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BULLETIN 2024-03

TO: Commercial Health Insurers; Blue Cross Blue Shield of Massachusetts, Inc.; and Health Maintenance Organizations Offering or Renewing Insured Health Products in Massachusetts ("Carriers")

FROM: Gary D. Anderson, Commissioner of Insurance

DATE: January 16, 2024

RE: Step Therapy Protocols Pursuant to Chapter 254 of the Acts of 2022 ("Chapter 254")

The Division of Insurance ("Division") issues this Bulletin to inform insured health carriers ("Carriers") regarding the requirements of Chapter 254 of the Acts of 2022 ("Chapter 254"), which amended Massachusetts laws to add M.G.L. c. 176O, §12A. As defined in M.G.L. c. 176O, §12A(a), a "Step therapy protocol" is a utilization management policy or program that establishes the specific sequence in which a prescription drug for a specified medical condition is covered by a Carrier. Pursuant to M.G.L. c. 176O, §12A(e), the provisions of M.G.L. c. 176O, §12A apply to Carriers "that provide coverage of a prescription drug pursuant to a policy that meets the definition of a step therapy protocol, regardless of whether the policy is described as a step therapy protocol."

Process to Request and Exception to Step Therapy Protocols

The provisions of M.G.L. c. 176O, §12A(c)(1) require the following:

> (c) (1) If coverage of a prescription drug for the treatment of any medical condition is restricted for use by a carrier directly or through a utilization review organization through the use of a step therapy protocol, the insured and prescribing health care provider shall have access to a clear, readily accessible and convenient process to request an exception to such step therapy protocol. An insured or their prescribing health care provider may request an exception to such protocol, and such request for an exception shall be granted if:
>
> (i) the prescription drug required under the step therapy protocol is contraindicated or will likely cause an adverse reaction in or physical or mental harm to the insured;
>
> (ii) the prescription drug required under the step therapy protocol is expected to be ineffective based on the known clinical characteristics of the insured and the known characteristics of the prescription drug regimen;
>
> (iii) (A) the insured or prescribing health care provider has provided documentation to the carrier or utilization review organization establishing that the insured has previously tried the prescription drug required under the step therapy protocol, or another prescription drug in the same pharmacologic class or with the same mechanism of

action; and

(B) such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or

(iv) the insured or prescribing health care provider has provided documentation to a carrier or utilization review organization establishing that the insured:

(A) is stable on a prescription drug prescribed by their health care provider; and

(B) switching drugs will likely cause an adverse reaction in or physical or mental harm to the insured.

The Division is mandated to develop and implement prior authorization forms for health services and considered developing modifications to previously standardized prior authorization forms for use in reviewing requests for medication. In order to enable a clear, readily accessible, and convenient process to request an exception to Carriers' step therapy protocols pursuant to M.G.L. c. 176O, §25(c), the Mass Collaborative, composed of representatives from insurance Carriers, provider groups, and associations, considered amendments to the following forms based on the specific provisions of M.G.L. c. 176O, §12A(c):

Massachusetts Standard Form for Medication Prior Authorization Requests (issued with Bulletin 2016-08)

Massachusetts Standard Form for Hepatitis C Medication Prior Authorization Requests (issued with Bulletin 2017-04)

Massachusetts Standard Form for Chemotherapy and Supportive Care Prior Authorization Requests (issued with Bulletin 2022-07)

The Division presented the draft amendments to the noted forms during an information session, held on August 23, 2023. The Division considered comments raised at and after the information session and now approves those forms, as included in the Appendix to this Bulletin, as the standard prior authorization forms to replace those issued along with Bulletins 2016-08, 2017-04, and 2022-07. Bulletins 2016-08, 2017-04, and 2022-07 are thus rescinded as of today's date. With respect to the applicable health services, Carriers may no longer require the use of any other paper form other than the standard forms included in the Appendix to this Bulletin, which Carriers shall make available for use by all contracted providers.

