Megan Lyon - **00:48**

Hi everyone. Thank you so much for joining the Genetics Policy Hub webinar series. We are 1 minute until 12:00 P.m. On the East Coast, so we'll just give it one more minute and then we'll get started. Thank you for joining. Hi everyone. My name is Megan Lyon, and I'm thrilled to welcome you to the first of our Genetics Policy Hub webinar series. I see that we have about 60 people on the call, which is great, and we will get started as it is 12:00 on the East Coast. A couple of housekeeping things. Everyone is muted at the moment while we go through our presentation, but please feel free to chat us any questions or thoughts you have along the way. At the end, we'll have time for question and answers and you'll be able to unmute and ask your question to myself or my other co presenter, Dr.

Megan Lyon - **02:43**

Ronnie Singh. With that, I'm thrilled to be kicking off our webinar series about medical foods coverage in April of 2023, and I'm ecstatic to have our Southeast Regional Genetics Network Project Director, Dr. Ronnie Singh, as my Copresenter during this webinar. This project is supported by the Health Resources and Services Administration, and so we're very thankful of their support. As I said, I'm Megan Lyon. I am the co project director of the National Coordinating Center for the Regional Genetics Networks, otherwise known as NCC, and NCC is the one that has the Genetics Policy Hub as one of our initiatives. I'm thrilled to be speaking with you all today about what we have in the genetics policy hub related to medical foods, along with Dr. Ronnie Singh, who not only can give us wonderful context for what medical foods is and what coverage of medical foods looks like, but what the policy implications are of medical foods at both a local level and at a national level.

Megan Lyon - **03:52**

For today's Webinar, we hope that by attending the Webinar, you'll be able to describe the importance of why medical foods coverage is needed, identify current policies that are either currently proposed or enacted throughout the United States, and apply lessons learned to understand how you can improve medical foods coverage in your work. Today we'll be splitting up the Webinar into three different parts. The first is a basic understanding of medical foods coverage, which Dr. Singh will cover. I will get back on and talk about what we have within the Genetics Policy Hub and give you really a national level look at medical foods coverage. And then Dr. Singh will talk about her work to improve access to medical foods coverage and the work she's done in terms of policy implications for medical foods coverage. We will have a question and answer session. With that, I will turn it over to Dr.

Megan Lyon - **04:49**

Singh to kick us off. Thank you so much.

Rani Singh - **04:52**

All right, thanks. Let me get myself here. Megan, thank you so much, and I do appreciate this opportunity very much to represent CERN and Emory and my experience in this area. And I welcome all our attendees today. I'm sure that there's a lot for us to discuss today. So, having said that, I'll start off with the definition which most of what a medical food is. In 1988, this is the medical food definition as Orphan Drug Amendments. The food that is formulated to be consumed or administered enterally. The key thing is here under the supervision of a physician and intended for the specific dietary management of a disease or a condition for which distinctive nutritional requirements based on recognized scientific principles are established by medical evaluation. There is some weakness in this, but nevertheless, this is the most recent definition of medical foods. What we go by, just a reminder to all of us.

Rani Singh - **06:11**

It was fascinating to me to realize that these medical foods were classified as drugs from 1958 to 1972. Because there were several, the usefulness was widely accepted and they were very limited in number. Also the goal was to make them less costly, to develop and add more variety by Orphan Drug Act Amendments created and defined this category. To the next step they did was foods for special dietary use in 1972. Came the definition of medical foods separate from drugs and yet associated with disease. So, so that's where we stand. In 1990 and 1993, there was little more activity with Nutritional Labeling and Education Act identifying five different criteria to qualify as medical food. And I listed those here. Next, please. So, like I indicated, the definition of medical foods, it narrowly constrained the types of products that fit within this category. It's challenging how we interpret this.

Rani Singh - **07:37**

In order for the clarification, then in May 13, 2016, there was a Medical Food Guidance Release. This is a nice little document about frequently asked questions about medical foods. Stated. These are stated a non binding recommendation. They are easy to read, question and answer form. They provide information and little further clarification of medical foods and the type of diseases and some label statements. Next, please. These are these they so now the medical foods, they stand between food which supplies nutrients and the drugs which prevent treats, cures or mitigates a disease. What has happened is there is blurring this line between food and health. Now, the food is used to mitigate a disorder. Therefore, therapeutic potential of medical foods is established. That's been great advancement in the field of nutrition. Along with it has generated valuable insights in the complex and dynamic transition from health to disease.

