HF 3339/ SF 3351 – Evaluation of Coverage for Orthotic and Prosthetic Devices

Report to the Minnesota Legislature Pursuant to Minn. Stat. § 62J.26

01/29/2024

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Executive Summary

House File (HF) 3339 and Senate File (SF) 3351 would require a health carrier to provide health insurance coverage for orthotic and prosthetic devices, supplies, and services. A health plan must cover orthoses and prostheses that are determined by the physician or provider to be medically necessary.

This mandate applies to a wide variety of conditions in which orthoses and prostheses may be used, such as lower limb amputation, stroke, and cerebral palsy. While a prosthesis is used to replace or restore a missing limb, appendage, or other external human body part, an orthosis is used to support and protect a body part. Services and associated treatments may include fitting of a device, repair of a device, physical or occupational therapy, and patient education.

Several other states have passed legislation for coverage of orthotic and/or prosthetic devices, with a variety of cost-sharing requirements. Medicare Part B provides coverage of prosthetics with 20% coinsurance after the yearly deductible.

The majority of public comments received for HF 3339 /SF 3351 stated that this mandate would improve the function, quality of life, safety, and overall health for individuals requiring orthotics and prosthetics for mobility. Some respondents noted that this mandate has the potential to increase health care costs by requiring coverage for specific orthotic and prosthetic devices, repair of the devices, and other services not currently included in health plans' medical necessity determinations.

Considering the wide variety of devices, associated medical conditions, and associated services, there is limited literature for addressing the broad coverage requirements of this mandate. Several studies have indicated that receipt of orthoses and/or prostheses may result in less expensive episodes of care and decreased overall health expenditures.

Given the current available data, the expenditures associated with this mandate are projected to result in a net increase of $0.39 per member per month (PMPM) for the total non-public insured population in the first year and to result in a net increase of $3.65 PMPM in Year 10.

The potential state fiscal impact of this mandate is as follows:

- There is no estimated fiscal impact for the State Employee Group Insurance Program associated with the proposed mandate.
- Commerce has determined that this proposed mandate would likely require partial defrayal under the Affordable Care Act, with an estimated cost between $350,000 and $520,000 in the first year.
- There is no estimated cost to state public programs.

Introduction

In accordance with Minn. Stat. § 62J.26, the Minnesota Department of Commerce (Commerce), in consultation with the Minnesota Department of Health (MDH) and Minnesota Management and Budget (MMB), performs a detailed evaluation of all relevant benefit mandate proposals. For evaluation criteria and required evaluation components, please review the Evaluation Report Methodology, available at https://mn.gov/commerce/insurance/industry/policy-data-reports/62j-reports/.

Bill Requirements

House File 3339 and Senate File 3351, which are sponsored by Rep. Koegel and Sen. Hoffman, were introduced in the 93rd Legislature (2023–24) on May 21, 2023, and May 20, 2023, respectively.

If enacted, these bills would require a health carrier to provide health insurance coverage for orthotic and prosthetic devices, supplies, and services. Medical necessity must be determined by a prescribing physician or licensed health care provider with the appropriate scope of practice in Minnesota for coverage. A health plan must cover orthoses and prostheses that are determined by the physician or provider to be the most appropriate model for meeting the medical needs of the enrollee, including recreational and bathing prostheses. Prior authorization may be required by a health plan for orthotic and prosthetic devices, supplies, and services in the same manner and to the same extent as required for any other covered benefit.

This mandate would apply to fully insured small and large group commercial health plans, individual market plans, and the State Employee Group Insurance Program (SEGIP). This would not apply to self-insured employer plans, grandfathered plans, Medicare and Medicare supplemental policies, and Minnesota public health insurance programs.

Key Terms

For the purposes of this mandate and as defined by the bill language (see Appendix A), the key terms are as follows:

- "Accredited facility" means any entity that is accredited to provide comprehensive orthotic or prosthetic devices or services by a Centers for Medicare & Medicaid Services (CMS)–approved accrediting agency.
- "Orthosis" means an external medical device that is custom-fabricated or custom-fitted to a specific patient based on the patient's unique physical condition; is applied to a part of the body to correct a deformity; provides support and protection; restricts motion; improves function or relieves symptoms of a disease, syndrome, injury, or postoperative condition; and is deemed medically necessary by a prescribing physician or licensed health care provider.
- "Orthotics" means the science and practice of evaluating, measuring, designing, fabricating, assembling, fitting, adjusting, or servicing an orthotic device as well as providing the initial patient training necessary to accomplish the fitting of an orthotic device for the support, correction, or alleviation of a neuromuscular or musculoskeletal dysfunction, disease, injury, or deformity.
- "Prosthesis" means an external medical device that is used to replace or restore a missing limb, appendage, or other external human body part and is deemed medically necessary by a prescribing physician or licensed health care provider. This also includes any provision, repair, or replacement of a device that is furnished or performed by a facility accredited in comprehensive prosthetic services or a health care provider licensed in Minnesota and operating within the provider's scope of practice.
- "Prosthetics" means the science and practice of evaluating, measuring, designing, fabricating, assembling, fitting, aligning, adjusting, or servicing a prosthetic device as well as providing the initial training necessary to accomplish the fitting of a prosthetic device through the replacement of external parts of a human body lost due to amputation or congenital deformities or absences.

Related Health Conditions and Associated Services/Treatments

Orthotic and prosthetic devices are used across a range of different conditions, such as lower limb amputation (LLA), stroke, and cerebral palsy. This mandate is not specific to any one condition.

Applicable orthotic and prosthetic services that must be covered by insurance include

- evaluation, treatment, and consultation related to an orthosis or prosthesis;
- assessing and designing an orthosis or prosthesis to maximize function and provide support and alignment necessary to improve the safety and efficiency of mobility and locomotion;
- clinical assessment of what is required to refine and mechanically fix various parts of the orthosis or prosthesis to maximize the function, stability, and safety of the patient;
- gait and postural analysis; and
- re-evaluation to assess the function and effects of an orthosis or prosthesis on the patient.

