Infliximab: Remicade®, Inflectra™, Renflexis™, Avsola™, Infliximab
Preauthorization Request
(Preauthorization is not a guarantee of payment)

SECTION I – General Information

Today's Date: / /	☐ New request
Fax completed form to:**1-866-805-4150 toll free**	☐ Re-Authorization

Level of Urgency:

Standard Request (Routine Care)—Care/treatment that is not emergent, urgent, or preventive in nature.

Expedited Request—Care/treatment that is emergent or the application of the timeframe for making Standard/Routine or nonlife-threatening care determinations:

- Could seriously jeopardize the life, health, or safety of the member or others, due to the member's psychological state, or
- In the opinion of the practitioner with knowledge of the member's medical or behavioral condition, would subject the member to adverse health consequences without the care or treatment that is the subject of the request.

For Expedited Request, Please Explain:

SECTION II – Member Information

Patients Name:	Member ID:	**Patient Information**: DOB:__/__/__ Sex: Age: Weight: ☐ lbs. ☐ Kg Will the patient self-administer the requested medication? ☐ Yes ☐ No
Patients Address:	Is CBC primary payer: ☐ Yes ☐ No	

Plan Type:

☐ PPO ☐ POS ☐ KHPC ☐ CHIP (aka Capital Cares 4Kids)
☐ Traditional ☐ Comprehensive ☐ Special Care ☐ Other* _____

NOTE: For all Medicare Advantage products, please contact Prime Therapeutics at https://www.covermymeds.com/main or via phone at 1-866-260-0452.

SECTION III – Provider Information Required

Requesting Provider Name: **Address**:	**Requesting Provider CBC #**_____ **NPI #** _____

Telephone #:	Secure Fax #:
Office Contact Name:	Office Contact Telephone #:
Is the Rendering/Servicing provider different? ☐ No ☐ Yes – Complete rendering provider information below.	
Rendering Provider Name: **Address**: **Telephone:**	**Rendering Provider CBC #**_____ **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 Clinical Criteria

Is the prescriber a specialist in the area of the patient's diagnosis or has the prescriber consulted with a specialist in the area of the patient's diagnosis? ☐ Yes Specialty: _____ ☐ No

☐ New to therapy ☐ Continuing therapy*: Initial start __/__/__ ☐ Reinitiating therapy: Last treatment __/__/__ *Please include documentation for changes in dose.	**Route of Administration:** ☐ Intravenous (IV) ☐ Injection (Sub Q or IM) ☐ Oral (PO) or Enteral ☐ Other: Specify _____
HCPC Code(s):	**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 ☐ Generic ☐ Biosimilar ☐ Other: Specify _____

Initial start date of therapy: __/__/__	Anticipated date of **next administration:** __/__/__

Dosing period for request: Start Date: __/__/__ End Date __/__/__	**Dosing Information:** Dose: Strength: 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 **medical testing** completed for use of this drug? (labs, imaging) ☐ Yes ☐ No Results:_____
Is drug being requested for an "**off label" indication**? ☐ Yes ☐ No If yes, please see Medical Policy 2.103 and include any applicable documentation.
Please list any previous medications that were **tried and failed**. Include reason for discontinuation (intolerance, hypersensitivity, inadequate response etc.). Please attach documentation. Drug(s) and strength: Documentation of failure:

Check drug being prescribed:

☐ **Remicade;** ☐ **Inflectra;** ☐ **Renflexis;** ☐ **Avsola ;** ☐ **Infliximab**

Other (enter name) _____

Check if there a contraindication or intolerance to a trial of any of the following:

- ☐ Remicade
- ☐ Infliximab
- ☐ Avsola

Has the patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment? ☐ Yes ☐ No
Has a physician assessed baseline disease severity utilizing an objective measure/tool? ☐ Yes ☐ No
Is the patient up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy? ☐ Yes ☐ No
Is the patient at least 18 years of age (unless otherwise specified);
Has the patient been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment? ☐ Yes ☐ No

- If yes, will the patient receive ongoing monitoring for presence of TB during treatment? ☐ Yes ☐ No

Does the patient have an active infection (including clinically important localized infections)? ☐ Yes ☐ No
Will the medication be administered concurrently with live vaccines or therapeutic infectious agents (i.e., BCG bladder instillation for bladder cancer, etc.)? ☐ Yes ☐ No
Is the patient on a concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, etc.)? ☐ Yes ☐ No
Does the patient have moderate or severe heart failure (i.e., New York Heart Association [NYHA] Functional Class III/IV)? ☐ Yes ☐ No

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COMPLETE BELOW FOR RELEVANT DIAGNOSIS

