ARKANSAS REGISTER

Proposed Rule Cover Sheet

Secretary of State
John Thurston
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Little Rock, Arkansas 72201-1094
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Name of Department Arkansas Department of Commerce

Agency or Division Name Arkansas Insurance Department

Other Subdivision or Department, If Applicable Compliance Division

Previous Agency Name, If Applicable

Contact Person Dan Honey, Counsel Product Compliance

Contact E-mail dan.honey@arkansas.gov

Contact Phone 501-371-2807

Name of Rule Proposed Amended Rule 127: "Authorization of Off-Label Use For Drug Treatments For Pediatric Acute-Onset and Autoimmune Neuropsychiatric Syndrome"

Newspaper Name Arkansas Democrat Gazette

Date of Publishing September 8, 9, 10, 2023

Final Date for Public Comment 10/11/2023

Location and Time of Public Meeting October 11, 2023, at 10:00 A.M.,Arkansas Department of Commerce, 1 Commerce Way, Little Rock, AR 72202

Michael Preston
SECRETARY OF COMMERCE

Alan McClain
COMMISSIONER,
ARKANSAS INSURANCE
DEPARTMENT

September 8, 2023

Arkansas Secretary of State
State Capitol Building
Little Rock, AR 72201
Attn. Arkansas Register

Re: Proposed Rule 127: "Authorization of Off-Label Use For Drug Treatments For Pediatric Acute-Onset and Autoimmune Neuropsychiatric Syndrome"

Dear Secretary:

Arkansas Act 1478 of 2003 adds to requirements for adoption and re-adoption of public agency rules and regulations. In that regard, the new Act:

(a) Requires notice of proposed Rule 127, as well as the Public Rule Hearing at the Arkansas Insurance Department, to be published by the Arkansas Secretary Of State on the Internet for thirty (30) days pursuant to Ark. Code Ann. § 25-15-218 of the Arkansas Administrative Procedure Act, as amended; and

(b) Requires DOI filing of its adopted and proposed rules and notices with the Arkansas Secretary Of State in an electronic format acceptable to the Secretary.

In that regard, the Department has scheduled a public hearing as to Proposed Rule 127: "Authorization of Off-Label Use For Drug Treatments For Pediatric Acute-Onset and Autoimmune Neuropsychiatric Syndrome".
Enclosed are the DOI Notices of Public Hearing and a copy of the proposed rule.

Please arrange to publish the information in a format acceptable to the Secretary for at least 30 days in advance. Can you send us confirmation that we can use in the transcript as a public hearing exhibit?

An electronic filing will be made within the statutorily required 7 days. Thanks for your help.

Sincerely,
Clara D. Mezza

Clara Mezza
Administrative Analyst/Legal Division
clara.mezza@arkansas.gov
501-683-3497

Enclosures

Michael Preston
SECRETARY OF COMMERCE

Alan McClain
COMMISSIONER,
ARKANSAS INSURANCE
DEPARTMENT

NOTICE OF PUBLIC HEARING

The Arkansas Insurance Department will host a Public Hearing on October 11, 2023, at 10:00 AM., in the Second Floor Diamond Mine Room Hearing Room, in the Arkansas Department of Commerce Building, One Commerce Way, Little Rock, Arkansas 72202. The Arkansas Insurance Commissioner is considering adopting proposed amended Rule 127, "Authorization of Off-Label Use For Drug Treatments for Pediatric Acute-Onset and Autoimmune Neuropsychiatric Syndrome" to consider adoption of an amendment to existing rule 127, necessitated by Act 876 of 2023, and as required by the Arkansas Administrative Procedures Act in Ark. Code Ann. § 25-15-206. Copies of the proposed Rule may be obtained by writing or calling the Arkansas Insurance Department, or by visiting its Internet site at https://www.insurance.arkansas.gov/pages/industry-regulation/legal/proposed-rules/. For more information contact the Legal Division, Arkansas Insurance Department at 501-371-2820.

