Effective Date **4/15/2024**
Coverage Policy Number **IP0245**

Adalimumab

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for the following adalimumab products:

- Abrilada™
- adalimumab-aacf
- adalimumab-adaz
- adalimumab-adbm
- adalimumab-fkjp
- Amjevita™
- Cyltezo®
- Hadlima™
- Hulio®
- Humira®
- Hyrimoz® (by Sandoz/Novartis)
- Idacio®
- Yuflyma®
- Yusimry™

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Adalimumab products (Abrilada, adalimumab-aacf, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Yuflyma, Yusimry) are considered medically necessary when ONE of the following is met:

1. **Ankylosing Spondylitis.** Individual meets **ALL** of the following criteria:
    A. Documentation of **ONE** of the following:
        i. Failure, contraindication or intolerance to **ONE** non-steroidal anti-inflammatory drug (NSAID)
        ii. Already tried a biologic or targeted synthetic DMARD for Ankylosing Spondylitis
    B. Medication is prescribed by, or in consultation with, a rheumatologist
    C. Non-Preferred Product Criteria is met, refer to below table(s)

2. **Behcet's Disease.** Individual meets **ALL** of the following criteria:
    A. Documentation of **ONE** of the following:
        i. Failure to **ONE** systemic conventional therapy, unless contraindicated or intolerant

            Examples of conventional systemic therapy: corticosteroids, other immunosuppressants or colchicine.

        ii. Already tried a biologic for Behcet's Disease
    B. Medication is prescribed by, or in consultation with, a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist
    C. Non-Preferred Product Criteria is met, refer to below table(s)

3. **Crohn's Disease.** Individual meets **ALL** of the following criteria:
    A. 6 years of age or older
    B. Documentation of **ONE** of the following:
        i. Failure, contraindication or intolerance to **ONE** corticosteroid, OR a corticosteroid will be taken concurrently with adalimumab
        ii. Failure to **ONE** other conventional systemic therapy, unless contraindicated or intolerant, OR conventional systemic therapy will be taken concurrently with adalimumab
        iii. Already tried a biologic for Crohn's Disease
        iv. Meets **ONE** of the following:
            a. Severe disease needing hospitalization
            b. Involvement of the upper GI tract
            c. Smoker
            d. Less than 40 years of age
            e. Stricturing disease
            f. Perianal disease
            g. Other enterocutaneous fistula
            h. Extraintestinal manifestations (ankylosing spondylitis, pyoderma gangrenosum, erythema nodosum)
            i. Previous Crohn's disease-related surgery (for example, ileocolonic resection (to reduce the chance of Crohn's disease recurrence)
            j. Bowel obstruction
            k. History of abscess or perforation (after healing)
    C. Medication is being prescribed by, or in consultation with, a gastroenterologist
    D. Non-Preferred Product Criteria is met, refer to below table(s)

4. **Hidradenitis Suppurativa.** Individual meets **ALL** of the following criteria:
    A. Documentation of failure to **ONE** conventional therapy, unless contraindicated or intolerant

        Examples of conventional therapy: intralesional or oral corticosteroids, systemic antibiotics.

B. Medication is prescribed by, or in consultation with, a dermatologist
C. Non-Preferred Product Criteria is met, refer to below table(s)

5. **Non-radiographic Axial Spondyloarthritis**. Individual meets **ALL** of the following criteria:
   A. Objective signs of inflammation, defined as **ONE** of the following:
      i. C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory
      ii. Sacroiliitis reported on magnetic resonance imaging (MRI)
   B. **ONE** of the following:
      i. Documented failure, contraindication or intolerance to **ONE** non-steroidal anti-inflammatory drug (NSAID)
      ii. Already tried a biologic or targeted synthetic DMARD (tsDMARD) for Non-radiographic Axial Spondyloarthritis
   C. Medication is prescribed by, or in consultation with, a rheumatologist
   D. Non-Preferred Product Criteria is met, refer to below table(s)

