PREMERA | BLUE CROSS

An Independent Licensee of the Blue Cross Blue Shield Association

ADMINISTRATIVE GUIDELINE – 10.01.525

Right-to-Try Laws and Coverage of Services

Effective Date:	Aug. 1, 2024	RELATED GUIDELINES / POLICIES:
Last Revised:	July 22, 2024	10.01.518 Clinical Trials
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

COVERAGE GUIDELINES | CODING | RELATED INFORMATION | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

During the past several years over 41 states have passed "right-to-try" laws that are meant to allow severely ill individuals to access drugs or devices that do not yet have FDA approval. A similar law was implemented at the federal level in May 2018. These laws are designed for people who have a life-threatening disease or illness and who may not qualify to participate in clinical trials. The laws allow members to seek drugs directly from manufacturers to access a treatment that might help, but is still being studied. The laws also protect doctors and providers from malpractice charges if they recommend an individual obtain these drugs. This guideline describes how your medical benefit plan may or may not cover services or treatments that a member may choose under state or federal "right-to-try" laws.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Coverage Guidelines

Services	Plan Coverage
For Washington and Alaska State Plans: Right-to-Try Investigational Services	
Investigational drug, device, or service	**Investigational drugs, devices, and services are contractually excluded because they are not approved by the U.S. Food and Drug Administration (FDA).**
Services to provide drug, device, or service	**This is contractually excluded as associated with the provision of a non-covered drug, biological product, or device.**
Complications arising from drug, device, or service	**Complications of a non-covered service are excluded from coverage by the contract.**
Life threatening or emergency complications	**Complications from non-covered services may be covered under emergency benefits when the complication is life threatening or emergent.**
Hospice or palliative care	**The member, after choosing to try an investigational service or treatment, may still have coverage under a hospice or palliative care benefit.**
Emergency use authorizations	**Drugs, biologic agents, or medical devices may be covered on a temporary basis when approved for Emergency Use Authorization (EUA) (see Related Information) under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the indication and time period indicated by the FDA.**

Coding

N/A

Related Information

Definition of Terms

Emergency Use Authorization: Allows the FDA to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions during public health emergencies when there are no adequate, approved, and available alternatives.

Experimental and Investigational: Member contracts exclude the coverage of drugs and devices that fail to meet the following criteria:

1. The technology must have final approval from the appropriate governmental regulatory bodies.
    - This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the FDA or any other federal governmental body with authority to regulate the technology.
    - Any approval that is granted as an interim step in the FDA or any other federal governmental body's regulatory process is not sufficient.

Serious or immediately life-threatening disease or condition: A stage of disease in which there is a reasonable likelihood that death will occur within six months or in which a premature death is likely without early treatment (From WA RCW 69.77)

Investigational Product: A drug, biological product or device that has successfully completed phase one and is currently in a subsequent phase of a clinical trial approved by the FDA assessing the safety of the drug, biologic product or device under section 505 of the federal food, drug and cosmetic act, 21 U.S.C. Sec. 355 (From WA RCW 69.77)

Washington State Right-to-Try Investigational Medical Products

The Washington Legislature passed Senate Bill 5035, which was signed into law, and became effective July 23, 2017. A new section was added to the Revised Code of Washington as RCW 69.77. This law provides that terminally ill patients may seek to use investigational drugs, biological products or devices, that do not yet have final FDA approval, but have completed at least phase one of the FDA approval process. The law further defines serious and life-threatening conditions and outlines patient eligibility and informed consent requirements. The law states that manufacturers are not required to provide the product, nor are physicians required to refer patients for the treatment. Physicians are provided immunity from civil or criminal liability from unprofessional conduct allegations under RCW 18.130.180, whether they choose to refer a patient for these treatments, or not. Similar protections are provided for other healthcare practitioners, manufacturers, hospitals and facilities. Issuers, including health care service contractors (health plans) are not required to provide coverage for the cost or the administration of the investigational product. An issuer may deny coverage of harm or complications that the patient develops due to the use of the investigational product. The law states that issuers may not deny coverage to an eligible patient for the following:

- An eligible patient's serious or immediately life-threatening disease or condition
- Benefits that accrued before the day on which the eligible patient was treated with an investigational product
- Palliative or hospice care for an eligible patient who was previously treated with an investigational product but is no longer being treated with that product

