

PHARMACY BENEFIT COVERAGE GUIDELINE – 5.01.622

Exception Request to Utilization Management Restrictions
for Washington State Fully-Insured Members

Effective Date: June 1, 2023
Last Revised: May 22, 2023
Replaces: N/A

RELATED GUIDELINES / POLICIES:


5.01.541 Medical Necessity Exception Criteria for Closed Formulary Benefits and
for Dispense as Written (DAW) Exception Reviews
5.01.549 Off-Label Use of Drugs and Biologic Agents
5.01.572 Coverage Criteria of Excluded Drugs for Essentials Formulary
5.01.607 Continuity of Coverage for Maintenance Medications

This policy **ONLY** applies to Washington fully-insured members.
This policy does not apply to member plans outside of Washington state or to those
who enrolled in a self-insured plan.

Please contact Customer Service and
refer to the member booklet for confirmation.

Select a hyperlink below to be directed to that section.

[COVERAGE GUIDELINES](#) | [CODING](#) | [RELATED INFORMATION](#) | [REFERENCES](#) | [HISTORY](#)

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Introduction

A formulary is the list of drugs that are routinely covered under your prescription drug benefit. The drugs on the formulary may require prior authorization or have limits such as quantity limits. Utilization management (UM) refers to any restrictions placed on drug coverage by your health plan. All UM requirements are overseen by an independent Pharmacy and Therapeutics (P&T) Committee, which is made of doctors and pharmacists who practice in the community. The P&T Committee reviews the medical and scientific evidence, guidelines from professional societies, and information in published medical studies when deciding whether to add any UM restrictions to a drug. However, there may be unique circumstances in which an exception to the UM restrictions are appropriate. This policy provides additional criteria for when exception requests

to the UM restrictions for a drug covered under the pharmacy benefit may be approved for Washington state fully-insured members.

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

Note: For Washington state fully-insured members, utilization management (UM) exception requests will follow guidelines set forth in this policy when the Pharmacy Exception Request Form is submitted as part of request. Otherwise, the request will be reviewed following existing drug coverage criteria. (See also [Related Guidelines / Policies](#)).

Exception Request Type	Medical Necessity
Request for substitute drug	<p>A request for a substitute drug may be covered when any of the following criteria are met and documented in chart notes:</p> <ul style="list-style-type: none">• Contraindication to the formulary drug• Previously tried another drug in the same pharmacologic class or a drug with the same mechanism of action and:• Experienced an adverse event (e.g., toxicity, allergy) <p>OR</p> <ul style="list-style-type: none">• Documentation is provided the drug was not therapeutically effective• For a brand drug requested with an interchangeable generic equivalent drug available, documentation that the interchangeable generic equivalent drug has been tried and that an adverse event occurred• For a brand biological drug requested with an interchangeable biological drug available, documentation that the interchangeable biological product has been tried and that an adverse event occurred



Exception Request Type	Medical Necessity
	<ul style="list-style-type: none"> • Use of the formulary drug is expected to result in one of the following: • Create a barrier to the adherence to or compliance with plan of care • Negatively impact a comorbid condition • Cause a clinically predictable negative drug interaction • Decrease the ability to achieve or maintain reasonable functional ability in performing daily activities <p>Note: Pharmacy Exception Request Form may be found on the Plan website.</p>
<p>Request to continue with current drug</p>	<p>A request to continue with current drug may be approved when any of the following criteria are met and documented in chart notes:</p> <ul style="list-style-type: none"> • The provider has determined that changing from the currently prescribed drug to the formulary drug may cause a predictable adverse clinical outcome and documentation is provided on why an adverse clinical outcome would be expected such as: • The condition has been difficult to control (e.g., many drugs tried, multiple drugs required to control condition, etc.) • The individual had a significant adverse outcome when the condition was not controlled previously (e.g., hospitalization or frequent acute medical visits, heart attack, stroke, falls, significant limitation of functional status, undue pain and suffering, etc.) • The provider has determined that changing from the currently prescribed drug to the formulary drug may cause physical or mental harm to the individual <p>Note: Pharmacy Exception Request Form may be found on the Plan website.</p>
<p>Request for a higher drug dosage</p>	<p>A request for a higher drug dosage than allowed by a quantity limit may be covered when any of the following criteria are met and documented in chart notes:</p> <ul style="list-style-type: none"> • The provider has determined that successful clinical treatment requires a dosage that differs from the quantity allowed by plan and that clinical documentation has been submitted to plan for review



Exception Request Type	Medical Necessity
	<ul style="list-style-type: none"> A medical reason exists regarding why a higher dose is required A documented reason is provided for why less frequent dosing with a higher strength is not an option if required to use a higher strength <p>Note: Pharmacy Exception Request Form may be found on the Plan website.</p>
Request for off-label use	Please see Policy 5.01.549 Off-Label Use of Drugs and Biologic Agents.

