VENTURA COUNTY HEALTH CARE PLAN

Drug Policy:
Prior Authorization of Medications
Effective: 07/23/2013
Review Date: 01/28/14; 1/27/15; 1/26/16; 10/25/16; 1/24/17; 1/23/18, 10/30/18, 1/22/19, 4/23/19; 2/18/20; 2/2/21, 2/1/22; 8/2/22; 11/1/22; 1/31/23; 11/7/23; 2/13/24; 5/7/24; 8/6/24; 11/5/24; 2/18/2025

PRIOR AUTHORIZATION PROGRAM POLICY AND PROCEDURE

POLICY:

Prior authorization is the utilization review process to determine whether a requested prescription drug meets VCHCP's clinical criteria for coverage.

Using a tiered system, most medications on Tiers 1, 2 and 3 are available by proper prescription from the physician to the Plan member. These prescriptions, whether for preferred or non- preferred drugs as set forth in the Plan's Preferred Drug List (PDL), are filled upon presentation of a valid prescription at a participating pharmacy. There are, however, certain medications that require prior authorization (PA). The Pharmacy and Therapeutics (P&T) Committee may designate any preferred or non-preferred medication as requiring PA by the Plan. Generally, these medications are high-cost medications or medications for which medical necessity must be demonstrated. These are labeled and documented in the PDL. Prior authorization encourages the appropriate and cost- effective use of a drug by allowing coverage only when certain conditions are met. The PDL has been compiled by the Pharmacy Benefit Manager (PBM) after extensive research and adopted by VCHCP's P&T and Quality Assurance (QA) Committees using, in part, current medical findings, FDA- approved manufacturer labeling information, pharmaceutical class coverage and medication availability to treat disease and medical conditions. Additionally, the PDL is regularly reviewed with additions and deletions made as appropriate.

The following drug categories require prior authorization regardless of their status (Preferred or Non-Preferred). Note that this list is not all inclusive. Refer to the current VCHCP Preferred Drug List.

- All injectables except for Insulins, headache medications, epinephrine, medroxyprogesterone acetate & approved immunization products
- All growth hormones
- All infertility drugs.
- Most antivirals/protease inhibitors, except Acyclovir, Amantadine, Famciclovir, Valacyclovir, Denavir, Famvir, Flumist, Relenza, Tamiflu, Tyzeka, Valtrex, Xerese
- All specialty drugs require prior authorization.

No prior authorization is required for non-preferred drugs based on their non-preferred status alone. However, the Plan, upon review with the P&T Committee, may institute prior authorization criteria for specific drugs.

Contraceptive Equity Act of 2022

VCHCP will not infringe upon an enrollee's choice of contraceptive drug, device or product and will not impose any restrictions, delays on the coverage require including prior authorization, step therapy or utilization control techniques.

PROCEDURE:

Submissions:

When a physician requests a medication that has a prior authorization (PA) requirement, the pharmacy or the prescribing physician must contact the Plan explaining the medical necessity of the request, including past therapeutic attempts, contraindications to medications and allergies when applicable.

Providers are required to use Form No. 61-211 to submit prior authorization requests for prescription drugs. The Plan allow providers to submit prior authorization requests for prescription drugs through CERNER, an electronic prior authorization request system. The Plan's electronic prior authorization system utilizes Form No. 61-211. The Plan has Form 61-211 electronically available on its website.

The Plan utilizes a step therapy process for prescription drugs. The Plan requires providers to use Form No. 61-211 to submit step therapy exception requests. The Plan follows its prior-authorization policy and procedure which treats and responds to step therapy exception requests in the same manner as requests for prior authorization for prescription drugs. Requests for exceptions to step therapy processes for prescription drugs may be submitted in the same manner as a request for prior authorization for prescription drugs and shall be treated in the same manner. (See UM Policy: Treatment Authorization Request: Authorization Process and Timeline Standards for details of authorization process and timeline standards for medications).

Step Therapy Exception Request (AB 347)

The health plan shall approve a step therapy exception request, or appeal of a denial, if any of the criteria listed below for a step therapy exception are present. An independent review organization's reversal of a health plan's denial of a request for an exception, prior authorization, or a step therapy exception is binding on the health plan and applies for the duration of the prescription, including refills.

Background

This bill requires health plans to expeditiously grant a request for a step therapy exception if the use of the drug required under step therapy is inconsistent with good professional practice. Providers should

submit the justification and clinical documentation supporting the provider's determination at the same time as they submit a step therapy exception request to health plans.

AB 347 provides an illustrative list of criteria that may form the basis for the provider's determination. The basis of the provider's determination may include, but is not limited to, any of the following criteria:

- The required prescription drug is contraindicated or is likely, or expected, to cause an adverse reaction or physical or mental harm to the enrollee in comparison to the requested prescription drug, based on the known clinical characteristics of the enrollee and the known characteristics and history of the enrollee's prescription drug regimen.
- The required prescription drug is expected to be ineffective based on the known clinical characteristics of the enrollee and the known characteristics and history of the enrollee's prescription drug regimen.
- The enrollee tried the required prescription drug while covered by their current or previous health coverage or Medicaid, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse reaction. The health care service plan may require the submission of documentation demonstrating that the enrollee tried the required prescription drug before it was discontinued.
- The required prescription drug is not clinically appropriate for the enrollee because the required drug is expected to do any of the following, as determined by the enrollee's prescribing provider:
    - Worsen a comorbid condition.
    - Decrease the capacity to maintain a reasonable functional ability in performing daily activities.
    - Pose a significant barrier to adherence to, or compliance with, the enrollee's drug regimen or plan of care. The enrollee is stable on a prescription drug selected by the enrollee's prescribing provider for the medical condition under consideration while covered by their current or previous health coverage or Medicaid. When information necessary for the health plan to make a determination is not included with a request for prior authorization or step therapy exception, AB 347 requires the plan notify the prescribing provider within 72 hours of receipt or within 24 hours of receipt if exigent circumstances exist. Once the health plan receives the requested information, the applicable time period to approve or deny a prior authorization or step therapy exception request begins. If the health plan, contracted physician group, or utilization review organization fails to notify the prescribing provider within the applicable time period, the request is deemed approved for the duration of the prescription, including refills.
- The Plan request for additional information necessary to make a decision and indicates what additional or clinically relevant information would be needed to approve or deny the request.

