

NYS Medicaid Drug Utilization Review
Board Meeting
December 15, 2022

Douglas Fish: Good morning, everyone. I'm Dr. Douglas Fish, I am the Drug Utilization Review or DUR Board Chairperson and it's my privilege to call to order the December 15th, 2022, meeting of the DUR Board. I would like to welcome everyone who is participating today whether on-site here in Albany or other remote sites or participating via audiovisual. Just a few logistical items. As we begin as usual, today's meeting is being webcast over the Internet. The webcast will be archived on the DOH website, posting of the archived webcast to the DOH website usually takes place within 1 to 2 business days from the day of the meeting. And the archived webcast will also include the information along with the power point slides that will be displayed on the screen throughout the meeting. For those actively participating in today's meeting including our Board members, our support staff and public speakers, please remember to keep your microphones or audio device on mute until such time as you are providing comments, speaking, or have questions, so that we can minimize any background noise. As you've learned, we are now meeting in person and are operating out of our four locations today; here in Albany, Rochester, Buffalo, and New York City, so we will be navigating this logistical challenge as we go through the presentations and through our discussions. So, at this time I'll turn it over to Kim Leonard. She the Medicaid Pharmacy Director for introductions her opening comments.

Kimberly Leonard: Thank you. Good morning, everyone. Thank you for taking time. we apologize for the delay, but we appreciate your patience in sticking with us. So, today's meeting, as Doug said is being hosted at four locations, and I think in terms of roll call it will be easier if we go by locations to do the attendance. So, I think we'll start with Buffalo. And if Dr. Wooldridge, if you could say hello and also introduce yourself.

Dr. Wooldridge: Can you hear me? I'm Jamie Wooldridge, I'm a Pediatric Pulmonologist at University of Rochester.

Kimberly Leonard: How about now? Dr. Wooldridge, can you hear us in Buffalo?

Dr. Wooldridge: Yes, you guys are back.

Kimberly Leonard: Oh, wonderful. I apologize everyone, oh what a morning. Okay. So, alright, so Dr. Wooldridge would you mind just doing a brief introduction for everyone here.

Dr. Wooldridge: Certainly, can you hear me?

Kimberly Leonard: Yes.

Dr. Wooldridge: So, I'm Jamie Wooldridge, I'm a Pediatric Pulmonologist at University of Rochester.

Kimberly Leonard: Thank you. And in Rochester, Dr. Lavigne, can you do an introduction?

Dr. Lavigne: Sure, I'm Jill Lavigne, I'm a Professor at Pharmacy Practice and Administration at the Wegman School of Pharmacy.

Kimberly Leonard: Okay, thank you for joining today. And then in New York City, I think, Dr. Anzisi can you start introductions and then pass the mic around the room?

Dr. Anzisi: Lisa Anzisi, Pharmacist Manager at NYU Clinically Integrated Network.

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Dr. Asa Radix: Asa Radix, Infectious Disease position at the Collin North Community Health Center in New York City.

Reverend Dr. Phillip Fleming: I'm Reverend Dr. Phillip Fleming with Fountain House as a peer specialist, certified in the State of New York.

Kimberly Leonard: Thank you for joining this morning. And then in Albany, I think we're going to start with you Mike, if you don't mind.

Dr. Eglowstein: My name is Marla Eglowstein, I'm a retired obstetrician, and I also represent the National Multiple Sclerosis Society, as a consumer.

Tara Thomas: Good morning, Tara Thomas, I'm the Director of Clinical Pharmacy Programs at CDPHP.

Jim Hopsicker: Morning, Jim Hopsicker, VP Health and Pharmacy Management for MVP Pharmacist.

Brock Lape: Brock Lape the consumer representative and engineering.

John Powell: John Powell, Deputy Superintendent for Health at the Department of Financial Services.

Pete Lopatka: Pete Lopatka, Actuary at Health First.

Michael Pasquarella: Michael Pasquarella, Director of Pharmacy Ellis Hospital.

Kimberly Leonard: Okay. And then we'll move to the Department of Health staff.

Monica Toohey: Hi, this is Monica Toohey, New York State Pharmacy Manager.

Barb Rogler: Hi, Barb Rogler, University of Buffalo.

Bob Correia: Bob Correia, Pharmacist Department of Health.

Tony Merola: Tony Merola, Department of Health.

Kimberly Leonard: Alright, thank you everyone. Before I turn the meeting over to Tony, I just have a few items. We want to first of all thank Casey Quinn who has served on the DUR Board as a Health Care Economist, we appreciate his dedication to the residents of the State of New York, and he will be missed. He has moved on, so he will be a hard person to replace. Second, we have appointed some new DUR Board members which is exciting. Beginning with Reverend Dr. Phillip Fleming who is with us today in New York City, welcome. He will be serving as one of our consumer representatives, and we appreciate his willingness to serve. In addition, we're going to have a new Nurse Practitioner, Jonathan Mizgala has been appointed to fill the vacant Nurse Practitioner/Midwife seat. And Dr. Andrea Leeds is a physician who will be joining, and she will be located down in New York City. And with that, I'm going to turn it over to Tony to get things started. He will do an overview of the agenda and order of the day.

Tony Merola: Yes, so thanks Kim. I'm going to have Georgia just bring up the agenda. I'm just going to do this quick knowing that we're a little behind scheduled and I apologize for that. So, on today's agenda there is actually four drugs under the Drug Utilization section. There will be

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three presentations, two of those drugs Risdiplam and Nusinersen are in the same presentation. So, there's actually three presentations, four drugs in the Drug Utilization area and knowing that we're a little behind schedule, if we can do the pharmacy program updates by 2:00 we'll do that. If not, those will probably end up falling off today and we'll put them on another agenda. I think that's probably the game plan for today, that we get through our Drug Utilization reviews and try to stick that 2:00 stop time, okay. With that said, we can begin the public comment period. So, Georgia if you can bring up the speaker list itself and then we'll have to unmute the speakers, but we'll do an audio check here. Maybe I should do an auto check now. So, I'm going to pick on Rae Ann Maxwell, Rae Ann can you hear us? Rae Ann.

Rae Ann Maxwell: Yes, I can hear you.

Tony Merola: Okay, loud and clear, thanks. Okay so now, I can give you...

Rae Ann Maxwell: I was probably unmuted the same time you guys were unmuting me, so I apologize.

Tony Merola: So, now I'm going to go ahead with the instructions. Rae Ann as you can see, you're first on the list here that's why I just wanted to do an auto check with you. So, at this time, scheduled speakers will present public testimony to the Board, public comments are limited to specific topics on the agenda, must be no longer than 2 minutes. Please keep in mind that the written testimony has already been provided to the DUR Board, so we ask that speaker highlight any public comments and stay within the allotted two-minute timeframe. Before introducing Rae Ann, we would just ask the speakers to introduce yourselves, noting who you work for, or who you are representing today and if you have any financial relationships, interests or conflicts of interest pertaining to today's proceedings. After you do that, we will start the two-minute time clock and you will have your two-minutes to provide your public comments. And then we will open it up to the Board to see if they have any questions. And then, we would move onto the next speaker. So, with that said, first speaker Rae Ann Maxwell, the microphone is yours.

Rae Ann Maxwell: Thank you, and good morning. My name is Dr. Rae Ann Maxwell, I am a medical account director for Biogen the manufacturer of Nusinersen or Spinraza. Spinraza was approved in December of 2016 for the treatment of spinal muscular atrophy known as SMA in both pediatric and adult patients based on the strength of the clinical data and the overall clinical trial program. At that time, the language in the first PI was based on both overall findings of the controlled trial in infantile onset and the open label uncontrolled trials which included teens, adults, and pre-symptomatic infants providing support for the effectiveness of Spinraza across the range of SMA patients and the early initiation of treatment. Over 6 years later, and with more than 13,000 patients treated worldwide with Spinraza, there is extensive clinical evidence of the efficacy both from our 5-year long-term extension trial SHINE as well as extensive real-world experience with a wider range of symptomatology in adult patients, as well as an established long-term safety profile. SMA is a rare genetic progressive and potentially life-threatening neuromuscular disease that leads to degeneration and loss of motor neurons in the spinal cord and lower brain stem resulting in severe and progressive muscular atrophy and weakness. Because the clinical effects of SMA are substantial, even disease stabilization or small improvements in motor function can have a significant impact on the patient's quality of

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life. Spinraza has shown long-term improvements in both motor function and survival and in doing so transformed the course of SMA. Biogen is committed to further research in the SMA populations and the change in landscape in SMA with ongoing clinical development programs such as Respond, Ascend and Abode which are clinically available on clinicaltrials.gov. Currently in the US, there are no approved therapeutic guidelines available for SMA. The landscape of available treatments has increased for the betterment of individuals with SMA, and provided opportunity for patients, caregivers and providers to discuss options that suit individual's clinical need. Biogen supports open and equal access of all SMA treatment modalities available to the SMA community. Thank you for your time and attention.

Tony Merola: Thank you. Any questions for Rae Ann? Okay, hearing none, thank you. The next speaker is Denise Cody.

Denise Cody: Denise Cody and I'm here on behalf of the medication known as Spinraza. First of all, I'd like to thank you all for the opportunity to speak on behalf of the medication known as Spinraza. Before each injection, I am required by the FDA to have several blood tests and a urinalysis. Some of the side effects of Spinraza include but are not limited to the risk of bleeding, kidney damage, lower respiratory infection, fever, constipation, headache, vomiting, back pain and post lumbar puncture syndrome. As I stated, these tests are required by the FDA. They are not all of the possible side effects. I was diagnosed with SMA 3 when I was 14 years old, and I have gotten progressively worse over the years. I got my first manual wheelchair in 1985 as walking became more difficult. In 2005, I got my first power wheelchair. Standing, walking, and doing most anything physical had become very painful and excessively hard. Before Spinraza, I was unable to talk, stand, pick up my feet off the floor, do ordinary household chores, and basic daily living skills. I became very lethargic and depressed. Life had become very challenging. In 2018, my neurologist asked if I wanted to try Spinraza. She explained the side effects at the possible outcome of treatment and said, "Not all results are the same." The FDA also states that. In June of 2018, I was retested for the diagnosis of SMA 3 with blood tests. I started my dosing on the 14th of June 2018. I am now living alone and beyond grateful to say that I am now able to live life to a fuller extent. Since being on Spinraza, I can lift my feet up off the floor, kick them up, stomp on the ground, and also kick them outward. I cook, clean, shower and continue with my every day daily living skills. My depression has subsided, and energy level has increased. I am hopeful to continue with my Spinraza injections, as the amount of confidence that I have gained is tremendous. If I weren't able to receive Spinraza, it would be detrimental to my wellbeing both physically and mentally. I am alive and thriving because of Spinraza. Thank you so much for your time.

Tony Merola: Thank you Denise. Any questions for Denise? Okay, next speaker Kathleen Maignan.

Kathleen Maignan: Good morning, everyone and thank you for the opportunity to provide testimony on Evrysdi. My name is Kathleen Maignan, I'm a Medical Executive Director at Genentech with which I have a financial relationship. Evrysdi I'm sorry is a disease modifying agent indicated for the treatment of spinal muscular atrophy SMA in pediatric and adult patients. SMA is a progressive debilitation neuromuscular disease characterized by progressive muscle denervation, atrophy, overall weakness, loss of motor function, and ambulation. Evrysdi is the first and only at home treatment for SMA and is taken orally or by feeding tube in liquid form

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each day. Evrysdi was approved based on a trial program designed to reflect the real-world population of patients with SMA. Across clinical trials, safety in ages 2 months to 60 years old, and efficacy in ages 2 months to 25 years old, are being studied in more than 450 patients with infantile onset SMA type 1 or later onset type A, SMA type 2 or type 3. The population includes patients with different levels of disease severity and functional ability. Efficacy was demonstrated across three pivotal trials. Participants who received Evrysdi experienced benefit in motor function for type A, type 1, type 2, and type 3 SMA. Safety was evaluated across four clinical trials that includes infants, children, and adults with SMA, and those have been previously treated with approved or investigational therapies. The most common adverse reactions in later onset SMA were fever, diarrhea, and rash. Additional adverse reactions were reported in over 10% of early onset SMA patients; upper/lower respiratory tract infection, constipation, vomiting, and cough. The safety profile for pre-symptomatic SMA patients is consistent with the safety profile for symptomatic SMA patients. Based on animal data, we know that this may compromise male fertility. Thank you. And if you'd like, I can move onto Ocrevus.

Tony Merola: Let's see if there's any questions on Evrysdi.

Kathleen Maignan: But this may compromise male fertility.

Tony Merola: I think we can move onto Ocrevus.

