Medical Drug Clinical Criteria

Subject:	Monoclonal Antibodies to Interleukin-17		
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Overview

This document addresses the use of monoclonal antibodies which bind to the interleukin-17A (IL-17) cytokine and disrupt its interaction with the IL-17 receptor thereby inhibiting the release of proinflammatory cytokines and chemokines. Indications are drug-specific but IL-17 inhibitors are approved for the treatment of plaque psoriasis, psoriatic arthritis, axial spondyloarthritis, enthesitis-related arthritis and hidradenitis suppurativa. Agents addressed in this document include:

- Bimzelx (bimekizumab-bkzx)
- Cosentyx (secukinumab)
- Siliq (brodalumab)
- Taltz (ixekizumab)

Plaque Psoriasis (otherwise known as psoriasis vulgaris): The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) published joint guidelines on the management and treatment of psoriasis with biologics. The guidelines do not include a treatment algorithm or compare biologics to each other or conventional therapy. The guideline notes that patients with mild-moderate disease may be adequately controlled with topical therapy and/or phototherapy while moderate to severe disease may necessitate treatment with a biologic. Moderate to severe disease is defined as involvement in > 3% of body surface area (BSA) or involvement in sensitive areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia). Tumor necrosis factor inhibitor (TNFi) biologics, ustekinumab, IL17 inhibitors, and IL23 inhibitors are all recommended as monotherapy treatment options for adult patients with moderate to severe plaque psoriasis. Guidelines were published prior to the approval of bimekizumab.

Psoriatic Arthritis: The American College of Rheumatology (ACR) guidelines recommend that initial treatment of patients with active severe PsA or concomitant psoriasis should include a TNFi biologic over an oral small molecule (OSM; including methotrexate, sulfasalazine, cyclosporine, leflunomide, and apremilast). For initial therapy, OSMs are preferred over IL-17 and ustekinumab; and may be considered over TNFi biologics in mild to moderate disease without comorbid conditions or in those who prefer oral therapy. Recommendations involving biologics over OSMs as first line therapy are conditional and based on low quality evidence. Evidence cited includes indirect comparisons of placebo-controlled trials, studies with open-label design, and extrapolation from studies in plaque psoriasis. Furthermore, most pivotal trials for TNFi biologics included a study population that were DMARD experienced. Overall, there is a lack of definitive evidence for the safety and efficacy of biologic drugs over conventional therapy for the initial treatment of most patients with psoriatic arthritis. The ACR guidelines also include recommendations for patients whose disease remains active despite treatment with an OSM. Here, TNFi biologics are recommended over other therapies including IL-17 inhibitors, ustekinumab, tofacitinib, and abatacept. When TNFi biologics are not used, IL-17 inhibitors are preferred over ustekinumab; both of which are preferred over tofacitinib and abatacept. For disease that remains active despite TNFi monotherapy, switching to a different TNFi is recommended over other therapies.

Axial Spondyloarthritis: Sponyloarthritis with predominantly axial involvement includes both ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA), based upon the presence or absence, respectively, of abnormalities of the sacroiliac joints on plain radiography. The American College of Rheumatology (ACR) and Spondylitis Association of America guidance recommend NSAIDs as initial treatment for AS and nr-axSpA. In adults with active AS despite treatment with NSAIDS, DMARDs [including sulfasalazine], TNF inhibitors, and IL-17 inhibitors are recommended. TNFi treatment is recommended over IL-17 inhibitors. IL-17 inhibitors are recommended over a different TNFi in patients with primary nonresponse to TNFi (no initial response). An alternative TNFi is recommended in patients with secondary nonresponse to the first TNFi used (relapse after initial response). Recommendations for nr-axSpA are largely extrapolated from evidence in AS; only certolizumab, ixekizumab, secukinumab, and bimekizumab have been approved for this indication. Guidelines were published prior to FDA approval of bimekizumab for AS and nr-axSpA.

