AHCCCS

Pharmacy and Therapeutics Committee Written Public Testimony

January 24, 2024

Name:	Jen Farmer
Company or Organization:	Friedreich's Ataxia Research Alliance
Business Address:	533 W Uwchlan Ave
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Representation:	Checked
Affiliation:	Unchecked
Please check the box of the statement that best applies.:	I do not have a current or recent (within the last 24 months) financial arrangement or affiliation with any organization that may have a direct interest in the business before the AHCCCS P&T Committee.
Summary of Testimony:	Friedreich's ataxia (FA) is a progressive, debilitating, life shortening condition that affects about 4,000 individuals in the US. Skyclarys is the first and only FDA approved drug for FA and has been shown to slow progression of neurological symptoms. I would like to address the inclusion of an mFARS score in the proposed prior authorization criteria. The mFARS was developed as a specialized research tool and is not regularly used in clinical practice. Instead of this specialized tool that requires training to administer and score, I recommend clinical assessment of the components of the mFARS including bulbar, upper limb, lower limb, and upright stability evaluations. Additionally, requiring patients to fall within a given range on the mFARS excludes patients with more advanced disease who can still benefit from Skyclarys.

Drug/Product:	Skyclarys
Therapeutic Drug Class:	Neurological
Testimony Format:	Oral

Name:	Aviva Rosenberg
Company or Organization:	Gaucher Community Alliance
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Please check the box of the statement that best applies.:	I do not have a current or recent (within the last 24 months) financial arrangement or affiliation with any organization that may have a direct interest in the business before the AHCCCS P&T Committee.
Summary of Testimony:	My name is Aviva Rosenberg. I am the co-founder and co-president of Gaucher Community Alliance, a national patient advocacy organization based in Pennsylvania. Both myself and my 16 year old son, Eli, have Gaucher disease type 1. We are so fortunate to have numerous treatments available that allow individuals with type 1 to lead a full life and individuals with more severe disease to slow the progression. As this disease impacts so many different areas of the body, including organs, bones, blood and central nervous system, physicians and families work very closely together to find a treatment option that affords the patient the highest quality of life possible. Over the course of my life, I have been on three different treatments until I found the one that works best for my body and life. It is so important that all patients, regardless of payor source, have access to the full range of treatments so that their physician can make the best medical decision for that patient. If patients are limited to a certain treatment, which is not optimal for their disease state, it can have detrimental effects on their health and their entire family.

	We have numerous community members living in Arizona. As Co-President of the national patient organization, I strongly encourage the AHCCCS Pharmacy & Therapeutics Committee to maintain all FDA approved treatments for Gaucher disease on the Preferred Drug List so that the best medical decisions can be left to the physician and patient. Thank you for your time.
Drug/Product:	Cerezyme VPRIV Elelyso Cerdelga Zavesca
Therapeutic Drug Class:	Enzyme Replacement - Gaucher Disease
Testimony Format:	Oral

Name:	Matthew Prentice
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Business Address:	7550 Teague Road, Suite 220 Hanover, Maryland 21076
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Affiliation:	Unchecked

Please check the box of the statement that best applies.:	I have a financial interest, affiliation or am employed by an organization that may have a direct interest in the business before the AHCCCS P&T Committee.
If yes, name organizations and roles::	The Immune Deficiency Foundation, a 501 (c)(3) organization, is dedicated to improving the diagnosis, treatment, and quality of life of people affected by primary immunodeficiency (PI) through fostering a community empowered by advocacy, education, and research. I am employed by the Immune Deficiency Foundation, which receives philanthropic funds from a variety of providers, including producers/distributors of immunoglobulin therapies. We have a strict policy that our advocacy efforts are independent of any funding received.
Summary of Testimony:	January 2, 2024 Arizona Health Care Cost Containment System - Pharmacy & Therapeutics Committee On behalf of the Immune Deficiency Foundation and individuals with primary immunodeficiency (PI), thank you for the opportunity to provide brief comments on your review of the class of Immune Globulins. The Immune Deficiency Foundation is dedicated to improving the diagnosis, treatment, and quality of life of people affected by PI through fostering a community empowered by advocacy, education, and research. Individuals with PI have one of the over 450 rare disorders in which a person's immune system fails to function properly because of genetic or intrinsic defects. Individuals with PI are highly susceptible to recurrent, persistent, and severe infections, which without treatment, can lead to organ damage and often require significant interventions and hospitalization. Fortunately, most people with PI can live healthy, productive lives if they receive lifelong immunoglobulin (Ig) treatments. Immunoglobulin (Ig) replacement therapy is the standard treatment for individuals with antibody deficiencies. Ig is given intravenously (IVIG) or subcutaneously (SCIG) and replaces the antibodies a person should be making. Ig products are biologics, derived from human donated plasma. They are not designated as interchangeable by the Food and Drug Administration (FDA) and have no generic equivalents. Individuals respond differently to each product and may have different side effects. Patients and their healthcare providers must be able to decide on the best route of replacement therapy for patients with PI. Dictation of specific Ig products by insurers can

