Tolebrutinib for Secondary Progressive Multiple Sclerosis: Final Policy Recommendations

JULY 15, 2025

Policy Recommendations

Introduction

The following policy recommendations reflect the main themes and points made during the Policy Roundtable discussion at the June 13, 2025, CTAF public meeting on the use of tolebrutinib for the treatment of secondary progressive multiple sclerosis (SPMS). At the meeting, ICER presented the findings of its revised report on these treatments, and the CTAF voting council deliberated on key questions related to their comparative clinical effectiveness, potential other benefits and contextual considerations. Following the votes, ICER convened a Policy Roundtable of two patient experts, two clinical experts, two payers, and one representative from a pharmaceutical manufacturer to discuss how best to apply the evidence and votes to real-world practice and policy. The discussion reflected multiple perspectives and opinions, and therefore, none of the statements below should be taken as a consensus view held by all participants.

A recording of the conversation can be accessed here, and a recording of the voting portion of the meeting can be accessed here. More information on Policy Roundtable participants, including conflict of interest disclosures, can be found in the appendix of this document. ICER's report on these treatments, which includes the same policy recommendations, can be found here.

The roundtable discussion was facilitated by Sarah Emond, President and Chief Executive Officer at ICER. The main themes and recommendations from the discussion are organized by audience and summarized below.

All Stakeholders

Recommendation 1: Health Equity

All stakeholders have a responsibility and an important role to play in ensuring that effective new treatment options for patients with non-relapsing SPMS (nrSPMS) are introduced in a way that will help reduce health inequities.

Safe and effective treatment for nrSPMS, especially for those with non-active disease, remains a significant unmet health care need. Efforts are needed to ensure that new therapies for nrSPMS, such as tolebrutinib, improve the health of patients and families and do not aggravate existing health inequities. Clinical experts and patients highlighted several existing inequities in care for SPMS, including unequal access to best supportive care, biases in the healthcare system that increase barriers for minoritized populations, knowledge gaps in the diagnosis of SPMS, the lack of data on the relative efficacy of treatments for SPMS in minority populations, as well as barriers to treatment access, including high costs and inadequate insurance coverage. A specific example in the

SPMS population is the difficulty persons living with SPMS have obtaining continued access to high quality physical therapy by therapists, in part due to a payment model that is predicated on "improvement" of function, whereas for patients with a progressive disease like SPMS, maintenance or slowing of decline is a more appropriate goal.

Safe treatment with tolebrutinib will likely include close monitoring of liver function tests, given the risk of severe liver toxicity from the drug. In populations that already have challenges with mobility and accessing care, the requirement for intensive lab monitoring without adequate support may limit access to treatment or place patients at greater risk of serious adverse events.

To address these concerns:

Manufacturers should take the following actions:

- Set the price for new treatments in fair alignment with added benefits for patients.
- Take steps necessary to include a more diverse patient population in MS clinical trials, including numbers of Black and Hispanic patients that are representative of their prevalence in the MS population.

Payers should take the following actions:

- Ensure that benefit designs developed in conjunction with employers and other plan sponsors do not create requirements for out-of-pocket spending that create major barriers to appropriate access for vulnerable patients.
- Ensure that their coverage networks include access to MS specialists who have the expertise to diagnose and treat nrSPMS. Given the scarcity of MS specialists, this may need to include coverage of peer consultations by neurologists, as well as telemedicine consultations across state lines.
- Ensure that patients have easy and equitable access to laboratory testing. This may include broadening laboratory network coverage such that patients are able to obtain laboratory testing at the most convenient location to them, and given the mobility challenges of the SPMS population, wraparound services such as transportation to obtain laboratory services and coverage of mobile phlebotomy services.
- Ensure full coverage of standard of care treatment, such as continued high quality physical therapy without requiring therapists to certify improvement to continue therapy.

Clinical specialty societies should take the following actions:

- Develop and disseminate educational materials to educate clinicians about the diagnosis and treatment of SPMS.
- Continue to use their voices to help advocate for better access to physical therapy for patients.

