# Clinical Policy: Immune Globulins for PANS/PANDAS

Reference Number: AR.CP.PHAR.103
Effective Date: 02/01/25
Last Review Date: 01/17/25
Line of Business: Arkansas Commercial, HIM, Medicaid

Coding Implications
Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**
For immune globulins requiring prior authorization review, the criteria below applies only when the requested diagnosis is pediatric acute-onset neuropsychiatric syndrome (PANDAS) or pediatric autoimmune neuropsychiatric (PANS) disorders associated with streptococcal infection.

**Contents:**


**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Arkansas Total Care, Arkansas Health and Wellness and QualChoice that immune globulins for the treatment of PANDAS/PANS are **medically necessary** when the following criteria are met:

## I. Initial Approval Criteria

**A. Pediatric acute-onset neuropsychiatric syndrome (PANDAS) and pediatric autoimmune neuropsychiatric (PANS) disorders associated with streptococcal infection** (must meet all):

1. Member is a pediatric patient and has a diagnosis for Pediatric acute-onset neuropsychiatric syndrome or pediatric autoimmuneneuropsychiatric disorders associated with streptococcal infection AND
2. Primary care physician (PCP), in consultation with an Arkansas licensed pediatric psychiatrist and an Arkansas licensed physician who is licensed in at least one pediatric subspecialty including a neurologist, rheumatologist, or infectious disease physician who has treated the pediatric patient agrees that the treatment is necessary.
    a. PCP may consult with the childhood post-infectious autoimmune encephalopathy center of excellence for treatment plan. AND
3. Member has had treatment with two or more less-intensive therapies (e.g. limited course of non-steroidal anti-inflammatory drugs, corticosteroids, selective serotonin reuptake inhibitors, behavioral therapy, short course antibiotic therapy), and these therapies were not effective.

4. Up to 3 monthly immunomodulatory courses of IVIG therapy may be recommended for treatment of PANDAS and PANS. Reevaluation for additional treatment at 3 months by the pediatric sub-specialist will be required for continued therapy.
    a. Reevaluation 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.
5. **Approval Duration:**
    a. **Medicaid** – 6 months
    b. **HIM** – 6 months
    c. **Commercial –** 6 months or to the member's renewal date, whichever is longer

**B. ALL OTHER INDICATIONS**

1. Member must meet medical necessity criteria in **CP.PHAR.103**.

## II. Continued Therapy

**A. Pediatric acute-onset neuropsychiatric syndrome (PANDAS) and pediatric autoimmune neuropsychiatric (PANS) disorders associated with streptococcal infection** (must meet all)**:**

1. Member meets one of the following (a or b):
    a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
    b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for a dose increase due to inadequate response to previous dose, request meets one of the following (a or b) [Note: for adults, calculate dosing based on TBW or IBW, whichever is less, and for obese members use adjBW, unless the newly calculated dose is lower than the currently administered dose. *(See Appendix F for weight-based dosing calculations)*]:
    a. Dose titration or conversion is appropriate per package insert labeling;
    b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*);
4. For adults with diagnoses other than primary immunodeficiency or cancer-related infection prophylaxis: the requested dose is calculated based on TBW or IBW, whichever is less, and for obese members adjBW is used for dose calculation, unless documentation supports the inability to adjust dosing in this manner *(See Appendix F for weight-based dosing calculations)*.**Approval Duration:**
    a. **Medicaid** – 6 months
    b. **HIM** – 6 months
    c. **Commercial –** 6 months or to the member's renewal date, whichever is longer

**B. ALL OTHER INDICATIONS**

1. Member must meet medical necessity criteria in **CP.PHAR.103**.

## III. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration
IG: immune globulin
IgA: immune globulin A
IgG: immune globulin G
IgM: immune globulin M
IGIV: immune globulin intravenous
IMIG: intramuscular immune globulin
IVIG: intravenous immune globulin

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created (adopted from corporate policy cp.phar.103 by adding state-mandated PANDAS/PAN coverage criteria). | 01/17/25 | N/A (provided by state) |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.