MARYLAND
Health Care
Commission

Randolph S. Sergent, Esq, Chairman
Ben Steffen, Executive Director

January 9, 2024

The Honorable Pamela G. Beidle
Chair, Senate Finance Committee
James Senate Office Building, Room 202
11 Bladen Street
Annapolis, MD 21401

Re: SB0075, 2023 - Insurance and Maryland Medical Assistance Program – Treatment of Alopecia Areata – Coverage Requirements - Mandated Health Insurance Services Evaluation Report

Dear Chair Beidle,

Pursuant to your request and in accordance with Insurance Article §15-1501, Annotated Code of Maryland, the Maryland Health Care Commission (MHCC) is pleased to submit the enclosed mandated health insurance services evaluation on *SB0075 - Insurance and Maryland Medical Assistance Program – Treatment of Alopecia Areata – Coverage Requirements* introduced during the 2023 legislative session but did not pass.

The bill would have required the Maryland Medical Assistance Program to cover one hair prosthesis for each recipient whose hair loss resulted from alopecia areata and to cover prescription drugs and medical devices approved by the U.S. Food and Drug Administration (FDA) for the treatment of alopecia areata. Additionally commercial insurers would have been required subject to state benefit mandates to cover the cost of one hair prosthesis (up to $350) prescribed by the physician treating an enrollee or insured for alopecia areata.

The MHCC contracted with Milliman, Inc. ("Milliman"), an actuarial consulting firm, to evaluate the social, medical, and financial impact of SB 75. The attached report provides the results of the evaluation related to the social, medical, and financial impact of SB 75 should this bill be reintroduced and pass in the 2024 legislative session.

A few key points from Millman's mandate evaluation on requiring coverage for the treatment of Alopecia Areata include:

- For fully insured commercial plans, we estimated that this increase is driven by approximately 1,200 current users without current coverage who will utilize the new $350 benefit to purchase cranial prostheses, and 270 new users who will only purchase a $350 cranial prosthesis because of SB 75.

- For the State Health Plan, the increase is driven by 490 current users without coverage who will purchase a cranial prosthesis and 110 new users who will purchase a cranial prosthesis. The estimated average cost of a cranial prosthesis trended to 2025 is $1,640.

- It is estimated that mandated coverage for cranial prostheses and FDA approved prescription drugs, such as the newly approved JAK inhibitors, would increase Medicaid costs in 2025 by approximately $6,195,000 to $10,320,000, $0.33 to $0.54 PMPM, $3.96 to $6.48 PMPY, depending on the number of alopecia areata patients who will use JAK inhibitors. Actual utilization of JAK inhibitors in the Maryland Medicaid population is not known as they are newly approved treatments.

- The Medicaid cost increase is estimated to be driven by 2,140 new users of cranial prostheses and an additional 100 to 440 JAK inhibitor users. Unlike the commercial population, the Medicaid benefit mandate pays in full for cranial prostheses. The assumption is that the new JAK inhibiter users will pay an additional $1.50 copay out-of-pocket for each script.

Finally, the Commission strongly urges the Legislature to proceed with caution when considering the adoption of additional mandated health insurance services given their cumulative deleterious impact on affordability over time despite a minimal impact on premiums of any single mandate at the time of adoption.

We appreciate your consideration. If you have any questions or if we may provide you with any further information, please do not hesitate to contact me at ben.steffen@maryland.gov or 410-764-3566 or Ms. Tracey DeShields, Director of Policy Development and External Affairs, at tracey.deshields2@maryland.gov or 410-764-3588.

Sincerely,

Ben Steffen,
Executive Director

cc:
The Honorable Joseline A. Pena-Melnyk, Chair, House Health and Government Operations Committee

The Honorable Jill Carter, Education, Energy, and the Environment Committee
House Health and Government Operations Committee
Senate Finance Committee
The Honorable Laura Herrera Scott, Secretary, Maryland Department of Health
Marie Grant, Assistant Secretary, Health Policy, Maryland Department of Health
Ryan Moran, Deputy Secretary, Healthcare Finance, Maryland Department of Health
Tricia Roddy, Deputy Medicaid Director, Healthcare Finance, Maryland Department of Health
Jonny Dorsey, Deputy Chief of Staff, Governor's Office
June Chung, Deputy Legislative Office, Governor's Legislative Office
Jason Heo, Governor's Office
Sophie Bergmann, Governor's Office
Sarah Albert, Department of Legislative Services (5 hard copies)
Lisa Simpson, Committee Counsel, House Health and Government Operations,
Patrick Carlson, Committee Counsel, Senate Finance
Kenneth Yeates-Trotman, Director, Center for Analysis And Information Systems
Tracey DeShields, Director of Policy Development and External Affairs, MHCC

MILLIMAN REPORT

Maryland Senate Bill 75 - Alopecia Areata Analysis

Prepared for Maryland Health Care Commission

December 5, 2023

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Milliman

Table of Contents

Introduction

Insurance Article §15–1501, Annotated Code of Maryland, requires the Maryland Health Care Commission (MHCC) to annually assess the medical, social, and financial impact of proposed mandated health insurance services that failed to pass during the preceding legislative session. Senate Bill 75 (SB 75), which did not pass, requires the following summarized from the bill text:

1) Maryland Medical Assistance Program to cover one hair prosthesis for each recipient whose hair loss resulted from alopecia areata.

2) Maryland Medical Assistance Program to cover prescription drugs and medical devices approved by the U.S. Food and Drug Administration (FDA) for the treatment of alopecia areata.

3) Commercial insurers that are subject to state benefit mandates must cover the cost of one hair prosthesis (up to $350) prescribed by the physician treating an enrollee or insured for alopecia areata.

At the request of MHCC, Milliman, Inc. (“Milliman”) was asked to provide a medical, social, and financial impact of SB 75.

The report requires a medical evaluation that includes the extent to which the medical community generally recognizes the services as being effective in the treatment of alopecia areata, evidence of effectiveness from peer-reviewed literature, and the extent to which they are available.

This report also requires a social evaluation that includes the extent to which the service is generally utilized by a significant portion of the population and to which insurance coverage is already generally available. And, if coverage is not generally available, the extent to which the lack of coverage results in individuals avoiding necessary health care treatments and to which the lack of coverage results in unreasonable financial hardship. And also, the impact to the level of public demand for the service, the level of public demand for insurance coverage of the service, the level of interest of collective bargaining agents in negotiating privately for inclusion of this coverage in group contracts; and the extent to which the mandated health insurance service is covered by self-funded employer groups of employers in the State who employ at least 500 employees.

This report also requires a financial impact assessment that includes the extent to which the coverage will increase or decrease the cost and appropriate use of the service, the extent to which the mandated service will be a substitute for a more expensive service, and the extent to which the coverage will increase or decrease the administrative expenses of insurers and the premium and administrative expenses of policy holders. The impact analysis also includes the impact of this benefit mandate on the total cost of health care; and the impact of all mandated health insurance services on employers' ability to purchase health benefits policies meeting their employees' needs.

Highlights

MEDICAL IMPACT

- Alopecia areata is an autoimmune skin disease that can cause hair loss on any part of the body and affects about 0.2% of the national population.
- Wig and cranial prosthesis usage can positively impact confidence for people with alopecia areata but does not appear to address all social distress caused by the disease.
- Janus kinase (JAK) inhibitors baricitinib and ritlecitinib have shown to be significantly more effective than placebo in treating alopecia areata and have been newly approved by the U.S. Food and Drug Administration (FDA).

SOCIAL IMPACT

- Alopecia areata affects people of color and females at a higher rate than males and white people. The higher rates of alopecia areata among women and people of color suggest that legislation related to cranial prostheses and alopecia areata treatment would have a greater impact on these populations.
- Some surveys have estimated up to 93.1% of alopecia areata patients have considered purchasing a cranial prosthesis, with cost cited as the main reason people do not receive one.
- Based on a survey of carriers, Maryland enrollees in Individual, State Health Plan and Medicaid plans do not have coverage for cranial prostheses. Approximately 28% of fully insured large group and 5% of small group enrollees have current coverage for cranial prostheses with an alopecia areata diagnosis.
- We estimate 76% of Maryland Medicaid enrollees have coverage for JAK inhibitors in 2024.
- In the recent HHS Notice of Benefit and Payment Parameters for 2023 final rule, federal regulators refined the essential health benefit nondiscrimination policy. Coverage limits must now be clinically based to be considered nondiscriminatory. SB 75 expands on existing coverage of cranial prostheses for cancer patients to alopecia patients. Based on this new guidance, enrollees in ACA markets may already have coverage.