Rani Singh - **08:54**

How do these things change? How can food be used to manage the disease? We are moving forward with this thought as we move the field of nutrition into this century. Next, please. Sorry, here is a patient in Georgia, this is a Georgia patient who was not treated before the new bunch screening was started. On the right you see the patients who are treated. Many dietitians are in the search and don't mean for me to tell them this, how the life of PKU has changed and how they can attend college and the outcomes and functionality can be improved. In addition to giving achieve these outcomes, I want to remind other colleagues of our that many other disorders that have emerged that we manage using the same principles. If you look on like MSUD organic acidemias, they require way more other than the medical food access. They need trained workforce to say how this needs to prescription needs to be created even though it's under the supervision of a physician.

Rani Singh - **10:21**

The dietitians need to create the prescription based on the weight growth and these have to be the biochemical lab markers and these have to be constantly changed by the trained dietitian. If we do not have access to these medical foods at any stage, they can result in morbidity. For some patients that means even death like an MSUD organic acidemias. We know that we have already shown that GPH medical foods works to help mitigate these disorders. Next please. We also have recognized you can click next, Megan. That there's a better survival and reduced mortality from previously lethal and debilitating conditions. That means greater numbers are transitioning to adulthood as functioning adults, they're having better quality of life, getting married, having families and once these conditions thought to be contraindicated, that the pregnancy cannot be successful. Now, we have several accumulating reports of successful pregnancies in a wide range of IEMs other than PKU and we need to kind of continue learning those from each other how the other pregnancies other than PKU impact the outcomes.

Rani Singh - **11:52**

What we have learned from PKU story is if we do not treat at conception and during gestation, these are associated with poor reproductive outcomes. GPH medical foods so important because if they do not have access, these can result intrauterine growth retardation congenital anomalies sphere compatible with life. Those are very common outcomes and these are associated with the lack of fee control. I have seen many women who fight these insurance issues and did not have access and they just come out during pregnancy and tell us that they are pregnant with high levels. I always wonder would we negate the effects of newborn screening if we don't care of these take care of these women because each one of them can produce more than one child, even if they don't have PKU or genetic disorders to produce some development lead to date children. Access to medical foods is very critical during that time.

Rani Singh - **13:08**

Next please. So, based on this premise of the success of utilization of medical foods and PKU as an exemplar, we know that many disorders were added to the Rust panel or recommended uniform standard panel that required access to medical food and a trained registered dietitian. And what did we learn? That the outcome of these children is just not dependent on early screening and diagnosis, but the rapidity and quality of intervention with what we work. I can particularly personally vouch for you for last 30 years. That the impact it has. If we get that medical food and treatment going for that child right away versus waiting few days or even months, that can result in some negative consequences. So, next please. I want to thank my friend Helen McHugh. She should have won an award for the slide. This tells a big story. If you look on the right hand side, a typical diet, what we serve a patient has three major components medical food, which provides 70% to 80% of their nutrients and protein needs for patients like PKU or other metabolic disorders.

Rani Singh - **14:36**

The second part is that they have low protein modified foods which are used as a source of energy to make up for the calories. The third component, which is very little, is the natural foods like you and I eat. If you look on the plate on the left side, if the patient did not have low protein modified food, GPH medical foods and had a classic figure, this is how their lunch meal would look like on about three to 400 milligrams of phenylalanine a day. Again, the importance of reliance on medical food as a nutrient and food as a source of mitigating a disease. Next, please. I want to again say that once we have a positive newborn screen, child need different foods to survive, as traditional foods can harm the child. Medical food caters to people identified with inherited metabolic disorder to survive and improve outcomes.

Rani Singh - **15:50**

And they are not optional. I always get indirect and it's been at least five decades in JAMA, 50 years ago we showed that all this works and it's about half a century that these are preventative and they are needed. I always question why are they not available to our patients? Also, one of the words that always touched my heart, when mom asked me, I can't afford this formula, the insurance was giving the hard time. She says, this is food for my child. Even if I have to sell my car or a house, I'm going to do it because I need to feed my child. This is how desperate some parents have felt if they cannot have access GPH medical foods once their child is diagnosed. I want to say that we know now that the primary recognized therapy for many inherited metabolic disorders identified on newborn screening and clinically, we can reduce the morbidity and mortality and improve outcomes.

Rani Singh - **17:01**

It have a half a century history of use. They're lower cost than drugs. Why aren't they accessible to all patients of all ages? With that opening remarks, I will pass this back to Megan to share some of the challenges we face and how the policy currently stands on this topic.