As is the case whenever the Division approves prior authorization forms, the Division expects that Carriers shall take all necessary steps to amend their utilization review systems to accept any standard prior authorization form that may be submitted by providers by mail, as an attachment to electronic mail, or by facsimile machine. The applicable standard prior authorization form will serve as sufficient information upon which the insured health plan should make its decisions about the medical necessity and appropriateness of the requested service or procedure, including step therapy decisions. The standard prior authorization forms are designed to create a clear, readily accessible, and convenient process for members and providers to request an exception to the step therapy protocol and submit information for the exceptions process.

Carriers wishing to modify the format from the standard form are required to submit screenshots of all such forms for the Division's review before their use in the market. Data collected electronically by Carriers for prior authorizations should be identical to the data collected on these paper forms.

The Division is aware that Carriers and providers may be at differing degrees of readiness for implementing standard prior authorization forms. Although many provider organizations may be ready to implement the new forms, other providers may not yet be prepared. The Division sends

this guidance to remind Carriers of their obligations. As the paper forms become available, the Division strongly encourages Carriers to consider taking steps to work with provider organizations to educate contracted and other providers about the use of uniform prior authorization forms for approved medications. Carriers are encouraged to work with contracted providers to use the standard and electronic forms within 90 days after the issuance of this Bulletin.

Conducting the Exceptions Process

M.G.L. c. 176O, §12A(d) requires the following:

> A carrier or a utilization review organization shall grant or deny a request for an exception to the step therapy protocol or a request to appeal a denial of an exception not more than 3 business days following the receipt of all necessary information to establish the medical necessity of the prescribed treatment. If additional delay would result in significant risk to the insured's health or well-being, a carrier or a utilization review organization shall respond not more than 24 hours following the receipt of all necessary information to establish the medical necessity of the prescribed treatment. If a response by a carrier or a utilization review organization is not received within the time required under this paragraph, an exception to the step therapy protocol shall be deemed granted.

As noted, Carriers that employ step therapy protocols are to adapt their utilization systems so that initial determinations of a request for an exception are made within 3 business days (not including Saturdays, Sundays, or holidays), or 24 hours as applicable, following the receipt of all necessary information to establish the medical necessity of the prescribed treatment. The Carrier will be deemed to have received "all necessary information" in an exception request if the applicable standard prior authorization form, as amended by this Bulletin 2024-03, has been completed and submitted to the Carrier for consideration. The denial of an exception request shall be considered an adverse determination pursuant to M.G.L. c. 176O and 211 CMR 52. The Carrier is expected to provide a notice of the adverse determination consistent with 211 CMR 52.07(6) and the provisions of M.G.L. c. 176O, §12A(d).

Likewise, Carriers that employ step therapy protocols are to adapt their utilization systems so that appeals of denials of a request for an exception regarding step therapy protocols are made within 3 business days (not including Saturdays, Sundays, or holidays), or 24 hours as applicable, following the receipt of all necessary information to establish the medical necessity of the prescribed treatment. Given the truncated appeals timeframes mandated by M.G.L. c. 176O, §12A(d), Carriers should follow the existing process for "expedited internal grievance process" pursuant to 958 CMR 3.300, Health Insurance Consumer Protection, when processing "appeals" of a denial of an exception request. Requirements at 3.309(1) (c) and (d) should be followed only if additional delay would result in significant risk to the insured's health or well-being.

If a Carrier does not make a determination within the timelines identified in M.G.L. c. 176O, §12A(d), this Bulletin 2024-03, and any other applicable laws or regulations, then the request for an exception to the step protocol process will be deemed granted.

Continuity of Coverage

M.G.L. c. 176O, §12A(c)(2) requires the following:

> All Carriers shall have a continuity of coverage policy in place to ensure that the insured does not experience any delay in accessing the drug prescribed by their health care provider, including a drug administered by infusion, while the exception request is being reviewed; provided, however, that the continuity of coverage policy shall include, but not be limited to, a 30-day fill of a United States Food and Drug Administration-approved drug

reimbursed through a pharmacy benefit that the insured has already been prescribed and on which the insured is stable; and provided further, that a carrier shall not apply any greater deductible, coinsurance, copayments or out-of-pocket limits than would otherwise apply to drugs covered by the plan.