Enthesitis-related arthritis: The American College of Rheumatology and Arthritis Foundation published joint guidelines on the treatment of juvenile idiopathic arthritis (JIA) manifesting as non-systemic polyarthritis, sacroiliitis, and enthesitis. In children and adolescents with JIA and active enthesitis, NSAID treatment is strongly recommended. These guidelines for enthesitis-related arthritis (ERA) were published prior to secukinumab gaining approval for ERA; and it is the first biologic to be approved specifically for ERA. The pivotal trial resulting in this approval included a study population who had an inadequate response or intolerance to at least one NSAID and DMARD (NCT03031782).

Hidradenitis Suppurativa (HS): Hidradenitis suppurativa is a chronic inflammatory skin condition that causes painful nodules and abscesses primarily occurring in intertriginous areas. HS is typically classified according to severity based on the number of abscesses and extent of skin involvement. General management includes antiseptic washes, intralesional therapies (steroids or antibiotics), and non-steroidal anti-inflammatories for pain. According to the United States and Canadian HS clinical guidelines, medical management may include oral antibiotics such as tetracyclines (level C recommendation) or rifampin and clindamycin (level B recommendation) for all stages of disease. Moderate to severe disease management includes biologics such as anti-TNF agents (Level A recommendation for adalimumab). Prior to secukinumab and bimekizumab, adalimumab was the first biologic approved for HS. Guidelines were published prior to FDA approval of secukinumab and bimekizumab.

Siliq (brodalumab) has a black box warning for suicidal ideation and behavior. Suicidal ideation and behavior, including completed suicides have occurred in individuals treated with Siliq. Potential risks and benefits should be weighed in individuals with a history of depression and/or suicidal ideation and behavior prior to initiation of therapy with Siliq. Due to the observed suicidal ideation and behavior in subjects treated with Siliq, discontinuation of therapy should be considered in individuals who do not achieve an adequate response within the first 12 to 16 weeks of therapy. The FDA has required the manufacturer to develop a comprehensive risk management program that includes the enrollment of prescribers in the Siliq REMS Program. Additional information and forms for individuals, prescribers, and pharmacists may be found on the manufacturer's website: http://www.siliqrems.com.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Bimzelx (bimekizumab-bkzx)

Initial requests for Bimzelx (bimekizumab-bkzx) may be approved for the following:

I. Plaque psoriasis (Ps) when each of the following criteria are met:
   A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2019):
      1. Plaque Ps involving greater than three percent (3%) body surface area (BSA); **OR**
      2. Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as, palms, soles of feet, head/neck, or genitalia);

   AND
   B. Individual has had an inadequate response to or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
   C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate;

OR

II. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
   B. Individual has had an inadequate response to, or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine or leflunomide)] (ACR 2019); **OR**
   C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

OR

III. Ankylosing spondylitis (AS) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe AS; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] (ACR 2019); **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine;

OR

IV. Non-radiographic axial spondyloarthritis (nr-axSpA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe nr-axSpA; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] (ACR 2019); **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine;

OR

V. Hidradenitis suppurativa (HS) when each of the following criteria are met:
   A. Individual is 18 years of age or older; **AND**
   B. Individual has moderate to severe HS; **AND**
   C. Individual has had an inadequate response to or is intolerant of conventional therapy (such as oral antibiotics); **OR**
   D. Individual has a contraindication to oral antibiotics.

Continuation requests for Bimzelx (bimekizumab-bkzx) may be approved if the following criteria are met:

I. Individual has been receiving and is maintained on a stable dose of Bimzelx; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Bimzelx (bimekizumab-bkzx) may not be approved for the following:

I. In combination with phototherapy; **OR**
II. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, other IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab; **OR**
III. Tuberculosis, other active serious infections, or a history of recurrent infections [Repeat TB testing not required for ongoing therapy]; **OR**
IV. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
V. When the above criteria are not met and for all other indications.

