JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP002
		Effective Date	01/01/2007
		Review Date	07/15/2020
	Subject **Provider-administered Biological Response Modifiers: Remicade, Inflectra, Renflexis, Ixifi, Avsola, Simponi Aria, Orencia IV, Cimzia [lyophilized powder], Stelara IV [for one-time induction dose only], Entyvio, Ilumya, Tremfya**	*Revision Date*	01/07/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Avsola, Cimzia (lyophilized powder), Entyvio, Ilumya, Inflectra, Ixifi, Orencia IV, Remicade, Renflexis, Simponi Aria, Stelara IV, Tremfya

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I. POLICY

A. Remicade, Inflectra, Renflexis, Ixifi, Avsola, Simponi Aria, Orencia IV, Cimzia powder, Stelara IV, Entyvio, Ilumya, and Tremfya will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

B. Biosimilar and Interchangeable biosimilar Usage Notice: Current clinical evidence supports that biosimilars are highly similar, and do not have a clinically meaningful difference in terms of efficacy and safety when compared to their originator biologic product. In addition, the FDA has stated that biosimilars and interchangeable biosimilars can be used in patients previously treated with the originator product, as well as treatment-naïve patients. For Plan approval of therapy with the originator product, patients must first have trial and inadequate response to a preferred biosimilar medication when available.

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II. POLICY CRITERIA

A. **Renflexis** (infliximab-abda) may be approved for the following:
   1. **Rheumatoid Arthritis**:
      a. Patient is 18 years of age or older
      b. Patient has been diagnosed with moderately to severely active rheumatoid arthritis
      c. Patient has tried and had insufficient response to one or more oral DMARDs
      d. Remicade is prescribed for concurrent use with methotrexate
   2. **Ankylosing Spondylitis**:
      a. Patient is 18 years of age or older
      b. Patient has been diagnosed with active ankylosing spondylitis
      c. Patient has tried and had insufficient response to an adequate trial of two full dose NSAID therapies
   3. **Crohn's Disease**:
      a. Patient is 6 years of age or older
      b. Patient has been diagnosed with moderately to severely active, or fistulizing Crohn's Disease
      c. Patient has tried and had insufficient reponse to at least ONE of the following conventional therapies:
         i. Salicylate (sulfasalazine, mesalamine)
         ii. Systemic corticosteroid
         iii. Oral Immunosuppressant (azathioprine, 6MP, methotrexate, cyclosporine)
   4. **Ulcerative Colitis**:
      a. Patient is 6 years of age or older
      b. Patient has been diagnosed with moderately to severely active ulcerative colitis
      c. Patient has tried and had insufficient response to the following:
         i. A trial course of at least one aminosalicylate (mesalamine, sulfasalazine, olsalazine)
   5. **Plaque Psoriasis**:
      a. Patient is 18 years of age or older
      b. Patient has been diagnosed with moderate to severe chronic plaque psoriasis as supported by ONE of the following:
         i. Plaque psoriasis involving greater than 5% of body surface area (BSA)
         ii. Plaque psoriasis involving less than or equal to 5% BSA, but located in sensitive areas that can impact daily activities:,head, neck, genitalia, palms, soles of feet
      c. Patient has tried and had insufficient response to phototherapy or systemic oral DMARDs including methotrexate
   6. **Psoriatic Arthritis**:
      a. Patient is 18 years of age or older
      b. Patient has been diagnosed with active psoriatic arthritis
      c. Patient has tried and had insufficient response to methotrexate

B. **Remicade** (infliximab), **Inflectra** (infliximab-dyyb), **Ixifi** (infliximab-qbtx), and **Avsola** (infliximab-axxq) may be approved for the following:
   1. **Rheumatoid Arthritis**:
      a. Patient is 18 years of age or older
      b. Patient has been diagnosed with moderately to severely active rheumatoid arthritis
      c. Patient has tried and had insufficient response to one or more oral DMARDs

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d. Patient has tried and had insufficient response to Renflexis
e. Remicade is prescribed for concurrent use with methotrexate