Megan Lyon - **17:26**

Megan thank you so much, Dr. Singh. That gives us a really good context for why this is such an important policy issue for us to be tracking. So, for those of you who are not aware of genetics policy hub or NCC, we want to give you of background before we get into what we are looking at in terms of medical foods coverage in the genetics policy hub. So, as I said when I was introducing myself, I work for the National Coordinating Center for the Regional Genetics Networks. We are a federally funded program, along with the seven regional genetics networks, which Dr. Singh is project director of our CERN region, as well as the National Genetics Education and Family Support Center. All nine organizations work together to improve access to genetic services for underserved populations. We do that in a variety of ways. Some of those I've highlighted on the slide, which range from genetics and genomics education activities, such as things you'll hear about that CERN is doing later on in the presentation, in terms of medical foods, it could be something specific to a specific genetic condition or something more broad.

Megan Lyon - **18:38**

The regions also focus on improving access to services via telemedicine, or we call telegenetics. Family Engagement Partnership is an integral part of our system and engaging those who have genetic conditions or at risk for genetic conditions to understand what their needs are. Finally, NCC also has a focus on policy, which is where our genetics policy work comes into play. This work began for us really a number of years ago with the passage of the Affordable Care Act. Once the Affordable Care Act was passed into law, HRSA, our funders came to NCC and the regional system to really begin to develop specific resources around policy to help support the delivery of genetic services. I'll stop here and clarify that what our system really focuses on is getting access to services. There are other components of genetics that are vitally important, but we're really looking at that delivery between patient and provider.

Megan Lyon - **19:42**

In 2015, NCC held a meeting with a large group of partners to identify really what were the policy issues and what resources were needed to better understand the policy landscape. Because we are federally funded, NCC is not positioned to advocate for certain policies or to really say we should go this direction versus that direction when it comes to policy. Were really looking at this through the lens of what policy resources are needed for you all, as providers, as public health professionals, as families, to understand what's happening in genetics and how that affects the delivery of care. Through the development of that meeting and through projects that we developed in 2017, HRSA specifically enumerated two objectives for NCC to accomplish, and those are really to look at monitoring, analyzing, and tracking of national policy issues that, again relate to the delivery of genetics with a specific focus on finance and insurance coverage, workforce and emerging issues.

Megan Lyon - **20:56**

We are also tasked with disseminating information on practices, policies, and resources related to the genetic service system. We have been doing this work obviously for a number of years. We've had some of these tools, which I'll talk about in for a number of years, but everything was in disparate systems. If you were, say, interested in medical foods coverage and one resource versus another, you couldn't find that information. Were very fortunate last year to be able to launch the Genetics Policy Hub webinar. I'm sorry. Genetics Policy Hub website. This is a website that you can go today to access all of our information. It's a fully searchable website where you can type in, say, medical foods and find everything we have related to medical foods. For the rest of my presentation, I'll be focusing on the tools that we have within the Genex Policy Hub that are related specifically to medical foods and what data we're seeing.

Megan Lyon - **22:03**

I will caution that this data is always evolving. So this data was pooled last week. That does not mean this is exactly the data you will see if you went into the Policy Hub today, because there are things that are constantly evolving from Medicaid programs to legislation. This is a snapshot in time of what we're seeing in terms of medical foods coverage across the United States. The first resource we have within the Hub is our Medicaid database. This database is something that we update annually and we look at all written policies related to genetic service delivery. We specifically look at policies related to medical foods because, as Dr. Singh exemplified at the beginning of this presentation, it is a crucial policy arm for genetics. We specifically look to see what policies Medicaid programs say they cover or say they do not cover related to medical foods.

Megan Lyon - **23:04**

In our 2022 update, which is on the website, currently, 81% of Medicaid programs say they have some coverage related to medical foods or some determination they make related to medical foods. This includes both state programs and territory programs. We pull the 50 states and four territories. So this is both states and territories. What we find is policies range from things related to medical necessity to who is actually covered. Coverage can be specified by a certain genetic condition, by your age if someone is considered an Epst eligible child. It really gives you a range when you look at the data and you look at your state specifically, you can see the range and policy. I wanted to highlight two different states. There are a lot of different policies. Sorry about that. You can go into the website and look at your state's policy currently that is written, but this from New Hampshire really shows that they look at medical foods related to medical necessity and who can render the services, and they also specify if prior authorization is required.

Megan Lyon - **24:30**

They're very specific in how New Hampshire writes their Medicaid policies. Versus Tennessee does say that they do not cover medical foods except for certain circumstances. In this instance it's PKU. What we hope to exemplify with this is it's really critical to go and see what your state says they cover. Obviously, there is case by case determination with any insurance program, and Medicaid is no exception. You can go onto our website and see what your state says they cover for medical food coverage. Another tool within the genetics Policy hub that we have is we track proposed legislation and regulation. We have Molly Case, who's our project coordinator, goes in every day into a system called Physical Note and looks to see what policies are popping up at both the state and federal level based on specific search terms. We have search terms related to medical food, medical nutrition, things like that.

