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Webinar Transcript

Medicare Part D in 2026: What CLL Prescribers Need to Know

August 12, 2026

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Hello and welcome to today's webinar, Medicare Part D in 2026: What CLL Prescribers Need to Know. This webinar was produced in partnership with the Association of Cancer Care Centers. I am Perla Salazar, Program Coordinator at CLL Society.

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Prior to beginning, we would like to mention a few pre-event items.

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All attendees in this webinar are muted, and only the speakers are on camera. We ask you to please direct all questions to the Q&A section displayed on your screen.

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Questions will be sent directly to our speakers in CLL Society staff and are not visible to the audience.

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After today's event, you will receive a brief survey, and we greatly appreciate your feedback.

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This program was made possible through generous donors and our Policy Institute supporters, AstraZeneca and B1.

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At this time, I would like to welcome our speaker, Saira Sultan.



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Good morning or good afternoon, everyone. Thank you for joining us today. My name is Saira Sultan, and I'm joined by my colleague Kay Scanlon. We are...

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bringing you this webinar today as two attorneys, two people who have worked in reimbursement policy for over 30 years, having worked with companies, with medical societies, and with patient organizations...

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And look forward to the discussion today.

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So today we will focus on changes that have been made to the Medicare program for 2026, and also what is coming in later years, '27-'28, etc.

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How Part D and Medicare Advantage plans are responding to these changes in terms of their financial liability, and incentives will be driving our discussion today. And then, of course, also real-world implications

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of an important issue we'll discuss MFP effectuation and what the challenges that that brings to practices such as yours.

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We'll also talk about utilization management. I'm sure you're all seeing this in your practices already. Prior authorization, step therapy, etc., is increasing. We'll talk a little bit about the costs of this increase to your practices

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Step therapy for BTK inhibitors, and also the revised NCCN guidelines is something we want to focus on today because we have found it is a way that we have been able to help reduce potentially some of the utilization and step therapy

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Utilization management and step therapy you may see. So we want to share a particular example there with you.



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And then finally, we'll talk about CMS' draft guidance out on effectuating the Part B MFP through their Medicare Transaction Facilitator. Would especially like to focus with you all on what you are experiencing there

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I think it's already clear from the topics how this matters to your practice, of course. At any time we have a payment rules or financial incentives at the health plans driving what patients are receiving, what's easier for physicians to prescribe

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None of that is something we'd like to see at either the patient from the patient perspective or the provider perspective.

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And any delays and denials and redirects we get, of course, land very heavily inside practices such as yours because it makes for more work internally, something that the rest of us, whether we are patients or the Medicare program, et cetera, don't see and maybe don't give it as much credit

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as it deserves.

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These barriers, we know are affecting high cost cancer therapies more than anything else. And of course, starting in 2028, that will extend to provider-administered Part B drugs. And so these are issues of grave concern to CLL in particular, but also rare cancers more generally.

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MFP's effectuation policy issue will also place a lot more pressure on practices that administer Part B drugs and will affect the economics of the integrated, medically integrated pharmacies and the in-office dispensing.

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So with that, I would like to turn things over to my colleague, Kay. I will just say that as you're watching this webinar, please be aware and be thinking about are there things, tools, toolkits, programs

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Future webinars that might be helpful in allaying some of these concerns or problems for your practice. We will be putting together a toolkit as we hear back

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From you all on the survey that Perla just mentioned, there'll be not only a survey of how you liked this webinar, but also a survey about how your practice is handling some of these changes, which will give us a good sense for how we may be able to help

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In the toolkits we are developing.

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Okay, with that, I'd like to go to the next slide and turn it over to my colleague, Kay.

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Thank you, Saira. Let's start with what changed in 2026.

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Part D redesign is now fully in effect. For most patients, the most important change there is the annual out-of-pocket cap

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Which for 2026, it's \$2,100, and that's a huge improvement for beneficiaries, especially beneficiaries with CLL. And it may actually be what makes a difference between being able to

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use a BTK inhibitor and not being able to due to cost

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And the other improvement from a patient perspective is the Medicare prescription payment plan, and that's available and it lets beneficiaries spread their Part D out-of-pocket costs over the year instead of front loading that first dose and the entirety of their

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Out-of-pocket obligation in, you know the first month where they're actually taking a treatment.

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It doesn't reduce the patient's total Part D obligation, but changing the timing can make it a whole lot less financially shocking. At the same time, we have pressures going on the other side. The first 10 negotiated drugs now have MFPs, maximum fare prices



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And that includes ibrutinib. This is the first year where the Medicare negotiation program isn't just a kind of a future policy thing. It's actually an operational reality for these selected drugs.

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For practices, and we've seen this year there was a great deal of difficulty at the beginning, because a lot of dispensing clinicians did not know they had to enroll with the Medicare transaction facilitator

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That facilitator moves the data and it gets the manufacturer's refund to the dispensing entity, whether that's a specialty pharmacy

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a brick and mortar retail pharmacy or a clinician's practice.

