

<b>Department:</b>	Pharmacy Management	<b>Original Approval:</b>	11/09/2021
<b>Policy No:</b>	PM571	<b>Last Approval:</b>	05/20/2024
<b>Policy Title:</b>	Cascade Select Prescription Drug Services Policy		
<b>Approved By:</b>	Clinical Services Leadership Team		
<b>Dependencies:</b>	N/A		

## Purpose

This Community Health Plan of Washington (CHPW) policy describes the Federal and State regulations as well as OIC requirements for prescription drug services.

## Policy

Community Health Plan of Washington in conjunction with its pharmacy benefit manager (PBM) shall be in compliance with the requirements set forth by federal and state regulations regarding the following prescription drug services. Please see the Appendix A for specific regulations and requirements.

- Eye Drop Refills
- Medication synchronization
- Anticancer medication
- Access to prescription drugs
- Publishing Formulary
- Drug Utilization Review Requirement to Maintain Documented Program
- Drug Exception/ Substitution
  - Follow Medicaid ETR Process
- Emergency Fills
- Cost sharing requirements
- Essential Health Benefit categories (ACA)
- Diabetes – coverage requirements
- Clinical trials requirements for coverage
- Required hospitalization services
- Maternity and newborn services – women’s direct access
- Mental Health and Substance Use Disorder

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## List of Appendices

- A. Cascade Select Regulations
- B. Detailed Revision History

## Citations & References

<b>CFR</b>	
<b>WAC</b>	284-43-5642
<b>RCW</b>	
<b>LOB &amp; Contract Citation</b>	<input type="checkbox"/> WAHIMC
	<input type="checkbox"/> BHSO
	<input type="checkbox"/> Wraparound
	<input type="checkbox"/> SMAC
	<input type="checkbox"/> HH
	<input type="checkbox"/> AHE
	<input type="checkbox"/> MA/DSNP
<input checked="" type="checkbox"/> CS	
<b>Other Requirements</b>	
<b>NCQA Elements</b>	
<b>References</b>	

## Revision History

<b>SME Review:</b>	12/18/2020; 09/19/2022; 05/18/2023; 05/20/2024
<b>Approval:</b>	11/15/2021; 09/22/2022; 05/19/2023; 05/20/2024

## Appendix A: Cascade Select Regulations

### ASCAD SELECT REGULATIONS

TOPIC	REGULATION LEGAL REFERENCE	PURPOSE	POLICY/PROCEDURE	EXISTING POLICY	NOTES
Eye Drop Refills	RCW 18.64.530	Community Health Plan of Washington shall be in compliance with the requirements set forth by OIC regarding eye drop refills	<p>CHPW shall authorize early refills for topical ophthalmic products based on the following:</p> <p>A pharmacist is authorized, without consulting a physician or obtaining a new prescription or refill from a physician, to provide for one early refill of a prescription for topical ophthalmic products if all of the following criteria are met:</p> <p>(1) The refill is requested by a patient at or after seventy percent of the predicted days of use of:</p> <p>(a) The date the original prescription was dispensed to the patient; or</p> <p>(b) The date that the last refill of the prescription was dispensed to the patient;</p> <p>(2) The prescriber indicates on the original prescription that a specific number of refills will be needed; and</p> <p>(3) The refill does not exceed the number of refills that the prescriber indicated under subsection (2) of this section.</p>	NONE	
Medication synchronization	RCW 48.43.096	Community Health Plan of Washington shall be in compliance with the requirements set forth by OIC regarding medication synchronization	<p>CHPW shall implement a medication synchronization policy for the dispensing of prescription drugs to the plan's enrollees.</p> <ul style="list-style-type: none"> <li>• If an enrollee requests medication synchronization for a new prescription, CHPW shall permit filling the drug: <ul style="list-style-type: none"> <li>○ For less than a one-month supply of the drug if synchronization will require more than a fifteen-day supply of the drug; or</li> <li>○ For more than a one-month supply of the drug if synchronization will require a fifteen-day supply of the drug or less.</li> </ul> </li> </ul>	NONE	

