



Proposed Rule Regarding Act 637- Hospital, Physician and Nurse Practitioner Provider Manuals and SPA to add PANS/PANDAS Treatment

June 1, 2022

PURPOSE

The Arkansas Department of Human Services (DHS), Division of Medical Services, is seeking Governor Hutchinson's review of proposed amendments to the Hospital, Physician and Nurse Practitioner Provider Manuals and SPA to add PANS/PANDAS treatment to comply with Act 637.

BACKGROUND

Pursuant to A.C.A. § 20-77-107 the Department of Human Services is authorized to establish and maintain an indigent medical care program. A.C.A. § 25-10-129 directs the Department to promulgate rules to assure compliance with federal statutes, rules, and regulations and to promulgate rules as necessary to receive any federal funds. Department rule promulgation authority is also provided under A.C.A. § 20-76-201(12) which directs the Department make rules that are necessary to provide public assistance.

KEY POINTS

The proposed rule:

- Provides coverage for the use of off-label drug treatments to treat Medicaid beneficiaries diagnosed with Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS). Requires a treatment plan with a prior authorization be submitted by the Postinfectious Autoimmune Encephalopathy Center of Excellence, as required by Act 637 (the approved provider).

DISCUSSION

The 93rd General assembly enacted Act 637 of 2021 authorizes the use of off-label drug treatments to treat Medicaid beneficiaries with PANS/PANDAS, and states that the off-label treatments include, but are not limited to, use of intravenous immunoglobulin (also known as "IVIG"). They must be included in a Treatment Plan created by and implemented by the approved provider. The Division of Medical Services (DMS) is requiring a Prior Authorization (PA) to these treatments so that the Treatment Plan can be submitted to the Quality Improvement Organization (QIO) along with the PA request. To implement the foregoing, the Division of Medical Services is updating the Hospital, Physician, and Nurse Practitioner provider manuals and amending the Medicaid State Plan.

RECOMMENDATION

We recommend that the amendments to the Act 637- Hospital, Physician and Nurse Practitioner Provider Manuals and SPA to add PANS/PANDAS treatment be approved as proposed by the Division of Medical Services of the Department of Human Services.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM
STATE ARKANSAS

ATTACHMENT 3.1-A
Page 5a

AMOUNT, DURATION, AND SCOPE OF
SERVICES PROVIDED

Revised: January-June 1, 2022

CATEGORICALLY NEEDY

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist

a. Prescribed Drugs

- (1) Each recipient age twenty-one (21) or older may have up to six (6) prescriptions each month under the program. Family Planning, tobacco cessation, oral prescription drugs for opioid use disorder prescribed by an X-DEA waived provider as part of a Medication Assisted Treatment plan, EPSDT, high blood pressure, ~~hypercholesterolemia~~hypercholesterolemia, blood modifiers, diabetes and respiratory illness inhaler prescriptions do not count against the prescription limit.
- (2) Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.
- (3) The Medicaid agency provides coverage, to the same extent that it provides coverage for all Medicaid recipients, for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses – with the exception of those covered by Part D plans as supplemental benefits through enhanced alternative coverage as provided in 42 C.F.R. §423.104 (f) (1) (ii) (A) – to full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit – Part D.

The following excluded drugs, set forth on the [Arkansas Medicaid Pharmacy Vendor's Website](#), are covered:

- a. select agents when used for weight gain:
Androgenic Agents;
- b. select agents when used for the symptomatic relief of cough and colds:
Antitussives; Antitussive-Decongestants; and Antitussive-Expectorants;
- c. select prescription vitamins and mineral products, except prenatal vitamins and fluoride:
B 12; Folic Acid; and Vitamin K;
- d. select nonprescription drugs:
Antiarthritics; Antibacterials and Antiseptics; Antitussives; Antitussives-Expectorants; Analgesics; Antipyretics; Antacids; Antihistamines; Antihistamine-Decongestants; Antiemetic/Vertigo Agents; Gastrointestinal Agents; Hematinics; Laxatives; Ophthalmic Agents; Sympathomimetics; Topical Antibiotics; Topical Antifungals; Topical Antiparasitics; and Vaginal Antifungals; and
- e. non-prescription products for smoking cessation and
- f. off-label use of drug treatment for Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS), including without limitation, intravenous immunoglobulin, also known as "IVIG".
- e. —

