From: DMHC Licensing eFiling

Subject: APL 22-004 – Assembly Bill 347 Step Therapy Exception Coverage Guidance

Date: Friday, January 21, 2022, 3:12 PM

Attachments: APL 22-004 – Assembly Bill 347 Step Therapy Exception Coverage Guidance (1.21.22).pdf

Dear Health Plan Representative:

Please find attached All Plan Letter (APL) 22-004, setting forth the Department of Managed Health Care's guidance regarding how health care service plans shall comply with AB 347.

Thank you.

Gavin Newsom, Governor
State of California
Health and Human Services Agency
DEPARTMENT OF MANAGED HEALTH CARE
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Sacramento, CA 95814
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ALL PLAN LETTER

DATE: January 21, 2022

TO: All Full-Service Commercial and Medi-Cal Managed Care Health Care Service Plans[1]

FROM: Jenny Mae Phillips
Deputy Director
Office of Plan Licensing

SUBJECT: APL 22-004 – Assembly Bill 347 Step Therapy Exception Coverage Guidance

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On October 9, 2021, Governor Gavin Newsom signed Assembly Bill (AB) 347. AB 347 requires health care service plans (health plans or plans), effective January 1, 2022, to expeditiously grant step therapy exceptions[2] within specified time periods when use of the prescription drug required under step therapy is inconsistent with good professional practice. AB 347 also permits providers to appeal a health plan's denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request.

This All Plan Letter (APL) sets forth the Department of Managed Health Care's (DMHC or Department) guidance regarding how plans shall comply with AB 347. The Department expects plans to comply with AB 347 effective January 1, 2022.

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[1] This APL does not apply to Medicare Advantage products or to specialized health care products that do not offer prescription drug coverage. In addition, the Department is not requiring a filing at this time with respect to Medi-Cal products.

[2] "Step-therapy exception" is defined as a decision to override a generally applicable step therapy protocol in favor of coverage of the prescription drug prescribed by a health care provider for an individual enrollee. *See* Health and Safety Code section 1367.244(c).

I. 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 has 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.[3]

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.[4] Once the health plan receives the requested

[3] Health and Safety Code section 1367.206(b)
[4] Health and Safety Code sections 1367.241(b)(2) and (h)(2)

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.[5]

The health plan shall approve a step therapy exception request, or appeal of a denial, if any of the criteria listed above for a step therapy exception are present.[6] 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.[7]

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.[8]

AB 347 neither expands nor limits the coverage of prescription drugs required under Medi-Cal Managed Care contracts.[9]

II. Compliance and Filing Requirements

Please submit by March 21, 2022, one filing to demonstrate compliance with AB 347 requirements discussed in this APL. Submit the filing via eFiling as an Amendment titled "Compliance with AB 347."

- In the "Compliance with AB 347" Amendment filing, include an Exhibit E-1 (the "Compliance E-1") that addresses how the plan intends to comply with AB 347 and affirm the following:
    - Affirm that the health plan has modified its contracts with utilization review organizations, medical groups or other contracted entities that perform utilization review or utilization management functions to ensure that the contracted entities comply with Health and Safety Code sections 1367.206 and 1367.241 as of January 1, 2022.
    - Affirm that the health plan has modified its utilization management criteria to provide for granting requests for a step therapy exception pursuant to Health and Safety Code section 1367.206(b) if a provider submits to the health plan necessary justification and supporting clinical documentation

[5] Health and Safety Code section 1367.241(b)(1)(A)
[6] Health and Safety Code section 1367.241(b)(3)
[7] Health and Safety Code section 1367.241(b)(1)(B)
[8] Health and Safety Code section 1367.206(c) and (d)
[9] Health and Safety Code section 1367.206(f)

supporting their determination that the required prescription drug is inconsistent with good professional practice.

- Affirm that the health plan has modified its policies and procedures regarding grievances and appeals whereby an appeal submitted by a provider regarding a denial for coverage of a nonformulary drug, prior authorization request, or step therapy exception is considered an appeal under Health and Safety Code section 1368.

- Submit any revised Utilization Management Policies and Procedures, as an Exhibit J-9, regarding requests for a step therapy exception pursuant to Health and Safety Code sections 1367.206(b), 1367.241(b)(2) and 1367.241(b)(3).

- Submit any revised Grievance Policies and Procedures, as an Exhibit W-1, regarding providers submitting appeals on behalf of enrollees pursuant to Health and Safety Code section 1367.206(c).

- Submit template notice(s), as an Exhibit I-7, the health plan will send to a provider informing the provider that the request for prior authorization or a step therapy exception is incomplete or missing clinically relevant material information.

- Submit template notice(s), as an Exhibit I-9, the health plan will send to an enrollee for a denial of a step therapy exception.

- Submit template notice(s), as an Exhibit I-7, the health plan will send to a provider for a denial of a step therapy exception.

- Health plans shall review the following documents to determine which documents are not consistent with the requirements of AB 347. Health plans shall make all necessary revisions to ensure these documents are consistent with AB 347 and submit the revised documents as part of this filing. If the health plan determines any of the documents listed below do not require revisions to comply with AB 347, affirm the health plan has reviewed the document and no revisions were necessary.

    - EOCs, Disclosure Forms, and/or Group Subscriber Agreements.

    - Contracts with Pharmacy Benefit Managers, Provider Contracts, Administrative Service Agreements, and/or Plan-to Plan Agreements.

If you have questions regarding the timelines for filing or other questions about the requirements of this APL, please contact your health plan’s assigned reviewer in the OPL.