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			<ul style="list-style-type: none"> <li>• CHPW shall adjust the enrollee cost-sharing for a prescription drug subject to coinsurance that is dispensed for less than the standard refill amount for the purpose of synchronizing the medications.</li> <li>• CHPW shall adjust the enrollee cost-sharing for a prescription drug with a copayment that is dispensed for less than the standard refill amount for the purpose of synchronizing the medications by: <ul style="list-style-type: none"> <li>○ Discounting the copayment rate by fifty percent;</li> <li>○ Discounting the copayment rate based on fifteen-day increments; or</li> <li>○ Any other method that meets the intent of this section and is approved by the office of the insurance commissioner.</li> </ul> </li> <li>• Upon request of an enrollee, the prescribing provider or pharmacist shall: <ul style="list-style-type: none"> <li>○ Determine that filling or refilling the prescription is in the best interest of the enrollee, taking into account the appropriateness of synchronization for the drug being dispensed;</li> <li>○ Inform the enrollee that the prescription will be filled to less than the standard refill amount for the purpose of synchronizing his or her medications; and</li> <li>○ Deny synchronization on the grounds of threat to patient safety or suspected fraud or abuse.</li> </ul> </li> <li>• For purposes of this section, the following terms have the following meanings unless the context clearly requires otherwise: <ul style="list-style-type: none"> <li>○ Medication synchronization" means the coordination of medication refills for a patient taking two or more medications for a chronic condition such that the patient's medications are refilled on the same schedule for a given time period.</li> <li>○ "Prescription" has the same meaning as in RCW <a href="#">18.64.011</a>.</li> </ul> </li> </ul>		
Anticancer medication	WAC 284-43-5200	Community Health Plan of Washington shall be in compliance with the	CHPW shall cover prescribed, self-administered anticancer medication that is used to kill or slow the growth of cancerous cells on at least a comparable basis to the plan's	NONE	

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		requirements set forth by OIC regarding medication synchronization	<p>coverage for the delivery of cancer chemotherapy medications administered in a clinical or medical setting.</p> <p>CHPW shall not impose dollar limits, copayments, deductibles or coinsurance requirements on coverage for orally administered anticancer drugs or chemotherapy that are less favorable to an insured or enrollee than the dollar limits, copayments, deductibles or coinsurance requirements that apply to coverage for anticancer medication or chemotherapy that is administered intravenously or by injection.</p> <p>CHPW shall not reclassify an anticancer medication or increase an enrollee's out-of-pocket costs as a method of compliance with the requirements of this section.</p>		
Access to prescription drugs	45 CFR 156.122(e)		<p>(e) For plan years beginning on or after January 1, 2017, a health plan providing essential health benefits must have the following access procedures:</p> <p>(1) A health plan must allow enrollees to access prescription drug benefits at in-network retail pharmacies, unless:</p> <p>(i) The drug is subject to restricted distribution by the U.S. Food and Drug Administration; or</p> <p>(ii) The drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.</p> <p>(2) A health plan may charge enrollees a different cost-sharing amount for obtaining a covered drug at a retail pharmacy, but all cost sharing will count towards the plan's annual limitation on cost sharing under § 156.130 and must be accounted for in the plan's actuarial value calculated under § 156.135</p>		
Publishing Formulary	45 CFR 156.122(d)		(d)(1) For plan years beginning on or after January 1, 2016, a health plan must publish an up-to-date, accurate, and complete list of all covered drugs on its formulary drug list,	PM500	r-2019-11-cr-102

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			<p>including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, the U.S. Office of Personnel Management, and the general public. A formulary drug list is easily accessible when:</p> <p>(i) It can be viewed on the plan's public Web site through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number; and</p> <p>(ii) If an issuer offers more than one plan, when an individual can easily discern which formulary drug list applies to which plan.</p> <p>(2) A QHP in the Federally facilitated Exchange must make available the information described in paragraph (d)(1) of this section on its Web site in an HHS-specified format and also submit this information to HHS, in a format and at times determined by HHS.</p>		
Drug Utilization Review Requirement to Maintain Documented Program (TAT)	WAC 284-43-2020 (amendatory section) NEW SECTION WAC 284-43-2022		<p>WAC 284-43-2020 Drug utilization review—Generally.</p> <p>(1) These definitions apply to this section only:</p> <p>(a) "Nonurgent review request" means any request for approval of care or treatment where the request is made in advance of the patient obtaining medical care or services, or a renewal of a previously approved request, and is not an urgent care request.</p> <p>(b) "Urgent care review request" means any request for approval of care or treatment where the passage of time could seriously jeopardize the life or health of the patient, seriously jeopardize the patient's ability to regain maximum function or, in the opinion of a provider with knowledge of the patient's medical condition, would subject the</p>	PM504, PM505, PM506, PM507	r-2019-11-cr-102

