GLP-1 Drugs and Breast Cancer: Science, Safety, and Solutions

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Melissa Rosen:

Welcome. Again, thank you for joining us for tonight's webinar. I am Melissa Rosen, Sharsheret's director of training and education. This evening's topic, GLP-1 Drugs and Breast Cancer is a very timely one. The popularity of these drugs is growing and new studies learning more about the potential benefits and complications of this class of drugs are coming out all the time. Together, we're going to explore all of this and how it relates to breast health and breast cancer.

Before we begin, I want to take a moment to thank our sponsors for tonight's program, Pfizer and the Cooperative Agreement 24-0061 of the Centers for Disease Control and Prevention, and to thank tonight's program partners, NYU Langone Health, Well by Messer, and the American Jewish Medical Association.

Today's webinar is being recorded and will be posted on Sharsheret's website alongside a transcript. If you have registered for the webinar, you will be receiving an email with those links. And of course, participants' names and faces will not be in the recording. Still, if you would like to remain private this evening, you have the option of turning off your video and renaming yourself or you can call into the webinar. Instructions are in the chat box now for both options.

We have closed captioning available. To display live captions on the bottom bar, click live captions, then click captions, and then show captions. You may have noticed everyone was muted upon entry. Please stay muted for throughout the call.

We received a very large number of questions during the registration process. If you have additional questions that come up during the presentation itself, please type them into the chat box. We will be monitoring the box for those questions. We will do our best this evening to answer as many as possible. I do want to note we cannot answer questions that are regarding someone's specific and unique medical situation.

Along the same lines, I want to remind you that Sharsheret is a national not-for-profit cancer support and education organization and does not provide any medical advice or perform any medical procedures. The information provided by Sharsheret and by tonight's speakers is not a substitute for medical advice or treatment for a specific medical condition. You should not use this information to diagnose or treat a health problem. If you have any questions specific to your medical care, always seek the advice of your physician or qualified healthcare provider.

Now, before we welcome our doctors to the screen, I'm happy to share that we have with us tonight, Jamie. Jamie is a Sharsheret caller who will share her personal experience with breast cancer and semaglutide. Jamie, welcome to the screen.

Jamie Mafdali:

Good evening everyone. My name is Jamie Mafdali, and I'm so appreciative of Sharsheret for asking me to share my story this evening.

For many years, due to my high risk for breast cancer, I would have a mammogram and an ultrasound and six months later I would have an MRI. My family has a history of breast cancer and it presented on both my maternal and paternal sides, and those who were tested were BRCA negative. In 2021, an ultrasound recommended a guided biopsy of an area of my left breast, which

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came back benign. In 2022, while supporting my mom through her breast cancer treatments and finding out that her cancer had metastasized, my MRI recommended a mammogram and ultrasound, which then indicated the need for another biopsy in the same area.

While this was happening, I was also in the process of getting my own genetic testing, which all came back negative. I was relieved. The next day I got a call with the results of the biopsy. I was diagnosed with invasive ductal carcinoma of the left breast. It was estrogen receptor positive, progesterone receptor positive, and HER2 negative. I think I expected breast cancer. Now it was time to move forward.

Along with my doctor and family, after weighing many factors, I decided to have a bilateral mastectomy. At the time of the surgery, tissue expanders were inserted with the plan to replace them with implants later. During my recovery and filling my expanders, I decided that I did not want implants and that I would instead prefer to have a DIEP flap surgery. This surgery takes my own tissue and uses it to recreate breasts. For me, not having a foreign object in my body feels right.

The plastic surgeon I met with told me I needed to lose about 20 pounds before seeing if the DIEP flap was an option for me. I was disappointed. Trying to lose weight on my own has been unsuccessful, not just during this time but throughout my life and I needed to move forward. When discussing this frustration with my endocrinologist, GLP-1s came up. I've learned that everyone is different and that one of these medications could be right for me. I was anxious to lose the weight. More importantly, I wanted to be done with the surgeries.

It has been about 15 months since I saw the plastic surgeon and about a year since I started taking a GLP-1. I've lost about 18 pounds and have an appointment with the plastic surgeon in April. I haven't had GI issues that I know some people experience. I felt satiated with less food and don't think about food all day now. For me, taking a GLP-1 has been helpful. I thought it would be a quicker process to losing the weight needed for surgery, but I also know that this is what has worked for me. I'm excited for my next steps along this journey, and again, thank you for allowing me to share my story.

Melissa Rosen:

Jamie, thank you so much for sharing. Like I've said, hearing personal stories makes it easier to understand the information. Thank you.

Okay, we are so honored to be joined this evening by doctors Ruth Oratz and Barrie Weinstein. Dr. Ruth Oratz has been practicing at NYU Langone since she completed her residency in internal medicine and fellowship in medical oncology. As a medical oncologist, she specializes in treating people of all stages of breast cancer as well as those who have an increase of risk of developing cancer. She spends a great deal of time and effort at NYU School of Medicine as a professor in clinical medicine where she works closely with, and mentors students at all stages of their professional development, guiding them in their clinical experiences, clerkships, and the residency application process. Dr. Oratz serves as a member of the Sharsheret Medical Advisory Board and is also a member of several additional local and national advocacy organizations. Her involvement in these organizations allows her to further support her patients and their families as they cope with breast cancer.

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We also have with us today, Dr. Barrie Weinstein. She is an endocrinologist with extensive experience in metabolic health, weight loss, and bone health. She completed her internal medicine residency and fellowship training at the Mount Sinai Hospital in New York City where she went on to practice as part of the faculty for 12 years. After 18 years at Mount Sinai, Dr. Weinstein left to become the medical director at Well by Messer, a metabolic and wellness health center specializing in weight loss. In this role, she has played a pivotal part in helping patients achieve lasting weight loss and optimal metabolic health. Her innovative approach to weight management has led her to become a featured expert in numerous media outlets where she shares her knowledge and insights on the latest advancements in weight loss medicine.

We're going to start by welcoming Dr. Oratz to the screen.