Effective January 1, 2022, CA AB347 creates the following requirements:

SECTION1. Section 1367.206(b) of the Health and Safety Code is amended that requires the Plan to:

(b) A health care service plan shall expeditiously grant a request for a step therapy exception within the applicable time limit required by Section 1367.241 if a prescribing provider submits necessary justification and supporting clinical documentation supporting the provider's determination that the required prescription drug is inconsistent with good professional practice for provision of medically necessary covered services to the enrollee, taking into consideration the enrollee's needs and medical history, along with the professional judgment of the enrollee's provider. The basis of the provider's determination may include, but not limited to, any of the following criteria:

(1) The required prescription drug is contraindicated or is likely, or expected, to cause an adverse reaction or physical or mental harm to the enrollee and the known characteristics and history of the enrollee's prescription drug regimen.

(2) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the enrollee and the known characteristics and history of the enrollee's prescription drug regimen.

(3) The enrollee has tried the required prescription drug while covered by their current or previous health coverage, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse reaction. The health care services plan may require the submission of documentation demonstrating that the enrollee tried the required prescription drug before it was discontinued.

(4) The required prescription drug is not clinically appropriate for the enrollee because the required drug is expected to do any of the following, as determined by the enrollee's prescribing provider.

(A) Worsen the comorbid condition.

(B) Decrease the capacity to maintain a reasonable functional ability in performing daily activities.

(C) Pose a significant barrier to adherence to, or compliance with, the enrollee's drug regimen or plan of care.

(5) The enrollee is stable on a prescription drug selected by the enrollee's prescribing provider fo the medical condition under consideration while covered by their current or previous health coverage.

Procedure to Comply with CA AB 347 Section 1367.206(b)

The bill allows the health plan to provide coverage for prescription drugs, through a step therapy, if there is more than one drug that is clinically appropriate for the treatment of a medical condition.

Prior to denial via a coverage determination, clinical criteria questions/assessments prior to coverage determination:

Q1) Is the member currently stable on the requested drug? If yes, approve for continuity of treatment. If not, go to Q2.

Q2) Would the required step therapy drug(s) be less effective than the requested medication in treating the patient's medical condition? If yes, approve. If not, go to Q3.

Q3) Is the required step therapy drug(s) contraindicated in the patient or likely to cause an adverse reaction or physical or mental harm to the patient? If yes, approve. If not, go to Q4.

Q4) Is the required step therapy drug(s) expected to worsen a comorbid condition, or decrease the patient's capacity to maintain a reasonable functional ability in performing daily activities, or pose a significant barrier to adherence or compliance of the patient's drug regimen or plan of care? If yes, approve. If not, deny.

SB 621—Health Care Coverage: Biosimilar Drugs

Codified in Section 1367.206. The bill applies to all plans that provide prescription drug coverage. The bill allows the health plan to require patients to try a biosimilar medication before providing coverage for the brand-name reference biologic, essentially implementing a "step therapy" approach where a biosimilar must be tried first before accessing the original drug; this means that under SB 621, patients may be required to use a biosimilar version of a drug before their insurance will cover the original, more expensive version of the drug. The bill allows the health plan to require an enrollee to try an AB-rated generic equivalent, biosimilar, as defined in Section 262(i)(2) of Title 42 of the United States Code, or interchangeable biological product, as defined in Section 262(i)(3) of Title 42 of the United States Code, before providing coverage for the equivalent branded prescription drug. The Plan may require an enrollee to try an AB-rated generic equivalent, biosimilar, as defined in Section 262(i)(2) of Title 42 of the United States Code, or interchangeable biological product, as defined in Section 262(i)(3) of Title 42 of the United States Code, before providing coverage for the equivalent branded prescription drug; as long as the Plan's requirement for AB-rated generic equivalent, biosimilar, or interchangeable biological product, will not prohibit or supersede a step therapy exception if the step therapy exception is medically necessary. The bill does not prohibit a health care provider from prescribing a prescription drug that is clinically appropriate. The bill does not prohibit the Plan from requiring an enrollee to try an AB-rated generic equivalent, biosimilar, as defined in Section 262(i)(2) of Title 42 of the United States Code, or interchangeable biological product, as defined in Section 262(i)(3) of Title 42 of the United States Code, before providing coverage for the equivalent branded prescription drug. The bill does not prohibit or supersede a step therapy exception request as described in subdivision (b). The step therapy exception request will be reviewed by the health plan within the applicable time limit required by Section 1367.241 (i.e. within 72 hours for nonurgent requests, or within 24 hours if exigent circumstances exist) if a prescribing provider submits necessary justification and supporting clinical documentation supporting the

provider's determination that the required prescription drug is inconsistent with good professional practice for provision of medically necessary covered services to the enrollee, taking into consideration the enrollee's needs and medical history, along with the professional judgment of the enrollee's provider.

Refer to Page 4 of this document (Prior Authorization of Medications Program Policy and Procedure) for the CA AB 347 Section 1367.206(b) requirements regarding step therapy exception.

Refer to Page 5 of this document (Prior Authorization of Medications Program Policy and Procedure) for the Plan's Procedure to Comply with CA AB 347 Section 1367.206(b)

Timelines for Decisions:

The Plan has an expeditious process in place to authorize exceptions to non-formulary prescription drugs, as medically necessary.

The Plan processes requests for prescriptions (including prior authorization of non-formulary drugs), and if applicable, certain formulary drugs according to the following timelines:

- For new prescriptions: Within 24 hours of the Plan's receipt of the request.
- For all exigent circumstances (step therapy & formulary exception requests): Within 24hours of the Plan's receipt of the request.
- For urgent refills: Within 24 hours of the Plan's receipt of the request.
- For other refills: Within 24 hours of the Plan's receipt of the request.
- For non- urgent prior authorization, step therapy and formulary exception requests, the Plan responds within 72 hours of the Plan's receipt of the request.
- If additional information is received, complete or not, after the request has been pended for additional information, decision must be made within 24 hours of receipt of information.

If the Plan grants a formulary exception request, the Plan does not limit or exclude coverage if the prescribing provider continues to prescribe the drug and the drug is appropriately prescribed for treating the enrollee's medical condition. In addition, the Plan provides coverage of the nonformulary drug for the duration of the prescription, including refills.

If the Plan grants an expedited formulary exception request, the Plan provides coverage of the nonformulary drug for the duration of the exigency.

If the Plan grants an external exception review request for a standard nonformulary and expedited nonformulary request, the Plan provides coverage of the non-formulary drug for the duration of the prescription including refills and exigency.

The Plan's independent review organization (vendor), IMEDECS/Kepro performs an external exception as required by State and Federal Law. The external exception review process requires a review of denial of

requests for a formulary exception, step therapy exception, and prior authorization denial, by an independent review organization when requested by an enrollee, enrollee's designee, or provider.

An enrollee, enrollee's designee or prescribing provider can request that the original formulary exception request and subsequent denial of such request be reviewed by an independent review organization.

