

**Title 23. Public Utilities and Regulated Industries**  
**Chapter I. State Insurance Department, Department of Commerce**  
**Subchapter B. Life, Health, and Accident**  
**Part 151. Authorization of Off-Label Use of Drug Treatments for Pediatric Acute-Onset and Autoimmune Neuropsychiatric Syndrome**

**Codification Notes.** This part as promulgated prior to codification into the Code of Arkansas Rules provided as follows:

"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 6. EFFECTIVE DATE

This Rule shall be effective upon approval by the Arkansas Legislative Council and shall go into effect ten (10) days after filing a final rule with the Secretary of State."

**Subpart 1. Generally**

**23 CAR § 151-101. Definitions.**

Unless otherwise separately defined in this part and consistent with state law, the terms or phrases as used in this part shall follow the definitions of such terms or phrases as defined in Arkansas Code § 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 Acts 2021, No. 1054, and herein;

(3) "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; and

(4) "PANS" means pediatric acute-onset neuropsychiatric syndrome, a clinically defined disorder characterized by 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.

**Authority.** Arkansas Code §§ 23-61-108, 23-79-1905.

**23 CAR § 151-102. Coverage requirement review.**

(a) Pursuant to Arkansas Code § 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 (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 part established in consultation with the Childhood Postinfectious Autoimmune Encephalopathy Center of Excellence.

(b)(1) Pursuant to Arkansas Code § 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.

(2) 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:

(A) Align with the normal appeal process of any other type of denial under the health benefit plan; and

(B) 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.

**Authority.** Arkansas Code §§ 23-61-108, 23-79-1905.

**23 CAR § 151-103. United States Food and Drug Administration 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 Insurance 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 23 CAR § 151-102(b) and the patient-specific treatment plan required under 23 CAR § 151-102(a) 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 Postinfectious Autoimmune Encephalopathy Center of Excellence.

**Authority.** Arkansas Code §§ 23-61-108, 23-79-1905.

**23 CAR § 151-104. 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 Postinfectious Autoimmune Encephalopathy Clinic established by the University of Arkansas for Medical Sciences in collaboration with Arkansas Children's Hospital, as described in 23 CAR § 151-102(a).

**Authority.** Arkansas Code §§ 23-61-108, 23-79-1905.

**23 CAR § 151-105. Enforcement and penalties.**

(a) Pursuant to Arkansas Code § 23-61-103 et seq., the Insurance Commissioner shall have the power and authority expressly conferred or reasonably implied by the Arkansas Insurance Code.

(b) This includes, but is not limited to, the power to fully investigate potential violations of Acts 2021, No. 1054, and this part, 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.

**Authority.** Arkansas Code §§ 23-61-108, 23-79-1905.

**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**

**Link:**

<https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendices/207/23CARpt.151Appendix.pdf>