Dear Oregon Pharmacy and Therapeutics Committee,

In response to the upcoming P&T posted agenda to review the Asthma class of medication, Amgen kindly requests consideration of the following information for TEZSPIRE® (tezepelumab-ekko).

Product Overview: TEZSPIRE® is a first-in-class severe asthma biologic that blocks thymic stromal lymphopoietin (TSLP), an epithelial cytokine located upstream in the inflammatory cascade. TEZSPIRE is the first and only biologic for severe asthma without phenotypic (eosinophilic/allergic) or biomarker limitations within its approved label.[1]

Indication: TEZSPIRE is indicated as an add-on maintenance treatment for patients 12 and older with severe asthma. TEZSPIRE is not indicated for the relief of acute bronchospasm or status asthmaticus and it is contraindicated in patients who have known hypersensitivity to tezepelumab-ekko or any of its excipients.[1]

Mechanism of Action: By inhibiting TSLP, TEZSPIRE reduces the levels of downstream mediators, including eosinophils, immunoglobulin E (IgE), FeNO, IL-5, and IL-13, thus reducing multiple drivers of airway inflammation in allergic and eosinophilic asthma. However, the mechanism of action in asthma has not been definitively established.[1,2]

Dosage and Administration: The recommended dosage of TEZSPIRE is 210 mg dose administered subcutaneously once every 4 weeks. TEZSPIRE is available as a Prefilled Syringe (PFS) for HCP administration and a Prefilled Pen (PFP) for HCP or self-administration.[1,2]

Efficacy of TEZSPIRE in Severe Uncontrolled Asthma: PATHWAY and NAVIGATOR Studies

Study Design: TEZSPIRE clinical trials program encompassed a broad, all-7comer severe asthma patient populations. PATHWAY (phase 2b, N = 550) and NAVIGATOR (phase 3, N = 1061) were multicenter, randomized, double-blind, placebo-controlled, 52-week trials in adults and adolescents with severe, uncontrolled asthma.[3,4]

Overall Results: TEZSPIRE treatment resulted in significant improvements vs placebo in asthma exacerbation, lung function, asthma symptom control, and health-related quality of life.[3,4]

AAER Results: TEZSPIRE significantly reduced annualized asthma exacerbation rates (AAERs) vs placebo:

- In PATHWAY, the AAER reduction was 71% (90% confidence interval [CI], 54%–82%; P < 0.001) vs placebo;[1,3,*†] in NAVIGATOR, the AAER reduction was 56% (95% CI, 47%–63%; P < 0.001) vs placebo.[4,*]
- The AAER that was associated with hospitalization, or an emergency department/urgent care visit was reduced by 79% vs placebo (95% CI, 63%-88%).[4,1] Results are descriptive only and from the NAVIGATOR study.

Lung Function Results: In NAVIGATOR, improvements in mean change from baseline in the prebronchodilator forced expiratory volume in 1 second (FEV1) were greater with TEZSPIRE (0.23) vs placebo (0.10) (difference 0.13 L; 95% CI, 0.08–0.18; P < 0.001).[1,4]

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*PATHWAY AAER: 0.20 for TEZSPIRE + SOC (n = 137) vs 0.72 for placebo + SOC (n = 138); RR 0.29 (95% CI, 0.16–0.51); NAVIGATOR AAER: 0.93 for TEZSPIRE + SOC (n = 528) vs 2.10 placebo + SOC (n = 531); RR 0.44 (95% CI, 0.37–0.53).

†NAVIGATOR AAER associated with hospitalizations/ED/urgent care visits: 0.06 for TEZSPIRE + SOC (n = 528) vs 0.28 for placebo + SOC (n = 531); RR 0.21 (95% CI, 0.12–0.37)

Symptom Control and QOL Results: Patients treated with TEZSPIRE had greater clinically meaningful improvements in ACQ-6 and AQLQ(S)+12, compared to placebo. Clinically meaningful improvement (responder rate) for both measures was defined as improvement in score of 0.5 or more.[1]

- In NAVIGATOR, the ACQ-6 (Asthma Control Questionnaire-6) responder rate for TEZSPIRE was 86% vs 77% for placebo (OR = 1.99; 95% CI, 1.43–2.76).[1]
- In NAVIGATOR, the AQLQ(S)+12 (Asthma Quality of Life Questionnaire with standardized activities for ages 12+) responder rate for TEZSPIRE was 78% vs 72% for placebo (OR = 1.36; 95% CI,1.02–1.82).[1]