Enrollee, an enrollee's designee, or a prescribing provider can request that the original formulary exception request and subsequent denial of such request be reviewed by an independent review organization by following the steps below:

- Submit an exception via online request available in the VCHCP member website (https://vchealthcareplan.org/members/requestPharmacyExceptionForm.aspx) or by calling the Plan.
- Ask the Plan to make an exception to its coverage rules.
- There are several types of exceptions that can be requested such as:
  - Cover a drug even if it is not on the Plan's formulary.
  - Waive coverage restrictions or limits on a drug. For example, the Plan limit the amount on certain drugs it covers. If the drug has a quantity limit, ask the Plan to waive the limit and cover more.
  - Provide a higher level of coverage for a drug. For example, if the drug is in the Non-Preferred Drug tier, ask the Plan to cover it at the cost-sharing amount that applies to drugs on the Preferred Brand Drug tier 3 instead. This applies so long as there is a formulary drug that treats your condition on the Preferred Brand Drug tier 3. This would lower the amount paid for medications.
- Once the Plan receives the exception request via website or via phone call, the Plan's Utilization Management will contact your doctor to process your External Exception Review Request.
- The Plan sends your external exception review request to an independent review organization called IMEDECS/Kepro
- VCHCP will ensure a decision and notification within 72 hours in routine/standard circumstances or 24 hours in exigent circumstances.
- The Plan will make its determination on the external exception request review and notify the enrollee or the enrollee's designee and the prescribing provider of its coverage determination no later than no later than 24 hours following receipt of the request, if the original request was an expedited formulary/prior authorization/step therapy exception request or 72 hours following receipt of the request, if the original request was a standard request for nonformulary prescription drugs/step therapy/prior authorization.
- If additional information is required to make a decision, the Plan in collaboration with IMEDECS/Kepro will send a letter via fax to your prescribing doctor advising that additional information is required.
- Exception request for step therapy/nonformulary/prior authorization will be reviewed against the criteria in Section 1367.206(b) and, if the request is denied, the Plan will explain why the

exception request for step therapy/nonformulary/prior authorization drug did not meet any of the enumerated criteria in section 1367.206(b).

- The exception request review process does not affect or limit the enrollee's eligibility for independent medical review or to file an internal appeal with VCHCP.
- The enrollee or enrollee's designee or guardian may appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request by filing a grievance under Section 1368.
- If the independent review organization reverses the denial of a prior authorization, formulary exception, or step therapy request, the decision is binding on the Plan.
- The decision of independent review organization to reverse a denial of a prior authorization, formulary exception, or step therapy request applies to the duration of the prescription including refills.

The process by which enrollees may obtain medically necessary step therapy/nonformulary/prior authorization is described in the Plan's evidence of coverage and disclosure forms. (See Evidence of Coverage and Disclosure Forms)

If the Plan delays, denies and/or modifies the request:

- The Plan's written notices include a clear and concise explanation of the reasons for the Plan's decision.
- In addition, the Plan's written denials include a description of the criteria or guidelines as well as the clinical reasons for the decision regarding medical necessity.
- The Plan's written notices to the requesting provider include the name and direct telephone number or telephone extension of the professional that made the determination.
- Only licensed physicians or health care professionals (competent to evaluate the clinical issues) make decisions to deny pain management for terminally ill patients and any denials and modifications of medication requests.
- If the request is denied, or if additional information is required, the Plan is required to contact the requesting provider within 24 hours of the Plan's determination, with an explanation of the determination, and the reason for the denial or the need for additional information.

Prior Authorization Request

The Plan provides an expeditious process for providers to obtain prior authorization for medically necessary prescription drugs.

Timelines for Decisions:

The Plan has an expeditious process in place to authorize exceptions to non-formulary prescription drugs, as medically necessary.

The Plan processes requests for prescriptions (including prior authorization of non-formulary drugs), and if applicable, certain formulary drugs according to the following timelines:

- For new prescriptions: Within 24 hours of the Plan's receipt of the request.
- For all exigent circumstances (step therapy & formulary exception requests): Within 24hours of the Plan's receipt of the request.
- For urgent refills: Within 24 hours of the Plan's receipt of the request.
- For other refills: Within 24 hours of the Plan's receipt of the request.
- For non- urgent prior authorization, step therapy and formulary exception requests, the Plan responds within 72 hours of the Plan's receipt of the request.
- If additional information is received, complete or not, after the request has been pended for additional information, decision must be made within 24 hours of receipt of information.

If the Plan grants a formulary exception request, the Plan does not limit or exclude coverage if the prescribing provider continues to prescribe the drug and the drug is appropriately prescribed for treating the enrollee's medical condition. In addition, the Plan provides coverage of the nonformulary drug for the duration of the prescription, including refills.

If the Plan grants an expedited formulary exception request, the Plan provides coverage of the nonformulary drug for the duration of the exigency.

If the Plan grants an external exception review request for a standard nonformulary and expedited nonformulary request, the Plan provides coverage of the non-formulary drug for the duration of the prescription including refills and exigency.

The Plan's independent review organization (vendor), IMEDECS/Kepro performs an external exception as required by State and Federal Law. The external exception review process requires a review of denial of requests for a formulary exception, step therapy exception, and prior authorization denial, by an independent review organization when requested by an enrollee, enrollee's designee or provider.

An enrollee, enrollee's designee or prescribing provider can request that the original formulary exception request and subsequent denial of such request be reviewed by an independent review organization.

Enrollee, an enrollee's designee, or a prescribing provider can request that the original formulary exception request and subsequent denial of such request be reviewed by an independent review organization by following the steps below:

- Submit an exception via online request available in the VCHCP member website (https://vchealthcareplan.org/members/requestPharmacyExceptionForm.aspx) or by calling the Plan.
- Ask the Plan to make an exception to its coverage rules.
- There are several types of exceptions that can be requested such as:

  - Cover a drug even if it is not on the Plan's formulary.
  - Waive coverage restrictions or limits on a drug. For example, the Plan limit the amount on certain drugs it covers. If the drug has a quantity limit, ask the Plan to waive the limit and cover more.
  - Provide a higher level of coverage for a drug. For example, if the drug is in the Non-Preferred Drug tier, ask the Plan to cover it at the cost-sharing amount that applies to drugs on the Preferred Brand Drug tier 3 instead. This applies so long as there is a formulary drug that treats your condition on the Preferred Brand Drug tier 3. This would lower the amount paid for medications.
- Once the Plan receives the exception request via website or via phone call, the Plan's Utilization Management will contact your doctor to process your External Exception Review Request.
- The Plan sends your external exception review request to an independent review organization called IMEDECS/Kepro
- VCHCP will ensure a decision and notification within 72 hours in routine/standard circumstances or 24 hours in exigent circumstances.
- The Plan will make its determination on the external exception request review and notify the enrollee or the enrollee's designee and the prescribing provider of its coverage determination no later than no later than 24 hours following receipt of the request, if the original request was an expedited formulary/prior authorization/step therapy exception request or 72 hours following receipt of the request, if the original request was a standard request for nonformulary prescription drugs/step therapy/prior authorization.
- If additional information is required to make a decision, the Plan in collaboration with IMEDECS/Kepro will send a letter via fax to your prescribing doctor advising that additional information is required.
- Exception request for step therapy/nonformulary/prior authorization will be reviewed against the criteria in Section 1367.206(b) and, if the request is denied, the Plan will explain why the exception request for step therapy/nonformulary/prior authorization drug did not meet any of the enumerated criteria in section 1367.206(b).
- The exception request review process does not affect or limit the enrollee's eligibility for independent medical review or to file an internal appeal with VCHCP.
- The enrollee or enrollee's designee or guardian may appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request by filing a grievance under Section 1368.
- If the independent review organization reverses the denial of a prior authorization, formulary exception, or step therapy request, the decision is binding on the Plan.
- The decision of independent review organization to reverse a denial of a prior authorization, formulary exception, or step therapy request applies to the duration of the prescription including refills.

The process by which enrollees may obtain medically necessary step therapy/nonformulary/prior authorization is described in the Plan's evidence of coverage and disclosure forms. (See Evidence of Coverage and Disclosure Forms)

If the Plan delays, denies and/or modifies the request:

- The Plan's written notices include a clear and concise explanation of the reasons for the Plan's decision.
- In addition, the Plan's written denials include a description of the criteria or guidelines as well as the clinical reasons for the decision regarding medical necessity.
- The Plan's written notices to the requesting provider include the name and direct telephone number or telephone extension of the professional that made the determination.
- Only licensed physicians or health care professionals (competent to evaluate the clinical issues) make decisions to deny pain management for terminally ill patients and any denials and modifications of medication requests.
- If the request is denied, or if additional information is required, the Plan is required to contact the requesting provider within 24 hours of the Plan's determination, with an explanation of the determination, and the reason for the denial or the need for additional information.

Formulary Exception Request Authorization

The Plan provides an expeditious process for providers to obtain authorization for medically necessary non-formulary prescription drugs.

Timelines for Decisions:

The Plan has an expeditious process in place to authorize exceptions to non-formulary prescription drugs, as medically necessary.

The Plan processes requests for prescriptions (including prior authorization of non-formulary drugs), and if applicable, certain formulary drugs according to the following timelines:

- For new prescriptions: Within 24 hours of the Plan's receipt of the request.
- For all exigent circumstances (step therapy & formulary exception requests): Within 24hours of the Plan's receipt of the request.
- For urgent refills: Within 24 hours of the Plan's receipt of the request.
- For other refills: Within 24 hours of the Plan's receipt of the request.
- For non- urgent prior authorization, step therapy and formulary exception requests, the Plan responds within 72 hours of the Plan's receipt of the request.
- If additional information is received, complete or not, after the request has been pended for additional information, decision must be made within 24 hours of receipt of information.

If the Plan grants a formulary exception request, the Plan does not limit or exclude coverage if the prescribing provider continues to prescribe the drug and the drug is appropriately prescribed for treating the enrollee's medical condition. In addition, the Plan provides coverage of the nonformulary drug for the duration of the prescription, including refills.

If the Plan grants an expedited formulary exception request, the Plan provides coverage of the nonformulary drug for the duration of the exigency.

If the Plan grants an external exception review request for a standard nonformulary and expedited nonformulary request, the Plan provides coverage of the non-formulary drug for the duration of the prescription including refills and exigency.

The Plan's independent review organization (vendor), IMEDECS/Kepro performs an external exception as required by State and Federal Law. The external exception review process requires a review of denial of requests for a formulary exception, step therapy exception, and prior authorization denial, by an independent review organization when requested by an enrollee, enrollee's designee, or provider.

An enrollee, enrollee's designee or prescribing provider can request that the original formulary exception request and subsequent denial of such request be reviewed by an independent review organization.

Enrollee, an enrollee's designee, or a prescribing provider can request that the original formulary exception request and subsequent denial of such request be reviewed by an independent review organization by following the steps below:

- Submit an exception via online request available in the VCHCP member website (https://vchealthcareplan.org/members/requestPharmacyExceptionForm.aspx) or by calling the Plan.
- Ask the Plan to make an exception to its coverage rules.
- There are several types of exceptions that can be requested such as:
  - Cover a drug even if it is not on the Plan's formulary.
  - Waive coverage restrictions or limits on a drug. For example, the Plan limit the amount on certain drugs it covers. If the drug has a quantity limit, ask the Plan to waive the limit and cover more.
  - Provide a higher level of coverage for a drug. For example, if the drug is in the Non-Preferred Drug tier, ask the Plan to cover it at the cost-sharing amount that applies to drugs on the Preferred Brand Drug tier 3 instead. This applies so long as there is a formulary drug that treats your condition on the Preferred Brand Drug tier 3. This would lower the amount paid for medications.
- Once the Plan receives the exception request via website or via phone call, the Plan's Utilization Management will contact your doctor to process your External Exception Review Request.
- The Plan sends your external exception review request to an independent review organization called IMEDECS/Kepro

- VCHCP will ensure a decision and notification within 72 hours in routine/standard circumstances or 24 hours in exigent circumstances.
- The Plan will make its determination on the external exception request review and notify the enrollee or the enrollee's designee and the prescribing provider of its coverage determination no later than no later than 24 hours following receipt of the request, if the original request was an expedited formulary/prior authorization/step therapy exception request or 72 hours following receipt of the request, if the original request was a standard request for nonformulary prescription drugs/step therapy/prior authorization.
- If additional information is required to make a decision, the Plan in collaboration with IMEDECS/Kepro will send a letter via fax to your prescribing doctor advising that additional information is required.
- Exception request for step therapy/nonformulary/prior authorization will be reviewed against the criteria in Section 1367.206(b) and, if the request is denied, the Plan will explain why the exception request for step therapy/nonformulary/prior authorization drug did not meet any of the enumerated criteria in section 1367.206(b).
- The exception request review process does not affect or limit the enrollee's eligibility for independent medical review or to file an internal appeal with VCHCP.
- The enrollee or enrollee's designee or guardian may appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request by filing a grievance under Section 1368.
- If the independent review organization reverses the denial of a prior authorization, formulary exception, or step therapy request, the decision is binding on the Plan.
- The decision of independent review organization to reverse a denial of a prior authorization, formulary exception, or step therapy request applies to the duration of the prescription including refills.