FINANCIAL IMPACT

- We estimate that the average cost of a cranial prosthesis in 2025 is $1,640.
- Mandated coverage for cranial prostheses is estimated to result in increased utilization of cranial prostheses. The estimated impact is 270 new users in the fully insured commercial market, 110 new users enrolled in the State Health Plan and 2,140 new users enrolled in the Medicaid plan.
- Mandated coverage for FDA approved drugs in the Medicaid plan is estimated to increase use of JAK inhibitor by 100 to 440 JAK inhibitor users.
- A summary of the estimated financial impact, assuming the high-end estimate of JAK inhibitor users, is provided in total and on per member per month (PMPM) and per member per year (PMPY) bases in Exhibit 1, below.

EXHIBIT 1: SUMMARY OF PREVALENCE AND FINANCIAL IMPACT OF SB 75, HIGH-END SCENARIO

	INDIVIDUAL	SMALL GROUP	FULLY INSURED LARGE GROUP	TOTAL FULLY INSURED COMMERCIAL	STATE HEALTH PLAN	MEDICAID
Alopecia Areata Prevalence (%)	0.21%	0.17%	0.21%	**0.20%**	0.31%	0.15%
Percent of the affected population taking up cranial prostheses after SB 75	93%	93%	93%	**93%**	93%	93%
Commercial Premium/Medicaid Cost PMPM Increase due to SB75	$0.07	$0.05	$0.05	**$0.06**	$0.10	$0.54
Commercial Premium/Medicaid Cost PMPY Increase due to SB75	$0.84	$0.60	$0.60	**$0.72**	$1.20	$6.48
Total Commercial Premium/Medicaid Cost Increase due to SB75	$215,000	$146,000	$266,000	**$627,000**	$247,000	$10,318,000

Sources and citations supporting the statements contained in the Highlights and Executive Summary sections may be found in the Social Evaluation, Medical Evaluation, and Financial Evaluation sections of this report. All citations are listed in the References section.

Executive Summary

Alopecia areata is an autoimmune skin disease that can cause hair loss on any part of the body. This condition affects about 0.2% of the national population in the United States. Presentations of the disease can cause one or more coin-sized patches of hair loss, to complete or near-complete hair loss on the scalp, to finally to complete or near-complete hair loss on the scalp, face, and rest of the body. Wig and cranial prosthesis usage can positively impact confidence for people with alopecia areata, but does not appear to address all social distress caused by the disease. Alopecia areata affects people of color and females at a higher rate than males and white people. The higher rates of alopecia areata among women and people of color suggest that legislation related to cranial prostheses (referred to as “hair prosthesis” in SB 75) and alopecia areata treatment could have a greater impact on these populations. It would also benefit low-income individuals who might not otherwise be able to purchase a cranial prosthesis.

Some surveys have estimated up to 93.1% of alopecia areata patients have considered purchasing a cranial prosthesis. Two states, (Minnesota and New Hampshire) have mandates requiring coverage for protheses for alopecia areata patients. Maryland would be one of 5 states with proposed mandated coverage. Currently in Maryland, the individual health insurance coverage, state health plan, and Medicaid populations do not have coverage for cranial prostheses and 5% of small groups and 28% of fully insured large groups have coverage. In contrast, 36% of self-funded groups in Maryland have coverage for cranial prostheses. Members without coverage do not utilize cranial prostheses or pay fully out-of-pocket.

Historically, alopecia areata has been treated with local injections of corticosteroids. In recent years, JAK inhibitors baricitinib and ritlecitinib have shown to be significantly more effective than placebo in treating alopecia areata and have been newly FDA approved for the treatment of alopecia areata. These JAK inhibitors, receiving FDA approval for the treatment of alopecia areata in 2022 and 2023, are expensive. For example, ritlecitinib has list prices of up to $49,000 for a full year of treatment. Currently, 76% of Maryland Medicaid enrollees have coverage for these newly approved JAK inhibitors.

For our financial analysis, we projected the population, cost of benefits, plan cost, and enrollee cost sharing for the 2025 calendar year under two scenarios; the first where the proposed legislation **does not** go into effect, baseline, and the second where the proposed legislation **does** go into effect, post mandate. The difference between the baseline and post mandate values is the impact of the proposed legislation. We also modeled two scenarios for Medicaid JAK inhibitor users, a low number of users and a high number of users in 2025, and produced two financial estimates for Medicaid.

Mandated coverage for cranial prostheses as required by SB 75 is estimated to result in a $627,000, or $0.06 per member per month (PMPM), or $0.72 per member per year (PMPY), increase to the fully-insured commercial market premium in 2025 and an increase of $247,000, or $0.10 PMPM, or $1.20 PMPY to 2025 State Health Plan premium. We estimate no change in commercial enrollee out-of-pocket costs, including State Health Plan enrollees. The financial analysis assumes that enrollees who pay out-of-pocket for cranial prostheses will continue to do so, and if the mandate is passed, they will use the new $350 benefits to purchase a more expensive, higher quality cranial prosthesis. Interested enrollees who do not use cranial prostheses will, if the mandate is passed, use the full $350 benefit to purchase a cranial prosthesis. These assumptions produce a high-end premium impact estimate as it is almost certain some enrollees will use the $350 to offset current out-of-pocket costs.

- For fully insured commercial plans, we estimated that this increase is driven by approximately 1,200 current users without current coverage who will utilize the new $350 benefit to purchase cranial prostheses, and 270 new users who will only purchase a $350 cranial prosthesis because of SB 75.

- For the State Health Plan, the increase is driven by 490 current users without coverage who will purchase a cranial prosthesis and 110 new users who will purchase a cranial prosthesis. The estimated average cost of a cranial prosthesis trended to 2025 is $1,640.

We estimate mandated coverage for cranial prostheses and FDA approved prescription drugs, such as the newly approved JAK inhibitors, would increase Medicaid costs in 2025 by approximately $6,195,000 to $10,320,000, $0.33 to $0.54 PMPM, $3.96 to $6.48 PMPY, depending on the number of alopecia areata patients who will use JAK inhibitors. Actual utilization of JAK inhibitors in the Maryland Medicaid population is not known as they are newly approved treatments. The Medicaid cost increase is estimated to be driven by 2,140 new users of cranial prostheses and an additional 100 to 440 JAK inhibitor users. Unlike the commercial population, the Medicaid benefit mandate pays in full for cranial prostheses. We assume these new JAK inhibiter users will pay an additional $1.50 copay out-of-pocket for each script.

Medical Evaluation

BACKGROUND

The National Institute of Arthritis and Musculoskeletal and Skin Diseases with the National Institutes of Health (NIH) defines alopecia areata as an autoimmune skin disease that can cause hair loss on any part of the body, but typically affects the head and face.[1]

This condition affects approximately 700,000 individuals in the United States, with a higher prevalence among women compared to men, and adults compared to children and adolescents.[2,3] While alopecia areata has varying presentations, three main types have been identified: patchy alopecia areata which causes one or more coin-sized patches of hair loss; alopecia totalis which causes complete or near-complete hair loss on the scalp; and alopecia universalis which causes complete or near-complete hair loss on the scalp, face, and rest of the body.[1]

The diagnosis of alopecia areata is typically made clinically, and different classification systems have been developed to quantify the extent of hair loss. The most widely-used of these systems is the Severity of Alopecia Tool (SALT), which provides a score from 0 (no hair loss) to 100 (complete hair loss) by separating the patient's scalp into four quadrants and then assessing the extent of hair loss within each quadrant. [4] While there is variation in how clinicians interpret SALT scores, a recent study by leading alopecia areata experts in the United States has determined that a score of 20 or less is typically considered mild disease, 21 to 49 is considered moderate disease, and greater than 50 is considered severe disease.[5]

The choice of treatment for alopecia areata depends on the severity of the patient's symptoms, age, and other comorbid conditions. While there are various treatment options available, most are not approved by the U.S. Food & Drug Administration (FDA) for the treatment of alopecia areata and are instead used off-label. Local treatments used off-label include topical corticosteroids, topical minoxidil, anthralin, bimatoprost, and contact immunotherapy.[6] Some intralesional corticosteroids are FDA-approved for the treatment of alopecia areata, including betamethasone (2008 latest recorded approval), methylprednisolone (2008 latest recorded approval), triamcinolone acetonide (2006 latest recorded approval), and dexamethasone (2014 latest recorded approval).[7 8 9 10] Similar to local treatments, systemic treatments often represent off-label use of drugs, such as oral corticosteroids, methotrexate, and cyclosporine.[6] Only in recent years have two systemic treatments been approved by the FDA for alopecia areata, specifically the janus kinase (JAK) inhibitors baricitinib (2022 approval) and ritlecitinib (2023 approval).[11,12] Non-pharmacologic treatments include wigs, cranial prostheses (referred to as hair prostheses in SB 75), artificial eyelashes/eyebrows, hair-styling products, and tattoos which are often recommended to camouflage hair loss.[6] There are currently no FDA-approved devices for the treatment of alopecia areata.