Related State and Federal Laws

This section provides an overview of state and federal laws related to the proposed mandate and any external factors that provide context on current policy trends related to this topic.

Relevant Federal Laws

The Patient Protection and Affordable Care Act (ACA) essential health benefits (EHBs) include coverage for "habilitative services and devices," which includes orthotic and prosthetic devices. Medicare Part B provides coverage of prostheses with 20% coinsurance after the yearly deductible.[1]

Relevant Minnesota Laws

In accordance with Minn. Stat. § 62E.06, all qualified health plans must cover prostheses, with the exception of dental prostheses.[2] According to Minn. Rule 4685.0700 subsection 3B, health maintenance organizations (HMOs) must cover durable medical equipment, such as orthotic and prosthetic devices, but may impose restrictions.[3]

State Comparison

Several states have established health benefit mandates related to the coverage of orthoses and prostheses. Medicaid also provides coverage of prostheses, although copayments and limits on services vary by state. Six states (New Jersey, New York, North Dakota, New Mexico, Texas, and Massachusetts) have passed laws or issued bulletins that are similar to the proposed mandate. Specifically, New Mexico House Bill (HB) 131 and Texas §1371.002 require that issuers of health insurance plans provide coverage of orthotic or prosthetic devices at parity with other diseases and conditions in relation to cost-sharing.[4,5] New Jersey Bulletin No. 08-10 requires issuers to provide coverage of orthotic and prosthetic devices at the same cost-sharing associated with a primary care provider office visit.[6] Additionally, North Dakota HB 4011 and Massachusetts Title 22 Chapter 176g § 4S require health insurance issuers to provide coverage of only prosthetic devices.[7,8] New York A6820C also requires coverage of prosthetic devices but only applies to veterans.[9]

Public Comments Summary

Commerce solicited public input on the potential health benefit mandate through a request for information (RFI) posted to Commerce's website and the Minnesota State Register. The summary below represents only the opinions and input of the individuals and/or organizations that responded to the RFI.

Key Stakeholder Comment Themes

For this proposed mandate, Commerce received 11 RFI responses. Stakeholder groups that submitted responses included four commercial health carriers, two clinical expert organizations, four health care organizations providing orthotic and prosthetic services and devices in Minnesota, and one individual impacted by limb loss, limb differences, or mobility impairment.

Some respondents submitted comments that were neither for nor against the bill but raised considerations related to insurance coverage requirements. Below are key takeaways these respondents shared:

- **The proposed mandate lacks detail about coverage and cost-sharing requirements.** The coverage requirements are broadly defined and suggest that health carriers would be required to cover any orthotic or prosthetic device(s) prescribed by a treating physician. This prohibits health plans from determining medical necessity. Additionally, the bill text does not specify the financial requirements of medical/surgical benefits that would serve as the threshold for applying financial requirements to orthotic/prosthetic benefits.
- **The proposed mandate could lead to a significant increase in the promotion, usage, and replacement of orthotic and prosthetic devices and services**. Without a coverage limit, insurance plans could be responsible for the full cost of these devices and services, which may result in increased premiums for policyholders. It is important for the mandate to provide clear and specific guidance on coverage requirements and cost-sharing responsibilities to ensure both that patients receive the necessary care and that costs are kept under control.
- **The proposed mandate may result in reduced insurance coverage denials for prescribed devices and services** because the bill requirements would shift medical necessity determination from issuers to providers.

Multiple respondents submitted comments voicing support for the bill. Below are key takeaways respondents shared:

- **Twenty-eight thousand Minnesotans[a] with limb loss, along with thousands more with a limb difference (e.g., a leg length discrepancy) or a mobility impairment, are unable to access prescribed life-changing orthotic and prosthetic care due to a lack of health care coverage and affordability.** Without health care coverage, orthotic and prosthetic devices and services can lead to high out-of-pocket costs, injury from using unsuitable devices, or sedentary lifestyles that cause expensive secondary health problems and comorbidities.

[a] This estimate was provided by industry advocates and clinical experts in response to the RFI. No source of information was provided for this statistic.

- **The proposed mandate could advance current coverage in Minnesota.** Several respondents highlighted that the proposed benefits would provide coverage at a level that is equivalent to the federal Medicare program, align the state's statutes with the ACA's nondiscrimination standards, and increase individuals' physical activity performance and ability to carry out daily activities (e.g., showering or bathing).
- **This bill would ensure that individuals with limb loss, limb difference, and mobility impairment receive the same standard of care and insurance coverage as individuals without a disability.** Clinical experts stated, "Knee and hip replacements, which are 'internal prostheses' rather than external prostheses, are routinely covered to eliminate pain; however, coverage of 'external prostheses,' such as microprocessor-controlled prosthetic knees, that similarly restore function, is often denied for people with disabilities."
- **Activity-specific orthoses and prostheses could already be inherently covered under the ACA EHBs as "rehabilitative and habilitative services and devices."**[b] However, currently private health insurers in Minnesota only provide coverage for one prosthetic or orthotic device for ambulatory functioning. Respondents noted that one custom prosthetic or orthotic device is not capable of replacing the wide range of movement children and adults needs to restore and maintain physical activity. There are specific prostheses or orthoses for running, biking, swimming, showering/bathing, and more.
- This bill would have a positive impact on health outcomes for adults and children with limb loss, limb difference, and mobility impairment by increasing human functioning and preventing immobility. Research has shown that preventing immobility is critical as it can result in lower health risk for obesity, heart disease, stroke, type 2 diabetes and various cancers,[c,d,e,f] and chronic loneliness and isolation,[c] and can reduce medical costs.[g]
- **Ensuring health care coverage for physical disabilities or injuries in children is essential to mitigate health inequality and promote equity.** Based on their experience working with Minnesotan families, clinical experts explained that some families are unable to pay for a second device that could accommodate a child's movement or growth needs beyond an ambulatory device. It is critical for children to have access to orthotic and prosthetic devices that not only are suitable for their growing bodies but also enable them to engage in social interactions with their peers and be physically active and thus support positive mental, physical, and developmental health outcomes.