Cosentyx (secukinumab)

Initial requests for Cosentyx (secukinumab) may be approved for the following:

I. Ankylosing spondylitis (AS) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe AS; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)]; **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine;

OR

II. Non-radiographic axial spondyloarthritis (nr-axSpA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe nr-axSpA; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)]; **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine;

OR

III. Plaque psoriasis (Ps) when each of the following criteria are met:
   A. Individual is 6 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2019):
      3. Plaque Ps involving greater than three percent (3%) body surface area (BSA); **OR**
      4. Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as, palms, soles of feet, head/neck, or genitalia); **AND**
   B. Individual has had an inadequate response to or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
   C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate;

OR

IV. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual is 2 years of age or older with moderate to severe PsA; **AND**
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine or leflunomide)] (ACR 2019); **OR**
   C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

OR

V. Enthesitis-Related Arthritis (ERA) when each of the following criteria are met:
   A. Individual is 4 years of age or older with moderate to severe ERA; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as methotrexate or sulfasalazine)]; **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine or methotrexate;

OR

VI. Hidradenitis suppurativa (HS) when each of the following criteria are met:
   A. Individual is 18 years of age or older; **AND**

B. Individual has moderate to severe HS; **AND**
C. Individual has had an inadequate response to or is intolerant of conventional therapy (such as oral antibiotics); **OR**
D. Individual has a contraindication to oral antibiotics.

Continuation requests for Cosentyx (secukinumab) may be approved if the following criteria are met:
I. Individual has been receiving and is maintained on a stable dose of Cosentyx; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Cosentyx (secukinumab) may not be approved for the following:
I. In combination with phototherapy; **OR**
II. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, other IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab; **OR**
III. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat TB testing not required for ongoing therapy]; **OR**
IV. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
V. When the above criteria are not met and for all other indications.

Siliq (brodalumab)

Initial requests for Siliq (brodalumab) may be approved for the following:
I. Plaque psoriasis (Ps) when each of the following criteria are met:
A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2019):
1. Plaque Ps involving greater than three percent (3%) body surface area (BSA); **OR**
2. Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as, palms, soles of feet, head/neck, or genitalia); **AND**
B. Individual has had an inadequate response to or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate.

Continuation requests for Siliq (brodalumab) may be approved if the following criteria are met:
I. Individual has been receiving and is maintained on a stable dose of Siliq; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Siliq (brodalumab) may not be approved for the following:
I. In combination with phototherapy; **OR**
II. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, other IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab; **OR**
III. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat TB testing not required for ongoing therapy]; **OR**
IV. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
V. Individual has Crohn's disease; **OR**
VI. When the above criteria are not met and for all other indications.

Taltz (ixekizumab)

Initial requests for Taltz (ixekizumab) may be approved for the following:
I. Ankylosing spondylitis (AS) when each of the following criteria are met:
A. Individual is 18 years of age or older with moderate to severe AS; **AND**
B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)]; **OR**
C. Individual has a contraindication to NSAIDs or sulfasalazine;

OR

II. Non-radiographic axial spondyloarthritis (nr-axSpA) when each of the following criteria are met:
A. Individual is 18 years of age or older with moderate to severe nr-axSpA; **AND**
B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] (ACR 2019, Deodhar 2020); **OR**
C. Individual has a contraindication to NSAIDs or sulfasalazine;

OR

III. Plaque psoriasis (Ps) when each of the following criteria are met:
   A. Individual is 6 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2019):
      1. Plaque Ps involving greater than three percent (3%) body surface area (BSA); **OR**
      2. Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as, palms, soles of feet, head/neck, or genitalia); **AND**
   B. Individual has had an inadequate response to or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
   C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate;

OR

IV. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine or leflunomide)] (ACR 2019); **OR**
   C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide.

Continuation requests for Taltz (ixekizumab) may be approved if the following criteria are met:

I. Individual has been receiving and is maintained on a stable dose of Taltz; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Taltz (ixekizumab) may not be approved for the following:

I. In combination with phototherapy; **OR**
II. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, other IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab; **OR**
III. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat TB testing not required for ongoing therapy]; **OR**
IV. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
V. When the above criteria are not met and for all other indications.

Step Therapy

Note: When a monoclonal antibody to interleukin-17 is deemed approvable based on the clinical criteria above, the benefit plan may have additional criteria requiring the use of a preferred[1] agent or agents.

Cosentyx Intravenous (IV) Step Therapy

A list of preferred targeted immune modulator(s) is available here.