Maryland Senate bill 75 addresses health insurance coverage of cranial prostheses and prescription drugs and medical devices approved by the FDA for the treatment of alopecia areata. Therefore, the medical evaluation presented in the following sections focuses on these items and services.

RECOGNITION OF EFFECTIVENESS BY MEDICAL COMMUNITY

Alopecia areata can affect patients of any age, and the American Academy of Dermatology Association (AAD) recommends different treatment regimens based on age group and severity of symptoms. There are limited treatment options available for children under 12 years old, for whom AAD recommends either topical corticosteroids or topical minoxidil due to their safety and tolerability.[6] For adolescents between 12 years and 18 years old, local treatment options include topical corticosteroids, topical minoxidil, anthralin, and contact immunotherapy, while ritlecitinib is the only recommended systemic option.[6] For adults aged 18 years and older, local treatment options include topical and intralesional corticosteroids, minoxidil, anthralin, and contact immunotherapy, while recommended systemic options include oral corticosteroids, methotrexate, cyclosporine, ritlecitinib, and baricitinib.[6]

Of these treatments, only intralesional corticosteroids (betamethasone, methylprednisolone, triamcinolone acetonide, dexamethasone) and JAK inhibitors (baricitinib, ritlecitinib) are FDA-approved for the treatment of alopecia areata.[7,8,9,10,11,12] Intralesional corticosteroids are recommended for patients ages 18 years and older, with

administration by a trained clinician every 4-6 weeks, and are considered the treatment of choice for patients with less extensive patchy hair loss.[6] Both JAK inhibitors are indicated for severe alopecia areata and are given in once-daily oral doses.[6]

Non-pharmacologic treatments, including wigs and cranial prostheses, are also available to help patients camouflage hair loss and are recommended for all age groups.[6]

EVIDENCE OF EFFECTIVENESS FROM PEER-REVIEWED LITERATURE

Intralesional corticosteroids have been used in the treatment of alopecia areata for decades, although there are no large-scale randomized controlled trials assessing their effectiveness.[13] Due to the discomfort associated with injecting these medications, they are only recommended for adults with less extensive patchy disease.[6] A systematic review done in 2019 showed that the most commonly used intralesional corticosteroid in the treatment of alopecia areata, triamcinolone acetonide, had treatment response rates between 62.3% and 80.9%.[14] However, the studies included in the systematic review were limited by small sample sizes and inconsistent methodologies, and they were mostly observational. [14]

Baricitinib is approved by the FDA for treatment of severe alopecia areata in patients 18 years old and above.[11] The BRAVE-AA1 and BRAVE-AA2 trials assessed the effectiveness of baricitinib on patients with alopecia areata from 2018 to 2021.[15] Both studies were randomized, double-blind, placebo-controlled trials lasting 36 weeks that compared treatment with baricitinib, in 4-mg and 2-mg daily doses, to placebo on adult patients with severe alopecia (SALT scores of 50 to 100).[15] The primary outcome was a SALT score of 20 or less at week 36, which was reached by 35.9-38.8% of patients taking 4-mg baricitinib daily, 19.4-22.8% of patients taking 2-mg baricitinib daily, and 3.3-6.2% of patients taking placebo.[15] Both 4-mg and 2-mg baricitinib were significantly more effective than placebo in treating alopecia areata.[15]

Ritlecitinib is approved by the FDA for treatment of severe alopecia areata in patients 12 years old and above.[12] The ALLEGRO trial assessed the effectiveness of ritlecitinib on patients with alopecia areata from 2018 to 2021.[16] This was a randomized, double-blind, placebo-controlled trial lasting 24 weeks that compared treatment with ritlecitinib, in 50-mg and 30-mg daily doses, with and without loading doses on the first day, to placebo on patients 12 years and older with severe alopecia areata.[16] The primary outcome was a SALT score of 20 or less at week 24, which was reached by 31% of patients taking 50-mg ritlecitinib daily with a 200mg loading dose, 22% of patients taking 30-mg ritlecitinib daily with a 200mg loading dose, 23% of patients taking 50-mg ritlecitinib daily with no loading dose, 14% of patients taking 30-mg ritlecitinib daily with no loading dose, and 2% of patients taking placebo.[16] Both 50-mg and 30-mg ritlecitinib, with and without a loading dose, were significantly more effective than placebo in treating alopecia areata.[16]

There are no randomized controlled trials studying the effectiveness of wigs and cranial prostheses in patients with alopecia areata. A systematic review of studies published between 1946 and 2014 on individuals with alopecia areata found that wearing a wig had a positive impact on health-related quality of life measures.[17] One study also determined that use of wigs was a positive coping strategy that increased confidence and self-esteem among patients with alopecia, although anxiety over discovery of wig use, concerns about affordability, discomfort, and reduced activity were also found among wig users.[18]

AVAILABILITY OF SERVICES

Baricitinib has been available in the United States since its initial FDA approval in 2018 for the treatment of rheumatoid arthritis, although it was only approved for alopecia areata in June 2022. Ritlecitinib was approved by the FDA in June 2023 for alopecia areata, its only indication. Intralesional corticosteroids are widely available in the United States and are the most commonly used treatment option for alopecia areata in adults from 2015 to 2020 according to one study.[19] While these drugs are available at relatively low cost, they require the services of a trained clinician for administration and need to be administered every four to six weeks. It is also important to note that pharmacologic treatments available to an individual patient may vary depending on geographic location, healthcare setting, and insurance coverage.

Lastly, wigs and cranial prostheses are widely available in the United States but are associated with substantial out of pocket cost due to lack of insurance coverage. The social evaluation section of this report goes into more detail on this financial burden.

Social Evaluation

ALOPECIA AREATA PREVALENCE

Studies have reported prevalence of Alopecia Areata at about 0.2% in the national population.[2,3] Prevalence has been found to vary across demographics. In general, point prevalence has been found to be 1.5 times higher for females (0.158%) than males (0.105%) and higher for adults (0.220%-0.245%) relative to children (0.120%-0.135%).[2] A study conducted in 2023 found that alopecia areata prevalence was 0.20% in females as compared to 0.13% in males.[20]

Based on alopecia areata diagnoses in the Maryland All Payer Claims Database (APCD), the prevalence of alopecia in Maryland is similar to the national population. Exhibit 2 shows the prevalence of alopecia areata in the Maryland population by line of business. The Medicaid population has the lowest prevalence of 0.15% and the State Health Plan has the highest prevalence of 0.31%. Fully insured commercial coverage hovers around the national prevalence rate of 0.20%.