			<p>patient to severe pain that cannot be adequately managed without the care or treatment that is the subject of the request.</p> <p>(2) Each issuer must maintain a documented drug utilization review program. The program must include a method for reviewing and updating criteria. Issuers must make drug review criteria available upon request to a participating provider. Beginning January 1, 2021, an issuer must post its clinical review criteria for prescription drugs and the drug utilization management exception process on its website. An issuer must also require any entity performing prescription drug benefit administration on the issuer's behalf to post the drug utilization management exception process and clinical review criteria used for the issuer's enrollees on the entity's website. The review criteria must be accessible to both providers and enrollees and presented in plain language that is understandable to both providers and enrollees. The clinical review criteria must include all rules and criteria related to the prescription drug utilization management exception process including the specific information and documentation that must be submitted by a health care provider or enrollee to be considered a complete exception request.</p> <p>(3) The drug utilization review program must meet accepted national certification standards such as those used by the National Committee for Quality Assurance except as otherwise required by this chapter.</p> <p>(4) The drug utilization review program must have staff who are properly qualified, trained, supervised, and supported by explicit written clinical review criteria and review procedures.</p> <p>(5) Each issuer must have written procedures to assure that reviews are conducted in a timely manner.</p>		
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			<p>(a) If the review request from a provider or enrollee is not accompanied by all necessary information, the issuer must tell the provider or enrollee what additional information is needed and the deadline for its submission. Upon the sooner of the receipt of all necessary information or the expiration of the deadline for providing information, the time frames for issuer determination and notification must be no less favorable than United States Department of Labor standards, and are as follows:</p> <p>(i) For urgent care review requests:</p> <p>(A) Must approve the request within forty-eight hours if the information provided is sufficient to approve the claim and include the authorization number, if a prior authorization number is required, in its approval;</p> <p>(B) Must deny the request within forty-eight hours if the requested service is not medically necessary and the information provided is sufficient to deny the claim; or</p> <p>(C) Within twenty-four hours, if the information provided is not sufficient to approve or deny the claim, the issuer must request that the provider submits additional information to make the prior authorization determination:</p> <p>(I) The issuer must give the provider forty-eight hours to submit the requested information;</p> <p>(II) The issuer must then approve or deny the request within forty-eight hours of the receipt of the requested additional information and include the authorization number in its approval;</p> <p>(ii) For nonurgent care review requests:</p>		
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			<p>(A) Must approve the request within five calendar days if the information is sufficient to approve the claim and include the authorization number in its approval;</p> <p>(B) Must deny the request within five calendar days if the requested service is not medically necessary and the information provided is sufficient to deny the claim; or</p> <p>(C) Within five calendar days, if the information provided is not sufficient to approve or deny the claim, the issuer must request that the provider submits additional information to make the prior authorization determination:</p> <p>(I) The issuer must give the provider five calendar days to submit the requested additional information;</p> <p>(II) The issuer must then approve or deny the request within four calendar days of the receipt of the additional information and include the authorization number in its approval.</p> <p>(b) Notification of the prior authorization determination must be provided as follows:</p> <p>(i) Information about whether a request was approved must be made available to the provider;</p> <p>(ii) Whenever there is an adverse determination resulting in a denial the issuer must notify the requesting provider by one or more of the following methods; phone, fax and/or secure electronic notification, and the covered person in writing or via secure electronic notification. Status information will be communicated to the billing pharmacy, via electronic transaction, upon the issuer's receipt of a claim after the request has been denied. The issuer must transmit these notifications within the time</p>		
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			<p>frames specified in (a)(i) and (ii) of this subsection in compliance with United States Department of Labor standards.</p> <p>(6) When a provider or enrollee requests an exception to an issuer's drug utilization program, the urgent and nonurgent time frames established in RCW 48.43.420, WAC 284-43-2021 and 284-43-2022 shall apply.</p> <p>(7) No issuer may penalize or threaten a pharmacist or pharmacy with a reduction in future payment or termination of participating provider or participating facility status because the pharmacist or pharmacy disputes the issuer's determination with respect to coverage or payment for pharmacy service.</p> <p><b>NEW SECTION</b></p> <p>WAC 284-43-2022 Time frame for exception and substitution request determinations.</p> <p>(1) A carrier must make an exception request determination in a timely manner as defined in this section. A carrier may not deny the exception request if the enrollee or provider does not receive a response to an exception request within the time frames in this section.</p> <p>(2) A carrier must maintain a sufficient record of each exception request to establish its compliance with the required exception process and time frames under chapter 284-43 WAC and RCW 48.43.420. Upon the commissioner's request, a carrier must make all records and documentation available and produce all requested documentation from any entity providing benefit administration or exception request decisions on its behalf within the time frame set by the commissioner.</p>		
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			<p>(3) If a provider fails to submit sufficient information for the carrier to approve or deny an exception request, a carrier must notify the provider of the specific information needed within three business days of receiving a nonurgent exception request and one business day of receiving an urgent exception request. A carrier must notify the provider that the documentation is insufficient and must explain what information is missing. A carrier may establish a specific reasonable time frame for submission of the additional information. This time frame must be communicated to the provider or enrollee with a carrier's request for additional information. If the additional information is not received within that time frame, a carrier may deny the request.</p> <p>(4) When a carrier receives sufficient information to make a decision regarding a nonurgent exception request, a carrier must make its determination and notify the enrollee or the enrollee's designee and the prescribing provider (or other prescriber, as appropriate) no later than three business days following receipt of the request.</p> <p>(5) When a carrier receives sufficient information to make a decision regarding an urgent exception request, a carrier must make its determination and notify the enrollee or the enrollee's designee and the prescribing provider (or other prescriber, as appropriate) no later than one business day following receipt of the request.</p> <p>(6) Use of a carrier's exception process is not a grievance or appeal pursuant to RCW 48.43.530 and 48.43.535. Denial of an exception request is an adverse benefit determination, and an enrollee, their representative provider or facility, or representative may request review of that decision using a carrier's appeal or adverse benefit determination review process.</p> <p>(7) A carrier's denial of an exception request is subject to the requirements of RCW 48.43.535 and chapter 284-43A WAC, which grants enrollees access to independent external review of carrier decisions to deny, modify, reduce or terminate coverage of or</p>		
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			<p>payment for a health care service or if the carrier exceeds the timelines for making an exception request decision and denies coverage. While the external review is conducted, the carrier must cover the drug if the exception request was urgent or was for an emergency fill. If such an exigency ceases, any drug previously covered under such exigency may only be reauthorized through the standard exception request process. If the independent external review reverses the carrier's denial of either an urgent or nonurgent exception request, the carrier must retrospectively cover the nonformulary drug and continue coverage for the duration of the prescription.</p> <p>(8) A carrier may not penalize or threaten a provider with a reduction in future payment or termination of a participating provider agreement because the provider disputes a carrier's determination with respect to coverage or payment for a substitute drug.</p>		
Drug Exception/ Substitution	<p>45 CFR 156.122(c); WAC 284-43- 5110 WAC 284-43- 5080 New section WAC 284-43- 2021</p>		<p>Drug Exception/substitution process(45 CFR 156.122(c)) (c) A health plan providing essential health benefits must have the following processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by the health plan (a request for exception). In the event that an exception request is granted, the plan must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing under § 156.130 and when calculating the plan's actuarial value under § 156.135.</p> <p>(1) Standard exception request. For plans years beginning on or after January 1, 2016: (i) A health plan must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request a standard review of a decision that a drug is not covered by the plan. (ii) A health plan must make its determination on a standard exception and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following receipt of the request.</p>	PM504	r-2019-11-cr- 102