Carriers are to make all continuity of coverage policies consistent with 211 CMR 52.07(8), including making this information clearly available to all insureds and to treating providers.

Implementation Plans

The Division is aware that Carriers and providers may be at differing degrees of readiness for implementing amended prior authorization forms and utilization system processes to align with Bulletin 2024-03. The Division expects all Carriers to forward an implementation plan to the Division by no later than February 15, 2024 that will present the detailed step-by-step process it will take to implement Bulletin 2024-03 and the dates by which all steps for updating its prior authorization forms and exceptions consideration process will be completed. The Division will review all implementation plans to determine whether they are reasonable, and the Division strongly encourages Carriers to work with provider organizations to educate contracted and other providers about the steps the Carrier is taking to implement these processes. The Division will monitor Carriers' implementation of their updated processes to confirm that they will come into compliance with Chapter 254 within the earliest possible timeframe.

Step Therapy Commission

Chapter 254 requires the establishment of a Step Therapy Commission to study and assess the step therapy process reforms and report on the implementation of Chapter 254. The Division expects that there will be additional guidance to supplement or replace Bulletin 2024-03 based on future recommendations of the Step Therapy Commission.

If you have any questions about Bulletin 2024-03, please contact Kevin Beagan at (617) 521-7323 or Kevin.Beagan@mass.gov.

APPENDIX

Massachusetts Standard Form for Medication Prior Authorization Requests

Massachusetts Standard Form for Hepatitis C Medication Prior Authorization Requests

Massachusetts Standard Form for Chemotherapy and Supportive Care Prior Authorization Requests

MASSACHUSETTS STANDARD FORM FOR MEDICATION PRIOR AUTHORIZATION REQUESTS

**Some plans might not accept this form for Medicare or Medicaid requests.*

This form is being used for:	
Check one:	☐ Initial Request ☐ Continuation/Renewal Request
Reason for request *(check all that apply)*:	☐ Prior Authorization, Step Therapy, Formulary Exception ☐ Quantity Exception ☐ Specialty Drug ☐ Other *(please specify)*: _____
Check if Expedited Review/Urgent Request:	☐ (In checking this box, I attest to the fact that this request meets the definition and criteria for expedited review and is an urgent request as defined by the carrier.)

Health Plan or Prescription Plan Name:	
Health Plan Phone:	Fax:

Patient Name:	DOB:	Member ID #
Sex assigned at birth: ☐ Male ☐ Female ☐ "X" or Intersex		
Current Gender: ☐ Male ☐ Female ☐ Transgender Male ☐ Transgender Female ☐ Other		

Plans do not discriminate based on race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

C. Prescriber Information	
Prescribing Clinician:	Phone #:
Specialty:	Secure Fax #:
NPI #:	DEA/xDEA:
Prescriber Point of Contact Name (POC) (if different than provider):	
POC Phone #:	POC Secure Fax #:
POC Email (not required):	
Prescribing Clinician or Authorized Representative Signature:	
Date:	

D. Medication Information *For medications subject to step therapy protocol for which you are seeking an exception, please also complete Section F. For more information, refer to the health plan's coverage policies, member benefits, and medical necessity guidelines.*	
Medication Being Requested:	
Strength:	Quantity:
Dosing Schedule:	Length of Therapy:
Date Therapy Initiated:	
Is the patient currently being treated with the drug requested? ☐ Yes ☐ No	If yes, date started:
Dispense as Written (DAW) Specified? ☐ Yes ☐ No	
Rationale for DAW:	

E. Compound and Off Label Use

Is Medication a Compound? ☐ Yes ☐ No

If Medication Is a Compound, List Ingredients:

For Compound or Off Label Use, include citation to peer reviewed literature:

F. Exceptions to Step Therapy

Please complete the applicable section(s).

Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

If yes, briefly describe details of contraindication, adverse reaction, or harm:

Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regiment? ☐ Yes ☐ No

If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No

If yes, please provide details for the previous trial(s):

Drug Name: **Dates/duration of use:**

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response:

Drug Name: **Dates/duration of use:**

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response:

Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member? ☐ Yes ☐ No

If yes, briefly provide details on the member's stability and the likely adverse reaction or physical or mental harm:

G. Patient Clinical Information

Please refer to plan-specific criteria for details related to required information.

Primary Diagnosis Related to Medication Request:

ICD Codes:

Pertinent Comorbidities:

If Relevant to This Request:

Drug Allergies:

Height: Weight:

Pertinent Concurrent Medications:

Opioid Mgmt Tools in Place: ☐ Risk assessment ☐ Treatment Plan ☐ Informed Consent ☐ Pain Contract ☐ Pharmacy/Prescriber Restriction

Previous Therapies Tried/Failed:

Previous Therapies

Drug Name	Strength	Dosing Schedule	Date Prescribed	Date Stopped	Description of Adverse Reaction or Failure	Check if Sample
						☐
						☐
						☐
						☐
						☐

Are there contraindications to alternative therapies? ☐ Yes ☐ No

If yes, please list details:

Were nonpharmacologic therapies tried? ☐ Yes ☐ No

If yes, provide details:

Relevant Lab Values

Lab Name and Lab Value	Date Performed	Lab Name and Lab Value	Date Performed

If renewal, has the patient shown improvement in related condition while on therapy? ☐ Yes ☐ No ☐ N/A

If yes, please describe:

Additional information pertinent to this request:

Complete this section for Professionally Administered Medications *(including Buy and Bill)*.

Start Date: _____ End Date: _____

Servicing Prescriber/Facility Name: _____ ☐ Same as Prescribing Clinician

Servicing Provider/Facility Address: _____

Servicing Provider NPI/Tax ID #: _____

Name of Billing Provider: _____

Billing Provider NPI #: _____

Is this a request for reauthorization? ☐ Yes ☐ No

CPT Code: _____ # of Visits: _____ J Code: _____ # of Units: _____

Providers should consult the health plan's coverage policies, member benefits, and medical necessity guidelines to complete this form. Providers may attach any additional data relevant to medical necessity criteria.

CLEAR FORM

MASSACHUSETTS STANDARD FORM FOR HEPATITIS C MEDICATION PRIOR AUTHORIZATION REQUESTS

**Some plans might not accept this form for Medicare or Medicaid requests.*

A. Destination	
Health Plan or Prescription Plan Name:	
Health Plan Phone:	Health Plan Fax:

B. Patient Information		
Patient Name:	DOB:	Member ID #
Sex assigned at birth: ☐ **Male** ☐ **Female** ☐ **"X" or Intersex**		
Current Gender: ☐ **Male** ☐ **Female** ☐ **Transgender Male** ☐ **Transgender Female** ☐ **Other**		

Plans do not discriminate based on race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

C. Prescriber Information	
Prescribing Clinician:	Phone #:
Specialty:	Secure Fax #:
NPI #:	DEA #:
Prescriber Point of Contact Name (POC) (if different than prescriber):	
POC Phone #:	POC Secure Fax #:
POC Email (not required):	
Prescribing Clinician or Authorized Representative Signature:	
Date:	

D. Medication Information

Check if Expedited Review/Urgent Request:

☐ (In checking this box, I attest to the fact that this request meets the definition and criteria for expedited review and is an urgent request as defined by the carrier.)

☐ Daklinza ☐ Epclusa ☐ Harvoni ☐ Olysio ☐ Ribavirin Generic ☐ Ribavirin Branded
☐ Sovaldi ☐ Technivie ☐ Viekira Pak ☐ Viekira XR ☐ Zepatier ☐ Vosevi ☐ Mavyret ☐ Other_____

Requested Duration of Treatment: _____ weeks

Type of Therapy: ☐ Initial ☐ Continuation — weeks remaining: _____

Anticipated or actual start date:

Is the medication prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or hepatologist? ☐ Yes ☐ No

For Zepatier only: Has there been confirmation that the patient does not have a genotype 1a with a baseline NS5A polymorphism?
☐ Yes ☐ No ☐ Unknown

For Ribavirin only: Does the patient require a dosage form other than generic ribavirin 200 mg capsules or tablets? ☐ Yes ☐ No If yes, please specify the following:

Dosage form requested: _____

Clinical reason for use: _____

Are any of the following statements true?