Patient advocacy groups should take the following actions:

- Develop and disseminate educational materials to ensure that people living with RRMS are aware of the potential transition to SPMS and ways of decreasing the risk of developing SPMS, including adherence to disease-modifying therapies (DMTs).
- Continue to advocate for adequate access to physical therapy to help maintain function.

Policymakers should take the following actions:

- Require commercial payers and Medicaid to follow Medicare's policy of not using an "Improvement Standard" as qualification for continued therapies or other services, as outlined in the *Jimmo v. Sibelius* settlement[1]. This will ensure that all MS patients have continued access to high quality physical therapy for maintenance of mobility.

Recommendation 2

All stakeholders should work together to support the development and implementation of improved measures of disease severity and outcomes that are meaningful to patients.

Clinical experts and patient representatives commented on the insufficiency of the EDSS scale in capturing many symptoms that affect the daily life of SPMS patients, as ambulatory ability may not fully reflect level of disability. For example, patient representatives mentioned that fatigue, cognition, bladder function, and upper extremity strength are not adequately captured in EDSS scores. While numerous other outcome measures such as the 9-hole peg test (measures upper extremity function), MSQoL-54 (measures quality of life), and the Multiple Sclerosis Functional Composite (MSFC) (composite measure) have been developed, clinical trials still most often use EDSS as a primary assessment of function, primarily due to regulatory agency preferences. However, EDSS may be less sensitive to disability progression in progressive forms of MS like SPMS, compared to relapsing-remitting MS (RRMS)[2]. Additionally, clinical experts advocated for the development of better cognitive function screening tests, citing the limitations of the commonly used Symbol Digit Modalities Test (SDMT). Development and validation of new measures will require the collaboration of researchers, funders, clinicians, and patients to ensure applicability and

feasibility to everyday clinical practice. Manufacturers and regulators should also endeavor to include such outcomes in clinical trials. Patient groups can take a leading role in collecting real-world data, as well as collaborating with researchers, manufacturers, and regulators to define patient-important severity and outcome measures and then in promoting their use in all clinical trials.

Payers

Recommendation 1

When approval of a drug that represents a first-in-class therapy for an underserved population is anticipated, payers should be evaluating the evidence and preparing policies in advance to avoid a new-to-market block on insurance coverage.

Many payers now institute "new-to-market" policies that block routine insurance coverage for new drugs up to 180 days after U.S. Food and Drug Administration (FDA) approval, and in some cases longer. Although in principle these blocks can be justified to allow an insurer adequate time to review the clinical evidence, discuss with clinical experts, and prepare special delivery or other policies, in practice, many insurers now place new-to-market blocks on virtually any new specialty drug. In the case of a progressive disease such as nrSPMS where earlier treatment is important to slowing or stopping progression, payers should recognize their responsibility to act prior to FDA approval to ensure that their coverage policies are ready at the time of approval. This preparation is facilitated when manufacturers share data in a timely and transparent way and engage with payers prior to the approval of their products to facilitate establishment of payment policies. Since SPMS is associated with higher costs and disability, prompt access to new therapies that slow disease progression could result in a reduce the increase in costs over the long term.[3]

Recommendation 2

Payers may wish to consider negotiating outcomes-based contracts for therapies such as tolebrutinib that are likely to be high cost but where the benefit is less certain.

Outcomes-based contracts are increasingly being used for high-cost therapies. Although such contracts are more common for potentially curative therapies such as gene therapies, use of outcomes-based contracts may be reasonable for tolebrutinib given the uncertainties in benefit, particularly in the long-term. For example, payers could follow the example set by Colorado Medicaid in negotiating outcomes-based contracts for dupilumab (https://hcpf.colorado.gov/press-release/colorado-medicaid-fifth-pharmaceutical-value-based-contract). In such cases, the payer pre-selects targets based on severity and progression (e.g., symptom measures) or based on spending reflected in claims. If those thresholds are not reached, then payers would receive rebates from the manufacturer.

Recommendation 3

Trial inclusion criteria are a reasonable starting point for developing coverage policies for tolebrutinib to identify patients with SPMS. Payers should engage clinical experts and patient representatives in considering how to address coverage requests for which there is limited or no evidence at the current time.