The process by which enrollees may obtain medically necessary step therapy/nonformulary/prior authorization is described in the Plan's evidence of coverage and disclosure forms. (See Evidence of Coverage and Disclosure Forms)

If the Plan delays, denies and/or modifies the request:

- The Plan's written notices include a clear and concise explanation of the reasons for the Plan's decision.
- In addition, the Plan's written denials include a description of the criteria or guidelines as well as the clinical reasons for the decision regarding medical necessity.
- The Plan's written notices to the requesting provider include the name and direct telephone number or telephone extension of the professional that made the determination.
- Only licensed physicians or health care professionals (competent to evaluate the clinical issues) make decisions to deny pain management for terminally ill patients and any denials and modifications of medication requests.

- If the request is denied, or if additional information is required, the Plan is required to contact the requesting provider within 24 hours of the Plan's determination, with an explanation of the determination, and the reason for the denial or the need for additional information.

Enrollees may appeal to the health plan through existing grievance procedures. Providers may also initiate appeals with the health plan as permitted under the health plan's existing utilization management procedures.

Requests for authorization during regular business hours may be made by telephone, in writing, or by facsimile by the pharmacy or the prescribing physician to the Plan. A DMHC Pharmacy Prior Authorization Form is available for submission convenience. Requests for emergency authorization during regular working hours are handled by the Plan's UM staff.

Requests for emergency authorization after regular business hours are to be made by telephone by the pharmacy or the prescribing physician to the Plan's voice mail system which connects the caller to the Plan's answering service, available 24 hours a day, 7 days a week. The service will contact the Plan Medical Director and/or designated Administrator on call having the authority to approve medications requiring prior authorization.

The process by which enrollees may obtain medically necessary non-formulary drugs is described in the Plan's evidence of coverage and disclosure forms. (See Evidence of Coverage and Disclosure Forms)

External Exception Review Process

The Plan's vendor IMEDECS/Kepro performs an external exception as required by State and Federal Law. The external exception review process requires a review of denial of requests for a formulary exception, step therapy exception, and prior authorization denial, by an independent review organization when requested by an enrollee, enrollee's designee or provider.

An enrollee, enrollee's designee or provider can request to have the Plan's denial reviewed by an independent review organization.

Enrollee, an enrollee's designee, or a prescribing provider can request that the original formulary exception request and subsequent denial of such request be reviewed by an independent review organization by following the steps below:

- Submit an exception via online request available in the VCHCP member website (https://vchealthcareplan.org/members/requestPharmacyExceptionForm.aspx) or by calling the Plan.
- Ask the Plan to make an exception to its coverage rules.
- There are several types of exceptions that can be requested such as:
  - Cover a drug even if it is not on the Plan's formulary.

  - Waive coverage restrictions or limits on a drug. For example, the Plan limit the amount on certain drugs it covers. If the drug has a quantity limit, ask the Plan to waive the limit and cover more.
  - Provide a higher level of coverage for a drug. For example, if the drug is in the Non-Preferred Drug tier, ask the Plan to cover it at the cost-sharing amount that applies to drugs on the Preferred Brand Drug tier 3 instead. This applies so long as there is a formulary drug that treats your condition on the Preferred Brand Drug tier 3. This would lower the amount paid for medications.
- Once the Plan receives the exception request via website or via phone call, the Plan's Utilization Management will contact your doctor to process your External Exception Review Request.
- The Plan sends your external exception review request to an independent review organization called IMEDECS/Kepro
- VCHCP will ensure a decision and notification within 72 hours in routine/standard circumstances or 24 hours in exigent circumstances.
- The Plan will make its determination on the external exception request review and notify the enrollee or the enrollee's designee and the prescribing provider of its coverage determination no later than no later than 24 hours following receipt of the request, if the original request was an expedited formulary/prior authorization/step therapy exception request or 72 hours following receipt of the request, if the original request was a standard request for nonformulary prescription drugs/step therapy/prior authorization.
- If additional information is required to make a decision, the Plan in collaboration with IMEDECS/Kepro will send a letter via fax to your prescribing doctor advising that additional information is required.
- Exception request for step therapy/nonformulary/prior authorization will be reviewed against the criteria in Section 1367.206(b) and, if the request is denied, the Plan will explain why the exception request for step therapy/nonformulary/prior authorization drug did not meet any of the enumerated criteria in section 1367.206(b).
- The exception request review process does not affect or limit the enrollee's eligibility for independent medical review or to file an internal appeal with VCHCP.
- The enrollee or enrollee's designee or guardian may appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request by filing a grievance under Section 1368.
- If the independent review organization reverses the denial of a prior authorization, formulary exception, or step therapy request, the decision is binding on the Plan.
- The decision of independent review organization to reverse a denial of a prior authorization, formulary exception, or step therapy request applies to the duration of the prescription including refills.

Communication to Enrollee/Requesting Provider and How the Plan Implements The Determination for an External Exception Request

Communication to Enrollee/Requesting Provider When There is a Determination

- Once a review is completed with a determination, by either the nurse reviewer or physician reviewer, a utilization management notification letter is generated in the VCHCP medical management system.
- The utilization management notification letter is faxed to the requesting provider regarding coverage determination within 72 hours of nonurgent prior authorization requests.
- The utilization management notification letter regarding coverage determination is manually mailed to the enrollee within 72 hours of nonurgent prior authorization requests.

Communication to Requesting Provider When Additional Information is Required

- The Plan will transmit the letter to the prescribing provider advising that additional information is required via fax, in order to ensure that the Plan notifies the prescribing provider within 72 hours of receipt or within 24 hours of receipt if exigent circumstances exist.
- The Plan request for additional information necessary to make a decision and indicate what additional or clinically relevant information would be needed to approve or deny the request.

How the Plan Implements the Determination for an External Exception Request

- VCHCP utilization management nurse reviewer enters the prior authorization override in its pharmacy system to adjudicate the pharmacy claim in the pharmacy so that the medication can be dispensed to the enrollee for those authorized medication external exception requests.
- If the request is denied by the physician reviewer, a denial letter is faxed to the requesting provider and manually mailed to the enrollee. The denial letter includes the reason for the denial including the suggested alternative medication. In addition, the denial letter includes the process for the enrollee to request an appeal for the denied medication external exception request.
- An enrollee or the enrollee's designee or guardian may appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request by filing a grievance under Section 1368.
- A health care service plan, contracted physician group, utilization review organization, or external independent review organization shall approve a step therapy exception request, or internal or external appeal of a denial thereof, if any of the criteria in subdivision (b) of Section 1367.206 are satisfied.