Amended PROPOSED RULE 127

AUTHORIZATION OF OFF-LABEL USE OF DRUG TREATMENTS FOR PEDIATRIC ACUTE-ONSET AND AUTOIMMUNE NEUROPSYCHIATRIC SYNDROME

TABLE OF CONTENTS

SECTION 1. AUTHORITY

This Rule is issued pursuant to Act 1054 of 2021 (hereafter, Act 1054), as amended by Act 876 of 2023, and codified in Ark. Code Ann. § 23-79-1905, which requires the Arkansas Insurance Department ("AID") to issue rules for the implementation and administration of coverage for use of off-label drug treatments to treat patients diagnosed with acute-onset neuropsychiatric syndrome and pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection under Ark. Code Ann. § 23-79-1905.

SECTION 2. DEFINITIONS

Unless otherwise separately defined in this rule and consistent with state law, the terms or phrases as used in this rule shall follow the definitions of such terms or phrases as defined in Ark. Code Ann. § 23-79-1905.

(1) "Healthcare service" means a healthcare procedure, treatment, or service provided by a medical provider.

(2) "Medical Provider" means a person who performs healthcare services for patients with PANS or PANDAS, as defined in Act 1054, and herein.

(3) "PANS" means pediatric acute-onset neuropsychiatric syndrome, a clinically defined disorder characterized by sudden onset of obsessive-compulsive symptom or eating restrictions, accompanied by two (2) or more symptoms of acute behavioral deterioration or motor and sensory changes, or both.

(4) "PANDAS" means pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection, described as a subset of symptoms affecting children and adolescents within the broader PANS classification.

SECTION 3. COVERAGE REQUIREMENT REVIEW

(a) Pursuant to Ark. Code Ann. § 23-79-1905(c), a health benefit plan that is offered, issued, provided, or renewed in this state shall provide coverage for off-label use of intravenous immunoglobin (hereafter "IVIG"), to treat individuals diagnosed with pediatric acute-onset neuropsychiatric syndrome and pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection, or both, on or after January 1, 2022, under a patient specific treatment plan consistent with protocols set forth in Appendix A of this Rule established in consultation with the Childhood Post-infectious Autoimmune Encephalopathy Center of Excellence.

(b) Pursuant to Ark. Code Ann. § 23-79-1905(f) a health benefit plan that is offered, issued, or renewed in this state shall provide coverage for the use of intravenous immunoglobulin to treat individuals diagnosed with pediatric acute-onset neuropsychiatric syndrome or pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection, or both, on or after January 1, 2024, if the pediatric patient's primary care physician, in consultation with an Arkansas licensed pediatric psychiatrist and an Arkansas licensed physician who practices in at least one (1) pediatric subspecialty, including a neurologist, rheumatologist, or infectious disease physician who have treated the pediatric patient, determines and agrees that the treatment is necessary and follows a patient-specific treatment plan. A primary care physician may continue to consult with the Center of Excellence, and the appeal process for a denial of coverage or adverse determination under this section shall align with the normal appeal process of any other type of denial under the health benefit plan, and apply to all plans.

(c) Coverage for off-label use of IVIG and associated drug treatment as set forth in this section above may be subject to policy deductions or copayment requirements of a healthcare insurer or health benefit plan, and such coverage for benefits shall not be diminished or limited as otherwise allowable under a health benefit plan.

SECTION 4. FDA APPOVAL AND REPORTING

(a) Upon approval by the United States Food and Drug Administration of the use of intravenous immunoglobulin to treat individuals diagnosed with pediatric acute-onset neuropsychiatric syndrome or pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection, or both, the Commissioner, with consultation and upon approval of the Arkansas State Medical Board and the Arkansas State Board of Pharmacy, will adopt by rule a written statewide protocol that provides clarification that the consultation required under section 3(b) and the patient-specific treatment plan required under subsection 3(a) of this Rule are no longer required for coverage under a health benefit plan.

(b) A primary care physician who prescribes intravenous immunoglobulin to treat individuals diagnosed with pediatric acute-onset neuropsychiatric syndrome or pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection, or both, shall report the data to the Childhood Post-infectious Autoimmune Encephalopathy Center of Excellence.

