Department of Legislative Services

Maryland General Assembly 2020 Session

FISCAL AND POLICY NOTE Third Reader - Revised

House Bill 447

(Delegate Carr, et al.)

Health and Government Operations

Finance

Health Insurance - Pediatric Autoimmune Neuropsychiatric Disorders -Coverage

This bill requires an insurer, nonprofit health service plan, or health maintenance organization (collectively known as carriers) to provide coverage for medically necessary diagnosis, evaluation, and treatment of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) and pediatric acute onset neuropsychiatric syndrome (PANS), including the use of intravenous immunoglobulin therapy (IVIG). Beginning January 1, 2021, Medicaid, subject to the limitations of the State budget, must provide similar coverage for eligible program recipients. A *carrier* is not required to cover rituximab unless the U.S. Food and Drug Administration (FDA) approves it for the treatment of PANDAS and PANS. The bill also specifies how PANDAS and PANS must be coded for billing and diagnosis purposes. The bill takes effect January 1, 2021, and applies to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after that date.

Fiscal Summary

State Effect: Minimal increase in special fund revenues for the Maryland Insurance Administration (MIA) in FY 2021 from the \$125 rate and form filing fee. Review of form filings can likely be handled with existing budgeted resources. No effect on Medicaid or the State Employee and Retiree Health and Welfare Benefits Program (State plan) at this time, as discussed below.

Local Effect: To the extent the mandate increases the cost of health insurance, expenditures for local governments that purchase fully insured medical plans may increase. Revenues are not affected.

Small Business Effect: Potential minimal.

Analysis

Bill Summary: A carrier may impose annual deductibles, copayments, or coinsurance on the required coverage if they are not greater than those imposed by the carrier for similar coverage under the same health insurance policy or contract. PANDAS and PANS must be coded as autoimmune encephalitis for billing and diagnosis purposes. If the American Medical Association and the federal Centers for Medicare and Medicaid Services create and assign a specific code for PANDAS or PANS for billing and diagnosis purposes, PANDAS and PANS may be coded as autoimmune encephalitis, PANDAS, or PANS.

Current Law: Under Maryland law, there are more than 50 mandated health insurance benefits that certain carriers must provide to their enrollees. The federal Patient Protection and Affordable Care Act requires nongrandfathered health plans to cover 10 essential health benefits (EHBs), which include items and services in the following categories: (1) ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services; including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) pediatric services, including dental and vision care.

Under § 31-116 of the Maryland Insurance Article, EHBs must be included in the State benchmark plan and, *not withstanding any other benefits mandated by State law*, must be the benefits required in (1) all individual health benefit plans and health benefit plans offered to small employers (except for grandfathered health plans) offered outside the Maryland Health Benefit Exchange (MHBE) and (2) all qualified health plans offered in MHBE.

Background: According to the National Institute of Mental Health (NIMH), a child may be diagnosed with PANDAS when obsessive compulsive disorder (OCD) and/or tic disorders suddenly either appear or worsen following a strep infection. Symptoms are usually dramatic, happen "overnight and out of the blue," and can include motor and/or vocal tics, obsessions and/or compulsions, anxiety, and irritability. The diagnostic criteria for PANDAS include (1) presence of OCD and/or a tic disorder; (2) pediatric onset of symptoms (age three years to puberty); (3) episodic course of symptom severity; (4) association with group A Beta-hemolytic streptococcal infection; (5) association with neurological abnormalities (physical hyperactivity or unusual, jerky movements that are not in the child's control); and (6) very abrupt onset or worsening of symptoms.

PANS includes all cases of acute onset OCD, not just those associated with streptococcal infection. PANS diagnostic criteria include (1) abrupt, dramatic onset of OCD or severely restricted food intake; (2) concurrent neuropsychiatric symptoms with similarly severe and acute onset (such as anxiety, extreme mood swings, irritability, aggression, behavioral

regression, deterioration in school performance, sensory or motor abnormalities, or somatic signs); and (3) symptoms not better explained by a known neurologic or medical disorder. The PANDAS Network estimates that PANDAS/PANS affects as many as 1 in 200 children.

In 2017, NIMH published comprehensive treatment recommendations for PANDAS and PANS. The recommendations include three levels: (1) psychiatric and behavioral interventions; (2) use of immunomodulatory therapies (including IVIG for moderate to severe cases if antibiotic therapy fails); and (3) treatment and prevention of infections.

IVIG is an intravenous pooled blood product comprising immunoglobulins used in treating immune deficiencies, encephalitis, and other medical conditions. According to the PANDAS Physicians Network, IVIG currently has FDA indications for the treatment of Kawasaki disease, idiopathic thrombocytopenic purpura, and other immune-mediated diseases of childhood. It is not yet indicated for treatment of PANDAS. However, IVIG has been shown to decrease symptom severity and shorten the course of illness in PANDAS and is endorsed for treating PANDAS by a consortium of physicians and researchers.

Rituximab is a medication used to treat certain autoimmune diseases such as rheumatoid arthritis and cancers such as non-Hodgkin's lymphoma and chronic lymphocytic leukemia. It is not FDA-approved for the treatment of PANDAS or PANS.

To date, five states (Arkansas, Delaware, Illinois, Minnesota, and New Hampshire) mandate insurance coverage for treatment of PANDAS/PANS, including the use of IVIG.

State Fiscal Effect:

Maryland Medicaid

Maryland Medicaid currently provides coverage for medically necessary services, including treatment of PANDAS/PANS. However, under federal Early and Periodic Screening, Diagnostic, and Treatment guidelines, Medicaid is not required to cover experimental or investigational treatments or services. As such, the State does not cover them for any reason. Medicaid advises that, at this time, as IVIG has not been FDA-approved as a treatment for PANDAS/PANS and is considered experimental, it would not be covered by Medicaid. As rituximab is not FDA-approved for PANDAS/PANS, it also would not be covered by Medicaid.

State Employee and Retiree Health and Welfare Benefits Program

The State plan is largely self-insured for its medical contracts and, as such, with the exception of one fully insured integrated health model medical plan (Kaiser), is not subject to this mandate. However, the State plan generally provides coverage for mandated health HB 447/ Page 3

insurance benefits. According to the Department of Budget and Management (DBM), all carriers participating in the State plan currently provide coverage for treatment of PANDAS/PANS. However, as with Medicaid, DBM has previously advised that medical plans in the State plan would not cover IVIG or rituximab for PANDAS/PANS until FDA-approved for these conditions.

Potential Additional Costs

To the extent IVIG becomes FDA-approved for PANDAS/PANS, Medicaid and State plan expenditures increase by an indeterminate amount. According to a 2015 <u>analysis</u> of similar legislation proposed in Massachusetts, the total cost of IVIG therapy (based on 2012 claims data) was \$7,059 per treatment. The analysis concluded that requiring coverage for treatment of PANDAS/PANS by fully insured health plans in Massachusetts 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.

Additional Comments: According to MIA, the bill establishes a new mandated benefit for the large group market and individual grandfathered market only.

Although the bill intends to waive the requirement for Medicaid to cover rituximab unless FDA approves it for the treatment of PANDAS and PANS, the cross reference in the bill does not have that effect.

Additional Information

Prior Introductions: HB 15 of 2019, a similar bill, received a hearing in the House Health and Government Operations Committee and was subsequently withdrawn.

Designated Cross File: SB 475 (Senator Sydnor, *et al.*) - Finance.

Information Source(s): Department of Budget and Management; Maryland Department of Health; Maryland Health Benefit Exchange; Maryland Insurance Administration; Department of Legislative Services

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