Exception Process for Enrollee

The enrollee may request an external exception review for coverage of a non-formulary drug, step therapy, or a prescription drug prior authorization. VCHCP will ensure a decision within 72 hours in routine circumstances or 24 hours in exigent circumstances. The exception request review process does not affect or limit an enrollee's eligibility for independent medical review or to file an internal appeal with VCHCP.

The enrollee or enrollee's doctor, other prescriber, or the enrollee's appointed representative can ask the Plan to make an exception to its coverage rules. There are several types of exceptions enrollee can request:

- Enrollees can ask the Plan to cover a drug even if it is not on the Plan's formulary.
- Enrollees can ask the Plan to waive coverage restrictions or limits on a drug. For example, the Plan limit the amount on certain drugs it covers. If the enrollee drug has a quantity limit, enrollee can ask the Plan to waive the limit and cover more.
- Enrollees can ask the Plan to provide a higher level of coverage for a drug. For example, if the enrollee drug is in the Non-Preferred Drug tier, enrollee can ask the Plan to cover it at the cost-sharing amount that applies to drugs on the Preferred Brand Drug tier 3 instead. This applies so long as there is a formulary drug that treats your condition on the Preferred Brand Drug tier 3. This would lower the amount you pay for your medications.

How do enrollees request an external exception review?

Submit an exception via online request available in the VCHCP member website (https://vchealthcareplan.org/members/requestPharmacyExceptionForm.aspx) or by calling the Plan.

Once the plan receives the exception request via website or via the enrollee's phone call, the Plan's Utilization Management will contact the enrollee's physician to implement the External Exception Review Process (Please see above section on External Exception Review Process).

Enrollee Right to File a Grievance Seeking an External Exception Request Review for a Non-Formulary Prescription Drug Denial
The enrollee has a right to file a grievance seeking an external exception review request when the Plan disapprove your provider's request for authorization of a medically necessary non-formulary prescription drug. The enrollee may initiate an external exception review through the Plan's grievance process.

Simultaneous Grievance (Plan's internal grievance and grievance for external exception review for disapproved medically necessary non-formulary prescription drugs)
For disapproved medically necessary non-formulary prescription drugs, the enrollee have a right to participate in the Plan's grievances process in addition to your right to file a grievance seeking an external exception review request.

Timelines for Decisions:

The Plan has an expeditious process in place to authorize exceptions to step therapy, external exception reviews and non-formulary prescription drugs, as medically necessary.

The Plan processes requests for prescriptions (including prior authorization of non-formulary drugs, and if applicable, certain formulary drugs, and any request for a step therapy exception and external exception reviews, according to the following timelines:

- For new prescriptions: Within 24 hours of the Plan's receipt of the request.
- For all exigent circumstances (step therapy & formulary exception requests): Within 24hours of the Plan's receipt of the request.
- For urgent refills: Within 24 hours of the Plan's receipt of the request.
- For other refills: Within 24 hours of the Plan's receipt of the request.
- For non- urgent prior authorization, step therapy and formulary exception requests, the Plan responds within 72 hours of the Plan's receipt of the request.
- If additional information is received, complete or not, after the request has been pended for additional information, decision must be made within 24 hours of receipt of information.

"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.

"Urgent" means any otherwise Covered Service including medications necessary to prevent serious deterioration of the health of a member, resulting from an unforeseen illness, injury, or complication of an existing condition, including pregnancy, for which treatment cannot be delayed until the Member is able to see his or her PCP.

The Plan requires a response to exigent prior authorization, step therapy and formulary exception requests within 24 hours. If the Plan fails to respond to the request within this timeframe, the request is deemed granted.

The Plan requires a response to non-urgent prior authorization, step therapy and formulary exception requests within 72 hours. If the Plan fails to respond to the request within this timeframe, the request is deemed granted.

Request by providers for authorization of appropriately prescribed pain management medications for an enrollee who has been determined to be terminally ill shall be approved or denied in a timely fashion, appropriate for the nature of the enrollee's condition, not to exceed 72 hours of the Plan's receipt of the information requested by the Plan to make the decision.

See UM Policy: Treatment Authorization Request: Authorization Process and Timeline Standards for details of authorization process and timeline standards for medications.

See Drug Policy: Pain Management for Terminally Ill Patients

Review/Decision Making:

The Ventura County Health Care Plan policy is that the Medical Management (MM) staff may apply the adopted criteria to approve drugs requiring prior authorization. The Plan adopted all Express Scripts Drug Policies including the following hierarchy use of policy/criteria: (1) Express Scripts Drug Policy; (2) MCG if there is no Express Scripts Drug Policy; (3) Custom VCHCP Drug Policy if there is no Express Script Drug Policy and no MCG; (4) Send to Physician Reviewers to use compendia such as UpToDate or NCCN, if there is no Express Scripts Drug Policy, no MCG, no Custom VCHCP Drug Policy. All requests that do not meet criteria are referred to the Medical Director or his/her designee for a decision.

The VCHCP Medical Director or Utilization Review physician approves or denies all requests for prior authorization of Preferred or Non-Preferred Drug List medications that do not meet the prior authorization criteria established by the Pharmacy & Therapeutics Committee.

The Medical Director or his/her designee may do any or all the following before making a coverage decision for a requested medication requiring prior authorization:

- Review Pharmacy and Therapeutics Committee criteria for prior authorization of medication in question.
- Review patient medical records that document the need for the requested drug, the efficacy of any sample medications tried, and the contraindications or ineffectiveness of other drugs tried, including allergies.
- Review correspondence from the prescribing physician supporting the requested drug.
- Review the patient's prescription drug usage history under the Plan.
- Review written information about the requested drug provided by the Plan's pharmacy benefit manager, in UpToDate or any other source of reliable information provided by the drug manufacturer.
- Contact the following individuals for additional information to support the medical necessity of the request: the prescribing physician, a qualified clinical pharmacist (with at least 3 years clinical experience or completion of a pharmacy residency) or a qualified.
- physician (a board-certified physician with special training or expertise in an area related to the proposed use of the drug).

When the authorization is approved, the Plan's Medical Management (MM) staff either enters the authorization in the PBM's network system or contacts the PBM's customer service representative by phone, who then enters the authorization in the PBM's network system. The Plan's MM staff completes the authorization process in its medical management/documentation system, known as QNXT, where a fax approval notification is created and faxed to the provider and a member approval letter is created and mailed to the member.

A verbal authorization may be given to the pharmacy or requesting physician.

When the request for prior authorization comes from the dispensing pharmacy, the Plan's MM staff informs the dispensing pharmacy via phone that authorization for the medication is in place.

When an authorization is denied, the denial shall be made in writing to the member and to the prescribing physician and will include the following information:

a. Reason for the denial
b. Any alternative drug or treatment offered by the Plan.
c. Information to the member regarding the Plan's Appeal/Grievance process.
d. Information to the member regarding the Independent Medical Review (IMR) process if the drug is denied because it is experimental or investigational.
e. Name and contact information for person who made the denial decision.

