



PRIOR AUTHORIZATION REQUEST

Ustekinumab Products (Stelara and biosimilars)

Patient Information:

Name:	
Member ID:	
Address:	
City, State, Zip:	
Date of Birth:	

Prescriber Information:

Name:	
NPI:	
Phone Number:	
Fax Number:	
Address:	
City, State, Zip:	

Requested Medication

Rx Name:	
Rx Strength:	
Rx Quantity:	
Rx Frequency:	
Rx Route of Administration:	
Diagnosis and ICD Code:	

Your patient's prescription benefit requires that we review certain requests for coverage with the prescriber. You have prescribed a medication for your patient that requires Prior Authorization before benefit coverage or coverage of additional quantities can be provided. Please complete the following questions then fax this form to the toll-free number listed below. Upon receipt of the completed form, prescription benefit coverage will be determined based on the plan's rules.

SECTION A: Please note that supporting clinical documentation is required for **ALL PA** requests. Pharmacy prior authorization reviews can be subject to trial with additional medications that are not listed within the criteria. The policies are subject to change based on COMAR requirements, MDH transmittals and updates to treatment guidelines.

- | | | Yes | No |
|---|--|-----|----|
| 1 | Will the requested medication be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or targeted synthetic DMARD?
[Note: Examples of biologics include but not limited to adalimumab SC products (Humira, biosimilars), Cimzia, etanercept SC products (Enbrel, biosimilars), infliximab IV products (Remicade, biosimilars), Actemra (IV or SC), Simponi, Simponi Aria (IV or SC), Orencia (IV or SC), rituximab IV products (Rituxan, biosimilars), Kineret, Siliq, Cosentyx, Taltz, Ilumya, Skyrizi, Tremfya, Entyvio. Examples of targeted synthetic DMARD include but not limited to Otezla, Olumiant, Rinvoq, or Xeljanz/XR.]
[If yes, no further questions.] | | |

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|----|--|-----|----|
| 2 | What is the requested medication formulation?
☐ INTRAVENOUS (If checked, go to 22)

☐ SUBCUTANEOUS (If checked, go to 3) | | |
| 3 | Is the request for a formulary Ustekinumab product (Pyzchiva, Steqeyma, or Yesintek)?
[If yes, skip to question 5.] | Yes | No |
| 4 | Does the patient have documented intolerance or failed treatment for at least 3 months with preferred Ustekinumab product(s) (Pyzchiva, Steqeyma, or Yesintek)? ACTION REQUIRED: Submit supporting documentation.
[If no, no further questions.] | Yes | No |
| 5 | Is the patient currently receiving the requested medication?
[If no, skip to question 10.] | Yes | No |
| 6 | Has the patient been receiving medication samples for the requested medication?
[If yes, skip to question 10.] | Yes | No |
| 7 | Does the patient have a previously approved PA on file with the current plan?
[Note: If the patient does NOT have a previously approved PA on file for the requested medication with the current plan, the renewal request will be considered under initial therapy.]
[If no, skip to question 9.] | Yes | No |
| 8 | Has the patient been established on therapy for at least 3 months?
[If yes, skip to question 34.]
[If no, skip to question 11.] | Yes | No |
| 9 | Has documentation been submitted to confirm that the patient has experienced a clinically significant response, as determined by the provider? ACTION REQUIRED: Submit supporting documentation.
[If yes, skip to question 11.]
[If no, no further questions.] | Yes | No |
| 10 | What is the indication or diagnosis?
☐ Plaque Psoriasis (If checked, go to 12)

☐ Psoriatic Arthritis (If checked, go to 17)

☐ Crohn's Disease [Note: Includes adults with fistulizing Crohn's disease or Crohn's disease of the ileal pouch.] (If checked, no further questions)

☐ Ulcerative Colitis (If checked, no further questions) | | |

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☐ Ankylosing Spondylitis (If checked, no further questions)

☐ Other (If checked, no further questions)

11 What is the indication or diagnosis?

☐ Plaque Psoriasis (If checked, go to 12)

☐ Psoriatic Arthritis (If checked, go to 17)

☐ Crohn's Disease [Note: Includes adults with fistulizing Crohn's disease or Crohn's disease of the ileal pouch.] (If checked, go to 26)