Cost Estimates Provided in Stakeholder Comments

Stakeholders and MMB provided the following cost estimates related to the proposed benefit mandate:

[b] Center for Medicare & Medicaid Services. *Information on essential health benefits (EHB) benchmark plans.* Updated September 19, 2023. https://www.cms.gov/marketplace/resources/data/essential-health-benefits

[c] U.S. Department of Health and Human Services. *Our epidemic of loneliness and isolation: The U.S. Surgeon General's advisory on the healing effects of social connection and community.* 2023. https://www.hhs.gov/sites/default/files/surgeon-general-social-connection-advisory.pdf

[d] Centers for Disease Control and Prevention. *Disability and obesity.* https://www.cdc.gov/ncbddd/disabilityandhealth/obesity.html

[e] Centers for Disease Control and Prevention. *Inactivity related to chronic disease in adults with disabilities.* May 6, 2014. https://www.cdc.gov/media/releases/2014/p0506-disability-activity.html

[f] American College of Sports Medicine. *Why we must prioritize equitable access to physical activity for children with disabilities.* March 22, 2021. https://www.acsm.org/blog-detail/acsm-blog/2021/03/22/prioritize-equitable-access-to-physical-activity-for-children-with-disabilities

[g] Dobson, A, Murray, K, Manolov, N, DaVanzo, JE. Economic value of orthotic and prosthetic services among Medicare beneficiaries: A claims-based retrospective cohort study, 2011–2014. *J Neuroeng Rehabil. 2018;15*(Suppl 1),55. Published September 5, 2018. https://doi.org/10.1186/s12984-018-0406-7

- MMB does not estimate any state fiscal impact to the state plan, as SEGIP currently provides coverage in its medical benefit package for orthotic and prosthetic devices.
- According to commercial health insurance carriers, reclassifying coverage for orthoses and prostheses from DME benefits to medical/surgical benefits would result in a cost increase of at most $0.45 PMPM.
- Four respondents referenced a study that evaluated PMPM costs of similar bills enacted into law in Colorado ($0.01–$0.08 PMPM) and Illinois ($0.01–$0.33 PMPM) and estimated increased PMPM costs of less than $1.00.[h]

Cost estimates shared in RFI responses may reflect different methodologies, data sources, and assumptions than those used in the actuarial analysis for this evaluation. Stakeholders' results may or may not reflect generalizable estimates for the mandate.

Evaluation of Proposed Health Benefit Mandate

Methodology

The following section includes an overview of the literature review and actuarial analysis performed to examine the potential public health and economic impact of the mandate. The literature review includes moderate- to high-quality relevant peer-reviewed literature and/or independently conducted domestic research that was published within the last 10 years and is related to the public health, economic, or legal impact of the proposed health benefit mandate. For further information on the literature review methodology, please reference https://mn.gov/commerce/insurance/industry/policy-data-reports/62j-reports/.

Public Health Impact

Prevalence of Limb Loss and Utilization of Prostheses and Orthoses. Lower limb loss is the most documented condition in the literature on prostheses. The rate of utilization of specific orthotic and prosthetic devices and services and the required frequency of replacement for different conditions are not available in the current literature. Across the range of conditions, devices, and services associated with this mandate, the literature is most robust in discussing LLA, primarily transtibial or transfemoral, and the associated protheses.[10] One study of 443 people with LLA found 64% had diabetic or vascular disease, although this rate may not be generalizable to the population of Minnesota.[11] According to most recent data from the Minnesota Hospital Discharge Dataset, there are 12.4 cardiovascular disease-related lower-extremity amputation hospitalizations per 100,000 persons, with 614 in 2020 alone.[12] This finding does not reflect the full range of amputations, nor the number of individuals in the state of Minnesota who are living with conditions requiring prostheses or orthoses for disease management or mobility. Complications resulting from diabetes mellitus are another primary driver for LLA.[13]

[h] Kehoe, S, Cain, J, Montgomery, A, Mitsou, L. A multi-state analysis of the fiscal and social impact of commercial insurance coverage for recreational prostheses in the United States. *European Society of Medicine. 2023;11*(5). Published May 26, 2023. https://doi.org/10.18103/mra.v11i5.3809.

One study identified a prevalence of 38.5 cases of lower limb loss per 100,000 commercially insured children. Congenital deficiencies accounted for the large majority cases requiring prostheses, and trauma was the second most prevalent cause.[i,14] For pediatric populations, orthoses may be prescribed for a variety of neurologic, congenital, and orthopedic conditions, such as cerebral palsy, spina bifida, and clubfoot. Orthoses use is associated with improved clinical and functional outcomes for this population.[15]

Associated Health Outcomes. While orthotic and prosthetic devices and associated services are considered broadly effective for improving functional outcomes, community participation, and emotional well-being, the effectiveness of different devices and device categories is not well documented in the literature. Prostheses may improve outcomes associated with mobility and independence.[11] Delayed fitting of a prosthesis or delayed rehabilitation can increase the risk of complications such as re-amputation and can result in lower functional status.[11,13] Well-documented physical, social, and mental benefits are associated with receipt of medically necessary protheses.[11,13,16] However, there is limited outcomes research to support the hypothesis that a reduction in fractures or falls is associated with lower limb protheses or spinal orthoses in Medicare populations.[13,16] The strength of evidence on clinical outcomes associated with orthotic and prosthetic devices varies widely from condition to condition and from device to device.[10] Adjunct services for prosthetic devices and associated services (physical therapy, inpatient care, evaluation, and fitting) have often been examined in cost- and clinical-effectiveness studies. It is therefore difficult to separate the effects of associated services (such as physical and occupational therapy) from the effects of the prosthetic or orthotic devices themselves. One study indicates improvement in some outcome measures, such as self-reported function and performance, associated with physical therapy during the prosthetic training phase of rehabilitation.[17] However, the clinical significance of this study is limited by lack of meaningful difference with other critical outcomes, such as fall risk.

