

# Infliximab: Remicade<sup>®</sup>; Inflectra<sup>™</sup>; Renflexis<sup>™</sup>; Avsola<sup>™</sup>; infliximab\* Preauthorization Request

(PREAUTHORIZATION IS NOT A GUARANTEE OF PAYMENT)

Today's date: / /		New request		
Fax completed form to: <u>866.805.4150</u>	toll free.	Re-authorization		
Level of urgency:	l			
Standard request (routine care) - care	e/treatment that is	s not emergent, urgent,	or preventive in nature.	
	care determinati life, health, or sa er with knowledge	ons:  Ifety of the member or o  of the member's medic	-	
For expedited request, please expla	<u>in:</u>			
SECTION II – Member information				
Patients name:	Member ID:		Patient information: DOB:/_/_	
Patients address:	Is Capital Blue Yes No	Cross primary payer:	Sex: Age: Weight:	
Plan type:  PPO POS Traditional Comprehensiv	☐ KHPC re ☐ Special Ca	CHIP  are Other*		
*NOTE: For all Medicare Advantage products, please contact Prime Therapeutics at <a href="https://www.covermymeds.com/main">www.covermymeds.com/main</a> or via phone at 866.260.0452.				
SECTION III – Provider information	required			
Requesting provider name: Address:		Requesting provider	Capital # NPI #	



Telephone #:	Secure fax #:		
Office contact name:	Office contact telephone #:		
<b>Is the rendering/servicing provider different?</b> No Yes – Complete rendering provider information below.			
Rendering provider name: Address: Telephone:	Rendering provider Capital #NPI #		
Site of service:  MD office. Home health. Non-hospital affiliated, outpatient infusion center. Hospital affiliated, outpatient infusion center. Other: Specify.  *Please refer to MP 3.016 for site of service requirements.	Check all that apply and include all applicable documentation:  There are contraindications to a less intensive site of care.  A less intensive site of care is not appropriate for the patient's condition.  Patient is being treated with a drug that cannot be administered in a less intensive site of care concurrently.  Less intensive site of care is not available.  *Please include all applicable documentation.		
SECTION IV – Preauthorization requirements and cl Is the prescriber a specialist in the area of the patient's in the area of the patient's diagnosis?   Yes Specialist	diagnosis or has the prescriber consulted with a specialist		
<ul> <li>New to therapy.</li> <li>Continuing therapy*: Initial start//</li> <li>Reinitiating therapy: Last treatment//</li> <li>*Please include documentation for changes in dose.</li> <li>HCPCS Code(s):</li> </ul>	Route of administration:  Intravenous (IV).  Injection (Sub Q or IM).  Oral (PO) or Enteral.  Other: Specify.  Diagnosis code(s):		
Medication requested:	Indication:		
Does the patient have late-stage metastatic disease?  Yes No  For patients with late-stage metastatic disease (Stage IV), please refer to MP 2.373 Step Therapy Treatment in Cancer, Including Treatments for Stage Four, Advanced Metastatic Cancer and Severe Related Health Conditions for additional guidance.			
Type of drug requested:   Brand name  Gene			
Initial start date of therapy://	Anticipated date of <b>next administration</b> ://		



Dosing period for request:	Dosing Information:		
	Dose:		
Start date://	Strength:		
End date://	Frequency:		
	Quantity requested per month:		
Attach documentation demonstrating the medical necessity of the requested drug. Please list all reasons for selecting the requested medication, strength, dosing schedule, and quantity over alternatives (e.g., contraindications, allergies, history of adverse drug reactions to alternatives, lower dose has been tried, information supporting dose over FDA max.)			
Has the patient had <b>medical testing</b> co	ompleted for use of this drug? (labs, imaging)		
Is drug being requested for an "off labe	el" indication?  Yes  No		
If yes, please see Medical Policy 2.103	and include any applicable documentation.		
Please list any previous medications the hypersensitivity, inadequate response of Drug(s) and strength:	at were tried and failed. Include reason for discontinuation (intolerance, etc.). Please attach documentation.		
Documentation of failure:			
Documentation of failure.			



