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<https://reachmd.com/programs/cme/menin-inhibitors-in-aml-six-clinical-showdowns-that-shape-real-world-practice/57259/>

Released: 08/10/2026

Valid until: 08/10/2027

Time needed to complete: 30 minutes

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## Menin Inhibitors in AML: Six Clinical Showdowns That Shape Real-World Practice

### Announcer:

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### Chapter 1

#### Dr. Zeidan:

Welcome to this educational activity of menin inhibitors on NPM1-mutated acute myeloid leukemia. My name is Amer Zeidan.

#### Dr. Issa:

And my name is Ghayas Issa.

#### Dr. Zeidan:

So 2 menin inhibitors have entered the acute myeloid leukemia therapeutic landscape within weeks of each other, creating exciting new opportunities but also practical questions. In this Versus discussion, we will explore 6 clinical dilemmas that face clinicians as they incorporate menin inhibitors into their daily clinical practice. In the first chapter, we'll discuss when to initiate a menin inhibitor.

So, Dr. Issa, when you identify an appropriate patient with a relapsed or refractory NPM1-mutated acute myeloid leukemia, in which patients do you favor initiating a menin inhibitor as quickly as possible rather than delaying treatment?

#### Dr. Issa:

Menin inhibitors are one of the greatest advances we've had in acute myeloid leukemia in the past few years. So there's a lot of excitement with these drugs, as you know, Amer, there are a lot of clinical trials on menin inhibitors, but we're also using them as standard of care with the approval of revumenib and ziftomenib.

For NPM1-mutant acute myeloid leukemia, I use a menin inhibitor whenever a patient has refractory NPM1 acute leukemia, and it's an easier decision when they don't have additional co-mutations like FLT3 or IDH mutations, and in that case, menin inhibitors are a very reasonable option. Whenever they have a FLT3 co-mutation, they tend to have a higher rate of proliferation, and sometimes it is harder to start a menin inhibitor at first. Our practice at MD Anderson is to do combination clinical trials with a FLT3 inhibitor, but in those patients the general practice is to use the FLT3 inhibitor, especially if they haven't had the FLT3 inhibitor gilteritinib or quizartinib, for example, and then maybe after that a menin inhibitor.

Now let's look at it in a different way, Amer. What patient factors would you favor for a brief stabilization or bridging approach before initiating menin inhibitor therapy? And can you review bridging options?

**Dr. Zeidan:**

Yeah, that's, again, an excellent question, and I think it's a very individualized decision based on the specific scenario. I think, as you mentioned, menin inhibitors can lead to therapeutic responses relatively quickly, within the first 1 to 2 months. This applies really to also intensive chemotherapy. Aza-ven type of approach, which sometimes we use also in the relapsed/refractory setting, can be a little bit slower, but all of these options generally will require weeks to achieve a clinical response.

So if the patient is already experiencing factors that could lead to end-organ damage, for example, very high white cell count or symptomatic leukostasis, generally I would intervene with either a flat dose of cytarabine, like 0.5 g of cytarabine, or high-dose hydroxyurea. I generally do not use leukapheresis because of low evidence that it makes a significant difference in patient outcomes, and logistically it's more challenging than giving chemotherapy.

So in those situations I might use a bridging therapy before I go to the definitive therapy. But as you mentioned, I think the choice between the different options that we have, which is a good problem to have really, between second-line intensive chemo, HMA-ven, maybe other targeted therapies if the patient has a FLT3 or an IDH mutation versus a menin inhibitor. I think all of these, again, have many factors that go into them.

This has been great. Before we wrap up, Dr. Issa, can you provide us with one key takeaway from this chapter?

**Dr. Issa:**

What I would say is that menin inhibitors have been game changers, and there's a lot more to come when we use menin inhibitors in combination, for example, the data that Dr. Zeidan presented at EHA, showing the menin inhibitor ziftomenib with standard chemotherapy 7+3 is leading to excellent outcomes. We have almost a plateau of survival in NPM1 and newly diagnosed NPM1 with excellent MRD negativity results. So that makes me really excited about the potential of adding menin inhibitors to frontline high-intensity chemotherapy or low-intensity chemotherapy.