Dr. Ruth Oratz:

Thank you, Melissa. It is a tremendous pleasure for me to be back with the Sharsheret community. I've been connected with Sharsheret for many years. And this is a topic that's been coming up in our clinical practice over the last several years and both Dr. Weinstein and I felt that it would be helpful for all of you to hear about the medical information related to these drugs and how we think the GLP-1 drugs may be linked to breast cancer.

I'm going to give a brief introduction and then turn over to Dr. Weinstein, but we know that breast cancer is for many, many people related to their hormonal system. Two thirds of breast cancers are both estrogen and/or progesterone receptor positive. And for many patients, metabolic concerns are a big issue in their breast cancer treatment and risk assessment. Obesity, being overweight, in and of itself is a risk factor for developing breast cancer and may also be associated with an increased risk of breast cancer recurrence. We also know that people who have diabetes may have an increased risk of complications from breast cancer treatment and possibly also have an increased risk of recurrence.

All of you who've gone through treatment for breast cancer know that the treatments we give are often very, very harsh. Chemotherapy can cause a lot of disorders in terms of what we're eating, how you're exercising, can lead to weight gain. The hormonal therapies, the anti-estrogen treatments, including tamoxifen and the aromatase inhibitors and ovarian suppression, also change the balance not only of the estrogen hormones but other metabolic hormones in the body, and Dr. Weinstein will discuss some of that.

So for both our pre and postmenopausal women, the treatments for breast cancer can cause some metabolic concerns and often also associated with weight gain. We know that the GLP-1 drugs, which are relatively new, have many, many different effects, and Dr. Weinstein will be going through all of those medical effects. But they touch on obesity, diabetes, cardiovascular disease, liver disease, polycystic ovary syndrome, GI disorders. And also now there's increasing evidence that there can be a positive interaction between the GLP-1 drugs and certain types of cancers.

So I'm now going to turn over to Dr. Weinstein, who is going to give you a little more background about the endocrinology of metabolic syndrome and the GLP-1 drugs.

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Dr. Barrie Weinstein:

So the word metabolism or metabolic is used a lot, but what is metabolic syndrome? Metabolic syndrome is a cluster of conditions that increase the risk of developing chronic disease such as heart disease, stroke, type 2 diabetes. It's diagnosed when a person has three or more of the following conditions, high blood pressure greater than or equal to 130 over 85, high blood sugar, fasting levels above 100, high triglyceride levels, which is usually checked as part of a regular cholesterol panel, levels above 150 are abnormal, low HDL levels, less than 40 in males and 50 in females, and then excess body fat around the waist, a waist circumference more than 40 inches in males and 35 inches in females. And all of these can be impacted by hormonal therapy of breast cancer.

So in relation to the GLP-1 and the title of this talk, which medications are we talking about? The GLP-1 agonists, the first ones came out in 2005. The most common ones we're speaking about today are semaglutide with the trade names of Ozempic and Wegovy. Also, semaglutide has a trade name of Rybelsus. And then GLP-1/ GIP dual agonists, we're speaking about tirzepatide, brand names Mounjaro and Zepbound.

So what are GLP-1 agonists and how do they work? GLP-1 agonists mimic the action of a naturally occurring gut hormone called glucagon-like peptide, which is much easier to say GLP-1. And although healthy bodies are constantly producing GLP-1 in small amounts, the small intestine will ramp up their production in response to the presence of glucose in the small intestine following a meal. GLP-1s then circulate in the bloodstream and they bind to receptors in the pancreas, which signal the pancreas to produce insulin. Insulin then signals the cells to absorb this stored glucose in the bloodstream and use it for energy.

GLP-1s also appear to slow down the movement of food through the small intestine and colon. Slower and better absorption of food maintains the feeling of fullness after a meal and it can improve the uptake of nutrients. GLP-1s naturally last only a few minutes after secretion, but the actions of these medications of the GLP-1 agonist last for days or weeks working to suppress appetite and maintain glucose control.

And as I mentioned before, semaglutide medications like Ozempic and Wegovy are GLP-1 agonists. Tirzepatide medications like Mounjaro and Zepbound are what we call GLP-1/GIP dual agonists where GIP stands for glucose-dependent insulinotropic polypeptide. Together, they work to enhance the effects of both GLP-1 and GIP. GIP is also a naturally occurring gut hormone released after eating to help with blood sugar regulation, fat metabolism and storage, and appetite reduction. The combination effect of both GLP-1 and GIP has been shown to have a synergistic effect leading to more weight loss and less nausea compared to the semaglutide.

Now we have a slide here showing the different medications and FDA indications. The slide is loading. As I mentioned, so semaglutide, Ozempic and Wegovy are both semaglutide, but there are different FDA indications for use and this becomes very important when you're submitting for insurance.

For Ozempic, people qualify if they have an A1C greater than or equal to 6.5. And for Wegovy, qualify if there's a BMI greater than or equal to 30 or greater than or equal to 27 with a weight-

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related health condition. And what does that mean? Pre-diabetes, high blood pressure, high cholesterol, fatty liver, cardiovascular disease, and sleep apnea. Then we have tirzepatide, Mounjaro and Zepbound. Mounjaro has an indication for an A1C greater than or equal to 6.5. And Zepbound has the indication similar to Wegovy, a BMI greater than or equal to 30 or a BMI greater than or equal to 27 with again, a weight-related health condition.

As you can see here, there are other medications listed below. As you see semaglutide listed, again, Rybelsus with an indication for diabetes. I mention these, these have been on the market for a long time. They have similar effects and similar side effect profile to semaglutide and tirzepatide. There isn't as much weight loss or as much diabetes control compared to semaglutide and tirzepatide.

Now, these medications have been on the market for a while, but more recently we've had the semaglutide and the tirzepatide, the versions that we're speaking about today, and we have really great data supporting their effectiveness and supporting their use. Okay, you can take down the slide down now.

In the STEP 5 trial, Wegovy 2.4 milligrams led to a mean weight loss of 15%. 77% users had more than a 5% weight loss, and 36% had more than 20% weight loss at two years, which is remarkable. Patients also saw improvements in cholesterol, sugar control as measured by the A1C and blood triglyceride levels. In the SURMOUNT-1 trial, tirzepatide led to body weight reductions of 16.5 to 22% over 72 weeks. 91% lost more than 5% body weight at 72 weeks.