6. **Plaque Psoriasis.** Individual meets **ALL** of the following criteria:
   A. 18 years of age or older
   B. Body Surface Area (BSA) of greater than 5%, OR BSA less than 5% and there is and there is involvement of the scalp, face, the palms and soles, or genitals
   C. Documentation of **ONE** of the following:
      i. Failure to **ONE** of the following, unless contraindicated or intolerant to **ALL** of the following:
         a. Topical therapy (for example, topical corticosteroids, topical vitamin D analogs)
         b. Systemic therapy (for example, methotrexate, cyclosporine, Soriatane)
         c. Phototherapy
      ii. Already tried a biologic or targeted synthetic DMARD (tsDMARD) for Plaque Psoriasis
   D. Medication is prescribed by, or in consultation with, a dermatologist
   E. Non-Preferred Product Criteria is met, refer to below table(s)

7. **Polyarticular Juvenile Idiopathic Arthritis (includes Juvenile Rheumatoid Arthritis, Juvenile Spondyloarthropathy/Active Sacroiliac Arthritis).** Individual meets **ALL** of the following criteria:
   A. 2 years of age or older
   B. Medication is prescribed by, or in consultation with, a rheumatologist
   C. Non-Preferred Product Criteria is met, refer to below table(s)

8. **Psoriatic Arthritis. Individual meets BOTH of the following:**
   A. Medication is prescribed by, or in consultation with, a rheumatologist or dermatologist
   B. Non-Preferred Product Criteria is met, refer to below table(s)

9. **Pyoderma Gangrenosum.** Individual meets **ALL** of the following criteria:
   A. Documented failure to conventional systemic immunosuppressant therapy, unless contraindicated or intolerant

      Examples of conventional systemic immunosuppressant therapy: mycophenolate mofetil, cyclosporine, corticosteroid.

   B. Medication is prescribed by, or in consultation with, a dermatologist or rheumatologist
   C. Non-Preferred Product Criteria is met, refer to below table(s)

10. **Rheumatoid Arthritis.** Individual meets **ALL** of the following criteria:
    A. Documented of **ONE** of the following:
       i. Failure to **ONE** conventional synthetic disease-modifying anti-rheumatic drug (csDMARD), unless contraindicated or intolerant

ii. Already tried a biologic or targeted synthetic DMARD (tsDMARD) for Rheumatoid Arthritis

B. Medication is prescribed by, or in consultation with, a rheumatologist
C. Non-Preferred Product Criteria is met, refer to below table(s)

11. Sarcoidosis. Individual meets **ALL** of the following criteria:
A. Documentation of failure, contraindication or intolerance to **ONE** corticosteroid
B. Documentation of failure to **ONE** other immunosuppressant, unless contraindicated or intolerant

Examples of other immunosuppressants: azathioprine, cyclosporine, methotrexate, mycophenolate mofetil.

C. Medication is prescribed by, or in consultation with, a pulmonologist, ophthalmologist, dermatologist, or rheumatologist
D. Non-Preferred Product Criteria is met, refer to below table(s)

12. Scleritis or Sterile Corneal Ulceration. Individual meets **ALL** of the following criteria:
A. Documentation of failure to **ONE** ophthalmic or systemic immunosuppressant therapy, unless contraindicated or intolerant

Examples of immunosuppressive therapy: corticosteroids, methotrexate, cyclosporine.

B. Medication is prescribed by, or in consultation with, an ophthalmologist
C. Non-Preferred Product Criteria is met, refer to below table(s)

13. Spondyloarthritis (non-axial disease): Reactive Arthritis (Reiter's disease) and Undifferentiated Arthritis. Individual meets **ALL** of the following criteria:
A. Has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet
B. Documentation of **ONE** of the following:
i. Failure to **ONE** conventional synthetic disease-modifying anti-rheumatic drug (csDMARD), unless contraindicated or intolerant
ii. Already tried a biologic for Reactive Arthritis [Reiter's disease] or Undifferentiated Arthritis
C. Medication is being prescribed by, or in consultation with, a rheumatologist
D. Non-Preferred Product Criteria is met, refer to below table(s)

