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| JOHNS HOPKINS HEALTH PLANS | Johns Hopkins Health Plans<br>**Pharmacy Public**<br>**Pharmacy Management Drug Policies** | *Policy Number* | MEDS007 |
| | | *Effective Date* | 04/17/2024 |
| | | *Approval Date* | 04/17/2024 |
| | *Subject*<br>**Self-administered Subcutaneous Biological Modifiers: Adalimumab products (Hadlima, Adalimumab-adaz [unbranded Hyrimoz], Adalimumab-fkjp [unbranded Hulio], etc.), Enbrel, Kineret, Simponi, Cimzia, Stelara, Cosentyx, Actemra, Orencia, Taltz, Kevzara, Siliq, Tremfya, Skyrizi, Bimzelx** | *SupersedesDate* | 01/17/2024 |
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This document applies to the following Participating Organizations:

Priority Partners

**Keywords**: Actemra, Adalimumab-adaz (unbranded Hyrimoz), Adalimumab-fkjp (unbranded Hulio), Amjevita , Bimzelx, Cimzia, Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Kevzara, Kineret, Orencia, Siliq, Simponi, Skyrizi, Stelara, subcutanous biological response modifiers, Taltz, Tremfya, Yuflyma, Yusimry

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## I. POLICY

A. Self-administered subcutaneous biologic medications will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

## II. POLICY CRITERIA

A. **Hadlima** (adalimumab-bwwd), **Adalimumab-adaz** (unbranded Hyrimoz), or **Adalimumab-fkjp** (unbranded Hulio) may be approved for patients meeting the following:
   1. **Rheumatoid Arthritis**
      a. Patient is 18 years of age or older
      b. Documentation has been submitted showing one of the following:
         I. Patient has had treatment failure with at least two formulary DMARDs including methotrexate unless contraindicated
         II. Patient has RA ≤ 6 months with high level disease activity and features of poor prognosis (such as extra-articular disease, positive rheumatoid factor, or bony erosions)
   2. **Juvenile Idiopathic Arthritis**
      a. Patient is 2 years of age or older
      b. Patient has tried and had insufficient response to an adequate trial of full dose NSAID therapy
      c. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
   3. **Psoriatic Arthritis**
      a. Patient is 18 years of age or older
      b. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
   4. **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
   5. **Plaque Psoriasis**
      a. Patient is 18 years of age or older
      b. Patient has chronic moderate to severe plaque psoriasis with documentation of either of the following:
         I. Body surface area involvement of > 10%
         II. Body surface area involvement of ≤ 10%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)
      c. Patient has tried and had insufficient response or contraindication to at least one of the following:
         I. Phototherapy
         II. Systemic therapy with methotrexate or cyclosporine

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III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogies, or retinoids) is required, unless their use is contraindicated.

6. **Crohn's Disease**
   a. Patient is 6 years of age or older
   b. Patient has a diagnosis of moderately to severely active Crohn's disease
   c. Patient has tried and had insufficient response to corticosteroids, or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate
7. **Ulcerative Colitis**
   a. Patient is 18 years of age or older
   b. Patient has a diagnosis of moderate to severe ulcerative colitis
   c. Patient has tried and had insufficient response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP)
8. **Hidradenitis Suppurativa (HS)**
   a. Patient is 18 years of age or older
   b. Patient has a diagnosis of moderate to severe HS
9. **Uveitis**
   a. Patient is 18 years of age or older
   b. Patient has a diagnosis of one of the following non-infectious uveitis:
      I. Intermediate uveitis
      II. Posterior uveitis
      III. Panuveitis