Commercial requests for diagnosis of Plaque Psoriasis**:**

Requests for Cosentyx IV may be approved if the following criteria are met:

I. Individual has been receiving and is maintained on a stable dose of Cosentyx IV; **OR**
II. Individual has had a trial and inadequate response or intolerance to ONE preferred agent; **OR**
III. Individual has any of the following concomitant clinical conditions:
   A. Demyelinating disease; **OR**
   B. Heart failure with documented left ventricular dysfunction; **OR**
   C. Malignancy.

Commercial requests for diagnosis of Ankylosing Spondylitis and Psoriatic Arthritis:

I. Requests for Cosentyx IV may be approved if the following criteria are met:
II. Individual has been receiving and is maintained on a stable dose of Cosentyx IV; **OR**
III. Individual has had a trial and inadequate response or intolerance to TWO preferred agent(s); **OR**
IV. Individual has any of the following concomitant clinical condition(s):
   A. Demyelinating disease; **OR**
   B. Heart failure with documented left ventricular dysfunction; **OR**
   C. Malignancy

[1]Preferred, as used herein, refers to agents that were deemed to be clinically comparable to other agents in the same class or disease category but are preferred based upon clinical evidence and cost effectiveness.

Quantity Limits

Bimzelx (bimekizumab-bkzx) Quantity Limits

Drug	Limit
Bimzelx (bimekizumab-bkzx) 160 mg/mL autoinjector 2-pack*	1 carton (2 x 160 mg/mL autoinjectors) every 8 weeks
Bimzelx (bimekizumab-bkzx) 160 mg/mL autoinjector 1-pack*	1 carton (1 x 160 mg/mL autoinjectors) per 28 days
Bimzelx (bimekizumab-bkzx) 160 mg/mL prefilled syringe 2 pack*	1 carton (2 x 160 mg/mL syringes) every 8 weeks
Bimzelx (bimekizumab-bkzx) 160 mg/mL prefilled syringe 1-pack*	1 carton (1 x 160 mg/mL syringe) per 28 days
Bimzelx (bimekizumab-bkzx) 320 mg/2 mL autoinjector 1-pack*	1 carton (1 x 320 mg/2 mL autoinjector) every 8 weeks
Bimzelx (bimekizumab-bkzx) 320 mg/2 mL prefilled syringe 1-pack*	1 carton (1 x 320 mg/2 mL syringe) every 8 weeks
Override Criteria	
*Initiation of therapy for Plaque Psoriasis (Ps) with or without concomitant Psoriatic Arthritis (PsA): May approve a total of 10 (ten) 160 mg/mL autoinjectors or syringes OR 5 (five) 320 mg/2 mL autoinjectors or syringes in the first 16 weeks of therapy to cover 320 mg loading doses at weeks 0, 4, 8, 12, and 16. *Maintenance therapy for Plaque Psoriasis (Ps) with or without concomitant Psoriatic Arthritis (PsA): May approve 2 (two) 160 mg/mL autoinjectors or syringes OR 1 (one) 320 mg/2 mL autoinjector or syringe every 4 weeks for individuals weighing ≥120 kg. *Initiation of therapy for Hidradenitis Suppurativa (HS): May approve a total of 18 (eighteen) 160 mg/mL autoinjectors or syringes OR 9 (nine) 320 mg/2 mL autoinjectors or syringes in the first 16 weeks of therapy to cover 320 mg loading doses at weeks 0, 2, 4, 6, 8, 10, 12, 14 and 16. *Maintenance therapy for Hidradenitis Suppurativa (HS): May approve 2 (two) 160 mg/mL autoinjectors or syringes OR 1 (one) 320 mg/2 mL autoinjector or syringe every 4 weeks.	

