non colon non prostate preventive test, there is NO POINT in going to do parallel review because CMS can't start doing anything until after that US public service does stuff.

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But here's another summary.

You've got your product, you've spent three, four or five years and FDA trials, FDA approval venture capital, you get the US public services gateway that takes an unknown number of years. You're note done. Then you go to the NCD that takes a year or two or three, then you get to the Medicare market. So that's been a real hurdle.

That's why it's so exciting to have this new NCD put in place today. It'll just sit there and wait for you. And if you meet the requirements, like the 74% and the 90% rule, the FDA approval, the FDA label,

thing, you will be covered without any of these long delays, very exciting, shouldn't be the stimulus to Investment and give a lot of certainty to developers as well.

Now there are some gray areas I'll just touch on this bone mass measurement or DEXA. screening for osteoporosis is often considered a preventive benefit, but it's actually historically defined as a specially regulated treatment for disease. So it's covered for estrogen deficient women. Is that disease? They don't exactly say yes, but they don't exactly say no. Bone mass measurement is covered for things like hyper thyroid, parathyroid ism, well, that's a disease. So you don't need to have a preventive benefit. You just treat the disease. It's covered. If you've got

daily steroid treatments for more than three months, you can get a bone mass density scan, about of course, that's also part of the management of disease, not really a preventive benefits. So I just want to flag here if you get into this, you'll often stumble across some sort of a gray area in between is that definitely diagnostic or are definitely preventative.

So here's a proposal, and it's actually made stronger by what just happened this week. I wrote this slide the first time in August.

Here's my idea. We should just let Medicare do an NCD for preventive service, regardless of the US Public Services Task Force and its weights and its backlogs.

A couple of reasons for this and the current status quo is, a Medicare NCD review after the US Public Services Task Force is going review EXACTLY the same papers and reaching exactly the same conclusions in the same 20 or 30 pages of text.

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If there are 10 papers in a topic, US public services task force will summarize them and discuss them for 20 pages, then they handed over to Medicare and Medicare repeats exactly the same process.

So "gating" the approval on the US Public Services Task Force and a Medicare approval does not really accomplish too much. Oh, they would say they're looking at Medicare for people over 65. But it probably doesn't require an extra three years.

Then we've just had a wonderful example for about 20 years, Medicare has been able to do this since 1997, CMS has been able to do an NCD for a new colorectal technology or a new prostate technology.

And Medicare is shown with those two options, it can make a very prudent decision.

It's only done new colon cancer technologies three times in 23 years, it hasn't done any prostate cancer technologies in 23 years, it hasn't found one it's ready to do yet, or impressed enough to do so Medicare can handle this authority to make a direct NCD for provided benefit perfectly well, and they proven it for a couple decades. So let's just let them make decisions on preventive benefits, um, as they see fit. So we'll remove this restriction. And if it's an a very an FDA approved test, or a pancreatic FDA approved test, let Medicare go at it in the prudent way that they've shown you.

The last slide. In summary, Medicare prevented benefits go back to 1991, several decades into the existence of the program. They were enhanced in ‘97, and again in 2008. But the agency is still struggling how to handle out of the box innovations, how to handle the different bottlenecks and delays of multi years.

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And I think by the October 16 decision, we just saw putting in a framework for covering future benefits

on a rolling basis.

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It is innovative and very encouraging, and I hope you take a chance to read this benefit. And if you 7:06

are interested in it, feel free to give the Medicare agency a comment in the next 30 days.

Thank you very much.