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And it creates a lot of operational questions, banking claims, data, refund timing, reconciliation issues.

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And the Part D

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rules also this year more on the bright side have a

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a bit more of an appeal process when

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Any of the plans

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try to implement a change in formulary mid-year

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they have to give notice, they have to permit a transition, and exception and appeals processes can apply, depending on the circumstances.

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And finally, CMS has issued draft guidance on how they're going to effectuate the



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MFP. The maximum fair price for Part B drugs, and that starts in 2028. We'll come back to that in more detail, because the Part B proposal is where provider-administered oncology therapies enter the same basic effectuation architecture

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So basically the patient affordability story is real. But so is a plan incentive story and a provider paperwork burden story.

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Well, as should surprise no one who's dealt with payers before, they are adapting to these changes.

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And unfortunately, practices and patients are left to absorb many of the consequences.

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One of the visible signs that we've seen is market contraction among standalone Part D plans. So it basically it decreased from 464 standalone Part D plans in 2025 to 360 in 2026.

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That doesn't mean every patient's automatically going to move into Medicare Advantage, but it does mean that individuals with fewer choices and maybe no real good choices as far as Part D standalone plans are concerned may

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you know when they see the fairly aggressive Medicare Advantage marketing may say, hey, maybe this is just going to be better.

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The market's changing, and in some areas it's changing more than in others. So the cost structure, the cost sharing structure is also changing. The Part D deductible maximum is \$615 in 2026

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It's up from 590 in 2025.

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A lot more standalone Part D plans are putting in the maximum deductible than they've done before. So, but that sits alongside the \$2,100 out-of-pocket cap

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It includes, you know, it's included within it, and, you know, it doesn't really have that much of a practical impact on patients with high-cost drugs

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And finally, we're also seeing a lot more tools that are familiar to offices being used more intensely, more frequently.

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prior authorization, step therapy, formulary management, quantity limits, pharmacy network design. Each of those tools is benefit management, and each one creates work inside the practice. So your team has to find out what rule fired, if there's a denial

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What documentation is needed and what timeline applies.

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And the last thing, as Saira mentioned, the effectuation. And that's going to add a new operational layer

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CMS is saying that the Part D MFP refunds are dispensing

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I mean, or be incentive dispensing entities about 21 days, an average of 21 days

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From the date of service, we're hearing that it can be much, much longer than that. And for MA plans, it's even longer. So it's not unusual for a plan, for a

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dispensing entity to be underwater or waiting for the refund for a month or more

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Okay

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So plan steering.

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As you probably have seen multiple times.

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Plans have multiple ways to push patients toward or away from certain drugs

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formulary tiering, prior authorization, step therapy, preferred specialty pharmacy arrangements, and other tools. The clinical issue is that these tools may be blunt instruments when therapy choice should be patient-specific. So, basically the plan is making a decision for all of their covered lives

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And for cancer patients, it's, you know, they rely on their clinician to make the decisions. The first thing to understand is that a rejection at the point of sale or in an electronic prior authorization workflow

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may not be a clinical decision. It could very easily be an automated edit. And that matters because the first response shouldn't always be a full appeal letter. Sometimes the first response is to identify the exact edit. Is it prior authorization? Is it step therapy?

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Is it a quantity limit? Is it a refill too soon at it? Is a drug excluded within that plan?

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And the second point is continuity. Even patients already stable on therapy can face new requirements, and that's really true at the start of a plan year.

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or after a plan switch, after a formulary change, or reauthorization.

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and it's going to become increasingly more important to identify those renewal and reauthorization points before they become treatment gaps, because

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with plans now that can easily, easily happen.

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Yeah, and I might just say there, Kay, that of course practices understand a lot of what you're saying there, but I think to the extent that providers... I'm sorry, I meant providers... to the extent providers are well aware of that

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Just be thinking if it would be useful for CLL Society or ACCC together to provide any sort of standardized prior authorization and appeal templates or a BTKi choice justification form that incorporates what Kay will talk about soon as the NCCN guidance

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So whatever we can be doing to provide some assistance and documentation in the toolkits to facilitate the people in your office being able to do some of what Kay has talked about there.

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Thank you, Saira.

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Yeah.

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Okay, so as you may know, CLL is one of the first real battlegrounds for IRA-related denials and step therapy in cancer at least

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It combines high-cost oral oncology drugs, multiple agents in the same class, and Medicare negotiation. You have rebates, patient-specific clinical selection

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It's kind of a real convergence.

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next year it's going to be acalabrutinib is going to be subject to an MFP. So effectuation will hit for acalabrutinib, and we expect that that's going to have a much greater impact on practices.

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Then, you know, and we'll talk about that more later.