2. **Ankylosing Spondylitis**:
   a. Patient is 18 years of age or older
   b. Patient has been diagnosed with active ankylosing spondylitis
   c. Patient has tried and had insufficient response to an adequate trial of two full dose NSAID therapies
   d. Patient has tried and had insufficient response to Renflexis
3. **Crohn's Disease**:
   a. Patient is 6 years of age or older
   b. Patient has been diagnosed with moderately to severely active, or fistulizing Crohn's Disease
   c. Patient has tried and had insufficient reponse to at least ONE of the following conventional therapies:
      i. Salicylate (sulfasalazine, mesalamine)
      ii. Systemic corticosteroid
      iii. Oral Immunosuppressant (azathioprine, 6MP, methotrexate, cyclosporine)
   d. Patient has tried and had insufficient response to Renflexis
4. **Ulcerative Colitis**:
   a. Patient is 6 years of age or older
   b. Patient has been diagnosed with moderately to severely active ulcerative colitis
   c. Patient has tried and had insufficient response to the following:
      i. A trial course of at least one aminosalicylate (mesalamine, sulfasalazine, olsalazine)
   d. Patient has tried and had insufficient response to Renflexis
5. **Plaque Psoriasis**:
   a. Patient is 18 years of age or older
   b. Patient has been diagnosed with moderate to severe chronic plaque psoriasis as supported by ONE of the following:
      i. Plaque psoriasis involving greater than 5% of body surface area (BSA)
      ii. Plaque psoriasis involving less than or equal to 5% BSA, but located in sensitive areas that can impact daily activities:,head, neck, genitalia, palms, soles of feet
   c. Patient has tried and had insufficient response to phototherapy or systemic oral DMARDs including methotrexate
   d. Patient has tried and had insufficient response to Renflexis
6. **Psoriatic Arthritis**:
   a. Patient is 18 years of age or older
   b. Patient has been diagnosed with active psoriatic arthritis
   c. Patient has tried and had insufficient response to methotrexate
   d. Patient has tried and had insufficient response to Renflexis

C. **Simponi Aria** (golimumab) may be approved for the following:
1. **Rheumatoid Arthritis**:
   a. Patient is 18 years of age or older
   b. Patient has been diagnosed with moderately to severely active rheumatoid arthritis
   c. Simponi Aria is prescribed for concurrent use with methotrexate
   d. Patient has tried and had insufficient response with at least one oral DMARD

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2. **Psoriatic Arthritis**
   a. Patient is 18 years of age or older
   b. Patient has tried and had insufficient response to at least one oral DMARD including methotrexate
   c. Patient has tried and had insufficient response with either etanercept or adalimumab or secukinumab
3. **Ankylosing Spondylitis**
   a. Patient is 18 years of age or older
   b. Patient has tried and had insufficient response to an adequate trial of two full dose NSAID therapies
   c. Patient has tried and had insufficient response to either etanercept or adalimumab or secukinumab

D. **Orencia** (abatacept) may be approved for the following:
1. **Rheumatoid Arthritis**:
   a. Patient is 18 years of age or older
   b. Patient has been diagnosed with moderately to severely active rheumatoid arthritis
   c. Patient has had trial and insufficient response with at least one oral DMARD, and either etanercept, adalimumab*, or infliximab
2. **Juvenile Idiopathic Arthritis**:
   a. Patient is 6 years of age or older
   b. Patient has been diagnosed with moderately to severely active juvenile idiopatic arthritis
   c. Patient has had trial and insufficient response with at least one oral DMARD, and either etancercept or adalimumab*
3. **Psoriatic Arthritis**:
   a. Patient is 18 years of age or older
   b. Patient has been diagnosed with active psoriatic arthritis
   c. Patient has tried and had insufficient response to methotrexate
   d. Patient has had trial and insufficient response with either etancercept or adalimumab*

E. **Cimzia** lyophilized powder (certolizumab pegol) may be approved for the following:
1. **Rheumatoid Arthritis**
   a. Patient is 18 years of age or older
   b. Patient has been diagnosed with moderately to severely active rheumatoid arthritis
   c. Patient has trial and insufficient response with at least one oral DMARD
   d. Patient must have tried and had insufficient response with etanercept or adalimumab or sarilumab
2. **Psoriatic Arthritis**
   a. Patient is 18 years of age or older
   b. Patient has tried and had insufficient response to at least one oral DMARD including methotrexate
   c. Patient has tried and had insufficient response with either etanercept or adalimumab or secukinumab
3. **Ankylosing Spondylitis**
   a. Patient is 18 years of age or older
   b. Patient has tried and had insufficient response to an adequate trial of two full dose NSAID therapies
   c. Patient has tried and had insufficient response to either etanercept or adalimumab or secukinumab
4. **Plaque Psoriasis**
   a. Patient is 18 years of age or older
   b. Patient has chronic moderate to severe plaque psoriasis with either of the following:
      i. Body surface area involvement of > 5%

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ii. Body surface area involvement of ≤ 5%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)

c. Patient has tried and had insufficient response to phototherapy or systemic oral DMARDs including methotrexate

d. Patient has tried and had insufficient response to brodalumab or etanercept or adalimumab or secukinumab

