EXHIBIT J

DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

SUBJECT: Hospital, Physician and Nurse Practitioner Manuals and SPA to Add PANS/PANDAS Treatment

DESCRIPTION: This proposed rule amends Section II of the Hospital, Physician and Nurse Practitioner Medical manuals to comply with Act 637 of the 93rd General Assembly. DMS makes corresponding changes to the Medicaid State Plan Amendment.

The amendments authorize the use of off-label drug treatments to treat Medicaid beneficiaries with Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS). The off-label treatments include, but are not limited to, use of intravenous immunoglobin (also known as "IVIG") and they must be included in a Treatment Plan.

The sole provider for creating the Treatment Plans and providing the treatments will be the Postinfectious Autoimmune Encephalopathy Center of Excellence, as required by Act 637 (the approved provider). A Prior Authorization (PA) will be required for these treatments so that the Treatment Plan can be submitted to the Quality Improvement Organization (QIO) with the PA request.

PUBLIC COMMENT: A public hearing was held on this rule on March 24, 2022. The public comment period expired on April 9, 2022. The agency indicated that it received no public comments.

The proposed effective date is June 1, 2022.

FINANCIAL IMPACT: The agency indicated that this rule has a financial impact.

Per the agency, the total cost to implement this rule is $900,000 for the current fiscal year ($255,420 in general revenue and $644,580 in federal funds) and $3,600,000 for the next fiscal year ($1,021,680 in general revenue and $2,578,320 in federal funds). The total estimated cost by fiscal year to state, county, and municipal government as a result of this rule is $255,420 for the current fiscal year and $1,021,680 for the next fiscal year.

The agency indicated that there is a new or increased cost or obligation of at least $100,000 per year to a private individual, private entity, private business, state government, county government, local government, or to two or more of those entities combined. Accordingly, the agency provided the following written findings:

(1) a statement of the rule's basis and purpose;

To authorize off-label use of drug treatments to treat Medicaid beneficiaries with pediatric acute-onset neuropsychiatric syndrome (PANS) and pediatric autoimmune neuropsychiatric disorders (PANDAS) associated with streptococcal infection.

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;

To comply with Act 637 which authorizes off-label use of drug treatments to treat Medicaid beneficiaries with pediatric acute-onset neuropsychiatric syndrome (PANS) and pediatric autoimmune neuropsychiatric disorders (PANDAS) associated with streptococcal infection.

(3) a description of the factual evidence that:
(a) justifies the agency's need for the proposed rule; and
(b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;

This advances treatment options for beneficiaries diagnosed with PANS/PANDAS.

(4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

None at this time.

(5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

None

(6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and

N/A

(7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
(a) the rule is achieving the statutory objectives;
(b) the benefits of the rule continue to justify its costs; and
(c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

DMS reviews all rules periodically.

LEGAL AUTHORIZATION: The Department of Human Services has the responsibility to administer assigned forms of public assistance and is specifically

authorized to maintain an indigent medical care program (Arkansas Medicaid). *See* Ark. Code Ann. §§ 20-76-201(1), 20-77-107(a)(1). The Department has the authority to make rules that are necessary or desirable to carry out its public assistance duties. Ark. Code Ann. § 20-76-201(12). The Department and its divisions also have the authority to promulgate rules as necessary to conform their programs to federal law and receive federal funding. Ark. Code Ann. § 25-10-129(b).

This rule implements Act 637 of 2021. The Act, sponsored by Senator Kim Hammer, authorized off-label use of drug treatments to treat Medicaid beneficiaries diagnosed with pediatric acute-onset neuropsychiatric syndrome (PANS) and pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS).

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Department of Human Services
DIVISION Division of Medical Services
DIVISION DIRECTOR Elizabeth Pitman
CONTACT PERSON Mac Golden
ADDRESS P. O. Box 1437, Slot S295 Little Rock, AR 72203-1437
PHONE NO. 501-320-6383 **FAX NO.** 501-404-4619 **E-MAIL** Mac.E.Golden @dhs.arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING Elizabeth Pitman
PRESENTER E-MAIL Elizabeth.Pitman@dhs.arkansas.gov

INSTRUCTIONS

A. Please make copies of this form for future use.
B. Please answer each question completely using layman terms. You may use additional sheets, if necessary.
C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Rebecca Miller-Rice
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201