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But



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When you hit a denial, the reason is probably economic rather than clinical. If it's a BTK inhibitor, a plan may prefer the covalent BTK inhibitor with the better net economics rather than that it's because of a negotiated MFP,

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a rebate, or any other contractual arrangement.

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The planned preferred drug, though, is, as you probably encountered, not always the right drug for the particular patient.

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And when that's the case, it can be incredibly burdensome. And this is where the NCCN CLL guidelines become really important

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The language previously fell short of saying that the BTK inhibitors are not interchangeable. It did suggest that patient-specific factors

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should guide decisions.

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Now it's much, much clearer. It says that the choice

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is made by the clinician based on patient-specific factors, and that the BTK, the covalent BTK inhibitors are not interchangeable. So that language is really useful because step therapy really rests on an assumption of substitutability

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If the premise is that the patient can simply try the plan for BTKi first, the practice response should be not necessarily.

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The guideline recognizes that they're not interchangeable. And so the cleanest appeal is not we prefer this drug. It is for this patient based on these facts, the requested agent is clinically appropriate

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And the plan preferred alternative is not an interchangeable substitute.



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That means that, you know, I think that the best thing is the practice shouldn't wait until denial to start building the clinical record. You know, make sure you have that

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all set, you know, within the, the medical record, you know, before you even present the prescription.

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So if we move to the next slide

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And I just want to pause there again and say that Kay led the effort on behalf of CLL Society to get this change and clarification made at NCCN and was the person who was the liaison to NCCN to explain why this was needed and how it needed to be worded and all of that. So to the extent that you all

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in your practices are running up against other issues with NCCN guidelines, or what have you, please let us know if that is happening, and maybe we can do the same with whatever issue you are seeing. Payers misuse

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NCCN guidelines for.

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Absolutely. And especially in this BTK inhibitor class because

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You know, CMS is saying that

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Plans are, you know, going along with the guidelines, you know, the NCCN guidelines. And what we're what we believe we're seeing in the real world is that that's just not the case. And unless we hear from patients, unless we and patients may not always know, but unless we hear from clinicians

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who have experienced this. You know, we don't have the receipts to go to CMS and say, hey, wait a minute, you said X, and we're showing you Y

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And unless they have that, they're, you know, it's difficult to push them to do anything.

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So

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For this next slide, we're shifting from the policy problem to a practice difference strategy.

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The core objective is to move from a reactive appeal workflow to proactive submission workflow. Basically, don't wait for the automated PBM or plan edit to deny the request and then begin gathering the medical facts. Build the facts into the first submission

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whenever the plan's workflow allows.

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The standard approach is a guideline first attachment or structured documentation field. And your practice should not submit a clean prescription alone when the therapy is likely to trigger the prior authorization or step therapy

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Or similar at it. Basically, the initial submission should include a concise clinical justification, diagnosis, line of therapy, guideline support, patient-specific factors, why the requested agent is medically appropriate

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All of that. Now, of course, you know, as we all know, all of that is just as likely to be, quote, 'lost' or not received by the plan, but

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You have it if it needs to be resubmitted

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And in CLL, if it's a BTK inhibitor, using that, very, very clear NCCN language where it's relevant, especially the non-interchangeability and clinician selection language

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That should be... that is very, very important. For other cancer therapies, the same logic applies. Make the guideline and the patient-specific rationale visible, right at the outset.

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The patient comorbidity

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The filter is the operational heart of this for a lot of patients. Medically integrated pharmacies

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financial navigators, nurse, PA coordinators should never should review the EHR before hitting submit

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The team needs to identify, you know, things like arrhythmia risk, bleeding risk, concomitant medications

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CYP3A interactions, prior intolerance, any of the other facts that might make one therapy more appropriate for that patient than another. The goal is to make the practice's strongest argument easy to find in the first review.

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And it should be built into templates, as Saira mentioned before, smart phrases, check boxes, so the team isn't reinventing the same justification every single time. Basically, the goal is not to write some beautiful appeal letter. The goal is to stop rewriting the same

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medical necessity documentation facts 40 times, 50 times, 100 times.

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So, you know, that's again, that's the goal. If we can move to the next slide.

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Okay, and this is very much a bit of a rehash with a little more specificity. You know, when you get a denial or stalled claim or stalled prior authorization

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The first step

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is to capture what's going on precisely, and it sounds really basic, but it's one of the most important workflow points that we can stress to you. I mean, it's kind of like when we, you know, Saira mentioned that we help change the NCCN guidelines



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To do that, we had to figure out what process, you know what is it that we're requesting? Are we requesting an evidence-based change? Are we requesting a administrative language, semantics change

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And what processes are required from NCCN to do that. So that's how we were able to get it done quickly because it was not an evidence-based thing. It was a semantics change and they changed it, I would say, within a week and a half, two weeks

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Which was, you know, because they didn't have to go to the full panel because that's not what the problem was.