Kathleen Maignan: Thank you. So, Ocrevus the first and only disease modifying therapy indicated for the treatment of both relapsing forms of multiple sclerosis and primary progressive multiple sclerosis, PPMS in adults. MS is a chronic degenerative disease of the central nervous system and the most common cause of nontraumatic disability in young adults worldwide, affecting nearly 1 million people living in the US. Ocrevus was studied in two identical double blind relapsing MS studies vs. Interferon. The study was called Opera 1 and 2. The Opera's trials demonstrated the efficacy of Ocrevus in reducing MS clinical disease activity, and MRI measures in patients with RMS. Trial data showed efficacy superior to Interferon with a similar safety profile through 96 weeks. These results led to the approval of Ocrevus for the treatment of relapsing forms of MS. In patients with primary progressive multiple sclerosis, Ocrevus is the only FDA approved DMT proven to slow disability progression. Ocrevus was studied in a phase 3 randomized double blind parallel group placebo-controlled study oratorio. Oratorio demonstrated that compared with the placebo, Ocrevus significantly reduced clinical disease activity, and MRI measures in patients with PPMS. Ocrevus has a well-established safety profile with over 7 years of clinical trial and real-world experience. Warning some precautions include infusion reactions, infections, and malignancies. In phase 3 trials the most common adverse events were infusion related reactions and infection. Rates of other common aids were similar between Ocrevus and the placebo. You can see Ocrevus full prescribing information for more detailed information and additional safety info. Thank you.

Tony Merola: Thank you. Any questions? Hearing none, next speaker Biran Patel.

Biran Patel: Good morning. my name is Dr. Biran Patel and I represent the Medical Affairs Division at Bluebird Bio and I do have a financial relationship. I appreciate the Board's time this morning to review information of Zynteglo. Beta balancing is a rare genetic blood disease

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caused by mutations in the beta-globin gene and is characterized by reduced production of the functional beta-globin protein necessary to form adult hemoglobin. Anemia can range from mild to severe with Transfusion Dependent Thalassemia or TDT representing the severe form and requiring patients to obtain regular transfusions, typically every 2 to 5 weeks for survival and resulting in both patients and their caregivers tethered to the healthcare system for life. In addition to the regular transfusions, iron chelation therapy is critical to mitigate the toxic effects of iron overload related to regular transfusions. Median age of death among known reported deaths was 37 years of age in the US with the latest US prevalent approximated at roughly 1,000 to 1,300 patients. Zynteglo is a onetime autologous hemopoietic stem cell-based gene therapy indicated for the treatment of adult and pediatric patients of beta thalassemia who require regular red blood cell transfusions. Zynteglo adds functional copies of a modified beta-globin gene into the collected patients hemopoietic stem cells through transduction of the patients CD34 positive cells with the BP305 Lentiviral vector. These trans new cells engraft in the bone marrow and differentiate to produce red blood cells containing the modified globin protein, increasing functional adult hemoglobin A and total hemoglobin. The primary endpoint used for the two phase 3 studies is proportionate to the patient's achieving transfusions. The majority of a valuable patients 89% in the pooled phase 3 study, the chief transfusion dependents regardless of age, sex, race, or genome type. The median time to last transfusion after Zynteglo administration was approximately 1 month, and all 32 patients-maintained transfusion independence through the last follow up for up to 3 ½ years in the pooled phase 3 studies. For safety information, please refer to the provided package insert for Zynteglo. Again, we appreciate your time and consideration for the review of Zynteglo by the Board. Thank you.

Tony Merola: Any questions? Hearing none, we'll move onto Craig Butler.

Craig Butler: Good morning. my name is Craig Butler, I am the National Executive Director of the Cooley's Anemia Foundation and I have no conflicts. The Cooley's Anemia Foundation is a national nonprofit based in New York City which was founded in 1954 and is dedicated solely to issues related to the blood disorder of thalassemia. Thank you for this opportunity to comment on your consideration of Zynteglo. Zynteglo has been approved by the FDA, it's a gene therapy process to treat people with Transfusion Dependent Beta Thalassemia and as such, it offers people born with thalassemia the opportunity for a cure. My colleague, Eileen Scott will talk more about what it means to live with thalassemia but in brief, Transfusion Dependent Thalassemia requires lifelong blood transfusions every 2 to 4 weeks starting in infancy. In addition, iron overload from these transfusions threatens to destroy the heart, liver, pancreas, and other organs, and so a difficult process of iron chelation is required daily to try to get rid of this excess iron and prevent a wide range of complications. Thalassemia care is inordinately expensive. A person with thalassemia who does not have adequate health insurance faces crushing expenses, far beyond the reach of most people, and even when a patient has adequate insurance, the cost of the insurance provider is substantial. That cost very significantly from patient to patient based upon their transfusion frequency, chelation needs, and care for specific thalassemia related complications. However, it is not unusual for an insurance provider to absorb annual costs of more than \$500,000 and often much higher for a person with Transfusion Dependent Thalassemia. A curative option would mean long-term financial savings in terms of thalassemia care for a patient. Beyond the physical and health issues related to thalassemia, this enormous cost of care impacts patients and their families in terms of career

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and life options. They often must make decisions based not on what would be their preferred choice, but on what will enable them to obtain appropriate insurance or to stay in an area which is geographically near one of the few thalassemia treatment centers in the nation. While I have been pointing out the financial benefits of the curative option, the foundation firmly believes that this curative option should be made available primarily because of the difference it can make in the health, life and future of those born with this burdensome and challenging disorder. Thank you.

Tony Merola: Any questions for Craig? Okay, and then our last speaker is Eileen Scott. Georgia, can you check if Eileen is unmuted, please? I think she's connecting right now. So, Eileen can you hear us? We don't have a good audio connection with you right now. You believe it might be an issue on your end. Craig do we still have a connection with you?

Craig Butler: Yes.

Tony Merola: Would you be able to provide Eileen Scott's testimony if you have a copy?

Craig Butler: Yes, I sure can. Okay, so Eileen thanks you for the opportunity to comment on your review of Zynteglo. Living with thalassemia can be very challenging, stressful, and difficult for the patient as well as for their families. Patients with severe forms of thalassemia require regular red blood cell transfusions as often as every 2 to 4 weeks as well as a daily chelation process in order to avoid the deadly complications of iron overload. As you can imagine, this is not an easy way to live. Having to commit to one full day every 2 weeks to be in a hospital for a transfusion affects so many things in a patient's life. Little things that are taken for granted by most people become huge obstacles for our patients. Missing school, and after school activities, play groups, sports programs, etc. For parents that are taking their children for treatment, they are dealing with missing work, possibly not getting paid for that day, being able to work a full-time job and the expenses associated with their children's care. In addition to the blood transfusions and chelations, patients require comprehensive care exams such as cardiac evaluation, MRIs of the heart and liver, glucose tolerance test, bone density exam, ophthalmology, and audiological evaluations to name just a few. More expenses and more time off from work or school. Our adult patients struggle with their career choices and employment as well. For many, it is impossible to manage both employment and all of the medical appointments. It can be very difficult to pay their medical bills and living expenses and the emotional toll of all of this is overwhelming. Having a cure as an option for thalassemia would be the answer to many patients hopes and dreams to not need a blood transfusion in order to stay alive. It's hard for them to imagine. What a life changing difference this would make for those who are eligible. A cure, it's all every patient in general has hoped for. I hope that all eligible patients will not be denied this opportunity for a new life. Thank you.

Tony Merola: Thanks for substituting Craig. Any questions at all from the DUR Board members? Okay, that concludes our public comment period Doug.

Douglas Fish: Okay, thank you Tony and thank you to all of our speakers, we appreciate it. I'm just noting that when we do open up for comments and questions, we'll probably need to give a little bit more time just for people to respond given they have to get up and unmute at the

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remote sites and so on, in case there are questions. Next up, I think we're ready for our first presentation. And Spinal Muscular Atrophy.

Tony Merola: One thing to mention Doug, that we didn't have any repeat recusals from our DUR Board members today, so I just wanted to mention that. And I think we'll probably stick with the Zynteglo or betibeglogene theme here and send it over to Barb Rogler.

Douglas Fish: Very good. Barbara.

Barbara Rogler: Thank you very much. It's time to take a deep breath. So, today we'll talk about betibeglogene which is also Zynteglo, beti-cel. It was also known in clinical trials as beta-globulin BB305. The purpose of our presentation today is to provide recommendations on the management of betibeglogene which I will refer to as beti-cel going forward to the New York State Medicaid Program. A very brief background. Adult hemoglobin which was also referred to HbA consists of 2 alpha-globin chains 2 beta-globin chains and in each of those complexes with the 2 alpha and the 2 beta-globins make up adult hemoglobin. That combined to 1 molecule of oxygen. Adult hemoglobin represents 98% of all adult hemoglobin. Thalassemia is an autosomal recessive inherited defect that affects the production of hemoglobin. Beta-thalassemia are monogenic single gene disorders caused by a beta-globin gene mutation which is also referred to as HBB mutation. The beta-globin mutation results in either reduced production which is referred to as a B⁺ or no production B⁰ a functional beta-globin in the adult hemoglobin leading to ineffective erythropoiesis, hemolysis, and anemia. Beta-thalassemia is caused by more than 200 mutations in the beta-globin gene. Beta-thalassemia are characterized as Beta-thalassemia major, intermediate, and minor. Characterizations have since been modified to include transfusion dependent and non-transfusion dependent. Just to summarize, so, we're all on the same page, beta-thalassemia is a rare genetic disorder characterized by a reduced or no production of beta-globin protein of the adult hemoglobin. This leads to the ineffective red blood cell production and profound anemia. The most severe form is the transfusion dependent thalassemia.

With the background – in 2008 the World Health Organization reported that approximately 40,000 infants are born annually with beta-thalassemia, and an estimated 25,000 infants have transfusion dependent beta-thalassemia. The highest prevalence is observed in the Mediterranean, the Middle East, the Indian subcontinent, East and Southeast Asia. In the United States, we are unsure of the true prevalence. Numbers do range. There was a survey conducted by the hospitals in the Thalassemia Western Consortium, and they reported approximately 1600 patients, but then when you look at others, they reported about 2600 patients in the United States have beta-thalassemia. In other literatures, there is a potential of the patients that have beta-thalassemia approximately 50% could have Transfusion Dependent Beta-thalassemia. The current standard of care which we heard this morning is regular red packed blood cells transfusion. The regular red blood transfusions often lead to iron accumulations that require iron chelation therapy. Transfusion induced iron overload can cause organ damage and is a major cause of morbidity and mortality. The only curative treatment for Transfusion Dependent Beta-thalassemia is an allogeneic hematopoietic stem cell transplantation. For patients who do receive the best results occur in patients less than 14 years of age and with a human leukocyte antigen identical sibling donor. For patients with

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Transfusion Dependent Beta-thalassemia would be considered a candidate for stem cell transplant but do not have a suitable donor, beti-cel is now an option.

I would like to provide just a brief overview of Zynteglo or beti-cel, manufactured by Bluebird Bio, the FDA approved indication per the package information is treatment of adults and pediatric patients with beta-thalassemia who require red blood cell transfusions. It was FDA approved on August 17th, 2022. It is administered via an IV infusion by a trained practitioner, and at Zynteglo qualified treatment center, is for autologous use only. Its mechanism is of an action. It is an Ex vivo gene therapy that requires the removal of the patient's hemopoietic stem cells followed by myeloablative conditioning and the infusion of the autologous CD34+ stem cells genetically modified with the BB305 lentiviral vector that contains functional copies of the engineered beta-globin with threonine to glutamine substitution at position 87. The dose is intended for a one-time administration. The minimum recommended dose is 5×10^6 CD34+ cells per kilogram. I'm going to stop there for a minute with the Board. I'm very sorry to do this, but do you have questions? That was a lot to go over, just the basics of this gene therapy. This is now an alternative to stem cell transplant for these patients. It is the first gene therapy to be approved. It is autologous. It requires patients who are clinically stable that can withstand not only the harvesting but also myeloablation. These patients must receive this drug at very few beta-thalassemia centers here across the United States. So, I do like to open it now for questions if you did have any. I know that's out of character but there's so much here.

Marla Eglowstein: It's really not a question but a comment. This is amazing. This is a miracle.

Barbara Rogler: It is very exciting therapy and it's very exciting that we're now talking about gene therapy, and we'll talk more about it. So, thank you for letting me stop there for a minute because I also need to catch my breath and refocus myself. So, I need to be honest. So, the use of beti-cel in special populations. Pregnancy, the drug has not been studied in pregnant persons. There is no information on lactation. Genetics and clinical trials individuals greater than 50 years of age were excluded. Pediatrics, the safety, and efficacy in pediatric patients less than 4 years of age have not been established. It cannot be used in patients with HIV. The drug has not been studied in patients with either renal impairment or liver impairment.

Now these next grouping of slides, what I'll do is go through the published clinical trials. So, going through the phase 1, 2, clinical trials. There were 22 patients. The two open label phase 1, 2 clinical trials were identical designs that were conducted in patients with Transfusion Beta-thalassemia. In the clinical trials, and this is important, Transfusion Dependent Beta-thalassemia was defined as a history of at least 100 ml/kg/year of packed red blood cells or greater than equal to 8 transfusions of packed red blood cells per year for the prior two consecutive years. patients with treatment dependent thalassemia were less than equal to 35 years of age and enrolled regardless of the genotype. So, the two trials were HGB 204 and 205. The 204 trial was patients had to be greater than equal to 12 years of age. For patients in the 205, patients had to be greater than equal to 5 years of age. The primary endpoint which we will focus on today was number of participants who achieved transfusion independence. Transfusion independence was defined as a weighted average hemoglobin of greater than 9 gm/dl without any packed red blood transfusion for a continuous period of greater than equal 12 months post infusion starting 60 days after the last packed red blood cell transfusions.