			<p>(iii) A health plan that grants a standard exception request must provide coverage of the non-formulary drug for the duration of the prescription, including refills.</p> <p>(2) Expedited exception request.</p> <p>(i) A health plan must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request an expedited review based on exigent circumstances.</p> <p>(ii) Exigent circumstances exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug.</p> <p>(iii) A health plan must make its coverage determination on an expedited review request based on exigent circumstances and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 24 hours following receipt of the request.</p> <p>(iv) A health plan that grants an exception based on exigent circumstances must provide coverage of the non-formulary drug for the duration of the exigency.</p> <p>(3) External exception request review. For plans years beginning on or after January 1, 2016:</p> <p>(i) If the health plan denies a request for a standard exception under paragraph (c)(1) of this section or for an expedited exception under paragraph (c)(2) of this section, the health plan must have a process for the enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request that the original exception request and subsequent denial of such request be reviewed by an independent review organization.</p> <p>(ii) A health plan must make its determination on the external exception request and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following its receipt of the request, if the original request was a standard exception request under paragraph (c)(1) of this section, and no later than 24 hours following its</p>		
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			<p>receipt of the request, if the original request was an expedited exception request under paragraph (c)(2) of this section.</p> <p>(iii) If a health plan grants an external exception review of a standard exception request, the health plan must provide coverage of the non-formulary drug for the duration of the prescription. If a health plan grants an external exception review of an expedited exception request, the health plan must provide coverage of the non-formulary drug for the duration of the exigency.</p> <p>(4) Application of coverage appeals laws.</p> <p>(i) A State may determine that a health plan in the State satisfies the requirements of this paragraph (c) if the health plan has a process to allow an enrollee to request and gain access to clinically appropriate drugs not otherwise covered by the health plan that is compliant with the State's applicable coverage appeals laws and regulations that are at least as stringent as the requirements of this paragraph (c) and include:</p> <p>(A) An internal review;</p> <p>(B) An external review;</p> <p>(C) The ability to expedite the reviews; and</p> <p>(D) Timeframes that are the same or shorter than the timeframes under paragraphs (c)(1)(ii), (c)(2)(iii), and (c)(3)(ii) of this section.</p> <p>(ii) [Reserved]</p> <p><b>WAC 284-43-2021 Prescription drug utilization management exception and substitution process.</b></p> <p>(1) For purposes of this section and WAC 284-43-2022:</p> <p>(a) "Emergency fill" means a limited dispensed amount of medication that allows time for the processing of prescription drug utilization management.</p> <p>(b) "Medically appropriate" means prescription drugs that under the applicable standard of care are appropriate:</p> <p>(i) To improve or preserve an enrollee's health, life, or function;</p> <p>(ii) To slow the deterioration of an enrollee's health, life, or function; or</p>		
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			<p>(iii) For the early screening, prevention, evaluation, diagnosis, or treatment of a disease, condition, illness, or injury.</p> <p>(2) Beginning January 1, 2021, a carrier must establish an exception request program so that enrollees and providers may request substitution of a preferred drug, therapy or medication, and exceptions to prescription drug benefit limitations and procedures under a carrier's drug utilization management program. The process must include both nonurgent and urgent exception request procedures.</p> <p>(3) A carrier must treat an exception request as urgent when an enrollee is experiencing a health condition that may seriously jeopardize the enrollee's life, health or ability to regain maximum function, or when the enrollee is undergoing a current course of treatment using a nonformulary drug.</p> <p>(4) A carrier's exception request standards, procedures and the process description must be available to the commissioner for review upon request. A carrier must require any entity the carrier uses to administer its prescription drug benefit or to make coverage decisions for prescription drug, therapy, or medication coverage, to comply with the carrier's exception process requirements. Neither the exception request process criteria nor the type or volume of documentation required to support an exception request may be unreasonably burdensome to the enrollee or their provider.</p> <p>(5) The exception request procedures must:</p> <p>(a) Clearly explain the process a provider and enrollee may use to request approval from the carrier, or any entity providing benefit administration, to substitute one drug, therapy or medication for another drug, therapy or medication on both an urgent and nonurgent basis.</p> <p>(b) Explain how the exception process provides an enrollee with access to drugs, therapies, or medication that are both on and off the carrier's formulary.</p> <p>(c) Permit an enrollee and their provider to use the exception request process when a formulary's tiering structure changes during the year and an enrollee is using a drug affected by the change.</p>		
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			<p>(d) Permit a request for an exception to utilization management restrictions applied by the carrier or any entity providing benefit administration, such as a requirement for step therapy, dosage limitations, or therapeutic substitution.</p> <p>(e) Permit substitution coverage for nonspecialty and specialty drugs, biologics, self-administered medication, and off-label prescriptions of medications, which means a prescription of a medication, drug, or therapy for an indication that deviates significantly from the approved U.S. Food and Drug Administration labeling. An indication is defined as a diagnosis, illness, injury, syndrome, condition or other clinical parameter for which a drug may be given. A carrier is not required to permit substitution coverage for vaccines.</p> <p>(6) A carrier must not establish a special formulary tier or copayment or other cost-sharing requirement that is only applicable to prescription drugs approved for coverage under an exception request. When an enrollee or their provider requests a formulary or tiering exception to obtain a nonpreferred drug that is in a higher cost-sharing tier, a carrier may apply the cost-share for the substituted drug based on the substituted drug's placement on the formulary. For a drug that is not on the formulary, the carrier must apply the enrollee's share of cost to their out-of-pocket maximum calculations. A carrier's prescription drug benefit must include a description of the enrollee's cost-share obligation for off-formulary coverage of substituted drugs, therapies, or medications accessed through the exception process.</p> <p>(7) A carrier must not require the enrollee to submit a new exception request for a refill if the enrollee's prescribing physician or other prescriber continues to prescribe the drug and the drug continues to be approved by the U.S. Food and Drug Administration for treating the enrollee's disease or medical condition, or if the drug was prescribed as part of the enrollee's participation in a clinical trial.</p> <p>(a) If the substituted drug is for an off-label drug use, a carrier may require the enrollee to submit a new exception request when a prescription fill and renewal cycle ends.</p>		
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			<p>(b) A carrier may require an enrollee to try an AB-rated generic equivalent or a biological product that is an interchangeable biological product prior to providing coverage for the equivalent branded prescription drug.</p> <p>(c) A carrier must consider exception requests for a U.S. Food and Drug Administration approved drug used for purposes other than what is indicated on the official label if the use is medically acceptable. A carrier must take into consideration major drug compendia, authoritative medical literature, and accepted standards of practice when making its decision.</p> <p>(8) Subject to the terms and conditions of the policy that otherwise limit or exclude coverage, the carrier must grant the exception request if it can determine at least one of the following from the information submitted by a provider or enrollee in support of the exception request:</p> <ul style="list-style-type: none"> <li>(a) The enrollee does not tolerate the covered generic or formulary drug;</li> <li>(b) The enrollee's provider has determined that the covered generic or formulary drug is not therapeutically efficacious for an enrollee. A carrier may require the provider to submit specific clinical documentation as part of the exception request;</li> <li>(c) The enrollee's provider has determined clinically efficacious treatment requires a dosage that differs from a carrier's formulary dosage limitation for the covered drug. A carrier may require the provider to submit specific clinical documentation as part of the exception request and must review that documentation prior to making a decision;</li> <li>(d) The enrollee has tried the required prescription drug or another prescription drug in the same pharmacologic class or a drug with the same mechanism of action and, based on the enrollee's documented history, establishes to their provider's satisfaction that they discontinued use of that drug because it was not therapeutically efficacious, effective, had a diminished effect or caused the enrollee an adverse event. A carrier may not deny an exception request solely on the basis that the enrollee's prior use of the required or preferred drug was not within a specific time frame;</li> </ul>		
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			<p>(e) The provider has determined that changing from a currently prescribed drug to a drug required by the carrier's formulary management protocols may cause clinically predictable adverse reactions, or physical or mental harm to the enrollee. A carrier's exception program must include uniform standards for the type of clinical documentation required to establish that an adverse reaction, or physical or mental harm is clinically predictable; or</p> <p>(f) The drug required by the carrier's formulary management protocols is not in the best interest of the enrollee. To grant an exception request under this standard, a carrier must require submission of documentation of medical appropriateness, including an explanation of why the provider expects the enrollee's use of the required drug to either create a barrier to the enrollee's adherence to or compliance with their plan of care, to negatively impact a comorbid condition of the enrollee, to cause a clinically predictable negative drug interaction or to decrease the enrollee's ability to achieve or maintain reasonable functional ability in performing daily activities.</p> <p>(9) A carrier must include specific direction in its process explaining how an enrollee may request coverage for an emergency fill of a substitute drug, therapy or medication. A carrier must cover an emergency fill if the treating health care provider determines that the emergency fill is necessary to keep the enrollee stable while the exception request is being processed.</p> <p>(a) A carrier is not required to grant an exception request for a substitute drug on the basis that an emergency fill was requested.</p> <p>(b) The emergency fill exception request process in subchapter D of this chapter provides an exception to the carrier's emergency fill policy as required by WAC 284-170-470(8).</p>		
Essential Health benefit categories Emergency Fills	WAC 284-43-5642 (2)iii WAC 284-43-5170		CHPW shall cover prescription medications associated with an emergency medical condition, including those purchased in a foreign country. (WAC 284-43-5642 (2)(a)(iii)) <PM516 – does not reflect this WAC>	PM516	