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So

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Whether it's prior authorization, step therapy, a non-formulary quantity limit, any of those things, they're all different problems and they require different responses and they can trigger different timelines.

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So the next is what kind of a decision you're dealing with. Is it a part D coverage determination? Is it just an automated claim edit that has not yet become a formal coverage decision?

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Whatever it is, the first thing is to first figure out, you know your patient. Is this a new start? Is this a patient with a prior new prior authorization with a different plan on the same therapy?

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If therapy's urgent or it's already underway, practices should really look at bridge supply and whether it's manufacturer free drug programs, foundations, any other options that can prevent treatment interruption while the coverage process

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proceeds through

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This is also where ownership matters and having one person accountable for that particular case until it closes can be super helpful. Otherwise, the case, you know, bounces among the pharmacy and navigator and nurse, a physician

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And nobody really knows who owns the clock.

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The next step is to escalate on the clock. For Part D, many expedited initial coverage determinations have to be decided within 24 hours

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And that's if the standard timeline could jeopardize the patient.

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expedited Part D redeterminations and a lot of the Medicare Advantage

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organization determinations may operate on more of a 72-hour standard. It's going to depend on the type and level of request

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At each level, you're going to want to put the clinical argument in writing, attach the guideline support and the patient-specific rationale, and don't assume that the reviewer has read the prior submission carefully. Chances are they haven't

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There's even a good chance that it's not even attached to whatever they're looking at. But you want to make the reason for the medical necessity impossible for them to miss when they look at it.

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And if we move to the next one

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Okay, so as we said before, we definitely don't want to wait for a denial on zanubrutinib or acalabrutinib.

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If you have a medically integrated pharmacy, that's a lot easier because you're seeing the patient, you have all of that information at the tip of your fingers.

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standardized if you create a standardized one page BTKi choice justification form that can be extremely helpful. I would say basically under current NCCN guidelines

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guidance, the covalent BTK inhibitors aren't interchangeable. The choice is determined by the treating clinician based on patient-specific factors, as we've said

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And then identify the requested agent and the patient-specific reason for choosing it.

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And those patient-specific reasons might include cardiovascular risk. It might include clinician judgment on tolerability. It might include clinician judgment on ease of use

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Maybe, you know, you're choosing one over another because you think you might need to reduce the dose

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or something like that, and you've got greater choice of dose strengths.

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to offer. So any of those things, you know, it's

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The guidelines say that it's a clinician decision based on patient-specific factors.

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And then peer-to-peer review.

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I think here this is super important, because first off, if you request a peer-to-peer, you want to make sure that you're requesting it with a board

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certified oncologist

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And someone like that is going to be very hesitant to put in writing that they are overriding NCCN guidelines



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So, you know, make it very, very clear.

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Because moving quickly through those other steps or escalating straight to peer-to-peer could actually, as much as it seems like it's not a time saver, if you request it and put the reason for the request and the NCCN guidelines in your email

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you might get past the denial without having to actually talk to somebody, which would be delightful

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And if we move to the next slide

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Okay, so as this slide says, fixed-duration BTK inhibitors

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With venetoclax creates a different coverage problem. It's not just because... it's not another monotherapy prescription. So, the regimen is planned as a time-limited combination. Administratively, right now, Part D plans

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are experiencing it, they're administering it as two separate drugs with two separate prior authorizations, two sets of coverage criteria, two specialty pharmacy processes, and even, you know, potentially two different quantity limit rules

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different... when do you have to do the reauthorization?

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So, acalabrutinib plus venetoclax was proved by the FDA in February of this year

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As an all-oral fixed-duration regimen for previously untreated CLL, ibrutinib plus venetoclax is also used in CLL care. And those regimens offer a defined treatment timeline. It's 12 to 14 months, 14 months for acalabrutinib

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rather than an indefinite daily monotherapy. And that defined timeline is clinically meaningful, because it can be administratively fragile. If one component is approved and the other stalls

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the entire regimen is not ready. If the ramp-up schedule is not reflected in the quantity limit request, the patient can be stopped by an automated edit in a week or two, or three. And if reauthorization is needed mid-regimen for one and not the other, or if they're not clicking up at the same time

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Nobody's tracking it. The treatment can end up being interrupted accidentally. So the practice implication is that access plan needs to follow the regimen, not the individual prescription or the individual or the components of it.

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And the team should know before treatment begins what needs to be approved in what order, for how long, and under what dosing schedule, and have flags in the system for when

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you know a reauthorization is required because if it's a 14-month regimen, it's more likely than not that you're going to need reauthorization on both.

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So clinically, it's one regimen administratively, Part D it looks more like a small group project, basically. And it can end up hitting some real hiccups.

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So if we move to the next one

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Sorry, did you have any thoughts before we move?

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Nope, I'm good. I was just going to reiterate that perhaps here there's a coverage checklist for fixed-duration combination regimens that might be helpful.