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Phase 1 and a half trials continuing for the 13 patients who were non B⁰ genotype, 12 patients stopped receiving packed red blood cell transfusions. The median duration of transfusion independence was 26 weeks. It ranged from 15 to 42 months. One patient did not achieve transfusion independence, the primary endpoint of the study. For the 8 patients who were B⁰ genotype, these were the patients who do not produce hemoglobin, and one patient was homozygous for IVS-I-110 mutation. For those 6 patients their median annualized transfusion volume decreased by 73%. 3 patients did discontinue red blood cell transfusions for 14 to 20 months.

Moving onto the phase 3 clinical trial. This had an n of 23 participants. This was an open label phase 3 clinical trial and again they were assessing transfusion independent beta-thalassemia trial for patients that were non B⁰ B⁰ genotype. Patients with B⁰ B⁰ genotype and patients that were homozygous for IVS-I-110 mutation were excluded from the study. So, these were patients who could produce hemoglobin. 23 patients received beti-cel, the final age distribution was 8 patients for less than 12 years of age, 6 patients were 12 to 18 years of age, and 9 patients were greater than equal to 18 years of age. 22 patients were evaluated, and 1 patient was excluded from analysis. 20 of the 22 patients, about 91% of patients achieved transfusion independence. The mean duration of transfusion independence was 20.4 months. It ranged from about 16 months to 21 or 22 months. In the cohort of 12 years of age to 50 years of age cohort 14 of the 15 patients achieved transfusion independence. And in the cohort of less than 12 years of age, 6 of the 7 patients achieved transfusion independence. I also need to mention that there's another trial going on now it closed at the end of this November. It is HGB 212 and that will look at the combination of patients both non B⁰ B⁰ genotype and also B⁰ B⁰ genotype.

So, in summer, Zynteglo is the first cell-based gene therapy approved by the FDA for the treatment of adult and pediatric patients with beta thalassemia who require regular red blood cell transfusions. The aim of beta cell therapy is to achieve long-term treatment independence for patients with Transfusion Dependent Beta-thalassemia. For the two identically designed phase 1, 2 clinical trials 68.2% of patients achieved transfusion independence. For the phase 3 trials, approximately 90.9% of patients evaluated achieved transfusion independence. Also, we need to note that there are long-term follow ups for the safety for subjects and Transfusion Dependent Beta-thalassemia treated with Ex vivo gene therapy, trial has been initiated and will follow patients for an additional 13 years to monitor for safety and efficacy.

Our recommendations are for coverage parameters are for patients who are less than 50 years of age, if the patient is less than 5 year of age the patient must be greater than equal to 6 kilograms, and it is anticipated that the minimum number of cells required to initiate the manufacturing process can be collected. The patient has a diagnosis of Transfusion Dependent Beta-thalassemia. We use the definition of Transfusion Dependent Beta-thalassemia that was used in the clinical trials. The patient is a candidate for allogenic hemopoietic cell transplantation but is ineligible due to the absence of a donor. Those are the three recommendations that we have from the University of Buffalo.

Douglas Fish: Okay, thank you Barbara for that presentation on betibeglogene autotemcel. That was a lot, right? There's a lot in there. A lot just to pronounce it. So, we'll open it up for questions, comments, discussion from the DUR board members. John Powell.

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John Powell: Barbara you mentioned that this is done only in a few places in the country. Do you know how many places do this and is it done in New York at all?

Barbara Rogler: I do not have the total of the number of Zynteglo qualified treatment centers. Yes, there is a qualified treatment center located in the metro area. That qualified center did participate in clinical trials.

Douglas Fish: Metro New York City.

Barbara Rogler: Yeah, what did I say? Oh, just metro, oh sorry, I just figured everybody know metro was New York City. Sorry.

Douglas Fish: Maybe they do, I don't know.

Barbara Rogler: Oh, 12 centers, thank you Jim. There are others on the east coast, Philadelphia is the next one.

Douglas Fish: That would be on their website, I'm not sure of the exact number. Jim Hopsicker thinks perhaps 12. Thank you. Other questions?

Jamie Wooldridge: This is Jamie Wooldridge. So, the third recommendation, I want to make sure I understand that. So, are we saying that for these patients the first choice of treatment would be stem cell transplant and only if they're ineligible because of absence of a donor would they then get access to this drug? Because it seems like this drug actually would be more beneficial than a stem cell transplant or as I misunderstanding that?

Barbara Rogler: Really, when you look at the guidelines, I didn't take a full review of the guidelines with this presentation is if there is, it is proven that for patients that stem cell transplant is the first course, but I must be honest with you Jaime, majority of patients do not have an acceptable donor. And again, it's really the highest level of success are in those patients less than 14 years of age. But the guidelines do recommend that as the first line of therapy.

Jamie Wooldridge: Okay, so these recommendations follow the guidelines.

Barbara Rogler: Yes, thank you.

Douglas Fish: And again, these are the University of Buffalo to DOH recommendations, you'll hear about the DOH recommendations in a little bit. Michael.

Michael Pasquarella: Yeah, this is just dovetails off that question. So, if I understand these studies correct, these folks remain transfusion independent for up to 20 months or longer?

Barbara Rogler: In the published literature, we know that. There are, there soon will be additional data that are published that show that the durability of this drug is longer. But this was in the clinical trials.

Michael Pasquarella: And once we get to that review of longer, when these patients are followed for a longer period of time, is this more just a bridge to the transplant potentially? If they relapse?

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Barbara Rogler: No, this is a one-time dose. These patients should technically in the best-case scenario be transfusion independent the rest of their life. But it should be the other way around as you said, it is if these patients don't have the ability to have a stem transplant with an acceptable donor, then they move onto the beti-cel. It is now the second option. So, the reverse of what you said.

Michael Pasquarella: Thank you.

Douglas Fish: Just for the record, the audio that was Michael Pasquarella asking the question. Other questions? Go ahead please and just state your name.

Jill Lavigne: I'm Jill Lavigne. Did you look at the ICE report when you were preparing this? I'm just wondering if that added to your recommendations.

Barbara Rogler: Yes, I did review the ICER report.

Jill Lavigne: These recommendations, they don't seem to be the same as those from ICER, so I'm just wondering.

Barbara Rogler: ICER is a nonclinical body. They are a nonprofit. I did read their guidelines. they do not want any clinical criteria on this product. That was ICER's recommendation. They did show that the product was cost effective. So, that is their recommendation. But again, ICER is a nonclinical body. So, I just want to clarify that.

Douglas Fish: Did that address your question Dr. Lavigne?

Jill Lavigne: Yes, thank you.

Douglas Fish: Okay, thank you. Other questions from our remote sites or here in the room? Okay, hearing none, do I have a motion to move to DOH recommendations which would be our next step. You'll hear from DOH recommendations to move to that section? Do I have a motion? Thank you. The motion was from Dr. Eglowstein, Tara, okay it was first and then Dr. Eglowstein seconded, okay, thank you, perfect. So, I'll turn it over to, do we have slides with the recommendations?

Tony Merola: Yes, we do. So, Georgia if you can pull up and Jackie can help you find those slides. So, these will be the DOH recommendation slides for betibeglogene or Zynteglo. They mirror the SUNY recommendations. So, they will look very similar. Here they come, okay. So, again betibeglogene its just our introductory slide, and then the second slide is just a clarification slide. So, the coverage policy will confirm FDA-approved use in accordance with FDA package labeling or compendia-supported use. So, that's our general policy. And then the next slide is the remaining slide. And there are the three recommendations. We put all three recommendations on the same slide, and they mirror the SUNY recommendations. So, I will read them, and we can discuss them individually if we need to, just as Jaime had a question on the last one Doug. So, let me just walk through them first, then we can regroup.

So, the first recommendation, the patient is less than or equal to 50 years of age. If the patient is less than 5 years of age, the patient weight must be greater than or equal to 6 kg.

2- the patient has a diagnosis of transfusion-dependent beta-thalassemia.

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3- the patient is a candidate for allogenic hematopoietic cell transplantation but is ineligible due to the absence of a donor.

Douglas Fish: Thank you, Tony. So, the floor is now open for further comments and discussion around these recommendations. As Tony said, it is similar to those that Dr. Rogler just presented. If there are no other questions or comments, we can move to a vote. We have been voting by...

Jamie Wooldridge: I hate to interrupt; this is Jaime again.

Douglas Fish: Oh, go ahead Dr. Wooldridge, go ahead.

Jamie Wooldridge: So, and this may not be the right forum, but number 3 is still confusing me because if I'm reading it correctly, we're basically saying, you first must try to go through stem cell transplant and run the risk of graft vs. host disease or we actually have a drug that we could treat you with and not have to have that side effect of graft vs. host. Am I correct? And is this something that the DOH is looking at? Do we have any idea?

Barbara Rogler: Jamie, I hear what you're saying with regards, but that is truly in the guidelines, the cure for beta-thalassemia. It's a stem transplant, right? And she's absolutely right, with the stem transplant you do run the risk of graft vs. host disease. But this gene therapy also has risks. You're monitoring this patient for 15 years, there is the potential for hematological cancers. We don't know the risk. But based on the guidelines, the only known cure right now is a stem cell transplant.

Jamie Wooldridge: Okay.

Barbara Rogler: From an eligible donor.

Jamie Wooldridge: From an eligible donor, okay. That helps. Thank you so much.

Douglas Fish: Yeah, I think that is an important point right, and its also how the studies were designed. So, this is in keeping with the criteria of the clinical trials supporting its approval. Other comments or questions?

Tony Merola: Any comments or questions from our New York City location? Yes, we can thank you.

Reverend Dr. Phillip Fleming: My question is how often is the drug administered?

Barbara Rogler: Once in a lifetime that's it.

Reverend Dr. Phillip Fleming: Once in a lifetime? Okay.

Barbara Rogler: Sorry, I missed the question. The one time and it's an IV and you have to take the patient's blood and mix it with this and push it back in the body.

Reverend Dr. Phillip Fleming: Okay, great. That's all I needed.

Douglas Fish: So, just to repeat that questions, it was how many infusions is this therapy, and it is one. One time. Any other questions from our remote sites or here in the room? Brock Lape.

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Brock Lape: Yes, I just had one question and maybe I missed this in your thing, just clarification, what if I'm 51 and I want to get this drug. Why is there such a limit on age? Maybe I missed it in the study, but could you just clarify?

Barbara Rogler: Yes, in the clinical trials people over the age of 50 were excluded. That's why. You know, when, I can tell you that we have had discussions with the providers down in New York City, and its important that these patients are clinically stable, and the one thing that the speakers really talked about today is with transfusion-dependent thalassemia, there isn't longevity. The average age that the patients live is 37. But in clinical trials in the clinical exclusions, it was for patients greater than 50 were excluded.

Lisa Anzisi: Just to amplify that, when I was a resident in Manhattan, we had a high population of people who were at risk for beta-thal because we had a lot of women that had recently immigrated from China and Hong Kong and it was considered to have, we couldn't look at all the different genes, we didn't have that ability yet, this was the late 80s. So, having beta-thal was considered a very near lethal condition. So, I think that there just weren't people that lived to be 50. So, that's probably why.

Douglas Fish: And also, just the prep for the infusion, the myeloablation, its rigorous, so part of that is taken into consideration when they look at the patient populations to give them the best chance of success.

Lisa Anzisi: Which is similar to what you have to do for a stem cell transplant also.

Douglas Fish: Correct, that's right. These are good questions. Other questions? Okay, so next we will vote on these recommendations, if there is no further discussion. And again, we are going to vote by consensus. But I think here in the room in Albany, what we can do is a show of hands, but first, is anybody abstained or not approve these recommendations, not in favor of these recommendations. So, anyone not in favor in the room. Anyone abstaining? Okay. No abstentions, no one is not in favor. Let's move to New York City where we have three DUR Board members. Is there anybody in the New York City site who is not in favor of these recommendations? Any abstentions? And again, as Tony noted, we have no conflicts of interest for our panels.

Lisa Anzisi: We're all in favor.

Douglas Fish: You're all in favor, thank you. We heard you, thank you. Now Buffalo we have one member.

Jamie Wooldridge: I'm in favor.

Douglas Fish: Thank you. Rochester are you in favor or not in favor or abstaining?

Dr. Lavigne: Yes, in favor.

Douglas Fish: Dr. Lavigne, we are having trouble hearing you. Can you turn on your mic and repeat again, please?

Dr. Lavigne: Yes, I am in favor.

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Douglas Fish: You're in favor, is that correct?

Dr. Lavigne: Yes.

Douglas Fish: I think we heard that correctly. I just want to double check Dr. Lavigne, you're in favor, is that right?

Dr. Lavigne: Yes.