TEZSPIRE Data Across Phenotypic Profiles and Biomarker Levels. Data presented are descriptive only: Reductions in the AAERs were observed across biomarker levels and clinically relevant subgroups, including: blood eosinophil (bEOS) levels, allergic status, and history of nasal polyps.[5]

TEZSPIRE has an established safety profile. Most common adverse reactions (incidence ≥ 3% and more common than placebo) are pharyngitis, arthralgia, and back pain.[1]

Comparative Data: Due to a lack of head-to-head trials with other biologics, an indirect-treatment comparison analysis was conducted and showed that TEZSPIRE had numerically greater reductions in exacerbations overall—and those leading to hospitalizations—compared to other asthma biologics. Two distinct statistical methodologies (NMA and STC) were used to assess the robustness of the comparison, and subgroup and sensitivity analyses were performed to address data heterogeneity across trials. The results were consistent across these approaches.[6]

The following were the NMA rate ratios (95% CI) vs. placebo for AAER and AAER leading to hospitalizations, respectively:[6]

- Tezepelumab (TEZSPIRE): 0.37 (0.23–0.57), 0.19 (0.07–0.47)
- Dupilumab (Dupixent): 0.44 (0.28–0.67), 0.54 (0.16–1.92)
- Mepolizumab (Nucala): 0.45 (0.29–0.69), 0.35 (0.13–0.89)
- Omalizumab (Xolair): 0.61 (0.46–0.82), 0.47 (0.17–1.15)
- Benralizumab (Fasenra): 0.59 (0.42–0.82), 0.54 (0.23–1.53)
- Reslizumab (Cinqair): 0.45 (0.30–0.69), 0.65 (0.25–1.63)

Recent Clinical Practice Recommendations: TEZSPIRE is included in the 2025 Global Initiative for Asthma (GINA) recommendations as an add-on biologic therapy option for patients with type 2 (e.g. allergic and/or eosinophilic) and non-type 2 severe asthma.[7]

Summary: TEZSPIRE is the first and only biologic to consistently and significantly reduce asthma exacerbations across Phase 2 and 3 clinical trials which included a broad population of severe asthma patients irrespective of key biomarkers, including bEOS counts and allergic status.[3-5] Therefore, TEZSPIRE could offer potential benefit for severe asthma patients regardless of their asthma phenotype, including those who may not be clinically eligible for other available therapies.[5,6]

We respectfully request that TEZSPIRE be included on the State Preferred Drug List as a Preferred Agent with coverage criteria aligned to the label with no phenotypic or biomarker requirements.

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ADBRY® (tralokinumab-ldrm): State Medicaid Testimony

This **reactive** document is a written testimony intended to summarize key points for the review of tralokinumab. Tralokinumab was approved by the FDA on December 27, 2021. **Please see Full Prescribing Information available at ADBRYHCP.com.**

Indication, Mechanism of Action, Dosage and Administration

- Tralokinumab is the first biologic developed to specifically target and neutralize IL-13, one of the key cytokines driving inflammation in AD.[1-3]
- Indicated for the treatment of moderate-to-severe AD in patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Tralokinumab can be used with or without TCS.[4]
- The recommended adult dosage of tralokinumab, administered subcutaneously, is an initial loading dose of 600 mg, followed by 300 mg administered every other week. A dosage of 300 mg every 4 weeks (Q4W) may be considered for patients <100 kg or 220 lbs. who achieve clear or almost clear skin after 16 weeks of treatment. Adults have the option to use the autoinjector, requiring half the number of injections compared to the prefilled syringe, which will continue to be available.[4]
- The approved dose for patients aged 12 to 17 years is half that of the adult dose. The adolescent dose is an initial loading dose of 300 mg (two 150 mg injections), followed by 150 mg (one 150 mg injection) administered every other week[4] without the option of a monthly maintenance dose.