Impact on Health Disparities. Recently, the National Institutes of Health (NIH) designated individuals with disability as a "population with health disparities" to motivate increased research on the health issues and unmet health needs of this population.[18] According to the CDC, 57% of individuals with a mobility-related disability are considered inactive, compared to 24% of those without disabilities.[19] The effects of physical activity on both mental and physical health are well documented, and pediatric clinical guidelines support the prescription of necessary devices and services to promote physical activity in children and adolescents with disabilities.[20] Lack of receipt of prosthetic devices appropriate for physical activity, such as recreational protheses, may be a barrier for physical activity. One qualitative study found that poor fitting protheses, due to lack of adjunct services needed for fitting or to mismatching of prostheses acquired for physical activity, were associated with pain and an increased risk of falling, which decreased motivation to engage in physical activity.[19] This mandate includes coverage for medically necessary recreational prosthetic devices, which may play a role in rates of physical activity for pediatric and adult populations living with a disability.

Coverage that minimizes barriers to access for appropriate orthotic and prosthetic devices and services may reduce existing health disparities for impacted enrollees. Receipt of appropriate devices may be disproportionately lower in Black and Hispanic communities. One study found that Black individuals were less likely to receive prescribed orthoses than White counterparts for similar diagnoses, even after controlling for insurance, associated services, conditions, and condition severity. Cost, which may result from lack of coverage or specific cost-sharing, was the most cited barrier to receiving a prescribed orthosis.[21] Another study found that in the pediatric population Black and Hispanic individuals were similarly less likely to receive a prescribed orthosis.[15] The degree to which the coverage changes associated with this mandate would alter any disparities

[i] This prevalence is not specific to Minnesota and may not reflect prevalence in the state.

faced in the Minnesota population is unknown, but reducing barriers to coverage may reduce the cost-related disparities that exist for orthotic and prosthetic devices.

Economic Impact

Orthoses and Prostheses Cost Data. Given the broad range of associated conditions, devices, and services and differences in the replacement frequency associated with this mandate, as well as variation in existing coverage across applicable plans in Minnesota, the literature is not specific on the potential costs of this mandate for issuers and largely addresses potential cost-saving outcomes associated with aspects of the proposed coverage. Broadly, the literature indicates that insurance coverage and out-of-pocket costs may be a barrier between prescription and receipt of the necessary devices.[11,20,21] For the pediatric population, there is great variability in average annual prosthesis-related costs, with a range between $50 and $29,112 and a median cost of $2,778. Nearly half of these costs are paid by patient families through co-insurance and co-payments.[14] This finding is not specific to Minnesota.

Cost-Effectiveness of Orthoses and Protheses. Adults receiving medically necessary orthotic and prosthetic devices report reduced disability and increased function.[13,16] Further, research indicates that receipt of an appropriate device may increase an individual's ability to remain at or return to work, possibly reducing the need for social services. Although outcomes data for certain devices are not conclusive, the potential for downstream economic savings from lower limb protheses is relatively well confirmed.[10]

Several studies have indicated that receipt of orthoses and/or prostheses may result in less expensive episodes of care and reduced health expenditures overall.[10,11,13,16,21] One retrospective cohort study found that receipt of a prostheses within 3 months following amputation was associated with a 25% reduction in total health care costs compared with not receiving a prosthetic device within 1 year of amputation.[11] In a Medicare population, receipt of lower extremity or spinal orthoses and associated services is correlated with reduced health care costs in other settings such as emergency room visits and hospitalization.[13,16] Lower morbidity and mortality may be associated with proper receipt of orthoses and associated services. However, because studies do not indicate the reasons why an individual may not receive a prosthesis, there may be confounding variables that explain the health care cost differences between those who are and are not receiving a prescribed prothesis. Neither study specifically concerned recreational or bathing protheses, and thus neither indicated the potential economic impact of this aspect of the proposed mandate on issuer or enrollee costs, nor did the studies indicate the degree to which these types of prostheses contribute to downstream savings.

Limitations

From the available literature, it is difficult to assess the potential economic and public health impact associated with the expanded coverage in this mandate. None of the studies in this review addresses the cost-effectiveness of the mandate as a whole, as none cover the full universe of devices and services.[10] The existing literature does not address the variation in clinical presentation that may affect health care costs, and lack of longitudinal data across devices makes it challenging to capture the potential costs or cost savings associated with the mandate.[11] There is limited consistent application of well-validated outcome measures in the available literature on orthotic and prosthetic devices. Many studies focus on Medicaid and Medicare claims, which present unique cost and population considerations.[13] As the proposed mandate may alter how health plans manage utilization and reach medical necessity determinations, including whether coverage for bathing and recreational prosthetic devices is required, the literature tends not to address such considerations specifically.

Actuarial Analysis[j]

Objective

This actuarial analysis includes analysis of the current prevalence of diagnoses, current utilization and expenditures, and the potential effects of increased utilization through expanded coverage on cost-sharing, premiums and overall expenditures.

Assumptions and Approach

MDH provided the Actuarial Research Corporation with tabulations from the Minnesota All Payer Claims Database (MN APCD) for all diagnoses typically associated with the use of orthotic and prosthetic devices and claims for Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) codes for devices and related services for 2019–2022 as a snapshot of current prevalence and utilization, expenditures, and enrollee cost-sharing for orthotics and prosthetics for Minnesota commercial health plan enrollees.[22]

The following criteria were used by MDH to identify enrollees with an associated diagnosis and claims for devices and related services:

- Enrollees were identified as having an associated diagnosis based on the International Classification of Diseases (ICD-10) codes listed in Appendix C.
- The CPT/HCPCS procedure codes listed in Appendix C were used to identify orthotic and prosthetic devices and related services.

