



VIRGINIA
ALLIANCE for
PANS/PANDAS
ACTION

SAVE OUR CHILDREN AND YOUNG ADULTS

The cost of a life \$0.0046 cents

per member per month (PMPM)

LEGISLATION INTRODUCED - HB513 & HB514 (Patron Del. Hope)

HB 1641 - Calls for Medicaid and private insurance coverage for the prophylaxis, diagnosis, and treatment of PANDAS and PANS.

PANS/PANDAS

PANS - PEDIATRIC ACUTE-ONSET NEUROPSYCHIATRIC SYNDROME

PANDAS - PEDIATRIC AUTOIMMUNE NEUROPSYCHIATRIC
DISORDER ASSOCIATED WITH STREPTOCOCCAL INFECTIONS



**Immune-mediated inflammatory brain disorders triggered by
infections, metabolic disturbances, and other inflammatory
reactions**

FOR INFORMATION, CONTACT

Virginia Alliance for PANS/PANDAS Action: vaforpa@gmail.com #VA4PA

 facebook.com/VA4PA  instagram.com/va4pa  twitter.com/VAAlliance4PA



PANS/PANDAS Symptoms

- OCD
- FOOD RESTRICTION
- TICS

- Developmental regression
- Decline in school performance

- ADHD
- Sensory seeking / avoiding

- Anxiety
- Emotional lability
- Depression

- Irritability
- Aggression

- Balance / gait issues
- Urinary frequency / urgency
- Sleep disturbance

- Fatigue
- Hallucinations
- Selective mutism

TREATMENT APPROACH

1. Treating the symptoms with psychoactive medications, psychotherapies (particularly cognitive behavioral therapy), and supportive interventions.
2. Removing the source of the inflammation with antimicrobial interventions.
3. Treating disturbances of the immune system with immunomodulatory and/or anti-inflammatory therapies.



WHY DO WE NEED PANS/PANDAS LEGISLATION?

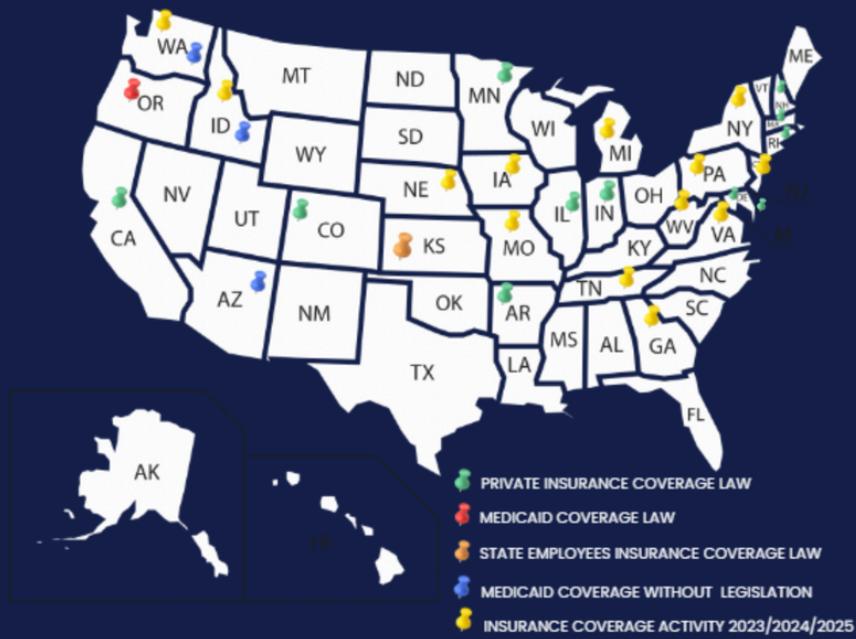
- Virginia health insurance companies routinely deny coverage of doctor-prescribed treatments, including IVIg and other immune therapies.
- Patients frequently endure months, if not years, of misdiagnosis, resulting in irreversible brain inflammation with associated profound disabilities.
- Permanent neurological damage may result in permanent dependence on the state.
- Suicides have occurred, in both affected individuals and their despondent parents.
- Most of the time, at least one parent must stop working to care full-time for the ill child.
- Desperate families sell their homes and go into debt to pay for medicine out-of-pocket.
- Police, ER, and child protective services are commonly involved as symptoms become increasingly erratic. Patients may be hospitalized medically or psychiatrically, resulting in more costs and unnecessary suffering due to inappropriate medical treatment.