B. **Amjevita** (adalimumab-atto), **Cyltezo** (adalimumab-adbm), **Hulio** (brand adalimumab-fkjp), **Idacio** (adalimumab-aacf) **Hyrimoz** (brand adalimumab-adaz), **Yuflyma** (adalimumab-aaty), or **Yusimry** (adalimumab-aqvh) may be approved for patients meeting the following:
   1. **Rheumatoid Arthritis**
      a. Patient is 18 years of age or older
      b. Documentation has been submitted showing one of the following:
         I. Patient has had treatment failure with at least two formulary DMARDs including methotrexate unless contraindicated
         II. Patient has RA ≤ 6 months with high level disease activity and features of poor prognosis (such as extra-articular disease, positive rheumatoid factor, or bony erosions)
      c. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp
   2. **Juvenile Idiopathic Arthritis**
      a. Patient is 2 years of age or older
      b. Patient has tried and had insufficient response to an adequate trial of full dose NSAID therapy
      c. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
      d. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp

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3. **Psoriatic Arthritis**
   a. Patient is 18 years of age or older
   b. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
   c. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp
4. **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 had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp
5. **Plaque Psoriasis**
   a. Patient is 18 years of age or older
   b. Patient has chronic moderate to severe plaque psoriasis with documentation of either of the following:
      I. Body surface area involvement of > 10%
      II. Body surface area involvement of ≤ 10%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)
   c. Patient has tried and had insufficient response or contraindication to at least one of the following:
      I. Phototherapy
      II. Systemic therapy with methotrexate or cyclosporine
      III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogies, or retinoids) is required, unless their use is contraindicated.
   d. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp
6. **Crohn's Disease**
   a. Patient is 6 years of age or older
   b. Patient has a diagnosis of moderately to severely active Crohn's disease
   c. Patient has tried and had insufficient response to corticosteroids, or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate
   d. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp
7. **Ulcerative Colitis**
   a. Patient is 18 years of age or older
   b. Patient has a diagnosis of moderate to severe ulcerative colitis
   c. Patient has tried and had insufficient response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP)
   d. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp
8. **Hidradenitis Suppurativa (HS)**
   a. Patient is 18 years of age or older

b. Patient has a diagnosis of moderate to severe HS
c. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp

9. **Uveitis**
   a. Patient is 18 years of age or older
   b. Patient has a diagnosis of one of the following non-infectious uveitis:
      I. Intermediate uveitis
      II. Posterior uveitis
      III. Panuveitis
   c. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp

C. **Humira** (adalimumab) may be approved for patients meeting the following:
1. **Rheumatoid Arthritis**
   a. Patient is 18 years of age or older
   b. Documentation has been submitted showing one of the following:
      I. Patient must have treatment failure with at least two formulary DMARDs including methotrexate unless contraindicated
      II. Patient has RA ≤ 6 months with high level disease activity and features of poor prognosis (such as extra-articular disease, positive rheumatoid factor, or bony erosions)
   c. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp
2. **Juvenile Idiopathic Arthritis**
   a. Patient is 2 years of age or older
   b. Patient has tried and had insufficient response to an adequate trial of full dose NSAID therapy
   c. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
   d. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp
3. **Psoriatic Arthritis**
   a. Patient is 18 years of age or older
   b. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
   c. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp
4. **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 had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp
5. **Plaque Psoriasis**
   a. Patient is 18 years of age or older

b. Patient has chronic moderate to severe plaque psoriasis with documentation of either of the following:
   I. Body surface area involvement of > 10%
   II. Body surface area involvement of ≤ 10%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)
c. Patient has tried and had insufficient response or contraindication to at least one of the following:
   I. Phototherapy
   II. Systemic therapy with methotrexate or cyclosporine
   III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogies, or retinoids) is required, unless their use is contraindicated.
d. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp

6. **Crohn's Disease**
   a. Patient is 6 years of age or older
   b. Patient has a diagnosis of moderately to severely active Crohn's disease
   c. Patient has tried and had insufficient response to corticosteroids, or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate
   d. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp
7. **Ulcerative Colitis**
   a. Patient is 5 years of age or older
   b. Patient has a diagnosis of moderate to severe ulcerative colitis
   c. Patient has tried and had insufficient response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP)
   d. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp
      I. *Age-related Caveat:
         i. For patients that are 5 to 17 years of age, a trial with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp is not required.
8. **Hidradenitis Suppurativa (HS)**
   a. Patient is 12 years of age or older
   b. Patient has a diagnosis of moderate to severe HS
   c. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp
      I. *Age-related Caveat:
         i. For patients that are 12 to 17 years of age, a trial with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp is not required.
9. **Uveitis**
   a. Patient is 2 years of age or older
   b. Patient has a diagnosis of one of the following non-infectious uveitis:
      I. Intermediate uveitis