☐ Patient is pregnant or plans to become pregnant within 6 months of completing treatment

☐ Patient is male with a female partner who is pregnant or plans to become pregnant within 6 months of completing treatment

☐ Patient has contraindications or intolerance to Ribavirin

E. Patient Clinical Information

Please refer to plan-specific criteria for details related to required information.

Diagnosis: ☐ B18.2 Hepatitis C (chronic) ☐ Other: _____

HCV Genotype: ☐ 1 ☐ 1a ☐ 1b ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Stage of Hepatic Fibrosis: ☐ F0 ☐ F1 ☐ F2 ☐ F3 ☐ F4

If F4: ☐ Compensated ☐ Decompensated

Check all methods of assessment that apply and include result:

Method	Result
☐ Liver biopsy	See above
☐ Transient elastography (FibroScan)	_____ kPa
☐ Shear wave elastography	_____ kPa
☐ MRE	_____ kPa
☐ FibroSure (FibroTest)	_____
☐ Echosens Fibrometer	_____
☐ Fibrospect	_____
☐ APRI	_____
☐ Fib-4	_____
☐ Hepascore	_____
☐ Other: _____	_____

Does the patient have HIV coinfection? ☐ Yes ☐ No ☐ Unknown

Is the patient status post liver transplant? ☐ Yes ☐ No

Confirm the patient's GFR range: ☐ 0–14 ☐ 15–29 ☐ 30 or greater *(Please specify.)* _____

HCV RNA levels:

Baseline (most recent): _____ IU/mL Date of lab work: _____

Week 8 of treatment (if continuation request): _____ IU/mL Date of lab work: _____

Previous Treatments

Has the patient been previously treated for Hepatitis C and failed treatment? ☐ Yes ☐ No

Adverse Reaction? ☐ Yes ☐ No

Drug Name	Date of treatment (MM/YY)	Response to treatment
		☐ Relapsed ☐ Partial response ☐ Null response (<2 log reduction in HCV RNA at Week 12) ☐ Did not complete ☐ Briefly describe details: _____
		☐ Relapsed ☐ Partial response ☐ Null response (<2 log reduction in HCV RNA at Week 12) ☐ Did not complete ☐ Briefly describe details: _____
		☐ Relapsed ☐ Partial response ☐ Null response (<2 log reduction in HCV RNA at Week 12) ☐ Did not complete ☐ Briefly describe details: _____

Additional information pertinent to this request:

F. Exceptions to Step Therapy

Please complete the applicable section(s).

Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

If yes, briefly describe details of contraindication, adverse reaction, or harm:

Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regiment? ☐ Yes ☐ No

If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No

If yes, please provide details for the previous trial:

Drug Name: **Dates/duration of use:**

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response:

Drug Name: **Dates/duration of use:**

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response:

Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member? ☐ Yes ☐ No

If yes, briefly provide details on the member's stability and the likely adverse reaction or physical or mental harm:

Providers should consult the health plan's coverage policies, member benefits, and medical necessity guidelines to complete this form. Providers may attach any additional data relevant to medical necessity criteria.

MASSACHUSETTS STANDARD FORM FOR CHEMOTHERAPY AND SUPPORTIVE CARE PRIOR AUTHORIZATION REQUESTS*

**Providers may use the health plan's portal in place of this form.*

Request Date:	Treatment Start Date:	☐ Standard	☐ Expedited

I.	
Health Plan Name:	
Health Plan Phone:	Health Plan Fax:

Member Information			
First:	Last:		MI:
DOB:	**Sex assigned at birth: ☐ Male ☐ Female ☐ "X" or Intersex** **Current Gender: ☐ Male ☐ Female ☐ Transgender Male ☐ Transgender Female ☐ Other[1]**		
Height:	Weight:	BSA (m^2):	
Diagnosis:	ICD-10:	Stage (0–4 or recurrent):	
Insurance:	Line of Business (ex: Medicare):	Member ID:	
*ECOG Score:	*Information in attached office note Yes ☐		
*Tumor Histology:			
*Allergies:			
*Comorbidities:			