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you know, I'm just continuing to throw out ideas that might be useful to practices as we

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As we all contend with sort of this year and into next year and the year after.



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Perfect. Thank you. And basically, this is, you know, here we're going to like reiterate the importance of front-loading the coverage work before cycle one, day one

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The practice really should verify, to the extent possible, coverage requirements for each component

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of the regimen

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and over time

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So where the plan allows obtaining authorization for the full plan treatment period. When it doesn't allow that, build a calendar that reflects every real refill, ramp-up quantity limit, reauthorization risk point

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And for venetoclax containing regimens, a dose escalation schedule is especially important

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Automated systems can reject a claim if the quantity looks unusual, and especially if it changes over time. So submitting the exact ramp-up or dose escalation schedule with the initial request

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I would love to say it would prevent a later quantity limit denial.

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But as you know, it's more likely that it supports, you know, if they deny it, you can say, hey, wait a minute, you know, we told you that this is what was going to happen, this is what was planned. We've already started it. It makes it easier to get past that

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So

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I think that the point is speed and clinical accountability



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As you work through the processes with plans to the extent possible, getting

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quick peer-to-peer request in that gives the full set of medical necessity that you would present

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Basically, you know, a fixed duration regimen only works if the coverage process understands

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The combination and the duration

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And the variability in doses due to the ramp-up.

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So if we move to the next one

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And I mentioned previously that medically integrated pharmacies can have a real edge in navigating some of these PBM hurdles

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And I know ACCC has done a lot of work with toolkits to kind of show practices how they can adopt this type of a framework

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One of the things is that they're closer to the patient, they're closer to the chart, they're closer to the prescriber, and that really matters. It allows the team to convert clinical facts

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what they're seeing in the patient into coverage facts really quickly, and to have those facts at their fingertips. So, for example, you know, if you're selecting a BTK inhibitor, you're probably going to need to document cardiovascular history

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History or atrial fibrillation risk, hypertension, any of those things. Any of the patient-specific factors, and those facts, you know, may very well already be in the EHR

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But they're not going to help the coverage request unless someone pulls them forward into the prior authorization or into the exception submission. So

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The real MIP, Medically Integrated Pharmacy Advantage, isn't just faster clicking, it's ability to see the clinical record, to understand the treatment plan and attach the right evidence before the plans rule and edit engine forces the wrong questions

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So

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it's basically the ability to see the patient work with the patient, and have one person responsible for the entire process.

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Okay, so

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Ibrutinib was the first

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oncology drug and also the first CLL drug of course

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to be selected for negotiation.

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is subject to an MFP and has been since the beginning of the year. Now, it's becoming prescribed

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far less frequently than in prior years, so it may not be a huge issue. The you know the the MFP, the effectuation process may not really be hitting

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practices full force.

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Next year, it's calibrutinib.



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And for CLL practices, that's going to matter because it's a core CLL therapy

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So the operational issue isn't simply that it has a lower negotiated price. The issue is how that lower price is, quote, 'effectuated'; to dispensing entities

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And dispensing entities may acquire inventory at costs above the MFP, and then they have to rely on subsequent manufacturer refunds that are done through what we discussed before, the Medicare transaction facilitator process.

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And it can create an inventory and reconciliation risk. So if the refund's delayed, if there's a mismatch, if it's disputed, if you've got an MA plan that's really taking a long time or

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If any time, any of those things happen, either the practice or the pharmacy has to float, you know, they have to carry the float and spend staff time resolving the issue.

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So even when the money eventually arrives, the process can create cash flow pressure and administrative costs. And that's one of the things that CLL Society has been emphasizing.

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To CMS is that, wait a minute.

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Adding all of this extra paperwork burden and practices are making less money. So you're giving them less money to do more work.

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So that can be a real difficult thing. And it's not the danger isn't really that the MFP exists

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It's that

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There are potentials for refund delays. So even though you have access, you have access to the MFP, that doesn't mean you're buying

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the drug at the MFP. More likely than not, you're going to be having to get a refund.

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And I think that issue is actually front and center on the policy table right this minute. And CLL Society will be writing about the provider burden of this issue. So to the extent that you all have questions, please put them in the Q&A, but also just any thoughts you have about how this has been affecting you or can affect you

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how significant it may be. Drop a note in the Q&A. It would be really helpful for us as we think through how best to represent the concerns we think are very valid that providers are facing on this issue.

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Yeah, and you know the other thing to remember is that at the beginning of this year

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There was a huge bottleneck because Medically Integrated Pharmacies, in-office dispensing

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practices with those models. Not all of them were aware that they needed to register with the Medicare transaction facilitator.

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So there were, there was

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you know, there was quite a bit of delay due to confusion there, not understanding that that was really the only way that they were going to be getting that refund.

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To quote 'effectuate the MFP'

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So here



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For 2026, there are some

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important, I guess, protections for beneficiaries.