And as Dr. Oratz had mentioned before, there have been other positive effects of these medications aside from just weight loss. In the SELECT trial, Wegovy users saw a 20% reduction in heart attack, stroke, or death from heart-related events. In the SURMOUNT trial, tirzepatide led to a 38% reduction in hospitalizations for heart failure among patients with obesity as well as a risk for heart disease.

The SYNERGY-NASH trial and phase two participants on the highest dose of tirzepatide experienced a 62% clearing of fatty liver compared to placebo. And more recently, the pivotal FLOW trial has shown that Ozempic is now indicated to reduce the risk of kidney disease, worsening kidney failure, and death from chronic kidney disease in adults with diabetes and CKD. And we are awaiting the cardiovascular trials for tirzepatide, which are expected to finish in mid-2025.

It's a very exciting time for these medications and for this field. I should also mention there are other studies that have shown improvements in inflammation, improvements in neuroprotective effects potentially for Parkinson's and for Alzheimer's and more studies showing benefits with kidney and liver disease.

Now, the safety of the medications. Patients are always asking me, "But are they safe?" The most common side effects include nausea, constipation, diarrhea, vomiting, acid reflux. There's also side effects like fatigue and headache, injection site reactions. Most of the time these effects are mild to moderate, get better with time. They might happen again when you go up on your dose, but most of the time the medications are well tolerated.

There are less common side effects which include gallbladder disease, pancreatitis, inflammation of the pancreas, kidney issues. And then this is another hot topic, medullary thyroid cancer. I would like to emphasize that current evidence does not support a link between these medications and

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thyroid cancer. However, there are some animal studies that have shown an increased risk of medullary thyroid cancer, which is a very rare genetic type of thyroid cancer. So it is recommended for those with a personal history or a family history of medullary thyroid cancer not to start on these medications.

Now these medications don't interact with other medications on the market, so side effects can be managed with over-the-counter medications and hydration and sometimes a prescription for an anti-nausea medication is needed. If you're not tolerating the medication, it is okay to switch and try another one in a different class as the tolerability might be different.

So now I'd like to pass it on to Dr. Oratz to continue talking about the GLP-1 drugs and cancer.

Dr. Ruth Oratz:

Thank you. Again, just to reiterate the concerns we have about metabolic syndrome in breast cancer, I think all of us in practice have observed that our patients who undergo treatment for breast cancer very often experience weight gain. And as I mentioned previously, those who are being treated with chemotherapy or receiving fluids, sometimes steroids, there are dietary changes that you make because of nausea and GI side effects from chemo, which lead to some weight gain, lack of exercise, and deconditioning, also contributes to gaining weight. And in addition in young women, chemotherapy does cause some suppression of ovarian function and decrease in estrogen levels. Again, all of that contributing to the metabolic syndrome.

In our patients who receive endocrine therapy for estrogen or progesterone receptor positive breast cancer, pre and post-menopausal women also notice these imbalances in their hormones related to the decreased estrogen levels. We sometimes see rises in the blood pressure, increases in the blood sugar levels and hemoglobin A1C. We can see increase in the cholesterol lipid panel profiles. And in some patients, we've even seen the development of what we call fatty liver, which is inflammation in the liver and often related particularly to tamoxifen. So for all of these reasons, we're very concerned about metabolic syndrome, which is not healthy in general for people and which also may ironically lead to problems that down the road can increase the risk of breast cancer.

In 2024, last spring at the ASCO Meetings, there were a number of papers that were presented that were really just beginning to explore how the GLP-1 drugs may impact people undergoing treatment for breast cancer. And in one very interesting study that was presented, they looked at weight loss related to GLP-1 drugs in patients undergoing breast cancer treatment. And again, this is a retrospective study, meaning looking back at people. We're not looking forward because we're just beginning to get the information about this.

And they looked at a few different patient groups, particularly those with hormone receptor positive breast cancer who were receiving endocrine therapy with either aromatase inhibitors or tamoxifen. And they looked at patients who were receiving semaglutide and tirzepatide with early stage breast cancer and compared them to a broader range of people who were on GLP-1 agonists, but who did not have a history of breast cancer.

And what was observed in that study was that there was still a positive benefit for patients who were on breast cancer treatment compared to people who were not on breast cancer treatment.

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We know that obesity is linked to an increased risk of breast cancer and we feel that weight loss is very important. So in these populations, they did see a significant amount of weight loss in patients who were on hormonal therapy. For example, semaglutide resulted in about a 4% decrease in weight compared to 14% in the general population. And tirzepatide resulted in a 2 to 3% weight loss compared to 15% in the general population.

So even though patients were on the anti-estrogen medicines, they were still able to lose a significant amount of weight and we saw corrections in their laboratory values as well. This is a little bit less than what we see in the general population who are not being treated for breast cancer, but nonetheless, benefits were definitely seen in breast cancer patients.

And this was repeated in other studies where investigators looked back and asked the question of the role of these drugs in their patients who are being treated. I can tell you in my own personal experience in my clinical practice, I certainly by now have many, many patients on these agents and have seen significant benefits.

I'd like to have you put up a slide which is a photograph of a young woman, 44 years old with breast cancer related lymphedema. There's the photograph. If you look at the picture on the left was before she started treatment with semaglutide. She had lymphedema in the arms, swelling of the arms.

Now lymphedema is not only related to body weight but is also, we feel, sort of an immunologic disease characterized by stasis or stagnation of the lymphatic fluid in the arm after surgery and perhaps radiation therapy. And this leads to inflammation and what we call up-regulation of certain chemicals that cause lymphocytes to migrate into the skin and to slow down the flow of the lymphatic fluid.

The GLP-1 drugs may also have anti-inflammatory properties. And in this particular patient who started treatment with a GLP-1 drug after 13 months of treatment without using any other modalities, there was a significant reduction not only in her weight but also in the lymphedema of the arm with a reduction in the volume of the limb, improvement in her subjective symptoms. And even on the bottom, those little black and white pictures show better flow of the lymphatic fluid through the arm.

