# STRUCTURE OF AN EXTERNAL APPEAL

*The information provided herein does not, and is not intended to, constitute legal or medical advice. All information and content is for general informational purposes only. Presentation Date: March 16, 2023*

1. Support letters from colleagues (regardless of whether they've actually treated the patient)
2. Overview of history of the patient's symptoms, treatments, and functional impairments
3. Published research
    a. Literally quote the studies in a letter to the payor or watchdog agency
4. State or federal laws relating to medical necessity, with explanation about how the requested service(s) satisfies medical necessity
5. Payor's own published medical necessity standards
    a. If the payor says, "We only pay for a certain service when the xyz factors are met," literally quote their criteria in the letter and break down how the service meets medical necessity in relation to each factor
6. Reiteration of the patient's functional impairment and probable consequences associated with the payor blocking payment for the requested service
    a. Specifically name it: Anorexia, self-harm, harm to others, permanent brain damage, failure to meet age-appropriate social norms, etc.)
    b. Overt 'the blood is on your hands'
7. Consequences if they do not authorize the service
    a. Involvement of media outlets (with family's consent), company-wide health insurance plan shift (coordinated with patient's HR), etc.
8. Attorney letterhead, if possible
    a. Can your practice/organization retain a healthcare attorney?
    b. Does the family have an attorney friend who can put this letter on their letterhead?

## RELEVANT LAWS & LINKS

*Remember: Some states have multiple insurance watchdog agencies... refer to the patient's denial letter for information about which state watchdog agency manages the patient's policy*

### FEDERAL

**Donald Dobson v. Secretary of Health and Human Services, No. 20-11996 (11th Cir. 2022)**
The appellate court in Dobson v. Secretary of Health and Human Services held that Medicare must provide coverage for a beneficiary's off-label use of a medication.

### CALIFORNIA

**Pending:** Legislation (AB907) introduced 2/14/2023 by CA Assemblyman Josh Lowenthal (District 69 Long Beach, Carson). The bill would prohibit a plan or insurer from denying or delaying coverage for medically necessary treatment of PANDAS or PANS solely because the enrollee or insured previously received treatment for PANDAS or PANS or has been diagnosed with or received treatment for the condition under a different diagnostic name.

**California Welfare And Institutions Code §14059.5**
"[A] service is 'medically necessary' or a 'medical necessity' when it is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain."

**California Health & Safety Code §1374.33, et seq., codified in 2015, relating to Independent Medical Review applications (DMHC):**
"...(b) Following its review, the reviewer or reviewers shall determine whether the disputed health care service was medically necessary based on the specific medical needs of the enrollee and any of the following:
(1) Peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service.
(2) Nationally recognized professional standards.
(3) Expert opinion.
(4) Generally accepted standards of medical practice..."

**CA Business And Professions Code §2400**
"...Corporations and other artificial entities shall have no professional rights, privileges, or powers. The policy expressed in Business and Professions Code section 2400 against the corporate practice of medicine is intended to prevent unlicensed persons from interfering with or influencing the physician's professional judgment. The decisions described below are examples of some of the types of behaviors and subtle controls that the corporate practice doctrine is intended to prevent. From the Medical Board's perspective, the following health care decisions should be made by a physician licensed in the State of California and would constitute the unlicensed practice of medicine if performed by an unlicensed person:

- Determining what diagnostic tests are appropriate for a particular condition.
- Determining the need for referrals to, or consultation with, another physician/specialist.
- Responsibility for the ultimate overall care of the patient, including treatment options available to the patient..."

California Department of Managed Healthcare File a Complaint

California Department of Insurance File a Complaint

## FLORIDA

**Florida Social Welfare Code §409.9131 (Medicaid)**
"'Medical necessity' or 'medically necessary' means any goods or services necessary to palliate the effects of a terminal condition or to prevent, diagnose, correct, cure, alleviate, or preclude deterioration of a condition that threatens life, causes pain or suffering, or results in illness or infirmity, which goods or services are provided in accordance with generally accepted standards of medical practice."

