

PROPOSED-PROPOSED AMENDED RULE 127

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

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RECEIVED

SEP 12 2023

BUREAU OF LEGISLATIVE
RESEARCH

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)~~ ~~(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 consistent with protocols set forth in Appendix A of this Rule established in consultation with by the Childhood Post-infectious Autoimmune Encephalopathy Center of Excellence Clinic established by the University of Arkansas for Medical Sciences in collaboration with Arkansas Children’s Hospital.

~~(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 has 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.

~~(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. FDA APPROVAL 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 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

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 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.

MARK-UP

State of Arkansas As Engrossed: S4/3/23 H4/5/23

94th General Assembly

A Bill

Regular Session, 2023

SENATE BILL 181

By: Senator K. Hammer

By: Representative Warren

For An Act To Be Entitled

AN ACT TO MANDATE COVERAGE FOR USE OF INTRAVENOUS
IMMUNOGLOBULIN TO TREAT PEDIATRIC ACUTE-ONSET
NEUROPSYCHIATRIC SYNDROME OR PEDIATRIC AUTOIMMUNE
NEUROPSYCHIATRIC DISORDERS ASSOCIATED WITH
STREPTOCOCCAL INFECTION; TO DECLARE AN EMERGENCY; AND
FOR OTHER PURPOSES.

Subtitle

TO MANDATE COVERAGE FOR USE OF
INTRAVENOUS IMMUNOGLOBULIN TO TREAT
CERTAIN PEDIATRIC DISORDERS CAUSED BY
INFECTIONS; AND TO DECLARE AN EMERGENCY.

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

SECTION 1. Effective January 1, 2024, Arkansas Code § 23-79-1903 is repealed.

~~23-79-1903. Arkansas PANS/PANDAS Advisory Council—Creation—
Membership—Duties.~~

~~(a) There is created the Arkansas PANS/PANDAS Advisory Council to
consist of the following members:~~

~~(1) Two (2) members of the House of Representatives appointed by
the Speaker of the House of Representatives;~~

~~(2) Two (2) members of the Senate appointed by the President Pro
Tempore of the Senate;~~

~~(3) One (1) member who is a medical professional with two (2)~~



~~years of professional experience working with PANS/PANDAS patients, appointed by the Governor;~~

~~(4) One (1) member who is a medical professional with two (2) years of professional experience working with PANS/PANDAS patients, appointed by the council;~~

~~(5) The Secretary of the Department of Health or his or her designee, serving as an ex officio nonvoting member;~~

~~(6) The Insurance Commissioner or his or her designee, serving as an ex officio nonvoting member;~~

~~(7) Three (3) members appointed by the Governor who are employed by a public school district, one (1) member to be a public school nurse, one (1) member to be a public school counselor, and one (1) member to be a public school teacher;~~

~~(8) One (1) member who is designated by the Arkansas Hospital Association, Inc.;~~

~~(9) One (1) member who is designated by the Arkansas State Board of Nursing;~~

~~(10) One (1) member who is designated by the Arkansas Pharmacist's Association;~~

~~(11) One (1) member who is designated by the American Academy of Allergy, Asthma, and Immunology;~~

~~(12) Two (2) members who are parents, appointed by the Governor; and~~

~~(13) One (1) member who is designated by the Arkansas Medical, Dental, and Pharmaceutical Association, Inc.~~

~~(b)(1) Upon appointment to the council, the initial members shall draw lots to determine the length of their terms.~~

~~(2) Appointments shall be for a term of four (4) years.~~

~~(3) Vacancies on the council shall be filled in the same manner as provided for the initial appointment.~~

~~(4) The new appointee shall serve for the remainder of the unexpired term.~~

~~(c) Members shall serve at the pleasure of the organizations they represent or of the Governor, as indicated.~~

~~(d)(1) The President Pro Tempore of the Senate shall appoint the Chair of the Arkansas PANS/PANDAS Advisory Council who shall be one (1) of the~~

~~legislative members of the council.~~

~~(2) The Speaker of the House of Representatives shall appoint the Vice Chair of the Arkansas PANS/PANDAS Advisory Council who shall be one (1) of the legislative members of the council.~~

~~(e)(1) A majority of the membership shall constitute a quorum.~~

~~(2) A majority vote of those members present shall be required for any action of the council.~~