Given the challenge of diagnosing SPMS, the uncertainty that remains about the safety and effectiveness of tolebrutinib for nrSPMS, and the expected high cost of this therapy, it is reasonable for payers to use prior authorization as a component of coverage. Prior authorization criteria should be based on clinical evidence and input from clinical experts and patient groups. The process for authorization should also be clear, accessible, efficient, and timely for providers. Perspectives on specific elements of cost sharing and coverage criteria within insurance coverage policy are discussed below. Relevant criteria set out in ICER's previous work Cornerstones of "Fair" Drug Coverage: Appropriate Cost-Sharing and Utilization Management Policies for Pharmaceuticals are included.

Cost Sharing

• Patient cost sharing should be based on the net price to the plan sponsor, not the unnegotiated list price.

• For drugs that will be first-in-class for treating an underserved population, such as tolebrutinib for the subset of nrSPMS patients with non-active disease, there should be little to no cost-sharing.

Coverage Criteria: General

ICER has previously described general criteria for fair coverage policies that should be considered as cornerstones of any drug coverage policy in the report: Cornerstones of "Fair" Drug Coverage: Appropriate Cost-Sharing and Utilization Management Policies for Pharmaceuticals.

Drug-Specific Coverage Criteria: Tolebrutinib

The difficulty in identifying the appropriate patients for treatment with tolebrutinib, combined with the potential for side effects and the high annual prices for newer generation treatments, will lead payers to develop prior authorization criteria and to consider other limits on utilization.

None of these limits, however, should undermine the tenets of fair access to which all patients have a fundamental right.[4] To explore the appropriate application of evidence to coverage policy, and to reflect the views of patient experts and clinicians on specific ways that payers might appropriately use coverage policy to manage resources prudently, we present the following perspectives on specific elements of cost sharing and coverage criteria for tolebrutinib.

Coverage Criteria Consideration for Tolebrutinib

- **Age:** This treatment is likely to be covered for adult patients with nrSPMS. Clinical trial eligibility criteria excluded people living with nrSPMS over the age of 60, thus, there may be greater uncertainty in outcomes for older patients and a differing risk/benefit ratio. However, given the lack of current FDA-approved treatment options for the subset of nrSPMS patients with non-active disease and the fact that a substantial proportion of SPMS patients are over the age of 60, it seems unlikely that payers will use clinical trial eligibility age criteria (≥18 and ≤ 60 years old) to narrow coverage.

- **Clinical eligibility**: Clinical experts advised that the diagnosis of SPMS is challenging, as it is a retrospective diagnosis and there are no specific biomarkers suggesting the transition from RRMS to SPMS. It is reasonable for payers to use the clinical trial eligibility criteria to identify whether patients have nrSPMS. However, given the uncertainties in the diagnosis, payers should also consider allowing for clinician attestation to identify appropriate candidates for treatment.

- **Exclusion criteria**: Payers will likely use the medical exclusions from the clinical trial eligibility criteria. There are currently no data on the use of tolebrutinib in combination with existing disease-modifying therapies (DMTs), so it is reasonable for payers to restrict the use of the drug to those patients not currently on DMTs.

- **Dose:** Tolebrutinib is dosed at 60 mg once daily.

- **Duration of coverage and renewal criteria**: Initial coverage will likely be for a period of 6 to 12 months, which is long enough for assessment of tolerability. For continuation of therapy, given the risk of toxicity, payers are likely to require clinical attestation that the patient is still an appropriate candidate for treatment.

- **Provider restrictions**: Given the difficulty in diagnosing SPMS and the potential severe liver toxicity of tolebrutinib, it is reasonable to restrict prescriptions to MS specialists or to general neurologists in consultation with MS specialists. Specialty clinicians are better suited to identify patients who are most likely to benefit, provide sufficient information for patients to make a well-informed decision, and monitor for response.

- ***Step Therapy***

- A subset of patients with nrSPMS have disease activity on MRI and would be considered to have active SPMS. There are multiple current DMTs approved for active SPMS, and it is reasonable for payers to require that patients with active SPMS trial currently available DMTs before tolebrutinib. However, patient representatives raised the concern about requirements to re-step through previously tried therapies that failed to work for them when insurance changed. If payers institute step therapy for the active SPMS population, it should be tailored in a clinically responsible fashion to avoid unnecessary trials of previous therapies that did not work that may delay care and cause poor outcomes.