More information can be found at the following link:
http://app.leg.wa.gov/RCW/default.aspx?cite=69.77&full=true (Accessed June 18, 2024)

Alaska State New Drugs for the Terminally Ill

The Alaska State Legislature passed House Bill 43, which was signed into law, and became effective October 11, 2018. AS 08.64.367 was amended to include a new subsection. This act provides that a physician may not be subject to disciplinary action by the State Medical Board for prescribing, dispensing, or administering an investigational drug, biological product, or device, or providing related treatment, to a patient for the purpose of sustaining the patient's life if the patient:

- Has a terminal illness
- Is ineligible or unable to participate in a current clinical trial for the investigational drug, biological product, or device
- Has considered, after consultation with the physician, all other treatment options currently approved by the United States Food and Drug Administration; and
- Has given informed consent in writing for the use of the investigational drug, biological product, or device.

The act further defines investigational drug, biological product, or device and terminal illness. Under AS 09.65 physicians or member of the medical team have immunity relating to use or nonuse of investigational drugs, biological products or devices when informed consent of the patient is obtained in writing and written notice of the immunity was provided to the patient. Manufacturers, importers or distributors of the investigational drug, biological product, or device have similar immunity if before providing the drug, product, or device to the patient's physician, they presented to the physician all treatment options currently approved by the FDA for treatment of the patient's terminal illness as well as providing the patient written notice of the immunity. Under AS 47.32.030 the department may not require a licensed entity to increase

services for the sole purpose of accommodating a physician's practice of prescribing, dispensing, or administering an investigational drug, biological product, or device or providing related treatment to a patient.

More information can be found at the following link:

https://www.akleg.gov/basis/Bill/Text/30?hsid=HB0043Z (Accessed June 18, 2024)

Benefit Application

Member contracts exclude the coverage of drugs, biological agents and devices that do not have FDA approval. Member contracts generally exclude coverage of complications that occur related to non-covered services.

References

1. Investigational Drugs, Biological Products, and Devices. Revised Code of Washington State, RCW Title 69, Chapter 69.77. Available at: **http://app.leg.wa.gov/RCW/default.aspx?cite=69.77&full=true** Accessed June 18, 2024.
2. An Act relating to prescribing, dispensing, and administering an investigational drug, biological product, or device by physicians for patients who are terminally ill for the purpose of sustaining the patient's life; providing immunity related to manufacturing, distributing, or providing investigational drugs, biological products, or devices; and relating to licensed health care facility requirements. HB 43. Chapter 53 SLA 18. **https://www.akleg.gov/basis/Bill/Text/30?hsid=HB0043Z** Accessed June 18, 2024.
3. U.S. Food & Drug Administration. Learn About Expanded Access and Other Treatment Options. Right to try. Silver Spring, MD, FDA. Content Current as of 01/23/2023. **https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try** Accessed June 18, 2024.
4. S.204. Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017. Public Law 115-176. One Hundred Fifteenth Congress of the United States of America. 1/3/2018. **https://www.congress.gov/115/bills/s204/BILLS-115s204enr.pdf** Accessed June 18, 2024.
5. U.S Food & Drug Administration. Emergency Preparedness and Response. MCM Legal, Regulatory and Policy Framework Emergency Use Authorization. Content current as of 05/21/2024. **https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization**. Accessed June 18, 2024.

History

Date	Comments
05/01/18	New Administrative Guideline, approved April 10, 2018.
11/01/18	Interim Review, approved October 26, 2018 Information regarding newly enacted House Bill 43 of the Legislature of the State of Alaska House added.
10/01/19	Annual Review, approved September 5, 2019. Guideline reviewed. Guideline statements unchanged.
09/01/20	Annual Review, approved August 20, 2020. Administrative guideline unchanged.
09/01/20	Interim Review. Approved August 31, 2020. Added policy statement for Emergency Use Authorizations.
06/01/21	Annual Review, approved May 4, 2021. Administrative guideline reviewed. References updated. Guideline statements unchanged.
04/01/22	Annual Review, approved March 21, 2022. Administrative guideline reviewed. References updated. Guideline statements unchanged.
04/01/23	Annual Review, approved March 6, 2023. Administrative guideline reviewed. References updated. Guideline statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
08/01/24	Annual Review, approved July 22, 2024. Administrative guideline reviewed. Guideline statements unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.