

Neupogen, Granix, Zarxio, Nivestym, Releuko

CareFirst Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720. If you have questions regarding the prior authorization, please contact CVS Caremark at 1-888-877-0518. For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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Patient's Name:	Date:
Patient's ID:	Patient's Date of Birth:
Physician's Name:	
Specialty:	NPI#:
Physician Office Telephone:	Physician Office Fax:
Referring Provider Info: 🗖 Same as Reque	sting Provider
Name:	NPI#:
Fax:	Phone:
Rendering Provider Info:	ring Provider 🛛 Same as Requesting Provider
Name:	NPI#:
Fax:	Phone:

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight:	kg	
Patient Height:		
Please indicate the place of service for the	e requested drug:	
\square Ambulatory Surgical	🗖 Home	Off Campus Outpatient Hospital
\square On Campus Outpatient Hospital	☐ Office	Pharmacy
What is the ICD-10 code?		

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

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Exception Criteria Questions:

- A. What product is being prescribed?
- □ Neupogen, *Continue to Question B*
- Granix, Continue to Question B

□ Nivestym, Skip to Clinical Criteria Questions

- □ Zarxio, Skip to Clinical Criteria Questions
- □ Releuko, *Continue to Question B*

B. Is the product being requested for the treatment of one of the following indications?

- Neutropenia associated with myelosuppressive anti-cancer therapy
- Neutropenia due to chemotherapy for acute myeloid leukemia
- Neutropenia associated with myeloablative chemotherapy after a bone marrow transplant for a non-myeloid cancer
- Autologous stem cell mobilization
- Severe chronic congenital neutropenia, severe chronic cyclic neutropenia, or severe chronic idiopathic neutropenia

 \square Yes, Continue to Question C

- □ No, Skip to Clinical Criteria Questions
- C. The preferred products for your patient's health plan are Nivestym and Zarxio. Can the patient's treatment be switched to one of the preferred products?
- TYes, Skip to Clinical Criteria Questions
- □ No, Continue to Question D

D. Did the patient have an inadequate response or contraindication to both preferred products (Nivestym and Zarxio)? *Action Required*: If 'Yes', attach supporting chart note(s)

Tes, Skip to Clinical Criteria Questions

 \square No, *Continue to Question E*

E. Has the patient failed treatment with both of the preferred products (Nivestym and Zarxio) due to an intolerable adverse event (e.g., rash, nausea, vomiting)? *Action Required*: If 'Yes', attach supporting chart note(s)

 \square Yes, Continue to Question F

 \square No, Continue to Question G

F. Was the intolerable adverse event an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product)? *Action Required*: If 'No', Attach supporting chart note(s)

- Tes Skip to Clinical Criteria Questions
- D No, Skip to Clinical Criteria Questions

G. Does the patient have a documented latex allergy? Action Required: If 'Yes', attach supporting chart note(s)

□ Yes, Continue to Question H

□ No Continue to Question H

H. Did the patient have an inadequate response or contraindication to Nivestym? *Action Required*: If 'Yes', attach supporting chart note(s)

- □ Yes, Skip to Clinical Criteria Questions
- □ No, *Continue to Question I*

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I. Has the patient failed treatment with Nivestym due to an intolerable adverse event (e.g., rash, nausea, vomiting)? *Action Required*: If 'Yes', attach supporting chart note(s)

 \Box Yes, Continue to Question J

□ No Skip to Clinical Criteria Questions

J. Was the intolerable adverse event an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product)? *Action Required*: If 'No', Attach supporting chart note(s)

🗖 Yes

🗖 No

Criteria Questions:

What product is being requested? Granix Neupogen Nivestym Releuko Zarxio

1. What is the patient's diagnosis?

D Neutropenia (prevention or treatment) associated with myelosuppressive anti-cancer therapy, Continue to 7

Agranulocytosis (non-chemotherapy drug induced), No further questions

□ Stem cell transplantation-related indications (including applicable gene therapy protocols), *No further questions*