Cosentyx (secukinumab) Quantity Limits

Drug	Limit
Cosentyx (secukinumab) 75 mg/0.5 mL Prefilled Syringe*	1 syringe per 28 days
Cosentyx (secukinumab) 150 mg/mL Sensoready® Pen*	1 pen per 28 days
Cosentyx (secukinumab) 150 mg/mL Prefilled Syringe*	1 syringe per 28 days
Cosentyx (secukinumab) 150 mg/mL Sensoready® Pen 2-Pack*^	1 pack (2 x 150 mg/mL pens) per 28 days
Cosentyx (secukinumab) 150 mg/mL Prefilled Syringe 2-Pack*^	1 pack (2 x 150 mg/mL syringes) per 28 days
Cosentyx (secukinumab) 300 mg/2 mL UnoReady Pen/Prefilled syringe*^	1 pen/syringe per 28 days
Cosentyx (secukinumab) 125 mg/5 mL single-dose vial*	1.75 mg/kg, up to a max limit of 300 mg [3 vials], every 4 weeks
Override Criteria	
*Initiation of therapy: May approve a total of 5 (five) single pens (150 mg/mL) or 5 (five) single syringes (150 mg/mL or 75 mg/mL/0.5 mL) in the first 35 days of treatment; **OR** May approve a total of 5 (five) 2-pack pens (2 x 150 mg/mL) or 5 (five) 2-pack syringes (2 x 150 mg/mL) in the first 35 days of treatment; **OR** May approve a total of 5 (five) 300 mg pens or 5 (five) 300 mg syringes in the first 35 days of treatment; **OR** May approve enough single-dose vials for a single 6 mg/kg loading dose for initiating intravenous treatment in PsA, nr-axSpA, and AS. ^Maintenance therapy: May approve up to two 2-pack pens (2 x 150 mg/mL) OR up to two 2-pack syringes (2 x 150 mg/mL) OR up to two 300 mg pen/syringes every 28 days for individuals with Hidradenitis Suppurativa who do not respond to standard dosing of 300 mg every 4 weeks.	

*FDA recommended dosing for Adult Psoriatic Arthritis (PsA) without coexistent plaque psoriasis (Ps), Ankylosing Spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA): Optional loading doses of 150 mg at weeks 0, 1, 2, 3, 4; maintenance dose of 150 mg every 4 weeks; continued active PsA/AS maintenance dose of 300 mg every 4 weeks.
*FDA recommended dosing for Enthesis-related arthritis (ERA) or Pediatric PsA without coexistent Ps: Loading doses of 150 mg or 75 mg (depending on weight) at weeks 0, 1, 2, 3, 4; maintenance dose of 150 mg or 75 mg (depending on weight) every 4 weeks.

*FDA recommended dosing Plaque Psoriasis (Ps) with or without coexisting Psoriatic Arthritis (PsA): Adults: Loading doses of 300 mg at weeks 0, 1, 2, 3, 4; maintenance dose of 300 mg every 4 weeks; loading and maintenance dose of 150 mg every 4 weeks may be acceptable. Pediatric: Loading doses of 150 mg or 75 mg (depending on weight) at weeks 0, 1, 2, 3, 4; maintenance dose of 150 mg or 75 mg (depending on weight) every 4 weeks.
*FDA recommended dosing for Hidradenitis Suppurativa: Loading doses of 300 mg at weeks 0, 1, 2, 3, 4; maintenance dose of 300 mg every 4 weeks; may increase to 300 mg every 2 weeks for inadequate response.
*FDA recommended intravenous dosing for adult PsA, AS, and nr-axSpA: Optional 6 mg/kg loading dose followed by maintenance dosing of 1.75 mg/kg [max 300 mg] every 4 weeks thereafter.

Siliq (brodalumab) Quantity Limit

Drug	Limit
Siliq (brodalumab) 210 mg/1.5 mL*	2 prefilled syringes per 28 days
Override Criteria	
*Initiation of therapy for adult Plaque Psoriasis (Ps): May approve up to 2 (two) additional syringes (210 mg) in the first 28 days (4 weeks) of treatment.	