14. Ulcerative Colitis. Individual meets **ALL** of the following criteria:
A. 5 years of age or older
B. Documentation of **ONE** of the following:
i. Failure to **ONE** conventional systemic therapy, unless contraindicated or intolerant
ii. Already tried a biologic or targeted synthetic DMARD (tsDMARD) for Ulcerative Colitis
iii. Has pouchitis AND has tried therapy with an antibiotic (for example, metronidazole, ciprofloxacin), corticosteroid enema or suppository, or mesalamine enema or suppository
C. Medication is prescribed by, or in consultation with, a gastroenterologist
D. Non-Preferred Product Criteria is met, refer to below table(s)

15. Uveitis (including other posterior uveitides and panuveitis syndromes). Individual meets **ALL** of the following criteria:
A. Documentation of **EITHER** of the following:
i. Failure to **ONE** ophthalmic or systemic immunosuppressant therapies, unless contraindicated or intolerant
ii. Already tried a biologic for Uveitis
B. Medication is prescribed by, or in consultation with, an ophthalmologist or rheumatologist
C. Non-Preferred Product Criteria is met, refer to below table(s)

Coverage varies across plans and requires the use of Preferred Products. Refer to the customer's benefit plan document for coverage details.

Employer Group Plans	
	Non-Preferred Product Criteria
Abrilada **adalimumab-aacf** **adalimumab-fkjp** **Amjevita**	**Standard/Performance/Legacy Drug List Plans** Documented trial of AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction to **ALL** of the following: A. **Adalimumab-adaz or Hyrimoz** (by Sandoz/Novartis) [requires prior authorization] B. **Adalimumab–adbm or Cyltezo** [requires prior authorization] C. **Humira** [requires prior authorization] **Value/Advantage/Cigna Total Savings Drug List Plans** Documented trial of AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction to **ALL** of the following: A. **Adalimumab-adaz or Hyrimoz** (by Sandoz/Novartis) [requires prior authorization] B. **Adalimumab–adbm or Cyltezo** [requires prior authorization] C. **Hadlima** [requires prior authorization] D. **Humira** [requires prior authorization]
Hadlima	**Standard/Performance/Legacy Drug List Plans** Documented trial of AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction to **ALL** of the following: A. **Adalimumab-adaz or Hyrimoz** (by Sandoz/Novartis) [requires prior authorization] B. **Adalimumab–adbm or Cyltezo** [requires prior authorization] C. **Humira** [requires prior authorization] **Value/Advantage/Cigna Total Savings Drug List Plans** **Preferred** [requires prior authorization]
Hulio **Idacio** **Yuflyma** **Yusimry**	**Standard/Performance/Legacy Drug List Plans** Documented trial of AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction to **ALL** of the following: A. **Adalimumab-adaz or Hyrimoz** (by Sandoz/Novartis) [requires prior authorization] B. **Adalimumab–adbm or Cyltezo** [requires prior authorization] C. **Humira** [requires prior authorization] **Value/Advantage/Cigna Total Savings Drug List Plans** Documented trial of AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the

Employer Group Plans	
	Non-Preferred Product Criteria
	prescriber, would result in a significant allergy or serious adverse reaction to **ALL** of the following: A. **Adalimumab-adaz or Hyrimoz** (by Sandoz/Novartis) [requires prior authorization] B. **Adalimumab–adbm or Cyltezo** [requires prior authorization] C. **Hadlima** [requires prior authorization] D. **Humira** [requires prior authorization]

Individual and Family Plans	
	Non-Preferred Product Criteria
Abrilada **adalimumab-aacf** **adalimumab-fkjp** **Amjevita** **Hulio** **Idacio** **Yuflyma** **Yusimry**	Documented trial of AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction to **ALL** of the following: A. **Adalimumab-adaz or Hyrimoz** (by Sandoz/Novartis) [requires prior authorization] B. **Adalimumab–adbm or Cyltezo** [requires prior authorization] C. **Hadlima** [requires prior authorization] D. **Humira** [requires prior authorization]

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of adalimumab products (Abrilada, adalimumab-aacf, adalimumab-adaz, adalimumab–adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Humira, Hulio, Hyrimoz, Idacio, Yuflyma, Yusimry) is considered medically necessary for **ALL** covered diagnoses when initial criteria are met AND beneficial response is demonstrated.