Treatment Guidelines

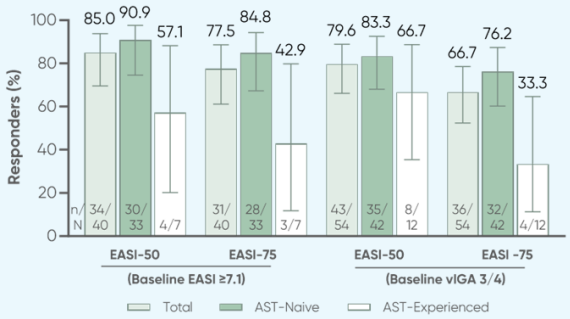
American Academy of Dermatology (AAD) and American Academy of Allergy, Asthma, & Immunology (AAAAI) guidelines for the systemic treatment of AD

- Both major guidelines for the management of moderate-to-severe AD recently updated to include a strong recommendation for tralokinumab as a first-line systemic therapy.[5-6]

Real-World Evidence

Tralokinumab has been studied in over 30 real-world analyses and case reports.[7-35] Three larger studies are summarized below:

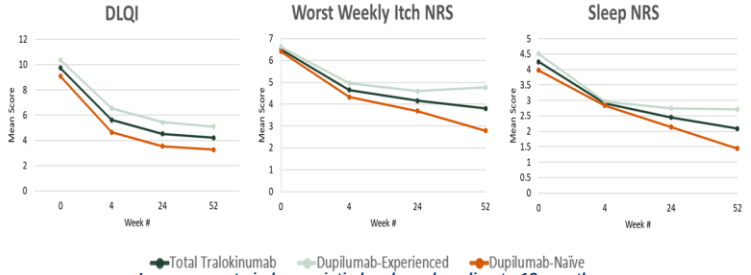
- **Study 1:** The CorEvitas AD Registry is a prospective, non-interventional registry. An effectiveness analysis using descriptive statistics included US patients who initiated tralokinumab between February 1, 2022, and May 31, 2023, had baseline data, and were persistent on tralokinumab at the 6-month follow-up was conducted. Data were stratified by advanced systemic therapy (AST) experience (dupilumab, abrocitinib, upadacitinib, or none). Total persistence was 74.1% among 81 patients with 6-month visits. Persistence among AST-naïve patients was 81.5%. EASI and pruritus NRS improvements in both groups were observed at the 6 months.[36-37]



Improvement in clinician-assessed outcomes at 6 months

- **Study 2:** A 12-month analysis* of 107 patients was conducted using data from specialty pharmacies dispensing tralokinumab through LEO Pharma's savings and support programs. Improvements in DLQI, worst weekly itch NRS, and sleep NRS were seen in both dupilumab-naïve and dupilumab-experienced groups. Among the total population, only 28.0% of patients were using TCS at week 52 vs. 48.6% at baseline. [38]

*Patient-reported outcomes were reported as the change in score or percentage change in score from baseline to week 52.



Improvements in humanistic burden – baseline to 12 months

- **Study 3:** TRACE is a non-interventional, single cohort study across 167 global sites. In three separate interim sub-analyses with up to 9 months of treatment with tralokinumab, difficult-to-treat areas of AD were examined, including head (face/scalp) and neck, genitals, and hand/foot. 79.5% of the total population had head/neck involvement, 14.9% had genital involvement, and 59.8% had hand/foot involvement. For head/neck and hand/foot disease, data were stratified by previous treatment experience with dupilumab. Improvements in IGA, DLQI, and sleep NRS were observed for all measures in all body areas studied, including previous dupilumab utilizers. Responses to therapy deepened over time with further treatment.[39-41]

Real-World Evidence* for Q4W Dosing

Q4W dosing for tralokinumab was evaluated in 2 recent analyses. Results ranged from 16.3% to 31.6%*

- In up to an 18-month claims-based analysis using Komodo Research Database, 584 patients were on tralokinumab for at least 6 months. 16.3% followed Q4W dosing frequency after week 16, while 29.6% followed Q4W dosing frequency at any point after the index date.[42]
- In a second retrospective analysis, data from the specialty pharmacies that dispensed Adbry through LEO Pharma's savings and support programs were used to calculate patients' average dose per 28 days and estimate the percentage of patients likely on a Q4W dosing schedule. In this cohort of 3678 patients, 1162 (31.6%) were calculated to have averaged less than 1.5 doses in 28 days, which qualified as Q4W dosing in this analysis. Patients' average dose per 28-day period was based on the interval between a patient's 16-week date and their last shipment date. During that time, patients may have discontinued or missed doses for any reason.[43]

AD, atopic dermatitis; DLQI, dermatology life quality index; EASI, Eczema Severity Area Index; IL, interleukin; NRS, Numerical Rating Scale; TCS, topical corticosteroids.