Check drug being prescribed:  Remicade Inflectra Renflexis Avsola Infliximab* (unbranded)
Other (enter name)
Check if contraindication or intolerance to a trial of any of the following:  ☐ Remicade ☐ Infliximab* (unbranded) ☐ Avsola
<ul> <li>Has the patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment?</li></ul>
COMPLETE BELOW FOR RELEVANT DIAGNOSIS
<u>Crohn's Disease (non-pediatric)</u> Has the physician assessed baseline disease severity utilizing an objective measuring tool? □ Yes □ No Is there documentation of moderate to severe disease? □ Yes □ No
Pediatric Crohn's Disease Has the physician assessed baseline disease severity utilizing an objective measuring tool? ☐ Yes ☐ No Is the patient is at least 6 years of age? ☐ Yes ☐ No Is there documented moderate to severe disease? ☐ Yes ☐ No
<u>Ulcerative Colitis (non-pediatric)</u> Has the physician assessed baseline disease severity utilizing an objective measuring tool? $\Box$ Yes $\Box$ No Is there documentation of moderate to severe disease? $\Box$ Yes $\Box$ No
Pediatric Ulcerative Colitis  Has the physician assessed baseline disease severity utilizing an objective measuring tool? □ Yes □ No Is the patient is at least 6 years of age? □ Yes □ No Is there documented moderate to severe disease? □ Yes □ No



Fistulizing Crohn's Disease Has the physician assessed baseline disease severity utilizing an objective measuring tool? $\Box$ Yes $\Box$ No Does the patient have at least one draining fistula (i.e., enterovesical, enterocutaneous, enteroenteric, or enterovaginal fistulas) for at least 3 months? $\Box$ Yes $\Box$ No
Rheumatoid Arthritis (RA) Has the physician assessed baseline disease severity utilizing an objective measuring tool? □ Yes □ No Is there documentation of moderate to severe disease? □ Yes □ No Has the patient had at least a 3-month trial and failed previous therapy with ONE oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, leflunomide, etc.? □ Yes □ No Will the drug be used in combination with methotrexate (MTX) unless contraindicated? □ Yes □ No
Psoriatic Arthritis  Has the physician assessed baseline disease severity utilizing an objective measuring tool? □ Yes □ No Is there documentation of moderate to severe disease? □ Yes □ No Does the patient have predominantly axial disease, a trial and failure of at least a 4-week trial of ONE non-steroidal anti-inflammatory agent (NSAID)? □ Yes □ No  • Is NSAID use contraindicated? □ Yes □ No Does the patient have peripheral arthritis or dactylitis or active enthesitis, a trial and failure of at least a 3-month trial of ONE oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, hydroxychloroquine, etc.? □ Yes □ No
Ankylosing Spondylitis  Has the physician assessed baseline disease severity utilizing an objective measuring tool? □ Yes □ No Is there documentation of active disease? □ Yes □ No Has the patient had an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs) over 4 weeks (in total) OR is use contraindicated? □ Yes □ No
Plaque Psoriasis  Has the physician assessed baseline disease severity utilizing an objective measuring tool? ☐ Yes ☐ No Is there documentation of moderate to severe chronic disease for at least 6 months? ☐ Yes ☐ No Does the patient have any of the following? (check all that apply) ☐ Involvement of at least 3% of body surface area (BSA) ☐ Psoriasis Area and Severity Index (PASI) score of 10 or greater ☐ Incapacitation or serious emotional consequences due to plaque location (i.e., hands, feet, head and neck, genitalia, etc.) or with intractable pruritis  Did the patient did not respond adequately (or is not a candidate) to a 4-week minimum trial of topical agents (i.e., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or vitamin D analogues)? ☐ Yes ☐ No  Did the patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of at least one non-biologic systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate, etc.)? ☐ Yes ☐ No  Did the patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of phototherapy (i.e., psoralens with UVA light [PUVA] or UVB with coal tar or dithranol, etc.)  ☐ Yes ☐ No
Uveitis Associated with Behçet's Syndrome  Has the physician assessed baseline disease severity utilizing an objective measuring tool? □ Yes □ No Is the patient's disease refractory to immunosuppressive therapy (e.g., corticosteroids, cyclosporine, azathioprine, etc.)? □ Yes □ No  Did the patient have an inadequate response to a self-administered biologic therapy (e.g., adalimumab)? □ Yes □ No