We feel that the way the GLP-1 drugs may be working in breast cancer is through a variety of mechanisms. One is this anti-inflammatory effect, which may really be a very powerful effect. And just another anecdote I'll share with you, but all of these observations are leading us to ask questions that hopefully our research will begin to answer as we go forward.

But I saw a young woman actually this week in the office who had very severe eczema and psoriasis and also has polycystic ovary syndrome. I saw her six months ago and since then she had been started on a GLP-1 drug and she came back in for her checkup and felt and looked dramatically better. She had lost some weight, but more importantly, the inflammation in her skin was markedly reduced. Her rheumatologist told her that her inflammatory markers were way down.

And her symptoms from her polycystic ovary disease were much better. She had less bloating, less discomfort, less menstrual irregularity. And I really believe that this was attributed to the anti-inflammatory effect of the GLP-1 drug. We also have seen in laboratory experiments that the GLP-1

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drugs cause a decrease in proliferation of tumor cells and of course the metabolic effects that we've been mentioning.

I think at this point I'd like to pause and leave enough time to answer questions, but I would say that in conclusion, we have good evidence so far that obesity and being overweight increases the risk of developing breast cancer and of developing breast cancer recurrence after treatment. We also know that diabetes and metabolic syndrome may contribute to this as well. And we know that breast cancer treatments, chemotherapy and the hormonal therapies, can cause weight gain and exacerbation of the metabolic syndrome.

The use of GLP-1 agonists can help with weight loss and improvement in the metabolic syndrome. It makes sense that these agents would also help in reducing side effects from breast cancer treatment as well as hopefully, and we need to really prove this in prospective trials, but hopefully also leading to some reduction in breast cancer risk and risk of recurrence.

We certainly know that our patients on these drugs feel better, are healthier overall, and we are hoping that we can with additional research prove that there's a reduced risk of breast cancer recurrence. There is data that in other kinds of cancers, GLP-1 drugs have already shown a benefit in reducing the incidence and the risk of recurrence of those cancers and ongoing research is moving forward in this field.

So I think we'll go back to Melissa and Dr. Weinstein and we can try to answer some specific questions you have.

Melissa Rosen:

Wow, wow. Thank you both so much. What an opportunity for all of us here tonight to get really up-to-the-minute information on this. Thank you for that. We are going to once again do our best to get through as many of them as possible. Again, if your question is very specific to your situation, we're going to encourage you to speak to a doctor. And because so many questions were similar, don't listen for me to ask for the exact words you used, but for the topic itself because we were able to combine a lot of them.

Let's get started and see how many we can go through. So in terms of some general GLP-1 questions, you talk about or a lot of people even tonight have asked about extended use. Now we know when somebody goes on one of these drugs for weight loss, the idea is that they stay on these drugs. Is it ever possible to stop those drugs once you've hit your weight loss goals? And also is the same thing needed to benefit in other ways? Do you need to stay on to reduce inflammation, to reduce the potential risk of recurrence or a diagnosis itself? And what happens when somebody stops?

Dr. Barrie Weinstein:

Okay, Dr. Oratz, I'll do the first part of the question. The medications were never designed to be stopped. They were meant for complicated weight issues, patients who had done everything, we know that patients weren't lying to us. They were really not eating much and exercise and just not losing weight. We know that it's complicated and there's other factors involved. There are patients though who go on with the intention of coming off of it and so patients can stop it.

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Will they gain the weight back? There are patients able to keep the weight off, but the majority of patients will gain some weight back, but it doesn't mean that it's all coming back. There are studies that have shown that people will keep weight off. However, it really does depend on what were the habits before and what are the habits after. And so there haven't been great studies following patients who have been on it and then working really hard on diet and exercise and meeting with a dietitian and really changing behaviors and habits.

However, what about the person who is doing everything that they can and they're just not able to lose weight? And that's a lot of patients that are patient population with breast cancer on these medications. This is perimenopausal women, postmenopausal women, patients with PCOS, they are really doing everything they can. And so the medications by acting on helping with glucose and insulin reduction, reducing insulin resistance, helping with inflammation, that is really what also leads to weight loss.

So what happens when you stop the medication, though? It's really hard to mimic that. And so a lot of my patients do find that weight might start to come back. And so instead, we'll try to find maybe the lowest effective dose that keeps them where they want to be. Maybe instead of every week, every two weeks, every three weeks, once a month, just to give them something. And I have found that that can definitely help with both reduction of inflammation and in terms of keeping the weight off. I'll defer to Dr. Oratz in terms of the cancer stuff.

Dr. Ruth Oratz:

Yeah, I agree with you, Barrie. I think that these medicines work while you're taking them. And one of the things I say to my patients who maybe are sometimes a little reluctant when I bring up this issue of, "Gee, we should think about a GLP-1 agonist for you," is, oh my goodness, they don't want to add another drug. And then they ask me, "How long do I have to be on it?" And then I kind of push back a little bit and I say, "Well, if you had diabetes or high blood pressure or high cholesterol, how long would you have to be on the antihypertensive and the statin and the diabetes medicines? Forever. So if we can deal with the underlying problem, the root cause of the problem, maybe you won't need all those other medicines or less of those medicines."

I feel that by addressing the underlying metabolic problem in a very natural way, because as Dr. Weinstein explained the mechanism of action of these drugs, we're working through pathways that we know are activated or deactivated through the gut hormones to rebalance what got out of balance. So for many, many, many people just causing that rebalance, reducing the inflammation, reducing the proliferation, it's better to take one medicine than four medicines and be healthier.

In terms of the breast cancer, we really don't know. We haven't done prospective studies yet. We're just getting started in organizing those kinds of clinical trials. The work has been done in the laboratory and then these observational studies. I think that we have to be careful as we design these clinical trials to really make sure that we are defining our study populations carefully. So for example, looking at postmenopausal women on aromatase inhibitors, which is certainly a large group of our patients. Remember, two thirds of all breast cancers are hormone receptor positive and the vast majority of women who are diagnosed with breast cancer are postmenopausal. So that might be a really good group for us to start looking at trying to understand these metabolic pathways. For our younger patients, our premenopausal patients, I think the questions may be a

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little different. And particularly people on tamoxifen may have different issues compared to the aromatase inhibitors.

