

Department of Legislative Services
Maryland General Assembly
2022 Session

FISCAL AND POLICY NOTE
Third Reader

House Bill 820 (Delegate Carr)
Health and Government Operations

Finance

Health Insurance - Pediatric Autoimmune Neuropsychiatric Disorders -
Modification of Coverage Requirements

This bill repeals the requirement that rituximab be approved by the U.S. Food and Drug Administration (FDA) for the treatment of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) and pediatric acute onset neuropsychiatric syndrome (PANS) to mandate coverage of the medication by Medicaid and health insurance carriers. **The bill takes effect January 1, 2023, 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 from the \$125 rate and form filing fee; review of filings can be handled within existing budgeted resources. Expenditures for the State Employee and Retiree Health and Welfare Benefits Program increase by an indeterminate amount beginning in FY 2023.

Local Effect: To the extent the requirement to cover rituximab for PANDAS and PANS increases the cost of health insurance, expenditures may increase for local governments that purchase fully insured medical plans. Revenues are not affected.

Small Business Effect: None.

Analysis

Current Law: Chapter 560 of 2020 requires an insurer, nonprofit health service plan, or health maintenance organization (collectively known as carriers) and Medicaid to provide coverage for the medically necessary diagnosis, evaluation, and treatment of PANDAS and PANS, including the use of intravenous immunoglobulin therapy (IVIG). A carrier and Medicaid are not required to cover rituximab unless FDA approves it for the treatment of PANDAS and PANS.

When a prescription drug is used for a disease or medical condition for which the drug has not been approved to treat by FDA, it is considered unapproved or off-label use.

Maryland regulations (10.09.03.06) authorize Medicaid to require preauthorization for an off-label use of a prescription drug. Medicaid (or its designee) may not grant preauthorization for an off-label use of a drug if (1) the off-label use is inconsistent with generally accepted standards of care; (2) the drug is prescribed for a nonmedically accepted indication; (3) the drug is prescribed in a manner not approved by FDA; or (4) the off-label use is not documented in and supported by the latest edition of either the *American Hospital Formulary Service Drug Information*, the *Thompson Micromedex Drugdex*, or the *United States Pharmacopeia*.

State Fiscal Effect:

Impact on Medicaid

Maryland Medicaid currently provides coverage for 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 is not covered by Medicaid.

As rituximab is not FDA-approved for the treatment of PANDAS/PANS and its off-label use for PANDAS/PANS is not documented in and supported by these reference manuals, it is not covered by Medicaid.

Impact on the State Employee and Retiree Health and Welfare Benefits Program

The State Employee and Retiree Health and Welfare Program is largely self-insured for its medical contracts and, as such, except for one fully insured integrated health model medical plan (Kaiser), is not subject to health insurance mandates. However, the program generally provides coverage for mandated health 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. DBM advises that the program would comply with this legislation. The annual cost for rituximab is estimated at \$50,000 per patient. All claimants will be subject to case and disease management protocols to determine medical appropriateness prior to approval. DBM expenditures for the program increase beginning in fiscal 2023 to provide off-label coverage of rituximab. Without additional information on the number of individuals who may seek coverage of the drug under the bill, the exact cost to the program cannot be reliably estimated at this time.

Additional Comments: 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.

Additional Information

Prior Introductions: None.

Designated Cross File: None.

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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