The number of enrollees in 2019–2022 who had a qualifying diagnosis and the number of enrollees utilizing orthotic or prosthetic devices and related services were tabulated by MDH. Total expenditures and enrollee cost-sharing were tabulated for each of the two categories. For the historical period 2019–2022, as tabulated by MDH, the proportion of enrollees with an amputation diagnosis was between 1.4% and 1.8%, and the proportion of enrollees with another diagnosis typically associated with use of an orthotic device was between 11.5% and 14.2% of the full commercial population in the MN APCD (which, per MDH, includes approximately 40% of the total commercial market in Minnesota).[23] The observed prosthesis utilization rates ranged from 32% to 36% for enrollees with an amputation diagnosis, and observed orthosis utilization rates ranged from 18% to 19% for enrollees with an associated diagnosis.

For the purposes of this analysis, associated diagnosis prevalence rates, utilization, and total expenditures for orthotics and prosthetics were projected under the current law as well as under the proposed mandated coverage. The current law scenario projects utilization of both orthotics and prosthetics among enrollees with an associated diagnosis to hold constant at historical rates. Among enrollees with an amputation diagnosis, under the proposed mandate the prosthetic utilization rate was assumed to increase by 5% annually, ultimately reaching a level of 60% in the 10th year of the projection. Among enrollees with an associated diagnosis, under the proposed mandate the orthotic utilization rate was assumed to increase by 4% annually. The per user expenditure rates for each of the two categories were trended forward to the projection period 2025–2034

[j] Michael Sandler and Anthony Simms are actuaries for Actuarial Research Corporation. They are members of the American Academy of Actuaries and meet the qualification standards of the American Academy of Actuaries to render the actuarial opinions contained herein.

using durable medical equipment prosthetics, orthotics, and supplies (DMEPOS) projection factors derived from the National Health Expenditure data compiled by CMS as well as the 2023 Medicare Trustees Report.

The overall Minnesota population projections for 2025 (the base year) through 2034 are based on the figures published by the Minnesota State Demographic Center. Given the historical non-public health insurance coverage levels from Minnesota Public Health Data Access, 65% of the total state population were assumed to be included in the non-public insured population.

Results

This analysis projects the incidence of amputation and other diagnoses associated with orthotics prevalence in Minnesota for the total non-public insured population as well as current law utilization and expenditures for the orthoses, prostheses, and related services, then projects potential utilization and total expenditures under the proposed mandated coverage.

Table 1 shows the total projected prevalence alongside projected current law utilization and expenditures based on historical claims.

Table 2 shows the total projected prevalence, projected utilization and expenditures, and net projected effect on the total non-public insured population PMPM under the proposed mandated coverage.

Table 1. Total Projected Current Law Orthosis and Prosthesis Device Prevalence and Expenditures[k]

	Population		Diagnoses prevalence		Enrollees utilizing …		Plan paid expenditures		Total cost-sharing	
	Total Minnesota population	Non-public insured population	Enrollees with amputation diagnosis	Enrollees with other associated diagnosis	Prostheses	Orthoses	Prostheses	Orthoses	Prostheses	Orthoses
2025	5,833,655	3,101,454	55,826	418,696	18,590	75,365	$56,238,649	$45,598,904	$6,248,739	$6,218,032
2026	5,863,731	3,107,430	56,773	419,503	18,905	75,511	$60,852,531	$48,610,729	$6,761,392	$6,628,736
2027	5,893,080	3,112,920	57,726	420,244	19,223	75,644	$66,081,901	$52,007,979	$7,342,433	$7,091,997
2028	5,921,625	3,117,886	58,686	420,915	19,542	75,765	$71,681,207	$55,581,045	$7,964,579	$7,579,233
2029	5,949,303	3,122,300	59,650	421,511	19,863	75,872	$77,449,565	$59,166,291	$8,605,507	$8,068,131
2030	5,976,058	3,126,137	60,619	422,028	20,186	75,965	$83,036,835	$62,497,135	$9,226,315	$8,522,337
2031	6,001,850	3,139,298	61,788	423,805	20,575	76,285	$89,800,086	$66,588,622	$9,977,787	$9,080,267
2032	6,026,651	3,151,878	62,966	425,504	20,968	76,591	$97,186,120	$71,000,512	$10,798,458	$9,681,888
2033	6,050,458	3,163,936	64,155	427,131	21,364	76,884	$105,160,594	$75,690,997	$11,684,510	$10,321,500
2034	6,073,273	3,175,472	65,354	428,689	21,763	77,164	$113,769,057	$80,676,919	$12,641,006	$11,001,398

[k] The state health benefit mandates generally only apply to fully insured individual and small group health plans regulated in Minnesota, except where explicitly indicated. However, the actuarial analysis is based on gross expenditures for all non-public insurance in Minnesota. Although the analysis was not limited to individual and small group data, this does not affect the accuracy of the PMPM estimates. Using all non-public claims improves the robustness and accuracy of the PMPM estimates because the analyses rely on a larger, more representative set of data.

Table 2. Total Projected Orthosis and Prosthesis Prevalence, Expenditures, and Total Non-Public Insured PMPM[l]