Crohn's Disease (non-pediatric):
Has the patient been diagnosed with Crohn's disease? ☐ Yes ☐ No

Is there documentation of moderate to severe disease? ☐ Yes ☐ No

- ☐

Pediatric Crohn's Disease
Has the patient been diagnosed with pediatric crohn's disease? □ 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 patient been diagnosed with fistulizing crohn's disease? □ Yes □ No
Does the patient have at least one or more draining fistulas (i.e., enterovesical, enterocutaneous, enteroenteric, or enterovaginal fistulas) for at least 3 months? □ Yes □ No

Ulcerative Colitis
Is there documented moderate to severe disease? □ Yes □ No

Rheumatoid Arthritis (RA)
Has the patient been diagnosed with RA? □ Yes □ No
Does the patient have documented 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)? □ Yes □ No
Is MTX contraindicated? □ Yes □ No

Psoriatic Arthritis
Has the patient been diagnosed with Psoriatic Arthritis? □ Yes □ No
Is there documentation of moderate to severe active disease? □ Yes □ No
Does the patient have predominantly axial disease OR active enthesitis? □ Yes □ No
- If yes, was there a trial and failure of at least a 4-week trial of ONE (1) non-steroidal anti-inflammatory agents (NSAIDs) □ Yes □ No
- OR was use use is contraindicated; □ Yes □ No

Does the patient have peripheral arthritis or dactylitis? □ Yes □ No
- If yes, was there 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 patient been diagnosed with Ankylosing Spondylitis? □ 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 patient been diagnosed with Plaque Psoriasis? □ Yes □ No
Is there documented moderate to severe plaque psoriasis 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 **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, etc.)? □ Yes □ No
Did the patient **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
Was the patient diagnosed with Uveitis associated with Behçet's Syndrome? □ Yes □ No
Is the patient's disease refractory to immunosuppressive therapy (e.g., corticosteroids, 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 been diagnosed with Graft Versus Host Disease (GVHD)? □ Yes □ No
Has the patient received a hematopoietic stem cell transplant? □ Yes □ No
Will the drug be used for steroid-refractory acute GVHD? □ Yes □ No
Will the drug be used in combination with systemic corticosteroids as additional therapy following no response to first-line therapies Management of Immune Checkpoint Inhibitor Related Toxicity?
□ Yes □ 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,
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 pulse-dose methylprednisolone
- ☐ Moderate (grade 2) to severe (grade 3-4) diarrhea or colitis
- ☐ Moderate (grade 2) pneumonitis if no improvement after 48-72 hours of corticosteroids
- ☐ Severe (grade 3-4) pneumonitis if no improvement after 48 hours of methylprednisolone□ Severe (grade 3) or life-threatening (grade 4) elevated serum creatinine/acute kidney injury if toxicity remains >grade 2 after 4-6 weeks of corticosteroidsUveitis (grade 1-4) that is refractory to high-dose systemic corticosteroids
- ☐ Severe inflammatory arthritis as additional disease-modifying therapy if symptoms
  - o do not improve within 1 week after starting high-dose corticosteroids or if unable to
  - o taper corticosteroids by week
- ☐ Moderate, severe, or life-threatening steroid-refractory myalgias or myositis

** Examples of contraindications to phototherapy (*PUVA or UVB*) include the following:

- Xeroderma pigmentosum
- Pregnancy or lactation (*PUVA only*)
- Lupus Erythematosus
- History of one of the following: photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage (*PUVA only*), treatment with arsenic or ionizing radiation
- Immunosuppression in an organ transplant patient (*UVB only*)
- Photosensitizing medications (*PUVA only*)
- Severe liver, renal, or cardiac disease (*PUVA only*)

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.), cerebrovascular accidents, cardiotoxicity/heart failure, neurotoxicity/ demyelinating disorders,, hepatotoxicity, lupus-like syndrome, , etc.*

Has the patient experienced a disease response as outlined below □ Yes □ No

Crohn's Disease (including Pediatric Crohn's 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 (CDAI) score, Pediatric Crohn's Disease Activity Index (PCDAI) score, or the Harvey-Bradshaw Index score].
Ulcerative Colitis Disease (including Pediatric Ulcerative Colitis): 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: 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. ≥ 1.1 improvement on the Ankylosing Spondylitis Disease Activity Score (ASDAS) or an improvement of ≥ 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-by-case 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: 1-866-805-4150** Telephone: 1-800-471-2242	**CONFIDENTIALITY NOTICE**: This communication is intended only for the use of the individual entity to which it is addressed, and may contain information that is privileged or confidential. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone at 1-800-471-2242. Thank you for your cooperation.
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