- Patients may be hospitalized medically or psychiatrically, resulting in more costs and unnecessary suffering due to inappropriate medical treatment.
- Patients may accumulate permanent neurological damage with resulting permanent dependence on the state.
- Children may require 504s, IEPs, and in some cases prolonged and intensive accommodations such as home hospital school (homebound education).
- Loss of income for the family (and loss of tax revenue for the state), since parents are often unable to work while caring for their sick child, and may require state unemployment or family medical leave benefits.
- Loss of income for the adult patient who might be unable to sustain full or part-time employment.
- PANS/PANDAS can result in the suicides of the affected individual or their desperate parents or death secondary to anorexia.
- Families are forced to leave the state, moving to other states that offer treatment coverage.

VIRGINIA'S YOUTH CANNOT WAIT!!

The VA Board of Insurance (BOI) estimated cost of coverage at **\$0.0046**—less than half a cent per member per month.



THIRTEEN states have some form of insurance coverage law for the treatment of PANS/PANDAS: Arkansas (2019), California (2024), Colorado (2024), Delaware (2018), Illinois (2017), Indiana (2020), Kansas (2022), Maryland (2020), Massachusetts (2021), Minnesota (2019), New Hampshire (2019), Oregon (2023), and Rhode Island (2022).

FOURTEEN states have established PANS/PANDAS Public Health Advisory Committees.



PUBLISHED RESEARCH

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8. Pavone P, Falsaperla R, Nicita F, et al. Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcal Infection (PANDAS): Clinical Manifestation, IVIG Treatment Outcomes, Results from a Cohort of Italian Patients. *Neuropsychiatry* 2018; 8(3): 854-860. DOI:10.4172/Neuropsychiatry.1000412
9. Pavone P, Falsaperla R, Cacciaguerra G, et al. PANS/PANDAS: clinical experience in IVIG Treatment and state of the art in rehabilitation approaches. *NeuroSci*. 2020;1:75-84. <https://doi.org/10.3390/neurosci1020007>.
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COMMON OPPOSITION CLAIMS & EVIDENCE-BASED RESPONSES

"It takes decision-making out of the hands of medical providers."

Just the opposite. A 2017 American Medical Association survey of 1,000 physicians found that 84% of those surveyed felt the burdens imposed by insurers to obtain care were high/extremely high and 92% surveyed indicated that these barriers can have a negative impact on patient's outcomes. The proposed bill removes these barriers, allowing the physician to determine the most clinically appropriate treatment for their patient.

"All of the children affected by these disorders will require IVIG and/or Plasmapheresis."

It is estimated that only a small subset, those with moderate-severe severity, will require IVIG and/or Plasmapheresis. According to the 2017 Journal Child and Adolescent Pharmacology guidelines, "A small but significant subset, estimated to be 10-15% of referred children, fail to improve with these conventional measures and require immunomodulatory therapy with intravenous immunoglobulin (IVIG), therapeutic plasmapheresis (also known as plasma-exchange), or other modalities". The National Institute of Mental Health confirms this small subset as well indicating that immunotherapies are reserved for the sickest children.

"IVIG and plasmapheresis, are NOT evidence-based treatments for PANDAS/PANS and should be considered experimental and/or investigational."

IVIG has been used for over 70 years and has well-established anti-inflammatory and immunomodulatory properties (Annals of American Thoracic Society). The efficacy of immunomodulatory treatment in PANDAS/PANS has been rigorously examined since 2015. Recent evidence overwhelmingly supports the inclusion of IVIG in the levels of treatment available for children with PANDAS and PANS. Based on extensive systematic reviews from several specialty areas, treatment studies, and the national consensus guidelines of the PANS Research Consortium and PANDAS Physician Network, "IVIG is indicated for the treatment of a small but significant subset of children who meet the criteria." The American Society for Apheresis (ASFA) included PANDAS in its guidelines published in the Journal of Clinical Apheresis (JCA) in its last two editions. 'In severely symptomatic patients with PANDAS or SC, immunomodulatory therapies, such as IVIG...or TPE, have been shown to be effective in reducing symptom severity or shorten the course.'" As you will see by the medical efficacy update and studies linked below, IVIG is the gold standard of care for a specific severity of P/P children and has been researched extensively.

"IVIG, plasma exchange, and other immunomodulating therapies are NOT FDA-approved treatments."