~~(f)(1) The council shall meet as often as is deemed necessary by the chair.~~

~~(2) The council shall meet at the State Capitol Building in Little Rock, Arkansas.~~

~~(g) Legislators shall be paid per diem and mileage as authorized by law for attendance at meetings of interim committees of the General Assembly.~~

~~(h)(1) The council shall receive staff support from the Bureau of Legislative Research.~~

~~(2) The council shall receive assistance from the Children's Postinfectious Autoimmune Encephalopathy Center of Excellence at the University of Arizona Steele Children's Research Center with the preparation of any reports required by this subchapter.~~

~~(i) The council may:~~

~~(1) Make recommendations designed to improve and increase knowledge and develop mechanisms to increase clinical awareness and treatment throughout the state for pediatric acute-onset neuropsychiatric syndrome, also known as "PANS", and pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections, also known as "PANDAS", especially for healthcare professionals;~~

~~(2) Operate along with the interdisciplinary panel on PANS/PANDAS at the University of Arkansas for Medical Sciences to determine quarterly information, including case statistics, outcome measures, and other relevant information;~~

~~(3) Make recommendations concerning standard practice guidelines for the diagnosis and treatment of PANS/PANDAS for adult and pediatric patients who have been diagnosed with PANS/PANDAS;~~

~~(4) Provide outreach to educators and parents;~~

~~(5) Develop a network of volunteer experts on PANS/PANDAS to serve as resources within this state; and~~

~~(6) Consider any related topics associated with the council's charge.~~

~~(j)(1) The council shall report to the Senate Committee on Insurance and Commerce, the House Committee on Insurance and Commerce, the Senate Committee on Public Health, Welfare, and Labor, and the House Committee on Public Health, Welfare, and Labor, as requested.~~

~~(2) The report described in subdivision (j)(1) of this section shall be submitted to the Legislative Council for final review.~~

SECTION 2. Arkansas Code § 23-79-1904 is repealed.

~~23-79-1904. Sunset.~~

~~This subchapter shall expire on December 31, 2023, unless extended by the General Assembly.~~

SECTION 3. Arkansas Code § 23-79-1905 is amended to read as follows:

23-79-1905. Off-label use and coverage 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 (2) or more symptoms of acute behavioral deterioration or motor and sensory changes, or both;

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

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

(4) Arkansas does not require coverage for off-label use of drug treatments to treat patients who are diagnosed with pediatric acute-onset neuropsychiatric syndrome and pediatric autoimmune neuropsychiatric disorders

1 associated with streptococcal infections.

2 (b) As used in this section:

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

8 (B) "Health benefit plan" includes:

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

12 (ii) Indemnity and managed care plans; and

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

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

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

18 (ii) A disability income plan;

19 (iii) A credit insurance plan;

20 (iv) Insurance coverage issued as a supplement to
21 liability insurance;

22 (v) Medical payments under an automobile or
23 homeowners insurance plan;

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

27 (vii) A plan that provides only indemnity for
28 hospital confinement;

29 (viii) An accident-only plan; or

30 (ix) A specified disease plan; and

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

35 (i) The insurance laws of this state;

36 (ii) Section 23-75-101 et seq., pertaining to

1 hospital and medical service corporations;

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

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

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

8 (c)(1) A Except as provided in subsection (f) of this section, a
9 health benefit plan that is offered, issued, or renewed in this state,
10 including a plan offered by a risk-based provider organization established
11 under the Medicaid Provider-Led Organized Care Act, § 20-77-2701 et seq.,
12 shall provide coverage for off-label use of intravenous immunoglobulin, also
13 known as "IVIG", to treat individuals diagnosed with pediatric acute-onset
14 neuropsychiatric syndrome or pediatric autoimmune neuropsychiatric disorders
15 associated with streptococcal infection, or both, on or after January 1,
16 2022, under a patient-specific treatment plan established by the Childhood
17 Post-infectious Autoimmune Encephalopathy Clinic established by the
18 University of Arkansas for Medical Sciences in collaboration with Arkansas
19 Children's Hospital consistent with established protocols and rules to be
20 developed by the Insurance Commissioner, in consultation with the Childhood
21 Post-infectious Autoimmune Encephalopathy Center of Excellence.