Taltz (ixekizumab) Quantity Limit

Drug	Limit
Taltz (ixekizumab) 80 mg/mL prefilled autoinjector*, prefilled syringe*	1 autoinjector/syringe per 28 days
Taltz (ixekizumab) 40 mg/0.5 mL prefilled syringe^	1 syringe per 28 days
Taltz (ixekizumab) 20 mg/0.25 mL prefilled syringe^	1 syringe per 28 days
Override Criteria	
*Initiation of therapy for adults with Plaque Psoriasis (Ps) with or without concomitant Psoriatic Arthritis (PsA): May approve up to 3 (three) additional prefilled autoinjectors or syringes (80 mg/mL) in the first 28 days (4 weeks) of treatment and up to 2 (two) additional prefilled autoinjectors or syringes (80 mg/mL) during days 29-84 (4-12 weeks) of treatment. *Initiation of therapy for individuals age 6 to 17 weighing >50 kg with Plaque Psoriasis (Ps): May approve up to one additional prefilled autoinjector or syringe (80 mg/mL) in the first 28 days (4 weeks) of treatment. ^Initiation of therapy for individuals age 6 to 17 weighing ≤50 kg with Plaque Psoriasis (Ps): May approve up to one additional prefilled syringe (40 mg/0.5 mL or 20 mg/0.25 mL) in the first 28 days (4 weeks) of treatment. *Initiation of therapy for Psoriatic Arthritis (PsA) without concomitant Plaque Psoriasis (Ps) or Ankylosing Spondylitis (AS): May approve up to 1 (one) additional prefilled autoinjector or syringe (80 mg/mL) in the first 28 days (4 weeks) of treatment.	

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals (Hospital Outpatient Use ONLY) [when specified as brodalumab (Siliq), ixekizumab (Taltz), or secukinumab (Cosentyx), Bimzelx (bimekizumab-bkzx)]
J3490	Unclassified drugs [when specified as brodalumab (Siliq), ixekizumab (Taltz), secukinumab (Cosentyx)]
J3590	Unclassified biologics [when specified as brodalumab (Siliq), ixekizumab (Taltz) or secukinumab (Cosentyx) Bimzelx (bimekizumab-bkzx)]
J3247	Injection, secukinumab, IV, 1 mg

ICD-10 Diagnosis

L40.0	Psoriasis vulgaris (plaque psoriasis) [brodalumab (Siliq), secukinumab (Cosentyx), ixekizumab (Taltz), or bimekizumab-bkzx (Bimzelx) only]
L40.50-L40.59	Arthropathic psoriasis [secukinumab (Cosentyx), ixekizumab (Taltz), or bimekizumab-bkzx (Bimzelx) only]
L40.8-L40.9	Other, unspecified psoriasis [brodalumab (Siliq), secukinumab (Cosentyx), ixekizumab (Taltz), or bimekizumab-bkzx (Bimzelx) only]
L73.2	Hidradenitis suppurativa [secukinumab (Cosentyx) only or bimekizumab-bkzx (Bimzelx) only]
M08.80-M08.89	Juvenile arthritis, unspecified [enthesitis-related arthritis] [secukinumab (Cosentyx) only]

M45.0-M45.9	Ankylosing spondylitis [secukinumab (Cosentyx), ixekizumab (Taltz), or bimekizumab-bkzx (Bimzelx) only]
M45.A0-M45.AB	Non-radiographic axial spondyloarthritis [secukinumab (Cosentyx), ixekizumab (Taltz), or bimekizumab-bkzx (Bimzelx) only]
M46.50-M46.59	Other infective spondylopathies [secukinumab (Cosentyx), ixekizumab (Taltz), or bimekizumab-bkzx (Bimzelx) only]

Document History

Revised: 12/09/02024
Document History:

- 12/09/2024 – Select Review: Update bimekizumab criteria and quantity limit to include new FDA approved indication for hidradenitis suppurativa. Coding Reviewed: Added Bimzelx to ICD-10-CM L73.2.
- 12/17/2024 – Coding update only: Updated description for L40.0 and L40.8-L40.9 to include Siliq, Cosentyx, Taltz, or Bimzelx only.
- 11/15/2024 – Annual Review: Update bimekizumab criteria to include new FDA approved indications for psoriatic arthritis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis; update bimekizumab quantity limit and overrides to include new package size and strength. Coding Reviewed: Updated descriptions for ICD-10-CM L40.50-L40.59, M45.0-M45.9, and M45.A0-M45.AB to include Bimzelx. Updated description for M46.50-M46.59 to include Cosentyx, Taltz, or Bimzelx only.
- 08/16/2024 – Select Review: Add quantity limit for new ixekizumab dosage strengths. Coding Reviewed: Added ICD-10-CM M08.80-M08.89 for Cosentyx.
- 07/01/2024 – Add new step therapy table.
- 11/17/2023 – Annual Review: Add clinical criteria and quantity limit for new agent bimekizumab and new IV dosage form for secukinumab; add new indication for secukinumab for hidradenitis suppurativa; update secukinumab quantity limit; add etrasimod to combination use exclusion for consistency; update contraindication to prior therapy language for clarity; clarify repeat TB testing requirements; add continuation of use language; wording and formatting updates. Coding Reviewed: Removed Bimzelx from J3490. Added Bimzelx to J3590 and C9399. Effective 4/1/24 Added HCPCS C9166. 5/8/24 Added ICD-10-CM M45.A0-M45.AB (Cosentyx, Taltz), L73.2 (Cosentyx). Effective 7/1/2024 Added HCPCS J3247 for Cosentyx IV. Removed HCPCS C9166.
- 03/13/2023 – Select Review: Update DMARD example criteria for consistency; wording and formatting updates. Coding. Reviewed: No changes.
- 11/18/2022 – Annual Review: Update combination exclusion list to include additional agents and specify biologic immunomodulators; include additional DMARD examples per guidelines; wording and formatting updates. Coding Reviewed: No changes.
- 02/25/2022 – Select Review: Add new indication for secukinumab in enthesitis-related arthritis; update age criteria in psoriatic arthritis for secukinumab. Coding Reviewed: No changes.
- 11/19/2021 – Annual Review: Remove option of trial of TNF for consistency where applicable; update exclusion list for combination use; clarify tuberculosis testing language; Coding reviewed: No changes.
- 06/14/2021 – Select Review: Add new pediatric indication for secukinumab in psoriasis; clarify may not be approved section; add quantity limit and override for new secukinumab dosage form. Coding Reviewed: No changes.
- 11/20/2020 – Annual Review: Add continuation of use sections; update secukinumab quantity limit to adjust to monthly dose per package size; update override criteria for clarity and to allow adequate time for loading dose; update tuberculosis testing language. Coding Reviewed: No changes.
- 08/21/2020 – Select Review: Add new indication for secukinumab in non-radiographic axial Spondyloarthritis and include in quantity limit override. Administrative update to add drug specific quantity limit. Coding reviewed: Add ICD-10-CM M46.50-M46.59. 9/21/2020-Added ICD-10-CM L40.50-L40.59.
- 06/08/2020 – Select Review: Add new indication for Taltz in non-radiographic axial spondyloarthritis. Coding reviewed: Added Taltz to M45.0-M45.9
- 05/15/2020 – Select Review: Add new pediatric indication for Taltz in Psoriasis. Coding Reviewed: No changes
- 11/15/2019 – Annual Review: Add new ankylosing spondylitis indication to ixekizumab criteria; update definition of moderate psoriasis using BSA based on guidelines; update combination therapy criteria for consistency with other agents; wording and formatting changes. Coding reviewed: No Changes.
- 11/16/2018 – Annual Review: Initial P&T review of Monoclonal Antibodies to Interleukin-17 Clinical Guideline. Update clinical criteria to delete “active” disease wording. Update criteria to delete requirement agent is being used “to reduce signs and symptoms, maintain clinical response” etc. Add examples of conventional therapy to approval criteria for clarity. Wording and formatting changes to criteria for consistency. Add Crohn’s disease to non-approval criteria for brodalumab per label. HCPCS and ICD-10 Coding Review. Added C9399.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

CC-0042 Monoclonal Antibodies to Interleukin-17

Commercial Medical Benefit

Ankylosing Spondylitis, Psoriatic Arthritis		
Effective Date	**Preferred Agents**	**Non-Preferred Agents**
10/01/2024	Avsola Remicade Infliximab Unbranded Simponi Aria	Cosentyx IV
Plaque Psoriasis		
Effective Date	**Preferred Agents**	**Non-Preferred Agents**
10/01/2024	Avsola Remicade Infliximab Unbranded	Cosentyx IV