



National
Multiple Sclerosis
Society

Streamline Step Therapy Protocols and Expedite Exceptions

North Carolina House Bill 1048, Reduce Barriers to Improve NC Health & Safety:

- Regulates the step therapy protocols in North Carolina health benefit plans which provide prescription drug benefits.
- Streamlines the process for providers to request an exception to a step therapy process for their patient.
- Expeditiously grants an override determination request if:
 - Likely causes harm
 - Expected to be ineffective
 - Previously tried treatment was discontinued due to lack of efficacy
 - Not medically appropriate
 - Stable under current treatment
- Authorizes coverage of prescription drug for treatment upon the override determination and if it is included in formulary.

What is multiple sclerosis (MS)?

- MS is an unpredictable, often disabling disease of the central nervous system.
- MS interrupts the flow of information within the brain, and between the brain and body.
- Symptoms range from numbness and tingling to blindness and paralysis.
- The progress, severity and specific symptoms of MS in any one person cannot yet be predicted.

Position: Support House Bill 1048.
Step Therapy Protocols Should be Accessible and Transparent for Both People with MS and their Healthcare Providers.

For individuals living with multiple sclerosis, delaying treatment or prolonging ineffective treatment may result in disease progression.

- Following a diagnosis of relapsing MS, the initiation of treatment with an FDA-approved disease-modifying treatment is recommended as soon as possible.
- Treatment with any given disease-modifying medication should be continued indefinitely except in the event of:
 - Sub-optimal treatment response as determined by the individual and his or her treating clinician;
 - Intolerable side effects
 - Inadequate adherence to the treatment regimen
- Movement from one disease-modifying treatment to another should occur only for medically appropriate reasons as determined by the treating clinician and patient.
- Consumer protections should be implemented to ensure that the provider may prescribe treatment that is determined to be medically appropriate.

Step therapy or “fail first” protocols are often utilized by insurers to review the use of prescribed treatments and control costs.

- The health plan may require a patient to try a lower-cost drug or service for a certain period of time, before they will provide coverage for a more expensive option.
- If the health plan’s preferred treatment is ineffective or harmful, the plan may authorize payment for the physician-prescribed treatment.
- Step therapy protocols vary in terms of their requirements—for example, how many “steps” a patient must cycle through, or how long the process takes. In addition, health plans’ exceptions procedures vary widely in terms of how clear and accessible they are, and how often physicians’ requests are approved or denied.
- Step therapy protocols may involve significant paperwork and documentation from healthcare providers and patients.

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