- (4) The State will reimburse only for the drugs of pharmaceutical manufacturers who have entered into and have in effect a rebate agreement in compliance with Section 1927 of the Social Security Act, unless the exceptions in Section 1902(a)(54), 1927(a)(3), or 1927(d) apply. The State permits coverage of participating manufacturers' drugs, even though it may be using a formulary or other restrictions. Utilization controls will include prior authorization and may include drug utilization reviews. Any prior authorization program instituted after July 1, 1991 will provide for a 24-hour

TN: 22-0005

Approved:

Effective: 06/01/22

Supersedes TN: 21-0009

turnaround from receipt of the request for prior authorization. The prior authorization program also provides for at least a seventy-two (72) hour supply of drugs in emergency situations.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM
STATE ARKANSAS

ATTACHMENT 3.1-A
Page 5aaa

AMOUNT, DURATION AND SCOPE OF
SERVICES PROVIDED
June 1, 2022

Revised: September 30, 2011

CATEGORICALLY NEEDY

12. Prescribed drugs, dentures and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist (Continued)

a. Prescribed Drugs (continued)

Prior authorization will be established for certain drug classes, particular drugs or medically accepted indication for uses and doses.

The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with Federal law.

When a pharmacist receives a prescription for a brand or trade name drug, and dispenses an innovator multisource drug that is subject to the Federal Upper Limits (FULs), the innovator multisource drug must be priced at or below the FUL or the prescription hand annotated by the prescriber "Brand Medically Necessary". Only innovator multisource drugs that are subject to the Federal Upper Limit at 42 CFR 447.332(a) and dispensed on or after July 1, 1991, are subject to the provisions of Section 1903(i)(10)(B) of the Social Security Act.

For drugs listed on the Arkansas Medicaid Generic Upper Limit List, the upper limit price will not apply if the prescribing physician certifies in writing that a brand name drug is medically necessary.

The Arkansas Medicaid Generic Upper Limit List is comprised of State generic upper limits on specific multisource drug products and CMS identified generic upper limits on multisource drug products.

The Medicaid agency will provide coverage of prescription and over-the-counter (OTC) smoking/tobacco cessation covered outpatient drugs for pregnant women as recommended in "Treating Tobacco Use and Dependence – 2008 Update: A Clinical Practice Guideline" published by the Public Health Service in May 2008 or any subsequent modification of such guideline.

(6) Off-Label Drug Treatment for Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS). The Medicaid agency will provide coverage of off-label use of drug treatments, including without limitation, intravenous immunoglobulin, also known as "IVIG", to treat Medicaid beneficiaries who are diagnosed with pediatric acute-onset neuropsychiatric syndrome or pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections, or both. Treatment must be under a treatment plan established by an approved PANS/PANDAS provider.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM
STATE ARKANSAS

ATTACHMENT 3.1-B
Page 4g

AMOUNT, DURATION, AND SCOPE OF
SERVICES PROVIDED

Revised: January-June 1, 2022

MEDICALLY NEEDY

12. Prescribed drugs, dentures and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist

a. Prescribed Drugs

- (1) Each recipient age twenty-one (21) or older may have up to six (6) prescriptions each month under the program. Family Planning, tobacco cessation, oral prescription drugs for opioid use disorder when prescribed by an X-DEA waived provider as part of a Medication Assisted Treatment plan, EPSDT, high blood pressure, hypercholesterolemia, blood modifiers, diabetes and respiratory illness inhaler prescriptions do not count against the prescription limit.
- (2) Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.
- (3) The Medicaid agency provides coverage, to the same extent that it provides coverage for all Medicaid recipients, for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses – with the exception of those covered by Part D plans as supplemental benefits through enhanced alternative coverage as provided in 42 C.F.R. §423.104 (f) (1) (ii) (A) – to full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit – Part D.

The following excluded drugs, set forth on the [Arkansas Medicaid Pharmacy Vendor's Website](#), are covered:

a. select agents when used for weight gain:

Androgenic Agents;

b. select agents when used for the symptomatic relief of cough and colds:

Antitussives; Antitussive-Decongestants; and Antitussive-Expectorants;

c. select prescription vitamins and mineral products, except prenatal vitamins and fluoride:

B 12; Folic Acid; and Vitamin K;

d. select nonprescription drugs:

Antiarthritics; Antibacterials and Antiseptics; Antitussives; Antitussives-Expectorants; Analgesics; Antipyretics; Antacids; Antihistamines; Antihistamine-Decongestants; Antiemetic/Vertigo Agents; Gastrointestinal Agents; Hematinics; Laxatives; Ophthalmic Agents; Sympathomimetics; Topical Antibiotics; Topical Antifungals; Topical Antiparasitics; and Vaginal Antifungals; and

e. non-prescription products for smoking cessation and

e.f. off-label use of drug treatment for Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS), including without limitation, intravenous immunoglobulin, also known as "IVIG".