EXHIBIT 2 – PREVALENCE OF ALOPECIA AREATA IN THE MARYLAND POPULATION

Individual	Small Group	Fully Insured Large Group	State Health Plan	Medicaid
0.21%	0.17%	0.21%	0.31%	0.15%

In studies of disaggregated alopecia areata prevalence by race in the US, people of color have been found to have a higher burden of alopecia areata relative to white people.[20] For example, Black and Hispanic patients and those identifying as Other/multiracial were found to have prevalence rates of 0.22% 0.21% and 0.3%, respectively, as compared to 0.16% in white patients.[20] In a study that used the National Alopecia Areata Registry to calculate the odds of having alopecia areata, Black patients were found to have greater odds of having alopecia areata (1.77) than white patients (1.00).[21] Similar results were seen in a 2023 cross-sectional study of alopecia areata that used Electronic Medical Record data to calculate odds of having alopecia areata by race. In this study, greater odds of alopecia areata were observed in Black patients (1.72) and Hispanic patients (2.13) relative to white patients (1.00).[22] Results have been more mixed for rates of alopecia areata in Asian patients. In the studies described above, one study found that Asian patients had an alopecia areata prevalence rate of 0.41% as compared to a rate of 0.16% in white patients,[20] the study reporting prevalence as odds Asian patients were found to have lower odds (0.4) of having alopecia areata relative to white patients (1.00).[21]

For reference, Maryland's population is 51.3% female, 48.3% white non-Hispanic, 31.7% Black, 11.5% Hispanic, 7.1% Asian, 0.7% American Indian and Alaska Native, 0.1% Native Hawaiian and Other Pacific Islander and 3.2% Two or more races.[23]

The higher rates of alopecia areata among women and people of color suggest that legislation related to cranial prostheses and alopecia areata treatment would have a greater impact on these populations.

INSURANCE COVERAGE

Currently, two states, Minnesota and New Hampshire, require insurance coverage for cranial prostheses for alopecia areata. There are five states, including Maryland, that have introduced legislation on expanding coverage for cranial prostheses to include individuals impacted by alopecia areata. Passed and introduced legislation has benefit limits ranging from $150 - $350 annually towards the cost of a cranial prosthesis. New York introduced legislation in 2022

that does not set a dollar limit but requires parity between coverage for cranial prostheses and other prosthetics, including that the plan will only pay for 80% of customary and usual costs of prosthesis exclusive of deductible. The Federal Wigs as Durable Medical Equipment Act was introduced in 2021 with the aim of covering wigs and cranial prostheses under Medicare by reclassifying them as durable medical equipment under the Social Security Act.[24]

Lack of benefit coverage is a major barrier to accessing wigs and cranial prostheses. One study conducted in 2018 determined that 75% of patients indicated that their medical insurance did not cover wigs and cranial prostheses, while another in 2022 found that 76.9% of patients who sought out insurance coverage for wigs and cranial prostheses did not receive it.[25,26]

According to carrier surveys (See Appendix A for the survey sent to carriers), Maryland enrollees in Individual health insurance market, State Health Plan and Medicaid plans do not have coverage for cranial prostheses. Approximately 28% of fully insured large group and 5% of small group enrollees have current coverage for cranial prostheses with an alopecia areata diagnosis. For comparison purposes, 36% of self-funded employer plan enrollees have coverage for cranial prostheses for alopecia areata. Self-funded employer plan enrollees would not be impacted by a benefit mandate.

Exhibit 3 shows current coverage of cranial prostheses by line of business, based on carrier survey results. For enrollees with coverage in Maryland, insurance benefit limits on cranial prostheses range from $300 up to $2,500.

In the recent HHS Notice of Benefit and Payment Parameters for 2023 final rule, federal regulators refined the essential health benefit nondiscrimination policy. Coverage limits must now be clinically based to be considered nondiscriminatory. SB 75 expands on existing coverage of cranial prostheses for cancer patients to alopecia patients. Based on this new guidance, enrollees in ACA markets may already have coverage.

EXHIBIT 3 – ENROLLEES WITH COVERAGE FOR CRANIAL PROSTHESES FOR ALOPECIA AREATA

Individual	Small Group	Fully Insured Large Group	State Health Plan	Other Self-Funded Employer Plan	Medicaid
0%	5%	28%	0%	36%	0%

SB 75 would also require coverage of drugs approved by the U.S. Food and Drug Administration for the treatment of alopecia areata. As mentioned above, only intralesional corticosteroids and JAK inhibitors are FDA-approved for the treatment of alopecia areata. Maryland's top five carriers by enrollment were surveyed regarding their coverage for FDA approved treatments of alopecia areata. Most carriers only mentioned the JAK inhibitors. Because corticosteroids have been approved for nearly a decade and were not mentioned by the carriers, we assume that they are covered by carriers for the treatment of alopecia areata.

Using carrier surveys, we estimate 76% of Maryland Medicaid enrollees have coverage for JAK inhibitors in 2023.

PUBLIC DEMAND & UTILIZATION

There is high demand for and utilization of cranial prostheses among those with alopecia areata. In a survey distributed to members of National Alopecia Areata Foundation in July 2022, 93.1% of respondents reported considering getting a hair piece and 85.7% of those considering actually got one.[26] The most common limitation to receiving cranial prostheses is cost.[26] The survey sample was predominantly female (92.1%) and reported having >= 50% scalp hair loss (75.7%). Given this population, we cannot extrapolate results to men with alopecia areata.

There was little awareness among respondents that insurance might cover cranial prostheses. In the same study, of those who got a wig or cranial prosthesis, only 38.2% inquired about insurance coverage, and of those members 23.0% received insurance coverage. Of those that received insurance coverage, 24.9% believed their insurance coverage of alopecia areata related benefits to be adequate or very adequate.

Assuming cost is the reason that only 85.7% of the 93.1% survey respondents who considered getting a hair piece actually got one, combined with the coverage above, we estimate a total of 270 additional fully insured commercial insured enrollees and 110 additional state health plan enrollees would use cranial prostheses if there were a benefit

mandate. Exhibit 4 shows the estimated number of enrollees who would use cranial prostheses in 2025 if the benefit mandate does not go into effect (Baseline) and if the benefit mandate does go into effect (Post Mandate).

EXHIBIT 4: ESTIMATED ENROLLEES USING CRANIAL PROSTHESES AT BASELINE AND POST MANDATE, 2025

	INDIVIDUAL	SMALL GROUP	FULLY INSURED LARGE GROUP	TOTAL FULLY INSURED COMMERCIAL	STATE HEALTH PLAN	MEDICAID
Enrollees with alopecia areata	530	380	960	**1,860**	650	2,300
Users of Cranial prostheses at Baseline	400	290	780	**1,470**	490	0
Users of Cranial prostheses Post Mandate	490	350	900	**1,740**	600	2,140
Change in Users of Cranial prostheses	90	60	120	**270**	110	2,140
% Change in Users of Cranial prostheses	23%	22%	16%	**19%**	23%	

At the time of this report, utilization of JAK inhibitors in the Maryland Medicaid population is unknown as Medicaid APCD data is only available through December 2021 and the JAK inhibitors were FDA approved in 2022 and 2023. These drugs are only approved as treatment of moderate-severe alopecia areata, which accounts for approximately 43% of all cases.[27] Scenario testing utilization of enrollees who may receive JAK inhibitor treatment, we estimate that there are between 100 and 440 Medicaid enrollees who would be interested in receiving JAK inhibitor treatment. Based on the carrier survey, only 76% of interested enrollees currently have coverage for JAK inhibitors. A benefit mandate requiring the coverage of JAK inhibitor treatment would add 30 to 100 users of JAK inhibitors to the Medicaid population. More details regarding the scenarios and assumptions are available in the Methodology and Assumptions section of this report.

See Appendix B for more information on users of cranial prostheses and FDA approved drugs.