How The Health Insurance Appeals Process Works In Florida By Verploeg & Marino

Florida Department Of Financial Services Health Insurance FAQs

The Division of Consumer Services (Florida)

## GEORGIA

**2010 Georgia Code; TITLE 33 - INSURANCE, CHAPTER 20A - MANAGED HEALTH CARE PLANS; ARTICLE 2 - PATIENT'S RIGHT TO INDEPENDENT REVIEW**
**§ 33-20A-40 - Determining medical necessity or whether a treatment is experimental**

“(a) For the purposes of this article, in making a determination as to whether a treatment is medically necessary and appropriate, the expert reviewer shall use the definition provided in paragraph (7) of Code Section 33-20A-31.
(b) For the purposes of this article, in making a determination as to whether a treatment is experimental, the expert reviewer shall determine:

(1) Whether such treatment has been approved by the federal Food and Drug Administration; ***or***
(2) Whether medical and scientific evidence demonstrates that the expected benefits of the proposed treatment would be greater than the benefits of any available standard treatment and that the adverse risks of the proposed treatment will not be substantially increased over those of standard treatments.

For either determination, the expert reviewer shall apply prudent professional practices and shall assure that at least two documents of medical and scientific evidence support the decision.”

**§ 33-20A-31 - Definitions**

“(6) "Medical and scientific evidence" means:

(A) Peer reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;
(B) Peer reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS data base or Health Services Technology Assessment Research (HSTAR);
(C) Medical journals recognized by the United States secretary of health and human services, under Section 1861(t)(2) of the Social Security Act;
(D) The following standard reference compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluation, the American Dental Association Accepted Dental Therapeutics, and the United States Pharmacopoeia-Drug Information; or
(E) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, the Centers for Medicare and Medicaid Services, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

(7) "Medical necessity," "medically necessary care," or "medically necessary and appropriate" means care based upon generally accepted medical practices in light of conditions at the time of treatment which is:

(A) Appropriate and consistent with the diagnosis and the omission of which could adversely affect or fail to improve the eligible enrollee's condition;
(B) Compatible with the standards of acceptable medical practice in the United States;
(C) Provided in a safe and appropriate setting given the nature of the diagnosis and the severity of the symptoms;
(D) Not provided solely for the convenience of the eligible enrollee or the convenience of the health care provider or hospital; and
(E) Not primarily custodial care, unless custodial care is a covered service or benefit under the eligible enrollee's evidence of coverage.
(8) "Treatment" means a medical service, diagnosis, procedure, therapy, drug, or device.

Office of Commissioner of Insurance and Safety Fire- The Consumer Services Division (Georgia)

## ILLINOIS

**Illinois Insurance Code (215 ILCS 5/356z.25)**
Health insurance must cover the treatment of PANDAS and PANS, including intravenous immunoglobulin therapy.

Illinois Department of Insurance Message Center for Insurance-Related Issues

## MASSACHUSETTS

**Bill S.2935; 191st (2019 - 2020)**
The bill requires insurance carriers to cover PANDAS/PANS, ensuring that children with PANDAS/PANS and their families have access to treatment and care, and it establishes a PANDAS/PANS Advisory Council within DPH to advise the Commissioner on ongoing research, diagnosis, treatment, and education related to PANDAS/PANS.
“Section 47NN. Any policy, contract, agreement, plan or certificate of insurance issued,
960 delivered or renewed within or without the commonwealth shall provide coverage for treatment
961 of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections and
962 pediatric acute-onset neuropsychiatric syndrome including, but not limited to, the use of
963 intravenous immunoglobulin therapy.”

**130 CMR 450.204 - Medical Necessity**
(A) A service is medically necessary if

(1) it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a handicap, or result in illness or infirmity; and

(2) there is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly to the MassHealth agency. Services that are less costly to the MassHealth agency include, but are not limited to, health care reasonably known by the provider, or identified by the MassHealth agency pursuant to a prior-authorization request, to be available to the member through sources described in 130 CMR 450.317(C), 503.007: Potential Sources of Health Care, or 517.007: Utilization of Potential Benefits.

(B) Medically necessary services must be of a quality that meets professionally recognized standards of health care, and must be substantiated by records including evidence of such medical necessity and quality. A provider must make those records, including medical records, available to the MassHealth agency upon request. (See 42 U.S.C. 1396a(a)(30) and 42 CFR 440.230 and 440.260.)
(C) A provider's opinion or clinical determination that a service is not medically necessary does not constitute an action by the MassHealth agency.
(D) Additional requirements about the medical necessity of MassHealth services are contained in other MassHealth regulations and medical necessity and coverage guidelines.
(E) Any regulatory or contractual exclusion from payment of experimental or unproven services refers to any service for which there is insufficient authoritative evidence that such service is reasonably calculated to have the effect described in 130 CMR 450.204(A)(1).