Graft Versus Host Disease (GVHD) Has the patient received a hematopoietic stem cell transplant? $\Box$ Yes $\Box$ No Will the drug be used for steroid-refractory acute GVHD? $\Box$ Yes $\Box$ No Will the drug be used in combination with systemic corticosteroids as additional therapy following no response to first-line therapies? $\Box$ Yes $\Box$ No
Management of Immune Checkpoint Inhibitor Relater Toxicity  Has the patient been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, dostarlimab, tremelimumab, retifanlimab, etc.)?  ☐ Yes ☐ No  Has the patient had any of the following toxicities related to their immunotherapy? (check all that apply)  ☐ Myocarditis if no improvement after 24-48 hours of starting high-dose methylprednisolone  ☐ Mild (G1) diarrhea or colitis if persistent or progressive symptoms and positive lactoferrin/calprotectin  ☐ Moderate (G2) to severe (G3-4) diarrhea or colitis  ☐ Moderate (G2) pneumonitis if no improvement after 48-72 hours of corticosteroids  ☐ Severe (G3-4) pneumonitis if no improvement after 48 hours of methylprednisolone  ☐ Stage 3 acute kidney injury/ elevated serum creatinine if toxicity remains > G2 after 4-6 weeks of corticosteroids or if creatinine increases during steroid taper  ☐ Uveitis (G1-4) that is refractory to high-dose systemic corticosteroids  ☐ Moderate to severe inflammatory arthritis and drug is used as an additional disease-modifying DMARD therapy
RENEWAL CRITERIA (complete in addition to above)  Has the patient experienced unacceptable toxicity* from the drug? □ Yes □ No  *Examples of unacceptable toxicity include the following: severe hypersensitivity reactions, malignancy (e.g., lymphoma including hepatosplenic T-Cell lymphoma, skin cancers, cervical cancer, etc.), significant hematologic abnormalities (e.g., leukopenia, neutropenia, thrombocytopenia, pancytopenia), serious infections (i.e., TB, serious fungal infections, HBV reactivation, etc.), cardiovascular and cerebrovascular accidents, heart failure, neurotoxicity/ demyelinating disorders, hepatotoxicity, lupus-like syndrome, etc.  Has the patient experienced a disease specific response as outlined below? □ Yes □ No

## Crohn's Disease (including Pediatric Crohn's Disease)

Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra-intestinal complications, tapering or discontinuation of corticosteroid therapy, use of anti-diarrheal drugs, and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Crohn's Disease Activity Index (PCDAI) score, Pediatric Crohn's Disease Activity Index (PCDAI) score, or the Harvey-Bradshaw Index score].

# <u>Ulcerative Colitis Disease (including Pediatric Ulcerative Colitis)</u>

Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score, an improvement on the Pediatric Ulcerative Colitis Activity Index (PUCAI) score or the Mayo Score].

## Fistulizing Crohn's Disease Disease

Disease response as indicated by improvement in signs and symptoms compared to baseline such as a reduction in number of enterocutaneous fistulas draining upon gentle compression, and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score].



#### **Psoriatic Arthritis**

Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool [e.g. defined as an improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria (PsARC), 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria].

#### **Rheumatoid Arthritis**

Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Disease Activity Score-28 (DAS28) of 1.2 points or more or a ≥20% improvement on the American College of Rheumatology-20 (ACR20) criteria].

#### **Ankylosing Spondylitis**

Disease response as indicated by improvement in signs and symptoms compared to baseline such as total back pain, physical function, morning stiffness, and/or an improvement on a disease activity scoring tool [e.g.  $\geq$  1.1 improvement on the Ankylosing Spondylitis Disease Activity Score (ASDAS) or an improvement of  $\geq$  2 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)].

## **Plaque Psoriasis**

Disease response as indicated by improvement in signs and symptoms compared to baseline such as redness, thickness, scaliness, and/or the amount of surface area involvement (a total BSA involvement ≤1%), and/or an improvement on a disease activity scoring tool [e.g. a 75% reduction in the PASI score from when treatment started (PASI 75) or a 50% reduction in the PASI score (PASI 50) and a four-point reduction in the DLQI from when treatment started].

## Uveitis Associated with Behçet's Syndrome

Disease response as indicated by an improvement in signs and symptoms compared to baseline [e.g. reduction in inflammation and/or lesions, dose reduction of oral glucocorticoids and/or immunosuppressive agents, improvement in vitreous haze, improvement in best corrected visual acuity (BCVA), disease stability and/or reduced rate of decline].

#### Acute GVHD

May not be renewed (Note: Requests for continued therapy beyond four doses will be reviewed on a case-bycase basis.)

## Management of Immune Checkpoint Inhibitor Related Toxicity

May not be renewed.

Please use a separate form for each drug.

To fill out form type or write using blue or black ink.

Please fax this form to: 866.805.4150.

Telephone: 800.471.2242.

Prior authorization is not a guarantee of payment; benefits and eligibility will apply at the time of claim adjudication.

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