§ 58-3-221. Access to nonformulary and restricted access prescription drugs.

(a) If an insurer (i) maintains one or more closed formularies for or restricts access to covered prescription drugs or devices or (ii) requires an enrollee in a plan with an open or closed formulary to use a prescription drug or sequence of prescription drugs, other than the drug the enrollee's health care provider recommends, before the insurer provides coverage for the recommended prescription drug, then the insurer shall do all of the following:

(1) Develop the formularies or protocols and any restrictions on access to covered prescription drugs or devices in consultation with and with the approval of a pharmacy and therapeutics committee.

(2) Make available to participating providers, pharmacists, and enrollees the complete drugs or devices formulary or formularies maintained by the insurer including a list of the devices and prescription drugs on the formulary by major therapeutic category that specifies whether a particular drug or device is preferred over other drugs or devices, as well as any utilization management program indicators.

(3) Update protocols based on a review of new evidence, research, and newly developed treatments.

(4) An insurer, or a pharmacy benefits manager under contract with an insurer, shall require that its pharmacy and therapeutics committee either meet the requirements for conflict of interest set by the Center for Medicare and Medicaid Services or meet the accreditation standards of the National Committee for Quality Assurance or another independent accrediting organization.

(b) An insurer may not void a contract or refuse to renew a contract between the insurer and a prescribing provider because the prescribing provider has prescribed a medically necessary and appropriate nonformulary or restricted access drug or device as provided in this section.

(b1) Exception Process. – Each insurer shall establish and maintain an expeditious process or procedure, published on either the insurer's website or in policies provided to health care providers, that allows an enrollee or the enrollee's prescribing provider acting on behalf of the enrollee to obtain, without penalty or additional cost-sharing beyond that provided for in the health benefit plan, coverage for a specific nonformulary drug or device or the drug requested by the prescribing provider, if it is determined to be medically necessary and appropriate by the enrollee's prescribing provider and the prescription drug is covered under the current health benefit plan. [The following provisions apply:]

(1) An insurer shall grant an exception request if the prescribing provider's submitted justification and supporting clinical documentation are sufficient to demonstrate any of the following:

a. The enrollee has tried the alternate drug or drugs while covered by the current or the previous health benefit plan.

b. The formulary or alternate drug or drugs has been ineffective in the treatment of the enrollee's disease or condition.

c. The formulary or alternate drug or drugs causes or is reasonably expected by the prescribing provider to cause a harmful or adverse clinical reaction in the enrollee.

d. Either (i) the drug is prescribed in accordance with any applicable clinical protocol of the insurer for the prescribing of the drug or (ii) the drug has been approved as an exception to the clinical protocol pursuant to the insurer's exception procedure.

e. The enrollee's prescribing provider certifies in writing that the enrollee has previously used an alternative nonrestricted access drug or device

and the alternative drug or device has been detrimental to the enrollee's health or has been ineffective in treating the same condition and, in the opinion of the prescribing health care provider, is likely to be detrimental to the enrollee's health or ineffective in treating the condition again.

(2) Nothing in this section shall preclude an insurer from requiring prior authorization for the coverage of a prescribed drug that was covered by the enrollee's previous health benefit plan.

(b2) Pharmaceutical drug samples or patient incentive programs, including coupons or debit cards, shall not be considered trial and failure of a preferred prescription drug in lieu of trying the formulary-preferred prescription drug.

(b3) Exception Process Requirements. –

(1) The insurer, health benefit plan, or utilization review organization may request relevant documentation from the patient or health care provider to support the exception request. Relevant information includes the results of any patient examination, clinical evaluation, or second opinion that may be required.

(2) A licensed physician or licensed pharmacist shall evaluate the clinical appropriateness of the exception request.

(3) For nonurgent exception requests for a prospective or concurrent review:

a. The insurer shall communicate to the enrollee's health care provider if additional information is required within 72 hours after the insurer receives the exception request.

b. The insurer shall communicate an exception request determination to the enrollee's providers within 72 hours after receiving all relevant information.

(4) In the case of an urgent review:

a. The insurer shall communicate to the enrollee's health care provider if additional information is required within 24 hours after the insurer receives the exception request.

b. The insurer shall communicate an exception request determination to the enrollee's providers within 24 hours after receiving all relevant information.

(c) As used in this section:

(1) "Closed formulary" means a list of prescription drugs and devices reimbursed by the insurer that excludes coverage for drugs and devices not listed.

(1a) "Health benefit plan" has definition provided in G.S. 58-3-167.

(2) "Insurer" has the meaning provided in G.S. 58-3-167.

(3) "Restricted access drug or device" means those covered prescription drugs or devices for which reimbursement by the insurer is conditioned on the insurer's prior approval to prescribe the drug or device or on the provider prescribing one or more alternative drugs or devices before prescribing the drug or device in question.

(d) Nothing in this section requires an insurer to pay for drugs or devices or classes of drugs or devices related to a benefit that is specifically excluded from coverage by the insurer.

(e) This section shall not be construed to prevent the health benefit plan from requiring an enrollee to try an A-rated generic equivalent drug, or a biosimilar, as defined under 42 U.S.C. § 262(i)(2), prior to providing coverage for the equivalent branded prescription drug. (1999-178, s. 1; 1999-294, s. 14(a), (b); 2001-446, s. 1.5; 2020-82, s. 4(a); 2025-25, s. 29(5).)