Megan Lyon - **25:35**

Currently there are six states that have legislation related to medical foods coverage. As you can see on our website, you can go and click on the map, or you can click on the side area and click on Medical Foods to see specifically what states are proposing legislation or regulation related to medical foods. You can also click on any of these buttons on the side and actually read the text of the bill so you can understand what's happening either your state, a neighboring state, or within your region. Again, we wanted to show you a proposed bill that was introduced earlier this year. This is so you can find that it was recently introduced. It was the Illinois house. The bill number and what the regulation or legislation says. We have a Twitter account that also publishes this information, and on the Twitter account it specifies how this policy is related to the subject matter can.

Megan Lyon - **26:37**

This is Medical Foods, and so you can see what they're specifically proposing related to medical foods. Finally we have our policy areas. One of the things that NCC is tasked with doing is disseminating policy statements from national organizations. We had collated all those policy statements together, but we really saw that there was a lack of context when you look at a policy statement sometimes. Within the Gen X policy hub, we have policy areas. So this is the medical foods one. What it does is it gives you a very brief introduction of why this is a policy concern. It highlights legislation and regulation at the federal level that's related to this policy area. For medical foods, there isn't an enacted policy at this point. And so we wouldn't have anything specific. It would tie back to our tracking system for legislation and regulation. We list all the policy positions from organizations such as American College of Medical Genetics and Genomics, Genetic, Metabolic Dietitian, international Society of Inheritance, metabolic Disorders, so on and so forth.

Megan Lyon - **27:49**

You can go in, you can download this as a PDF, so you can give it to somebody else or you can go in and explore more about why this is a policy concern. Along with this information, we also created a policy overview, a policy brief to give you an overview of what was presented today. So you can download that as well. I would encourage you to go in, download it if you want to learn more. Again, this is a snapshot. This is a constantly evolving area, as all policy is. This, we hope, gives you a good overview of what's happening at the national level and what we're seeing as trends. And now I'll invite Dr. Singh back to speak about her efforts to look at medical foods coverage in Georgia and the policy implications. Thank you so much.

Rani Singh - **28:40**

Thank you. That was wonderful resources for us. Okay, so we'll get back in here. You can go to the next slide making so we know listening to this, how source of supply and coverage is very highly variable in each state. This is a paper we worked my colleague or friend, Dr. Susan Berry, Sue Berry, who's very passionate about this topic and worked at hersa together. Were able to demonstrate and confirm that the variation that patients are paying expenses out of pocket through pharmacies hospitals, health departments, medical supply and medical food companies. We also showed the Reimbursement by private insurance can happen or not happen programs are administered by states Medicaid, Chipwick, there's military health benefits, newborn screening programs or metabolic clinics and multiple sources. So, as you can see, it is very difficult, challenging for families. This is what I tell the parents don't give up when your insurer says no, you don't have to give it up.

Rani Singh - **30:02**

I thought this picture really kind of portrayed what our parents feel dealing with this. And also next slide, please. Also we know that there's a lot of debate that has continued for the last five decades after we have shown the efficacy of the use, their Afflicted community continues to legislate and lobby GPH. Medical foods companies, of course, are very supportive of getting the support for Reimbursement because it takes a lot of energy in that direction. We have a mixed group who are not sure at this time what they are positioning and then the insurance industry? It depends. It's not yes for everybody, at least. And so the legislative debate continues. We also know there's a lot of support of professional organization. All American Academy of Pediatrics Genetic Metabolic Dietitian, international Society of Inherited Metabolic Disorders, and American College of Medical Genetics all have said yes and have created statements to say we need to move on and support this effort to ensure access to medical food.

Rani Singh - **31:26**

What I want to share with you is the efforts. Next slide, please. Efforts, what we decided to do in Georgia while all this debate is going on and how do we kind of meet the gaps at this time? You can click the next button, Megan. We started the program called Medical Nutrition Therapy for Prevention Program. And it has several components. It has an education arm, research arm, and healthcare services arm, both for clinical support in the clinic. What I'm going to focus on today is the community outreach arm. What we have developed under the nutrition program, and that is GPH, medical foods access, and a trained or registered dietitian support with the community outreach effort beyond the clinic. Our goals were for this program overall to prevent poor health outcomes, improve health related quality of life, evaluate MMT for continuous quality improvement. How can we continuously improve what we are doing and generate new knowledge in the field of IMDs, paving the way for precision nutrition?