			Contract must include a clear statement explaining consumers may be eligible to receive an emergency fill for prescription drugs and include the process for obtaining an emergency fill and if the carrier charges cost sharing for emergency prescription fills as defined under WAC 284-170-470, they must include any cost sharing requirements for the emergency fill. WAC 284-43-5170(1)c		
Cost sharing requirements	<a href="#">SHB 2464</a>		<p>The applicable cost sharing for the prescription medication must be;</p> <ul style="list-style-type: none"> <li>o A health carrier or pharmacy benefit manager may not require a pharmacist to dispense a brand name prescription medication when a less expensive therapeutically equivalent generic prescription medication is available <ul style="list-style-type: none"> <li>• "pharmacy benefit manager" has the same meaning as in RCW 19.340.010(21)</li> </ul> </li> </ul> <p>NEW SECTION. Sec. 1. A new section is added to chapter 48.435RCW to read as follows</p> <p>(1) Beginning January 1, 2021, the maximum amount a health carrier or pharmacy benefit manager may require a person to pay at the point of sale for a covered prescription medication is the lesser of</p> <ul style="list-style-type: none"> <li>(a) The applicable cost sharing for the prescription medication;</li> <li>(b) The amount the person would pay for the prescription medication if the person purchased the prescription medication without using a health plan.</li> </ul> <p>(2) A health carrier or pharmacy benefit manager may not require a pharmacist to dispense a brand name prescription medication when a less expensive therapeutically equivalent generic prescription medication is available.</p> <p>(3) For purposes of this section, "pharmacy benefit manager" has the same meaning as in RCW 19.340.010.21</p>	NONE	
Essential health benefit categories	WAC 284-43-5642 (6)(a)(iv)		Certain preventive medications including, but not limited to, aspirin, fluoride, and iron, and medications for tobacco use cessation, according to, and as recommended by, the United States Preventive Services Task Force, when obtained with a prescription order;	NONE	ACA DRUGS
Diabetes – coverage requirements	RCW 48.44.315 (2)(a);		CHPW shall provide appropriate and medically necessary equipment and supplies, as prescribed by a health care provider, for all subscribers diagnosed “Insulin using”, “Non-insulin using”, and “elevated blood glucose induced by pregnancy. This includes insulin,		