[Mass.Gov Filing An Insurance Complaint]

## NEW YORK

**New York State Department of Health Glossary**
MEDICALLY NECESSARY SERVICE means health care and services that are necessary to prevent, diagnose, manage or treat conditions in the person that cause acute suffering, endanger life, result in illness or infirmity, interfere with such person's capacity for normal activity or threaten some significant handicap

**New York Social Services Law, § 365-a**
New York law defines "medically necessary medical, dental, and remedial care, services, and supplies" in the Medicaid program as those "necessary to prevent, diagnose, correct, or cure conditions in the person that cause acute suffering, endanger life, result in illness or infirmity, interfere with such person's capacity for normal activity, or threaten some significant handicap and which are furnished an eligible person in accordance with state law. Reportedly, this definition applies to both the fee-for-service and managed care populations.

**Assembly Bill A877 - Insurance Coverage for Pediatric Acute-Onset Neuropsychiatric Syndrome (In Assembly Committee as of 2/15/23)**
Every health plan, and health insurance issuer offering health insurance coverage in connection with a group health plan, shall provide coverage for a participant or beneficiary who has pediatric acute-onset neuropsychiatric syndrome if the attending physician of the participant or beneficiary certifies in writing the medical necessity of that proposed course of rehabilitative treatment. *(Please note that this bill is currently being reviewed and has not been passed as of 2/15/23)*

[New York Department of Financial Services File a Complaint]

## OHIO

**Ohio Administrative Code/5160/Chapter 5160-1 Medicaid medical necessity: definitions and principles.**
Effective:February 24, 2022
(A) Medical necessity for individuals covered by early and periodic screening, diagnosis and treatment (EPSDT) is criteria of coverage for procedures, items, or services that prevent, diagnose, evaluate, correct, ameliorate, or treat an adverse health condition such as an illness, injury, disease or its symptoms, emotional or behavioral dysfunction, intellectual deficit, cognitive impairment, or developmental disability.
(B) Medical necessity for individuals not covered by EPSDT is criteria of coverage for procedures, items, or services that prevent, diagnose, evaluate, or treat an adverse health condition such as an illness, injury, disease or its symptoms, emotional or behavioral dysfunction, intellectual deficit, cognitive impairment, or developmental disability and without which the person can be expected to suffer prolonged, increased or new morbidity; impairment of function; dysfunction of a body organ or part; or significant pain and discomfort.
(C) Conditions of medical necessity for a procedure, item, or service are met if all the following apply:
(1) It meets generally accepted standards of medical practice;
(2) It is clinically appropriate in its type, frequency, extent, duration, and delivery setting;
(3) It is appropriate to the adverse health condition for which it is provided and is expected to produce the desired outcome;

(4) It is the lowest cost alternative that effectively addresses and treats the medical problem;
(5) It provides unique, essential, and appropriate information if it is used for diagnostic purposes; and
(6) It is not provided primarily for the economic benefit of the provider nor for the sole convenience of the provider or anyone else other than the recipient.

(D) The fact that a physician, dentist or other licensed practitioner renders, prescribes, orders, certifies, recommends, approves, or submits a claim for a procedure, item, or service does not, in and of itself make the procedure, item, or service medically necessary and does not guarantee payment.
(E) The definition and conditions of medical necessity articulated in this rule apply throughout the entire medicaid program. More specific criteria regarding the conditions of medical necessity for particular categories of service may be set forth within the Ohio department of medicaid (ODM) coverage policies or rules.

**OPINION NO. 99-044**
https://www.ohioattorneygeneral.gov/getattachment/8c6bc3d9-bb34-406f-aece-4231c6c30f03/1999-044.aspx

Ohio Department of Insurance File a Consumer Complaint

## PENNSYLVANIA

**28 Pa. Code § 9.677 - Requirements of definitions of "medical necessity"**
The definition of "medical necessity" shall be the same in the plan's provider contracts, enrollee contracts and other materials used to evaluate appropriateness and to determine coverage of health care services. The definition shall comply with the HMO Act, the PPO Act, Act 68 and this chapter.