Rani Singh - **32:40**

I think the goal is to make sure that none of our patients go without care if we have started the new one screening program. By the way, we did patent the name Medical Nutrition Therapy for Prevention for Emory. So, having said that next slide, please. With that program, we work with our legislatures to get some funding for that little piece of medical food access. After 25 years of hard work, were given limited funding approved by the Georgia legislature. We wanted to use that funding not just to give away formula. We combined our resources with our research funds and other contributions to create we decided we'll create a national model for medical nutrition therapy for metabolic disorders identified through newborn screening. Focusing more on genetic disorders which are identified through newborn screening as a starting point. Given the limited funding, our first premise was that the insurance should pay for this.

Rani Singh - **33:52**

Okay? Because our aim was to not let any patient go without interruptions in care who are underserved, not only in rural areas, but what I call the working poor people who have the insurance. And yet the insurance is not giving. We should not let them fall through the cracks or have any interruptions in the care, and to also, at the same time, gather point of care data to inform program development and inform the field about the need of these nutrition services, how they are utilized and what they cost. Because when I would go to the hearsaw meetings with the Medicaid directors and insurance directors. They say give us the cost and literally nobody is doing research in this area to show what the cost looks like. I thought were in a unique position having worked in the clinical program for 30 years for me to kind of try to see if we can take a stab at this.

Rani Singh - **34:54**

We started this research based program with the consent from every patient and enrolled them officially in our database for the service. We have a big, very committed, dedicated MNT for 15 and what we offer here are the services medical foods to our patients if they fall through the cracks with the insurance company we give $100 to $150 voucher of low protein modified foods and I'll talk about you the impact of that on the patients. We give dietary supplements. Many patients I was surprised before I started this program who could not even afford things like biotin and know which kind of biotin to get insurance navigation we offered even though social work and worker and all in our clinic that should be a part of the service, but it wasn't working GPH medical foods. We have contracted an insurance navigator with those funds and also the constant filter paper monitoring was a big gap and we do that in addition to telemedicine with CERN collaboration.

Rani Singh - **36:01**

As you saw, telegenetics was a big thing and this is a picture which I take a lot of pride in, where were able to do during COVID Were ready to go our first positive newborn screening case 4 hours away. We were able to give both combined peer to peer teaching to the doctors and nurses in the outlying hospital along with the patient education in Augusta Hospital or Macon all the way 4 hours away from memory and were able to shift the formulas. This model actually has done wonders for our newborn screening program to get situated, like give them the services right away to the families and we will be hopefully gathering data on them backed off all this and on the outcomes as we move along. Next please. I'm going to share with you some stories in the trenches, what we are faced with, what does T 4ft teaching me, which lot of dietitians who work with DMEs and already know, but I think it really brings home some of the cases.

Rani Singh - **37:14**

Here's a 45 year old male with PKU, he has insurance plan, it does not cover the medical foods coverage applies only from birth to twelve months only. It GPH medical foods coverage, but only for first twelve months of life. We did insurance benefit investigations and it said in the insurance it covers 100% no deductible, it's only for first twelve months. Though authorization is required and out of network it will cover 70 30% deductible will be about 259 hundred and DME charged high. Amounts. The DME for this patient charged very high amounts of to the GPH medical foods. MMT four P actions that were taken there were benefit investigation conducted on the insurance offered by his work. We could not overturn the medical food exclusion in his employer based insurance. We breached the coverage of medical foods and low protein modified foods for this patient. When we looked at the cost, of course ours is a bridge program and we could not continue to give.

Rani Singh - **38:28**

This patient volunteered and said he could afford half of that cost. Patient opted to keep the employer based insurance despite the medical food exclusion because we do look at other insurances and say next year you could enroll for another insurance. He was not interested in switching insurance during open enrollment because the benefits for other things were huge for his clinic visits and all that he didn't want to let it go and find that paying out of pocket expense for medical foods were more feasible. So here next click please. This was age limited coverage in this example is what we see next one. This is a 39 year old female with home assistant urea cigna and this medical exclusion exists entropy feeds only age gap at 22 years of age. Again, insurance benefits investigate showed her insurance coverage was only in network deductible of 500. No out of network benefits were available, no prior authorization required and predetermination was recommended.

Rani Singh - **39:48**

What did we do for the predetermination recommended? We got that it got submitted and certain codes under the entry feeding exclusion it got excluded, then it was submitted under the S code which is under the pharmacy benefits and prior authorization was submitted for my pharmacy and then it was denied because the age gap. Now we provided all the documents, clinical notes and letter of medical necessity. Lot of workforce hours won't go to support this service. In most clinics dietitians literally I had done a survey at one time are spending 40% of their time instead of seeing patients. That's what they're doing letters and these are master's level dietitians who have been trained to take care of patients. Image for P continues to bridge medical food and dietary supplements for this. Can you please next please. This was refused due to age gap. The other problem, what we found with this case was the betane was not covered the drug for the patient and so it is also sold as a dietary supplement.

