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**PROPOSED RULE 127**

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

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**SECTION 1. AUTHORITY**

This Rule is issued pursuant to Act 1054 of 2021 (hereafter, Act 1054), as 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 immunoglobulin (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 established by the Post-infectious Autoimmune Encephalopathy Clinic established by the University of Arkansas for Medical Sciences in collaboration with Arkansas Children’s Hospital.

(b) Coverage for off-label use of IVIG and associated drug treatment as set forth in § 3(a) above may be subject to policy deductions or copayment requirements and any standard prior authorization review 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. 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 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.

### **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 January 1, 2022.

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ALAN MCCLAIN  
INSURANCE COMMISSIONER

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DATE

State of Arkansas                      *As Engrossed: S4/15/21 H4/21/21*  
93rd General Assembly                      **A Bill**  
Regular Session, 2021

SENATE BILL 639

By: Senator K. Hammer  
By: Representative Cloud

**For An Act To Be Entitled**

AN ACT TO AUTHORIZE OFF-LABEL USE OF DRUG TREATMENTS  
TO TREAT PATIENTS DIAGNOSED WITH PEDIATRIC ACUTE-  
ONSET NEUROPSYCHIATRIC SYNDROME AND PEDIATRIC  
AUTOIMMUNE NEUROPSYCHIATRIC DISORDERS ASSOCIATED WITH  
STREPTOCOCCAL INFECTION; AND FOR OTHER PURPOSES.

**Subtitle**

TO AUTHORIZE OFF-LABEL USE OF DRUG  
TREATMENTS TO TREAT PATIENTS DIAGNOSED  
WITH PEDIATRIC ACUTE-ONSET  
NEUROPSYCHIATRIC SYNDROME AND PEDIATRIC  
AUTOIMMUNE NEUROPSYCHIATRIC DISORDERS  
ASSOCIATED WITH STREPTOCOCCAL INFECTION.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code Title 23, Chapter 79, Subchapter 19, is  
amended to add an additional section to read as follows:

23-79-1903. Off-label use of drug treatment to treat pediatric acute-  
onset neuropsychiatric syndrome and pediatric autoimmune neuropsychiatric  
disorders associated with streptococcal infection – Legislative findings –  
Definitions.

(a) The General Assembly finds that:

(1) Pediatric acute-onset neuropsychiatric syndrome, also known  
as "PANS", is a clinically defined disorder characterized by the sudden onset  
of obsessive-compulsive symptoms or eating restrictions, accompanied by two



1 (2) or more symptoms of acute behavioral deterioration or motor and sensory  
2 changes, or both;

3 (2) Pediatric autoimmune neuropsychiatric disorders associated  
4 with streptococcal infection, also known as "PANDAS", is a term used to  
5 describe a subset of symptoms affecting children and adolescents within the  
6 broader PANS classification;

7 (3) Other states may require coverage for off-label use of drug  
8 treatments to treat pediatric acute-onset neuropsychiatric syndrome and  
9 pediatric autoimmune neuropsychiatric disorders associated with streptococcal  
10 infection; and

11 (4) Arkansas does not require coverage for off-label use of drug  
12 treatments to treat patients who are diagnosed with pediatric acute-onset  
13 neuropsychiatric syndrome and pediatric autoimmune neuropsychiatric disorders  
14 associated with streptococcal infections.

15 (b) As used in this section:

16 (1)(A) "Health benefit plan" means an individual, blanket, or  
17 any group plan, policy, or contract for healthcare services issued, renewed,  
18 or extended in this state by a healthcare insurer, health maintenance  
19 organization, hospital medical service corporation, or self-insured  
20 governmental or church plan in this state.

21 (B) "Health benefit plan" includes:

22 (i) A plan offered by a risk-based provider  
23 organization as established under the Medicaid Provider-Led Organized Care  
24 Act, § 20-77-2701 et seq.;

25 (ii) Indemnity and managed care plans; and

26 (iii) Plans providing health benefits to state and  
27 public school employees under § 21-5-401 et seq.

28 (C) "Health benefit plan" does not include:

29 (i) A plan that provides only dental benefits or eye  
30 and vision care benefits;

31 (ii) A disability income plan;

32 (iii) A credit insurance plan;

33 (iv) Insurance coverage issued as a supplement to  
34 liability insurance;

35 (v) Medical payments under an automobile or  
36 homeowners' insurance plan;

1 (vi) A health benefit plan provided under Arkansas  
2 Constitution, Article 5, § 32, the Workers' Compensation Law, § 11-9-101 et  
3 seq., and the Public Employee Workers' Compensation Act, § 21-5-601 et seq.;

4 (vii) A plan that provides only indemnity for  
5 hospital confinement;

6 (viii) An accident-only plan; or

7 (ix) A specified disease plan; and

8 (2)(A) "Healthcare insurer" means any insurance company,  
9 hospital and medical service corporation, or health maintenance organization  
10 that issues or delivers health benefit plans in this state and is subject to  
11 any of the following laws:

12 (i) The insurance laws of this state;

13 (ii) Section 23-75-101 et seq., pertaining to  
14 hospital and medical service corporations;

15 (iii) Section 23-76-101 et seq., pertaining to  
16 health maintenance organizations; or

17 (iv) A risk-based provider organization established  
18 under the Medicaid Provider-Led Organized Care Act, § 20-77-2701 et seq.

19 (B) "Healthcare insurer" does not include an entity that  
20 provides only dental benefits or eye and vision care benefits.

21 (c) A health benefit plan that is offered, issued, or renewed in this  
22 state, including a plan offered by a risk-based provider organization  
23 established under the Medicaid Provider-Led Organized Care Act, § 20-77-2701  
24 et seq., shall provide coverage for off-label use of intravenous  
25 immunoglobulin, also known as "IVIG", to treat individuals diagnosed with  
26 pediatric acute-onset neuropsychiatric syndrome and pediatric autoimmune  
27 neuropsychiatric disorders associated with streptococcal infection, or both,  
28 on or after January 1, 2022, under a patient-specific treatment plan  
29 established by the Childhood Post-infectious Autoimmune Encephalopathy Clinic  
30 established by the University of Arkansas for Medical Sciences in  
31 collaboration with Arkansas Children's Hospital.

32 (d) The coverage for off-label use of drug treatment to treat  
33 pediatric acute-onset neuropsychiatric syndrome and pediatric autoimmune  
34 neuropsychiatric disorders associated with streptococcal infection under this  
35 section:

36 (1) May be subject to policy deductions or copayment

1 requirements and any standard prior authorization review of a healthcare  
2 insurer or a health benefit plan; and

3 (2) Does not diminish or limit benefits otherwise allowable  
4 under a health benefit plan.

5 (e) The Insurance Commissioner shall develop and promulgate rules for  
6 the implementation and administration of this section.

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/s/K. Hammer

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APPROVED: 4/29/21

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