The FDA approves drugs for specific indications that are included in the drug's labeling. There are a limited number of conditions that are included within the labeling for IVIG, although IVIG is used for hundreds of illnesses. There are a vast number of off-label uses for this blood product that encompass the fields of Hematology, Neurology, Obstetrics, Pulmonology, and Rheumatology, as well as conditions in which acquiring an infectious disease could be deleterious. Children with PANS/PANDAS (and related diagnoses) meet the criteria for the off-label uses of IVIG.

Off-Label use of FDA-approved drugs as prescribed by a physician to treat chronic, disabling, or life-threatening illnesses may be covered when it has been approved by the FDA for at least one indication and is supported by clinical research that appears in peer-reviewed literature specific for the indication in question. The use of IVIG for many of our children with PANS/PANDAS is warranted on all fronts. Their condition is well-documented with potential of causing irreparable damage and possibly being life-threatening. IVIG is FDA approved for other conditions, and peer-review research solidly supports the use of IVIG for PANS/PANDAS. Furthermore, legislation in 11 states recognizes IVIG as one of many treatments for PANS/PANDAS. IVIG has been approved to treat many medical conditions, in particular, other forms of autoimmune encephalitis. With sufficient peer-review research to back its clinical use, and sufficient clinical data to support medical necessity. "Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics, and devices according to their best knowledge and judgment[2]." Denials of requests for IVIG directly challenge the premise clearly underscored by the FDA when addressing the off-label use of FDA-approved medications. [1] <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label>. [2] <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices>

"There is no consensus on diagnostic and treatment guidelines, including the use of immunotherapies."

In 2017, the PANS Research Consortium (PRC) published a guideline series in four parts with contributing experts from more than two dozen academic institutions across the United States. Researchers and clinicians from the National Institute of Mental Health (NIMH), Harvard, Yale, Georgetown, Columbia, Stanford and other academic institutions pooled their data and clinical experience with more than 1,000 PANDAS and PANS patients to develop best practice recommendations. These can be summarized as: Treat the SYMPTOMS, remove the SOURCE, and modulate the IMMUNE SYSTEM to reduce neuroinflammation. In December 2020, PANDAS Physician Network, a national expert body, released updated diagnostic and treatment guidelines further clarifying diagnostic and treatment guidelines via clinical algorithm. JCAP 2017 Guidelines for treating PANS/PANDAS Please also see: PANDAS Medical Efficacy UpdatePANDAS Physicians NetworkMassachusetts Child Psychiatry Access Program (MCPAP)



"NIMH does not recognize PANDAS/PANS and does not support IVIG and Plasmapheresis."

The original research regarding PANDAS/PANS originated in the NIMH with Dr. Sue Swedo's revelation that strep caused OCD. Dr. Sue Swedo is now recognized as a NIMH Emerita. This legislation provides access to immune treatment in a manner consistent with NIMH recommendations. NIMH website: "Plasma exchange or immunoglobulin (IVIG) may be a consideration for acutely and severely affected children with PANDAS."

Further, the Massachusetts Child Psychiatry Access Program (MCPAP), which is funded by the Department of Mental Health, substantiates these guidelines: Massachusetts Child Psychiatry Access Program (MCPAP) NEWS: Clinical Conversation: November 20, 2018 "Immune therapies – used when there is clear evidence of neuroinflammation or postinfectious autoimmunity...In moderate to severe cases, intravenous immunoglobulin (IVIG) may be used."

"There is insufficient research and/or the published research that exists is too limited, without control groups."

IVIG has been rigorously examined since 2015. Recent evidence overwhelmingly supports inclusion of IVIG in the levels of treatment available for children with PANDAS and PANS and is agreed upon by a national body of medical experts and given as a treatment option listed by the NIMH. Randomized clinical trials are not always feasible in every population, especially in vulnerable populations. The very sickest patients (and their parents) may not consent to a trial with a placebo just because the risk of not getting potential treatment is too high. There is controversy even amongst researchers when it comes to the inclusion of pediatric subjects in clinical trials because of their inability to consent for themselves and when receipt of a placebo could delay much-needed treatment for a child who is already severely ill. See published research.

"Insurance mandates add to the cost of healthcare for plan members, insurers and the state."