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1. What is the short title of this rule? Act 637- Hospital, Physician and Nurse Practitioner Provider Manuals and SPA to add PANS/PANDAS treatment

2. What is the subject of the proposed rule? See Attached.

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes ☐ No ☒
   If yes, please provide the federal rule, regulation, and/or statute citation. _____

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act?
   Yes ☐ No ☒
   If yes, what is the effective date of the emergency rule? _____

   When does the emergency rule expire? _____

   Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act?
   Yes ☐ No ☐

5. Is this a new rule? Yes ☐ No ☒
If yes, please provide a brief summary explaining the regulation. _____

Does this repeal an existing rule? Yes ☐ No ☒
If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does. _____

Is this an amendment to an existing rule? Yes ☒ No ☐
If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

See attached.

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. Arkansas Code §§ 20-76-201, 20-77-107, and 25-10-129

7. What is the purpose of this proposed rule? Why is it necessary? See Attached.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b).

https://humanservices.arkansas.gov/do-business-with-dhs/proposed-rules/

9. Will a public hearing be held on this proposed rule? Yes ☒ No ☐
If yes, please complete the following:

Date: March 24, 2022
Time: 11:00 a.m.
Place: **https://us02web.zoom.us/j/83367620116**

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
April 9, 2022

11. What is the proposed effective date of this proposed rule? (Must provide a date.)
June 1, 2022

12. Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice. See Attached.

13. Please provide proof of filing the rule with the Secretary of State as required pursuant to Ark. Code Ann. § 25-15-204(e). See Attached.

14. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known. Unknown

NOTICE OF RULE MAKING

The Director of the Division of Medical Services of the Department of Human Services announces for a public comment period of thirty (30) calendar days a notice of rulemaking for the following proposed rule under one or more of the following chapters, subchapters, or sections of the Arkansas Code: §§20-76-201, 20-77-107, and 25-10-129.

Effective June 1, 2022:

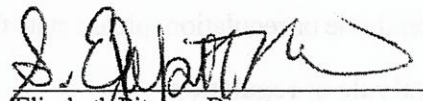
The Director of the Division of Medical Services amends Section II of the following provider manuals to comply with Act 637 of the 93rd General Assembly: Hospital, Physician, and Nurse Practitioner; as well as corresponding changes to the Medicaid State Plan Amendment (SPA). The amendments authorize the use of off-label drug treatments to treat Medicaid beneficiaries with Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS). The off-label treatments include, but are not limited to, use of intravenous immunoglobulin (also known as "IVIG") and they must be included in a Treatment Plan. The sole provider for creating the Treatment Plans and providing the treatments will be the Postinfectious Autoimmune Encephalopathy Center of Excellence, as required by Act 637 (the approved provider). A Prior Authorization (PA) will be required for these treatments so that the Treatment Plan can be submitted to the Quality Improvement Organization (QIO) with the PA request. The proposed rule estimates a financial impact of $900,000 ($644,580 of which is federal funds) for state fiscal year (SFY) 2022 and $3,600,000 ($2,578,320 of which is federal funds) for SFY 2023.

The proposed rule is available for review at the Department of Human Services (DHS) Office of Rules Promulgation, 2nd floor Donaghey Plaza South Building, 7th and Main Streets, P. O. Box 1437, Slot S295, Little Rock, Arkansas 72203-1437. You may also access and download the proposed rule at https://humanservices.arkansas.gov/do-business-with-dhs/proposed-rules/. Public comments must be submitted in writing at the above address or at the following email address: ORP@dhs.arkansas.gov. All public comments must be received by DHS no later than April 9, 2022. Please note that public comments submitted in response to this notice are considered public documents. A public comment, including the commenter's name and any personal information contained within the public comment, will be made publicly available and may be seen by various people.

A public hearing by remote access only through a Zoom webinar will be held on March 24, 2022, at 11:00 a.m. and public comments may be submitted at the hearing. Individuals can access this public hearing at **https://us02web.zoom.us/j/83367620116**. The webinar ID is 833 6762 0116. If you would like the electronic link, "one-tap" mobile information, listening only dial-in phone numbers, or international phone numbers, please contact ORP at ORP@dhs.arkansas.gov.

If you need this material in a different format, such as large print, contact the Office of Rules Promulgation at 501-396-6428.