II. Posterior uveitis
III. Panuveitis

c. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp
I. *Age-related Caveat:
i. For patients that are 2 to 17 years of age, a trial with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp is not required.

D. **Enbrel** (etanercept) may be approved for patients meeting the following:
1. **Rheumatoid Arthritis**
a. Patient is 18 years of age or older
b. Documentation has been submitted showing one of the following:
I. Patient must have treatment failure with at least two formulary DMARDs including methotrexate unless contraindicated
II. Patient has RA ≤ 6 months with high level disease activity and features of poor prognosis (such as extra-articular disease, positive rheumatoid factor, or bony erosions)
2. **Juvenile Idiopathic Arthritis**
a. Patient is 2 years of age or older
b. Patient has tried and had insufficient response to an adequate trial of full dose NSAID therapy
c. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
3. **Psoriatic Arthritis**
a. Patient is 2 years of age or older
b. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
4. **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
5. **Plaque Psoriasis**
a. Patient is 4 years of age or older
b. Patient has chronic moderate to severe plaque psoriasis with documentation of either of the following:
I. Body surface area involvement of > 10%
II. Body surface area involvement of ≤ 10%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)
c. Patient has tried and had insufficient response or contraindication to at least one of the following:
I. Phototherapy
II. Systemic therapy with methotrexate or cyclosporine
III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogies, or retinoids) is required, unless their use is contraindicated.

E. **Kevzara** (sarilumab) may be approved for patients meeting the following:
1. **Rheumatoid Arthritis**

a. Patient is 18 years of age or older
b. Documentation has been submitted showing one of the following:
I. Patient must have treatment failure with at least two formulary DMARDs including methotrexate unless contraindicated
II. Patient has RA ≤ 6 months with high level disease activity and features of poor prognosis (such as extra-articular disease, positive rheumatoid factor, or bony erosions)

2. **Polymyalgia Rheumatica**
a. Patient is 18 years of age or older
b. Documentation has been submitted showing one of the following:
1. Patient has had inadequate response, or contraindication to a trial of corticosteroids, evidenced by a breakthrough flare
2. Patient is unable to tolerate a corticosteroid taper, evidenced by symptoms of a breakthrough flare (shoulder and/or hip girdle pain associated with inflammatory stiffness)

F. **Kineret** (anakinra) may be approved for patients meeting 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 two formulary DMARDs including methotrexate unless contraindicated
d. Patient has had trial and insufficient response with etanercept, adalimumab, or sarilumab
2. **Cryopyrin-Associated Periodic Syndromes (CAPS)**
a. Patient has been diagnosed with Neonatal-Onset Multisystem Inflammatory Disease
3. **Deficiency of Interleukin-1 Receptor Antagonist (DIRA)**
a. Patient has a confirmed diagnosis of DIRA

G. **Cosentyx** (secukinumab) may be approved for patients meeting the following:
1. **Psoriatic Arthritis**
a. Patient is 2 years of age or older
b. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
2. **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 therapie
3. **Plaque Psoriasis**
a. Patient is 6 years of age or older
b. Patient has chronic moderate to severe plaque psoriasis with documentation of either of the following:
I. Body surface area involvement of > 10%
II. Body surface area involvement of ≤ 10%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)
c. Patient has tried and had insufficient response or contraindication to at least one of the following:
I. Phototherapy
II. Systemic therapy with methotrexate or cyclosporine

III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogies, or retinoids) is required, unless their use is contraindicated.