So we have to design those questions carefully. We're going to need large numbers of patients to enroll in studies. And then the question is are we doing randomized controlled trials where some people get the medicine and some people don't? These are all the scientific questions that have to be hammered out for us to be able to answer these questions clearly. But I think that there's enough interest in this that we'll be able to design some studies that can get us some information. Might take a little while to get FDA approval for using the drugs for this indication, but certainly for weight loss and metabolic syndrome, I think we have good indication for many of our patients.

Melissa Rosen:

Thank you. So I was going to try and stay with one topic and then move to the next, but so many questions have come up about this other topic, so I want to move into insurance coverage. But before I do, I did notice one thing that was very relevant in the chat box. Somebody asked if you take a GLP-1 and then stop, does your body lose its ability to ramp its own production back up?

Dr. Barrie Weinstein:

No. If you stop, then you are able to produce. However, I do want to say that part of the dysregulation in overweight and obese patients is that they might not be producing these GLP-1s or the receptors may not respond to them. So if you stop and then you gain weight back, then you might go back to the original problem to begin with.

Melissa Rosen:

That's an interesting thing to consider. Okay, great. Let's go to insurance coverage. So right now, does Medicare or any insurance cover these drugs for cancer risk reduction?

Dr. Ruth Oratz:

No.

Melissa Rosen:

Right. I just want to make sure we understand this. In order to get a prescription for these drugs, you need to either have diabetes or metabolic syndrome or be overweight, significantly overweight? So that puts a lot of our community in a difficult spot. They may want to use it for reducing inflammation or inflammatory factors. They may want to be doing it for other reasons. Now I'm going to ask for suggestions about what people might do in that case, including what type of doctor would prescribe. And then as long as we're moving in this direction, let's talk about compounded medicines and if that's a better way to go if we can't get a prescription.

Dr. Barrie Weinstein:

Okay, so the first part of ... I think if you want to try to get the medication covered by insurance, then you would have to have the indications I mentioned before, which is different from getting a prescription for the medications. And I just want to emphasize that, that if you feel the medication would benefit you, go see an endocrinologist and talk it out with them. Because a lot of us, we have

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been using these medications for years. We've been using them off-label. We understand the benefits. And when we have a patient in front of us who has just not been able to get to where they need to be and doing all these things and have other medical conditions that we know would benefit, then oftentimes we're moving forward with a prescription. However, we are then limited by if it is off-label, then you're talking about out of pocket.

And so there are various ways. What does that mean? Most people cannot afford the true out-of-pocket cost, which is like $1,000 to $1,200 per month. I will say though that there are patients where they might qualify but not have coverage, but there's coupons. It's still expensive, still makes it like $500 to $600 each month, but at least it's half the cost. I will say I have patients getting medication, FDA medication from Canada. There are different options there that defray the cost. Eli Lilly now has a direct-to-consumer that also defrays cost. It's a vial and syringe as opposed to the fancy pen dispensers, but it's still FDA medication.

Now for your question about compounded medication, I was definitely one of those people during the Super Bowl who was outraged by the first commercial. And I'm actually kind of outraged by the response that they don't fall under FDA regulation. I have patients on compound medication and in that situation it is because they really feel it would benefit them. The doctor feels it would benefit them, but they cannot get it any other way and it is significantly cheaper. And if you know the source, then it's a completely different story as long as patients are educated, as long as they understand what does it mean to be on a compound. It is not a generic, it is not an FDA approved medication.

And the problem is, depending on the source, it could be coming from different places and so you have to understand where is it coming from, who is making it. And then the decision is made between the doctor and the patient about whether or not it makes sense. There are definitely safety concerns, but I think a lot of people in the community of prescribing these medications, we have been incredibly frustrated by the lack of insurance coverage for most patients and it is option as long as patients understand what it is.

Dr. Ruth Oratz:

I would echo what Dr. Weinstein is saying about that. Many of my patients do have insurance coverage, they meet those criteria. But there are other people for whom we feel this would be very beneficial and who do get prescriptions from a doctor. But again, this is not something that you should go on to some online site and sign up and just get stuff to shoot yourself up with. You must be under the care of a qualified endocrinologist who is monitoring you, who's checking your blood tests, who's weighing you, who's examining you, who's checking your muscle mass. We didn't talk about muscle mass. And for our breast cancer patients, this might also be the person who's managing your bone density issues and looking at the whole metabolic picture of what's going on while you're on these anti-estrogen treatments.

And that endocrinologist should be in communication with your oncologist so that if this is part of your treatment plan, it needs to be part of your medical treatment plan by qualified medical professionals who understand the complexity of all the medicines you're on and of all of your medical problems. This is not like just going into a place on the street. You need to really be careful about what you're doing. Don't just go online and say, "I'm going to buy this from Canada" or, "I'm

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going to get this from somewhere." Which drug is the best for you, what dose to take, how to manage side effects and being monitored carefully is very, very, very important. So we don't take this lightly and we're not advocating that people in any way self-medicate or demand that they get medicines without consulting with an expert.

Melissa Rosen:

Thank you. Let's go back for a second to some general GLP-1 questions. We keep hearing about bone health and these types of medicines, so can you talk a little bit about that and possibly some other side effects other than mostly the GI ones that people are aware of?

Dr. Barrie Weinstein:

In terms of bone health, the medications are safe to use in patients with osteopenia, osteoporosis. However, it's important to be monitored very closely to make sure that the weight doesn't get too low, that the person is doing strength training, helping to keep the muscle intact. If you are on the medications and losing a significant amount of weight fast, not only are you going to lose fat, but there will be muscle. It doesn't have to be that case. If you do lose it at a reasonable rate, if you are exercising and specifically doing strength training and resistance training, then you can keep that muscle intact and that will be great for bone health.

I actually find that I end up having very similar conversations with my weight loss patients and my bone patients. I'm constantly talking about getting enough protein and strength training. I'm putting both populations on an InBody, which is a type of scale, which can help measure muscle and fat. I do both populations to both track the muscle, whether or not they're losing or whether or not they're doing enough.