POTENTIAL BENEFITS

As was stated in the Medical Evaluation section, people with alopecia areata have been found to have lower Health Quality of Life scores [17,28,29] and higher prevalence of behavioral health conditions relative to the general population.[21] A recent meta-analysis found that the prevalence of depression for people with alopecia areata was 9% as compared to 3.8% in the general population and prevalence of anxiety was 13% as compared to 7.3% in the general population.[21]

Qualitative research on patient experience indicates that people with alopecia areata often feel isolated, depressed and embarrassed by their condition which impacts their relationships and lifestyle.[26,30]

In a survey of National Alopecia Areata Registry members, 31.2% of respondents pursued therapy related services and 29% attended alopecia areata related support groups.[31]

Wig usage can positively impact confidence for people with alopecia areata but does not appear to address all social distress caused by the disease. A survey out of the UK found that 26% of patients reported a positive impact of wearing a wig including improved confidence in public and reduced worry about the likelihood of negative comments towards hair loss, but 43% of respondents reported negative impact on confidence primarily related to worry that the wig would be noticeable or come off.[18]

Authors suggest that the high number of people choosing to wear wigs despite social anxiety suggests it is the ‘better of two evils’, but that wigs cannot address psychological impacts alone.[18]

As previously noted in the Medical Evaluation section, JAK inhibitors have only recently been approved for the treatment of alopecia areata and there is limited evidence regarding their social and psychological benefits as of this time. Post-hoc analysis of results from the BRAVE-AA1 and BRAVE-AA2 trials showed that patients who reached the primary outcome of a SALT score of 20 or less at week 36 on baricitinib also experienced greater improvements in

health-related quality of life and symptoms of anxiety and depression than patients without significant scalp hair regrowth.[32]

FINANCIAL BARRIERS

Financial burden is the largest barrier to accessing the service. In a survey of National Alopecia Areata Foundation members (n=675) on the financial burden of alopecia areata, most respondents reported that their financial burden due to alopecia areata was moderately (31.7%) or seriously burdensome (25.2%). Respondents reported spending a total of $537-$3300 (median $1354) out-of-pocket for alopecia areata related expenses (which includes expenses such as transportation, copays, medications, complementary and alternative therapies, etc.) with headwear or cosmetic options, such as wigs, makeup, or scarves, being the greatest expense. Members reported spending between $50-1500 annually (median $450) in this category.[33] Respondents reported that their spending on alopecia areata related expenses impacted their finances elsewhere in their life.[33]

One study found that the average price of a cranial prosthesis was $1543 and insurance coverage ranged from $50 to full cost of wig.[26] There is a large gap in the average cost of a cranial prosthesis and required coverage for states with current or proposed legislation, which requires insurance to cover $150-$350 toward a cranial prosthesis annually. Based on a review of current and past state legislation, required costs have not been adjusted since legislation was initially passed between 1987-2000.[34,35,36,37,38]

Given the financial barriers, legislation that lowers the out-of-pocket costs of cranial prostheses will likely have a greater impact to low-income individuals although this will depend on the actual utilization of the benefits.

Financial Evaluation

The financial evaluation projects the population, cost of benefits, Commercial premium and Medicaid Cost, and enrollee cost sharing for the 2025 calendar year under the following two scenarios:

1. Baseline – Proposed legislation **does not** go into effect.
2. Post Mandate – Proposed legislation **does** go into effect.

The difference between the baseline and post mandate values is the impact of the proposed legislation.

To perform the financial evaluation, we made the following key assumptions:

- Commercial and Medicaid enrollees with alopecia areata would have access to one cranial prosthesis covered by insurance annually.
- Commercial carriers must cover the cost of one cranial prosthesis up to $350. Medicaid is required to cover the entire cost of the cranial prostheses, without a dollar limit.
- Drugs traditionally used to treat alopecia areata are covered by insurance companies. The financial evaluation only includes the impact of adding the two systemic treatments that were recently approved by the FDA for alopecia areata.
- In the recent HHS Notice of Benefit and Payment Parameters for 2023 final rule, federal regulators refined the essential health benefit nondiscrimination policy. Coverage limits must now be clinically based to be considered nondiscriminatory. SB 75 expands on existing coverage of cranial prostheses for cancer patients to alopecia patients. Based on this new guidance, enrollees in ACA markets may already have coverage. This analysis relies on coverage as reported by the carriers. The estimated impacts of SB 75 presented here are overstated to the extent that carriers change their cranial prosthesis coverage in response to the nondiscrimination policy.

COST PER SERVICE AND ENROLLEE COST SHARING

Cranial Prosthesis

Available cranial prostheses vary in price and quality. We assumed that the average cost per cranial prosthesis differs by coverage status such that enrollees with coverage select a higher quality cranial prosthesis than enrollees without coverage. We assumed that the cost per cranial prosthesis for enrollees that have coverage for cranial prosthesis at baseline is $2,170. We assumed that enrollees without coverage pay $1,480 for cranial prosthesis at baseline. The differential between these two estimates is the assumed benefit paid by insurance, such that enrollee payment is the same.

Post mandate, we assumed that enrollees who have coverage at baseline would continue to purchase a $2,170 cranial prosthesis. Enrollees who do not have coverage but purchased cranial prostheses at baseline would purchase a higher quality cranial prosthesis of $1,830 ($1,480 baseline + $350 benefit limit). Enrollees that did not have coverage and did not use a cranial prosthesis at baseline would purchase a $350 cranial prosthesis.

We did not assume that the cost of cranial prostheses would change as a result of this mandate for two reasons. The maximum amount paid by the insurance company is $350 which is approximately 20% of the average cost of a cranial prosthesis in 2022. Because the enrollee is financially responsible for the larger share of the cranial prosthesis, the enrollees remain price aware and factor it into their selection. Secondly, the estimated number of new cranial prosthesis utilizers into the market is relatively small and will not cause a large enough increase in overall utilization to have a meaningful impact on cranial prosthesis demand.

FDA Approved Drug Therapies

We assumed the monthly 2025 costs per service of baricitinib and ritlecitinib are $2,900 and $4,510, respectively. Both treatments were recently approved, and insurers are currently considering adding them to their formularies. We project that the passage of a coverage mandate would not change the monthly costs per service in 2025. It is possible that the cost of these therapies increases in the future.

SUBSTITUTIONS OF OTHER SERVICES

Cranial prosthesis

It is possible that some of the new users of cranial prostheses will replace or reduce their use of cosmetics, hats, or head wraps. These items are not covered by insurance companies and are not included in commercial premium or Medicaid cost, so these substitutions were not modeled.

FDA Approved Drug Therapies

New users of the JAK inhibitors may replace their utilization of corticosteroids. We assumed new users reduce their utilization of corticosteroids resulting in a $55 offset to the $2,900-$4,500 monthly increase from using JAK inhibitors.

ADMINISTRATION OF BENEFITS

Carriers did not report any undue burden from administering this additional benefit. Administration costs will increase in proportion to the cost of additional mandated benefits. We do not expect SB 75 to impact individuals or employers' ability to purchase health benefits policies meeting their own or employees' needs.

STATE BENEFIT DEFRAYAL EXCEEDING ESSENTIAL HEALTH BENEFIT

SB75 does not exceed essential health benefits (EHBs) and does not require the state to defray costs of exceeding essential health benefits. According to Final 2019 HHS Notice of Benefit and Payment Parameters, benefits mandated by a State action prior to or on December 31, 2011 would be considered EHB in that State and would not require State defrayal. The state has mandated coverage for cranial prostheses for cancer patients prior to 2012. SB 75 expands this existing coverage to alopecia areata patients. Treatment limits for EHBs are quantitative and not condition specific as defined by Subpart B – Essential Health Benefits of the Affordable Care Act. Adding alopecia as an additional condition does not increase quantitative coverage/treatment limits and thereby does not require the state to defray costs of exceeding EHBs.

COMMERCIAL PREMIUM AND MEDICAID COST IMPACT

The estimated commercial premium and Medicaid cost impact from passing SB 75 is in Exhibit 5 below. Total fully insured commercial premiums are estimated to increase $627,000 or $0.06 PMPM ($0.72 PMPY). The impact varies by line of business with small and fully insured large group premiums increasing $0.05 PMPM ($0.60 PMPY) and individual premiums increasing $0.07 PMPM ($0.84 PMPY).

Medicaid costs are estimated to increase $6,194,000 to $10,318,000, or $0.33 to $0.54 PMPM ($3.96 to $6.48 PMPY). The range in estimates is from different FDA approved drug uptake scenarios. FDA approved drugs are estimated to account for $1,152,000 to $5,276,000 or $0.06 to $0.28 PMPM ($0.72 to $3.36 PMPY) of the total cost increase. Cranial prostheses are estimated to cost $5,042,000 or $0.27 PMPM ($3.24 PMPY) of the total. These estimates are greater than the commercial estimates because no benefit limit was applied to the cranial prostheses.

Both commercial premium and Medicaid costs include administrative fees.