4. **Non-radiographic Axial Spondyloarthritis (nr-axSpA)**
   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 full dose NSAID therapies
5. **Enthesitis-related arthritis (ERA)**
   a. Patient is 4 years of age or older
   b. Patient has tried and had insufficient response to an adequate trial of full dose NSAID therapy
   c. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
6. **Hidradenitis Suppurativa (HS)**
   a. Patient is 18 years of age or older
   b. Patient has a diagnosis of moderate to severe HS
   c. Patient has had trial and inadequate response or intolerance with Hadlima, Adalimumab-adaz, or Adalimumab-fkjp

H. **Cimzia** (certolizumab pegol) may be approved for patients meeting 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 two formulary DMARDs including methotrexate unless contraindicated
   d. Patient has had trial and insufficient response with etanercept, 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 two DMARDs including methotrexate unless contraindicated
   c. Patient has tried and had insufficient response with either etanercept, 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, 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 documentation of either of the following:
      I. Body surface area involvement of > 10%
      II. Body surface area involvement of ≤ 10%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)

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c. Patient has tried and had insufficient response or contraindication to at least one of the following:
   I. Phototherapy
   II. Systemic therapy with methotrexate or cyclosporine
   III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogies, or retinoids) is required, unless their use is contraindicated.
d. Patient has tried and had insufficient response to brodalumab, etanercept, 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 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 (nr-axSpA)**
   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 full dose NSAID therapies
   e. Patient has had trial and insufficient response to secukinumab

I. **Actemra** (tocilizumab) may be approved for patients meeting 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 two formulary DMARDs including methotrexate unless contraindicated
   d. Patient must have tried and had insufficient response with etanercept, adalimumab, or sarilumab
2. **Juvenile Idiopathic Arthritis**
   a. Patient is 2 years of age or older
   b. Patient has tried and had insufficient response to an adequate trial of full dose NSAID therapy
   c. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
   d. Patient has tried and had insufficient response to either etanercept or adalimumab
3. **Giant Cell Arteritis (GCA)**
   a. Patient is 18 years of age or older
   b. Patient has a diagnosis of Giant Cell Arteritis
   c. Patient has had trial and insufficient response to one systemic corticosteroid
4. **Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)**
   a. Patient is 18 years of age or older
   b. Patient has a diagnosis of SSc-ILD confirmed through chest high resolution computed tomography (HRCT) scan showing ground glass opacification or fibrosis
   c. Patient has elevated acute phase reactants, defined as at least one of the following:

I. C-reactive protein (CRP) ≥6 mg/mL

II. Erythrocyte sedimentation rate (ESR) ≥28 mm/h

III. Platelet count ≥330 x $10^9$/L

d. Patient has a Forced vital capacity (FVC) >55% of the predicted value

e. Patient has had trial and insufficient response or contradiction to mycophenolate mofetil

J. **Orencia** (abatacept) may be approved for patients meeting 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 two formulary DMARDs including methotrexate unless contraindicated
   d. Patient must have tried and had insufficient response with etanercept, adalimumab, or sarilumab
2. **Juvenile Idiopathic Arthritis**
   a. Patient is 2 years of age or older
   b. Patient has tried and had insufficient response to an adequate trial of full dose NSAID therapy
   c. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
   d. Patient has tried and had insufficient response to either etanercept or adalimumab
3. **Psoriatic Arthritis**
   a. Patient is 2 years of age or older
   b. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
   c. Patient has tried and had insufficient response with either etanercept, adalimumab, or secukinumab

K. **Simponi** (golimumab) may be approved for patients meeting 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 two formulary DMARDs including methotrexate unless contraindicated
   d. Patient must have tried and had insufficient response with etanercept, 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 two DMARDs including methotrexate unless contraindicated
   c. Patient has tried and had insufficient response with either etanercept, 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, adalimumab, or secukinumab
4. **Ulcerative Colitis**
   a. Patient is 18 years of age or older

b. Patient has a diagnosis of moderate to severe ulcerative colitis
c. Patient has tried and had insufficient response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP).
d. Patient has had treatment failure or intolerance to adalimumab

L. **Siliq** (brodalumab) may be approve for patients meeting the following:
1. **Plaque Psoriasis**
a. Patient is 18 years of age or older
b. Patient has chronic moderate to severe plaque psoriasis with documentation of either of the following:
I. Body surface area involvement of > 10%
II. Body surface area involvement of ≤ 10%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)
c. Patient has tried and had insufficient response or contraindication to at least one of the following:
I. Phototherapy
II. Systemic therapy with methotrexate or cyclosporine
III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogies, or retinoids) is required, unless their use is contraindicated.