Douglas Fish: Okay, thank you. So, this is unanimous, recommendations on the betibeglogene autotemcel. So, I think we're ready for the next topic for the next presentation, right Tony? So, we're going to do the Spinal Muscular Atrophy therapies and we went out of order just a little bit just to give Barb a break until we get to the hepatitis discussion here later. So, presenting is our Pharm D, Dr. Irene Riley, and the slides are up and let's just do an audio check for Irene.

Irene Riley: Hi, can you hear me?

Douglas Fish: Yes, very well, you're very clear.

Irene Riley: Okay, great. So, thank you. I'll be presenting on Nusinersen and Risdiplam, two drugs for the treatment of Spinal Muscular Atrophy. The aim of our review is to examine the utilization of Nusinersen trade name Spinraza and Risdiplam trade name Evrysdi across the entire New York State Medicaid population which includes the fee-for-service program and managed care organizations. Recommendations for the management of these drugs will be provided based on a review of the literature and results from the utilization data analyses.

So, as we heard in the public comment period, Spinal Muscular Atrophy or SMA is a group of genetic diseases that is characterized by a progressive loss of motor neurons leading to muscle weakness and atrophy. The most common form of SMA is caused by mutations or defects in both copies of the survival motor neuron 1 or SMN1 gene which is located on chromosome 5Q. This is also referred to as Chromosome 5 SMA or SMN related SMA. SMN 1 mutations lead to reduced production of functional SMN protein, which then presents as muscle weakness and atrophy. Notably, the loss of SMN proteins due to mutations in SMN1 can be partially off-set by the neighboring SMN2 genes. It is thought that the larger number of SMN2 gene copies there is associated with the greater availability of functional SMN proteins. The presentation of SMA does vary with regard to age of onset and level of motor function.

In the next slide you can see a listing of different characteristics of the various types of SMA. So, talking about Chromosome 5 SMA there are 5 different types that are recognized: types 0 through type 4. These classifications can be characterized not only by the age at onset and highest motor milestone achieved, but also some other characteristics including what you can see in that top header, so the number of SMN2 copies, the progression and then life expectancy. So, generally speaking, the earlier this disease presents, the worst prognosis and lower life expectancy. Type 0 SMA presents before birth, so it's usually appreciated in patients during the third trimester so based on their fetal movements. Type 1 SMA is also known as infantile SMA usually presents in the first 3 months of life. These patients generally have a life expectancy of under 2 years. Their disease progresses rapidly. Type 2 SMA is also known as Chronic Childhood or Intermediate SMA, usually presents a little later in life so 6 to 18 months of age. The progression is a little slower than type 1. Patients can sit up without support, but they

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are unable to walk, and they have a slightly greater life expectancy compared to patients with type 1 or type 0 SMA. Then there is type 3 SMA also known as Juvenile SMA presenting later in childhood. So, after 18 months of age and the progression is gradual and patients generally survive into adulthood. Then type 4 SMA is adult onset, is more rare. Of these types of SMA type 1 is expected to account for more than 50% of all new SMA cases. And the New York State Department of Health Wadsworth Center estimates that approximately 60% of all cases are attributable to type 1 SMA. And then type 2 SMA is the next most common with about 30% of all cases, and then type 3 at about 10% of cases.

So, treatment options for SMA are limited with only 3 medications that are approved by the Food and Drug Administration or FDA. All three of these medications target SMN. So, the first to be approved was Nusinersen which was approved in December of 2016. Following that gene therapy known as onasemnogene abeparvovec trade name Zolgensma was approved in May of 2019, and Risdiplam was approved most recently in August of 2020.

Nusinersen and Risdiplam are both messenger ribonucleic acid or mRNA splicing modulators. And they increase the amount of full-length SMN transcripts. Just for your information, onasemnogene abeparvovec is a gene transfer therapy. It's a recombinant adeno-associative virus type 9 based therapy, and it's intended to transduce a copy of the human SMN gene and increase expression of the SMN protein. So this product is administered at intravenous infusion and its excluded from our review because there is a practitioner administered drug policy that was recently implemented.

So, on slides 5 and 6 are some characteristics of Nusinersen and Risdiplam. So, you can see the characteristics listed in the first column and then Nusinersen information is in the middle column and Risdiplam information in the final column. So, both of these drugs are approved for treatment of SMA in patients of all ages, pediatric and adult, and they have no additional compendia-supported uses. Some notable differences between the two products is how they're supplied, administered, and dosed. So Nusinersen is an injection solution that's intended for intrathecal administration. The recommended dosing is to have 4 loading doses that are administered bi-weekly for the first 3 doses and then the 4th would be administered 30 days after the third dose and maintenance doses once every 4 months thereafter. The recommended dose is 12 mg per dose. For Risdiplam in contrast, this is a powder for constitution as an oral solution. So, it's administered orally after meals at the same time each day, so once daily, and the dosing that's recommended is age and weight based. So, you can see in the middle row in the right column, dosing for under 2 months of age is .15 mg/kg/day, for 2 months to under 2 years of age it's a little greater at .2 mg/kg/day, and then for 2 years and older with weight less than 20 kg, 0.25 mg/kg/day, and then for all other patients 5 mg per day.

So, continuing this table some safety concerns are listed. So, for Nusinersen the manufacturer warns against the potential for thrombocytopenia and coagulation abnormalities, as well as renal toxicities. Some adverse events that were observed in clinical trials are also listed. So, those occurring more frequently in patients with infantile onset SMA included various types of infections including lower respiratory infection, urinary tract infection, upper respiratory tract congestion, and constipation to name a few. And in patients with later onset SMA, fever, headache, vomiting, back pain, nose bleeds were reported more frequently. In terms of use in specific populations, the manufacturer reported inadequate data in pregnant women, lactation

and in geriatric patients. In terms of monitoring, the manufacturer does recommend monitoring patients for their quantitative spot urine, and platelet counts, and coagulation laboratory markers at baseline and prior to each dose.

For Risdiplam, the manufacturer doesn't report any warnings or precautions. More frequently occurring adverse events that were reported in patients with infantile onset SMA and later onset SMA were similar to those that we've seen in the label for Nusinersen. So, upper respiratory tract infection, lower respiratory tract infection, constipation, vomiting. And in older patients, fever, diarrhea, mouth and aphthous ulcers have also been reported. In terms of use in specific populations, as noted, with the dosing recommendations body weight and age have significant effects on the pharmacokinetics of Risdiplam, and its use in patients with severe hepatic impairment has not been evaluated in clinical studies. No monitoring parameters have been specified for Risdiplam by the manufacturer.

Before I get into the literature for these products, I did want to call your attention to the availability of motor function skills. So, these are instruments that have been developed to monitor the course of disease and measure treatment effectiveness. Actually, all of these have been established before the development of the SMN targeting therapies. So, they are not necessarily specific to SMA but may be used to monitor these patients. And different scales have been identified as being more or less appropriate depending on the patient's age and the type of SMA. The ones that I think are most notable of the instruments that are listed on this slide include the Hammersmith Function Motor Skill Expanded version or HFMSE. The second section of the Hammersmith Infant Neurological Examination or HINE-2, Motor Function Measure 32 or MFM32, and then the revised Upper Limb Module, as these were included in the primary endpoints of drug development trials and/or the inclusion criteria for these studies.

Multiple guidelines and consensus statements have been published on the treatment of SMA, but most were offered by organizations outside of the United States. Overall, what we observed was that the recommendations highlight the need for established and experienced practitioners and treatment centers. Early initiation of therapy in newly diagnosed patients, particularly infants, genetic testing to confirm both the diagnosis and the number of SMN2 copies with the later being important in predicting response to therapy. And monitoring of motor function and functional status at baseline and regularly thereafter with validated age-appropriate scales.

The efficacy of Nusinersen has been investigated in a number of studies including clinical trials and observational studies. For the FDA's review of Nusinersen, evidence of effectiveness was derived primarily from two sham procedure-controlled trials which are described on this slide, ENDEAR and CHERISH. So, ENDEAR looked at patients with infantile onset SMA, whereas CHERISH investigated the efficacy and safety of Nusinersen in patients with later onset SMA. So, these were multiple center randomized double blind sham controlled trials. ENDEAR was events driven, whereas CHERISH was planned for an overall period of 15 months with treatment for 9 months and an additional follow up of 6 months. For ENDEAR, patients with infantile onset SMA had to have their onset of clinical symptoms before the age of 6 months and were 7 months or younger at the screening. You can see various patients were also excluded. So, for example, patients with oxygen saturation less than 96% without ventilation support or history of gene therapy, or antisense oligonucleotide therapy. As I mentioned, these trials were sham procedure controlled. So, Nusinersen is an intrathecal injection. The sham procedure

basically involved a small needle prick to the skin above the lumbar spine and this was covered with a bandage to mimic the appearance of a lumbar puncture injection. So, patients in ENDEAR or CHERISH were randomized to receive Nusinersen or this sham procedure. For ENDEAR, the primary endpoint was motor milestone response which was defined according to HINE-2 and also event free survival which was defined as time to death or use of permanent assisted ventilation. All infants in this study were symptomatic, hypotonic and weak at baseline. And they had a median disease duration of about 13 weeks. What was observed in terms of the primary endpoint outcomes was clinically important and statistically significant differences between the Nusinersen group and control group favoring treatment with Nusinersen.

With CHERISH, so these were patients with later onset SMA. The primary endpoint was LS mean change from baseline and total HFMSE score at month 15. In this study, all patients were able to sit without support at baseline, but none were able to walk independently. And similarly, to ENDEAR, the primary endpoint outcome results were significant and favoring treatment with Nusinersen.

Risdiplam was investigated in multiple trials. Looking at the published studies, there were two, Phase 2/3 trials known as Sunfish and Firefish. These were 2-part studies with part 1 designed to be dose finding, and evaluating safety, pharmacokinetics, and pharmacodynamic characteristics of Risdiplam. So, we are focusing on part 2 of these trials which looked at the efficacy and safety of Risdiplam. So, similar to Nusinersen, Risdiplam was investigated in patients with infantile onset SMA and later onset SMA. So, infantile onset SMA was investigated in Firefish Part 2. This was a multicenter open label historical control study. So, patients in the historical control did not receive treatment. The definition of infantile onset SMA was similar to what we saw in ENDEAR with Nusinersen with the onset of clinical symptoms occurring between 28 days of age and 3 months. And patients having to be 7 months of age at screening or younger but older than 28 days. The interventions again for Risdiplam were or no treatment. And the primary endpoint of Firefish Part 2 was the ability to sit without support for at least 5 seconds after 12 months of treatment. All patients in this study were symptomatic at baseline and in terms of the outcomes, there was a clinically and statistically significant difference favoring treatment with Risdiplam. For Sunfish Part 2, the patients with later onset SMA included those that were age 2 to 25 years at screening. The primary endpoint of this study was change from baseline in MFM32 total score at 12 months. Patients in this study had SMA type 2 at baseline or were non-ambulant with type 3 and outcomes were also, again, statistically and clinically significant favoring treatment with Risdiplam.

One thing that I wanted to reiterate, actually before discussing the coverage of these products is that the trials excluded patients with advanced SMA.

So, first looking at the comparative state Medicaid coverage, there were 9 programs we looked at, those of California, Colorado, Florida, Illinois, Massachusetts, Michigan, Pennsylvania, Texas, and Washington.

So, starting with Nusinersen 8 of the 9 programs as of September of this year were found to cover Nusinersen and 7 of those programs required prior authorization. What we found was that the criteria for those 7 programs was similar for initiation of therapy and continuation of therapy. So, some of the more common criteria included requirement for involvement of a

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specialist, genetic laboratory confirmation of the diagnosis, having results of at least 1 neuromotor assessment, to name a few.

For Risdiplam, all 9 programs were found to cover Risdiplam. 8 programs required prior authorization and criteria were identified for 6 of the programs. So, you can see a listing of the criteria for initiation and continuation. Some of the more common ones for initiation include an involvement of a specialist, genetic laboratory confirmation of the diagnosis, and again, results of at least 1 neuromotor assessment. Some differences comparing Nusinersen and Risdiplam criteria, some of the programs required a negative pregnancy test, and confirmation of no hepatic impairment for usage of Risdiplam.

In terms of the New York State Medicaid Managed Care Organizations, coverage information was found for 14, 16 plans, and all were for Nusinersen, and all required prior authorization. And criteria were identified for 11 of these plans. So, with all requiring a diagnosis and having quantity limits in place, you can see there is additional criteria for some of the other plans.

For Risdiplam, this was found to be covered as a pharmacy benefit by 11 of the 16 plans with all requiring prior authorization. Criteria were identified for 9 of these plans similar to Nusinersen, all of the plans identified what criteria, had a diagnosis requirement, and all had also duration limits in place.

So, in terms of the utilization data, a retrospective analysis was conducted to evaluate utilization of Nusinersen and Risdiplam. Procedure and pharmacy claims for these drugs were reviewed for members in fee-for-service, and managed care with service dates between April 1, 2017, and March 31, 2022. And the data were derived from the Medicaid Data Warehouse or MDW.

The utilization was further broken down by state fiscal year. So, this period included state fiscal year 18 through 22. So, state fiscal year is defined as April 1st of one year to March 31st of the subsequent calendar year.