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	<p>WAC 284-43-5642(6)(a)(ii); WAC 284-43-5642 (1)(d)(iii);  E2SHB 2662</p>		<p>syringes, injection aids, blood glucose monitors, test strips (for blood glucose monitors, visual blood sugar reading, and urine testing); insulin pumps and accessories to the pumps, insulin infusion devices, prescriptive oral agents for controlling blood sugar levels, foot care appliances for prevention of complications associated with diabetes, and glucagon emergency kits. (RCW 48.44.315 (2)(a); WAC 284-43-5642(6)(a)(ii); WAC 284-43-5642 (1)(d)(iii); WAC 284-43-5642(7)(f)(ii))</p> <p>CHPW shall provide prescription drug coverage of insulin drugs for the treatment of diabetes must cap the total amount that an enrollee is required to pay for a covered insulin drug at an amount not to exceed one hundred dollars per thirty-day supply of the drug.</p> <p>Prescription insulin drugs shall be covered without being subject to a deductible, and any cost sharing paid by an enrollee must be applied toward the enrollee's deductible obligation.</p> <p>If the federal internal revenue service removes insulin from the list of preventive care services which can be covered by a qualifying health plan for a health savings account before the deductible is satisfied, CHPW shall establish the plan's cost sharing for the coverage of prescription insulin for diabetes at the minimum level necessary to preserve the enrollee's ability to claim tax exempt contributions from his or her health savings account under internal revenue service laws and regulations. Benefits may be subject to customary cost sharing for all other similar services or supplies within the policy. (E2SHB 2662) Services shall be covered when deemed medically necessary (RCW 48.44.315 (5))</p>		
<p>Clinical trials: requirements for coverage</p>	<p>WAC 284-43-5420(2)</p>		<p>Plan must cover the cost of prescription medication used for direct clinical management of the enrollee, unless the trial is for the investigation of the medication or the medication is typically provided free by the research sponsors for anyone in the trial.</p>		