Rani Singh - **41:02**

We ended up and I can talk more about it in MNT for PV. I've done some studies to show the purity of these powders from some of the companies and verified. This patient is using instead of beta as a drug, betane is being used as a dietary supplement. How do we make those decisions? The point I'm making is it's complex what the benefits are how we navigate through them and what the outcomes look like. Next one please. The next example is patient with PKU Harvard Pilgrim plan. This was main issue was the DME and the pharmacy look in the network. Insurance benefits investigate and check that it covers 100% in network. Sounds wonderful. It's deductible for 5000 before 100% coverage and 10,000 for out of network. It's covering diagnosis driven and requires a prior authorization. Benefit investigation was done pharmacy, were able to unable to locate a pharmacy supplier and the DME that was there, it was not even contracted with the plan.

Rani Singh - **42:29**

It sounds really good what the benefits are. When you start digging into it, actually it doesn't get the patient what they need. Dietitians are not trained to do this really and they have to learn it as they go along. For each patient and MIT, if we provided medical food, bridge clinic already referred to company food, medical food, company nutrition provided medical food and nutrition sentient referral and provider time for navigation, but still no solution. Again, I use the name nutrition but I do want to give a shout out to all the companies widerflow advent. All these companies are very supportive and have put in plan. So look at the effort. Dietitians are doing this, companies are doing this. Each company is coming with insurance navigation. Social workers in the clinics are trying to do this. It shouldn't be that expensive, right? Complicated. This is another example.

Rani Singh - **43:36**

This is next one please. This is next please. This is a one year old male with glutaric acidemia who had humana. This was covered under pharmacy benefits. However, local pharmacy did not carry the medical foods. So insurance navigation, it sounds good. 100% network in network pharmacies which is there only $1,000 deductible prior authorization required for products. Anything more than $750 clearly stated. These directions are different for different insurance companies. Out of network 3000 and covered under pharmacy benefits. We here look at both parents and insurance options. Chose the one with both medical and pharmacy benefits. DME did not carry the product. Switched to pharmacy benefits. Local pharmacy did not carry the product. Nmnt continues to bring the medical fruits until a medical supplier is confirmed. This is a new parent had no knowledge of insurance navigation. They had no knowledge of the disorder their child had.

Rani Singh - **44:49**

They vaguely remembered their child had a test done in the hospital which they thanked newborn screening for admit for P. Provided all the supplies immediately through this program, this Gap Bridge program, we provided the education right away to the families, medical food, access scales, everything they needed and did insurance navigation and still no solution. We in Georgia will hold their hand until they get the thing, get situated in the clinic and get the insurance company. Here is another example of a 39 year old female uninsured, cannot afford to play clinic visit due to high copay, high deductible. She has tried many times. Despite our charity program, there have been barriers that this patient can get in. She's living by herself, she lives paycheck to paycheck, she works long hours, and part of the reasons she has to finish the paperwork in order to even get in the clinic.

Rani Singh - **45:59**

Because she works long hours, she keeps missing the phone calls with the people she's supposed to meet with and make appointments. She lives 30 miles away from the clinic and she has multiple comorbidities. Okay, she was scheduled for an appointment. We did a telemedicine around her, convenient in the convenience of her home. We got her insurance navigation Navigator offered insurance through Marketplace, bridge coverage of medical foods and low protein modified fats. So we've got her all starting. She is going to revisit open enrollment with some options in 2023. We are encouraging her to take time to engage insurance obtainment and prioritize health insurance expenditure. In the meantime, we are giving her medical food access globe Protein Modified $100 $150 voucher nutrition Education support with a goal to link her to the clinic. This is one example I'm sharing with you. I'll tell you, after starting this program, my heart goes out.

Rani Singh - **47:05**

There are several women who are trying to get pregnant. I feel so joyful that we can bring them and get them in the clinic and support them throughout for good outcomes. So with that next please. I think I already talked about this. Can you go to the next, please? Okay, I can go on and on for another hour telling you the stories about how we have using the money, working with the state with a small amount of money, how we have boosted and injected our nutrition program both for workforce training and GPH medical foods access. And so what have we learned? We find that families often did not know if they had caps or insurance, what the dollar amount of the cap was. Families had a hard time telling us their out of pocket costs. Most insurance companies do not cover low protein modified foods.