	Population		Diagnoses prevalence		Enrollees utilizing …		Plan paid expenditures		Total cost-sharing		
	Total Minnesota population	Non-public insured population	Enrollees with amputation diagnosis	Enrollees with other associated diagnosis	Prostheses	Orthoses	Prostheses	Orthoses	Prostheses	Orthoses	Total non-public insured population PMPM change
2025	5,833,655	3,101,454	55,826	418,696	21,520	84,776	$65,103,266	$51,292,566	$7,233,696	$6,994,441	$0.39
2026	5,863,731	3,107,430	56,773	419,503	22,980	88,337	$73,966,632	$56,867,677	$8,218,515	$7,754,683	$0.57
2027	5,893,080	3,112,920	57,726	420,244	24,534	92,032	$84,339,112	$63,275,658	$9,371,012	$8,628,499	$0.79
2028	5,921,625	3,117,886	58,686	420,915	26,189	95,866	$96,059,673	$70,327,754	$10,673,297	$9,590,148	$1.05
2029	5,949,303	3,122,300	59,650	421,511	27,950	99,842	$108,979,316	$77,858,803	$12,108,813	$10,617,109	$1.34
2030	5,976,058	3,126,137	60,619	422,028	29,824	103,964	$122,683,224	$85,531,645	$13,631,469	$11,663,406	$1.67
2031	6,001,850	3,139,298	61,788	423,805	31,919	108,577	$139,309,407	$94,776,373	$15,478,823	$12,924,051	$2.06
2032	6,026,651	3,151,878	62,966	425,504	34,154	113,373	$158,305,949	$105,098,102	$17,589,550	$14,331,559	$2.52
2033	6,050,458	3,163,936	64,155	427,131	36,539	118,359	$179,860,303	$116,522,812	$19,984,478	$15,889,474	$3.04
2034	6,073,273	3,175,472	65,354	428,689	39,083	123,542	$204,312,880	$129,166,347	$22,701,431	$17,613,593	$3.65

[l] The state health benefit mandates generally only apply to fully insured individual and small group health plans regulated in Minnesota, except where explicitly indicated. However, the actuarial analysis is based on gross expenditures for all non-public insurance in Minnesota. Although the analysis was not limited to individual and small group data, this does not affect the accuracy of the PMPM estimates. Using all non-public claims improves the robustness and accuracy of the PMPM estimates because the analyses rely on a larger, more representative set of data.

Under the proposed mandated coverage, the total statewide non-public insured population potential plan paid expenditures for orthotics, prosthetics, and related services are projected to be $116.4 million in Year 1 and to increase to $333.5 million in the 10th and final year of the projection period. These expenditures are projected to result in a net increase of $0.39 PMPM for the total non-public insured population in Year 1 and $3.65 PMPM in Year 10.

A more comprehensive actuarial analysis and modeling of all services related to and associated with orthotic and prosthetic devices, including potential downstream effects, and a full picture of what current coverage and expenditures are for Minnesota were not possible with the available data. A literature review was conducted to assess the broader environment of coverage, utilization, and expenditures and look at avenues of potential long-term savings and improved health outcomes.

- A *Journal of NeuroEngineering and Rehabilitation* study concluded that Medicare patients with lower extremity orthotics and with spinal orthotics experienced lower 18-month episode costs—savings of $1,939 and $2,094 per enrollee, respectively—compared to comparable enrollees who did not receive orthotic treatment. Additionally, enrollees receiving both types of orthoses had significantly lower Part D expenditures during that time period than those who did not receive treatment. Interestingly, enrollees who received lower extremity prostheses had comparable 15-month episode expenditures to matched enrollees who did not.[13]
- An Amputee Coalition study assessed the potential impact of expanded coverage of protheses on both cost of insurance to the public as well as all the ancillary benefits in terms of health outcomes and quality of life for the affected individuals. An examination of Colorado Medicaid coverage expansion found that by providing prosthetic and orthotic benefits to enrollees, the state saved $195,482 in the first 6 months of implementation and projected annual savings of $448,666 due to a reduction in costly secondary health complications. Overall, the study concluded that mandating coverage of prostheses had minimal effect on the cost of insurance for the population at large while greatly benefiting amputees, their families, and communities at large by providing adequate coverage up front.[24]
- An NIH study examined the effects of the speed with which recent amputees receive their prescribed prosthetics. The study found significant savings—a reduction of approximately 25% in total direct health care costs—among enrollees who received their prosthesis within 12 months compared to otherwise similar enrollees who did not.[11]

Data Sources

- Minnesota state population projections are from the "Long-Term Population Projections for Minnesota" published by the Minnesota State Demographic Center.[25]
- Minnesota non-public health insurance coverage levels are from Minnesota Public Health Data Access.[26]
- Trends and projection factors are derived from the National Health Expenditure data compiled by CMS as well as the 2023 Medicare Trustees Report.[27,28]
- MDH tabulations of the MN APCD from 2019 to 2022 were used for the estimation of associated diagnosis prevalence and historical utilization, expenditures, and enrollee cost-sharing for orthotics, prosthetics, and related services.[22]

State Fiscal Impact

The potential state fiscal impact of this legislation includes the estimated cost to SEGIP as assessed by MMB in consultation with health plan administrators, the cost of defrayal of benefit mandates as understood under the ACA, and the estimated cost to state public programs.

- This proposed mandate is estimated to have no fiscal impact on SEGIP.
- Commerce has determined that this proposed mandate would likely require partial defrayal under the Affordable Care Act, with an estimated cost of up to $520,000 in the first year.
- There is no estimated cost to state public programs.

Fiscal Impact Estimate for SEGIP

MMB does not estimate any fiscal impact on the state plan from this legislation. SEGIP currently provides coverage in its medical benefit package for orthotic and prosthetic devices. The durable medical equipment benefit requires member cost-sharing in the form of coinsurance (with the deductible also applying for plan enrollees in Cost Level 4).

ACA Mandate Impact and Analysis

States may require qualified health plan issuers to cover benefits in addition to the 10 EHBs defined by the ACA but must defray the costs, either through payments to individual enrollees or directly to issuers, and can partially defray the costs of proposed mandates if some of the care, treatment, or services are already covered in the state's benchmark plan or mandated by federal law, pursuant to section 1311(d)(3)(b) of the ACA.[29,30] For further defrayal requirements and methodology, please visit https://mn.gov/commerce/insurance/industry/policy-data-reports/62j-reports/.