Hospitalization – required hospitalization services	WAC 284-43-5642(3)(a)(i) WAC 284-43-5642(3)(a)(ii)		Hospital visits, facility costs, provider and staff services and treatments delivered during an inpatient hospital stay, including inpatient pharmacy services; Skilled nursing facility costs, including professional services and pharmacy services and prescriptions filled in the skilled nursing facility pharmacy;		
Maternity and new born services – women’s direct access	WAC 284-170-350(2) WAC 284-170-350(1)(b)		Plan must not deny coverage for medically appropriate laboratory, imaging, or diagnostic services, or prescriptions for pharmaceutical or medical supplies, ordered by a directly accessed women's health care practitioner within the practitioner's scope of practice, if such services would be covered when provided by another type of health care practitioner. Plan must not require authorization by another type of health care practitioner for these services. For example, if plan would cover a prescription written by the primary care provider, the issuer must cover that prescription if written by the directly accessed women's health care practitioner.		
Mental health and SUD	WAC 284-43-5642(5)(a)(v) RCW 48.44.341(2)(b) "WAC 284-43-7020(2) WAC 284-43-7020(6)(a)"		Prescription medication including medications prescribed during an inpatient and residential course of treatment; Prescription drugs intended to treat any of the disorders covered to the same extent, and under the same terms and conditions, as other prescription drugs covered under the plan Classifications: Inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care; and prescription drugs. Outpatient services may be subclassified into office visits and all other outpatient items and services.		
PKU formulary	RCW 48.44.440(2) WAC 284-44-450(3) WAC 284-44-450(3)		Plan must provide coverage for the formulas necessary for the treatment of phenylketonuria. Coverage may be limited to the usual and customary charge for such formulas. Coverage may be subject to deductibles, copayments, coinsurance or other reductions applicable to other benefits.		