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That can be helpful. It's an upside downside type of thing because we're also seeing that CMS has kind of given their blessing on things like step edits.

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So

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Part D plans, if they make a formulary change mid-year

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They're permitted to do it, but now what they have to do is they have to give notice.

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And their change is kind of deemed to be a

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you know, a plan decision and

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Patients who are using those drugs have an appeal right at that point, not... they don't have to wait for a denial

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They'll have an appeal right at the point where they get notification that there's a change. So if the change is, you know, a step at it, if the change is, you know, more intense prior authorization or limiting to certain patient types, anything that constricts access

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If a patient is potentially impacted by that, the appeal right attaches at the time they get notice of the decision.

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And the expedited review is also important. If applying the standard timeline could jeopardize the patient's health, their life, or ability to regain maximum function



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Definitely, definitely make an expedited request. And we've heard about individuals. We've heard from individuals who've said that, you know, the reauthorization

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Caused a gap in therapy. And that every time they know that it's coming up again, they start to worry.

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So so it's something that patients, a lot of patients are very aware of and that offices can help ease that kind of stress, ease that tension by, you know.

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making sure that when those problems arise, that they're resolved as quickly as possible

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At patients who stable on a particular CLL agent is a very different clinical case from a patient starting therapy for the first time

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So stability doesn't guarantee victory in every coverage dispute, but it really does strengthen the clinical rationale. And I would suggest really highlighting it.

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So, you know, basically preserve the record, use the right request type document urgency, and don't let an informal rejection sit unconverted into a formal appealable decision

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when treatment is at risk.

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And if we go to the next page

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We're looking into, we're looking 2 years ahead to when the fund really starts for oncology practices. And that's when

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the maximum fair price reaches Part B drugs



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And that means the negotiation program is moving toward provider-administered therapies which a lot of oncology treatments obviously are purchased through a buy-and-bill

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CMS is taking kind of the easiest road possible for them

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They basically said, oh, we've got this Medicare transaction facilitator. Excellent. We'll use that for Part B. So they're suggesting extending that that way. So it would again be the practice floating

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The excess cost until they get reimbursed.

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And, you know, from CMS' standpoint, yeah, it makes sense because they're trying to move data, verify eligibility, and facilitate manufacturers refunds. But, you know, from a provider standpoint, you know, the question is whether the mechanism

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is ever going to work.

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with provider cash flow as we get, you know, we start layering more and more and more drug subject to these negotiations.

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And as you know, in Buy-and-Bill, you're purchasing the drug before the patient receives it. You're carrying inventory risk

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You submit the claim, the payment refund process has come later. So, if the MFP is effectuated through a delayed refund, this time it becomes a real access issue.

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And that's why the draft guidance matters now. CMS is asking operational questions, really that providers are uniquely positioned to answer. You know, you know how long inventory is held, how claim submission works, how Medicare Advantage and counter data



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How that timing is different from fee-for-service claims and also what level of float changes

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you know what level of timing on the float is going to really change stocking behavior.

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So, you know, the easiest way to see the problem is to walk through the proposed process step by step.

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And we're not talking about 2028 now just because we are looking ahead. It's actually because CMS is looking for feedback and comments on these policies and proposals now

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Because they will begin to think about our feedback, our input, and then begin to finalize things ahead of 2028. So, this is not sort of an academic issue that we're discussing, that this will happen two years from now. We're really trying to get

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Your all's thoughts on how this will affect your practice. So whether it's in the survey you receive about this webinar or the larger survey about what's happening in your practices, please do take time to note where you can, sort of the anticipated burden

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of things coming in 2028.

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Absolutely.

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Thanks.

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Okay, so here's the proposed Part B process in slow motion. First, the practice purchases a drug and they do that through the normal buy-and-bill process.

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And that's when your money theoretically goes out the door.

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The next thing is, you administer the drug to the patient.

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Then Medicare claim is submitted

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It's adjudicated

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And that's by the MAC and fee for service or through encounter data in Medicare Advantage.

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And then the next step is CMS transmits the claim information to the manufacturer, and that goes through the Medicare transaction facilitator

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Fifth, the manufacturer sends the refund

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Through to the not to the practice, not to, you know, whoever purchased the drug, but to the Medicare transaction facilitator

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And then that the MTF then sends the refund to that came from the manufacturer to the practice.

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So the key point, you know, one of the things they did try to do was put in a 14-day clock

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But that clock when that clock starts is important.

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So

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You're going to look at the clock starting at about step four.



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In the process.

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It starts after claim information moves through that adjudication or encounter data submission, and CMS transmits the information to the manufacturer.

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So the provider financing period's longer than the manufacturer refund window when you hear 14 days, no, you're not going to get it within 14 days of

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purchasing, certainly, and not even within 14 days of administering it. All these other processes have to happen first.