Cost-Per-Responder Analysis from Matching-Adjusted Indirect Comparison (MAIC)

Through an indirect comparison of efficacy assessing EASI-75 and IGA 0/1 at 52 weeks among week 16 responders, tralokinumab was compared with lebrikizumab. An anchored MAIC analysis was conducted using individual patient data (IPD) from patients in the ECZTRA 1 & 2 tralokinumab trials and aggregate data from patients in the ADvocate 1 & 2 lebrikizumab trials. Tralokinumab IPD were weighted to match the baseline and Week 16 characteristics of the lebrikizumab patients. Maintenance of efficacy after 52 weeks was comparable between initial responders to both therapies.[44] The cost-per-responder was calculated by multiplying the cost of each biologic with the expected Number Needed to Treat (NNT). At 52 weeks, tralokinumab demonstrated lower overall treatment costs and cost-per-responder than lebrikizumab for EASI-75 at Q2W and Q4W dosing, EASI-90 at Q2W and Q4W dosing, and IGA 0/1 at Q2W dosing.[45]

Limitations: There are currently no head-to-head trials comparing FDA-approved biologics for the treatment of moderate-to-severe atopic dermatitis. Indirect treatment comparison studies are not representative of head-to-head trials that directly compare biologics. These indirect studies may introduce potential bias and make comparisons between studies that can vary in design and methodology.

Efficacy

Efficacy of Q4W dosing in 3 pivotal trials

- Q4W dosing was shown to be effective in weeks 16-32 (ECZTRA 3) or 52 (ECZTRA 1 and 2) in all three pivotal trials, representing a flexible maintenance dosing option for eligible* adult patients and HCPs.[48,49]

*Adult patients below 100 kg who achieved clear or almost clear skin after 16 weeks of treatment

Shown to reduce worst daily pruritis in four Phase 3 clinical trials

- Tralokinumab was shown to be effective in meeting the primary endpoints (EASI-75 and IGA 0/1) and the reduction of worst daily pruritus Numeric Rating Scale (NRS) weekly average of ≥4 points, in four Phase 3 pivotal, double-blind, placebo-controlled, randomized clinical trials as monotherapy in ECZTRA 1 (N=798), ECZTRA 2 (N=770), ECZTRA 6 (N=289), and in combination with TCS (mometasone furoate 0.1% cream) as needed in ECZTRA 3 (N=366) at 16 weeks, and maintained with long- term treatment (32 weeks, ECZTRA 3; 52 weeks, ECZTRA 1, 2, 6).[4,47-49]

Rapid improvement in patient-reported outcomes (PROs)

In a post-hoc analysis of pooled data for ECZTRA 1 & 2 (N=1596) and ECZTRA 3 (N=380), there was significant early improvement vs placebo in weekly average of symptoms. Improvement continued through week 16.[50]

- Worst daily pruritus NRS:
  Week 1 (ECZTRA 1 and 2, difference 5.6%; P<0.001) or week 2 (ECZTRA 3, difference 6.2%; P<0.03)
- Worst daily eczema-related sleep interference:
  Week 1 (ECZTRA 1 and 2, difference 7.4%; P<0.001,) or week 2 (ECZTRA 3, difference 3.7%; P<0.047)

Patients who received rescue medication were considered non-responders. Patients with missing data at week 16 were imputed as non-responders.

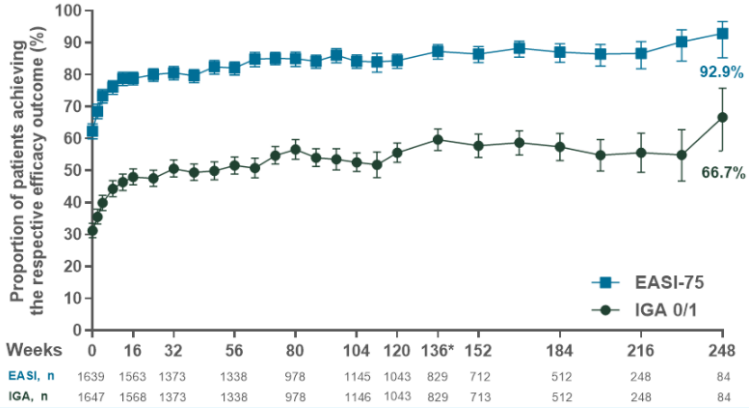
Please see Full Prescribing Information in Section 14, Table 2.