The Plan provides a process for an enrollee, and enrollee's designee, or a prescribing provider to request that the original formulary exception request and subsequent denial of such request be reviewed by an independent review organization. The process to request the review by an independent review organization is included in the med new, med refill, and med exigent UM denial letters. (See UM Policy: Treatment Authorization Request: Authorization Process and Timeline Standards for details of authorization process and timeline standards for medications).

Notifications:

(See UM Policy: Treatment Authorization Request: Authorization Process and Timeline Standards for details of authorization process and timeline standards for medications. See UM Policy: TAR Timeframe Workflow Grid). See Drug Policy: Pain Management for Terminally Ill Patients)

The Plan makes its determination on the external exception review request and notify the enrollee or the enrollee's designee and the prescribing provider of its coverage determination no later than 72 hours following receipt of the request if the original request was a standard request for nonformulary prescription drugs. The application of the external exception review process applies to prior authorization, step therapy exceptions and formulary exception requests.

The Plan make its determination on the external exception review request and notify the enrollee or the enrollee's designee and the prescribing provider of its coverage determination no later than 24 hours following receipt of the request, if the original request was an expedited formulary exception request

The Plan notifies the prescribing provider and the enrollee or the enrollee's designee of its decision within 24 hours of receipt of an exigent request. The application of the external exception review process applies to prior authorization, step therapy exceptions and formulary exception requests.

The Plan notify the prescribing provider and the enrollee or the enrollee's designee of its decision within 72 hours of receipt of a non-urgent request. The application of the external exception review process applies to prior authorization, step therapy exceptions and formulary exception requests.

VCHCP is required to maintain an external exception request review process pursuant to subdivision (k) and indicates in the notice required under this subdivision that the enrollee may file a request seeking an external exception request review. To comply with Section 1367.24(b), VCHCP's written denial and modification notification includes information about enrollees right to request an external exception request review.

- Prior

Continuation of Drug Therapy:

The Plan will continue to cover a drug for an enrollee if the drug previously had been approved for coverage by the Plan for the enrollee's medical condition and the Plan's prescribing practitioner continues to prescribe the drug for the medical condition, provided that it is appropriately prescribed, and is considered safe and effective for treating the enrollee's medical condition.

If the Plan grants a formulary exception request, the Plan does not limit or exclude coverage if the prescribing provider continues to prescribe the drug and the drug is appropriately prescribed for treating the enrollee's medical condition. In addition, the Plan provides coverage of the nonformulary drug for the duration of the prescription, including refills.

If the Plan grants an expedited formulary exception request, the Plan provides coverage of the nonformulary drug for the duration of the exigency.

If the Plan grants an external exception review request for a standard nonformulary and expedited nonformulary request, the Plan provides coverage of the non-formulary drug for the duration of the prescription including refills and exigency.

The Plan conforms effectively and efficiently with the continuity of care requirements of the Act and regulations. In circumstances where an enrollee is changing plans and VCHCP is the new Plan, VCHCP does not require the enrollee to repeat step therapy when that enrollee is already being treated for that medical condition by a prescription drug provided that the drug is appropriately prescribed and is considered safe and effective for the enrollee's condition. Nothing in this section shall preclude the new Plan from imposing prior authorization requirement pursuant to Section 1367.24 for the continued coverage of a prescription drug prescribed pursuant to step therapy imposed by the former plan or preclude the prescribing provider from prescribing another drug covered by the new plan that is medically appropriate for the enrollee. For purposes of this section, "step therapy'' means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are to be prescribed.

For Renewal of Prior Authorized Medications, the MM Nurse may renew the following:

Medications requiring a prior authorization previously authorized by the MM Nurse (according to Pharmacy and Therapeutics Committee criteria) or by the Medical Director or Utilization Review Physician when a VCHCP physician continues to prescribe the drug without a break for >130 days for the member for the same condition.

Authorization numbers are valid for prescription refills for up to one year. If the member has paid for the refill, and it would be otherwise approved, retroactive authorization may be made by the MM

Nurse. The member may return to the Pharmacy for a refund, or the member may submit a claim form to the PBM.

Exceptions/Limitations include the following:

- Claims processed in error related to member's eligibility are excluded.
- Drugs prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA are excluded.
- Generic drug substitution is required unless the prescriber indicates "dispense as written" and the brand name drug is authorized by the Plan.
- Coverage is subject to the copayments and maximums of the member's pharmacy benefit.
- When the Competitive Pricing Class closes and the drug is no longer available through our PBM, written notification is made to those members with recent claims for the deleted drug and to their prescribing providers. The letter will provide the names of alternate drugs of similar efficacy covered by the Plan and a reasonable grace period to transition to the new drug.

A. Supporting Documents: See Drug Policy: Pain Management for Terminally Ill Patients; See UM Policy: Treatment Authorization Request: Authorization Process and Timeline Standards; TAR Timeframe Workflow Grid
B. References: None
C. History: Created: Catherine Sanders, MD July 2013
Reviewers: Pharmacy & Therapeutics Committee; Quality Management Committee; Medical Director; Senior Level Physician; Director of Health Services
Date Approved by P&T Committee: 7/23/13; QA Committee: 8/27/13.
Date Approved by P&T Committee: 1/28/14; QA Committee: 2/25/14.
Date Approved by P&T Committee: 1/27/15; QA Committee: 2/24/15.
Date Approved by P&T Committee: 1/26/16; QA Committee: 2/23/16.
Date Approved by P&T Committee: 10/25/16; QA Committee: 11/22/16.
Date Approved by P&T Committee: 1/24/17; & QA Committee: 2/28/17
Date Approved by P&T Committee: 1/23/18; & QA Committee: 2/27/18
Date Approved by P&T Committee: 10/30/18; & QA Committee: 11/27/18
Date Approved by P&T Committee: 1/22/19; & QA Committee: 2/26/19
Date Approved by P&T Committee: 4/23/19; & QA Committee: 5/28/19
Date Approved by P&T Committee: 2/28/20; & QA Committee: 2/25/20
Date Approved by P&T Committee: 2/2/21; & QA Committee: 2/23/21
Date Approved by P&T Committee: 2/1/22; & QA Committee: 2/22/22
Date Approved by P&T Committee: 8/2/22; & QA Committee: 8/23/22
Date Approved by P&T Committee: 11/1/22; & QA Committee: 11/22/22
Date Approved by P&T Committee: 1/31/23; & QA Committee: 2/7/23
Date Approved by P&T Committee: 11/7/23; & QA Committee: 11/28/23