Authorization Duration

Initial approval duration is up to 12 months.
Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).** An adalimumab product should not be administered in combination with another biologic or with a targeted synthetic DMARD used for an inflammatory condition, Combination therapy is generally not recommended due to a potentially higher rate of adverse events with combinations and lack of data supportive of additional efficacy.

This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with an adalimumab product.

2. **Polymyalgia Rheumatica (PMR).** EULAR/ACR guidelines for the management of PMR (2015) strongly recommend against the use of TNFis for treatment of PMR.[17] This recommendation is based on lack of evidence for benefit as well as considerable potential for harm.

Background

OVERVIEW

Adalimumab products are tumor necrosis factor inhibitors (TNFis) approved for the following uses:[1]

- **Ankylosing spondylitis**, for reducing signs and symptoms in patients with active disease.
- **Crohn's disease**, for treatment of moderately to severely active disease in patients ≥ 6 years of age.
- **Hidradenitis suppurativa**, for the treatment of moderate to severe disease in patients ≥ 12 years of age.
- **Juvenile idiopathic arthritis (JIA)**, ± methotrexate for reducing signs and symptoms of moderately to severely active polyarticular disease in patients ≥ 2 years of age.
- **Plaque psoriasis**, for the treatment of adults with moderate to severe chronic disease who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate.
- **Psoriatic arthritis (PsA)**, ± conventional synthetic disease-modifying antirheumatic drugs (DMARDs), for reducing the signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function.
- **Rheumatoid arthritis**, ± methotrexate or other conventional synthetic DMARDS to reduce the signs and symptoms, induce major clinical response, inhibit the progression of structural damage, and improve physical function in adults with moderately to severely active disease.
- **Ulcerative colitis**, for treatment of moderately to severely active disease in patients ≥ 5 years of age. However, efficacy has not been established in patients with ulcerative colitis who have lost response or were intolerant to another TNFi.
- **Uveitis**, in patients ≥ 2 years of age with noninfectious intermediate, posterior, and panuveitis.

Guidelines

TNFis are featured prominently in guidelines for treatment of inflammatory conditions.

- **Ankylosing Spondylitis and Spondyloarthritis:** Guidelines for ankylosing spondylitis and non-radiographic axial spondylitis are published by the American College of Rheumatology (ACR)/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019).[3] TNFis are recommended as the initial biologic. In those who are secondary non-responders to a TNFi, a second TNFi is recommended over switching out of the class.
- **Crohn's Disease:** The American College of Gastroenterology (ACG) has guidelines for Crohn's disease (2018).[4] TNFis are listed as an option for disease that is resistant to corticosteroids, severely active disease, perianal fistulizing disease, and maintenance of remission. In post-operative Crohn's disease, a TNFi should be started within 4 weeks of surgery to prevent recurrence. Guidelines from the American Gastroenterological Association (AGA) [2021] include TNFis among the therapies for moderate to severe Crohn's disease, for induction and maintenance of remission.[17]
- **Hidradenitis Suppurativa:** British guidelines (2018) recommend consideration of adalimumab for those with moderate to severe disease who do not respond to conventional therapy.[19]
- **JIA:** There are guidelines from ACR and the Arthritis Foundation for the treatment of JIA (2021) which address oligoarthritis and temporomandibular joint (TMJ) arthritis. For oligoarthritis, a biologic is recommended following a trial of a conventional synthetic DMARD.[6] In patients with TMJ arthritis, scheduled nonsteroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids are recommended first-line. A biologic is a therapeutic option if there is an inadequate response or intolerance. Additionally, rapid escalation to a biologic ± conventional synthetic DMARD (methotrexate preferred) is often appropriate given the impact and destructive nature of TMJ arthritis. In these guidelines, there is not a preferred biologic that should be initiated for JIA. ACR guidelines (2019) are

also available specifically for juvenile non-systemic polyarthritis, sacroiliitis, and enthesitis.[5] TNFis are the biologics recommended for polyarthritis, sacroiliitis, and enthesitis. Biologics are recommended following other therapies (e.g., following DMARDs for active polyarthritis or following an NSAID for active JIA with sacroiliitis or enthesitis). However, there are situations where initial therapy with a biologic may be preferred over other conventional therapies (e.g., if there is involvement of high-risk joints such as the cervical spine, wrist, or hip; high disease activity; and/or those judged to be at high risk of disabling joint damage).

