Clinical Policy Title:	secukinumab
Policy Number:	RxA.733
Drug(s) Applied:	Cosentyx®
Original Policy Date:	04/18/2022
Last Review Date:	01/01/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Ankylosing Spondylitis (must meet all):

1. Diagnosis of active ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA);
2. Trial and failure, unless contraindicated or clinically significant adverse effects are experienced (a and b):
   a. Trial of at least 30 days of two NSAIDs (e.g., ibuprofen, naproxen);
   b. Trial of Taltz®;
3. For Ankylosing Spondylitis:
   a. Trial and failure of at least two (2) of the following agents, unless contraindicated or clinically significant adverse effects are experienced: adalimumab (adalimumab-adaz, Amjevita™, Hadlima, Humira, Yusimry), Cimzia®, Enbrel®, Rinvoq®, Simponi®/Simponi Aria®, Xeljanz®/ XR;
4. For non-radiographic axial spondylarthritis:
   a. Trial and failure of Cimzia®and Rinvoq®, unless contraindicated or clinically significant adverse effects are experienced;
5. Prescribed by or in consultation with a rheumatologist;

Approval duration

All Lines of Business (except Medicare): 12 months

B. Plaque Psoriasis (must meet all):

1. Diagnosis of Plaque Psoriasis (PsO);
2. Trial and failure of ≥ 3 months of at least one (1) conventional systemic therapy, unless contraindicated or clinically significant adverse effects are experienced:
   a. Methotrexate [MTX]
   b. Cyclosporine
   c. Acitretin
   d. Phototherapy (psoralen plus ultraviolet A light [PUVA])
3. Trial and failure of both the following, unless contraindicated or clinically significant adverse effects are experienced (a and b):
   a. Trial of at least three (3) of the following agents: adalimumab (adalimumab-adaz, Amjevita™, Hadlima, Humira, Yusimry), Cimzia®, Skyrizi®, Enbrel®, Tremfya® or Stelara®;
   b. Trial of Taltz®;
4. Prescribed by or in consultation with a dermatologist or a rheumatologist;

Approval duration
All Lines of Business (except Medicare): 12 months

C. Psoriatic Arthritis (must meet all):
1. Diagnosis of Psoriatic Arthritis (PsA);
2. Trial and failure of both the following, unless contraindicated or clinically significant adverse effects are experienced (a and b):
   a. Trial of at least two (2) of the following agents: adalimumab (adalimumab-adaz, Amjevita™, Hadlima, Humira, Yusimry), Enbrel®, Cimzia®, Rinvoq®, Simponi®/ Simponi Aria®, Skyrizi®, Tremfya®, Stelara® or Xeljanz®/ XR;
   b. Trial of Orencia® and Taltz®
3. Prescribed by or in consultation with a dermatologist or a rheumatologist;

Approval Duration
All Lines of Business (except Medicare): 12 months

D. Enthesitis-related Arthritis (ERA) (must meet all):
1. Diagnosis of Enthesitis-related arthritis **(**ERA);
2. Trial and failure of all the following, unless contraindicated or clinically significant adverse effects are experienced (a and b):
   a. Trial of oral or intraarticular corticosteroids, unless contraindicated or clinically significant adverse effects experienced;
   b. Trial of ≥ 3 months of at least one (1) conventional systemic therapy, unless contraindicated or clinically significant adverse effects are experienced (e.g. sulfasalazine, methotrexate);
3. Prescribed by or in consultation with a rheumatologist;

Approval Duration
All Lines of Business (except Medicare): 12 months

E. Hidradenitis suppurativa (must meet all):
1. Diagnosis of moderate to severe hidradenitis suppurativa (HS);
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Documentation of Hurley stage II or stage III;
4. Trial and failure of a least ≥3 months of systemic antibiotic therapy (e.g. clindamycin with rifampin, minocycline, doxycycline), unless contraindicated or clinically significant adverse effects are experienced;
5. Trial and failure of one (1) of the following agents, unless contraindicated or clinically significant adverse effects are experienced: Amjevita, Hadlima, Humira, Yusimry, or adalimumab-adaz.

Approval duration
All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications:
1. Patient is currently receiving medication, excluding manufacturer samples;

Approval Duration
All Lines of Business (except Medicare): 12 months

References

1. Boulos P, Dougados M, MacLeod SM, et al. Pharmacological Treatment of Ankylosing Spondylitis. Drugs. 2005; 65: 2111-2127. Available at: https://pubmed.ncbi.nlm.nih.gov/16225367/. Accessed November 21, 2023.
2. Braun J, Davis J, Dougados M, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with ankylosing spondylitis. Ann Rheum Dis. 2006; 65:316-320. Available at: https://pubmed.ncbi.nlm.nih.gov/16096329/. Accessed November 21, 2023.
3. Braun J, van den Berg R, Baraliako X, et al. 2010 Update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis 2011; 70:896-904. Available at: https://pubmed.ncbi.nlm.nih.gov/21540199/. Accessed November 21, 2023.
4. Menter A, Gottlieb A, Feldman SR, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol. 2008; 58:826-850. Available at: https://www.jaad.org/article/S0190-9622(08)00273-9/fulltext. Accessed November 21, 2023.
5. Ward M, Deodhar A, Akl E, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Available at: http://www.rheumatology.org. Accessed November 21, 2023.
6. van der Heijde D, Ramiro S, Landewe R, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. Ann Rheum Dis. 2017; 76:978- 991. doi:10.1136/annrheumdis-2016-210770. Available at: https://pubmed.ncbi.nlm.nih.gov/28087505/. Accessed November 21, 2023.
7. Zochling J, van der Heijde D, Burgos-Vargas, R, et al. ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis. 2006; 65:442-452. Available at: https://pubmed.ncbi.nlm.nih.gov/16126791/. Accessed November 21, 2023.
8. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. Ann Rheum Dis 2015; 0:1-12. doi:10.1136/annrheumdis-2015-208337. Available at: https://pubmed.ncbi.nlm.nih.gov/26644232/. Accessed November 21, 2023
9. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. American College of Rheumatology. 2019; 71(1):5-32. doi: 10.1002/art.40726. Available at: https://pubmed.ncbi.nlm.nih.gov/30499246/. Accessed November 21, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
RxA.592.Biologic_DMARDs was last reviewed and updated on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Biologics_DMARDs.	01/05/2022	4/18/2022
Drug specific policy for Cosentyx was created based on RxA.592.Biologics_DMARDs: 1. Initial Approval Criteria, I.A.5: Updated to remove prior trial and failure criteria "Failure of two (2) of the following: Humira®, Cimzia®, Inflectra®, Renflexis™, Simponi®, Simponi Aria®, Xeljanz®, Xeljanz® XR and Taltz®; each used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced". 2. Initial Approval Criteria, I.A.5: Updated to include new trial and failure criteria (a and b):	02/09/2022	4/18/2022