Just a reminder that there is a Medicaid Confidential Data Cell Size Policy which requires that no cell containing a value of 1 to 30 be reported. Any value in this range must be reported as less than equal to 30 in all public based documents. And there are some additional things to consider. So, the time periods that are analyzed take into account inherent delays in claiming counter submissions. However, our data may not be fully complete. Also, there was a memo that was issued by the MDW Customer Care Center in late September of this year indicating that the encounters intake system was rejecting pharmacy national council prescription drug programs. So, the encounters were a subset of the NDCs were missing from its reference data and encounters containing these National Drug Codes were added to the approved formulary since December 2021 were being rejected, and this would potentially result in incorrect data reporting. That being said, in the next slide you can see our summary utilization. So, in this overall time period, we found that 147 members had about 1626 claims for either Nusinersen or Risdiplam.

In the next slide you can see a figure depicting the utilization by drug and by state fiscal year. So, the X axis shows the state fiscal years 18-22, the blue bars represent utilization of Nusinersen and then the orange bar is utilization of Risdiplam. So, you can see that Nusinersen utilization increased from state fiscal year 18 through 20 and then started to decrease in 21, and

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then further decreased in 2022. So, the utilization basically appeared to shift from Nusinersen to Risdiplam. There is no orange bar in the state fiscal year 21, but there was some utilization, it was just under 30 which is why it is not presented in the figure. As a reminder, Nusinersen was approved in December of 2016 and Risdiplam was more recently approved in August of 2020. Another thing to note was that some of the members actually had claims for both of the drugs in the same state fiscal year.

So, we looked at the age and sex of members utilizing Nusinersen or Risdiplam and in this pie chart, you can see a breakdown by age. So, the age overall ranged from 0 to 59 years with more than 20% of the members being 2 years of age or younger at their first claim. And nearly 60% of the members were pediatric or under 18 years of age at their first claim. In terms of gender, of the 147 members, 54% were male and the remainder were female.

Diagnosis of members utilizing Nusinersen or Risdiplam were also assessed. These were assessed using International Classification of diseases, temp revision or ICD 10 codes. The codes of interest for SMA were identified from practitioner, clinic, or hospital claims between April 1st of 2016 and March 31st of 2022. So, we included or extended our drug utilization analysis period by 1 year to be conservative and capture more patients potentially with this diagnosis and found that over 98% of members had ICD 10 codes of interest, suggesting they had a diagnosis of SMA.

So, in conclusion, SMA is a progressive neurodegenerative disease that leads to muscle weakness and atrophy and the most common form is caused by defect in both copies of the SMN1 gene chromosome 5q. SMA presentation varies with regard to age of onset and level of motor function and treatment options are limited with only 3 FDA approved agents, Nusinersen, Risdiplam, and gene therapy Onasemnogene abeparvovec. Nusinersen was approved in 2016 for treatment of SMA of all types in pediatric and adult patients and Risdiplam was approved in 2020 for treatment of SMA of all types in pediatric and adult patients.

Available guidelines and consensus statements underscore the need for established and experienced practitioners in treatment centers. Early initiation of therapy, genetic confirmation of the diagnosis, number of SMN2 copies, and monitoring of motor function at baseline and regularly thereafter. The published clinical trials are limited to drug development studies at the time of preparation, and patients with advanced disease were excluded from these trials.

Based on a retrospective analysis of procedure claims and pharmacy claims from the MDW, 147 members in the overall population utilized Nusinersen or Risdiplam between April 1st, 2017, and March 31st of this year. The ages of members range from 0 to 59 years with about 60% being under 18 years at their first claim and 23% being 2 years or younger at their first claim. Over 98% of the members had a diagnosis code for SMA during the analysis period.

So, our UB recommendations are presented on this slide. The following should be considered: Development of a practitioner-administered drug policy for Nusinersen with criteria consistent with those of other therapies for SMA and recommendations from the FDA-approved labeling. And implementation of clinical criteria for Risdiplam consistent with those of other therapies for SMA and recommendations from the FDA-approved labeling.

This concludes my presentation; I'll take any questions.

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Douglas Fish: Thank you very much Irene. Nicely done. Questions for Irene? How about from our remote sites, New York City, Buffalo, Rochester, any comments, questions anybody has? Either people are tired, hungry or both. So, if there are no questions, it was very clear, do I have a motion to move to our DOH recommendations? Jim Hopsicker moves do I have a second? Okay Broke Lape for seconding the motion. Thank you both. So, we'll pull up that slide and thank you and turn it over to Tony.

Tony Merola: Sure, for Nusinersen and Risdiplam, Georgia you can go to that next slide where is their standard slide that the coverage policy will confirm at the approved use in accordance with FDA package labeling or compendia-supported use. And then there's one recommendation to the Board from DOH is the coverage policy would require the patient must not have advanced disease, and we provide a couple of examples there. The examples are complete limb paralysis or permanent ventilator dependence.

Douglas Fish: Thank you Tony. This recommendation is now open for discussion. Again, just to read it, the patient must not have advanced disease as examples, complete limb paralysis or permanent ventilator dependence as a coverage policy recommendation.

Jim Hopsicker: Just for clarification, is that the only clinical PA criteria that you're having on these two?

Douglas Fish: The question is, is this the only PA clinical criteria that would be considered?

Irene Riley: Yes, that is the only clinical criteria that is being considered from the DOH recommendations.

Douglas Fish: What you saw earlier were the SUNY recommendations to the Department, this is the singular department...

Jim Hopsicker: There's no current criteria in place I guess is what I'm saying. This would be like the complete criteria for a physician wanting to treat somebody with SMA?

Irene Riley: Correct.

Douglas Fish: Other questions or comments? Okay, hearing none. Maybe we'll do it the opposite here. Let's see in the room those in favor may I see a show of hands so we can count. Those in favor of the DOH recommendation. Eight in the room. And we move to New York City, those in favor of the recommendation. Tony says he sees 3 hands, okay.

Tony Merola: Yeah, a little closer to the screen, there are 3 hands up.

Douglas Fish: Alright and in Buffalo?

Jamie Wooldridge: I'm in favor, this is Jaime.

Douglas Fish: Thank you Dr. Wooldridge and in Rochester?

Dr. Lavigne: Yes, I'm in favor.

Douglas Fish: Thank you so much, Dr. Lavigne. Okay so 13, passes unanimously. And Tony, I'm thinking at this time we might want to take at least a bio break.

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Tony Merola. Yeah, how much time would you want to take Doug, maybe 20 minutes?

Douglas Fish: How does that feel to the Board, 20 minutes sufficient? Okay. So, we're going to take a 20-minute break, we'll resume at 12:35. Okay. Thanks all.

I think we have our team in New York City and Buffalo. Do we have Dr. Lavigne in Rochester, can you hear us?

Dr. Lavigne: Yes, I can hear you.

Douglas Fish: Was that Dr. Lavigne, okay very good, okay. So, I think we're all present and this meeting is being recorded. If you object, this would be a time to hang up. So, next up is the DUR topic of ocrelizumab and Pharm D Holly Coe will be presenting from SUNY Buffalo. So, Holly take it away.

Holly Coe: Hi, good afternoon, can you hear me, okay?

Douglas Fish: Very clearly, yes, you're very clear, thank you.

Holly Coe: Alright wonderful. So, as Dr. Fish mentioned, I will be reviewing ocrelizumab for the Board today. So, the primary objective here today is to examine the utilization of this product across the entire New York State Medicaid population which includes

Female: Excuse me, can you increase the volume?

Holly Coe: Yes, can you hear me now?

Female: Better.

Holly Coe: So, as I was saying the primary objective today is to examine the utilization of ocrelizumab trademark Ocrevus across the entire New York State Medicaid population, which includes the fee-for-service and managed care programs. And recommendations for the management of this product will be provided based on a review of the literature as well as utilization analyses.

Some background regarding this product. It's a monoclonal antibody that binds to CD20 receptors on lymphocytes which then depletes these cells. The product was approved by the FDA in 2017 for treatment of primary progressive multiple sclerosis or PPMS in adults, as well as relapsing forms of MS in adults which includes Clinically Isolated Syndrome, relapsing-remitting disease, and active secondary progressive disease. I just want to point out that for the indication of PPMS, ocrelizumab is the only agent that is approved by the FDA for this indication. This product is covered by the New York State Medicaid fee-for-service program.

Briefly some information regarding dosage and administration. The drug is administered as an IV infusion given as 300 mg as a starting dose followed 2 weeks later by a second 300 mg infusion. Subsequent doses are then administered every 6 months at a dose of 600 mg IV. Due to the risk for infusion reactions, patients need to be closely monitored during and for at least 1 hour following the infusion. The product must be administered by an experienced healthcare professional with access to medical support in the event of a serious adverse reaction.

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There are several requirements prior to the first dose. Hepatitis B virus and qualitative serum immunoglobulin screening are required prior to the first dose. The infusion should be delayed if the patient has an active infection. In terms of vaccines, live and live-attenuated should be administered at least 4 weeks prior to starting treatment as they are not recommended during treatment. And then for non-live vaccines, these should be administered at least 2 weeks prior to starting ocrelizumab.

There are two contraindications, the first is active hepatitis B virus, and then the second is having a history of a life-threatening infusion reaction to ocrelizumab.

There are several warnings and precautions for this product. Again, there is the risk for infusion reactions. If this does occur, the product should be permanently discontinued if it's life-threatening or disabling. Again, there is an increased risk for infection, so treatment should be delayed in patients who have an active infection until its resolved. And then in terms of Progressive Multifocal Leukoencephalopathy or PML, the product should not be administered at the first sign or symptom indicative of PML as this is a very serious and life-threatening condition.

So, ocrelizumab causes a reduction in immunoglobulins. So, these need to be monitored prior to, during and following treatment continuation until B cells replete themselves, especially if there is a recurrent serious infection that is expected. Treatment discontinuation should also be considered in patients with serious opportunistic or recurrent serious infections, and if hypogammaglobulinemia is prolonged and requires treatment with IVIG.

In terms of malignancies, there may exist an increased risk especially for breast cancer. And finally for post-marketing reported, there are some reports of immune-mediated colitis; patients should be monitored for new or persistent diarrhea or GI symptoms.

So, the next few slides focus on the guideline and consensus statement recommendations. Overall, the all the guidelines assert that choice of a disease modifying treatment or DMT depends on the type of MS, the stage of treatment, whether the patient is naive vs. treatment experience, the level of disease activity, as well as patient specific factors. The American Academy of Neurology issued guidelines in 2018. So, for those patients that are starting treatment with high disease activity, the current evidence supports higher efficacy in reduction of relapses and MRI activity with fingolimod and other agents that are administered by IV infusion. For the specifically mentioned natalizumab and alemtuzumab. So, this is compared to other self-injectable agents such as the Interferon data treatments. This is a considered a level B recommendation which means the guidelines states it's a more common recommendation with less stringent requirements, but it is based on evidence and risk benefit profile. For patients who have breakthrough disease activity despite treatment, so that as they continue to have relapses and MRI activity, based on current evidence, alemtuzumab, fingolimod, natalizumab and ocrelizumab have a higher efficacy compared to previously improved self-injectable DMTs. And for this recommendation, the level of evidence was not provided in the guidelines.

In terms of ocrelizumab, the guideline notes it's the only DMT to alter disease progression in ambulatory patients who have PPMS. So, patients should be offered this project until the potential risks outweigh the benefits of treatment. That is a level B recommendation as well.

And then the guideline does not the risk for PML with several agents as listed on this slide and that's a level B recommendation.

The European Committee of Treatment and Research in MS and the European Academy of Neurology issued guidelines for MS in 2018 specifically for active RRMS or relapsing-remitting MS. They recommend that multiple agents can be considered, so this includes the Interferon products, peginterferon, glatiramer acetate, teriflunomide, dimethyl fumarate, cladribine, they do list daclizumab however that was taken off the market the same year this guideline was published. The other agents include natalizumab, ocrelizumab, fingolimod, alemtuzumab, so all these can be considered for active RRMS.

For patients who have a disease activity despite being treated with an interferon or glatiramer acetate, switching to another agent should be considered, and this is a strong recommendation. Then patient characteristics, safety, and disease activity and severity should also be considered. That's the consensus statement.

Then the final two bullets are considered weak recommendations. So treating with ocrelizumab should be considered for patients with PPMS and treatment with ocrelizumab or cladribine should be considered for patients who have active Secondary Progressive MS or SPMS.

So, the National Institute for Health and Care Excellence issued a specific document for ocrelizumab. So, in 2018, they issued one for Relapsing-remitting MS and then 2019 for PPMS. Specific for RMS, the guideline recommends that ocrelizumab be used in adults with active disease but only if alemtuzumab is contraindicated or unsuitable. They stated that this agent does reduce the number of relapses and slowed disabilities when compared to interferon, beta 1a in clinical trials. At this point, there has not been any other trials directly comparing ocrelizumab to other DMT. There have been in direct comparisons though to several agents including interferon beta 1b, glatiramer acetate, dimethyl fumarate, fingolimod and teriflunomide that did show that ocrelizumab did reduce the number of relapses compared to these products. Other indirect comparisons to alemtuzumab and natalizumab which are also administered by IV infusion also show that ocrelizumab was as effective.