Rani Singh - **48:13**

Vic, I want to give a shout out to them is a very important source for support for many families on a state by state basis. We see more and more WIC patients are covered, which is patients under five years of age, and then when they get pregnant, patterns of coverage vary even within the same insurance company. Depending on the contract or the employer, they can have Cigna. I showed you three examples of Cigna coverage and the different programs at different companies. How are dietitians in the clinics expected to learn and understand all that lack of knowledge about insurance navigations patients due to complex terminology, b code Descode we have a full time person who's teaching us, our wonderful friend Tammy Jones, who's become an expert in this and helps us and helps navigate our kids to get through this. When the dietitians rent into roadblocks lower premium usually equate to high deductible plan.

Rani Singh - **49:13**

It was interesting for me to review some of the data I was looking at that a lot of these young people say oh, I have a lower premium, I'm going to sign up for that. Those are the ones we do not cover medical foods, but they didn't know they were going to get a child with a genetic disorder. Insurance navigation fatigue by providers and patients. I have heard clinical dietitians resign from their jobs telling me they're just tired, they don't get to do as much nutrition work because they spend more time doing insurance. Navigation International another group which has come to my attention and with several patients which I didn't give you example international visitors which we take care, they can't even get in the clinic immigrants and some foreign students which we are helping and I'm sure other examples will come. These are all falling through the backs with care, lack of clarity and understanding the term medical foods when new dietitians and physicians start.

Rani Singh - **50:16**

I'm not sure how many really understand what those medical food terms mean and different state policies, they get so confused about foods and patients discourage and leading to poor outcomes in next. I'm worried that I see so many adult patients discouraged and leads to poor outcomes and next generation I see that we'll see the impact of it despite newborn screening and it's important for us to keep that in mind. Next please. What did Son and MIT for P Partnership also do during this? It's needed and were able to mobilize or bring all the stakeholders, including then with the GMDI, which took the role later created clearer messaging to patients and families affected by this disruption. It caused a lot of pain at that time formidated Transition plan to other products based on the diagnosis and a lot of companies stepped up to create standard comparisons how we can substitute and that not only saved time for the dietitians but also resulted in much more accurate or less errors in patient because it was a huge burden on the dietitians.

Rani Singh - **51:39**

So I think it's very important. The point I'm making is that the medical food is so specialized that when some disruption occurs, it even gets more exaggerated in how we handle medical foods and the policies around it. How do we kind of handle that? Next please. So what do these cost next? The thing I wanted we wanted to address and I literally see no data for policymakers to do next. Can you click on that please? So we look at the cost comparison. I wanted to look at the cost and these are the low cost, moderate cost and liberal food plans. Three fundamental parts of us. Food guidance system that have been revised by USDA's Center for Nutrition Policy and Promotion with assistance from USDA's Food and Nutrition Service, Economic Research Service and Agricultural Research Service brand and what these are representative of healthful market baskets at three different cost levels, one at a lower cost, moderate and liberal.

Rani Singh - **52:54**

I decided to see how much GPH medical foods cost related to that. Can you go back to the previous slide, please? I was talking yeah, this is a slide. Sorry, I was talking about so these are the three comparisons for the USDA costs. How the thrifty plan? What the thrifty plan? Sorry, the liberal plan is the highest plan, and I wanted to see how much do next click, please. How do medical foods cost compare to this? For the next slide, this is a cost comparison of low protein modified foods, what they cost to the patient. Can you go back, please? Previous slide. There's a slide missing of my graph. Very important slide is missing. Okay, keep going. I think that there's a slide which I would like to show for the cost. Megan, go to the next slide, please. Yeah, so this is the cost comparison of low protein modified foods and the cost.

Rani Singh - **54:21**

They were 141% more than the real food cost. The affected families with metabolic formulas, they are financially straight, and we give about $150 for those costs to our patients. We don't have the exact cost at this time, but we are going to study the patterns, how the families are ordering these foods, and we'd be able to report for that later. Next, please. Okay, now, Megan, I need to show a very important slide. I'm sorry, how can I send that? I can take over this. Share? Yes, share. Okay, let me see. I apologize. I don't know if it will show on my screen. Do you see the slide?

Megan Lyon - **55:19**

We do see the notes version, yes.

Rani Singh - **55:22**

You do see the slide?

Megan Lyon - **55:24**

Yes.