a. Trial and failure of at least two (2) of the following agents: Humira®, Cimzia®, Simponi® or Simponi Aria® unless contraindicated or clinically significant adverse effects are experienced;
*Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®, Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required.
b. Trial and failure of at least one (1) of the following agents: Xeljanz®/XR or Taltz® unless contraindicated or clinically significant adverse effects are experienced;

3. Initial Approval Criteria, 1.B.4: Updated trial and failure criteria to rephrase and include phototherapy (psoralen plus ultraviolet A light [PUVA]).
4. Initial Approval Criteria, I.B.5: Updated to include new trial and failure criteria (a and b):
   a. Trial and failure of at least three (3) of the following agents: Humira®, Cimzia®, Skyrizi®, Tremfya® or Stelara® unless contraindicated or clinically significant adverse effects are experienced;
   *Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®, Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required.
   b. Trial and failure of Taltz® unless contraindicated or clinically significant adverse effects are experienced.
5. Initial Approval Criteria, I.B.6: Updated dosing criteria from general dosing to age and weight-based dosing.
6. Initial Approval Criteria I.C.3 from Age ≥ 18 years to Age ≥ 2 years.
7. Initial Approval Criteria, I.C.4: Updated to remove prior trial and failure criteria "Failure of a trial of two (2) of the following, each used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced: Cimzia®, Humira®, Inflectra®, Otezla®, Renflexis™, Rinvoq™, Simponi®, Simponi Aria®, Stelara®, Taltz®, or Xeljanz®/ Xeljanz XR®."
8. Initial Approval Criteria, I.C.4: Updated to include new trial and failure criteria (a and b):
   a. Trial and failure of at least two (2) of the following agents: Humira®, Cimzia®, Rinvoq®, Simponi®/ Simponi Aria®, Skyrizi®, Tremfya®, Stelara® or Xeljanz®/ XR unless contraindicated or

clinically significant adverse effects are experienced; *Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®, Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required. b. Trial and failure of both Orencia® and Taltz® unless contraindicated or clinically significant adverse effects are experienced; 9. Initial Approval Criteria, I.D: Updated to include approval criteria for indication, Enthesitis-related Arthritis. 10. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include drug Enbrel® and Xeljanz®/ XR. 2. Initial Approval Criteria, I.A.5.b: Updated trial and failure criteria from Trial and failure of at least one (1) of the following agents: Xeljanz®/XR or Taltz® unless contraindicated or clinically significant adverse effects are experienced to Trial and failure of Taltz® unless contraindicated or clinically significant adverse effects are experienced. 3. Initial Approval Criteria, I.B.5.a and I.C.4.a: Updated to remove exception trial and failure criteria "Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®, Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required." 4. Initial Approval Criteria, I.B.5.a and I.C.4.a: Updated trial and failure criteria to include drug Enbrel®. 5. References were reviewed and updated.	10/03/2022	10/19/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include new drug Rinvoq and added disclaimar "*Trial of Rinvoq®, Xeljanz®/XR®* requires inadequate response to one or more TNF inhibitors." 2. Initial Approval Criteria, I.A.6: Updated trial and failure criteria from For non-radiographic axial spondyloarthritis: Trial and failure of both Cimzia® and Taltz®, unless contraindicated or clinically significant adverse effects are experienced to For non-radiographic axial spondyloarthritis, Patient meets both (a and b): a. Trial and failure of all of Cimzia® and Rinvoq®*, unless contraindicated or clinically significant	01/06/2023	01/17/2023

adverse effects are experienced; * Trial of Rinvoq® requires inadequate response to one or more TNF inhibitors b. Trial and failure of Taltz unless contraindicated or clinically significant adverse effects are experienced; 3. Initial Approval Criteria, I.C.4: Updated to include new disclaimar "*Trial of Rinvoq®, Xeljanz®/XR®* requires inadequate response to one or more TNF inhibitors." 4. References reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.5.a, I.B.5.a and I.C.4.a: Updated trial and failure criteria to include new drug Amjevita™. 2. References were reviewed and updated.	04/05/2023	04/13/2023
Policy was reviewed: 1. References were reviewed and updated.	06/28/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed prior age criteria. 2. Removed prior dosing criteria. 3. Removed Exception criteria from trial and failure for Ankylosing Spondylitis and Enthesitis-related Arthritis (ERA). 4. Removed requirement to try/fail Humira for ERA. 5. Update approval duration. 6. Updated trial and failure criteria to include Humira biosimilar. 7. Removed reauthorization requirement for positive response to therapy. 8. References were reviewed and updated.	11/21/2023	01/01/2024
Policy review	3/1/2024	3/1/2024