lead to compromised care, decreased quality of life, and eventually increased costs for both the patient and insurer.

We thank you for your review of this critical class of therapies for the PI community. The Immune Deficiency Foundation is a resource for the Committee in their review and recommendation regarding Immune Globulins. We recommend you refer to the Immune Deficiency Foundation's Medical Advisory Committee's Model Coverage Policy for Immunoglobulin Replacement Therapy, available at https://primaryimmune.org/sites/default/files/MAC%20Model%20Coverage%20Policy%20for%20Ig%20with%20Appendix%207.22.21.pdf.

Sincerely,

Matthew Prentice, MPH
Director of State Policy
Immune Deficiency Foundation
(443) 901-4579
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Drug/Product:	No specific immunoglobulin drug or product.
Therapeutic Drug Class:	Immune Globulins
Testimony Format:	Written

Name:	Cindy Lee Herrick
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Please check the box of the statement that best applies.:	I have a financial interest, affiliation or am employed by an organization that may have a direct interest in the business before the AHCCCS P&T Committee.
If yes, name organizations and roles::	Senior Research & Editorial Manager, Policy Center for Maternal Mental Health
Summary of Testimony:	The new postpartum depression drug Zurzuvae is now available in the U.S., however, only 17 of 1000+ insurers (less than 1%) and one PBM have published coverage guidelines. Only one of the six largest insurers, Centene, has issued coverage guidelines however, with restrictions on coverage. Without an insurer's published coverage guidelines, prescribing providers and patients are more likely to experience delays and restrictions accessing this new treatment. Of the 17 insurers with published coverage guidelines, five are requiring patients to try another drug first, three limit whether an Ob/Gyn can prescribe, three require a comprehensive evaluation inconsistent with DSM-5 guidelines, and one requires a diagnosis of severe depression.
Drug/Product:	Zurzuvae
Therapeutic Drug Class:	neuroactive steroid antidepressant drug
Testimony Format:	Written

Name:	Carmen Koiscek, Nurse Midwife and Board Certified Psychiatric Mental Health Nurse Practitioner
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Summary of Testimony:	This is not a 'new' medication but rather a new formulation of the IV medication Zulresso (brexanolone) that was approved by the FDA 3.2019 for PPD, post partum depression. The IV version required in patient status with a 60 hour infusion which was clearly limiting to suburban and rural candidates, interrupted the bonding of mother/baby and required transportation, with others, to aid both the mother and the baby and shared the burden of caregiving to others during the hospitalization thereby limiting uptake of the PPD treatment option. These challenges were fiscally limiting, time challenging and logistically challenged leading to a clunky and often times overlooked option for PPD as is historically demonstrated with limited utilization of the IV form for PPD. As technology has advanced, now with the oral FDA indication of Zuranolone (zurzuave), mothers in the PPD period, up to 24 months post birth, are afforded with an oral treatment of medication for 14 days to treat PPD symptoms due to the unique MOA, mechanism of action, although not fully understood, is thought to be related to its positive allosteric modulation of GABAa receptors both inside and outside of the synapse. With the consideration today, it is imperative to realize that having access for all women across the far reaching corners of Arizona for further improvement of mental health, including in this PPD timeframe as truly, PPD impacts not only the mother, but the baby, nuclear family, extended family and the extending community as well. Standing up for women is what approving access for this product truly will do.
Drug/Product:	Zuranolone, sold under the brand name Zurzuvae
Therapeutic Drug Class:	Neuroactive Steroid GABAa Receptor Positive Allosteric Modulator
Testimony Format:	Written