M. **Stelara** (ustekinumab) may be approve for patients meeting the following:
1. **Psoriatic Arthritis**
a. Patient is 6 years of age or older
b. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
c. Patient has tried and had insufficient response with either etanercept, adalimumab, or secukinumab
2. **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 corticosteroids, or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate
d. Patient has had treatment failure or intolerance to adalimumab
3. **Ulcerative Colitis**
a. Patient is 18 years of age or older
b. Patient has a diagnosis of moderate to severe ulcerative colitis
c. Patient has tried and had insufficient response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP).
d. Patient has had treatment failure or intolerance to adalimumab
4. **Plaque Psoriasis in Adults**
a. Patient is 18 years of age or older
b. Patient has chronic moderate to severe plaque psoriasis with documentation of either of the following:
I. Body surface area involvement of > 10%
II. Body surface area involvement of ≤ 10%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)

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| | | *Effective Date* | 04/17/2024 |
| | | *Approval Date* | 04/17/2024 |
| | *Subject*<br>**Self-administered Subcutaneous Biological Modifiers: Adalimumab products (Hadlima, Adalimumab-adaz [unbranded Hyrimoz], Adalimumab-fkjp [unbranded Hulio], etc.), Enbrel, Kineret, Simponi, Cimzia, Stelara, Cosentyx, Actemra, Orencia, Taltz, Kevzara, Siliq, Tremfya, Skyrizi, Bimzelx** | *SupersedesDate* | 01/17/2024 |
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c. Patient has tried and had insufficient response or contraindication to at least one of the following:
   I. Phototherapy
   II. Systemic therapy with methotrexate or cyclosporine
   III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogies, or retinoids) is required, unless their use is contraindicated.
d. Patient has tried and had insufficient response to brodalumab, etanercept, adalimumab, or secukinumab

5. **Plaque Psoriasis in Pediatrics**
   a. Patient is between 6 and 17 years of age
   b. Patient has chronic moderate to severe plaque psoriasis with documentation of either of the following:
      I. Body surface area involvement of > 10%
      II. Body surface area involvement of ≤ 10%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)
   c. Patient has tried and had insufficient response or contraindication to at least one of the following:
      I. Phototherapy
      II. Systemic therapy with methotrexate or cyclosporine
      III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogies, or retinoids) is required, unless their use is contraindicated.
   d. Patient has tried and had insufficient response to etanercept or secukinumab

N. **Skyrizi, Skyrizi On-Body** (risankizumab-rzaa) may be approved for patients meeting the following:
   1. **Plaque Psoriasis**
      a. Patient is 18 years of age or older
      b. Patient has chronic moderate to severe plaque psoriasis with documentation of either of the following:
         I. Body surface area involvement of > 10%
         II. Body surface area involvement of ≤ 10%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)
      c. Patient has tried and had insufficient response or contraindication to at least one of the following:
         I. Phototherapy
         II. Systemic therapy with methotrexate or cyclosporine
         III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogs, or retinoids) is required, unless their use is contraindicated.
      d. Patient has tried and had insufficient response to brodalumab, etanercept, adalimumab, or secukinumab
   2. **Psoriatic Arthritis**
      a. Patient is 18 years of age or older
      b. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
      c. Patient has tried and had insufficient response with either etanercept or adalimumab or secukinumab
   3. **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 corticosteroids, or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate
d. Patient has had treatment failure or intolerance to adalimumab
e. Skyrizi is being used as maintenance therapy after completing the 3-dose induction therapy using Skyrizi IV