- **Plaque Psoriasis:** Guidelines from the American Academy of Dermatologists and National Psoriasis Foundation (2019) recommend adalimumab as a monotherapy treatment option for adults with moderate to severe disease.[7]
- **PsA:** Guidelines from ACR (2019) recommend TNFis over other biologics for use in treatment-naïve patients with PsA and in those who were previously treated with an oral therapy.[8]
- **Rheumatoid Arthritis:** Guidelines from ACR (2021) recommend addition of a biologic or a targeted synthetic DMARD for a patient taking the maximum tolerated dose of methotrexate who is not at target.[2]
- **Ulcerative Colitis:** Guidelines from the ACG for ulcerative colitis (2019) note that the following agents can be used for induction of remission in moderately to severely active disease: budesonide extended-release tablets, oral or intravenous systemic corticosteroids, Entyvio® (vedolizumab intravenous infusion), Xeljanz®/XR (tofacitinib tablets/extended-release tablets), or TNFis.[9] Guidelines from the AGA (2020) recommend Xeljanz only after failure of or intolerance to a TNFi.[10] In addition to the approved indication, clinical guidelines for the management of pouchitis (2009) indicate that first-line therapy for pouchitis is antibiotic therapy (e.g. metronidazole, ciprofloxacin).[11] Other treatment options include maintenance probiotics, oral or topical budesonide, anti-inflammatory drugs (e.g., mesalamine), or immunosuppressive agents (e.g., infliximab).
- **Uveitis and Ocular Inflammatory Disorders:** American Academy of Ophthalmology (AAO) guidelines (2014) note that adalimumab may be used in patients with uveitis due to various causes (e.g., spondyloarthropathy-associated or human leukocyte antigen [HLA]-B27-associated uveitis, JIA-associated uveitis, and other posterior uveitides and panuveitis syndromes).[12] Adalimumab should be considered second-line in vision-threatening JIA-associated uveitis when methotrexate has failed or is not tolerated (strong recommendation) and may be used as corticosteroid-sparing treatment for vision-threatening chronic uveitis from seronegative spondyloarthropathy (strong recommendation). Adalimumab may also be considered in other patients who have vision-threatening or corticosteroid-dependent disease who have failed first-line therapies. Adalimumab should be considered as a second-line immunomodulatory agent for severe ocular inflammatory conditions including chronic and severe scleritis. ACR/Arthritis Federation guidelines (2019) for uveitis associated with JIA make recommendations for use of conventional systemic DMARDs and biologics. In patients with severe active chronic anterior uveitis associated with sight-threatening complications, a TNFi (monoclonal antibody) + methotrexate is recommended.[19]

Other Uses with Supportive Evidence

There are guidelines and/or published data supporting the use of adalimumab products in the following conditions:

- **Behcet's Disease:** The European Union Against Rheumatism (EULAR) recommendations (2018) include TNFis for initial or recurrent sight-threatening uveitis.[13] For patients refractory to first-line treatments (e.g., corticosteroids), TNFis are among the treatment options for mucocutaneous manifestations, venous thrombosis, severe or refractory gastrointestinal disease, and recurrent/chronic joint involvement. Recommendations for the use of TNFis in ocular inflammatory disorders from the AAO (2014) note that TNFis may be used first-line in patients with ophthalmic manifestations of Behcet's disease and for acute exacerbations of preexisting Behcet's disease.[12]
- **Pyoderma Gangrenosum:** Although guidelines are not current, multiple topical and systemic therapies have been used for pyoderma gangrenosum. Oral prednisone is the most common initial immunosuppressant medication.[14] Other systemic therapies include cyclosporine, methotrexate, azathioprine, cyclophosphamide, mycophenolate mofetil, and TNFis (i.e., infliximab, etanercept, and adalimumab products). In case reports, TNFis have been effective.

- **Sarcoidosis:** According to European Respiratory Society guidelines for sarcoidosis (2021), a TNFi is recommended after a trial of glucocorticoids and immunosuppressants for pulmonary and neurosarcoidosis.[15]

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Appendix

Table 1. Approved TNFis for Targeted Indications.