ECZTEND 6-Year Data

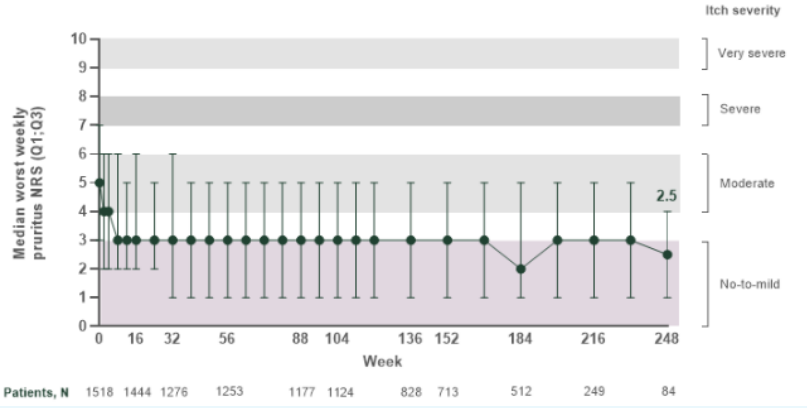
ECZTEND: long-term extension evaluating safety and efficacy of tralokinumab in patients treated for up to 6 years

- Continuous use of tralokinumab ± optional TCS demonstrated sustained efficacy, with EASI-75 and IGA 0/1 observed in 92.9% and 66.7% of patients at Week 248, respectively.[51]
- Safety findings were consistent with the known profile of tralokinumab, with no new safety signals detected.
- Itch severity was maintained at levels equivalent to no-to-mild in adult patients.

Limitations and context associated with the open-label study design include decreasing sample size, potential continued involvement of responders, and attrition of non-responders. Data presented are descriptive in nature and no statistical comparisons are made.



Proportion of patients achieving IGA 0/1 and EASI-75 as observed over 248 weeks of treatment in ECZTEND



Median worst weekly pruritus NRS as observed over 248 weeks of treatment in ECZTEND

Safety

AEs in the initial treatment period at week 16 were comparable to the maintenance treatment periods at weeks 32 and 52[47-49]

- Most common adverse reactions (incidence ≥1%) were upper respiratory tract infections, conjunctivitis, injection-site reactions, and eosinophilia.[4]
- No requirement for initial lab tests or ongoing lab monitoring. There is no boxed warning in the tralokinumab Prescribing Information.[4]

Open-label, long-term extension data showed that the use of tralokinumab for up to 6 years revealed no new safety signals.[51]

- In a long-term, open-label extension trial, the pattern of AEs was consistent with previously reported data with no new safety signals.
- The incidence rate (n/100 PYE) of discontinuations due to AEs was 1.71.

Please see Full Prescribing Information in Section 14, Table 2.

Summary

Tralokinumab represents a therapeutic option in the treatment paradigm of moderate-to-severe AD in patients 12 years and older.

- First-approved and only fully human anti-IL-13 monoclonal antibody to treat AD. Up to 6 years of safety and efficacy data. Suite of real-world evidence, including first-line treatment and dupilumab-experienced patients.[1-4,7-42,51]
- Only anti-IL-13 to be guideline-endorsed as first-line systemic therapy in moderate-to-severe AD.[5-6]
- Only anti-IL-13 to offer flexible dosing* once skin clearance is achieved. Uptake rate of Q4W dosing in RWD indicates patients and providers value optionality in AD therapies.[4,42-43]

Please see Full Prescribing Information available at ADBRYHCP.com.

*Adult patients below 100 kg or 220 lbs. who achieved clear or almost clear skin after 16 weeks of treatment

AAD, American Academy of Dermatology; AAAAI, American Academy of Allergy, Asthma and Immunology; EASI, Eczema Severity Area Index; HCP, healthcare professional; IR, incident rate; N, number; PYE, patient years of exposure; Q, quartile; Q2W/Q4W, every 2/4 weeks; RWE, real-world evidence; SD, standard deviation; TCS, topical corticosteroids.

**Real-world evidence limitations: These results were not from a randomized trial. Data presented are descriptive in nature, whereby no statistical comparisons are made. Patients and single-arm treatments were unblinded and unrandomized. Generalizability of results may be limited due to sample size.

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National
Multiple Sclerosis
Society

September 9, 2025

Oregon Pharmacy & Therapeutics Committee
College of Pharmacy, Oregon State University
Corvallis, Oregon

RE: Multiple Sclerosis drug class reviews for October 2, 2025, Oregon Pharmacy & Therapeutics Committee

Thank you for the opportunity to offer comments to the Pharmacy & Therapeutics Committee meeting for October 2025. The National Multiple Sclerosis Society (the Society) appreciates the time and care that is required to design a complete and cost-effective formulary for state plans. Our comments today relate to the preferred/non-preferred classification of multiple sclerosis disease modifying therapies (DMTs) and the need for continued access to the full suite of available and approved medications. **The National Multiple Sclerosis Society urges you to provide access to the full range of MS disease-modifying therapies** – with consideration to efficacy, route of administration, mechanism of action, and interchangeability or non – as well as other medications to treat the disease symptoms to ensure the needs of every individual are met.