In terms of other side effects other than stomach, fatigue I would say is a pretty common side effect. I'll do blood tests, I'll check B12 and iron and all the vitamin levels and make sure a person's getting enough hydration and protein intake. But sometimes patients are just fatigued, headache, a reaction at the injection site and then-

Melissa Rosen:

What about vision loss? Some people are hearing about vision loss or anxiety as a side effect.

Dr. Barrie Weinstein:

Okay. Vision loss is not a common side effect that I hear about at all. And then I'm sorry, what was the second? You said vision loss-

Melissa Rosen:

Anxiety actually.

Dr. Barrie Weinstein:

Oh, anxiety. Yes, there are patients that are reporting more anxiety and I'm hearing it from the psychiatrist. I'm usually working very closely with the referring providers. Sometimes it's dose dependent. If you reduce the dose, it gets better. Sometimes you hold it, sometimes it gets better

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over time. Yes, I've heard of anxiety. There are though also studies showing improvement in depression and anxiety. So I think it can actually go both ways and I've seen it go both ways.

Melissa Rosen:

Okay, before we move on to the different types of breast cancer and breast cancer treatments and potential interactions, a couple more insurance things that have come in. Do you know if insurance doesn't cover this, can we still use our FSA accounts to pay for them, flexible spending accounts?

Dr. Barrie Weinstein:

That's a great question. I assume if you pay for the medication at the pharmacy and you get an itemized receipt that you could submit, so yes.

Melissa Rosen:

Okay, so we'll have to look into that one a little more. Okay, so let's talk about different types of breast cancer. Do the recommendations change depending on the type of breast cancer? Are they the same if one has a triple negative diagnosis, a HER2 positive, estrogen receptor positive? Does that change the thinking-

Dr. Ruth Oratz:

Again, we're not specifically prescribing the medicine for breast cancer treatment. We're recommending it in people who are either overweight or have signs of metabolic syndrome. In my own practice, for the most part that has been in the estrogen positive breast cancer population, lobular or ductal, and at all stages of disease, whether they're being treated adjuvantly or for more advanced disease.

Melissa Rosen:

So to clarify, you would also prescribe this for someone living with metastatic disease?

Dr. Ruth Oratz:

Yes, absolutely. I have a number of patients with metastatic disease who are doing very, very well and where I think that this has contributed significantly to the stability of their disease by losing weight and correcting the metabolic syndrome. And we've also used it in patients who are on adjuvant therapy or in follow-up.

I'm just thinking about the triple negative breast cancer question. There's no contraindication. There would be no reason why someone who otherwise would benefit from the drug and has a history of triple negative breast cancer couldn't take it. There are no drug-drug interactions between the GLP-1 drugs and the aromatase inhibitors or tamoxifen.

Melissa Rosen:

That's the next question.

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Dr. Ruth Oratz:

Right. Or the ovarian suppression drugs like Lupron or Zoladex, there are no drug-drug interactions and it's safe to use.

Melissa Rosen:

So it doesn't impact the efficacy of any type of breast cancer treatment?

Dr. Ruth Oratz:

No, I think it enhances the efficacy. I don't think it lowers the efficacy. For some of the more complicated treatments, for example, immunotherapy drugs and so on, I'd have to look into that and think about that. We don't have a lot of experience in that particular setting and I'd have to look into that. Similarly, if people are also on other medicines for let's say inflammatory rheumatologic conditions, that's something that would have to be reviewed with their rheumatologist to make sure that there are no interactions. But by and large, I see patients who are taking these medicines who have many other medical problems and there are no big issues or problems.

Melissa Rosen:

Okay.

Dr. Ruth Oratz:

If someone had a history of triple negative breast cancer and she would benefit from this medicine, she should take it.

Melissa Rosen:

For point of clarification, some people here have been told they can't take hormones, mostly I guess for estrogen receptor positive cancer. There are none of those types of hormones in these drugs, correct?

Dr. Ruth Oratz:

No, correct.

Melissa Rosen:

Okay. A couple of people asked, can use of this drug elevate estrogen levels and cause uterine lining thickening?

Dr. Ruth Oratz:

No.

Melissa Rosen:

No? Okay, great. And then I know you've answered this in a lot of different ways, but just in a very simple question. At this point for what we know, are there benefits for patients who are at heightened risk or have cancer who are not overweight or have no metabolic syndrome right now?

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Dr. Ruth Oratz:

That's the $64 million question, right?

Melissa Rosen:

Okay. Well, I had to ask it.

Dr. Ruth Oratz:

Yeah, we don't know the answer to that question. I'll give you a roundabout answer, which is that we did a study, this goes back at least 10 or 15 years ago, looking at metformin, which is a medicine that's used to lower blood sugar, and we asked the question of whether or not giving metformin to patients, whether or not they had diabetes, would reduce the risk of breast cancer recurrence because we were thinking about this question already. We were concerned about the blood sugars and obesity and so on. And that was a negative study, did not show that giving metformin had a significant impact on reducing the risk of breast cancer recurrence. Now, metformin is not the greatest drug in the world. These drugs are way better. Will these drugs do better than metformin did in people who don't have diabetes but are at increased risk of breast cancer recurrence? We don't know, and those are the kinds of questions that we're asking.

Melissa Rosen:

But exciting that this research seems to be happening right now. One thing we didn't talk about is hereditary cancer mutations. Do we know if that changes the equation, if somebody carries either a BRCA mutation or any other of these mutations that raise cancer diagnostic risk? Does that change how you think about it?

Dr. Ruth Oratz:

There's no interaction with those genetic mutations. I would say that if someone has a BRCA-related breast cancer, she's been diagnosed with breast cancer, it's perfectly safe to use these medicines. I don't think that we have any medicine, whether it's GLP-1 drugs or tamoxifen or aromatase inhibitors, I don't think that any of these drugs are powerful enough in their cancer prevention activity to overcome the risk associated with a genetic mutation. That doesn't mean you can't take medicine. If it's indicated for other reasons for you, it would be additive, it would be beneficial, but it's not a substitute for all the other things we do for risk reduction in our very high risk patients with hereditary cancer syndromes.

Melissa Rosen:

Excellent point. Here's what I would like to do right now. I'm going to ask both doctors to stay on the screen with me for a second. Nine o'clock Eastern is when we usually end our webinars, and for those who have to sign off by 9:00, I want to share more information with you. But Dr. Weinstein and Dr. Oratz have generously agreed to stay on for another 15 minutes and we have plenty more questions that still need to be asked.