Anemia in myelodysplastic syndrome, No further questions

□ Neutropenia in myelodysplastic syndrome, *No further questions*

Acute myeloid leukemia, *No further questions*

□ Neutropenia associated with HIV/AIDS, No further questions

□ Neutropenia related to renal transplantation, *No further questions*

□ Aplastic anemia, *No further questions*

Severe chronic neutropenia - Congenital neutropenia, *No further questions*

Severe chronic neutropenia - Cyclic neutropenia, No further questions

Severe chronic neutropenia - Idiopathic neutropenia, No further questions

Hematopoietic syndrome of acute radiation syndrome, *Continue to 2*

CAR-T cell related toxicities, *Continue to 3*

Hairy cell leukemia, Continue to 4

Chronic myeloid leukemia, Continue to 5

Glycogen storage disease (GSD) Type 1, *Continue to 6*

□ Other, please specify. ______, No further questions

2. Will the requested drug be used for the treatment of radiation-induced myelosuppression following a radiological/nuclear incident?

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□ Yes, *No Further Questions* □ No, *No Further Questions*

3. Will the requested drug be used as supportive care for neutropenia?

□ Yes, No Further Questions

□ No, No Further Questions

4. Will the requested drug be used for treatment of neutropenic fever following chemotherapy?

□ Yes, No Further Questions

□ No, No Further Questions

5. Will the requested drug be used to treat persistent neutropenia due to tyrosine kinase inhibitor therapy? Yes, *No Further Questions*

□ No, No Further Questions

Ino, no Further Questions

6. Will the requested drug be used for the treatment of low neutrophil counts?

□ Yes, No Further Questions

□ No, No Further Questions

7. Will the requested drug be used in combination with any other colony stimulating factor products within any chemotherapy cycle?

□ Yes, *Continue to 8* □ No, *Continue to 8*

8. Will the patient be receiving chemotherapy at the same time as they receive radiation therapy?

□ Yes, Continue to 9

□ No, Continue to 9

9. For which of the following indications is the requested drug being prescribed?

□ Primary prophylaxis of febrile neutropenia in a patient with a solid tumor or non-myeloid malignancy, *Continue to 10*

□ Secondary prophylaxis of febrile neutropenia in a patient with a solid tumor or non-myeloid malignancy, *Continue to 17*

Treatment of high risk febrile neutropenia, Continue to 19

□ Other, please specify. , *No further questions*

10. Has the patient received, is currently receiving, or will be receiving myelosuppressive anti-cancer therapy that is expected to result in 20% or higher incidence of febrile neutropenia? *ACTION REQUIRED*: If Yes, please submit documentation confirming the patient's diagnosis and the chemotherapeutic regimen.

[Refer to policy "APPENDIX A: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 20% or Higher"]

□ Yes, *No Further Questions* □ No, *Continue to 11*

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11. Has the patient received, is currently receiving, or will be receiving myelosuppressive anti-cancer therapy that is expected to result in 10-19% incidence of febrile neutropenia? *ACTION REQUIRED*: If Yes, please submit documentation confirming the patient's diagnosis and the chemotherapeutic regimen. *ACTION REQUIRED*: Submit supporting documentation

[Refer to policy "APPENDIX B: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 10% to 19 %"]

Tes, Continue to 13

 \square No, Continue to 12

12. Has the patient received, is currently receiving, or will be receiving myelosuppressive anti-cancer therapy that is expected to result in less than 10% risk incidence of febrile neutropenia? *ACTION REQUIRED*: If Yes, please submit documentation confirming the patient's diagnosis and the chemotherapeutic regimen.

□ Yes, Continue to 14

□ No, Continue to 14

13. Is the patient considered to be at high risk for febrile neutropenia because of bone marrow compromise, comorbidities, or other patient specific risk factors including any of the following? *ACTION REQUIRED*: If Yes, please submit documentation confirming the patient's risk factors.

G Yes, active infections, open wounds, or recent surgery *ACTION REQUIRED*: Submit supporting documentation, No further questions

G Yes, age greater than or equal to 65 years *ACTION REQUIRED*: Submit supporting documentation, No further questions

G Yes, bone marrow involvement by tumor producing cytopenias *ACTION REQUIRED*: Submit supporting documentation, No further questions

□ Yes, previous chemotherapy or radiation therapy *ACTION REQUIRED*: Submit supporting documentation, No further questions

Submit supporting documentation, No further questions

Tyes, poor performance status ACTION REQUIRED: Submit supporting documentation, No further questions