MS is an unpredictable disease of the central nervous system. Currently, there is no cure. Symptoms vary from person to person and may include disabling fatigue, mobility challenges, cognitive changes, and vision issues. An estimated one million people live with MS in the United States. Early diagnosis and treatment are critical to minimizing disability. Significant progress is being made to achieve a world free of MS.

No single agent is 'best' for all people living with MS, and, as MS presents differently in each person, every person's response to a DMT will vary. Early and ongoing treatment with a DMT is the only way to modify the course of the disease, slow the accumulation of disability and protect the brain from damage due to MS. People with MS and their treating clinicians require access to the full range of treatment options that represent different mechanisms of action and routes of administration with varying efficacy, side effects, and safety profiles.

It is common for people with MS to move through several different DMTs throughout their life with MS, as they "breakthrough" on medication - have disease activity or need to try a different DMT. Delays or disruptions in treatment can risk permanent, irreversible disease progression, worse health outcomes, and increased healthcare costs over time. Managing MS can be a difficult process that requires several "trial and error" changes to the

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medication before finding the one most effective at controlling disease progression with the fewest negative side effects for each individual.

Access to the full range of options is essential for optimal MS management.
Early and ongoing treatment with a DMT is the best way to modify the course of the disease, slow the accumulation of disability and protect the brain from damage due to MS.[1] According to a consensus paper by the MS Coalition, people with MS and their treating clinicians require access to the full range of treatment options for several reasons[2]:

- Individual differences related to tolerability and adherence may necessitate access to different medications within the same class.
- Individuals' access to treatment should not be limited by their frequency of relapses, level of disability, or personal characteristics such as age, sex, or ethnicity.
- Different mechanisms of action allow for treatment change in the event of a sub-optimal response.
- Potential contraindications limit options for some individuals.
- Risk tolerance varies among people with MS and their treating clinicians.
- Route of delivery and side effects may affect adherence and quality of life.
- Absence of relapses while on treatment is a characteristic of treatment effectiveness and should not be considered a justification for discontinuing treatment.
- Treatment should not be withheld to allow for determination of coverage by payers as this puts the patient at risk for recurrent disease activity.

Prior Authorization
Following a diagnosis of relapsing MS, the initiation of treatment with an FDA-approved disease-modifying treatment is recommended as soon as possible. Movement from one disease-modifying treatment to another should occur only for medically appropriate reasons as determined by the treating clinician and patient. Because prior authorization reviews can sometimes result in delays or disruptions in treatment, the National MS Society supports standards to streamline and strengthen prior authorization reviews. Physicians report that they alter their treatment course to save time; **76 percent of physicians** have stated that they changed treatments to avoid dealing with the prior authorization process. **For patients living with serious or chronic illnesses like MS,**

[1] The Multiple Sclerosis Coalition has published an evidence-based consensus paper entitled The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. This document was developed and endorsed by the eight Coalition member organizations and subsequently endorsed by the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS). The paper is designed to: summarize current evidence about disease modification in MS; highlight the importance of early and ongoing treatment; and provide support for broad access to FDA-approved MS disease-modifying therapies for people with MS in the United States.
[2] https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf

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prolonging ineffective treatment (and delaying access to the right treatment) may result in increased disease activity, loss of function and possible irreversible progression of disability. The Society urges reasonable solutions to make the process more transparent, timely, and user-friendly

Considering this information, **we ask the Oregon Pharmacy and Therapeutics Committee to lessen the number of restrictions placed on prescribing DMTs and provide access to the full range of MS DMTs and other medications used to treat symptoms of the disease.** We strongly believe people with MS should be at the center of their healthcare decision-making, and that they and their physicians must be allowed to determine the most appropriate medication through a shared decision-making process that considers individual factors.

Thank you for your work on behalf of all Oregonians. The Society is here to serve as a resource and advocate for medications and services critical for people living with and affected by MS. Please contact Seth Greiner, Senior Manager of Advocacy, with any questions or clarifications.

Sincerely,

Seth M. Greiner
Senior Manager, Advocacy
Seth.Greiner@NMSS.org