☐ Ulcerative Colitis (If checked, go to 29)

☐ Ankylosing Spondylitis (If checked, no further questions)

☐ Other (If checked, no further questions)

12	Is the patient greater than or equal to 6 years of age? [If no, no further questions.]	Yes	No
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13	Is the requested medication being prescribed by, or in consultation with, a dermatologist? [If no, no further questions.]	Yes	No
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14	Has documentation been provided to confirm that the patient has tried at least TWO traditional systemic agents for psoriasis for at least 3 months or has a documented intolerance or contraindication to at least TWO traditional systemic agents for psoriasis? ACTION REQUIRED: Submit supporting documentation. [Note: Examples of traditional systemic agents include methotrexate, cyclosporine, or acitretin.] [If no, no further questions.]	Yes	No
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15	Has documentation been submitted to confirm that the patient has an intolerance, contraindication to, or failed treatment for at least 3 months with preferred TNF inhibitor, an adalimumab product (Hadlima, Simlandi, Yusimry, or adalimumab-adbm)? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
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16	Does the dose of the requested medication exceed the Food and Drug Administration (FDA) approved label dosing for the indication? (Dosing weight less than 60 kg: 0.75 mg/kg at weeks 0, 4 and then every 12 weeks thereafter. Dosing weight 60 kg to 100 kg: 45 mg at weeks 0, 4 and then every 12 weeks thereafter. Dosing weight greater than 100 kg: 90 mg at weeks 0, 4 and then every 12 weeks thereafter) [No further questions.]	Yes	No
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17	Is the patient greater than or equal to 6 years of age?	Yes	No
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[If no, no further questions.]

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| 18 | Has the patient tried TWO conventional synthetic disease-modifying antirheumatic drugs (DMARDs) for at least 3 months such as methotrexate (oral or injectable), leflunomide, hydroxychloroquine and/or sulfasalazine?
[If yes, skip to question 20.] | Yes | No |
| 19 | Has the patient experienced an intolerance to at least TWO conventional synthetic disease-modifying antirheumatic drugs (DMARDs) such as methotrexate (oral or injectable), leflunomide, hydroxychloroquine and/or sulfasalazine?
[If no, no further questions.] | Yes | No |
| 20 | Has documentation been submitted to confirm that the patient has an intolerance, contraindication to, or failed treatment for at least 3 months with preferred TNF inhibitor, an adalimumab product (Hadlima, Simlandi, Yusimry, or adalimumab-adbm)? ACTION REQUIRED: Submit supporting documentation.
[If no, no further questions.] | Yes | No |
| 21 | Does the dose of the requested medication exceed the Food and Drug Administration (FDA) approved label dosing for the indication? (Dosing weight less than 60 kg: 0.75 mg/kg at weeks 0, 4 and then every 12 weeks thereafter. Dosing weight 60 kg to 100 kg: 45 mg at weeks 0, 4 and then every 12 weeks thereafter. Dosing weight greater than 100 kg: 90 mg at weeks 0, 4 and then every 12 weeks thereafter)
[No further questions.] | Yes | No |
| 22 | Is the request for a formulary Ustekinumab product (Pyzchiva, Steqeyma, or Yesintek)?
[If yes, skip to question 24.] | Yes | No |
| 23 | Does the patient have documented intolerance or failed treatment for a least 3 months with preferred Ustekinumab product(s) (Pyzchiva, Steqeyma, or Yesintek)? ACTION REQUIRED: Submit supporting documentation.
[If no, no further questions.] | Yes | No |
| 24 | Will the requested medication be used as induction therapy?
[If no, no further questions.] | Yes | No |
| 25 | What is the indication or diagnosis?
☐ Crohn's Disease [Note: Includes adults with fistulizing Crohn's disease or Crohn's disease of the ileal pouch.] (If checked, go to 26)

☐ Ulcerative Colitis (If checked, go to 29)

☐ Plaque Psoriasis (If checked, no further questions)

☐ Psoriatic Arthritis (If checked, no further questions) | | |

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☐ Other (If checked, no further questions)