22 (2) Rules to implement this subdivision have to be promulgated
23 by August 31, 2023.

24 (d) The coverage for ~~off-label~~ use of drug treatment to treat
25 pediatric acute-onset neuropsychiatric syndrome and pediatric autoimmune
26 neuropsychiatric disorders associated with streptococcal infection under this
27 section:

28 (1) May be subject to policy deductions or copayment
29 requirements ~~and any standard prior authorization review~~ of a healthcare
30 insurer or a health benefit plan; and

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

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

35 (f)(1)(A) A health benefit plan that is offered, issued, or renewed in
36 this state shall provide coverage for the use of intravenous immunoglobulin

1 to treat individuals diagnosed with pediatric acute-onset neuropsychiatric
2 syndrome or pediatric autoimmune neuropsychiatric disorders associated with
3 streptococcal infection, or both, on or after January 1, 2024, if the
4 pediatric patient's primary care physician, in consultation with an Arkansas
5 licensed pediatric psychiatrist and an Arkansas licensed physician who
6 practices in at least one (1) pediatric subspecialty, including a
7 neurologist, rheumatologist, or infectious disease physician who has treated
8 the pediatric patient determines and agrees that the treatment is necessary
9 and follows a patient-specific treatment plan.

10 (B) A primary care physician may continue to consult with
11 the Childhood Post-infectious Autoimmune Encephalopathy Center of Excellence.

12 (C) The appeal process for a denial of coverage or adverse
13 determination under this subdivision (f)(1):

14 (i) Shall align with the normal appeal process of
15 any other type of denial under the health benefit plan; and

16 (ii) Applies to all health benefit plans.

17 (2) Upon approval by the United States Food and Drug
18 Administration of the use of intravenous immunoglobulin to treat individuals
19 diagnosed with pediatric acute-onset neuropsychiatric syndrome or pediatric
20 autoimmune neuropsychiatric disorders associated with streptococcal
21 infection, or both, the Insurance Commissioner, with consultation and upon
22 approval of the Arkansas State Medical Board and the Arkansas State Board of
23 Pharmacy, shall adopt by rule a written statewide protocol that provides
24 clarification that the consultation required under subdivision (f)(1) of this
25 section and the patient-specific treatment plan required under subsection (c)
26 of this section are no longer required for coverage under a health benefit
27 plan.

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

33
34 SECTION 4. EMERGENCY CLAUSE. It is found and determined by the
35 General Assembly of the State of Arkansas that certain children in this state
36 who are diagnosed with pediatric acute-onset neuropsychiatric syndrome or

pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection, or both, are receiving limited treatment options; that requiring healthcare insurers to provide coverage of intravenous immunoglobulin, also known as "IVIG", to treat individuals diagnosed with pediatric acute-onset neuropsychiatric syndrome or pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection, or both, could alleviate some symptoms; and that this act is immediately necessary to ensure that children receive the greatest chance to be healthy and live productive lives. Therefore, an emergency is declared to exist, and this act being immediately necessary for the preservation of the public peace, health, and safety shall become effective on:

(1) The date of its approval by the Governor;

(2) If the bill is neither approved nor vetoed by the Governor, the expiration of the period of time during which the Governor may veto the bill; or

(3) If the bill is vetoed by the Governor and the veto is overridden, the date the last house overrides the veto.

SECTION 5. TEMPORARY LANGUAGE. DO NOT CODIFY. Rules.

(a) The Insurance Commissioner, in consultation with the Staff of the Childhood Post-infectious Autoimmune Encephalopathy Center of Excellence, shall promulgate rules necessary to implement Section 3 of this act.

(b)(1) When adopting the initial rules to implement this act, the final rule shall be filed with the Secretary of State for adoption under § 25-15-204(f):

(A) On or before August 31, 2023; or

(B) If approval under § 10-3-309 has not occurred by August 31, 2023, as soon as practicable after approval under § 10-3-309.

(2) The commissioner shall file the proposed rule with the Legislative Council under § 10-3-309(c) sufficiently in advance of August 31, 2023, so that the Legislative Council may consider the rule for approval before August 31, 2023.

/s/K. Hammer

APPROVED: 4/13/23