O. **Taltz** (ixekizumab) may be approved for patients meeting the following:

1. **Psoriatic Arthritis**
   a. Patient is 18 years of age or older
   b. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
   c. Patient has tried and had insufficient response with either etanercept or adalimumab or secukinumab
2. **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
3. **Plaque Psoriasis in Adults**
   a. Patient is 18 years of age or older
   b. Patient has chronic moderate to severe plaque psoriasis with documentation of either of the following:
      I. Body surface area involvement of > 10%
      II. Body surface area involvement of ≤ 10%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)
   c. Patient has tried and had insufficient response or contraindication to at least one of the following:
      I. Phototherapy
      II. Systemic therapy with methotrexate or cyclosporine
      III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogies, or retinoids) is required, unless their use is contraindicated.
   d. Patient has tried and had insufficient response to brodalumab, etanercept, adalimumab, or secukinumab
4. **Plaque Psoriasis in Pediatrics**
   a. Patient is between 6 and 17 years of age
   b. Patient has chronic moderate to severe plaque psoriasis with documentation of either of the following:
      I. Body surface area involvement of > 10%
      II. Body surface area involvement of ≤ 10%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)
   c. Patient has tried and had insufficient response or contraindication to at least one of the following:
      I. Phototherapy
      II. Systemic therapy with methotrexate or cyclosporine
      III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogies, or retinoids) is required, unless their use is contraindicated.
   d. Patient has tried and had insufficient response to etanercept or secukinumab

5. **Non-radiographic Axial Spondyloarthritis (nr-axSpA)**
   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 full dose NSAID therapies
   e. Patient has had trial and insufficient response to secukinumab

P. **Tremfya** (guselkumab) may be approved for patients meeting the following:
   1. **Plaque Psorasis**
      a. Patient is 18 years of age or older
      b. Patient has chronic moderate to severe plaque psoriasis with documentation of either of the following:
         I. Body surface area involvement of >10%
         II. Body surface area involvement of ≤10%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)
      c. Patient has tried and had insufficient response or contraindication to at least one of the following:
         I. Phototherapy
         II. Systemic therapy with methotrexate or cyclosporine
         III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogies, or retinoids) is required, unless their use is contraindicated.
      d. Patient has tried and had insufficient response to brodalumab, etanercept, adalimumab, or secukinumab
   2. **Psoriatic Arthritis**
      a. Patient is 18 years of age or older
      b. Patient has tried and had insufficient response to at least two DMARDs including methotrexate unless contraindicated
      c. Patient has tried and had insufficient response with either etanercept, adalimumab, or secukinumab

Q. **Bimzelx** (bimekizumab-bkzx) may be approved for patients meeting the following:
   1. **Plaque Psorasis**
      a. Patient is 18 years of age or older
      b. Patient has chronic moderate to severe plaque psoriasis with documentation of either of the following:
         I. Body surface area involvement of >10%
         II. Body surface area involvement of ≤10%, but involves sensitive areas (palms/soles of feet, genitalia and head/neck)
      c. Patient has tried and had insufficient response or contraindication to at least one of the following:
         I. Phototherapy
         II. Systemic therapy with methotrexate or cyclosporine
         III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogies, or retinoids) is required, unless their use is contraindicated.
      d. Patient has tried and had insufficient response to brodalumab, etanercept, adalimumab, or secukinumab

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## III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be restricted to 6 months based on the indication, requiring follow-up approvals for future prescriptions.
   1. Caveat: Siliq will be restricted to an initial 3 months in accordance with the FDA-approved label guidance.

