



Authorization Duration Exception-REG

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Authorization Duration Exception-REG	1
Summary	2
Definitions	2
Coverage Criteria	4
Illinois	4
Healthcare Professional Requested Duration	4
Acute or Non-Chronic Conditions	4
Chronic Conditions	5
New Jersey	5
Chronic Conditions	5
Oklahoma	5
Chronic Conditions	5
Texas	6
Autoimmune Disease, Hemophilia, or Von Willebrand Disease	6
References	7
Appendix A: Illinois	8
Appendix B: New Jersey	9

Appendix C: Oklahoma	10
Appendix D: Texas	10
Clinical Guideline Revision / History Information	11

Summary

This coverage policy is developed in accordance with the following:

- Illinois: 215 ILCS 200/ *et seq.* Prior Authorization Reform Act
- New Jersey: N.J.S.A. §17B:30-55 *et seq.* Ensuring Transparency in Prior Authorization Act
- Oklahoma: 36 O.S. § 6570.50 *et seq.* Ensuring Transparency in Prescription Drugs Prior Authorization Act
- Texas: V.T.C.A., Insurance Code § 1369.654 Prohibition On Multiple Prior Authorizations

This policy only applies to the state(s) above. See [Appendix](#) for additional details.

Disclaimer: This policy is intended to address specific state and/or regulatory requirements as outlined herein. It is not exhaustive of all federal, state, or local regulatory exceptions or requirements that may apply to the Plan. The Plan remains committed to full compliance with all applicable laws, regulations, and contractual obligations, including but not limited to those not explicitly referenced in this document. Additional regulatory exceptions, requirements, or coverage determinations may be addressed in other Plan policies, procedures, or documents, which are available upon request or as otherwise required by law. For comprehensive information regarding coverage, regulatory exceptions, or Plan obligations, please refer to the member's policy documents or contact the Plan directly.

Definitions

“Acute Condition” is sudden in onset and self-limiting in nature. Acute conditions resolve in days or weeks. Acute conditions may lead to a chronic condition if untreated.

“Autoimmune Disease” is when the body's immune system attacks and destroys healthy body tissue by mistake. Examples of common autoimmune disorders include Crohn's disease, multiple sclerosis, myasthenia gravis, psoriasis, rheumatoid arthritis, systemic lupus erythematosus (lupus), type 1 diabetes, and ulcerative colitis.

“Barbiturate” sedative-hypnotic medications used for treating seizure disorders, neonatal withdrawal, insomnia, preoperative anxiety, and the induction of coma to address increased intracranial pressure (ICP). Examples include phenobarbital, butalbital, and pentobarbital.

“Benzodiazepines” are depressants that produce sedation and hypnosis, relieve anxiety and muscle spasms, and reduce seizures. Examples include alprazolam, clonazepam, diazepam, lorazepam, temazepam, and triazolam.

“Boxed warnings or Black box warning” are the highest safety-related warnings that drugs can have assigned by the Food and Drug Administration (FDA) to bring attention to major risks of the drug. Boxed warnings are present on the FDA label

“Chronic Condition” is a long-developing condition. Generally the condition is persistent, recurring, and a duration measured in months and years.

“Drug” is defined as:

- A substance recognized by an official pharmacopoeia or formulary; *or*
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; *or*
- A substance (other than food) intended to affect the structure or any function of the body; *or*
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device; *or*
- Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

“FDA,” or the Food and Drug Administration, is an agency of the United States federal government responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter medications, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices, cosmetics, and veterinary products. The FDA's main goal is to ensure that these products are safe and effective for their intended use, and that their labeling and marketing are truthful and not misleading.

“FDA label” is a document that provides important information about a drug, including its indication and usage, dosage and administration, contraindications, warnings and precautions, adverse reactions, drug interactions, use in specific populations, clinical pharmacology, clinical studies, and storage and handling.

“Formulary” means the list of covered pharmaceutical products, developed in consultation with Physicians and pharmacists, approved for their quality and cost effectiveness.