If enacted, HF 3339/ SF 3351 would likely create a partial state benefit mandate beyond the 10 EHBs defined under the ACA, as new coverage requirements for bathing and recreational prosthetic and orthotic devices are not currently broadly required under Minnesota's benchmark plan.[31] The state's benchmark plan does include coverage for general orthotic and prosthetic devices, supplies, and services, and the ACA EHBs include coverage for "habilitative services and devices," which includes orthoses and prostheses as well as associated services.[31,32]

The cost of defrayal associated with HF 3339/ SF 3351 is estimated to be between $350,000 and $520,000 in the first year. Commerce based this estimate on data, methods, and assumptions that are consistent with those used by the Actuarial Research Corporation in their actuarial analysis, with adjustments to reflect enrollment and enrollee cost-sharing specific to the individual qualified health plan market.

Costs associated with defrayal are estimated to increase in future years due to expected medical cost trends as well as anticipated utilization increases because of the coverage requirement and projected increasing rates of diabetes and associated amputation.

Fiscal Impact on State Public Programs

There is no estimated cost to Minnesota public health coverage programs, as the state insurance mandate does not apply to public plans.

Appendix A. Bill Text

A bill for an act relating to insurance; requiring coverage for orthotic and prosthetic devices; authorizing rulemaking; proposing coding for new law in Minnesota Statutes, chapter 62Q.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[62Q.665] COVERAGE FOR ORTHOTIC AND PROSTHETIC DEVICES.**

Subdivision 1. **Definitions.** (a) For the purposes of this section, the following terms have the meanings given.

(b) "Accredited facility" means any entity that is accredited to provide comprehensive orthotic or prosthetic devices or services by a Centers for Medicare and Medicaid Services approved accrediting agency.

(c) "Orthosis" means:

(1) an external medical device that is:

(i) custom-fabricated or custom-fitted to a specific patient based on the patient's unique condition;

(ii) applied to a part of the body to correct a deformity, provide support and protection, restrict motion, improve function, or relieve symptoms of a disease, syndrome, injury, or postoperative condition; and

(iii) deemed medically necessary by a prescribing physician or licensed health care provider who has authority in Minnesota to prescribe orthotic and prosthetic devices, supplies, and services; and

(2) any provision, repair, or replacement of a device that is furnished or performed by:

(i) an accredited facility in comprehensive orthotic services; or

(ii) a health care provider licensed in Minnesota and operating within the provider's scope of practice which allows the provider to provide orthotic or prosthetic devices, supplies, or services.

(d) "Orthotics" means:

(1) the science and practice of evaluating, measuring, designing, fabricating, assembling, fitting, adjusting, or servicing and providing the initial training necessary to accomplish the fitting of an orthotic device for the support, correction, or alleviation of a neuromuscular or musculoskeletal dysfunction, disease, injury, or deformity;

(2) evaluation, treatment, and consultation related to an orthotic device;

(3) basic observation of gait and postural analysis;

(4) assessing and designing orthosis to maximize function and provide support and alignment necessary to prevent or correct a deformity or to improve the safety and efficiency of mobility and locomotion;

(5) continuing patient care to assess the effect of an orthotic device on the patient's tissues; and

(6) proper fit and function of the orthotic device by periodic evaluation.

(e) "Prosthesis" means:

(1) an external medical device that is:

(i) used to replace or restore a missing limb, appendage, or other external human body part; and

(ii) deemed medically necessary by a prescribing physician or licensed health care provider who has authority in Minnesota to prescribe orthotic and prosthetic devices, supplies, and services; and

(2) any provision, repair, or replacement of a device that is furnished or performed by:

(i) an accredited facility in comprehensive prosthetic services; or

(ii) a health care provider licensed in Minnesota and operating within the provider's scope of practice which allows the provider to provide orthotic or prosthetic devices, supplies, or services.

(f) "Prosthetics" means:

(1) the science and practice of evaluating, measuring, designing, fabricating, assembling, fitting, aligning, adjusting, or servicing, as well as providing the initial training necessary to accomplish the fitting of, a prosthesis through the replacement of external parts of a human body lost due to amputation or congenital deformities or absences;

(2) the generation of an image, form, or mold that replicates the patient's body segment and that requires rectification of dimensions, contours, and volumes for use in the design and fabrication of a socket to accept a residual anatomic limb to, in turn, create an artificial appendage that is designed either to support body weight or to improve or restore function or anatomical appearance, or both;

(3) observational gait analysis and clinical assessment of the requirements necessary to refine and mechanically fix the relative position of various parts of the prosthesis to maximize function, stability, and safety of the patient;

(4) providing and continuing patient care in order to assess the prosthetic device's effect on the patient's tissues; and

(5) assuring proper fit and function of the prosthetic device by periodic evaluation.

Subd. 2. **Coverage.** (a) A health plan must provide coverage for orthotic and prosthetic devices, supplies, and services, including repair and replacement, at least equal to the coverage provided under federal law for health insurance for the aged and disabled under sections 1832, 1833, and 1834 of the Social Security Act, United States Code, title 42, sections 1395k, 1395l, and 1395m, but only to the extent consistent with this section.

(b) A health plan may subject orthotic and prosthetic device coverage under this section only to an annual or lifetime dollar maximum that applies generally to all terms and services covered under the plan.

(c) A health plan must not subject orthotic and prosthetic benefits to separate financial requirements that apply only with respect to those benefits. A health plan may impose co-payment and coinsurance amounts on those benefits, except that any financial requirements that apply to such benefits must not be more restrictive than the financial requirements that apply to the health plan's medical and surgical benefits, including those for internal restorative devices.

(d) A health plan may limit the benefits for, or alter the financial requirements for, out-of-network coverage of prosthetic and orthotic devices, except that the restrictions and requirements that apply to those benefits must not be more restrictive than the financial requirements that apply to the out-of-network coverage for the health plan's medical and surgical benefits.

(e) A health plan must not subject coverage for orthotic and prosthetic devices, supplies, and services to any limitations for preexisting conditions.

(f) A health plan must cover orthoses and prostheses when furnished under an order by a prescribing physician or licensed health care prescriber who has authority in Minnesota to prescribe orthoses and prostheses, and that coverage for orthotic and prosthetic devices, supplies, accessories, and services must include those devices or device systems, supplies, accessories, and services that are customized to the covered individual's needs.