	WAC 284-44-450(4)		<p>Relating the PKU formula to a special expense benefit, such as a prescription drug benefit, is not acceptable unless it results in the PKU formula benefit being paid at an amount no less than other benefits."</p> <p>Premium charged must be no greater as a result of a family or individual receiving PKU benefits.</p>		
Prescription drug services –			<ul style="list-style-type: none"> <li>• Required prescription drug services</li> <li>• Sole available drug</li> <li>• No unreasonable restrictions</li> <li>• Coverage of drugs for off-label use</li> <li>• Allowable limitations</li> <li>• State benefit requirements classified to this category</li> <li>• Formulary</li> <li>• Access to prescription drugs</li> </ul>		

## Appendix B: Detailed Revision History

### Detailed Revision History

Revision Date	Revision Description	Revision Made By
12/18/2020	Policy created	Sonya Ou, Pharm.D.
11/05/2021	Reviewed and approved with minor edits	Omar Daoud, Pharm D.
11/09/2021	Approval	CMO Cabinet
09/19/2022	Reviewed, no changes	Omar Daoud
09/20/2022	Approval	CMO Cabinet
05/18/2023	Reviewed with minor edits	Omar Daoud
05/19/2023	Approval	Clinical Services Leadership Team
05/20/2024	Reviewed; no changes	Omar Daoud
05/20/2024	Approval	Clinical Service Leadership Team

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