“Hemophilia” is a bleeding disorder in which the blood does not clot properly. This can lead to spontaneous bleeding or bleeding after an injury or surgery. Types of hemophilia include Hemophilia A (classic hemophilia, factor VIII deficiency), Hemophilia B (Christmas disease, FIX deficiency), and Hemophilia C (Rosenthal syndrome, factor XI deficiency).

“Medical benefit drugs” are those that are given by a health care provider in a health care setting. Examples include drugs given by intravenous infusion such as chemotherapy or immunotherapy

infusions. Some drugs can be covered by either the pharmacy benefit or a medical benefit such as vaccines or drugs given by subcutaneous injections.

“Narcotics”, also called opioids, are used to relieve pain.

- Examples of Schedule II narcotics include hydromorphone, methadone, meperidine, oxycodone, fentanyl, morphine, opium, codeine, and hydrocodone.
- Examples of Schedule III narcotics include products containing not more than 90 milligrams of codeine per dosage unit (acetaminophen with codeine), and buprenorphine.
- Examples of Schedule IV narcotics include tramadol.

“Pharmacy benefit drugs” are those you can pick up at a drugstore or sent by mail order. Examples include oral antibiotics or antihypertensives. Some drugs can be covered by either the pharmacy benefit or a medical benefit such as vaccines or drugs given by subcutaneous injections.

“Prescription drug” requires a doctor's authorization to purchase.

“von Willebrand Disease”, or VWD, is a bleeding disorder in which the blood does not clot properly due to low levels of von Willebrand factor (VWF) in their blood or the VWF protein does not work properly.

Coverage Criteria

Illinois

Healthcare Professional Requested Duration

The Plan will provide authorization (initial review or continued care) for the length of treatment (up to 12 months) for a prescription drug as requested by the member's health care professional if the member's plan is issued for Illinois. If no treatment duration is specified within the prior authorization request, the below criteria ([Chronic Conditions](#) or [Non-Chronic Conditions](#)) will be applied.

Acute or Non-Chronic Conditions

The Plan will provide at least 6 month authorization duration (initial review or continued care) for the requested prescription drug when **ALL** the following criteria are met:

1. The member's plan is issued for Illinois; **AND**
2. The prescription drug is being prescribed to treat a non-chronic condition; **AND**
3. The prescription drug is **NOT** a benzodiazepine or schedule II narcotic drug.

If the above criteria are met, the prescription drug will be authorized for 6-months, or for the duration stipulated by the class-, drug-, or indication-specific clinical guideline if that authorization duration is longer.

- *An exception applies to acute conditions if the drug's prescribing information specifies a duration that aligns with the class-, drug-, or indication-specific clinical guideline duration. In that case the specified duration in the clinical guideline will be used.*

Chronic Conditions

The Plan will provide at least 12 month authorization duration (initial review or continued care) for the requested prescription drug when ALL the following criteria are met:

1. The member's plan is issued for Illinois; *AND*
2. The prescription drug is being prescribed to treat a chronic or long-term condition; *AND*
3. The prescription drug is NOT a benzodiazepine or schedule II narcotic drug.

If the above criteria are met, the requested prescription drug will be authorized for 12-months, or for the duration stipulated by the class-, drug-, or indication-specific clinical guideline if that authorization duration is longer.

- *An exception applies to chronic conditions if the drug's prescribing information specifies it is administered as a one-time treatment or other specified duration. In that case the specified duration in the class-, drug-, or indication-specific clinical guideline will be used if aligned with the prescribing information.*

New Jersey

Chronic Conditions

The Plan will provide at least 6 month authorization duration (initial review or continued care) for the requested prescription drug when ALL the following criteria are met:

1. The member's plan is issued for New Jersey; *AND*
2. The prescription drug is being prescribed to treat a chronic or long-term condition.

If the above criteria are met, the requested prescription drug will be authorized for 6-months, or for the duration stipulated by the class-, drug-, or indication-specific clinical guideline if that authorization duration is longer.

