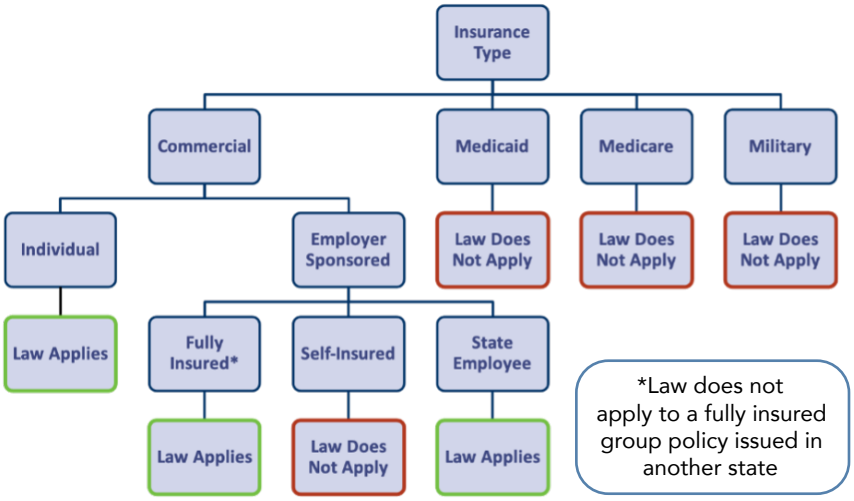
Issue Brief: North Carolina Step Therapy Law (§58-3-221)

North Carolina law §58-3-221 requires health insurance plans to offer a clear and transparent step therapy exception process when medically necessary. The following is a summary of state law.

Submitting an Exception Request

Under NC Law §58-3-221, patients and prescribing providers must have access to a process easily accessible either on the insurer's website or in its provider policies to request a non-formulary or covered medication/device requested by the prescribing provider.

It is advisable to provide a citation for the specific criteria in the law you believe a patient meets, as well as information supporting that judgment with your exception request.



Exceptions Criteria

Under §58-3-221, certain health plans must grant an exception request if the prescribing provider's justification and documentation demonstrate any of the following:

- The patient has tried the prescriber- requested drug while covered by a current or previous health plan;
- The insurer-required drug has been ineffective in treatment of the patient's condition;
- The insurer-required drug causes or is expected to cause a harmful or adverse clinical reaction;
- The patient has previously tried the insurer-required drug or device, and it has been detrimental to the patient's health or has been ineffective in treating the condition, and is likely to be detrimental or ineffective again.

Note, however, that the health plan may still require the patient to try an A-rated generic or biosimilar medication prior to providing coverage for the equivalent branded drug.

Response Timeframes

The health plan must issue a determination within 24 hours of receipt for urgent claims and within 72 hours non-urgent claims once all relevant information has been received. If additional information is required, the health plan must communicate the missing information to the patient's health care provider within either the urgent or non-urgent response time previously stipulated. Once the plan has received all relevant information, the relevant timeline will once again apply.

If an exception is granted, the health plan must provide coverage "without penalty or additional cost-sharing beyond that health benefit plan" for the specific nonformulary drug or device or the prescription drug prescribed by the provider.

Appeals & Complaints

If at any point you feel the health plan has failed to comply with the law or acted unethically, you may file a complaint with the North Carolina Department of Insurance.

Providers can file a "provider appeal" of the insurer's denial to advocate for an approval for the patient. If the provider's appeal is not approved, an insured can file a medical appeal of the insurer's non-certification decision. Under G.S. 58-50-61, first levels of appeal must be filed to the insurer within the timeframe outlined under the non-certification, which can range from 30-180 days of the date of the denial. The insurer has 30 days from the time of filing to make a determination. Under G.S. 58-50-62, a second level grievance may be filed if the first level appeal is upheld. The grievance must be filed within the timeframe outlined by the insurance company, usually 30-180 days. Under the second level grievance statue the insurer has 45 days to make a determination to uphold or overturn the previous non-certification decision. Consult your benefits booklet for information about your plan's appeal and grievance process.