Analyses from trials suggest that ocrelizumab may slow disease progression but did not that the effect is uncertain in patients with highly active or rapidly evolving severe disease. And then in the UK, ocrelizumab is more costly than alemtuzumab. And then finally for PPMS, the guidelines recommend ocrelizumab as a treatment option in patients who have imaging features that are suggestive of inflammatory activity. They state that one trial did show that this product can slow the worsening of disability but did not the uncertainty of the size and duration of the effects. Again, ocrelizumab was the only agent that is approved for the treatment of PPMS.

In terms of comparator state Medicaid program, Colorado had several requirements in place for ocrelizumab. They require a prior authorization, or a PA and the drug must be administered by a healthcare professional and prescribed by or in consultation with a neurologist. They do have a maximum dose requirement which is consistent with FD labeling. For the two types, PPMS and RMS the member has to be 18 years of age and older and that is specific for PPMS to not be taking any other DMTs.

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And then RMS has several clinical criteria in place. I'll touch on some of the major ones. So, they have to have the diagnosis, have experienced a relapse within the prior year or two relapses within prior 2 years and does not have an active HBV or anti-JC virus antibodies at baseline. In addition to that, there is a step therapy requirement. So, I'll just briefly touch on this, I'm not going to read through all the information, but it requires trial and failure with any two high efficacy DMTs which they list. Or the member has a diagnosis of highly active RRMS and has had a trial and failure with any one high efficacy DMT.

Moving onto Massachusetts, they also require a PA along with an appropriate diagnosis and it must be administered by a neurologist, and it may have the maximum dose which is consistent with FDA labeling.

Washington State lists the product as nonpreferred in the PDL. It requires an intolerance due to serious adverse event, contraindication, or inadequate response to at least 2 preferred agents. For RRMS it requires appropriate diagnosis, being 18 years of age and older, inadequate response to 2 or more agents with the same indication, and/or medications which are considered to be the standard of care, and not currently taking other DMTs, received a negative HBV test, and does not exceed the FDA compendia-supported limitations. And then they go on to list a few other items that they require.

Specific for PPMS they do require appropriate diagnosis, 18 years of age and older, documentation of inflammatory activity, and the patient cannot be currently taking other DMTs and they had to have received a negative HBV test and does not exceed the FDA or compendia-supported limitations. They also have a quantity limit which is consistent with the FDA labeling. In terms of the other comparator states not listed in the PDL or did not indicate that the product required a prior authorization, that included California, Florida, Michigan, Texas, and then Illinois and Pennsylvania listed ocrelizumab as nonpreferred in their PDL.

So, the data source here is the Medicaid Data Warehouse or MDW. The timeframe for our retrospective analysis was April 1, 2019, through March 31, 2022. The sample included members who enrolled in the New York State Medicaid fee-for-service program, that includes both fee-for-service and managed care, with either a medical or pharmacy claim for ocrelizumab. And then in terms of some of the limitations, Dr. Irene Riley reviewed those previously, so I won't go through those again.

So, looking at the utilization of this product and fee-for-service and both managed care, this slide focuses on the members. We can see that there was approximately 45% increase in the number of members who utilized ocrelizumab between state fiscal year 2020 and state fiscal year 2022.

So, similar slide but this slide focuses on the number of claims. Again, we did see an increase approximately 50% increase between state fiscal year 2020 and state fiscal year 2022.

Some additional results approximately 500 members started ocrelizumab for the first time in State fiscal year 2022 and an estimated 20% had evidence of step therapy within 365 days. So, this means that they tried a drug from the fee-for-service Preferred Drug Program MS therapeutic category prior to receiving ocrelizumab. So, there are about 20 drugs listed in the category. And then finally, ocrelizumab should be administered as 300 mg on days 1 and 15,

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and then 600 mg every 6 months. 9% of members who received this product did so before the recommended duration of two weeks and that was for the initial claims. And then for the 6 month or noninitial claims, it presented 6.9% of service dates that were earlier than recommended.

In conclusion, ocrelizumab is approved by the FDA for treatment of RRMS and PPMS in adult patients, and it is currently the only approved product for PPMS. Guidelines assert that choice of a DMT depends on the type of MS, stage of treatment, whether the patient is naïve vs experienced, and disease activity. In our data, we saw that there is approximately 45% increase in the number of members who utilized this product between state fiscal year 2020 and 22, and likewise there was a 50% roughly increase in the number of claims during the same time period. Approximately 500 members started ocrelizumab for the first time in state fiscal year 2022 and an estimated 20% had evidence of step therapy within the 365 days.

So, in terms of the UB recommendations to the Department of Health, there are two.

The first is step therapy with an agent subject to the fee-for-service Preferred Drug Program multiple sclerosis therapeutic class prior to ocrelizumab and this would exclude patients with primary progressive MS who are ambulatory and have documentation of inflammatory activity. And then the second recommendation is based on FDA labeling of the dosage given as 300 mg on days 1 and 15, and then 600 mg every 6 months.

So, that concludes my presentation. I would be happy to take any questions.

Douglas Fish: Thank you very much Holly. Questions, comments?

Dr. Eglowstein: This is your MS advocate here. I've worked with MS for almost 19 years and seen the development of the B cell drugs such as Ocrevus which is the last 12 or 13 years. It was a game changer because prior to that we thought MS was related to a different kind of cell acting on the central nervous system. And finding that B cells were part of the picture and treatment that removes the B cells such as Ocrevus and before that it was Rituxan, which was invented for B cell leukemia, being able to be on Rituxan changed my life and many other people's because it's much more effective and as Holly mentioned, it's a higher efficacy drug as opposed to drugs such as interferon, glatiramer, fingolimod and many of the others. Now, we know that MS being so different in different people and my suspicion is someday we're going to find out that it's a whole constellation of diseases rather than just one, because we don't know the pathway by which the nervous system is triggering the attack on it. We know what the attack is from its from the immune system, but we're not really sure why the immune system gets set off. That's what makes me think we're going to find out its different things, but different drugs work differently for everybody. I was on one of the lower efficacy drugs in the beginning because that's all they had. And there wasn't a step therapy yet recognized. But the lower efficiency drug didn't help me very much so I had to go onto Cytoxan which as you may know, is a chemotherapy drug still used for breast cancer and other cancers. And we didn't have something like Rituxan or Ocrevus to call on, which would have been a lot nicer than being on Cytoxan. But I voted for Rituxan because after going off the Cytoxan and back to a lower efficacy drug, I was still having problems. And being on Rituxan has taken care of that. Things have advanced a lot more slowly. You may have noticed, I was ready my phone rather than the

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thing because I can't see distance as well as I used to, that's one of my problems right now. But I don't want to just talk about myself, I want to talk about the fact that for some people, I do want to backtrack one little bit. Is that in the early 2000s when I was diagnosed, we were just beginning to find out that it was a good idea to get on treatment immediately rather than wait and see to see how you progressed because being proactive and relatively aggressive was good at slowing the disease down. And now that's a recommendation made by I would say most neurologists and most MS specialists. So, I want to talk in favor of the ability of a neurologist to choose to put someone on the cell therapy right away as opposed to step therapy. I don't necessary think it's the most effective way to help somebody avoid disability. And avoiding disability is really important because the reason I'm on this committee is because of this disease having forced me to leave (music playing over the speaker). And I believe from having spoken, not from my own experience again but my doctors in Boston that I go to are some of the people who came up with the idea of using B cell therapy. And they would tell you if they were standing here that they think it's a good idea to start people on that right away despite the fact that it requires infusions twice a year, and there are numerous side effects, we are keeping people possibly mobile and functioning better. And that's what really the goal of the treatment is, is to keep you functioning. And that's why I would say we should give neurologists the option, and patients and doctors the option of going to the more efficacious treatment first. It's fine to do step therapy if that's what a person prefers. Some people don't want to have injections, they would rather take a pill, again, an option that I didn't have. But the oral medications cut your relapses by 30 to 40% and the infusible drugs cut your relapses by 60 to 70%. It all depends on what your feeling is that you want to do to get after this disease. That's it. Oh, wait, I did think of one more thing. The thing about B cell Ocrevus and Rituxan and the other drugs that are similar to it, because there are a couple more, is that these are the culprits for making us more susceptible to COVID. I had COVID twice, so I know, despite vaccines. The vaccines don't really, you're depending on B cells to do a lot of vaccine effectiveness and that's one thing you do not get your B cells back for 6 to 12 months. If you were to say, "Okay, I'm not going to take my Ocrevus anymore, so I won't get COVID" you're still vulnerable for 6 to 12 months. That's all, now I'm finished.

Douglas Fish: Thank you. Other comments or questions? Pete Lopatka.

Lisa Anzisi: Question from New York.

Douglas Fish: We have a question in the room and then we'll come to New York City. Yes, you're very loud so you might want to turn your volume down there if you can.

Peter Lopatka: The thing is I'm a non-clinician, so this is a high-level question and hopefully it can be answered. What's the length of time, if you do step therapy like the whole pathway to get to Ocrevus, does step therapy take 2 months, does it take a year?

Douglas Fish: So, Holly, could you hear the question? The question is for step therapy, how long would it take in your recommendation before you would determine that another agent wasn't working to move on?

Holly Coe: Yeah, good question. From what I've seen in the guidelines, they recommend trying an agent for up to 1 year to see if it does help with the relapses and disability and MRI activity.

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So, specifically the AAN suggests that a patient is tried DMT for 1 year and if they experience 1 or more relapses or have two or more lesions on MRI or disability, then at that point it would be appropriate to try a different agent.

Douglas Fish: Thank you. Now to New York City please, thank you.

Reverend Dr. Phillip Fleming: I was wondering are there reasons why some states like Illinois, PA, and Washington doesn't list this drug as nonpreferred on the PDL?

Holly Coe: I can't answer for those states, but it might be sometimes information is just not available right away when we do the research. So, they may have policies in place, but we weren't just able to capture that information.

Douglas Fish: Other questions?

Jamie Wooldridge: This is Jamie Wooldridge; I just have a clarification. Just based on the discussion, I want to make sure I understand where we are. So, we have these recommendations about using step therapy, but we have another board member who has put a request out that we eliminate step therapy and make this a primary option? Is that correct?

Dr. Eglowstein: Yes, that's what I'm saying. For someone who seems to be having more aggressive illness with a lot of activity and relapses, it really might be a better choice according to the researchers that I'm in touch with.

Douglas Fish: And just a reminder, we have not moved to the DOH recommendation yet, so we are now just addressing questions related to the presentation and the conversation, but we will get to the DOH recommendation and then talk more specifically if there are recommendations to amend it, we can take those motions. Other questions or comments? Okay, I'm hearing none. Thank you, Holly. So, do I have a motion to the DOH recommendations? Dr. Eglowstein moved and the second? Okay Broke Lape for the second. So, Georgia will pull up the DOH recommendations, turn it back to Tony Merola.

Tony Merola: Sure, so for ocrelizumab Georgia you can go to the next slide which is our clarification slide that the coverage policy will confirm FDA-approved use in accordance with FDA packaging labeling or compendia-supported use. And then the recommendation to the DUR Board and there is a step therapy recommendation. Trial of an agent subject to the Preferred Drug Program Multiple Sclerosis Agents therapeutic class. with the exception for patients with a diagnosis of primary progressive multiple sclerosis or PPMS who are ambulatory and have documented inflammatory activity.

Douglas Fish: Comments, questions, discussion, we'll open it up now regarding the DOH recommendation. Dr. Eglowstein.

Dr. Eglowstein: My feeling is that we should first of all have Ocrevus on the preferred drug program, if it isn't already, and second of all to not require step therapy.

Douglas Fish: Are you making a motion to amend?

Dr. Eglowstein: Yes.

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Douglas Fish: Okay, and is there a second?

Male: Second.

Douglas Fish: Thank you. Discussion? Jim Hopsicker.

Jim Hopsicker: If I remember right, there was 500 new starts on Ocrevus in the last fiscal year, is that correct?

Douglas Fish: That's right.

Jim Hopsicker: Do you know how many new starts of the preferred agents so we can just kind of get a comparison?

Holly Coe: I didn't hear the last part but you're correct, there was 500 new starts in state fiscal year 2022.

Jim Hopsicker: So how many new starts on the PDL were there on the preferred agents that we're going to ask to step through?

Holly Coe: I don't have that information; I would have to we'd have to get back to you.

Douglas Fish: So, we don't know what the other number might be for non-ocrelizumab therapies for members?

Holly Coe: No, but we could certainly look at that.

Douglas Fish: Sure.

Tony Merola: Holly, did you present the number of people that have tried the product on fee-for-service PDL before they got to Ocrevus? That might not have been Jim's question, but you've got that number, right?

Holly Coe: I did have the number that started one of the preferred products or preferred drug program products before starting ocrelizumab so that was like 20% of patients had evidence of step therapy.

Dr. Eglowstein: So, what you're saying is 20% of the 500 had evidence of step therapy, correct?

Holly Coe: Yes. Yeah, so that was, I'm looking at the numbers that was 105 members had step therapy before starting ocrelizumab. So, that presented almost 20%.