EXHIBIT 5: ESTIMATED COMMERCIAL PREMIUM AND MEDICAID COST IMPACT OF SB 75, 2025 (HIGH FDA DRUG UPTAKE SCENARIO)

	INDIVIDUAL	SMALL GROUP	FULLY INSURED LARGE GROUP	TOTAL FULLY INSURED COMMERCIAL	STATE HEALTH PLAN	MEDICAID
Total Dollars	$215,000	$146,000	$266,000	**$627,000**	$247,000	$10,318,000
PMPM	$0.07	$0.05	$0.05	**$0.06**	$0.10	$0.54
PMPY	$0.84	$0.60	$0.60	**$0.72**	$1.20	$6.48

ENROLLEE OUT-OF-POCKET AND TOTAL COST OF CARE IMPACT

There is no change to the out-of-pocket costs for cranial prostheses for fully insured commercial and State Health Plan enrollees because we assume current users with new coverage will purchase a $350 more expensive cranial prosthesis and new users will use all $350 to purchase a cranial prosthesis. In the high-end JAK inhibitor usage scenario, Medicaid enrollee out-of-pocket costs are estimated to increase by $2,000 from $6,000 to $8,000 because of an assumed $1.50 copayment per brand drug for new users of JAK inhibitors. The estimated enrollee out-of-pocket cost post mandate is in Exhibit 6 below.

EXHIBIT 6: ESTIMATED POST MANDATE ENROLLEE OUT-OF-POCKET EXPENSE OF SB 75, 2025 (HIGH-END SCENARIO OF FDA DRUG UPTAKE)

	INDIVIDUAL	SMALL GROUP	FULLY INSURED LARGE GROUP	TOTAL FULLY INSURED COMMERCIAL	STATE HEALTH PLAN	MEDICAID[1]
Total Out-of-Pocket	$594,000	$427,000	$1,147,000	**$2,167,000**	$725,000	$8,000
Out-of-Pocket PMPM	$0.20	$0.16	$0.20	**$0.19**	$0.29	$0.00
Out-of-Pocket PMPY	$2.40	$1.92	$2.40	**$2.28**	$3.48	$0.00

[1]Medicaid out-of-pocket PMPM rounds to $0.00.

The total estimated cost of care, including out-of-pocket costs, from passing SB 75 is in Exhibit 7 below.

EXHIBIT 7: ESTIMATED POST MANDATE TOTAL COST OF CARE OF SB 75, 2025 (HIGH-END SCENARIO OF FDA DRUG UPTAKE)

	INDIVIDUAL	SMALL GROUP	FULLY INSURED LARGE GROUP	TOTAL FULLY INSURED COMMERCIAL	STATE HEALTH PLAN	MEDICAID
Total Cost of Care	$809,000	$587,000	$1,612,000	**$3,007,000**	$972,000	$27,210,000
Total Cost of Care PMPM	$0.27	$0.22	$0.29	**$0.27**	$0.39	$1.44
Total Cost of Care PMPY	$3.24	$2.64	$3.48	**$3.24**	$4.68	$17.28

See Appendix C and D for more detailed information on PMPM and Total Cost of Care.

Methodology and Assumptions

As noted in the prior section, the financial evaluation projects the population, cost of benefits, Commercial premium and Medicaid costs, and enrollee cost sharing for the 2025 calendar year under the following two scenarios:

1. Baseline – Proposed legislation **does not** go into effect.
2. Post Mandate – Proposed legislation **does** go into effect.

The difference between the baseline and post mandate values is the impact of the proposed legislation.

To perform the financial evaluation, we made the following key assumptions:

- Commercial and Medicaid enrollees with alopecia areata would have access to one cranial prosthesis covered by insurance annually.
- Commercial carriers must cover the cost of one cranial prosthesis up to $350. Medicaid is required to cover the entire cost of the cranial prostheses, without a dollar limit.
- Drugs traditionally used to treat alopecia areata are covered by insurance companies. The financial evaluation only includes the impact of adding the two systemic treatments that were recently approved by the FDA for alopecia areata.

MARYLAND POPULATION

We used the Maryland population changes from the 2020 census to the 2030 census projection to trend 2021 and 2022 enrollment data from Maryland's All Payer Claims Database (APCD) to 2025. We adjusted our initial 2025 population estimate for Medicaid redetermination, which began in Maryland in April 2023. Based on Maryland Medicaid redetermination data through October 2023, we shifted 51,000 Medicaid enrollees out of Medicaid and into other populations for our 2025 estimate. We shifted 40% of the 51,000 enrollees to uninsured, 10% to individual, 3.6% to small group, 7.4% to fully insured large group, 3.4% to the State Health Plan, and 35.6% to self-funded employer plans using transitional estimates from the Congressional Budget Office.

BENEFIT COVERAGE

We surveyed insurance carriers in Maryland about current coverage of cranial prostheses for patients with alopecia areata. We received responses from 5 carriers who in total make up 93% - 99% of the fully insured commercial population, 99% of the State Health Plan population, and 24% of the Medicaid population.

EXHIBIT 7 – CARRIER SURVEY REPRESENTATION

Individual	Small Group	Fully Insured Large Group	State Health Plan	Medicaid
99%	99%	93%	99%	24%

Carriers reported a total of 0% coverage of cranial prostheses for the individual population, 5% coverage for the small group population, 28% coverage for the fully insured large group population, 0% for the State Health Plan population, and 0% coverage for the Medicaid population. Carriers with coverage for cranial prostheses had benefit coverage ranging from one cranial prosthesis for each plan year to one cranial prosthesis in a lifetime and benefit amounts that ranged from $300 to $2,500.

EXHIBIT 8 – CRANIAL PROSTHESES FOR ALOPECIA AREATA COVERAGE RATE

Individual	Small Group	Fully Insured Large Group	State Health Plan	Medicaid
0%	5%	28%	0%	0%

We also surveyed carriers with Medicaid plans who reported having an average of 76% coverage for FDA approved prescriptions drugs for the treatment of alopecia areata.

Post mandate, we assumed coverage for hair protheses would be 100% for all populations and Medicaid coverage of FDA approved prescriptions drugs for alopecia areata would also be 100%.

ALOPECIA AREATA ENROLLEES

We used the APCD to identify claims and membership for enrollees with alopecia areata. Fully insured commercial and State Health Plan enrollees with at least one claim in 2020, 2021, or 2022 containing an alopecia areata diagnosis were identified as alopecia areata patients. Medicaid alopecia areata patients were identified with at least one claim in 2020 or 2021 with an alopecia areata diagnosis. The alopecia areata diagnosis codes used were L630, L631, L632, L638, and L639 in ICD-10 format.

CRANIAL PROSTHESIS UTILIZATION AND COST

Based on the survey distributed to members of National Alopecia Areata Foundation in July 2022[26], we assumed of state health plan and fully insured commercial patients without coverage, 13.3% would consider but not purchase a hair prothesis while 79.8% would consider and purchase a hair prothesis. For state health plan and fully insured commercial patients with coverage, we assumed 93.1% would purchase a cranial prosthesis. We assumed Medicaid patients without coverage would not purchase a cranial prosthesis.

We trended the 2022 average cost of a cranial prosthesis in the study to 2025, from $1,543 to $1,640. We used a 6% annual trend based the *Personal Consumption Expenditures Price Index, Excluding Food and Energy* from the Bureau of Economic Analysis. We assumed the average 2022 insurer payment amount of $685 from the study did not change in 2025 since benefit limits do not typically change annually.

The study reports 23% of alopecia patients requested and received insurance coverage for cranial prostheses and the average cost of a cranial prosthesis for all enrollees surveyed trended to 2025 is $1,640. We assumed coverage status did not impact out-of-pocket payments for those who purchase hair protheses. An enrollee with coverage would receive a more expensive cranial prosthesis and pay the same amount out of pocket as the enrollee without coverage. Using the average cost per cranial prosthesis from the study trended to 2025, the average insurance payment, and the coverage distribution provided in the study, we estimated the average cost per cranial prosthesis for enrollees without coverage at baseline is $1,480 and $2,170 for enrollees with coverage at baseline. The projected average out-of-pocket cost of a cranial prosthesis was $1,480 in 2025 regardless of coverage.

All per member per year calculations assume enrollees are enrolled in the plan for 12 months.

FDA APPROVED PRESCRIPTION DRUGS UTILIZATION AND COST

The Medicaid plans surveyed reported 76% coverage for FDA approved prescriptions drugs for the treatment of alopecia areata.