- (4) The State will reimburse only for the drugs of pharmaceutical manufacturers who have entered into and have in effect a rebate agreement in compliance with Section 1927 of the Social Security Act, unless the exceptions in Section 1902(a)(54), 1927(a)(3), or 1927(d) apply. The State permits coverage of participating manufacturers' drugs, even though it may be using a formulary or other restrictions. Utilization controls will include prior authorization and may include drug utilization reviews. Any prior authorization program instituted after July 1, 1991, will provide for a 24-hour turnaround from receipt of the request for prior authorization. The prior authorization program also provides for at least a 72-hour supply of drugs in emergency situations.

TN: 22-0005

Supersedes TN: 21-0009

Approved:

Effective: 06/01/22

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM
STATE ARKANSAS

ATTACHMENT 3.1-B
Page 4i

AMOUNT, DURATION AND SCOPE OF
SERVICES PROVIDED
1, 2022

Revised: ~~September 30, 2011~~ June

MEDICALLY NEEDY

12. Prescribed drugs, dentures and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist (Continued)

a. Prescribed Drugs (continued)

Prior authorization will be established for certain drug classes, particular drugs or medically accepted indication for uses and doses.

The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with Federal law.

When a pharmacist receives a prescription for a brand or trade name drug, and dispenses an innovator multisource drug that is subject to the Federal Upper Limits (FULs), the innovator multisource drug must be priced at or below the FUL or the prescription hand annotated by the prescriber "Brand Medically Necessary". Only innovator multisource drugs that are subject to the Federal Upper Limit at 42 CFR 447.332(a) and dispensed on or after July 1, 1991, are subject to the provisions of Section 1903(i)(10)(B) of the Social Security Act.

For drugs listed on the Arkansas Medicaid Generic Upper Limit List, the upper limit price will not apply if the prescribing physician certifies in writing that a brand name drug is medically necessary.

The Arkansas Medicaid Generic Upper Limit List is comprised of State generic upper limits on specific multisource drug products and CMS identified generic upper limits on multisource drug products.

The Medicaid agency will provide coverage of prescription and over-the-counter (OTC) smoking/tobacco cessation covered outpatient drugs for pregnant women as recommended in "Treating Tobacco Use and Dependence – 2008 Update: A Clinical Practice Guideline" published by the Public Health Service in May 2008 or any subsequent modification of such guideline.

(6) Off-Label Treatment for Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS). The Medicaid agency will provide coverage of off-label use of drug treatments, including without limitation, intravenous immunoglobulin, also known as "IVIG", to treat Medicaid beneficiaries who are diagnosed with pediatric acute-onset neuropsychiatric syndrome or pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections, or both. Treatment must be under a treatment plan established by an approved PANS/PANDAS provider.

b. Dentures

Refer to Attachment 3.1-B Item 4.b(7) for coverage of dentures for Child Health Services (EPSDT) recipients.

Dentures are available for eligible Medicaid beneficiaries age 21 and over, but are benefit limited. Specific benefit limits and prior authorization requirements for beneficiaries age 21 and over are detailed in the Dental Provider Manual.

Dentures are excluded from the annual limit but are limited to one set per lifetime.

*TOC required***272.502 Drug Treatment for Pediatric PANS and PANDAS****6-1-22**

- A. Effective for dates of service on and after 6/1/2022 drug treatment will be available to all qualifying Arkansas Medicaid beneficiaries when specified conditions are met for one (1) or both of the following conditions:
1. Pediatric acute-onset neuropsychiatric syndrome (PANS).
 2. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS).
- B. The drug treatments include off-label drug treatments, including without limitation intravenous immunoglobulin (IVIG).
- C. Medicaid will cover drug treatment for PANS or PANDAS under the following conditions:
1. The drug treatment must be authorized under a Treatment Plan; and
 2. The Treatment Plan must be established by the **approved PANS/PANDAS provider**.
- D. A Prior Authorization (PA) must be obtained for each treatment. Providers must submit the current Treatment Plan to the Quality Improvement Organization (QIO) along with the request for Prior Authorization. (Add link to AFMC.)
- E. The authorized procedure codes and required modifiers are found in the following link:
- View or print the procedure codes for Hospital/Critical Access Hospitals/ESRD services, including PANS and PANDAS procedure codes.**