Dr. Eglowstein: I could point out in general numbers that we have 12,000 people in New York State with MS approximately what that's worth. You have several hundred people being diagnosed every year that would mean.

Douglas Fish: So, I will just point out, does the exception really make up for that, so the exception is for patients with a diagnosis of Primary Progressive Multiple Sclerosis or ambulatory and have documented inflammatory activity. Can you just explain Holly what this exception or Tony or the team what that exception really means?

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Tony Merola: So, those patients would not have to go through a trial of these drugs on the fee-for-service PDP if you will, Preferred Drug Program, so those patients would be exempt from that step therapy. I have that right?

Holly Coe: Yes.

Tony Merola: Thank you.

Douglas Fish: And that's for the FDA indication of PPMS which is for this drug right, so they wouldn't have step therapy.

Holly Coe: Correct.

Douglas Fish: Dr. Eglowstein.

Dr. Eglowstein: That would include 15% of new diagnoses approximately. It's about 85% that are relapsing remitting, about 15% of people have primary progressive.

Douglas Fish: Just a question for myself. If they've had relapsing-remitting, would they have been on other therapies to have that diagnosis?

Dr. Eglowstein: Not necessarily. That's your initial, for post people it is their initial diagnosis and until we had Ocrevus a lot of people got offered these other therapies, but many people don't find them totally effective. And addressing the question that you asked before, sorry I forgot your name, it can take up to a year to learn that it wasn't effective. But people who have active disease everybody's tempo is a little different. People who have active disease might have another relapse within 5 to 6 months.

Douglas Fish: Thank you. Are there other comments or discussions? There has been a motion and second to revise this recommendation, so we need to think about how we would do that.

Jaime Wooldridge: This is Jaime Wooldridge out in Buffalo. So, the motion that's out on the table right now just seems like a really big motion for us to be able to make any decision about without an attempt to look at data and really understand exactly what prescribing practices are. I don't know if we can get that. Because it also seems to be stepping away from what guidelines say and what other states say. So, is it possible for us to table this and bring it back at the next meeting with some more information?

Douglas Fish: Let me turn to our DOH colleagues here on the pharmacy side, Dr. River, Monica to respond.

Monica Toohey: We are okay with pulling additional data to look at prescribing trends of all the agents subject to the preferred drug program. We would also like to recommend that we would include the other infusible agents too when we did that evaluation. Not only would we include the PDL drugs but the other several infusible MS drugs. So, we would do a complete review, and that would be just utilization.

Douglas Fish: Dr. Eglowstein.

Dr. Eglowstein: Well, I guess my question here is do we need a separate motion to put Ocrevus on the preferred list? I think that's what's making it, I hear what Dr. Wooldridge is saying, it's a

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big ask. Do we need to make, do we break this into two separate things by making Ocrevus on the preferred list cause it's not, I guess, and second of all the change away from step therapy.

Douglas Fish: So, I think the suggestion from Dr. Wooldridge, because that is a big step that have it be data informed since we don't have all of the answers of the questions being asked today around that. we could do a deeper dive on the data piece and then bring it back at the next meeting. Tony.

Tony Merola: Yes, so in terms of putting it on the preferred drug list that's a little bit of a type of different review, because that brings in the financial components. We would have to do that. In terms of doing some more data mining, it would be helpful if we knew exactly what the DUR Board is looking for and help us craft that so we don't necessarily have to do it right here, but I think it would help us Barb if we did get some feedback from the DUR Board members in terms of what types of data you're looking for. You guys all know working with data, you can go crazy with the amount of data and the digging that you can do. So, if the DUR Board members could maybe, again, we can reach out to you after this meeting, just to give us a little more specificity on what you would be looking for, that would be helpful.

Barbara Rogler: I would just like to make one recommendation for the utilization, I don't know if I'm allowed. I do hear what you're saying, we definitely need to look at the trends and things like that but what I think that you may also want to look at is that switch rate, that seems to be big. And the other thing is how long can people stay on therapy?

Douglas Fish: What rates?

Barbara Rogler: Switch rate between agents and those would be the three tenants I would look at. I would look at the utilization overall, switch rates would be what I'd also look at and how long people stay on each one of the therapies. And I think it goes to your point Marla about how people go through treatment and would give us a better understanding of treatment. What we cannot tell you though from the dataset is their severity of disease. Okay, so that is a limitation of our dataset.

Holly Coe: Yeah, I just want to add to that there's only one diagnosis code for MS, they don't differentiate into the different types like PPMS and so on.

Douglas Fish: Yeah, thank you Holly, that's important.

Dr. Eglowstein: But the kind of data that Barb was suggesting I think is exactly the data that we would need to be looking at. I like that idea of looking at switching and how long somebody's on one therapy vs. another because it's going to be an association, but I think it could give you some kind of picture of what's happening and where this drug needs to sit in the selection process of therapies.

Douglas Fish: So, procedurally Tony, we have a motion on the floor and now there is a second suggestion, I'll ask Dr. Wooldridge can we have a second motion when we have another motion, or do we need to vote on that one first?

Tony Merola: I don't think we need to vote because we're going to do more research. So, I think in terms of when recommendations come out of the DUR Board, they go to Commissioner for

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final determination in terms of doing more research, I don't think that would need to go to that level, that's kind of my train of thought.

Douglas Fish: Okay. Is there anyone who is opposed to this approach if we take this back, we'll table this recommendation for now and bring back more data and information to you at the next meeting. Okay. Remotely New York City, Buffalo, Rochester, any objections to taking this back and tabling this motion for now, this recommendation? Okay. Hearing none, that's what we'll do. This is very helpful, thank you and good discussion. I appreciate it. So, next I think we have time for our additional presentation right Tony?

Tony Merola: Yeah, we just had a couple of updates to do. So, no more voting items, just a couple of updates to the Board, one was Hepatitis C and some new data that Barb had pulled for us out of more recent claims information. And then we just wanted to give the DUR Board an update on the medical prescriber education program. So, just two updates here.

Douglas Fish: Great, this one is only 100 slides so, (laughing), Barbara you are up. Hepatitis C Direct-Acting Antivirals. Thank you.

Barbara Rogler: But 100 slides I can do in 10 minutes. Alright. We're going to talk about Hepatitis C. Last time we talked about this was in November of ah 2021 and its always important that we give the Board an update and I think what's important about this discussion, it really shows the thoughtful approach that the DURB has taken over the years to the management of Hepatitis C. So, moving onto slide #1. So, we're going to discuss the NYS Medicaid DURB actions related to the hep C the direct-acting antiviral agent and we're going to take a look at the utilization.

Just some very, very brief background. You all know that Hep C is a blood born virus. Exposure can occur as a result of injection drug use in the US this accounts for 60% of the acute hepatitis cases. I'm not going to go through the rest of the list because really when we look at it here, we do know that most of the cases are due to injection drug use or the use of drug paraphernalia. So, moving onto the next slide, now what happened was since November last year, the New York State Department of Health has also posted two 2020 and 21 their annual reports for hepatitis C and B, right. At the time that this presentation was approved, I did not have access to those reports. I'll only briefly touch on the 2021. So, what you see here on this slide is actually HCV US stats. And this comes from the CDC. So, during 2013 to 2016 an estimated 2.4 million US adults were living with chronic Hep C and then it goes down through in 2019 it breaks the numbers out from 2012 to 2019 there was 133% increase. The most rapid increase in the instance of acute Hep C infections was in patients between the ages of 20 to 39 years of age who injected drugs. When we look at the NYS Hepatitis B and C annual report, 2021, during 2021, there were 4,249 cases of hepatitis C that was reported to the NYS Department of Health and that included 138 acute and 4,076 newly reported chronic cases. Chronic cases accounted for 96% of the newly reported cases. Acute cases accounted for 4%. The newly reported chronic cases increased by 3% while the newly reported acute cases which represents a recent infection decreased by 7% compared to 2020. The case rate was the highest in males being 2,633 and in persons aged 30 to 34 years of age. And among males, more than 60% of the newly reported cases were men under the age of 40 years of age.

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And now we're just going to talk about what happened in the DURB over the years. This has been a long haul. I think there's only maybe 1 or 2 people here that had voted through 2014 and on. So, our approach to this was, we first had the New York State Standardized Clinical Criteria, right, and our criteria and as we progressed really looked at the successful hepatitis treatment and then the results are for sustained virological response, okay. And how this changed over time with therapies changed, the guidelines changed, it was really a very interesting process with these products. Because when they first came out, we had the cost issues and we had an idea out there, we had warehouse patients especially those baby boomers right. So, this Board was established. And we came up with Standard Clinical criteria across fee-for-service and managed care organizations.

I know this is small here, but it really shows where we started. So, we started with our initial criteria, we encouraged the prioritization of therapy to patients that would benefit the most, such as those with extrahepatic manifestation, HIV, chronic Hep B, diabetes, debilitating fatigue, or coexisting liver disease. And again, our criteria in the State of New York was much less restrictive than what we saw in the rest of the United States. We did not have criteria related to substance use disorder or alcoholism or alcohol use. So, our criteria really, even back in 2014 was just ahead of everyone else. I don't know if I can say that, but we are. So, if we now go onto the next slide and now look at our timelines and what happened. This is really impacted by the weighted therapy change. So, when we look back before the DAA; s you know therapy was interferon. But now in February of 2015, Viekira Pak received the first status right which was exciting, and it was excluded from the HCV clinical criteria. So, we no longer had to have disease prognosis and severity, it really opened up therapy to our patients. And this is back in 2015. In 2016, the clinical criteria were updated to remove disease prognosis and severity for the preferred agents and nonpreferred agents. And in 2017 now here's where we really see the PDL change with the additions of the pangenotypic therapies. Mavyret was only 8 weeks. In March 2018 we have the Governor's Initiative that really that encouraged prescribing among all practitioners, not just those practitioners with experience and clinical training. And in July 2020, removal of prior authorization for HCV, DAA agents prescribed to persons not previously treated with HCV for our preferred agents.

Our current HCV treatment for DAA agents really focuses on those patients that are requiring retreatment. Our criteria really look at the patient demographic, confirmation of chronic disease for these patients requiring retreatment you do need genotyping and things. Because therapy does change with retreatment. HCV history, treatment readiness, and retreatment and reinfection just some information on that.

Now focusing on the retrospective, looking at our data. So, our methods, this is a retrospective analysis from medical claims that was conducted using the Medicaid data warehouse. It doesn't matter in this, we didn't have any cells less than 30, but it is important to say that we don't report any cells less than 30.

I think this is the one that I think I'm most pleased with. If we look from 2011, this is when we see the first approval of the PIs, right the protease inhibitors Incivek and Victrelis. Since then, since their approval, because that was really the change. Now we move from that interferon treatment to a whole new world of treating Hep C. We've treated 44,638 New Yorkers from 6/1/2022 through 7/31/2022.

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Now this is looking at members who utilize an HCV DDA agent by state fiscal year. At the bottom we do have really what happened with some of our clinical criteria, and as you can see, we peaked in state fiscal year 16 and its kind of declined, but we have to think about what happened in that timeframe? In 2016 and 2017, 2016 we get Epclusa the first oral pangenotropic fixed dose regimen which was exciting. That's our first one. 2017 Abbey comes out with Mavyret, 8 weeks of therapy for treatment naïve treatment experienced patients. I mean it was really a game changer when that 8-week treatment came out. and as you can see down below that timeline shows what happened to our clinical criteria across the state fiscal years.

I would be remiss if we did not look at the impact of the pandemic on utilization. If you look at the first four bars to the left, that's 2019, so that is truly the year before COVID. On March 1, 2020, that was our first COVID case in New York City and as you can see, since then our utilization has dropped and again, I think it's a changing environment and we're starting to see our numbers come back up, but there's all different thoughts out there. There was less screening during COVID, things like that, potentially less treating. But again, we're seeing our numbers kind of take a change. So, we'll continue to monitor this to see what happens to our utilization of DAA agents.

Moving onto slide #14, the only reason I've included this slide is because it really shows that our data from the NYS Medicaid program really matches what they saw in the NYS annual report and what they presented there. We really see that 60/40 split. We see that 60% male, 40% female. So that's what this is really showing us and its showing us that our data is consistent with what was presented in the annual report.

Now we look at utilization of these agents by age. We look at the blue is less than 50 and then the red is greater than equal to 50. And here's where you really see our data change. So again, 2016 we see all our baby boomers using it, 17, 18 we're getting close, 2018. And in 2019 we see the switch. We see members less than 50 overtake those greater than equal to 50. Again, symbolizing the same trends as they are presenting in the annual report.

Now we take it and we break it down by looking at patients less than 50 years of age. Because again, we want to look at those populations. We want to see those patients, its hard to see on this, I should have done a bolder line. The bottom line is 19 to 20, 30 to 39, and 40 to 49. So, you again can see that high utilization among our members between the ages of 30 and 39.