Length of Approval	
Approval	Criteria
Initial authorization	A drug approved under this policy will be approved for 12 months.
Re-authorization criteria	Future re-authorization of a drug approved under this policy will be approved for 12 months as long as chart notes demonstrate that the individual continues to show a positive clinical response to therapy.

Documentation Requirements
<p>The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:</p> <ul style="list-style-type: none"> Office visit notes that contain the diagnosis, relevant history, physical evaluation, medication history, and any prior medication related adverse events

Coding

N/A

Related Information

Definition of Terms

Pharmacologic class: Means a group of active moieties that share scientifically documented properties and is defined on the basis of any combination of three attributes of the active moiety: (1) mechanism of action (MOA); (2) physiologic effect (PE); (3) chemical structure (CS).¹

Benefit Application

This policy is managed through the Pharmacy benefit and applies only to Washington fully-insured plan members.

References

1. Pharmacologic Class. U.S. Food & Drug Administration. <https://www.fda.gov/industry/structured-product-labeling-resources/pharmacologic-class> Accessed May 5, 2023.

History

Date	Comments
01/01/21	New policy, approved December 8, 2020 added to Prescription Drug section. This policy ONLY applies to Washington fully-insured plan members. Exception requests to utilization management restrictions have been added for requests for a substitute drug, to continue with current drug, and for a higher drug dosage. These exception requests may be considered medically necessary when criteria are met.
12/01/21	Annual Review, approved November 18, 2021. No changes to policy statements.
10/01/22	Annual Review, approved September 26, 2022. No changes to policy statements. Changed the wording from "patient" to "individual" throughout the policy for standardization.
06/01/23	Annual Review, approved May 22, 2023. No changes to policy statements.



Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2023 Premera All Rights Reserved.

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.



Discrimination is Against the Law

Premera Blue Cross (Premera) complies with applicable Federal and Washington state civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera provides free aids and services to people with disabilities to communicate effectively with us, such as qualified sign language interpreters and written information in other formats (large print, audio, accessible electronic formats, other formats). Premera provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, contact the Civil Rights Coordinator. If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation, you can file a grievance with: Civil Rights Coordinator — Complaints and Appeals, PO Box 91102, Seattle, WA 98111, Toll free: 855-332-4535, Fax: 425-918-5592, TTY: 711, Email AppealsDepartmentInquiries@Premera.com. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Ave SW, Room 509F, HHH Building, Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Washington residents: You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at <https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status>, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at <https://fortress.wa.gov/oic/online-services/cc/pub/complaintinformation.aspx>.

Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 800-722-1471 (TTY: 711).

注意: 如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-722-1471 (TTY: 711)。

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-722-1471 (TTY: 711).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-722-1471 (TTY: 711) 번으로 전화해 주십시오.

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-722-1471 (телетайп: 711).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 800-722-1471 (TTY: 711).

MO LOU SILAFIA: Afai e te tautala Gagana fa'a Sāmoa, o loo iai auaunaga fesoasoan, e fai fua e leai se totagi, mo oe, Telefoni mai: 800-722-1471 (TTY: 711).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ຄ່າ, ຄມມຸນິພົມໃຫ້ທ່ານ. ໂທ 800-722-1471 (TTY: 711).

注意事項: 日本語を話される場合、無料の言語支援をご利用いただけます。800-722-1471 (TTY: 711) まで、お電話にてご連絡ください。

PAKDAAR: Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyam. Awagan ti 800-722-1471 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-722-1471 (телетайп: 711).

ប្រយ័ត្ន: បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតល្បួល គឺអាចមានសំរាប់អ្នក។ ចូរ ទូរស័ព្ទ 800-722-1471 (TTY: 711)។

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም አርዳታ ድርጅቶች በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-722-1471 (መስማት ለተሳናቸው: 711)፡፡

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajjila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bililaa 800-722-1471 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-722-1471 (رقم هاتف الصم والبكم: 711).

मिथान सिछि: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-722-1471 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-722-1471 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-722-1471 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-722-1471 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-722-1471 (TTY: 711).

ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-722-1471 (ATS: 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-722-1471 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-722-1471 (TTY: 711).

توجہ: اگر بہ زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-722-1471 (TTY: 711) تماس بگیرید.