Manufacturers

Recommendation 1

Manufacturers should set prices that will foster affordability and good access for all patients by aligning prices with the patient-centered therapeutic value of their treatments. In the setting of a new intervention for nrSPMS, while there is considerable hope associated with the promise of tolebrutinib, there also remains substantial uncertainty regarding its effectiveness and safety. Manufacturer pricing should also reflect these considerations by moderating launch pricing.

Drug prices that are set well beyond the cost-effective range cause not only financial toxicity for patients and families using the treatments but also contribute to general health care cost growth that pushes families out of the insurance pool, and that causes others to ration their own care in ways that can be harmful.

Manufacturers should therefore price novel treatments in accordance with the demonstrated benefits to patients. In the case of tolebrutinib, where there is some uncertainty of net health benefit, initial pricing should err on the side of being more affordable. This would allow more patients access, generating additional data on the real-world effectiveness of novel treatments that could be used in future assessment updates. With the accumulation of evidence of substantial patient benefit, manufacturers should be allowed to increase pricing in accordance with benefit.

Recommendation 2

Manufacturers have a responsibility to release clinical trial data in a timely manner such that all relevant data is available to payers, clinicians, and patients prior to the time of FDA approval to facilitate timely coverage and treatment decisions.

The release of clinical trial data relating to the efficacy and safety of a new therapy has traditionally taken place in conjunction with major scientific meetings. However, the timelines of such meetings may not align with the regulatory process. For example, in the case of tolebrutinib, data on some

secondary outcomes and subgroups were not made available with the main publication of the clinical trial findings. The manufacturer has indicated that more data will be presented at a major European MS conference taking place at the end of September 2025; however, the potential regulatory action date for tolebrutinib is also in late September 2025. Therefore, payers and other purchasers may not have access to the data needed to make decisions about coverage policies, and clinicians and patients may not have the information needed to make fully informed decisions about treatment at the time of FDA approval. Manufacturers should work with medical journals and conference organizers to ensure that data embargoes do not inhibit timely access to relevant data.

Recommendation 3

The manufacturer should work with payers to assist clinicians and patients with any potential monitoring costs for liver toxicity, including for laboratory tests.

Given the potential for severe liver toxicity from tolebrutinib and the intense laboratory monitoring required during the clinical trials, it is possible that the FDA will require a Risk Evaluation and Mitigation Strategies (REMS) program upon approval of tolebrutinib. Under a REMS program, the manufacturer is responsible for setting up and implementing a monitoring program. However, there may be costs that are borne by the patient, such as fees for laboratory testing. Given the intensity of testing necessary for safe administration of tolebrutinib, the manufacturer should work with payers, clinicians, and patients to ensure easy access to laboratory testing and minimize any costs to clinicians, patients, and the health system for required monitoring. This should occur whether or not a REMS program is required.

Clinicians and Clinical Societies

Recommendation 1

Ensure timely updates to treatment guidelines for patients with SPMS to reflect current treatment options in a form that is easy to interpret and use by clinicians, patients, and payers.

The most recent clinical practice guidelines from the American Academy of Neurology for the treatment of MS were published in 2018. Clinical societies should have processes in place to be able to update their practice guidelines quickly when new therapies such as tolebrutinib that may change clinical practice are approved, since payers base their coverage decisions and integration of utilization management tools to a great extent on clinical guidelines. Clinical societies should follow the example of National Comprehensive Cancer Network, which updates their guidelines for cancer treatment at least annually and when needed with the approval of significant new treatments (https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines).

Recommendation 2

Clinical specialty societies should endeavor to facilitate the education of general neurologists about SPMS diagnosis and treatment, including education to help clinicians make more prompt diagnoses of SPMS, improve standard of care treatment for SPMS, and understand the efficacy and safety of new therapies such as tolebrutinib.