**Dr. Zeidan:**

Yeah, thank you so much. I echo your excitement on the combinations and the future for these therapies. So this is the end of Chapter 1. Please stay tuned for Chapter 2.

## Chapter 2

**Dr. Issa:**

Welcome back. In Chapter 2, we're discussing standard versus intensified approach to menin inhibitor monitoring. Let's get started.

So, Dr. Zeidan, not every patient requires the same level of monitoring after starting a menin inhibitor. Which patients can safely begin a menin inhibitor using a standard monitoring approach versus adding additional testing?

**Dr. Zeidan:**

Yeah, that's a great question, and I think it's also important to remember that when you are treating relapsed and refractory acute myeloid leukemia patients, it's not only about the drug but it's clearly about the patient. So those patients generally are sick. They often need frequent monitoring and management. For example, many of them will need transfusions for platelet twice a week. They will need monitoring of their kidney function, liver function, etc.

So my general approach is really to bring the patient at least once a week and sometimes twice a week, regardless of what drug I'm giving them before they achieve remission. Once they achieve remission, it's a different situation.

But when you talk about the specific drug, clearly also the level of monitoring varies depending on whether you are using intensive chemo, where I often will put them in the hospital and will monitor them every day, versus using a targeted approach like a FLT3 inhibitor or a menin inhibitor.

But even within the different targeted agents, for example within the menin inhibitors, I think the level of requirement for monitoring can also vary. For example, 2 things that we are kind of careful about when we start menin inhibitors in particular are issues related to QTc prolongation as well as differentiation syndrome. Both of those tend to be an issue in the first few weeks generally of treatment.

So when you think about QTc, for example, both ziftomenib and revumenib can prolong QTc, and this is something that requires close monitoring, although the level of QTc prolongation is actually significantly different. Revumenib does seem to have a serious risk related to that, and in some patients in the clinical trials, it caused actually Torsades de Pointes, which is a severe form of malignant ventricular arrhythmia. While in ziftomenib this has not been seen, both of them will require initially weekly EKGs for the first 4 weeks and then subsequently once a month, but it varies depending on other clinical needs.

For example, if the patient has low electrolytes, you often have to replace those frequently and monitor the patient's magnesium and potassium. If there are other drugs that could prolong QTc, so you have to tell your patient that they really need to tell you about any drug that anybody else is giving them, including their primary care physician or cardiologist. And many times, like in my institution, we also involve our pharmacist so that they are closely monitoring all the drug-drug interactions, which is an important part in the management of those patients.

For differentiation syndrome, I think we'll discuss that more later in this discussion.

**Dr. Issa:**

So I agree with you, Amer. The main things I think of when I'm starting a menin inhibitor and trying to choose a menin inhibitor is think about the risk of cardiac arrhythmia. So for revumenib, especially for older patients who tend to have higher risk of arrhythmia, or they tend to have more con meds or other additional medications that may prolong QT, I recommend following the label, which means doing those EKG monitorings as suggested in the label, as recommended in the label.

Also, being really judicious with the electrolytes, making sure that magnesium and potassium are repleted, and trying to avoid, if possible, additional QT prolongation or additional QT-prolonging medicines because, as you mentioned, there had been serious arrhythmia as seen with revumenib. So this is probably the factor that would make me decide on a menin inhibitor in someone who has risk of QT prolongation.

Otherwise, the monitoring is similar to other targeted therapies or any treatment for acute leukemia, watching the counts and monitoring for risk of differentiation syndrome at initiation of therapy.

So this has been great. Before we wrap up, Dr. Zeidan, what are the key takeaways from this chapter?

**Dr. Zeidan:**

Yeah, I think the word you'll hear from me very often during this talk is individualized approach. A lot of things depend on the particulars of the patient. Patients, as you mentioned, who have risk factors that predispose to cardiac problems, such as baseline arrhythmias, poor EF, patients who have low electrolytes who are on a number of medications that can interfere, I think those patients require closer monitoring.

And the second important, I think, word is multidisciplinary approach, where you involve other team members, including your nurses, nurse practitioners, the pharmacist, the patient themselves as well to kind of do it as a team effort to make sure the patient is monitored very well so that we avoid dangerous situations.