The Arkansas Department of Human Services is in compliance with Titles VI and VII of the Civil Rights Act and is operated, managed and delivers services without regard to religion, disability, political affiliation, veteran status, age, race, color or national origin. 4502035775



Elizabeth Pitman, Director
Division of Medical Services

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Human Services

DIVISION Division of Medical Services

PERSON COMPLETING THIS STATEMENT Jason Callan

TELEPHONE 501-320-6540 **FAX** 501-682-8155 **EMAIL:** Jason.Callan@dhs.arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE Act 637- Hospital, Physician and Nurse Practitioner Provider Manuals and SPA to add PANS/PANDAS treatment

1. Does this proposed, amended, or repealed rule have a financial impact? Yes ☒ No ☐

2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule? Yes ☒ No ☐

3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes ☒ No ☐

   If an agency is proposing a more costly rule, please state the following:

   (a) How the additional benefits of the more costly rule justify its additional cost;

   (b) The reason for adoption of the more costly rule;

   (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;

   (d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

   (a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	$	General Revenue	$
Federal Funds	$	Federal Funds	$
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	

Other (Identify)		Other (Identify)	
Total	$	Total	$

(b) What is the additional cost of the state rule?

Current Fiscal Year		Next Fiscal Year	
General Revenue	$255,420	General Revenue	$1,021,680
Federal Funds	$644,580	Federal Funds	$2,578,320
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$ 900,000	Total	$ 3,600,000

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

Current Fiscal Year
$ _____

Next Fiscal Year
$ _____

6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year
$ 255,420

Next Fiscal Year
$ 1,021,680

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars ($100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes ☒ No ☐

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

(1) a statement of the rule's basis and purpose; - *To authorize off-label use of drug treatments to treat Medicaid beneficiaries with pediatric acute-onset neuropsychiatric syndrome (PANS) and pediatric autoimmune neuropsychiatric disorders (PANDAS) associated with streptococcal infection.*

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute; - *To comply with ACT 637 which authorizes off-label use of drug treatments to treat Medicaid beneficiaries with pediatric acute-onset neuropsychiatric syndrome*

(PANS) and pediatric autoimmune neuropsychiatric disorders (PANDAS) associated with streptococcal infection.

(3) a description of the factual evidence that:

(a) justifies the agency's need for the proposed rule; and - *New Legislation*

(b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs; - *This advances treatment options for beneficiaries diagnosed with PANS/PANDAS.*

(4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule; - *None at this time.*

(5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule; - *None*

(6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and - *N/A*

(7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:

(a) the rule is achieving the statutory objectives;

(b) the benefits of the rule continue to justify its costs; and

(c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives. - *DMS reviews all rules periodically.*

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 waivered provider as part of a Medication Assisted Treatment plan, EPSDT, high blood pressure, **hypercholesterolemia**~~hypercholesteriolemia,~~, 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; Opthalmic 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

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.

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.

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 waivered provider as part of a Medication Assisted Treatment plan, EPSDT , high blood pressure, ~~hypercholesteriolemia~~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; Opthalmic 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.

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED

Revised: ~~September 30, 2011~~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 (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**~~ ~~2-15-15~~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 Physician/Independent Lab/CRNA/Radiation Therapy Center services, including PANS and PANDAS procedure codes.

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 waivered 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; Opthalmic 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".

(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 seventy-two (72) hour supply of drugs in emergency situations.

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.

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 waivered 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;
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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; Opthalmic 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".

(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.

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 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 Physician/Independent Lab/CRNA/Radiation Therapy Center services, including PANS and PANDAS procedure codes.

Stricken language would be deleted from and underlined language would be added to present law.
Act 637 of the Regular Session

State of Arkansas *As Engrossed: S3/9/21*
93rd General Assembly **A Bill**
Regular Session, 2021 SENATE BILL 387

By: Senators K. Hammer, Irvin
By: Representatives Warren, Cloud

For An Act To Be Entitled

AN ACT TO AUTHORIZE OFF-LABEL USE OF DRUG TREATMENTS TO TREAT MEDICAID BENEFICIARIES 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 MEDICAID BENEFICIARIES 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 20, Chapter 77, Subchapter 1, is amended to add an additional section to read as follows:

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

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

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

(b) The Arkansas Medicaid Program shall provide coverage for 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, under a treatment plan established by the Postinfectious Autoimmune Encephalopathy Center of Excellence clinic in Arkansas.

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

/s/K. Hammer

APPROVED: 4/12/21