Rani Singh - **55:25**

Very good. Okay, so this is the cost side, average annual cost side cost prescribed medical food. What we did was we took 103 prescriptions, actual prescriptions of medical food, and divided them the same as the USDA groups. Adults, 18 and older, children about 31 of those, and then the infants less than five years of age. What we saw, this was based on the actual prescription by the dietitians, the Npku patients only. We have done this because I have saw no actual cost data calculated on the real prescriptions. It's about 3893 for medical food cost for infants, 10,000 for children, and about 21,000 for adults. On the right, you see medical food plus low protein modified food cost two together. The cost would be around $34,744 if we combine. There was no difference in low protein modifieds in age groups because what was interesting was we allow $150 voucher.

Rani Singh - **56:58**

All the three ages were using all of it about the same cost, price per year. If were to go to policymakers and they wanted in the state to say what the cost was based on. This cost is the price we used was actual prices which are posted for institutional price plus a 50% markup. So these are with the markup prices. These are very real prices, what the cost actually would be. The cost is about $24,744 a month. You see the GPH medical foods cost plus low protein fibs is nearly three to four times the monthly cost of the USDA liberal plan. I think we will publish this data now as we move forward and add more for other disorders too. This is the beginning and I did want to share with you and you could use this numbers and I'll be happy to share them with you if you do need to need them for any policy issues.

Rani Singh - **58:07**

The next slide is our cost, which I've already gone over the low protein modified cost. If the patients were using the about 141%, I'll now move quickly. I'm sorry, this was very important to me but I say that this is much lower cost than the drugs. This is directly from drugs.com, the cost and you can see that the drugs are eight to ten fold cost from GPH medical foods and yet they're all covered. We can afford it in this country. I'm sure we can afford the medical food if we pay attention to that. The next one is so I wanted to see how are we doing with our policy dilemma? Food is we feel food at this time is a responsibility of consumer with no state reimbursement policies. They are typically covered by insurance company we are state legislative mandates which are all over the place.

Rani Singh - **59:16**

You already heard that. I don't think I'll spend too much time since I'm running a little behind, I'll just kind of mainly these are the facts that there's a variety of different things going on. Newborn screening was started so that everyone could be treated early. Is this happening for everyone? I want to emphasize when I sit and reflect on my career, I say no. It doesn't feel good to feel that at this stage and this is going to have an impact on our outcome of our patients. Does this negate the effect of newborn screening for some despite proven benefits with interventions? I think we need to study those things. We need to see and this MMT four P program I think will be at least shedding some light on. We hope to shed some light on that and I think I know personally, both policymakers at federal and state levels recognize that the change is needed.

Rani Singh - **01:00:12**

My question is how do we work together to navigate through this? 100% of our families have access to care in this country like many other countries. There's no reason in the United States we shouldn't be able to do that. What I did again I won't spend too much time. I want to acknowledge my friend Kathy Camp. Dr. Barry and Kathy Camp are two partners in crime who have taught me a lot in this area and have inspired me. Kathy is a retired digestion. Now, I've just summarized what has happened legislatively in this field. Medical food equity equit has come and gone, and I'll talk a little more about it. There's a lot of advocacy through professional organization. I think National PKU Alliance, Nord have played a huge role we worked on. I personally had the honor to chair the consensus statement for NIH on PKU in 2000 and also having attended as a Pi for CERN, the Secretary's Advisory Committee, they are in huge support.

Rani Singh - **01:01:24**

They wrote the letters and the Secretary of Health. This is the last response we have in December 14, 2010. I'm going to click now. I have the control, so I should be doing this now. As of 2023, federal Employee Health Benefit program now covers medical food for IMD regardless of age. We are starting to make some progress with all this. Okay, so now I want to end my talk by saying that Medical Food Equity Act of 2023 has a potential for closing gaps. It's a federal legislation requiring coverage of medically necessary nutrition for patients with specific inherited metabolic and genetic GI conditions for federal health programs. We have precedent TRICARE and federal Employee Health program for IMD for all ages is there and there's bipartisan endorsement. I think we all need to be educated and be aware about all this to see how we can move the needle to take care of our patients and the impact on our patients.

Rani Singh - **01:02:36**

With that, I say let's all stay engaged. I use this flight for teaching medical students and my nutrition students. I end by saying medical food is a right and not a privilege. I personally want to thank MNT 14, Saran Grang, project manager Kristen Narlo and all the dieticians, clinical dietitians who work on our team. I want to thank everybody for their participation and helping us make this program a success. So thank you. Sorry I went a little over.

Megan Lyon - **01:03:16**

It is absolutely okay. I know that we are at 01:00 now, so we will be respectful of everyone's time and say thank you so much for joining the webinar. If you do have any questions, please feel free to reach out to either myself or Dr. Singh. We will be posting the recording of this webinar as well as the policy brief on the Hub. We will send out an email shortly. Thank you all so much for joining. Have a great day. Bye.