*TOC required***252.483 Drug Treatment for Pediatric PANS and PANDAS****6-1-22**

- A. Effective for dates of service on and after 6/1/2022 drug treatment will be available to all qualifying Arkansas Medicaid beneficiaries when specified conditions are met for one (1) or both of the following conditions:
1. Pediatric acute-onset neuropsychiatric syndrome (PANS).
 2. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS).
- B. The drug treatments include off-label treatments, including without limitation intravenous immunoglobulin (IVIG).
- C. Medicaid will cover drug treatment for PANS or PANDAS under the following conditions:
1. The drug treatment must be authorized under a Treatment; and
 2. The Treatment Plan must be established by the **approved PANS/PANDAS provider**.
- D. A Prior Authorization (PA) must be obtained for each treatment. Providers must submit the current Treatment Plan to the Quality Improvement Organization (QIO) along with the request for Prior Authorization. (Add link to AFMC.)
- E. The authorized procedure codes and required modifiers are found in the following link:
- View or print the procedure codes for Nurse Practitioner services, including PANS and PANDAS procedure codes.**

*TOC required***292.930****Drug Treatment for Pediatric PANS and PANDAS****Reserved****2-15-156-1-
22**

- A. Effective for dates of service on and after 6/1/2022 drug treatment will be available to all qualifying Arkansas Medicaid beneficiaries when specified conditions are met for one (1) or both of the following conditions:
1. Pediatric acute-onset neuropsychiatric syndrome (PANS).
 2. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS).
- B. The drug treatments include off-label drug treatments, including without limitation intravenous immunoglobulin (IVIG).
- C. Medicaid will cover drug treatment for PANS or PANDAS under the following conditions:
1. The drug treatment must be authorized under a Treatment Plan; and
 2. The Treatment Plan must be established by the **approved PANS/PANDAS provider**.
- D. A Prior Authorization (PA) must be obtained for each treatment. Providers must submit the current Treatment Plan to the Quality Improvement Organization (QIO) along with the request for Prior Authorization. (Add link to AFMC.)
- E. The authorized procedure codes and required modifiers are found in the following link:
- View or print the procedure codes for Physician/Independent Lab/CRNA/Radiation Therapy Center services, including PANS and PANDAS procedure codes.**

1 State of Arkansas

As Engrossed: S3/9/21

2 93rd General Assembly

A Bill

3 Regular Session, 2021

SENATE BILL 387

5 By: Senators K. Hammer, Irvin

6 By: Representatives Warren, Cloud

For An Act To Be Entitled

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

Subtitle

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

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

28 SECTION 1. Arkansas Code Title 20, Chapter 77, Subchapter 1, is
29 amended to add an additional section to read as follows:

30 20-77-140. Off-label use of drug treatment to treat pediatric acute-
31 onset neuropsychiatric syndrome and pediatric autoimmune neuropsychiatric
32 disorders associated with streptococcal infection.

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 infections, 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 state Medicaid programs provide coverage for off-label
8 use of drug treatments to treat pediatric acute-onset neuropsychiatric
9 syndrome and pediatric autoimmune neuropsychiatric disorders associated with
10 streptococcal infections; and

11 (4) However, the Arkansas Medicaid Program does not provide
12 coverage for off-label use of drug treatments, to treat Medicaid
13 beneficiaries who are diagnosed with pediatric acute-onset neuropsychiatric
14 syndrome and pediatric autoimmune neuropsychiatric disorders associated with
15 streptococcal infections.

16 (b) The Arkansas Medicaid Program shall provide coverage for off-label
17 use of drug treatments, including without limitation intravenous
18 immunoglobulin, also known as "IVIG", to treat Medicaid beneficiaries who are
19 diagnosed with pediatric acute-onset neuropsychiatric syndrome or pediatric
20 autoimmune neuropsychiatric disorders associated with streptococcal
21 infections, or both, under a treatment plan established by the Postinfectious
22 Autoimmune Encephalopathy Center of Excellence clinic in Arkansas.

23 (c) The Department of Human Services shall apply for any federal
24 waiver, state plan amendment, or other authorization necessary to implement
25 this section.

26
27 */s/K. Hammer*
28

29
30 **APPROVED: 4/12/21**
31
32
33
34
35
36