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So CMS owns that 14-day clock, and the practice owns

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all the days before the clock starts

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And you know, sure, you know 14 days is a meaningful improvement over an open-ended process. But you know we've seen in the Part D effectuation

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at least in the initial year, entities are waiting way longer than the 21 days that CMS, you know, cites as average.

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We move to the next slide.

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Okay, so this is kind of like the good and the bad. This part's the good. The CMS did adopt a firm 14-day payment deadline

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And that's better. They appear to understand that settlement timing matters, and the providers need predictability.

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They also have really explicitly acknowledged that Medicare Advantage and counter data timing is going to be a problem.



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In traditional Medicare, they have access. They have access to adjudicated claims through the MAC processes. In Medicare Advantage, they're relying on encounter data and counter data that's submitted by the MA organization, and it just adds, you know, another entity and another timing variable

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So, you know, one of the things that they're asking for comment on is whether this encounter data should be submitted faster or with specific data elements like NDC information. And those types of things are opportunities for providers to weigh in, whether it's through your specialty society

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through CLL Society. Any all, honestly, you know, if you have an opinion, let it be known if it is going to impact your practice, let it be known because this is really the time

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you know, just to get CMS to make changes if they were going to do so.

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So yeah, basically, we're hoping that they've asked the right questions, and we also know that they absolutely understand that the

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The precise mechanism that they have picked is a mechanism that providers, patients, and manufacturers have all said

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you know, it's potentially the worst choice they could have made, you know, mostly because of the timing, the uncertainty. And again, you know, you're

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The clinician is going to be getting less money just by virtue of no longer working off ASP plus 6. You're going to get less money because you're working off the MFP. And required to do more work

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and required to finance the Medicare program for a period of time.

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So



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If we move to the next slide.

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Okay, like I said, providers are still going to purchase your inventory.

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In your usual way at whatever your acquisition cost is.

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Waiting for the claim to be submitted, waiting for it to be adjudicated. CMS verification, transmission through the MTF. All of those things really can cause a lot more than 14 days

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So for high-cost infused oncology drugs

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That can be a huge problem for a smaller practice, and can even be a huge problem for teaching hospitals that are, you know, relying on timely

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Recoupment of drug costs.

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So, basically, the access question is not whether the refund eventually arrives in an abstract

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It sounds it's whether the time between acquisition and refund is going to be workable for the providers that patients really rely on to buy, store, administer the drugs.

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And one of the things, you know, CLL Society has pointed out to CMS that

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The IRA was designed, yes, to save money to Medicare, but also to preserve and even to improve

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beneficiary experience, and that's experience and access experience in how much it costs, etc. So you know, one of the things that we've really seen is that CMS in choosing this mechanism really

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Kind of optimized.

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their own administration, not really access

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You know, they've already built the system that moves data, so they're like, okay, good enough.

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But the clinically relevant questions different. It's how do we preserve patient access? So a technically functional fund system, it can still fail patients if it changes provider stocking decisions

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If it makes smaller practices, I'm willing to carry inventory or to take new Medicare patients even

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Or if it creates different incentives by payer mix, pushes care to less convenient or more expensive sites, or sites where it's, you know, almost impossible for the patient to make an appointment just by the fact that it's overloaded

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So we really believe that the yardstick should be beneficiary access. It does the process preserve the ability and willingness of providers

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To just go ahead and stock administer these therapies. And does it treat Medicare Advantage and fee-for-service patients similarly?

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You know, what type of cash flow burden is going to be too much?

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And when is that a problem?

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has anything accounted for the staff time needed for enrollment, reconciliation, payment tracking, and all of that. So, you know, our policy standard

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It's less about does

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does this refund eventually reach providers? If the drugs no longer sitting on the shelf when the patient arrives, it's

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It's a patient access issue.

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So if we move to the next slide

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Okay.

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The gaps here are the cash flow and Medicare Advantage, and the guidance assumes that the 14-day manufacturer payment window is sufficient.

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And they don't really seem to understand that the acquisition clock, that the financing clock is based on acquisition timing, and that that starts earlier.

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So

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And when you put on Medicare Advantage, you're adding another layer. So that's going to depend on the encounter data submission by the MA organization. And it's really a whole lot less predictable, as you probably know.

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So providers could end up facing different economics that depend on payer mix. So if you have a whole pile of Medicare Advantage population, then you're going to likely carry a longer float than if you have

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you know, mostly commercial and traditional Medicare patients.



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So that means, you know, stock, you're going to need to focus more on stocking drugs based on cash flow, predictability, inventory risk, administrative burden

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And that's again, that's where, you know, providers can really

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help by adding their voices to this policy decision.

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you know, letting CMS know how long these MA encounters take to appear.

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And how much variability there is

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So basically if two patients are receiving the same drug and the same chair on the same day, we don't believe that providers should face materially different financing just because one says Medicare, one says Medicare Advantage, another says commercial

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So, you know, for us, that's the real issue.