And then we did an analysis of those patients that restarted therapy with 365 days. So, we looked at those patients that restarted therapy which was defined as a greater than 8 week or 56-day gap between HCV DAA agents. And so, the results for state fiscal year 2021 and 22 is we saw that 3.9% of members receiving HCV DAA treatment were restarted on therapy within 365 days. And then if we broke it down to the next step, we looked at patients who restarted therapy and we saw that that occurred within 48.1% of the population. And then of those patients that restarted in a brief time within 56 days, greater than 70% of them restarted with the same therapy.

Moving to the summary. Since June of 2011, we've treated 44,638 unique members, I didn't emphasize that before, these are unique members. We did see our utilization peak in state

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fiscal year 2016 and utilize state fiscal 2021 could potentially have been impacted by the COVID-19 pandemic. Our demographics truly match what we see in the annual report. We see from members greater than equal than 50 years of age that their utilization has declined annually since state fiscal year 2019. For those less than 50 years of age, it increased annually from 2012 to state fiscal year 2019. And again, for those members that restarted therapy within 1 year, it's a small number about 4% and when we breakdown that 4% we see that 70% never finished their first treatment, they received less than 56 days but then they were restarted on the same therapy.

At this time, we recommend no changes to the current clinical criteria, but we do believe its worth continuing monitoring the use of these agents and presenting the results to the DURB annually. At this time, I'll take any questions.

Douglas Fish: Thank you Barb. You brought up COVID, yesterday was the 2-year anniversary of the first vaccination of someone for prevention of COVID in New York. We've come a long way. Questions for Barb on the Hepatitis C presentation?

Lisa Anzisi: Yeah, this is Lisa in New York. Barb, restarting within a year, any thoughts about like patient's weren't ready to start, didn't realize the therapy had been prescribed, was it an adherence issue? What's causing all that?

Barbara Rogler: You know what, we're not really sure, but I can tell you that when we look at those restarts, we have about 4% that weren't ready because they received less than 56 days and of those that received less than 56 days, they restarted the same therapy. There's any number of reasons why patients may not have finished their therapy. We can't tell from our dataset if they had an adverse event to the first drug, or they couldn't tolerate the first drug and they needed to switch to the next drug. So, those are things that we can't tell from our retrospective data but the one thing that I didn't talk about and I think it's important and I hope you all have an opportunity to look at the annual report, some of the strides that NYS has made with harm reduction and really opening up and emphasizing treatment at different clinics, and things like that and I think there's been some real progress made in those areas. So, hopefully when we see our next set of data, yeah there's always going to be patients that things happen. And the other thing Lisa I don't have in this is I didn't include enrollment. The impact of either enrolled or not enrolled. So, that is also a limitation.

Lisa Anzisi: The fact that 70% were on the same agent doesn't make me think it was intolerance, it makes me think that maybe it was just not good communication and patients did realize or weren't committed to therapy initially.

Barbara Rogler: We can't tell that from our dataset. It would just be anecdotal for me to say that.

Lisa Anzisi: We have another comment in our room.

Asa Radix: So, this is Asa Radix. Reinfection because we certainly have a significant number of folks who are treated and successfully and then have another Hep C infection like a year later. So, are you able to tell?

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Barbara Rogler: No, I'm not able to tell reinfection because I don't have, in our dataset we don't have access to if they actually achieved sustained virological response off the first regimen. And additionally, I can't tell if they've had a change in their genotype. So, when their initial infection was with, we'll say genotype 1 and then the next infection was with genotype 3, I don't have that data to tell about reinfections, I'm sorry Asa.

Douglas Fish: Dr. Radix and Dr. Anzisi I have the same questions and one of my thoughts was that and I would see this when I was actually prescribing these, they would get the prescription filled for that first start and then have an event that lands them in the hospital, or they get COVID or something happens and they don't actually start it. So, it looks to us like a restart, but in fact it may just be that they never started the prescription. They had the 30-day supply and then they're getting 2 more months, so I'm wondering if we can even look at whether those subsequent ones had a 2 month fill or a 3 month fill for those when it was the same drug. Because if it's the same drug, there seems to me there's probably a common explanation. But wondered what you all thought of that as a plausible element.

Reverend Dr. Phillip Fleming: Well, definitely argue that COVID had something to do with either to the delayed treatment or the treatment may have stopped for a period of time. And due to the fact that a lot of places including clinics and things closed down for a few months so it definitely was the COVID impacted either delay in treatment or the treatment may have stopped during that time.

Douglas Fish: Thank you. Other comments or questions for Barb? Okay, and then we have one last presentation, it's short, it's not 100 slides. So, this is on our Prescribed Education Program, Alexia Sroka is up and Georgia is going to pull up the slides here and there they are.

Alexia Sroka: Good afternoon, I'll just do a quick check here. Are you able to hear me well?

Douglas Fish: Yeah, you might just get a little closer to the mic.

Alexia Sroka: Is this better?

Douglas Fish: Yes.

Alexia Sroka: Okay, perfect. Okay, so today I'll provide a quick brief overview of the Medical Prescriber Education Program MPEP for short and this will include what's new in the program relaunch as well as future direction.

Starting with the legislation that prompted the formation of MPEP this currently resides in the New York State Public Health Law charter 45, section 279, the full text is here but an abridged summary of that is that the Department shall collaborate with an academic institution to deliver evidence-based, noncommercial pharmaceutical information to prescribers.

In line with that legislation, MPEP has defined its mission to assist prescribers in making therapeutic recommendations in accordance with the best practices through the delivery of accredited evidence based educational activities.

To direct the program to that mission, MPEP will not only provide information about pharmacotherapy, but also use best practices in education to maximize those learning benefits.

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Before we look to where the program is currently, we will give a historical nod to the program's formation in 2008. Throughout the years, the program has utilized academic detailing one on one visits, and live webinar events which were met with logistical challenges and then a global pandemic. Now moving to the present and beyond, the emphasis will be on program enhancements and key elements of this launch including the enduring activity format which will still offer continuing education credit and be free of charge to prescribers.

To define enduring material, it's on demand activities that a participant can determine when and where they would like to complete them. To see how one of these enduring activities come to life and the synergy behind it, this graphic depicts those very elements of that development process. Starting with the concept MPEP programs often arise from an educational need or a gap in knowledge which, for example, could come from conversations with key New York State stakeholders or subject matter experts. The subject matter experts then contribute to that content which throughout the process of the development of the activity undergoes a rigorous internal peer review by UB faculty staff among others. One of the key features of this enduring format is the audio and video recorded by the UB Center for the Arts. By offering the video-based learning a variety of learning styles can be accommodated in that format. While the content is in production, the learning platform is at the same time being constructed with items such as pre and post questions as well as activity feedback evaluations. In the postproduction or the implementation phase, the video is edited, integrated into that delivery platform and then reviewed by a pilot group. After it's released, that activity will be marketed through various channels and in total this entire process can take anywhere from 4 to 6 months from start to launch.

In addition to creating content, getting the word out about the program relaunch has been a focus, marketing is a huge piece of that which has taken place using digital campaigns such as targeted e-mails to past participants, notifications using the Integrated Health Alerting and Notification System. MPEP also continues to explore additional ways to reach prescribers, for example through networking contacts and the program also strives to create a valuable space for information. Phase 1 of this was a complete website revamp.

So, the MPEP website available at the URL listed here on this slide has a whole new look and feel with intuitive navigation and mobile responsiveness. The website can be available in a variety of formats, especially to those on the go. Several new features were also added. Tying back into the marketing aspects, there are constant ways to join the MPEP mailing list to be alerted to new activity releases, contact us, and suggestion forms for enhanced communication and engagement are also now available. On the next two slides, we'll demo what the website looks like.

So here is a snapshot of what the homepage looks like in the overall visual feel now. There are multiple ways to access the various pages, both using the bars at the top as well as the images near the bottom of the screen here. Looking at the top, there is a new MPEP logo that serves as a home navigation button and across the top, educational programs is where you can find specific programs, and then under other learning opportunities, this opens into a list of other educational programs from the UB DOH collaborative such as defending the lock zone via nonpatient specific order.

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Another important link that you can find under this, other opportunities tab is the OVA prescriber training program. That's the training that fulfills the prescriber training mandate in New York State. The MPEP website contains a link to the program to serve as another gateway to access that activity which has seen over 75,000 prescriber participants over the last 3-year requirement period. I will mention that that program is currently undergoing updates which will include the newly released 2022 CDC opioid prescribing guidelines, and while those updates are underway, the current program will remain accessible.

On this slide, this is showing those added features that I had mentioned such as the sidebar there where participants can interact and subscribe to be alerted to new program releases among other items.

The program that has led to this relaunch is a 1.0 contact hour program on outpatient antibiotic stewardship as a tool to curb antibiotic resistance. I will mention here that that underlying item throughout this presentation are hyperlinked if you have digital access to this presentation and throughout this, if a participant chooses to complete this activity, they can receive continuing medical education credits and/or continuing pharmacy education credits.

Using this antibiotic activity to further highlight the collaborative team approach, specific examples here are listed of those interactions, some are UB accreditation partners to a multiple disciplinary review by groups of DOH. There is an emphasis here on collaboration to diversify ideas and reach the end goal of meaningful high-quality education.

Here on the left-hand side of the slide, you'll see a list of benefits that has been observed with the relaunch of the program in this enduring format. One is for flexibility for persons to take the course at a time that is good for them as well as success with being able to reach providers across many disciplines. Here on the right-hand side, as of October 20th of this year, which was about 6-months after the launch of the antibiotic program, 386 people have registered for that antibiotic activity with over 200 completing it beginning to end. As of last week on December 8th, those numbers have increased to over 263 completing the program, and participants have been from a variety of professions from physicians, nurse practitioners, physician assistants, pharmacists, students.

We can get into a little bit more of where those practice settings were. So, from voluntary self-reported information, we were able to see that the antibiotic enduring activity was able to reach participants in outpatient clinics all the way to correctional facilities and school based clinics. All those are listed here.

And from those same voluntary survey evaluations, we were able to ask participants satisfaction and improvement in knowledge after taking the program, both of which are favorable and showed that most participants either strongly agreed, which is represented here by the green bar, or agreed, the blue bar that they were satisfied with the content, they felt that they would be able to apply those concepts discussed during the program to their current practice, as well as they felt that their knowledge of the subject was improved.

So, overall, the program relaunch has offered valuable positive feedback and will continue to develop an expanded library of programming. The next activity and progress will focus on hyperlipidemia and there will continue to be ongoing monitoring of feedback to allow MPEP to

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respond to topics or any preferences and or delivery methods to remain a premiere resource for New York State Medicaid Prescribers. And with that it is the last slide. I thank you for your time and encourage you to check out the new website or any of the educational offerings.

Douglas Fish: Thank you, Alexia. We had some feedback there, just a minute. Let's try it again. Do we have our sites?

Female: Yes, we can hear you.

Douglas Fish: Okay, good. Questions for Alexia on the Medicaid Prescriber Education Program?

Reverend Dr. Phillip Fleming: So, I know this was mentioned but how are constant updates being loaded up? Because I know for Services, which is specialist training platform, they actually shut down for a month after each term to implement other suggestions that Academy of Peer Services give to Buffalo University. Maybe I'm just talking as a suggestion, I don't know how feasible that would be, but that's something that the Academy of Peer Services does.

Douglas Fish: Did you hear that, Alexia?

Alexia Sroka: Yes, I did. Thank you for that input. So, each of the programs, so the way the enduring programs, they have a lifespan because they are accredited both for medical education and pharmacy education, and the way that sort of works into the program is that program updates go on while they're still online so there won't be an interruption in those.

Reverend Dr. Phillip Fleming: Maybe that's something I can bring back to some of my colleagues with their services because they shut down for a period of 4 weeks and I know students are eager to have the option to continue on while those updates happen. So, I am going to bring that back to them.

Douglas Fish: Other questions or comments? Okay. Hearing none, it's 2:01 perfect timing. I want to thank everyone for your patience today, also for getting to the sites, clearing your schedule to be flexible with the reschedule as it relates to quorum. So, really glad we could get this meeting in this year. When we do these multisite and virtual pieces, there is a lot of logistics, so thanks to the team for making it all work today. We had some other unexpected surprises, which is fine, we worked through all that. So, really grateful for your participation and wish everyone a wonderful holiday and safe travels home today. I'm going to turn it over to Kim for final comments, and then to Tony to wrap us up.

Kim: Thanks Doug. I would just echo Doug's appreciation for your patience, also making time today. We know we had to reschedule and this time of year it's different for everyone, but hopefully, we will get better with the foresight technology. But I think that's it for today. We also appreciate our new members who have signed on, so, Tony. Any final words?

Tony Merola: Just apologizing for the technical difficulties that we had, appreciate everybody's patience on getting us through those. I think we did okay. I would just ask the DUR Board members to look forward to an e-mail coming to your inbox regarding your availability for 2023 DUR Board meetings that will be coming soon. We are trying to get those meetings on the calendar. So, get holds on everybody's calendar and that plays into getting quorum for these

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meetings. So, we appreciate everything you've done over this another year. it's hard to believe we're through another year, 2022 going into 2023, but your patience and dedication is truly appreciated. So, with that Doug, I think we can officially adjourn.

Douglas Fish: Thank you and thanks at the remote sites for all the hosts, we really appreciate it. Be well.