- *An exception applies to chronic conditions if the drug's prescribing information specifies it is administered as a one-time treatment or other specified duration. In that case the specified duration in the class-, drug-, or indication-specific clinical guideline will be used if aligned with the prescribing information.*

Oklahoma

Chronic Conditions

The Plan will provide at least 36 month authorization duration (initial review or continued care) for the requested prescription drug when ALL the following criteria are met:

1. The member's plan is issued for Oklahoma; *AND*
2. The prescription drug is being prescribed to treat a chronic or long-term condition; *AND*

3. The prescription drug is on the formulary; *AND*
4. The member remains on the same health plan; *AND*
5. ALL of the following criteria are met:
 - a. NO clinical criteria changes to the requested drug's prior authorization; *and*
 - b. The plan did NOT remove the requested generic prescription drug from the formulary OR the plan did NOT move the requested prescription drug to a less preferred tier status on its formulary; *and*
 - c. The prescription drug is NOT an opioid; *and*
 - d. The prescription drug is NOT a controlled substance that is prohibited from being dispensed without a prescription under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C., Section 301 et seq., as amended; *and*
 - e. The prescription drug is NOT for the treatment of weight loss.

If the above criteria are met, the requested prescription drug will be authorized for 36-months, or for the duration stipulated by the class-, drug-, or indication-specific clinical guideline if that authorization duration is longer.

- *An exception applies to chronic conditions if the drug's prescribing information specifies it is administered as a one-time treatment or other specified duration. In that case the specified duration in the class-, drug-, or indication-specific clinical guideline will be used if aligned with the prescribing information.*

Texas

Autoimmune Disease, Hemophilia, or Von Willebrand Disease

The Plan will provide at least 12 month authorization duration (initial review or continued care) for the requested prescription drug when ALL the following criteria are met:

1. The member is a resident of Texas; *AND*
2. The prescription drug is being prescribed to treat ONE of the following conditions:
 - a. Autoimmune Disease; *or*
 - b. Hemophilia; *or*
 - c. Von Willebrand Disease; *AND*
3. The prescription drug meets ALL of the following criteria:
 - a. Not an opioid, benzodiazepine, barbiturate, or carisoprodol; *and*
 - b. Not a prescription drug that has a typical treatment period of less than 12 months; *and*
 - c. Not a drug that has a boxed warning assigned by the United States Food and Drug Administration for use AND has specific provider assessment; *and*
 - d. Not used in a manner other than the approved use by the United States Food and Drug Administration.

If the above criteria are met, the requested prescription drug will be authorized for 12-months, or for the duration stipulated by the class-, drug-, or indication-specific clinical guideline if that authorization duration is longer.

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Appendix A: Illinois

Table 1: Illinois Law Applicable to this Policy

Law	Description
215 ILCS 200/10	Applicability; scope. This Act applies to health insurance coverage as defined in the Illinois Health Insurance Portability and Accountability Act, and policies issued or delivered in this State to the Department of Healthcare and Family Services and providing coverage to persons who are enrolled under Article V of the Illinois Public Aid Code or under the Children's Health Insurance Program Act, amended, delivered, issued, or renewed on or after the effective date of this Act, with the exception of employee or employer self-insured health benefit plans under the federal Employee Retirement Income Security Act of 1974, health care provided pursuant to the Workers' Compensation Act or the Workers' Occupational Diseases Act, and State, employee, unit of local government, or school district health plans. This Act does not diminish a health care plan's duties and responsibilities under other federal or State law or rules promulgated thereunder. This Act is not intended to alter or impede the provisions of any consent decree or judicial order to which the State or any of its agencies is a party.
215 ILCS 200/60	A prior authorization approval shall be valid for the lesser of 6 months after the date the health care professional or health care provider receives the prior authorization approval or the length of treatment as determined by the patient's health care professional or the renewal of the plan, and the approval period shall be effective regardless of any changes, including any changes in dosage for a prescription drug prescribed by the health care professional. All dosage increases must be based on established evidentiary standards and nothing in this Section shall prohibit a health insurance issuer from having safety edits in place. This Section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.
215 ILCS 200/65	If a health insurance issuer requires a prior authorization for a recurring health care service or maintenance medication for the treatment of a chronic or long-term condition, the approval shall remain valid for the lesser of 12 months from the date the health care professional or health care provider receives the prior authorization approval or the length of the treatment as determined by the patient's health care professional. This Section shall not apply to the

Law	Description
	prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.