So with that, I'd like to thank you.

**Dr. Issa:**

Thank you. See you for Chapter 3.

### Chapter 3

**Dr. Zeidan:**

Welcome back. Now we are looking at drug-drug interactions with menin inhibitors.

So question for you, Dr. Issa: As oral antifungals are often essential in the management of acute myeloid leukemia and frequently prescribed, how do you navigate through the use of antifungal prophylaxis while maintaining the therapeutic intent with menin inhibitor therapy?

**Dr. Issa:**

Yeah, that's a great question, Dr. Zeidan. And because of the treatment venetoclax that's used for acute myeloid leukemia, physicians have been able to recognize this concept that using certain medicines like azoles, which affect the enzymes on the liver, CYP3A, could increase the therapeutic level of a leukemia drug, in this case venetoclax, and now in this case the menin inhibitor revumenib.

So whenever we're using revumenib, it is very important to know what is the azole that is used for prophylaxis, which is a standard approach in many centers across the US. There are some centers that may not use prophylaxis or antifungal for preventing fungal infections.

So when using a strong CYP3A inhibitor, we are in this case talking about the antifungals of posaconazole or voriconazole. This would lead to increase in the level of the menin inhibitor revumenib, and the dose of revumenib, as indicated in the label, would be 160 mg twice a day, whereas if using a weak CYP3A inhibitor or no CYP3A inhibitor azole, such as Cresamba [isavuconazonium sulfate], fluconazole or miconazole, for example, the dose of revumenib, or the pill that's given to the patients, would be higher. That's 270 twice a day.

No dose adjustment is needed for the menin inhibitor ziftomenib. So in this case, regardless of the azole that is used, the dose for NPM1-mutant relapsed/refractory acute myeloid leukemia is 600 mg daily.

Dr. Zeidan, when do you favor a more proactive modification strategy when faced with potential interaction? And how do you decide to modify or adjust a medication?

**Dr. Zeidan:**

Yeah, thank you so much. This is again, I think, an important question. I go back to my favorite word, the individualized decision-making. So it really depends on the situation. Like, are you using the antifungal therapy for a treatment approach or for a prophylactic approach?

When you are using it for a treatment approach, or for a patient who has already had a history of severe fungal infection, you are more reluctant to kind of deviate away from using the antifungal, depending on whether there are other alternatives or not. So if I really want to use a specific antifungal, I might change the menin inhibitor or start with one that has less chance of causing problems, and as you mentioned, that tends to be more ziftomenib, that it generally does not have significant interactions. When you use revumenib, you can use it with the severe or strong inhibitors, but you have to adjust the dose.

And ultimately, the pharmacist is my best friend in the clinic. They are very involved with our patients. They often will see the patients actually directly and talk to them through the side effects. They confirm the doses, they confirm that the patients are taking the drugs the right way. Not only that, but they also confirm whether they are taking it on empty stomach or full stomach. Sometimes patients are taking herbal medications that we don't think about, and they are not listed, and they could interfere.

So I think a multidisciplinary approach is very important, and while we tend to focus on the big picture decision as physicians, I think all these small details matter, and this is why it's very important to do it in a team structure.

So this has been great. Before we wrap up, Dr. Issa, what are your key takeaway messages for our audience from this chapter?

**Dr. Issa:**

My key takeaways are to be cognizant of potential drug interactions with menin inhibitors, to recognize what patients are taking for prophylaxis if you decide to give antifungal prophylaxis, and that certain medicines can affect drug levels of menin inhibitors, so CYP3A inhibition, for example, for revumenib, or antacids for ziftomenib. So these are things that need to be monitored when patients are taking these medicines.

**Dr. Zeidan:**

Perfect. Thank you so much. Stay tuned for Chapter 4.

## Chapter 4

**Dr. Issa:**

Welcome back. In Chapter 4, we're looking at managing adverse events with menin inhibitors. Let's get started.

Dr. Zeidan, one decision clinicians face is determining when to manage through a toxicity versus when to hold treatment. How do you approach that decision?

**Dr. Zeidan:**

Yeah, so I think this is a very important thing when, generally, you think through the side effect profile and the need of the patient. So I think one important factor is, do I have alternatives? If I generally don't have alternatives, I tend to stick with any kind of treatment for much longer, and I try to navigate through adverse events as long as I can keep the patient safe.