	Rheumatology					Dermatology	Gastroenterology	
	RA	JIA	AS	nr-axSpA	PsA	PsO	CD	UC
Tumor Necrosis Factor Inhibitors								
Cimzia	√	--	√	√	√	√	√	--
Enbrel	√	√	√	--	√	√	--	--
Adalimumab products (Humira, biosimilars)	√	√	√	--	√	√	√	√
Infliximab Products	√	--	√	--	√	√	√	√
Simponi Subcutaneous	√	--	√	--	√	--	--	√
Simponi Aria	√	√	√	--	√	--	--	--

TNFis – Tumor necrosis factor inhibitors; RA – Rheumatoid arthritis; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; nr-axSpA – Non-radiographic spondyloarthritis; PsA – Psoriatic arthritis; PsO – Plaque psoriasis; CD – Crohn's disease; UC – Ulcerative colitis.

Table 2. Approved IL-17, IL-23, and IL-12/23 Blockers for Targeted Indications.

	Rheumatology			Dermatology	Gastroenterology	
	Ankylosing Spondylitis	nr-axSpA	Psoriatic Arthritis	Plaque Psoriasis	Crohn's Disease	Ulcerative Colitis
Interleukin-17 Blockers						
Cosentyx	√	√	√	√	--	--
Siliq	--	--	--	√	--	--
Taltz	√	√	√	√	--	--
Interleukin-23 Blockers						
Ilumya	--	--	--	√	√	--
Skyrizi Intravenous	--	--	--	--	√#	--
Skyrizi Subcutaneous	--	--	√	√	√^	--
Tremfya	--	--	√	√	--	--
Interleukin-12/23 Blockers						
Stelara Subcutaneous	--	--	√	√	√^	√^
Stelara Intravenous	--	--	--	--	√#	√#

IL – Interleukin; nr-axSpA – Non-radiographic spondyloarthritis; ^ Maintenance dosing only; # Induction dosing only.

Table 3. Approved Oral tsDMARDs for Targeted Indications.

	Rheumatology					Dermatology	Gastro-enterology
	Rheumatoid Arthritis	Juvenile Idiopathic Arthritis	Ankylosing Spondylitis	nr-axSpA	Psoriatic Arthritis	Plaque Psoriasis	Ulcerative Colitis
Janus Kinases Inhibitors							
Olumiant	√	--	--	--	--	--	--
Rinvoq	√	--	√	√	√	--	√
Xeljanz tablets	√	√#	√	--	√	--	√
Xeljanz oral solution	--	√#	--	--	--	--	--
Xeljanz XR	√	--	√	--	√	--	√
Phosphodiesterase Type 4 Inhibitor							
Otezla	--	--	--	--	√	√	--
Sphingosine 1-Phosphate Receptor Modulator							
Zeposia	--	--	--	--	--	--	√

	Rheumatology					Dermatology	Gastro-enterology
	Rheumatoid Arthritis	Juvenile Idiopathic Arthritis	Ankylosing Spondylitis	nr-axSpA	Psoriatic Arthritis	Plaque Psoriasis	Ulcerative Colitis
Tyrosine Kinase 2 Inhibitor							
Sotyktu	--	--	--	--	--	√	--

tsDMARDs – Targeted synthetic disease-modifying antirheumatic drugs; # Indicated in polyarticular JIA.

Table 4. Other Approved Biologics for Targeted Indications.

	Rheumatology		
	Rheumatoid Arthritis	Juvenile Idiopathic Arthritis	Psoriatic Arthritis
Interleukin-6 Blockers			
Actemra Intravenous	√	√^	--
Actemra Subcutaneous	√	√^	--
Kevzara	√	--	--
Interleukin-1 Blocker			
Kineret	√	--	--
T-Cell Costimulation Modulator			
Orencia Intravenous	√	√#	√
Orencia Subcutaneous	√	√#	√
CD20-Directed Cytolytic Antibody			
Rituximab Intravenous Products	√	--	--

^ Indicated in polyarticular and systemic JIA; # Indicated in polyarticular JIA.