Yes, previous episodes of FN ACTION REQUIRED: Submit supporting documentation, No further questions
 Yes, other serious co-morbidities, including renal dysfunction, liver dysfunction, HIV infection, cardiovascular disease. Please specify.
 ACTION REQUIRED: Submit supporting documentation, No further questions

□ Yes, persistent neutropenia *ACTION REQUIRED:* Submit supporting documentation, No further questions
□ Yes, other bone marrow compromise, comorbidities, or patient specific risk factors not listed above. Please
specify. ______ *ACTION REQUIRED:* Submit supporting documentation, No further
questions

□ No, the patient does not have any risk factors, *No further questions*

14. Please indicate which risk factor applies to the patient: *ACTION REQUIRED*: Please submit documentation confirming the patient's risk factors.

[Please verify at least two risk factors are indicated. Refer to policy "APPENDIX C: Patient Risk Factors"] Active infections, open wounds, or recent surgery *ACTION REQUIRED*: Submit supporting documentation, Continue to 15

□ Age greater than or equal to 65 years *ACTION REQUIRED*: Submit supporting documentation, Continue to 15

□ Bone marrow involvement by tumor producing cytopenias *ACTION REQUIRED*: Submit supporting documentation, Continue to 15

□ Previous chemotherapy or radiation therapy *ACTION REQUIRED*: Submit supporting documentation, Continue to 15

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Department Poor nutritional status *ACTION REQUIRED*: Submit supporting documentation, Continue to 15

Deor performance status ACTION REQUIRED: Submit supporting documentation, Continue to 15

Previous episodes of FN ACTION REQUIRED: Submit supporting documentation, Continue to 15
 Other serious co-morbidities, including renal dysfunction, liver dysfunction, HIV infection, cardiovascular disease. Please specify.
 ACTION REQUIRED: Submit supporting documentation, Continue to 15

□ None of the above, *Continue to 15*

15. Does the patient have a second risk factor?

□ Yes, Continue to 16

□ No, *Continue to 16*

16. Please indicate the patient's second patient risk factor: *ACTION REQUIRED*: Please submit documentation confirming the patient's risk factors.

[Please verify at least two different risk factors are indicated (see answers to question 12 and 14). Refer to policy "APPENDIX C: Patient risk factors"]

□ Active infections, open wounds, or recent surgery *ACTION REQUIRED*: Submit supporting documentation, No further questions

□ Age greater than or equal to 65 years *ACTION REQUIRED*: Submit supporting documentation, No further questions

□ Bone marrow involvement by tumor producing cytopenias *ACTION REQUIRED*: Submit supporting documentation, No further questions

□ Previous chemotherapy or radiation therapy *ACTION REQUIRED*: Submit supporting documentation, No further questions

Department Poor nutritional status *ACTION REQUIRED*: Submit supporting documentation, No further questions

Dependence of the performance status ACTION REQUIRED: Submit supporting documentation, No further questions

Previous episodes of FN ACTION REQUIRED: Submit supporting documentation, No further questions
 Other serious co-morbidities, including renal dysfunction, liver dysfunction, HIV infection, cardiovascular disease. Please specify.
 ACTION REQUIRED: Submit supporting documentation, No further questions

Persistent neutropenia ACTION REQUIRED: Submit supporting documentation, No further questions
 Other, please specify. ACTION REQUIRED: Submit supporting

documentation, No further questions

□ None of the above, *No further questions*

17. Has the patient experienced a febrile neutropenic complication or a dose-limiting neutropenic event (a nadir or day of treatment count impacting the planned dose of chemotherapy) from a prior cycle of similar chemotherapy?

Tes, Continue to 18

□ No, *Continue to 18*

18. For the planned chemotherapy cycle, will the patient receive the same dose and schedule of chemotherapy as the previous cycle (for which primary prophylaxis was not received)?

□ Yes, No Further Questions

D No, *No Further Questions*

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19. Does the patient have any of the following prognostic factors that are predictive of clinical deterioration?