But as we wrap up, I want to thank of course Jamie for sharing her story and both doctors for sharing their insights into this new information and their clear passion about it. Again, thank you to our sponsors, Pfizer and the Cooperative Agreement 24-0061 from the Centers for Disease Control and

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Prevention, and to tonight's program partners, NYU Langone Health, Well by Messer, and the American Jewish Medical Association.

I know that your chat boxes are very full, but right now we're going to put a link to our evaluation survey in there. Please take a moment to fill it out. It'll take less than three minutes. But since this is a new topic, it's very important that we have the feedback.

There are several programs coming up in the next few weeks I want to make you aware about. On Monday the 24th, we will be presenting a special daytime webinar on the latest breast and ovarian cancer research coming out of Israel. The link to register for that is in the chat box now. Again, if you were interested in the research about GLP-1s, this might interest you. And on Wednesday, February 26th, consider joining us for your anti-cancer morning routine with nutritionist Rachel Beller. If you're here to learn more about losing weight and reducing risk by eating healthfully, then this is one for you. The link is in there now. And of course you can always go on our website to the events page to find those events and many more for you to check out.

I just want to remind you that Sharsheret is here for you and your loved ones. We provide emotional support, mental health counseling, and programs to help navigate you through your cancer experience, including a lot of healthy living programs, which we will include a link to in the follow-up email you receive. All of them are completely free and completely confidential. Our contact information is in the chat right now.

Let's get back to questions for those of you who can stay and then we'll put the evaluation in right before we end. Okay, if we could bring both doctors back onto the screen right now, I would be grateful. Thank you so much. We have some general questions that didn't fit into any of those categories but are still very important. I don't know that you'll have answers to all of these because this is so new. But somebody asked, they have frozen embryos that they made before chemo, could taking these drugs have any impact, both positive or negative on having a successful transfer?

Dr. Barrie Weinstein:

I can't reference a study for this, but my instinct is no, because I've had plenty of patients undergo it. I think it's just important for note, you really want to be off them at least eight weeks before you get pregnant. That's number one. In addition, the fertility doctors will usually hold the medications before transfer. But just like with cancer, if you have reduction in weight, if you have reduction in insulin, you're more likely to have a successful healthy pregnancy and to also conceive.

Melissa Rosen:

Can you take these medicines while pregnant, which isn't really the focus but you-

Dr. Barrie Weinstein:

It is not recommended to take them while pregnant.

Melissa Rosen:

Okay.

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Dr. Barrie Weinstein:

And I know there's a lot of reports out there of patients getting pregnant on these. It doesn't mean that you should. I've had some patients very confused about that. These medications, especially for patients who are overweight or obese who might have irregular periods due to their weight, they lose weight, they regulate, they ovulate and surprise, they never thought they could get pregnant or they had tried for years and they couldn't and so they don't really think about it too much and boom, they conceive. But it is recommended to be off at least eight weeks before trying to get pregnant.

Melissa Rosen:

Okay, thank you. Somebody asked a very interesting question. For those taking these medicines during chemotherapy, are there concerns about inadequate calorie intake because people tend to lose weight because of nausea and-

Dr. Ruth Oratz:

Right. So if someone is coming and newly diagnosed with breast cancer and we have to give adjuvant chemotherapy or neoadjuvant chemotherapy, I don't generally recommend that we start a GLP-1 agonist at the same time. Chemotherapy is difficult. There are a lot of side effects. There are a lot of other medicines that we give around chemotherapy, anti-nausea drugs, growth factor drugs and so on. So I don't recommend that we add this into the mix, but rather that we hold it until we're finished with chemotherapy and patients have recovered. And then we can use it as part of our, if you will, survivorship and maintenance programs. Certainly during endocrine therapy, it's fine.

For people with metastatic disease where treatments are changing because over time there's an ebb and flow with the way that the course of the disease is going and what treatments we have to use, I think that's on a case-by-case basis. For people who are on chemotherapy for long periods of time, my experience is that they're not needing to take these drugs so much. It's really more our hormonal therapy group of patients.

Melissa Rosen:

Several people asked if there is an oral equivalent or if anybody's working on creating an oral equivalent for these medicines, whether it's liquid or pill form.

Dr. Barrie Weinstein:

So there is going to be soon an oral equivalent of semaglutide that has the same percentage of weight loss as Ozempic and Wegovy. I would like to say that there is oral semaglutide on the market and it has been on the market for quite a few years as Rybelsus. That's why I put it in that chart. Rybelsus does not have as much weight loss as Wegovy and Ozempic. I do know though that all over the internet there are advertisements for getting cheap oral semaglutide Ozempic and Wegovy. It is definitely misleading because the percentage of weight loss is not the same, but there will be.

Melissa Rosen:

It's coming. It's coming.

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Dr. Barrie Weinstein:

It was supposed to have already come to market, so I can't say the date because it's already gone past when it was supposed to come out, but it is there and it will be coming out. But I will say that the oral medications tend to have a lot of side effects. They have to be taken a very specific way, and so sometimes the once a week can sometimes be easier.

Melissa Rosen:

Okay. Somebody asked if there are any other non-prescription natural GLP-1 plant-based substances that would not reduce cancer treatment efficacy or diagnostic risks, something like an appetite suppressant. And the person mentioned something called Amarasate, if I'm pronouncing that correctly. Okay, we haven't heard of that?

Dr. Ruth Oratz:

I'm not familiar with that. There are other medicines that have been around for a long time that suppress appetite. None of them really work that well. I'm thinking of phentermine. And Barrie, you know some of these other medicines also.

Dr. Barrie Weinstein:

Topamax, naltrexone, Wellbutrin. Phentermine and Topamax are the ingredients in an FDA-approved weight loss medication called Qsymia. Wellbutrin and Contrave are the ingredients in an FDA-approved medication called Contrave. You don't hear about them as much. There's weight loss with them and for some patients, patients can lose a lot of weight, but there isn't as high a percentage of weight loss. But not only that, there can be medical contraindications like high blood pressure or older age or anxiety and there can be a lot of medication interactions. So you have to be very careful before starting. There are limitations in that way.