Massachusetts did a cost analysis in 2015, updated in 2019, that reflected the negligible cost impact to plan members which is highlighted in the 2015 CHIA report, and summarized in the PANDAS Medical Efficacy Update. "Given the narrow subset of patients requiring IVIG (an estimated 10-15%) ...coverage of treatment would result in a slight increase in premiums for insurance holders in the Commonwealth of Massachusetts. According to the report, "requiring coverage for this benefit by fully insured health plans would result in an average annual increase, over five years, to the typical member's monthly health insurance premiums of between \$0.003 (0.001%) and \$0.039 (0.008%) per year." California's CHBRP Final Report, under the Cost to State, notes: "AB 907 would increase total net annual expenditures by total net annual \$2,990,000, or total net annual 0.0020%, for enrollees with DMHC-regulated plans (including DMHC-regulated Medi-Cal Managed Care Plans) and CDI-regulated policies. This is due to a \$2,838,000 increase in total health insurance premiums, plus \$153,000 paid by enrollees for covered and/or non-covered benefits. This is a very low cost to the state. According to CHBRP analysis and reflected in the committee analysis, the increase to total net annual expenditures if AB907 were enacted is relatively low, constituting a 0.0016% increase...less than one cent." <https://www.chbrp.org/sites/default/files/bill-documents/AB907/AB%20907%20Report%20-%20FINAL.pdf> The upstream cost of not treating the most severely affected PANDAS/PANS children in our state could result in costs related to lifetime mental illness, social security disability, education costs (504s, IEPs, 1:1 tutors, special education), Medicaid enrollment, psychiatric residency and hospitalization, homelessness, and suicide. The lifetime burden of serious mental illness is estimated to be 1.84 million per patient.

"There isn't an ICD code for PANDAS/PANS."

Effective 10/1/2020, ICD 10 has assigned a corresponding code for PANDAS which is D89.89 (other specified disorders involving the immune mechanism, not elsewhere classified). The new version of the ICD-11 will include a specific code for PANDAS (8E4A.0 Paraneoplastic or autoimmune disorders of the central nervous system, brain or spinal cord). "Paraneoplastic and autoimmune disorders of the central nervous system, brain and spinal cord nervous system result from a targeted immune attack on neurons or glial cells in the central (e.g. encephalopathy, ataxia, myelopathy, myelitis) nervous system...In the non-paraneoplastic context termed 'autoimmune' the etiology remains elusive though increasing evidence indicates a preceding infectious trigger in at least some cases...Response to immunotherapy may support the diagnosis."

"IVIG and Plasma Exchange are invasive and expensive."

According to the Hospital for Sick Kids, IVIG is a safe treatment for children. Most side effects (headache, nausea, dizziness) are mild and easy to control. The process of administering is as simple as placing a hollow needle into a vein in your child's hand or arm to infuse healthy antibodies. According to the UT Southwestern Medical Center, "plasma exchange is a safe procedure with a few side effects". The total cost of IVIG therapy ranges from \$5000 to \$10,000, depending on the patient's weight. The private pay cost of these therapies is cost prohibitive for most Virginia families however, the cost to insurers is much lower due to contracted rates and their practice of passing costs on to their plan members. Despite this practice, a 2015 Massachusetts financial analysis of member impact by the inclusion of IVIG treatment resulted in less than pennies a month even at the highest utilization (20%). Meanwhile, Virginia insurers post revenue and profitability in the multi-millions.

"The bill allows for billing of another condition rather than PANS/PANDAS; it is a tacit acknowledgment that we may be racing ahead of the medical evidence."

The bill states "...may be coded as autoimmune encephalitis until the American Medical Association and the Centers for Medicare and Medicaid Services create and assign a specific billing and diagnostic code for PANDAS/PANS". Autoimmune encephalitis is NOT another condition. Recently, a number of studies have proven that PANS/PANDAS is a form of autoimmune encephalopathy. Research published in 2020 specifically identifies that PANDAS, Sydenham Chorea, including basal ganglia and/or dopamine receptor encephalitis all have findings of autoimmunity and neuroinflammation. The inclusion of 'autoimmune encephalitis' is reflective of the growing consensus that PANDAS/PANS is a form of encephalitis that the emerging scientific evidence supports.



"The treatment you are asking for is not medically necessary."

The State of Virginia defines "medical necessity" or "medically necessary" as means appropriate and necessary health care services that are rendered for any condition which, according to generally accepted principles of good medical practice, requires the diagnosis or direct care and treatment of an illness, injury, or pregnancy-related condition, and are not provided only as a convenience[1].

Medical necessity to mean that the denial of certain proposed medical care will worsen the already compromised...If the proposed medical care is likely to substantially improve the patient's quality of life then it is medically necessary...medically necessary because its denial worsens the expected development improvement curve.