(g) A health plan must cover orthoses and prostheses determined by the enrollee's provider to be the most appropriate model that meets the medical needs of the enrollee for purposes of performing physical activities, as applicable, including but not limited to running, biking, and swimming, and maximizing the enrollee's upper limb function.

(h) A health plan must cover orthoses and prostheses for showering or bathing.

Subd. 3. **Prior authorization.** A health plan may require prior authorization for orthotic and prosthetic devices, supplies, and services in the same manner and to the same extent as prior authorization is required for any other covered benefit.

EFFECTIVE DATE. This section is effective August 1, 2023, and applies to all health plans offered, issued, or renewed on or after that date.

Sec. 2. **MEDICAL NECESSITY AND NONDISCRIMINATION STANDARDS FOR COVERAGE OF PROSTHETICS OR ORTHOTICS.**

(a) When performing a utilization review for a request for coverage of prosthetic or orthotic benefits, a health plan company shall apply the most recent version of evidence-based treatment and fit criteria as recognized by relevant clinical specialists. The commissioner may identify such criteria by rule.

(b) A health plan company shall render utilization review determinations in a nondiscriminatory manner and shall not deny coverage for habilitative or rehabilitative benefits, including prosthetics or orthotics, solely on the basis of an enrollee's actual or perceived disability.

(c) A health plan company shall not deny a prosthetic or orthotic benefit for an individual with limb loss or absence that would otherwise be covered for a nondisabled person seeking medical or surgical intervention to restore or maintain the ability to perform the same physical activity.

(d) A health plan offered, issued, or renewed in Minnesota that offers coverage for prosthetics and custom orthotic devices shall include language describing an enrollee's rights pursuant to paragraphs (b) and (c) in its evidence of coverage and any benefit denial letters.

(e) A health plan that provides coverage for prosthetic or orthotic services shall ensure access to medically necessary clinical care and to prosthetic and custom orthotic devices and technology from not less than two distinct prosthetic and custom orthotic providers in the plan's provider network located in Minnesota. In the event that medically necessary covered orthotics and prosthetics are not available from an in-network provider, the health plan company shall provide processes to refer a member to an out-of-network provider and shall fully reimburse the out-of-network provider at a mutually agreed upon rate less member cost sharing determined on an in-network basis.

(f) If coverage for prosthetic or custom orthotic devices is provided, payment shall be made for the replacement of a prosthetic or custom orthotic device or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions, if an ordering health care provider determines that the provision of a replacement device, or a replacement part of a device, is necessary because of:

(1) a change in the physiological condition of the patient;

(2) an irreparable change in the condition of the device or in a part of the device; or

(3) the condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device or of the part being replaced.

(g) Confirmation from a prescribing health care provider may be required if the prosthetic or custom orthotic device or part being replaced is less than three years old.

Appendix B. Key Search Terms for Literature Scan

Amputations

Amputee(s)

Artificial limbs

Device

Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS)

Gait training

Insurance coverage

Lower extremity surgery

Orthotics

Orthotics evaluation

Pediatrics

Prosthesis design

Prosthetic rehabilitation

Prosthetics

Prosthetics evaluation

Prosthetics repair

Prothesis

Rehabilitation

Services

Supplies

Appendix C. Associated Codes

Diagnosis (ICD-10) Code(s):

Name	Code
Acquired absence of limb	Z89
Amputation limb abnormal reaction/later complication	Y835
Avulsion & traumatic amputation of part of head	S08
Complications of peculiar reattachment and amputation	T87
Encounter fitting & adjustment external prosthetic	Z44
Encounter fitting & adjustment other specified device	Z4689
Flat foot pes planus acquired left foot	M2142
Flat foot pes planus acquired right foot	M2141
Flat foot pes planus acquired unspecified foot	M2140
Hallux valgus acquired left foot	M2012
Hallux valgus acquired right foot	M2011
Hallux valgus acquired unspecified foot	M2010
Metatarsalgia left foot	M7742
Metatarsalgia right foot	M7741
Metatarsalgia unspecified foot	M7740
Other acquired deformities of left foot	M216X2
Other acquired deformities of right foot	M216X1
Other acquired deformities of unspecified foot	M216X9
Pain in left foot	M79672
Pain in right foot	M79671
Pain in unspecified foot	M79673
Plantar fascial fibromatosis	M722
Presence of complete or partial artificial limb	Z791
Traumatic amputation of ankle and foot	S98
Traumatic amputation of breast	S282
Traumatic amputation of elbow and forearm	S58
Traumatic amputation of hip and thigh	S78
Traumatic amputation of lower leg	S88
Traumatic amputation of shoulder and upper arm	S48
Traumatic amputation of wrist, hand and fingers	S68
Valgus deformity NEC left ankle	M21072
Valgus deformity NEC right ankle	M21071

CPT/HCPCS Code(s):

Code type	CPT/ HCPCS	Procedure description
CPT	21086	Under prosthesis-impression and custom preparation
CPT	97760, 97761, 97763	Orthotic management and training and prosthetic training
HCPCS	L3000, L3020	Foot, insert, removable, molded to patient model
HCPCS	L2350	Add low extreme prosthetic type socket mold PT MDL
HCPCS	L2768	Orthotic side bar disconnect device per bar
HCPCS	L3913	Hand finger orthotic w/o joints custom fab
HCPCS	L4205, L4210	Repair orthotic device: labor and minor parts
HCPCS	L7510, L7520	Repair prosthetic device: labor and minor parts
HCPCS	L7600	Prosthetic donning sleeve any material each
HCPCS	L8400, L8410, L8420, L8430, L8435, L8440, L8460, L8470, L8480, L8485, L8499	Prosthetic sheath, sock or shrinker
HCPCS	S1040	Cranial remolding orthotic, rigid custom fabrication

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