Date Approved by P&T Committee: 2/13/24; & QA Committee: 2/27/24
Date Approved by P&T Committee: 8/6/24; & QA Committee: 8/27/24
Date Approved by P&T Committee: 2/18/25; & QA Committee: 2/25/25

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/26/2016	No	Faustine DelaCruz, RN; Catherine Sanders, MD; Robert Sterling, MD	Annual review
10/25/16	Yes	Faustine DelaCruz, RN; Catherine Sanders, MD; Robert Sterling, MD	Updated with DMHC definition of urgent and including prior authorization of non-formulary drugs, and if applicable, certain formulary drugs, and any request for a step therapy exception in the Plan's processing of request for prescriptions.
1/24/17	Yes	Faustine DelaCruz, RN; Catherine Sanders, MD; Robert Sterling, MD	Annual Review and updated with DMHC definition of "exigent circumstances" and review turnaround time of 24 hours from receipt of request.
1/23/18	No	Faustine DelaCruz, RN; Catherine Sanders, MD; Robert Sterling, MD	Annual review
9/13/18	Yes	Faustine DelaCruz, RN; Catherine Sanders, MD; Robert Sterling, MD	See UM Policy: Treatment Authorization Request: Authorization Process and Timeline Standards for details of authorization process and timeline standards for medications.
1/22/19	Yes	Faustine DelaCruz, RN; Meriza Ducay, RN; Robert Sterling, MD Catherine Sanders, MD	DMHC required updates: • Annual Review • Provider submission of request procedure with the use of DMHC required form • Added reference to EOC for enrollees to request non-formulary drugs

			• Timelines for Decisions especially with Exigent request • Review/Decision making: verbal authorization to pharmacy or requesting physician • Appeals process to clarify how members can obtain Independent Medical Reviews • Notification process especially exigent requests • Continuation of drug therapy: clarified that the Plan grants approval for the duration of exigency and if drug is appropriately prescribed • Reference to: Drug Policy: Pain Management for Terminally Ill Patients • Reference to UM Policy: Treatment Authorization Request: Authorization Process and Timeline Standards; TAR Timeframe Workflow Grid
1/22/19	Yes	Faustine DelaCruz, RN; Meriza Ducay, RN; Robert Sterling, MD Catherine Sanders, MD	The Plan adopted all Express Scripts Drug Policies including the following hierarchy use of policy/criteria: (1) Express Scripts Drug Policy; (2) MCG if there is no Express Scripts Drug Policy; (3) Custom VCHCP Drug Policy if there is no Express Script Drug Policy and no MCG; (4) Send to Physician Reviewers to use compendia such as UpToDate or NCCN, if there is no Express Scripts Drug Policy, no MCG, no Custom VCHCP Drug Policy.
4/23/19	Yes	Faustine DelaCruz, RN; Meriza Ducay, RN; Robert Sterling, MD Catherine Sanders, MD	The Plan conforms effectively and efficiently with the continuity of care requirements of the Act and regulations. In circumstances where an enrollee is changing plans and VCHCP is the new Plan, VCHCP does not require the

			enrollee to repeat step therapy when that enrollee is already being treated for that medical condition by a prescription drugs provided that the drug is appropriately prescribed and is considered safe and effective for the enrollee's condition. Nothing in this section shall preclude the new Plan from imposing prior authorization requirement pursuant to Section 1367.24 for the continued coverage of a prescription drug prescribed pursuant to step therapy imposed by the former plan, or preclude the prescribing provider from prescribing another drug covered by the new plan that is medically appropriate for the enrollee. For purposes of this section, "step therapy'' means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are to be prescribed.
2/18/20	No	Faustine DelaCruz, RN; Howard Taekman, MD	Annual Review
2/2/21	Yes	Faustine DelaCruz, RN; Howard Taekman, MD	Updated with DMHC Requirement: If the request is denied, or if additional information is required, the Plan is required to contact the requesting provider within one working day of the Plan's determination, with an explanation of the determination, and the reason for the denial or the need for additional information.
2/1/22	Yes	Faustine DelaCruz, RN; Howard Taekman, MD	Updated with AB 347 DMHC Requirement on Step Therapy Exception Coverage Guidance

8/3/22	Yes	Faustine DelaCruz, RN; Howard Taekman, MD	Updated with additional DMHC requirements on AB 347 Step Therapy Exception Coverage Guidance
11/1/22	Yes	Faustine DelaCruz, RN; Howard Taekman, MD	Updated with additional DMHC requirements on AB 347 Step Therapy Exception Coverage Guidance
1/31/23	Yes	Faustine DelaCruz, RN; Howard Taekman, MD	Updated with DMHC Requirements/RX Drug TAG Module Updated with Contraceptive Equity Act of 2022 requirements
11/7/23	Yes	Faustine DelaCruz, RN; Meriza Ducay, RN; Howard Taekman, MD	Updated to include DMHC requirement on External Exception Review Request right to file review grievance with the Plan's internal grievance process and grievance for external exception review request.
2/13/24	Yes	Faustine DelaCruz, RN; Howard Taekman, MD	Updated to meet CA AB621 requirements.
5/7/24	Yes	Faustine DelaCruz, RN; Howard Taekman, MD	Updated with additional language to comply with CA SB 621.
6/18/24	Yes	Faustine DelaCruz, RN; Howard Taekman, MD	Updated with SB621 Amended Section 1367.06(e): Health Care Coverage – Biosimilar Drugs. For Clarity - Updated to change SB621 to AB347 documentation on top of page 4. Updated to change Procedure to Comply with from CA SB 621 to AB 347 – bottom of page 4.
8/7/2024	Yes	Faustine DelaCruz; Howard Taekman	Updated to revise the legal citation for SB 621 and effective date for AB 347.
10/1/24	Yes	Faustine DelaCruz; Howard Taekman; Gia Zabala, RN	Updated to revise & provide clarity on Page 5 language - SB 621 "explains that the requirement set forth in the bullet point above does not allow the plan to prohibit or supersede a step therapy request as described in Section 1367.206(b)." As requested by DMHC.

			Updated page 4 to revise effective date for AB347 from January 21, 2022, to January 1, 2022, as requested by DMHC.
11/22/24	Yes	Faustine DelaCruz; Howard Taekman; Gia Zabala, RN	Updated to provide clarity on the SB 621 on Biosimilars language.
2/13/25	Yes	Faustine DelaCruz; Howard Taekman; Gia Zabala, RN	Updated to transfer the language, "allows the health plan to provide coverage for prescription drugs, through a step therapy, if there is more than one drug that is clinically appropriate for the treatment of a medical condition." From SB 621 to AB 347 – response to Filing 20241376-7 received 2/5/25.