

ARKANSAS REGISTER

Proposed Rule Cover Sheet



Secretary of State
John Thurston
500 Woodlane Street, Suite 026
Little Rock, Arkansas 72201-1094
(501) 682-5070
www.sos.arkansas.gov



Name of Department _____

Agency or Division Name _____

Other Subdivision or Department, If Applicable _____

Previous Agency Name, If Applicable _____

Contact Person _____

Contact E-mail _____

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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. § 23-79-1903, 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. § 23-79-1903.

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. § 23-79-1903.

- (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. § 23-79-1903(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.

ALAN MCCLAIN
INSURANCE COMMISSIONER

DATE

1 State of Arkansas

As Engrossed: S4/15/21 H4/21/21

2 93rd General Assembly

A Bill

3 Regular Session, 2021

SENATE BILL 639

4
5 By: Senator K. Hammer

6 By: Representative Cloud

For An Act To Be Entitled

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

Subtitle

16
17 TO AUTHORIZE OFF-LABEL USE OF DRUG
18 TREATMENTS TO TREAT PATIENTS DIAGNOSED
19 WITH PEDIATRIC ACUTE-ONSET
20 NEUROPSYCHIATRIC SYNDROME AND PEDIATRIC
21 AUTOIMMUNE NEUROPSYCHIATRIC DISORDERS
22 ASSOCIATED WITH STREPTOCOCCAL INFECTION.

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

26
27 SECTION 1. Arkansas Code Title 23, Chapter 79, Subchapter 19, is
28 amended to add an additional section to read as follows:

29 23-79-1903. Off-label use of drug treatment to treat pediatric acute-
30 onset neuropsychiatric syndrome and pediatric autoimmune neuropsychiatric
31 disorders associated with streptococcal infection – Legislative findings –
32 Definitions.

33 (a) The General Assembly finds that:

34 (1) Pediatric acute-onset neuropsychiatric syndrome, also known
35 as "PANS", is a clinically defined disorder characterized by the sudden onset
36 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.

7
8 /s/K. Hammer

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11 APPROVED: 4/29/21
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EXECUTIVE SUMMARY

ARKANSAS INSURANCE DEPARTMENT PROPOSED RULE 127

Coverage for Off-Label Drugs for Treatment of PANS and PANDA

To: Arkansas Legislative Council & Arkansas Bureau of Legislative Research
From: Dan Honey, Counsel, Product Compliance, Arkansas Insurance Department
CC: Alan McClain, Arkansas Insurance Commissioner; Russ Galbraith, Deputy Insurance Commissioner; Jimmy Harris, Compliance Director; Jim Brader, General Counsel; Steve Porch, General Counsel, Arkansas Department of Commerce; Jennifer Bruce, Public and Legislative Affairs Director
Date: July 12, 2021

LEGISLATIVE AUTHORITY FOR RULE

Act 1054 of 2021, codified at Ark. Code Ann. § 23-79-1903, which requires the Arkansas Insurance Department (“AID”) to issue rules for the implementation and administration of coverage of off-label use for drug treatments for pediatric acute-onset neuropsychiatric syndrome (“PANS”), and pediatric autoimmune neuropsychiatric disorders associated with streptococcal (“PANDAS”) infection.

BACKGROUND AND PURPOSE OF RULE

The purpose of this Rule is to enforce Act 1054 of 2021, codified at Ark. Code Ann. § 23-79-1903, pertaining to insurance coverage for off-label use of drug treatments for pediatric acute-onset neuropsychiatric syndrome (“PANS”), and pediatric autoimmune neuropsychiatric disorders associated with streptococcal (“PANDAS”) infection. (hereafter, Act 1054).

EXPLANATION OF THE PROPOSED RULE

The proposed Rule implements Act 1054:

- (1) creates a mechanism to review and evaluate coverage for off-label drug treatment for PANS and PANDAS insurance adjudications;
- (2) permits fees or charges for reimbursement from insurers for the off-label drug treatment for PANS and PANDAS; and
- (3) the proposed Rule also provides needed definitions not in Act 1054 of 2021