The FDA-approved systemic drugs ritlecitinib and baricitinib are only indicated for moderate-severe alopecia. We assumed 43% of alopecia areata enrollees have moderate-severe alopecia areata[27] and that 56% of moderate-severe alopecia areata patients are currently treated while the remaining 44% remain untreated.[39]. We estimated the number of JAK inhibitor users by shifting 5% of the untreated and 20% of the treated to the new drugs for a low end scenario or shifting 50% of the untreated and 70% of the treated to the new drugs for a high end scenario. We applied a Maryland Medicaid age distribution to alopecia areata patients to limit new JAK inhibitor users to ages 12 and up. We assume these new users will utilize 12 scripts of FDA-approved oral prescription drugs annually.

We assumed an average 2025 cost of $2,900 and $4,510 per month based on the 2023 list price of the drugs, trended by 5% annually and discounted 0% off list price, including the Maryland Medicaid dispensing fee per script of $10.67.

Brand copays range from $0 to $3 per script. We assumed a $1.50 copayment for all Medicaid enrollees using FDA approved prescription drugs.

All per member per year calculations assume enrollees are enrolled in the plan for 12 months.

PRESCRIPTION DRUG OFFSETS

We assumed usage of the new systemic drugs would offset corticosteroid usage among Medicaid patients. We assumed 20% of corticosteroid users who were not covered for systemic drugs in the baseline switched as a result of SB 75. We offset 12 annual injections of $55 per injection from those users. The cost of the corticosteroid injections was calculated using the 2023 Maryland Medicaid fee schedule and trended at 0% to 2025. The cost was composed of the average cost of injection CPT*/HCPCS 11900 and 11901, in addition to the average cost of outpatient visit drug CPT/HCPCS codes J0702, J1020, J1030, J1040, J3300, J3301, J3304, J1094, and J1100.

COMMERCIAL PREMIUM, MEDICAID COST, AND RETENTION

We assumed a medical loss ratio of 80% for fully insured commercial individual and small group plans, a medical loss ratio of 85% for fully insured large group plans, and a medical loss ratio of 92% for the Medicaid population.

We assumed no additional administrative costs due to this mandate beyond the typical proportional increase in retention costs when applied to medical cost increases.

CONSIDERATIONS AND LIMITATIONS

The survey distributed to members of National Alopecia Areata Foundation in July 2022 had 92% female respondents. [26] If male respondents do not use cranial prostheses as the same rate as females our estimate may be high or low depending on the extent to which male usage is different.

We assumed alopecia areata patients without coverage at baseline who purchased cranial protheses would use SB 75 mandated benefits to supplement their existing out-of-pocket payments and purchase more expensive protheses, but it is possible some patients will replace their out-of-pocket costs with the new benefit. Similarly, we assumed new users would only use the benefit amount, but some may purchase more expensive prosthetics by supplementing the costs out-of-pocket.

We relied on treated and untreated statistics to create our low- and high-end range for JAK inhibitor use. However, these treatment statistics were from time periods before the availability of the two FDA-approved oral drugs, and treatment patterns may change with the introduction of these to the market.

In the recent HHS Notice of Benefit and Payment Parameters for 2023 final rule, federal regulators refined the essential health benefit nondiscrimination policy. Coverage limits must now be clinically based to be considered nondiscriminatory. SB 75 expands on existing coverage of cranial prostheses for cancer patients to alopecia patients. Based on this new guidance, enrollees in ACA markets may already have coverage.

Variability of Results

Differences between our estimates and actual amounts depend on the extent to which future experience conforms to the assumptions made in this model. It is almost certain that actual experience will not conform exactly to the assumptions used in this model. Actual amounts will differ from projected amounts to the extent that actual experience is better or worse than expected.

Model and Data Reliance

Milliman has developed certain models to estimate the values included in this report. The intent of the models was to estimate the impact of bill SB 75. We have reviewed this model, including its inputs, calculations, and outputs for consistency, reasonableness, and appropriateness to the intended purpose and in compliance with generally accepted actuarial practice and relevant actuarial standards of practice (ASOP).

The models rely on data and information as input to the models. We have relied upon certain data and information for this purpose and accepted it without audit. To the extent that the data and information provided is not accurate, or is not complete, the values provided in this report may likewise be inaccurate or incomplete.

Milliman's data and information reliance includes:

- Data from Maryland's All Payer Claims Database
- US Census data and projections
- Maryland Medicaid Age Distribution
- All other sources mentioned inline and in references, including survey and studies.

The models, including all input, calculations, and output may not be appropriate for any other purpose.

We have performed a limited review of the data used directly in our analysis for reasonableness and consistency and have not found material defects in the data. If there are material defects in the data, it is possible that they would be uncovered by a detailed, systematic review and comparison of the data to search for data values that are questionable or for relationships that are materially inconsistent. Such a review was beyond the scope of our investigation.

Qualifications to Perform Analysis

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. One of the developers of this model and author of this paper, Casey Hammer, is a member of the American Academy of Actuaries and meets the qualification standards for performing the analyses supported by this model.

Distribution and Usage

We understand that MHCC intends to distribute this report to the Commissioners and it may be published on their website. We consent to this distribution as long as the work is distributed in its entirety. Milliman does not intend to benefit any third-party recipient of its work product and assumes no duty or liability to other parties who receive this work.

Appendix A: Carrier Coverage Survey

COVERAGE SURVEY FOR THE TREATMENT OF ALOPECIA AREATA

Insurance Article §15–1501, Annotated Code of Maryland, requires the Maryland Health Care Commission (MHCC) to annually assess the medical, social, and financial impact of proposed mandated health insurance services that failed to pass during the preceding legislative session. Senate Bill 75 (SB 75), which did not pass, requires the following:

1) Maryland Medical Assistance Program to cover one hair prosthesis for each recipient whose hair loss resulted from alopecia areata.
2) Maryland Medical Assistance Program to cover prescription drugs and medical devices approved by the U.S. Food and Drug Administration for the treatment of alopecia areata.
3) Commercial insurers that are subject to state benefit mandates must cover the cost of one hair prosthesis (up to $350) prescribed by the physician treating an enrollee or insured for alopecia areata.

This survey is intended to inform this analysis. Please return this survey to Kenneth Yeates-Trotman via email at kenneth.yeates-trotman@maryland.gov by **Friday, October 27.**

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1) What is the name of the insurance carrier?

2) Please complete the following table with how many people are enrolled in the following lines of business as of September 30, 2023?

Individual Market	Small Group Market	Large Group Market	State Employee Health Plan	Self-Funded Employer Plan†	Medical Assistance Program
#	#	#	#	#	#

3) Please complete the following table with the percentage of enrollees who currently have coverage for at least one hair prosthesis whose hair loss results from Alopecia Areata?

† DO NOT include State Health Plan

Individual Market	Small Group Market	Large Group Market	State Employee Health Plan	Self-Funded Employer Plan‡	Medical Assistance Program
#	#	#	#	#	#

4) For enrollees with coverage for hair prosthesis for alopecia areata, are there any benefit limitations such as dollar limits or frequency with which hair prosthesis can be received?

Individual Market	Small Group Market	Large Group Market	State Employee Health Plan	Self-Funded Employer Plan†	Medical Assistance Program
#	#	#	#	#	#

5) What percentage of enrollees have coverage for prescription drugs and medical devices that are approved by the U.S. Food and Drug Administration for the treatment of alopecia areata?

Individual Market	Small Group Market	Large Group Market	State Employee Health Plan	Self-Funded Employer Plan[1]	Medical Assistance Program
#	#	#	#	#	#

6) For enrollees with coverage for prescription drugs and medical devices that are approved by the U.S. Food and Drug Administration for the treatment of alopecia areata, which drugs and devices are covered benefits?

7) Do you expect any additional administrative burden resulting from this benefit mandate?

8) Is there any additional information you would like to share as we consider mandating coverage of this benefit?