5. **Crohn's Disease**
   a. Patient is 18 years of age or older
   b. Patient has been diagnosed with moderately to severely active Crohn's disease
   c. Patient has tried and had insufficient response with conventional therapies including corticosteroids, or immunomodulators, such as azathioprine, 6-mercaptopurine, or methotrexate
   d. Patient has had treatment failure or intolerance to adalimumab
6. **Non-radiographic Axial Spondyloarthritis**
   a. Patient is 18 years of age or older
   b. Patient has a diagnosis of adult-onset active axial spondyloarthritis
   c. Patient has objective signs of inflammation indicated by C-reactive protein (CRP) levels above the upper limit of normal OR sacroiliitis on magnetic resonance imaging (MRI)
   d. Patient has had trial and insufficient response to at least two NSAIDs at optimal dosage

F. **Stelara IV** (ustekinumab) may be approved for the following:
1. **Crohn's Disease** (Induction dose only):
   a. Patient is 18 years of age or older
   b. Patient has been diagnosed with moderately to severely active Crohn's disease
   c. Patient has tried and had insufficient response with conventional therapies including corticosteroids, or immunomodulators, such as azathioprine, 6-mercaptopurine, or methotrexate
   d. Patient has had treatment failure or intolerance to adalimumab*
2. **Ulcerative Colitis** (Induction dose only):
   a. Patient is 18 years of age or older
   b. Patient has been diagnosed with moderately to severely active Ulcerative Colitis
   c. Patient has tried and had insufficient response with conventional therapies including corticosteroids, or immunomodulators, such as azathioprine, 6-mercaptopurine, or methotrexate
   d. Patient has had treatment failure or intolerance to infliximab

G. **Entyvio** (vedolizumab) may be approved for the following:
1. **Crohn's Disease:**
   a. Patient is 18 years of age or older
   b. Patient has been diagnosed with moderately to severely active Crohn's disease
   c. Patient has tried and had insufficient response with conventional therapies including corticosteroids, or immunomodulators, such as azathioprine, 6-mercaptopurine, or methotrexate
   d. Patient has had treatment failure or intolerance to infliximab
2. **Ulcerative Colitis:**
   a. Patient is 18 years of age or older
   b. Patient has been diagnosed with moderately to severely active Ulcerative Colitis

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c. Patient has tried and had insufficient response with conventional therapies including corticosteroids, or immunomodulators, such as azathioprine, 6-mercaptopurine, or methotrexate
d. Patient has had treatment failure or intolerance to infliximab

H. **Ilumya** (Tildrakizumab-asmn) may be approved for the following:
1. **Plaque Psoriasis**
a. Patient is 18 years of age or older
b. Patient has chronic moderate to severe plaque psoriasis with either of the following:
i. Body surface area involvement of > 5%
ii. Body surface area involvement of ≤ 5%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)
c. Patient has tried and had insufficient response to phototherapy or systemic oral DMARDs including methotrexate
d. Patient has tried and had insufficient response to brodalumab or etanercept or adalimumab or secukinumab

I. **Tremfya** (guselkumab) may be approved for the following:
1. **Plaque Psoriasis**
a. Patient is 18 years of age or older
b. Patient has chronic moderate to severe plaque psoriasis with either of the following:
i. Body surface area involvement of > 5%
ii. Body surface area involvement of ≤ 5%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)
c. Patient has tried and had insufficient response to phototherapy or systemic oral DMARDs including methotrexate
d. Patient has tried and had insufficient response to brodalumab or etanercept or adalimumab or secukinumab

*Patients will not be required to undergo a trial of etanercept and/or adalimumab if they have one of the diagnoses listed above AND either a functional impairment, or social circumstance that preludes self-administered injections.

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be restricted to 6 months of therapy.
B. Approval of Stelara IV will be restricted to a single induction dose.
C. Approval for continuation of therapy can be extended up to 12-month intervals with documentation showing the patient's clinical improvement from treatment as supported by one of the following condition-indicated outcomes:
1. Arthritis indications, ankylosing spondylitis, plaque psoriasis:
a. reduction in the signs and symptoms
b. prolonged beneficial clinical response
c. inhibition of structural damage progression
d. improved physical functioning
2. Crohn's disease and ulcerative colitis:
a. reduction in gastrointestinal signs and symptoms
b. prolonged clinical remission and mucosal healing

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c. reduced number of draining enterocutaneous or rectovaginal fistulas for at least a 3-month period (only applies to fistulizing CD)