Dr. Ruth Oratz:

I think you also don't get that rebalancing of the hormones where you're really correcting that underlying metabolic problem. You're not going to get the benefit on the lipid profile and the A1C and fatty liver for example. You may get some appetite suppression that leads to weight loss, but I think there's a difference in the way the GLP-1 drugs work that's fundamentally more physiologic.

Melissa Rosen:

Wow, okay. That's amazing that this new class is so different than what came before it. A few people asked about micro-dosing these drugs specifically to reduce inflammatory markers.

Dr. Barrie Weinstein:

So micro-dosing or just giving smaller doses than before, you can't do that with some of the injectors. Wegovy or Mounjaro and Zepbound, the way the injectors come, you can't microdose. You can do that with an Ozempic pen and you can do that with the compounded medication vials. You can do that with the Eli Lilly direct to consumer. So it is something that we are doing with patients either for patients who are concerned about fast weight loss and they want to go slower, so you'll give them a lower than starting dose, which a lot of times doesn't work as well for weight loss.

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But from an inflammation perspective, you can monitor both the inflammatory markers in the blood and you can monitor how the patient does and you can start low and then just increase as needed. But it is a good option for some patients, but you are limited in which medications you can actually use it for.

Melissa Rosen:

Okay. All right, that's good to know. Somebody asked a question that I thought was interesting. What happens if somebody is on one of these medicines and doesn't lose weight? What are the implications? Does that mean there's something else going on? Does that mean it's just the wrong drug for them? What's happening there?

Dr. Barrie Weinstein:

So the medications don't work in everyone and there are a percentage of patients where either they lose 5, 10, 15 pounds right away and then it just doesn't work anymore or they don't lose at all. There are different phenotypes of reasons for why patients gain weight and have difficulty losing. That's when I'll start talking to patients about the other medications on the market because for example, Qsymia, which is the combination of Topamax and phentermine, that's helping to increase energy expenditure. It's helping you to burn calories. For some people that's part of the problem is you have to raise the metabolism, which they're unable to do say with exercise.

For others, there's a lot of emotional eating and so Contrave, another FDA-approved medication, a combination of Wellbutrin and naltrexone that tries to get at the underlying cause there. Sometimes we'll use a combination of medications, but it can be tricky. And there's nothing wrong with them. It's just medications don't work in everyone. They don't work to the same degree in everyone and these are included.

Melissa Rosen:

Somebody is asking again, and I know you've answered this, but these are slightly different circumstances and maybe it'll trigger some more information. But again, someone who doesn't have high blood pressure or diabetes but really does have extreme lymphedema, is there any way with compassionate use circumstances for insurance to cover it?

Dr. Ruth Oratz:

No, insurance is certainly not going to cover it for that. I think lymphedema is a very difficult problem for many of our patients and it's complex. So it depends what the causes are. If someone has had axillary surgery and or radiation therapy, how long the lymphedema has been present for, if they've tried other techniques for reducing lymphedema, compression, lymphatic massage and so on.

So as I mentioned briefly in that slide, it's not just about weight. There are many factors involved. But there's not an indication specifically either for lymphedema or in fact for inflammatory conditions. This is just an observation that in some patients with lymphedema, losing weight on GLP-1 drugs help their lymphedema. So it's something that we can think about, but I can't say that would be a specific treatment for lymphedema.

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Melissa Rosen:

Two more questions. We'll have time for two more questions. And this is a two part, so maybe two and a half more questions. But a couple people ask about cancer risk in terms of pancreatic cancer, if they've already had it or does it put them at higher or lower risk, but also what about if one's had pancreatitis? Does that change the ability to take these meds?

Dr. Barrie Weinstein:

It is a case-by-case basis, I have to say. When a patient has had pancreatitis due to a very specific reason that is no longer there, for example, a gallstone. The gallstone led to blockage, which led to inflammation. The gallbladder was removed and they've been well with no issues for a bunch of years. Then I would say, listen, it's definitely on the basis of the individual doctor to feel comfortable with it, but I have in that situation, prescribed it. I'm usually talking to the gastroenterologist, but clear that that issue is to the side. Maybe there was an episode of an alcoholic pancreatitis that's not recurrent. It was a very specific situation.

It's a case-by-case basis, but in certain situations, if you've had pancreatitis once, it can be increased risk for having it again. And so in some situations it is advised or not recommended to go on. So just because you've had it doesn't mean you can't go on it, but you would definitely want to talk to your doctor and talk about the risks and benefits about going onto it.

Melissa Rosen:

Thank you, that's helpful. Somebody just asked, and I got a couple of other messages about this, if this is covered for pre-diabetes. So you say yes, if they also have signs of metabolic syndrome?

Dr. Barrie Weinstein:

Yes, if they have a BMI greater than or equal to 27. And I would just like to say with insurance, unfortunately it's very black and white with them. It really is. It's really strictly related to the FDA indications. It's really hard with our Medicare patients. Even like today, I saw an obese patient with obstructive sleep apnea and I am going to be begging, I'm begging. And so it's just unfortunately very black and white as of right now. Although as of today, things are probably going to change a lot. So we don't know how it'll go.

Melissa Rosen:

Which leads me to my last question. When I first spoke to you guys about coming on to speak, you said, "You have to give us a few weeks because a study was just published. We need time to read and learn what that study said." And it sounds like there's so much more research that's going on and we'll learn about new indications and things like that. So my last question is, when things advance enough that there's new information, will you come back and do another one of these for our community?

Dr. Ruth Oratz:

Yes!

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Dr. Barrie Weinstein:

I'm honored. I would love to.

Melissa Rosen:

Absolutely. This was so eye-opening and so encouraging. And somebody just said, "Yes, please." in the chat. Thank you both of you and thank you to Jamie for sharing her story. We're going to put the evaluation link in one more time. And be on the lookout for a follow-up email probably early next week that will have a link to the recording, a link to a transcript, and oh, the SurveyMonkey just went in and I saw it, and a link to some healthy living resources on our Sharsheret website. Thank you and everyone have a great night. Bye-bye.

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