But generally, I think the main things we kind of look for with menin inhibitors, as we have discussed before, are differentiation syndrome. This is something that tends to occur in the first few weeks of treatment, although sometimes it can occur late. One of the problems with it is that it tends to be sometimes difficult to recognize. It can manifest almost like an infection picture. Patients can have fever, can have a pleuritic pain, can have shortness of breath. They can have infiltrates on the X-ray, so they might be mistaken for a pneumonia. And sometimes it can look almost like a progression of the acute myeloid leukemia, where the differentiating cells sometimes might still look like blasts, and that could look like a patient is progressing. So this requires, I think, a very high index of suspicion and close monitoring and a quick intervention.

And also patient education. It's very important that the patient knows what's going on. We often will give the patient a card so that they will show it to the emergency room if they go somewhere else, if they live far, so that the doctors in the ER will call, and also be vigilant that this could be a differentiation syndrome.

QTc, I think, is something that we discussed very carefully about how to monitor and manage.

Aside from that, I think the side effects are generally well tolerated. There could be some degree of myelosuppression. What generally is related more to the leukemia, in my opinion, but once a patient is in remission, I think adjusting the dose and the duration of the drugs can be important to mitigate some of these cytopenias.

So, Dr. Issa, when do you believe early interruption of therapy is more appropriate than continuation?

**Dr. Issa:**

Yes, for the majority of side effects we see with menin inhibitors, my approach is to try to work on the side effects, let's say nausea or potentially change in taste, or there are really minimal side effects that are happening with menin inhibitors, so giving nausea medicines. But the side effects that require dose interruptions are going to be either differentiation syndrome or QT prolongation or, in some instances, the cytopenias. So the parts where I would recommend immediate dose interruption instead of trying to mitigate the side effects are particularly related to QT prolongation and differentiation syndrome.

With QT prolongation, specifically for revumenib, or in case you think QT prolongation is related to ziftomenib, even though it's less common, the recommendation is to adjust all the electrolytes, stop all the other con meds, and maybe hold the menin inhibitor until the QT prolongation is resolved. For revumenib, which has more commonly QT prolongation, there's a clearly outlined algorithm or dose modification strategy in the label on how to do that.

For differentiation syndrome, whenever there is a severe differentiation syndrome, it is probably better to hold the menin inhibitor and give steroids while the picture gets clearer and then restart. And you can restart at the same dose, the menin inhibitor. You don't have to do dose reduction.

For cytopenias, we are learning more on how to do that. The challenging part is that leukemia can cause cytopenia, like Dr. Zeidan had mentioned. So the question comes up usually when the patients have had response, especially if they're MRD negative and they have cytopenia, and in that case dose holds or dose modifications could be strategies to mitigate the side effect.

This has been great. Before we wrap up, Dr. Zeidan, what's your key takeaway from this chapter?

**Dr. Zeidan:**

Yeah, so I think the main thing is that the main 2 side effects to watch for carefully and that might require dose interruption and even dose reductions, and rarely dose discontinuations, are differentiation syndrome, which requires a high index of suspicion and aggressive management, as well as QTc prolongation, which requires consideration of other factors, such as electrolyte imbalances, as well as other concomitant medications, and low counts, myelosuppression, which we tend to think more of once a patient is in a clinical remission, especially MRD-negative remission.

Other side effects, such as GI side effects, which can be a problem rarely in some patients, generally are well mitigated with antiemetics without needing to stop or discontinue. Or things such as pruritus, which we can see sometimes with ziftomenib, or other myalgias or fatigue, things like that, generally, we manage with supportive therapy.

**Dr. Issa:**

Thank you. See you in Chapter 5.

## Chapter 5

**Dr. Zeidan:**

Welcome back to Chapter 5. Now we are looking at patient counseling considerations about when choosing therapy.

So, Dr. Issa, when discussing treatment options with patients, how do you choose between a menin inhibitor and other available therapies? And how do you counsel patients about the rationale of your decision?