**§ 1101.21a. Clarification regarding the definition of ‘‘medically necessary’’—statement of policy.**
A service, item, procedure or level of care that is necessary for the proper treatment or management of an illness, injury or disability is one that:
(1) Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
(2) Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.=
(3) Will assist the recipient to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the recipient and those functional capacities that are appropriate of recipients of the same age.

Pennsylvania Insurance Department File a Complaint

## TEXAS

**Texas Administrative Code**
TITLE 25; RULE §33.2- Definitions
(8) Medically necessary--Medical services that are supported by documentation which show the services are:
(A) reasonable and necessary to prevent illness, medical or dental conditions, or provide early screening, interventions, and/or treatments for conditions that cause suffering or pain, cause physical deformity or limitations in function, threaten to cause or worsen a disability, cause illness or infirmity of a client, or endanger life;

(B) consistent with health care practice guidelines and standards that are issued by professionally recognized health care organizations or governmental agencies;

(C) consistent with the diagnoses of the conditions;

(D) no more intrusive or restrictive than necessary to provide a proper balance of safety, effectiveness, and efficiency;

(E) not experimental or investigative; and

(F) not primarily for the convenience of the client or provider.

Texas Department of Insurance- Get Help With An Insurance Complaint

## VIRGINIA

**12VAC5-408-10. Definitions.**

“Medical necessity" or "medically necessary" means appropriate and necessary health care services which 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.

Virginia State Corporation Commission File A Complaint

Overview Of Virginia Managed Care Laws Affecting Physicians And Their Patients

## Recommended Reading

- Insurance Coverage Requirements for the Treatment of PANDAS/PANS (2022)
- Understanding the Corporate Practice of Medicine Doctrine and the Role of the Management Services Organization (2011)
- How to Appeal Health Insurance Company Denials. By Tom Wilson, Leader, WI NCAN Support Group (geared at cancer treatment but applicable to PANS/PANDAS)
- The National Association of Insurance Commissioners (NAIC)

## Relevant Studies to Establish a Medical Standard

**Intravenous Immunoglobulin**

IVIg for children with selective IGg deficiency/ hypogammaglobulinemia:

- Compagno N, Malipiero G, Cinetto F, Agostini C. Immunoglobulin replacement therapy in secondary hypogammaglobulinemia. Front Immunol. 2014;5:626. Published 2014 Dec 8. doi:10.3389/fimmu.2014.00626
- Garcia-Lloret M, McGhee S, Chatila TA. Immunoglobulin replacement therapy in children. Immunol Allergy Clin North Am. 2008 Nov;28(4):833-49, ix. doi: 10.1016/j.iac.2008.07.001. PMID: 18940577; PMCID: PMC2585601.

IVIg efficacy in PANS patients:

- Chang K, Frankovich J, Cooperstock M, et al. Clinical evaluation of youth with pediatric acute-onset neuropsychiatric syndrome (PANS): recommendations from the 2013 PANS Consensus Conference. J Child Adolesc Psychopharmacol. 2015;25(1):3-13. doi:10.1089/cap.2014.0084
- Frankovich J, Swedo S, Murphy T, et al. Clinical Management of Pediatric Acute-Onset Neuropsychiatric Syndrome: Part II-Use of Immunomodulatory Therapies. J. Child. Adolesc. Psychopharmacol 27(7), 574-593 (2017).
- Kovacevic M, Grant P, Swedo SE. Use of intravenous immunoglobulin in the treatment of twelve youths with pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections. J Child Adolesc Psychopharmacol. 2015;25(1):65-69. doi:10.1089/cap.2014.0067
- Pavone et al., PANS/PANDAS: Clinical Experience in IVIG Treatment and State of the Art in Rehabilitation Approaches. NeuroSci 2020;1:75-84
- Perlmutter SJ, Leitman SF, Garvey MA, et al. Therapeutic plasma exchange and intravenous immunoglobulin for obsessive-compulsive disorder and tic disorders in childhood. Lancet 354(9185), 1153-1158 (1999).