IV. EXCLUSIONS

A. The IV Biologic Response Modifiers will not be approved for the following:
   1. Other diagnoses not included in the criteria stated above including, but not limited to:
      a. Congestive heart failure
      b. Hidradenitis suppurativa (except for Remicade in severe refractory cases, where Humira treatment has failed)
      c. Graft-versus-host disease
      d. Interleukin-2 toxicity
      e. Langerhan's cell histiocytosis
      f. Myositis
      g. Nephrotic syndrome
      h. Amyloidosis
      i. Periodic fever syndrome
      j. Renal transplant syndrome
      k. Multiple sclerosis
      l. Definitive radiographic Axial Spondyloarthritis with evidence of structural damage on sacroiliac joints
   2. Patients who meet any of the following:
      a. History of recurrent infections, tuberculosis, invasive fungal infections, or other active serious infections
      b. Pretreatment tuberculosis screening with TB skin test or other CDC-recommended testing to assess for latent tuberculosis
      c. Continuing a concurrent regimen with another biologic DMARD

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. RECOMMENDED DOSAGE

1. All FDA approved dosage(s) and dosing interval(s) for the FDA approved indication(s).

VI. CODES

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Remicade 100 MG SOLR Injection, infliximab, excludes biosimilar, 10 mg	J1745
Inflectra 100 MG SOLR Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg	Q5103

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Renflexis 100 MG SOLR Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg	Q5104
Simponi Aria 50 MG/4ML SOLN Injection, golimumab, 1 mg	J1602
Orencia 250 MG SOLR Injection, abatacept, 10 mg	J0129
Cimzia 2 X 200 MG KIT Injection, certolizumab pegol, 1 mg	J0717
Stelara 130 MG/26ML SOLN Ustekinumab, for intravenous injection, 1 mg	J3358
Entyvio 300 MG SOLR Injection, vedolizumab, 1 mg	J3380
Ilumya 100 MG/ML SOSY, Injection, tildrakizumab, 1 mg	J3245
Tremfya 100 MG/ML SOSY J1628 Injection, guselkumab, 1 mg	J1628
Ixifi 100 MG SOLR Injection, infliximab-qbtx, biosimilar, (Ixifi), 10 mg	Q5109
Avsola 100MG Solution Injection, infliximab-axxq, biosimilar, 10 mg	Q5121

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VIII. APPROVALS

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DATE OF REVISION	SUMMARY OF CHANGE
10/03/2013	Addition of Xeljanz; clarification of indications for Actemra and Remicade; Reduction in authorization period; Update of guidelines in background; Removed "How Supplied & Procedure Codes"; Rearranged format
01/09/2015	Removed all references to Xeljanz
07/20/2016	Updated Clinical Criteria, clarification of authorization duration and exclusion criteria; removal of background information & specific dosage, moved Orencia criteria from MEDS27, and added Simponi Aria criteria per package insert
10/19/2016	Addition of induction criteria for Stelara for Crohn's Disease indication. Removal of step edit to etanercept or adalimumab for Remicade.
11/01/2016	Removal of step edit to etanercept or adalimumab for Simponi Aria

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07/19/2017	Addition of Entyvio with PA criteria, and updated indications for Orencia
07/27/2017	Updated Exclusion section regarding physician samples
12/19/2018	Added criteria for provider-administered Cimzia powder; updated criteria for Actemra and Simponi Aria per PI
01/16/2019	Added clinical criteria for Ixifi, Ilumya, and Tremfya
04/17/2019	Updated indications for Cimzia
07/05/2019	Updated hidradenitis suppurativa exclusion based on new clinical guidelines
07/17/2019	Modified clinical criteria to reflect Renflexis as the preferred Remicade-biosimilar product
1/6/2020	Updated criteria layout
1/15/2020	Presented policy for USFHP adoption effective 3/1/2020, and clarified Acetmra IV would not be included for USFHP
05/04/2020	Added biosimilar usage notice; clarified Stelara IV induction dose authorization parameters, and indications
07/15/2020	Added clinical criteria for Avsola
11/09/2021	Removed Priority Partners as an applicable LOB
01/07/2022	Updated clinical criteria; removed Actemra IV as an applicable drug

Review/Revision Dates: 10/03/2013, 11/1/2013, 1/9/2015, 7/20/2016, 10/19/16, 11/1/16, 7/19/2017, 07/27/2017, 12/19/2018, 01/16/2019, 04/17/2019, 07/05/2019, 07/17/2019, 1/6/2020, 1/15/2020, 05/04/2020, 07/15/2020, 11/09/2021, 01/07/2022

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