‡ DO NOT include State Health Plan

Appendix B: Enrollees Impacted by SB 75 Mandate

PROJECTED 2025 USERS OF CRANIAL PROSTHESIS AND FDA APPROVED DRUGS

	Individual	Small Group	Fully Insured Large Group	Total Fully Insured Commercial	State Health Plan	Total Commercial	Medicaid
Total enrollees subject to state mandates	248,900	224,200	466,300	939,400	210,400	1,149,800	1,578,700
Total enrollees with alopecia areata	530	380	960	1,860	650	2,510	2,300
Baseline Cranial Prosthesis Users							
With Coverage	0	20	250	270	0	270	0
Without Coverage	400	270	530	1,200	490	1,690	0
Total Users	**400**	**290**	**780**	**1,470**	**490**	**1,960**	**0**
Post Mandate Cranial Prosthesis Users							
Users with and without coverage at Baseline	**400**	**290**	**780**	**1,470**	**490**	**1,960**	**0**
New Users	90	60	120	270	110	380	2,140
Total Users	**490**	**350**	**900**	**1,740**	**600**	**2,340**	**2,140**
FDA Approved Drug Users							
Baseline							70 to 340
New Users Post Mandate							30 to 100
Total Users Post Mandate							100 to 440

Appendix C: Low-End Scenario of FDA Drug Uptake

COMMERCIAL PREMIUM, MEDICAID COST, AND ENROLLEE OUT OF POCKET PMPM

	Individual	Small Group	Fully Insured Large Group	Total Fully Insured Commercial	State Health Plan	Total Commercial	Medicaid
Total enrollees subject to state mandates	248,900	224,200	466,300	939,400	210,400	1,149,800	1,578,700
Total enrollees with alopecia areata	530	380	960	1,870	640	2,510	2,300
Baseline							
Commercial premium/Medicaid Cost attributable to mandated benefits	$0.00	$0.01	$0.04	$0.02	$0.00	$0.02	$0.20
Enrollee out-of-pocket expenses attributable to mandated benefits	$0.20	$0.16	$0.20	$0.19	$0.29	$0.21	$0.00
Total Cost of Care for Mandated Benefits	**$0.20**	**$0.16**	**$0.24**	**$0.21**	**$0.29**	**$0.23**	**$0.20**
Post Mandate							
Commercial premium/Medicaid Cost attributable to mandated benefits	$0.07	$0.06	$0.08	$0.07	$0.10	$0.08	$0.52
Enrollee out-of-pocket expenses attributable to mandated benefits[1]	$0.20	$0.16	$0.20	$0.19	$0.29	$0.21	$0.00
Total Cost of Care for Mandated Benefits	**$0.27**	**$0.22**	**$0.29**	**$0.27**	**$0.39**	**$0.29**	**$0.52**
Financial Impact of Mandate							
Change in Commercial premium/Medicaid Cost	$0.07	$0.05	$0.05	$0.06	$0.10	$0.06	$0.33
Change in enrollee out-of-pocket expenses	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Total Mandate Impact	**$0.07**	**$0.05**	**$0.05**	**$0.06**	**$0.10**	**$0.06**	**$0.33**

[1]Medicaid enrollee out of pocket expenses are $0.00 due to rounding.

Appendix C: Low-End Scenario of FDA Drug Uptake (Cont.)

TOTAL COST OF CARE

	Individual	Small Group	Fully Insured Large Group	Total Fully Insured Commercial	State Health Plan	Total Commercial	Medicaid
Total enrollees subject to state mandate	248,900	224,200	466,300	939,400	210,400	1,149,800	1,578,700
Total enrollees with alopecia areata	530	380	960	1,870	640	2,510	2,300
Baseline							
Commercial premium/Medicaid Cost attributable to mandated benefits	$0	$14,000	$199,000	$213,000	$0	$213,000	$3,697,000
Enrollee out-of-pocket expenses attributable to mandated benefits	$594,000	$427,000	$1,147,000	$2,167,000	$725,000	$2,893,000	$1,000
Total Cost of Care for Mandated Benefits	**$594,000**	**$441,000**	**$1,346,000**	**$2,380,000**	**$725,000**	**$3,106,000**	**$3,698,000**
Post Mandate							
Commercial premium/Medicaid Cost attributable to mandated benefits post mandate	$215,000	$160,000	$465,000	$840,000	$247,000	$1,087,000	$9,891,000
Enrollee out-of-pocket expenses attributable to mandated benefits post mandate	$594,000	$427,000	$1,147,000	$2,167,000	$725,000	$2,893,000	$2,000
Total Cost of Care for Mandated Benefits	**$809,000**	**$587,000**	**$1,612,000**	**$3,007,000**	**$972,000**	**$3,980,000**	**$9,893,000**
Financial Impact of Mandate							
Change in Commercial premium/Medicaid Cost	$215,000	$146,000	$266,000	$627,000	$247,000	$874,000	$6,194,000
Change in enrollee out-of-pocket expenses	$0	$0	$0	$0	$0	$0	$1,000
Total Mandate Impact	**$215,000**	**$146,000**	**$266,000**	**$627,000**	**$247,000**	**$874,000**	**$6,195,000**

Appendix D: High-End Scenario of FDA Drug Uptake

COMMERCIAL PREMIUM, MEDICAID COST AND ENROLLEE OUT OF POCKET PMPM

	Individual	Small Group	Fully Insured Large Group	Total Fully Insured Commercial	State Health Plan	Total Commercial	Medicaid
Total enrollees subject to state mandates	248,900	224,200	466,300	939,400	210,400	1,149,800	1,578,700
Total enrollees with alopecia areata	530	380	960	1,870	640	2,510	2,300
Baseline							
Commercial premium/Medicaid Cost attributable to mandated benefits	$0.00	$0.01	$0.04	$0.02	$0.00	$0.02	$0.89
Enrollee out-of-pocket expenses attributable to mandated benefits	$0.20	$0.16	$0.20	$0.19	$0.29	$0.21	$0.00
Total Cost of Care for Mandated Benefits	**$0.20**	**$0.16**	**$0.24**	**$0.21**	**$0.29**	**$0.23**	**$0.89**
Post mandate							
Commercial premium/Medicaid Cost attributable to mandated benefits	$0.07	$0.06	$0.08	$0.07	$0.10	$0.08	$1.44
Enrollee out-of-pocket expenses attributable to mandated benefits[1]	$0.20	$0.16	$0.20	$0.19	$0.29	$0.21	$0.00
Total Cost of Care for Mandated Benefits	**$0.27**	**$0.22**	**$0.29**	**$0.27**	**$0.39**	**$0.29**	**$1.44**
Financial Impact of Mandate							
Change in Commercial premium/Medicaid Cost	$0.07	$0.05	$0.05	$0.06	$0.10	$0.06	$0.54
Change in enrollee out-of-pocket expenses	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Total Mandate Impact	**$0.07**	**$0.05**	**$0.05**	**$0.06**	**$0.10**	**$0.06**	**$0.54**

[1]Medicaid enrollee out of pocket expenses are $0.00 due to rounding.

Appendix D: High-End Scenario of FDA Drug Uptake (Cont.)

TOTAL COST OF CARE

	Individual	Small Group	Fully Insured Large Group	Total Fully Insured Commercial	State Health Plan	Total Commercial	Medicaid
Total enrollees subject to state mandates	248,900	224,200	466,300	939,400	210,400	1,149,800	1,578,700
Total enrollees with alopecia areata	530	380	960	1,870	640	2,510	2,300
Baseline							
Commercial premium/Medicaid Cost attributable to mandated benefits	$0	$14,000	$199,000	$213,000	$0	$213,000	$16,884,000
Enrollee out-of-pocket expenses attributable to mandated benefits	$594,000	$427,000	$1,147,000	$2,167,000	$725,000	$2,893,000	$6,000
Total Cost of Care for Mandated Benefits	**$594,000**	**$441,000**	**$1,346,000**	**$2,380,000**	**$725,000**	**$3,106,000**	**$16,890,000**
Post Mandate							
Commercial premium/Medicaid Cost attributable to mandated benefits post mandate	$215,000	$160,000	$465,000	$840,000	$247,000	$1,087,000	$27,202,000
Enrollee out-of-pocket expenses attributable to mandated benefits post mandate	$594,000	$427,000	$1,147,000	$2,167,000	$725,000	$2,893,000	$8,000
Total Cost of Care for Mandated Benefits	**$809,000**	**$587,000**	**$1,612,000**	**$3,007,000**	**$972,000**	**$3,980,000**	**$27,210,000**
Financial Impact of Mandate							
Change in Commercial premium/Medicaid Cost	$215,000	$146,000	$266,000	$627,000	$247,000	$874,000	$10,318,000
Change in enrollee out-of-pocket expenses	$0	$0	$0	$0	$0	$0	$2,000
Total Mandate Impact	**$215,000**	**$146,000**	**$266,000**	**$627,000**	**$247,000**	**$874,000**	**$10,320,000**

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