SECTION 4. CODING FEE FOR EVALUATION

Every health benefit plan shall permit appropriate claims, coding fees, or charges for related healthcare services, including evaluations, performed by medical providers in association or collaboration with the Childhood Post-infectious Autoimmune Encephalopathy Center of Excellence, as described in § 3(a) above.

SECTION 5. ENFORCEMENT AND PENALTIES

Pursuant to Ark. Code Ann. § 23-61-103 et seq. the Insurance Commissioner shall have the power and authority expressly conferred or reasonably implied by the Insurance Code. This includes, but is not limited to, the power to fully investigate potential violations of Act 1054 and this Rule, conduct examinations, take injunctive and administrative action as necessary and appropriate, and impose fines and penalties upon a finding that a health benefit plan has failed to comply herewith.

SECTION 6. EFFECTIVE DATE

The effective date of this Rule is August 31, 2023

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ALAN MCCLAIN
INSURANCE COMMISSIONER

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DATE

APPENDIX A

University of Arkansas for Medical Sciences/Arkansas Children's Hospital

Childhood Postinfectious Autoimmune Encephalopathy (CPAE) Center of Excellence

Protocol for Evaluation and Treatment of PANS/PANDAS

To make treatment for children with Postinfectious Autoimmune Encephalopathy (PANS/PANDAS) consistent across the state of Arkansas:

1. The University of Arkansas for Medical Sciences/Arkansas Children's Hospital Childhood Postinfectious Autoimmune Encephalopathy (CPAE) Center of Excellence, provides information on the latest, evidence-based evaluation and management guidelines for diagnosing and treating Pediatric Acute-onset Neuropsychiatric Syndrome (PANS) and Pediatric Acute-onset Neuropsychiatric Disorders Associated with Streptococcus (PANDAS).

2. The information incorporates the guidance provided by the available evidence-based medical literature on evaluation and management of children with PANS and PANDAS (e.g., Chang et al. 2015, Swedo et al. 2017, Thienemann et al. 2017, Frankovich & Swedo et al. 2017, Cooperstock et al. 2017).

3. Based on the latest evaluation and management guidelines and in order to provide best-practice treatment of PANS/PANDAS, the following considerations will guide recommendations for intravenous immunoglobulin (IVIG) therapy:

    A. Only after a licensed physician (e.g., pediatrician, psychiatrist, developmental pediatrician, etc.) has treated the patient with two or more less-intensive therapies (e.g., limited course of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, selective serotonin reuptake inhibitors (SSRIs), behavioral therapy, short-

course antibiotic therapy); and these therapies were not effective; AND

B. Only after a consultation and recommendation is issued by a pediatric subspecialist (e.g., pediatric neurologist, pediatric immunologist, pediatric rheumatologist, or pediatric infectious disease specialist) for IVIG treatment; THEN
C. Up to 3 monthly immunomodulatory courses of IVIG therapy may be recommended for treatment of PANDAS and PANS. In addition, a reevaluation at 3 months by the pediatric sub-specialist will be required for continued therapy of IVIG. This evaluation must include objective clinical testing by a specialist trained in structured and/or semi-structured interview assessments, such as a neuropsychologist, which must be performed both pre-treatment and post-treatment to demonstrate significant clinical improvement.

The University of Arkansas for Medical Sciences/Arkansas Children's Hospital CPAE Center of Excellence physicians will be available on a consultation or referral basis to work with referring physicians on the utilization of IVIG prescriptions for PANS/PANDAS patients.

MARKUP

PROPOSED AMENDED RULE 127

AUTHORIZATION OF OFF-LABEL USE OF DRUG TREATMENTS FOR PEDIATRIC ACUTE-ONSET AND AUTOIMMUNE NEUROPSYCHIATRIC SYNDROME

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Every health benefit plan shall permit appropriate claims, coding fees, or charges for related healthcare services, including evaluations, performed by medical providers in association or collaboration with the Post-infectious Autoimmune Encephalopathy Clinic established by the University of Arkansas for Medical Sciences in collaboration with Arkansas Children's Hospital, as described in § 3(a) above.

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SECTION 6. EFFECTIVE DATE

The effective date of this Rule is January 1, 2022.

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ALAN MCCLAIN
INSURANCE COMMISSIONER

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