□ Yes, age greater than 65 years, *No further questions*

I Yes, being hospitalized at the time of the development of fever, *No further questions*

□ Yes, sepsis syndrome, No further questions

□ Yes, invasive fungal infection, No further questions

I Yes, pneumonia or other clinically documented infection, *No further questions*

 \Box Yes, prolonged (neutropenia expected to last greater than 10 days) or profound (absolute neutrophil count less than 0.1 x 10⁹/L) neutropenia, *No further questions*

T Yes, prior episodes of febrile neutropenia, *No further questions*

□ No, the patient does not have prognostic factors that are predictive of clinical deterioration., *No further questions*

APPENDIX

- A. <u>APPENDIX A: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 20% or</u> <u>Higher</u>^{*†}
 - 1. Acute Lymphoblastic Leukemia:
 - Select ALL regimens as directed by treatment protocol (see NCCN guidelines ALL)
 - 2. Bladder Cancer:

Dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)

- 3. Bone Cancer
 - i. VAIA (vincristine, doxorubicin, ifosfamide, and dactinomycin)
 - ii. VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide)
 - iii. Cisplatin/doxorubicin
 - iv. VDC (cyclophosphamide, vincristine, doxorubicin or dactinomycin)
 - v. VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)
- 4. Breast Cancer:
 - i. Dose-dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel
 - ii. TAC (docetaxel, doxorubicin, cyclophosphamide)
 - iii. TC (docetaxel, cyclophosphamide)
 - iv. TCH (docetaxel, carboplatin, trastuzumab)
- 5. Head and Neck Squamous Cell Carcinoma
- TPF (docetaxel, cisplatin, 5-fluorouracil)
- 6. Hodgkin Lymphoma:
 - i. Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine)
 - ii. Escalated BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)
- 7. Kidney Cancer:

Doxorubicin/gemcitabine

- 8. Non-Hodgkin's Lymphoma:
 - i. CHP (cyclophosphamide, doxorubicin, prednisone) + brentuximab vedotin
 - ii. Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)
 - ± rituximab
 - iii. ICE (ifosfamide, carboplatin, etoposide) \pm rituximab
 - iv. Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) ± rituximab
 - v. MINE (mesna, ifosfamide, mitoxantrone, etoposide) ± rituximab
 - vi. DHAP (dexamethasone, cisplatin, cytarabine) ± rituximab

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vii. ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine) ± rituximab

viii. HyperCVAD \pm rituximab (cyclophosphamide, vincristine, doxorubicin, dexamethasone \pm rituximab)

ix. Pola-R-CHP (polatuzumab vedotin-piiq, rituximab, cyclophosphamide, doxorubicin, prednisone)

9. Melanoma:

Dacarbazine-based combination with IL-2, interferon alpha (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)

- 10. Multiple Myeloma:
 - i. VTD-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide + bortezomib)
 - ii. DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide)
- 11. Ovarian Cancer:
- i. Topotecan \pm bevacizumab
- ii. Docetaxel
- 12. Soft Tissue Sarcoma:
 - i. MAID (mesna, doxorubicin, ifosfamide, dacarbazine)
 - ii. Doxorubicin
 - iii. Ifosfamide/doxorubicin
- 13. Small Cell Lung Cancer:
 - Topotecan
- 14. Testicular Cancer:
 - i. VelP (vinblastine, ifosfamide, cisplatin)
 - ii. VIP (etoposide, ifosfamide, cisplatin)
 - iii. TIP (paclitaxel, ifosfamide, cisplatin)
- 15. Gestational Trophoblastic Neoplasia:
 - i. EMA/CO (etoposide, methotrexate, dactinomycin/cyclophosphamide, vincristine)
 - ii. EMA/EP (etoposide, methotrexate, dactinomycin/etoposide, cisplatin)
 - iii. EP/EMA (etoposide, cisplatin/etoposide, methotrexate, dactinomycin)
 - iv. TP/TE (paclitaxel, cisplatin/paclitaxel, etoposide)
 - v. BEP (bleomycin, etoposide, cisplatin)
 - vi. VIP (etoposide, ifosfamide, cisplatin)
 - vii. ICE (ifosfamide, carboplatin, etoposide)
- 16. Wilms Tumor:
 - i. Regimen M (vincristine, dactinomycin, doxorubicin, cyclophosphamide, etoposide)
 - ii. Regimen I (vincristine, doxorubicin, cyclophosphamide, etoposide)

*Applies to chemotherapy regimens with or without monoclonal antibodies (e.g., trastuzumab, rituximab)

[†] This list is not comprehensive; there are other agents/regimens that have an intermediate/high risk for development of febrile neutropenia.