- | | | | |
|----|---|-----|----|
| 26 | Is the patient greater than or equal to 18 years of age?
[If no, no further questions.] | Yes | No |
| 27 | Has the patient tried TWO other conventional systemic therapies for Crohn's disease or was intolerant to other conventional systemic therapies?
[Note: Examples of other agents for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate.]
[If no, no further questions.] | Yes | No |
| 28 | Has documentation been submitted to confirm that the patient has had an intolerance, contraindication to, or failed treatment for at least 3 months with preferred TNF inhibitor, an adalimumab product (Hadlima, Simlandi, Yusimry, or adalimumab-adbm)? ACTION REQUIRED: Submit supporting documentation.
[If yes, skip to question 32.]
[If no, no further questions.] | Yes | No |
| 29 | Is the patient greater than or equal to 18 years of age?
[If no, no further questions.] | Yes | No |
| 30 | Has the patient had a trial of TWO systemic agents for ulcerative colitis or was intolerant to systemic agent?
[Note: Examples of systemic agents include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone.]
[If no, no further questions.] | Yes | No |
| 31 | Has documentation been submitted to confirm that the patient has had an intolerance, contraindication to, or failed treatment for at least 3 months with preferred TNF inhibitor, an adalimumab product (Hadlima, Simlandi, Yusimry, or adalimumab-adbm)? ACTION REQUIRED: Submit supporting documentation.
[If no, no further questions.] | Yes | No |
| 32 | Does the dose exceed the Food and Drug Administration (FDA) approved label dosing for the indication? (Dosing weight less than 55 kg: 260 mg. Dosing weight 55 to 85 kg: 390 mg. Dosing weight greater than 85 kg: 520 mg)
[If yes, no further questions.] | Yes | No |
| 33 | Is the requested medication being prescribed by, or in consultation with, a gastroenterologist?
[No further questions.] | Yes | No |
| 34 | What is the indication or diagnosis?
☐ Crohn's Disease [Note: Includes adults with fistulizing Crohn's disease or Crohn's disease of the ileal pouch.] (If checked, go to 35) | | |

☐ Plaque Psoriasis (If checked, go to 36)

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☐ Psoriatic Arthritis (If checked, go to 37)

☐ Ulcerative Colitis (If checked, go to 38)

☐ Ankylosing Spondylitis (If checked, no further questions)

☐ Other (If checked, no further questions)

- | | | | |
|-----------|--|-----|----|
| 35 | <p>Has documentation been submitted to confirm that the patient has experienced a clinically significant response, as determined by the provider? ACTION REQUIRED: Submit supporting documentation.
 [Note: Examples of a response to therapy include a decrease in symptoms such as diarrhea, pain, and/or bleeding; and/or improvement in erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), complete blood count (CBC), and/or fecal calprotectin (fCal). The patient may not have a full response, but there should have been a recent or past response to Stelara.]
 [No further questions.]</p> | Yes | No |
| 36 | <p>Has documentation been submitted to confirm that the patient has experienced a clinically significant response, as determined by the provider? ACTION REQUIRED: Submit supporting documentation.
 [Note: The patient may not have a full response, but there should have been a recent or past response to Stelara.]
 [No further questions.]</p> | Yes | No |
| 37 | <p>Has documentation been submitted to confirm that the patient has experienced a clinically significant response, as determined by the provider? ACTION REQUIRED: Submit supporting documentation.
 [Note: Examples of a response to therapy include less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improvements in acute phase reactants (for example, C-reactive protein). The patient may not have a full response, but there should have been a recent or past response to Stelara.]
 [No further questions.]</p> | Yes | No |
| 38 | <p>Has documentation been submitted to confirm that the patient has experienced a clinically significant response, as determined by the provider? ACTION REQUIRED: Submit supporting documentation.
 [Note: Examples of a response to therapy include decreased stool frequency or rectal bleeding.]</p> | Yes | No |



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Please document the diagnoses, symptoms, and/or any other information important to this review:

SECTION B: Physician Signature

PHYSICIAN SIGNATURE

DATE

FAX COMPLETED FORM TO: 1-833-896-0656

Disclaimer: An authorization is not a guarantee of payment. Member must be eligible at the time services are rendered. Services must be a covered Health Plan Benefit and medically necessary with prior authorization as per Plan policy and procedures.

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