**Plasmapheresis**

- Cortese I, Chaudhry V, So YT, Cantor F, Cornblath DR, Rae-Grant A: Evidence-based guideline update: Plasmapheresis in neurologic disorders: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 76:294–300, 2011.
- Elia J, Dell ML, Friedman DF, Zimmerman RA, Balamuth N, Ahmed AA, Pati S: PANDAS with catatonia: A case report. Therapeutic response to lorazepam and plasmapheresis. J Am Acad Child Adolesc Psychiatry 44:1145–1150, 2005.
- Garvey MA, Snider LA, Leitman SF, Werden R, Swedo SE: Treatment of Sydenham's chorea with intravenous immunoglobulin, plasma exchange, or prednisone. J Child Neurol 5:424–429, 2005. Nicolson R, Swedo SE, Lenane M, Bedwell J, Wudarsky M, Gochman P, Hamburger SD, Rapoport JL: An open trial of plasma exchange in childhood-onset obsessive-compulsive disorder without poststreptococcal exacerbations. J Am Acad Child Adolesc Psychiatry 39:1313–1315, 2000.

- Latimer ME, L'Etoile N, Seidlitz J, Swedo SE. Therapeutic plasma apheresis as a treatment for 35 severely ill children and adolescents with pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections. J Child Adolesc Psychopharmacol. 2015;25(1):70-75. doi:10.1089/cap.2014.0080
- Perlmutter SJ, Leitman SF, Garvey MA, Hamburger S, Feldman E, Leonard HL, Swedo SE: Therapeutic plasma exchange and intravenous immunoglobulin for obsessive-compulsive disorder and tic disorders in childhood. Lancet 354:1153–1158, 1999.
- Szczepiorkowski ZM, Bandarenko N, Kim HC, Linenberger ML, Marques MB, Sarode R, Schwartz J, Weinstein R, Shaz BH, Apheresis Applications Committee of theAmerican Society for Apheresis: Guidelines on the use of therapeutic apheresis in clinical practice: evidence-based approach from the Apheresis Applications Committee of the American Society for Apheresis. J Clin Apher 22:106–175, 2007a.
- Szczepiorkowski ZM, Shaz BH, Bandarenko N, Winters JL: The new approach to assignment of AFA categories – introduction to the fourth special issue: Clinical applications of therapeutic apheresis. J Clin Apher 22:96–105, 2007b.


**Rituximab**


- Frankovich J, Swedo S, Murphy T, et al. Clinical Management of Pediatric Acute-Onset Neuropsychiatric Syndrome: Part II-Use of Immunomodulatory Therapies. J. Child. Adolesc. Psychopharmacol 27(7), 574-593 (2017).
- Frankovich J, Thienemann M, Rana S, Chang K. Five youth with pediatric acute-onset neuropsychiatric syndrome of differing etiologies. J Child Adolesc Psychopharmacol. 2015;25(1):31-37. doi:10.1089/cap.2014.0056
- Krouse A, Li H, Krenzer JA, Rose WN. Plasmapheresis, Rituximab, and Ceftriaxone Provided Lasting Improvement for a 27-Year-Old Adult Male with Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS). Case Rep Psychiatry. 2021 Nov 2;2021:8697902. doi: 10.1155/2021/8697902. PMID: 34765265; PMCID: PMC8577953.
- Nepal G, Shing YK, Yadav JK, Rehrig JH, Ojha R, Huang DY, Gajurel BP. Efficacy and safety of rituximab in autoimmune encephalitis: A meta-analysis. Acta Neurol Scand. 2020 Nov;142(5):449-459. doi: 10.1111/ane.13291. Epub 2020 Jun 16. PMID: 32484900.
- Nosadini M, Mohammad SS, Ramanathan S, Brilot F, Dale RC. Immune therapy in autoimmune encephalitis: a systematic review. Expert Rev Neurother. 2015;15(12):1391-419. doi: 10.1586/14737175.2015.1115720. Epub 2015 Nov 24. PMID: 26559389.
- Shin YW, Lee ST, Park KI, et al. Treatment strategies for autoimmune encephalitis. Ther Adv Neurol Disord. 2017;11:1756285617722347. Published 2017 Aug 16. doi:10.1177/1756285617722347
- Thaler, Franziska S., et al. Rituximab treatment and long-term outcome of patients with autoimmune encephalitis: real-world evidence from the GENERATE registry. Neurology-Neuroimmunology Neuroinflammation 8.6 (2021).