B. Approval for continuation of therapy can be extended in 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, CAPS, HS, and uveitis:
      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
      c. Reduced number of draining enterocutaneous or rectovaginal fistulas for at least a 3-month period (only applies to fistulizing CD)
   3. SSc-ILD:
      1. Less than or equal to a 10% decrease in predicated forced vital capacity

C. Approvals will be limited to the FDA-approved dosages and dosing intervals for covered indications.

## IV. EXCLUSIONS

A. The following are not recommended for off-label use:
   1. Uveitis (except for Humira)
   2. Sarcoidosis
   3. Graft-versus-host disease
   4. Interleukin-2 toxicity
   5. Langerhans cell histiocytosis
   6. Myositis
   7. Nephrotic syndrome
   8. Amyloidosis
   9. Periodic fever syndrome
   10. Renal transplant syndrome
   11. First-line therapy for pediatric patients with moderate to severe Crohn's Disease *(Infliximab is FDA-approved for pediatric Crohn's Disease and should be used prior to other biologic DMARDs in this population)*
   12. Definitive radiographic Axial Spondyloarthritis with evidence of structural damage on sacroiliac joints

B. The subcutaneous Biologic DMARDs will not be approved for concurrent use with another biologic DMARD

C. 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.

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## VI. APPROVALS

Signature on file at JHHP

| DATE OF REVISION | SUMMARY OF CHANGE |
|---|---|
| 10/04/2013 | Change in authorization period; addition of new approved indications to each biologic; addition of ulcerative colitis and CAPs background info; modifications to how supplied and recommended dose. |
| 01/21/2015 | Removal of how supplied section; addition of new indication |
| 07/15/2015 | Addition of Cosentyx, removal of background information from the policy |
| 01/20/2016 | Updated the indications for Humira |
| 07/20/2016 | Updated the indications and criteria for Cosentyx and Humira; Inserted criteria for Actemra and Orencia (moved from MEDS14 and MEDS27); Added criteria for Taltz, and updated references |
| 10/19/2016 | Updated indication for Stelara |
| 01/18/2017 | Updated the age-restriction for Enbrel |
| 07/19/2017 | Updated indications for Orencia |
| 07/27/2017 | Updated Exclusion section regarding physician samples |
| 10/18/2017 | Addition of clinical criteria for Kevzara, Siliq, and Tremfya; updated age restriction for Stelara; revised policy criteria layout |
| 03/01/2018 | Updated clinical criteria |
| 06/08/2018 | Updated indication for Cimzia; Removed EHP Line of Business |
| 10/17/2018 | Updated indications for Actemra |

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|---|---|
| 04/17/2019 | Updated indications for Cimzia |
| 04/26/2019 | Clarified exclusion regarding concurrent Biologic DMARD use; this is consistent with MMDP002 and MEDS089 |
| 05/15/2019 | Updated HS age criteria for Humira based on new FDA-approval update |
| 07/17/2019 | Clarifed clinical criteria based on clinical guidelines; added criteria for Skyrizi |
| 10/24/2019 | Updated indications for Stelara |
| 11/20/2019 | Clarified Uveitis criteria for Humira and updated applicable patient population to include pediatrics |
| 10/08/2020 | Updated indications for Cosentyx, Taltz, Tremfya; clarified criteria for pediatric psoriasis patients; clarified continuation of therapy requirements for patients with CAPS and HS |
| 03/09/2021 | Updated age-related criteria for Humira based on new FDA-approved prescribing information |
| 10/26/2021 | Added criteria for Actemra for new SSc-ILD indication |
| 02/07/2022 | Updated clinical criteria sections based on updated FDA-approved prescribing information; Updated policy layout |
| 04/20/2022 | Updated clinical criteria sections based on updated FDA-approved prescribing information |
| 07/20/2022 | Added CD criteria for Skyrizi based on updated FDA-approved prescribing information; clarified plaque psoriasis criteria |
| 04/19/2023 | Added Amjevita as a drug applicable under this policy |
| 07/19/2023 | Updated clinical criteria, and age parameters per FDA-approved prescribing information |
| 09/27/2023 | Added criteria for adalimumab biosimilars, and updated policy layout |
| 01/17/2024 | Updated criteria; Added Bimzelx as an applicable drug |
| 04/17/2024 | Updated criteria for Cosentyx |

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