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And if we move to the

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And again, and again, there'll be an opportunity when you get the survey from us to continue to not only in the survey, but also just continually to provide your thoughts on some of these topics so that as Kay talks about, you know, it's good to make sure that your experience is being known to the agency

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You know, sharing that information with us will allow us to share that and make it known, so to speak. So we're not, you know, anticipating that each of you will individually be interested in writing to CMS, etc. Although, if you are planning to do that and can use any support in being able to do that

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Even if it's logistical or what have you, please let us know. But I think the easier effort may be to share your perspective and your experience with us



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and you know on a continual basis, as as you experience things, so that we can let it be known on your behalf to CMS as well.

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Thanks, Kay.

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Okay.

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And, you know, the fifth... oh, if we move to the next slide, sorry.

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If you look at the fifth gap, and I think this is the most important one

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It's what does it mean to keep providers whole?

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And a narrow view is kind of that, okay, well, your whole if you eventually receive the manufacturer refund

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But that is really, really a poor workable operational definition for oncology practices. You know, it's a more meaningful definition is that providers shouldn't be economically disadvantaged by the effectuation mechanism

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And that means they shouldn't have to finance negotiated discounts for an extended period, right? They shouldn't have to lose intended economics of ASP reimbursement. They shouldn't absorb material new administrative costs that are created just by the effectuation process

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The administrative costs matter. I mean, they matter to practices, and if they matter to practices, they matter to patients because at some point all of those pressures end up changing the landscape patients face when they're looking for treatment.

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You know, whether it's enrollment, the banking setup, getting third-party support arrangements, data matching, dispute resolution, payment reconciliation, even the Medicare transaction facilitator onboarding



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And staff training. That work doesn't appear in the drug payment formula. But it's real work inside the practice, and it's real work that is accompanied with a reduction in the amount of reimbursement

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So the policy point for us is that administrative burden changes provider behavior, then

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It's going to reduce access. If pressed, decide the process just isn't feasible, isn't workable as a business model. And that's one of the biggest reasons we want to get to CMS quickly

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with the best information available. And a lot of that information, once again, as Saira said, comes from providers.

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So, you know, if I could sum this slide up at all, it would be that eventually receiving the right dollars isn't the same thing as being economically neutral. If it took a new full-time employee and a line of credit to get there.

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So, you know, that's the point.

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Okay, if we move to the next slide

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Okay, so I think closing with a couple of takeaways.

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First, utilization management is now one of the primary levers that payers are going to be using to control specialty drug costs.

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If you see a lot of Medicare patients, if you see a lot of CLL patients

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It's going to become, you know, as you start with 10 drugs. If you add 15 drugs, 15 are the most costly drugs each year.



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You can imagine that there would be a point where, you know, the majority of agents infused or dispensed may be subject to an MFP by some practice, you know, within some practices.

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So

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Basically

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Oh, okay.

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Kay, we have one minute. Just wanted to give you a heads up.

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Alrighty. So basically

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I think that we need to hear from providers, and providers need to be prepared. So

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That would be the best thing to say.

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All right.

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Thanks so much, Kay. Can we move to the next slide, please?

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We have one question in the Q&A, and the question really relates to being able to choose one's health plan and Medicare, whether that's traditional Medicare or Medicare Advantage.

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And what sort of supplemental coverage to have and how good that coverage is. We can't really say whether something is good coverage or not. That's really a question one has to think about with one's doctor

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And if we're in a watch-and-wait situation, that's especially difficult to do because you don't know what treatments you're going to need and what's covered and what's not. But also keep in mind that in the context of this entire presentation, that a lot is changing right now

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And that health plans will be reacting differently to all these different incentives and structures that Kay talked about today. So it's really important to annually keep an eye on what plan you're signing up for

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And that, I think that's about all we can provide by way of answer to that

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Next slide, please.

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So we'd like to thank our partners, the Association of Cancer Care Centers, for partnering with us on this event. This program, as was said earlier, was made possible through the generous donors and grant support from AstraZeneca and BeOne.

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Next slide, please. Thank you.

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We'd like to thank everyone for joining us today. Please remember to complete the event survey and provide your feedback to help CLL Society plan for future events and also plan for the toolkits we are thinking about putting together.

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Please complete the provider...It's called the provider perspective on access to prescribe CLL Treatments Survey. It's a mouthful, but that will be emailed to you after this event, and that actually will be the ones that will be the survey guiding our work on the toolkits to provide

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Afterwards, the webinar was recorded and will be available on our website along with the slide deck. And if your question was not answered today, please send it along to support@cllsociety.org, or even if you have not yet asked your question or shared a thought

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Please send it along to support@cllsociety.org.



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Please remember CLL Society is invested in your long life and the long lives of our patients, I should say, and you can invest in the long life of CLL Society by supporting their work. Thank you so much.