1 Plans do not discriminate based on race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

II. Anti-cancer Treatment Request New: ☐ Retrospective: ☐ Re-Authorization: ☐

#	Billing Code/ J CODE	Administrative Code	Route	Dose	Frequency and Schedule	Cycles or Refills	Billing Method (B=Buy and Bill or P = Pharmacy)	FDA Approved for the Diagnosis?	For single use vials, is provider willing to dose round?
1							☐ B ☐ P	☐ Y ☐ N	☐ Y ☐ N ☐ Unknown
2							☐ B ☐ P	☐ Y ☐ N	☐ Y ☐ N ☐ Unknown
3							☐ B ☐ P	☐ Y ☐ N	☐ Y ☐ N ☐ Unknown
4							☐ B ☐ P	☐ Y ☐ N	☐ Y ☐ N ☐ Unknown

(continued on next page)

III. Supporting Care Drugs Requested

#	Billing Code/ J CODE	Administrative Code	Drug Name	Route	Dose	Frequency and Schedule	Condition (ex: Nausea)	Billing Method (B = Buy and Bill or P = Pharmacy)
1								☐ B ☐ P
2								☐ B ☐ P
3								☐ B ☐ P
4								☐ B ☐ P

If bone strengthening agents or b one antiresorptive agents are requested, select indication:
☐ Osteo ☐ Bone Metastases ☐ Hypercalcemia ☐ Adjuvant Breast Cancer

If ESAs requested, select indication:
☐ CKD ☐ Chemotherapy Induced Anemia (CIA) ☐ MDS ☐ Anemia of Chronic Disease (ACD)

IV. Provider and Place of Treatment Information

Ordering Provider:

NPI #:	TIN #:	DEA #:
Phone:	Fax:	

Treating Provider: (if different)

NPI #:	TIN #:
Phone:	Fax:

Place of Treatment: (if different)

NPI #:	TIN #:
Phone:	Fax:

Address of Treatment Center:

Is the patient currently being treated with the requested regimen(s)? ☐ Yes ☐ No ☐ Unknown

Line of Treatment:

What therapies has the patient previously tried?

Has the patient been screened for tumor mutations/biomarkers/genetic testing? ☐ Yes ☐ No ☐ Unknown

If so, what tumor mutations/biomarkers/genetic testing result has the patient been tested for?

_____

If this is an out-of-network request, is this provider the only available treating/servicing provider within a reasonable distance that can provide this treatment/service for the patient? ☐ Yes ☐ No ☐ Unknown

Has the member been receiving cancer treatments from the requesting treating provider? ☐ Yes ☐ No ☐ Unknown

Is treating provider in-network? ☐ Yes ☐ No ☐ Unknown

Site of Service: ☐ Outpatient Hospital ☐ Home Infusion ☐ Other _____

Attachments: ☐ Labs ☐ Imaging ☐ Chemo Orders ☐ Pathology ☐ Progress Notes

Authorized Representative:

Phone:	Fax:

(continued on next page)

V. Exceptions to Step Therapy

Please complete the applicable section(s).

Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

If yes, briefly describe details of contraindication, adverse reaction, or harm:

Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regiment? ☐ Yes ☐ No

If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No

If yes, please provide details for the previous trial:

Drug Name: **Dates/duration of use:**

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response:

Drug Name: **Dates/duration of use:**

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response:

Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member? ☐ Yes ☐ No

If yes, briefly provide details on the member's stability and the likely adverse reaction or physical or mental harm:

Providers should consult the health plan's coverage policies, member benefits, and medical necessity guidelines to complete this form. Providers must attach any additional data required relevant to medical necessity criteria, including PROGRESS NOTES, CHEMO ORDERS, LABS, PATHOLOGY, AND IMAGING RESULTS WITH REQUEST.