**Dr. Issa:**

Yes, this is a great question. For relapsed/refractory KMT2A-rearranged leukemias, the evidence in my mind is very clear that menin inhibitors are critical in relapsed/refractory disease. So any patient who has not had a menin inhibitor should be getting a menin inhibitor.

For relapsed/refractory NPM1-mutant acute myeloid leukemia, which is as bad as any relapsed acute myeloid leukemia, we still have a few options. And those options include either chemotherapy or, importantly, combinations that include venetoclax. NPM1-mutant acute myeloid leukemia responds well to venetoclax. And then because of the co-mutations, either IDH or FLT3, we have the options of choosing targeted therapies for these patients. So the choice depends on, like Dr. Zeidan had been saying, individualizing the treatment choice for these patients.

I tend to use menin inhibitors in combinations. That's our practice at MD Anderson, which is yielding excellent results.

For standard of care, my recommendation is to tailor based on the FLT3 mutational status. If the FLT3 burden is high and the patient has not had a potent FLT3 inhibitor, it is important to use a FLT3 inhibitor. Now, if the FLT3 allelic burden or the ITD is low, or they have additional co-mutations, I think menin inhibitors are great in this case to choose, especially if they have progressed on venetoclax-based treatments.

Dr. Zeidan, how do you counsel your patients on choosing therapy or monitoring expectations and the importance of adherence?

**Dr. Zeidan:**

Yeah, again, I think this is a great question, and this speaks to kind of the required experience to manage these patients. I think these patients with acute myeloid leukemia in general, but in particular those with relapsed/refractory disease, should be really managed in centers with the required resources and the experienced physicians because these discussions are often nuanced and they are not really straightforward. So I generally tell the patients that there is almost no evidence in the relapsed/refractory setting about choosing therapies because we essentially have almost no randomized phase 3 trials comparing different strategies for when it comes to menin inhibitors.

And for most of the other treatments, the only high-level evidence we have really in the relapsed/refractory setting is choosing a FLT3 inhibitor as you mentioned, gilteritinib, over other treatments. But even this was done before the availability of menin inhibitors, so we

don't know how these compare when the patient has both mutations, a FLT3 and NPM1, for example.

So I think I discuss the single-arm trials and my rationale of making the decision and the recommendation and involve the patient in the decision-making. Most of the time, the patients will agree.

I also take into consideration factors such as what I am trying to achieve. Am I trying to bridge the patient to transplant, in which I would accept a more intensive treatment approach, for example, a triple combination, aza-ven-menin inhibitor, or even intensive chemo FLAG-IDA with a menin inhibitor, for example, as a bridge to transplant versus a lower-intensity approach if the goal is palliative and I'm trying to keep the patient out of the hospital and prolong survival, where sometimes we could use menin inhibitor monotherapy.

And in that setting, I think the frequency of the dosing can also be important. For example, ziftomenib is given once a day, while revumenib is generally given twice a day. So I think it's certainly easier to take drugs once a day.

But you still need to monitor the patient. And I always say, again, despite using an oral drug, it does not mean that you forget about the patient and just see them once a month. Those patients, when they are refractory and relapsed, they often need to be seen at least once a week, sometimes twice a week.

So it's not a straightforward kind of a decision but requires a lot of active discussion with the patient about the rationale, the monitoring, whether the patient needs to be inpatient, outpatient, what are you trying to achieve, and the goals of therapy.

So before we wrap up, Dr. Issa, what is your key takeaway from this chapter to our audience?

**Dr. Issa:**

Yeah, I would piggyback on what you just said. It's important to remember that even though these are pills, that we have to ensure adherence, and we have to ensure that the patients are taking the medicines the way they should for these medicines to work. That would be my main takeaway.

**Dr. Zeidan:**

Perfect. Thank you so much and stay tuned for Chapter 6.

## Chapter 6

**Dr. Issa:**

Welcome to our last chapter. As menin inhibitors become integrated into routine practice, how can we optimize workflow to reduce initiation delays and improve early adverse event detection?

Dr. Zeidan, can you start by outlining important drivers of successful menin inhibitor implementation? Why is individualized clinical judgment important?