Appendix B: New Jersey

Table 2: New Jersey Law Applicable to this Policy

Law	Description
N.J.S.A. 17B:30-55.3	• "Authorization" means a determination required under a health benefits plan that, based on the information provided, satisfies the requirements under the member's health benefits plan for medical necessity, and includes, but is not limited to, prior authorization. • "Prior authorization" means the process by which a payer determines the medical necessity of an otherwise covered service prior to the rendering of the service including, but not limited to, preadmission review, pretreatment review, utilization review, and case management. "Prior authorization" also includes a payer's requirement that a covered person or health care provider notify the carrier or payer prior to providing a health care service. • "Generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and specialty society recommendations, and the views of physicians practicing in relevant clinical areas.
N.J.S.A. 17B:30-55.7	• Except where shorter time frames are necessary to monitor patient safety or treatment effectiveness and with notice to the treating provider, if a payer requires prior authorization for a health care service for the treatment of a chronic or long-term care condition, the prior authorization shall remain valid for 180 days and the payer shall not require the covered person to obtain a prior authorization again for the health care service within the 180-day period.

Appendix C: Oklahoma

Table 3: Oklahoma Law Applicable to this Policy

Law	Description
36 Okl.St. Ann. § 6570.50(2), (15)	• "Chronic condition" means a condition that lasts one (1) year or more and requires ongoing medical attention or limits activities of daily living or both. • "Prior authorization" means the process by which utilization review entities determine the medical necessity and medical appropriateness of otherwise covered prescription drug prior to the dispensing of such prescription drug. The term shall include "authorization", "pre-certification", and any other term that would be a reliable determination by a health benefit plan.
36 Okl.St. Ann. § 6570.56	• If a prior authorization is required for a prescription drug for the treatment of a chronic condition of an enrollee, and the enrollee remains on the same health plan, then the prior authorization shall remain valid for three (3) years from the date the health care provider receives the prior authorization approval, unless clinical criteria changes, the enrollee's health plan removes the generic prescription drug from the formulary, or moves the prescription drug to a less preferred tier status on its formulary. • This section shall not apply to prior authorizations approved for: ○ A prescription drug that is an opioid or is a controlled substance that is prohibited from being dispensed without a prescription under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C., Section 301 et seq., as amended; or ○ A prescription drug for the treatment of weight loss.

Appendix D: Texas

Table 4: Texas Law Applicable to this Policy

Law	Description
V.T.C.A., Insurance Code § 1369.652	• This subchapter applies only to a health benefit plan that provides benefits for medical, surgical, or prescription drug expenses incurred as a result of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or an individual or group evidence of coverage or similar coverage document that is issued by: [continued, see law].

Law	Description
	• This subchapter applies to coverage under a group health benefit plan provided to a resident of this state regardless of whether the group policy, agreement, or contract is delivered, issued for delivery, or renewed in this state.
V.T.C.A., Insurance Code § 1369.654	• Prohibition On Multiple Prior Authorizations. (a) A health benefit plan issuer that provides prescription drug benefits may not require an enrollee to receive more than one prior authorization annually of the prescription drug benefit for a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease. • This section does not apply to: (1) opioids, benzodiazepines, barbiturates, or carisoprodol; (2) prescription drugs that have a typical treatment period of less than 12 months; (3) drugs that: (A) have a boxed warning assigned by the United States Food and Drug Administration for use; and (B) must have specific provider assessment; or (4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use.

Clinical Guideline Revision / History Information

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