There is a shortage of MS specialists in the US, with most patients living more than 60 miles from the nearest MS specialist and wait times for appointments are long.[5,6] As a result, more than 40% of persons living with MS do not see an MS specialist for their care. Given workforce limitations, it will be a challenge for persons living with SPMS who may qualify for treatment with tolebrutinib to be able to get treatment in a timely manner. Clinical specialty societies have a role in facilitating the education of non-MS specialists to raise awareness about the diagnosis of SPMS and potential treatments, such that patients can get referrals to MS specialists for treatment or generalists can consult with MS specialists to ensure timely access to treatment if indicated.

Patient Organizations

Recommendation 1

Patient organizations play a central role in advocating and promoting clinical trial recruitment that is more reflective of the US population of persons living with SPMS and should continue to work with manufacturers, funders, and researchers to increase the recruitment of diverse populations into clinical trials.

Black Americans are known to have a higher incidence of MS and more severe disease, Hispanic Americans are known to have earlier onset of MS than other groups, and a substantial proportion of persons living with SPMS are over the age of 60. However, these groups are underrepresented in MS clinical trials, with the HERCULES trial being no exception. This can lead to issues of generalizability of trial results, as treatments may not be equally effective in subpopulations.

There are many barriers to clinical trial participation for minoritized populations, including a lack of trust in the medical community, a lack of awareness about trials, as well as logistical barriers such as transportation, time commitment, costs of participation, and language barriers.[7] Additionally, older populations are often excluded from MS trials. Patient organizations should continue to work with manufacturers and researchers to provide patient input into study design, recruitment, and retention in clinical trials, to ensure studies reflect the needs of minority populations. The CHIMES trial, which tested the efficacy and safety of ocrelizumab in Black and Hispanic populations, can be used as an example of successful recruitment of diverse populations into a clinical trial.[8] However, though the CHIMES trial recruited exclusively Black and Hispanic Americans with MS, it should be a goal for all clinical trials to be adequately representative of the US population.

Researchers/Regulators

Recommendation 1

The research agenda for SPMS should focus both on improving ways to diagnose SPMS and finding ways to stop or reverse the progression of the disease.

Clinical experts and patient representatives expressed frustration with the delays in diagnosis of SPMS, given that it is currently primarily a retrospective clinical diagnosis, which leads to delays in treatment and progression of disease. Funders should support and encourage research into new ways of establishing the diagnosis of SPMS, including novel biomarkers that could establish the diagnosis of SPMS earlier in the course and monitor disease progression. Additionally, it is often unclear when to stop therapy, and real-world data are needed to understand whether stopping DMT is a reasonable course of action and, if so, the optimal time to stop DMT.

Patient representatives also pointed out that while slowing the progression of disease is a positive outcome, a huge area of need is research into treatments to stop or reverse the progression of disease. Thus, funders and manufacturers should be encouraged to support research that would lead to treatments with mechanisms of action that would stop the destruction of axons and/or result in remyelination of the central nervous system.

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Appendix

Appendix Tables 1 through 3 contain conflict of interest (COI) disclosures for all participants at the June 13, 2025 Public meeting of tolebrutinib for SPMS.

Appendix Table 1. ICER Staff and External Collaborators Conflict of Interest Disclosures

ICER Staff and External Collaborators	Conflict of Interest
Foluso Agboola, MBBS, MPH	No conflicts to disclose.
Anna Geiger, BS	No conflicts to disclose.
Shahariar Mohammed Fahim, PhD	No conflicts to disclose.
Grace Ham, MSc	No Conflicts to disclose.
Grace Lin, MD	No conflicts to disclose.
Brett McQueen, PhD	R. Brett McQueen reports compensation from Sanofi for a special speaker series in April 2024 related to type 1 diabetes and fees for reviewing a project attempting to improve early diagnosis of type 1 diabetes. He has not received any funding directly related to a product or directly related to multiple sclerosis.
Marie Phillips, BA	No conflicts to disclose.
Becca Piltch, MPP	No conflicts to disclose.
Finn Raymond, BS	No conflicts to disclose.
Marina Richardson, PhD, MSc	No conflicts to disclose.
Antal Zemplenyi, PhD	No conflicts to disclose.