**Dr. Zeidan:**

Yeah, I think this is very important and kind of reflects on what I mentioned earlier about the importance of being treated in a large center. While in the US, a lot of the management of cancer patients takes place in the community, including some patients with acute myeloid leukemia. Often those patients should be really treated in big centers. And that's not because the doctors don't necessarily know what they are doing in the community setting; it's just sometimes because they don't have the necessary resources to manage very complicated patient situations.

For example, those patients often need transfusions. They need to be brought frequently to get transfusions. But also, we often need specialized personnel. We need a specialized pharmacist not only to help the drug interactions and to counsel the patient, but also to educate them. They sit down with them. They tell them in detail about when to take the drug, empty stomach, full stomach, what are the drugs to avoid, to talk to them about any herbal supplements. But also, they are helping us with the quick initiation. Sometimes these drugs need prior authorizations, and it can be a process that could take time.

So having very well-established workflows and dedicated people who help with the process of getting the drugs, as well as a very good

checklist for the practice and very standardized approach of monitoring and bringing the patient to the clinic, all of these, I think, are very important. You should be able to do EKGs and CBC in your practice, and it's important to kind of work as a team.

And it's very also important to make sure who is responsible for what. Sometimes, as I mentioned, patients can be prescribed medications by their primary care physician or cardiologist without letting the leukemia doctor know, and that can lead to problems. So we always educate the patient that whoever prescribes a new drug to you, very important to tell them that you are on leukemia therapy and they should talk to us, and don't take any new drug without talking to us.

Same thing applies if they go to the emergency room. They have these alert cards, and we tell them to have the emergency room doctor call us.

And this reminds me somewhat of the early experience with the IDH inhibitors, which rolled out several years ago, and those patients could also suffer from differentiation syndrome, which can be difficult to recognize. And I think we learned a lot from the approach there in terms of how do we streamline kind of the management approach and the communication and making sure everybody works as a team to get the best outcome for the patient.

So, Dr. Issa, how do you implement a standardized workflow built around specific monitoring and drug interaction requirements for menin inhibitors?

**Dr. Issa:**

Yeah, this is a great question, and I think it goes back to your initial point about the importance of treating leukemia patients in centers that have the expertise. These are targeted therapies, and the hope is to have the largest possible portion of patients take these lifesaving medicines. But it's important to know the potential risks that come with these medicines. And generally, big centers in the United States have implemented workflows to monitor these medicines and ensure that they can be given safely.

So the approach to implement these workflows should follow the label of either ziftomenib or revumenib. So for revumenib, it's important to monitor the EKGs as indicated in the label and monitor the electrolytes. And regarding differentiation syndrome, it is important to have a wide net of people who are interacting with the patients be aware of the risk of differentiation syndrome, for example, emergency department doctors or the nurse practitioners that may be seeing the patients when reviewing labs or other consultants who may be seeing these patients. And this is important just to recognize differentiation syndrome because treatment can be important. Giving steroids can reverse differentiation syndrome.

So that's my main key takeaway about standardized pathways which center around these adverse events to make sure that these medicines are given safely.

Regarding other monitoring such as blood counts, this is similar to any other monitoring in acute leukemia and has been relatively easy to implement because we're used to giving these medicines or similar medicines in acute myeloid leukemia patients.

This has been great. Before we wrap up, Dr. Zeidan, what key takeaway should our audience focus on from this chapter?

**Dr. Zeidan:**

Yeah, so I think my main takeaway from this is that it's very important for patients with relapsed and refractory acute myeloid leukemia to be treated in tertiary centers where there are very established workflows and experienced not only leukemia doctors but experienced staff. Our nurses, our nurse practitioners are very experienced, and they know a lot about these situations, and they are always available for patients. Our pharmacists also are very experienced with situations that require drug interactions and to manage through prior authorizations and issues related to insurance. And the whole team works together in a multidisciplinary approach to try to have the best outcome for patients. And of course, we implement very standardized workflows that are very important for the safe delivery of these treatments.

**Dr. Issa:**

And that's all the time we have today. So I want to thank our audience for listening in and thank you, Dr. Zeidan, for joining me and sharing all of your valuable insights. It was great speaking with you today.

**Dr. Zeidan:**

Thank you so much. My pleasure, and goodbye.

**Announcer:**

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