B. <u>APPENDIX B: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 10% to 19%</u>*^{\dagger}

1. Occult Primary – Adenocarcinoma:

Gemcitabine/docetaxel

- 2. Breast Cancer:
 - i. Docetaxel \pm trastuzumab
 - ii. AC (doxorubicin, cyclophosphamide) + sequential docetaxel (taxane portion only)
 - iii. AC + sequential docetaxel + trastuzumab
 - iv. Paclitaxel every 21 days \pm trastuzumab
 - v. TC (docetaxel, cyclophosphamide)

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- 3. Cervical Cancer:
 - i. Irinotecan
 - ii. Cisplatin/topotecan
 - iii. Paclitaxel/cisplatin \pm bevacizumab
 - iv. Topotecan
- 4. Colorectal Cancer:
 - FOLFIRINOX (fluorouracil, leucovorin, oxaliplatin, irinotecan)
- 5. Esophageal and Gastric Cancers:
 - Irinotecan/cisplatin
- 6. Non-Hodgkin's Lymphomas:
 - i. GDP (gemcitabine, dexamethasone, cisplatin/carboplatin)
 - ii. GDP (gemcitabine, dexamethasone, cisplatin/carboplatin) + rituximab
 - iii. CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) including regimens with pegylated liposomal doxorubicin
 - iv. CHOP + rituximab (cyclophosphamide, doxorubicin, vincristine, prednisone, rituximab) including regimens with pegylated liposomal doxorubicin
 - v. Bendamustine
- 7. Non-Small Cell Lung Cancer:
 - i. Cisplatin/paclitaxel
 - ii. Cisplatin/vinorelbine
 - iii. Cisplatin/docetaxel
 - iv. Cisplatin/etoposide
 - v. Carboplatin/paclitaxel
 - vi. Docetaxel
- 8. Ovarian Cancer:
- 9. Pancreatic Cancer:
 - FOLFIRINOX (fluorouracil, leucovorin, oxaliplatin, irinotecan)
- 10. Prostate Cancer:
 - Cabazitaxel
- 11. Small Cell Lung Cancer:
- Etoposide/carboplatin 12. Testicular Cancer:
 - i. BEP (bleomycin, etoposide, cisplatin)
 - ii. Etoposide/cisplatin
- 13. Uterine Sarcoma: Docetaxel
- *Applies to chemotherapy regimens with or without monoclonal antibodies (e.g., trastuzumab, rituximab)
- [†] This list is not comprehensive; there are other agents/regimens that have an intermediate/high risk for development of febrile neutropenia.

C. APPENDIX C: Patient Risk Factors*

- 1. Active infections, open wounds, or recent surgery
- 2. Age greater than or equal to 65 years
- 3. Bone marrow involvement by tumor producing cytopenias
- 4. Previous chemotherapy or radiation therapy
- 5. Poor nutritional status
- 6. Poor performance status
- 7. Previous episodes of FN

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- 8. Other serious co-morbidities, including renal dysfunction, liver dysfunction, HIV infection, cardiovascular disease
- 9. Persistent neutropenia

Step Therapy Override: Complete if Applicable for the state of Maryland.		Please Circle	
Is the requested drug being used to treat stage four advanced metastatic cancer?	Yes	No	
Is the requested drug's use consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer and is supported by peer-reviewed medical literature?	Yes	No	
Is the requested drug being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No	
Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No	
Do patient chart notes document the requested drug was ordered with a paid claim at the pharmacy, the pharmacy filled the prescription and delivered to the patient or other documentation that the requested drug was prescribed for the patient in the last 180 days?	Yes	No	
Has the prescriber provided proof documented in the patient chart notes that in their opinion the requested drug is effective for the patient's condition?	Yes	No	

Step Therapy Override: Complete if Applicable for the state of Virginia.		
Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
Is the request for a brand drug that has an AB-rated generic equivalent or interchangeable biological product available?	Yes	No
Has the patient had a trial and failure of the AB-rated generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient?	Yes	No
Is the preferred drug contraindicated?	Yes	No
Is the preferred drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen?	Yes	No
Has the patient tried the preferred drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?	Yes	No
Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition?	Yes	No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

Х

Prescriber or Authorized Signature

Date (mm/dd/yy)

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