It is undeniable that some children diagnosed with PANS/PANDAS meet the criteria of medical necessity. They have physical, cognitive, and neuropsychiatric symptoms that leave them unable to attend school and engage in age-appropriate activities, with a myriad of neuropsychiatric symptoms. Obsessions and compulsions develop and leave them powerless and restricted. Thought intrusions can include thoughts of hurting themselves and others. A myriad of symptoms impact them with the potential accumulating effects that could dramatically mark their future. Withholding of medically necessary treatment could dramatically impact not only our children's well-being today, but their future well-being--to the extreme of presenting a real threat to their life.

The Centers for Medicare & Medicaid Services indicate that for diagnoses, D89.89 G04.81 (often given to children with PANS/PANDAS) they support medical necessity for the use of IVIG[2].

[1]<https://law.lis.virginia.gov/admincode/title12/agency5/chapter408/section10/#:~:text=%22Medical%20necessity%22%20or%20%20medically,%2C%20or%20pregnancy%2Drelated%20condition%2C>

[2][https://law.lis.virginia.gov/admincode/title12/agency5/chapter408/section10/#:~:text=%22Medical%20necessity%22%20or%20%20medically,%2C%20or%20pregnancy%2Drelated%20condition%2C\[2\]](https://law.lis.virginia.gov/admincode/title12/agency5/chapter408/section10/#:~:text=%22Medical%20necessity%22%20or%20%20medically,%2C%20or%20pregnancy%2Drelated%20condition%2C[2])

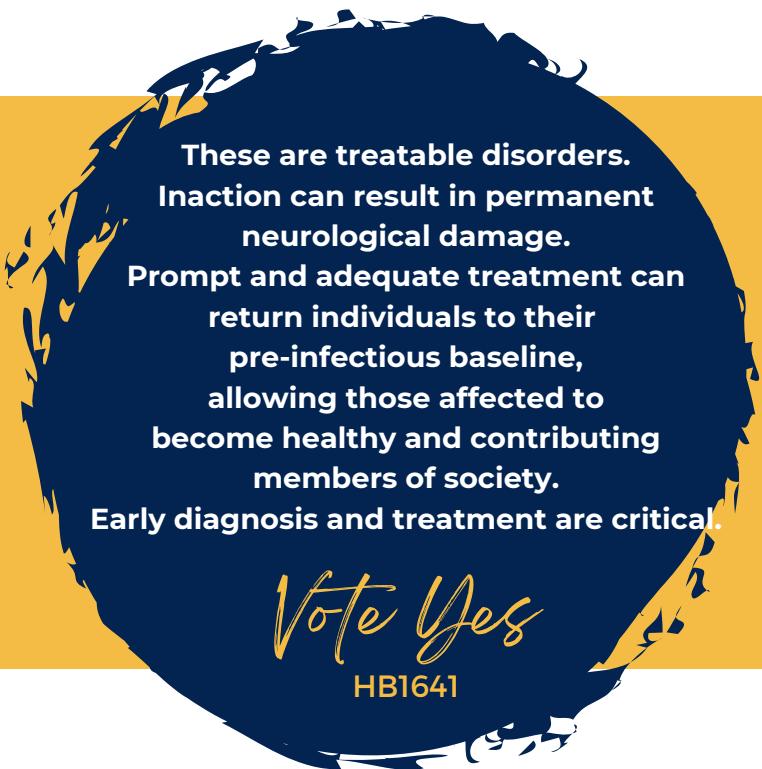
<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=56718>

AAP does not support treatments included in the bill (IVIg)

The AAP, a professional trade organization and not a research entity, states that its pre-publication study is not clinical guidance. The AAP 2024 pre-publication guidance has already been challenged and debunked by PANS/PANDAS experts.

Bill mandates specific treatments

HB1641 does not mandate coverage specifically for IVIg. The medical community's understanding of the effectiveness of specific treatments is expected to evolve over time, as such it would be inappropriate to name a specific list of treatments to mandate coverage. HB1641 allows for specific treatments to be determined by the experts in the field of PANS/PANDAS and based on the evolution of the Diagnostic Treatment Guidelines.



These are treatable disorders.
Inaction can result in permanent
neurological damage.
Prompt and adequate treatment can
return individuals to their
pre-infectious baseline,
allowing those affected to
become healthy and contributing
members of society.
Early diagnosis and treatment are critical.

Vote Yes
HB1641