Appendix Table 2. CTAF Panel Member Participants Conflict of Interest Disclosures

CTAF Member	Conflict of Interest
Ralph Brindis, MD, MPH Professor of Medicine, UCSF	Dr. Ralph Brindis holds stock options in GENinCode issued to him for consulting performed for the company. These options are not currently vested and have no value. Dr. Brindis will provide ICER with an update to the value of these stock options if they are converted to stock to ensure that the value does not exceed ICER's Policies to Manage Conflicts of Interest.
Robert Collyar Patient Advocate, Patient Advocates in Research	No conflicts to disclose.
Paul Heidenreich, MD, MS Professor of Medicine, Stanford University	No conflicts to disclose.
Jeffrey Hoch, MA, PhD Professor, University of California, Davis	No conflicts to disclose.
Jeff Klingman, MD Emeritus Chair of Neurology, The Permanente Medical Group	No conflicts to disclose.
Annette Langer-Gould, MD, PhD	Kaiser Permanente plans to enroll patients in a multi-center RCT for non-relapsing secondary progressive multiple sclerosis. While Kaiser Permanente will receive

CTAF Member	Conflict of Interest
Regional Lead for Clinical and Translational Neuroscience, Kaiser Permanente Southern California	funding from Sanofi to support study personnel, Dr. Langer-Gould does not receive any salary support or other type of compensation.
Sei Lee, MD, MAS Professor of Medicine, UCSF	No conflicts to disclose.
Joy Melnikow, MD, MPH Professor emeritus, University of California Davis	Dr. Melnikow received $8750 from ADVI for consulting on the USPSTF process in 2024.
Lisa Murphy, MD, DPhil Professor of Medicine, UCSF	Dr. Murphy royalties via UCSF $1166.66 from a company that licensed the technology. Dr. Murphy gives CME talks to "Big Island Docs" in Hawaii. She receives travel reimbursement from the organization.
Kathryn Phillips, PhD Professor, Health Economics, UCSF	Dr. Phillips received $20K in consulting income from Illumina to Chair a Global Economics working group. She finished her service as Chair as of Dec 2024. She expects to later receive $2500 for a presentation to Danaher May 29th on biomarker testing for Alzheimer's disease.
Rita Redberg, MD, MSc Professor of Medicine, UCSF	No conflicts to disclose.
Joanna Smith, MSW, MPH Healthcare Advocate, Joanna Smith, LCSW	No conflicts to disclose.
Tony Sowry, MA National Patient Advocate Foundation	No conflicts to disclose.

Appendix Table 3. Policy Roundtable Participants and COI Disclosures

Policy Roundtable Participant	Conflict of Interest
Robert Bermel, MD, MBA, FAAN, Director, Mellen Center for Multiple Sclerosis, Cleveland Clinic	Dr. Bermel has served as a consultant for Genzyme/Sanofi, Genentech/Roche, Novartis, and TG Therapeutics and received consulting fees in excess of $5,000. He also serves as a volunteer member of the Medical Advisory Board, which has received >25% of its funding from healthcare companies.
Kathleen Costello, CRNP, MSCN, Interim CEO, Consortium of MS Centers; President, Multiple Sclerosis Foundation	The Consortium of MS Centers and Can Do MS receive sponsorships and educational grants from the following Pharmaceutical Companies: Amgen, Biogen, EMD Serono, Bristol Myers Squibb, Genentech, Kyverna, Novartis, Sandoz, Sanofi, Octave Bioscience, TG Therapeutics, Vanda and Viatris. Kathleen Costello has no personal disclosures.
Aaron Dush, PharmD, Senior Clinical Pharmacist, UnitedHealthcare	Dr. Dush is a full-time employee of UnitedHealthcare.
Lisa Farnett, PharmD, Global Medical Director, Sanofi	Dr. Farnett is a full-time employee of Sanofi.
Nancy Garcia, MTS, BCC, Retired Chaplain	No conflicts to disclose.
Ellen Mowry, MD, MCR, Professor of Neurology & Epidemiology, Johns Hopkins University	Johns Hopkins University has received funding from Roche/Genentech and Biogen.
Jeff White, PharmD, MS, Staff Vice President, Clinical Pharmacy Services, Elevance Health	Dr. White is a full-time employee of Elevance Health.