Biologic Immunomodulators Prior Authorization with Quantity Limit Program Summary

This program applies to FocusRx, FlexRx Closed, FlexRx Open, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx.

This is a FlexRx Standard and GenRx Standard program.

There are two criteria modules, Option A and Option B, with different preferred adalimumab products. These options are based on a member's formulary.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

For target agents that are not yet available on the market, PA and QL will apply upon launch

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Abrilada™ (adalimumab-afzb) Subcutaneous injection	Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA) Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years of age and older Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with psoriatic arthritis (PsA) Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS) Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older Treatment of moderately to severely active ulcerative colitis (UC) in adult patients • Limitations of Use: ○ Effectiveness has not been established in patients who have lost response to or were intolerant to tumor necrosis factor (TNF) blockers Treatment of adult patients with moderate to severe chronic plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	83

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Agent(s)	FDA Indication(s)	Notes	Ref#
	Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients		
Actemra® (tocilizumab) Intravenous infusion Subcutaneous injection	Treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs) Treatment of giant cell arteritis (GCA) in adult patients Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis associated interstitial lung disease (SSc-ILD) • Limitation of use: o SC administration with the prefilled ACTPen autoinjector and IV administration has not been studied in SSc-ILD Treatment of active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older Treatment of active systemic juvenile idiopathic arthritis (SJIA) in patients 2 years of age and older Treatment of chimeric antigen receptor (CAR) T-cell induced severe or life-threatening cytokine release syndrome (CRS) in adults and pediatric patients 2 years of age and older Treatment of Coronavirus disease 2019 (COVID-19) in hospitalized adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)	Interleukin-6 Inhibitor	1
Amjevita® (adalimumab-atto) Subcutaneous injection	Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA) Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA) Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS) Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older Treatment of moderately to severely active ulcerative colitis (UC) in adult patients • Limitation of use: o The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF blockers	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	71

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Agent(s)	FDA Indication(s)	Notes	Ref#
	Treatment of adult patients with moderate to severe chronic plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients		
Bimzelx® (bimekizumab-bkzx) Subcutaneous injection	Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or photo therapy	Interleukin F17A and F antagonist	84
Cimzia® (certolizumab pegol) Subcutaneous injection	Reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy Treatment of adults with moderately to severely active rheumatoid arthritis (RA) Treatment of adult patients with active psoriatic arthritis (PSA) Treatment of adults with active ankylosing spondylitis (AS) Treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation Treatment of adults with moderate-to-severe plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	2
Cosentyx® (secukinumab) Intravenous injection Subcutaneous injection	Treatment of moderate to severe plaque psoriasis (PS) in patients 6 years and older who are candidates for systemic therapy or phototherapy Treatment of active psoriatic arthritis (PSA) in patients 2 years of age and older Treatment of adult patients with active ankylosing spondylitis (AS) Treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation Treatment of active enthesitis-related arthritis (ERA) in patients 4 years of age and older Treatment of adults with moderate to severe hidradenitis suppurativa (HS)	Interleukin-17 Inhibitor	3
Cyltezo®/Adalimumab-adbm	Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA)	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	76

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Agent(s)	FDA Indication(s)	Notes	Ref#
Subcutaneous injection	Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA) Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS) Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older Treatment of moderately to severely active ulcerative colitis (UC) in adult patients • Limitation of use: ○ The effectiveness has not been established in patients with UC who have lost response to or were intolerant to TNF blockers Treatment of adult patients with moderate to severe chronic plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients		
Enbrel® (etanercept) Subcutaneous injection	Reduce the signs and symptoms, including major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA) Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients ages 2 and older Reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (PSA) Reducing signs and symptoms in patients with active ankylosing spondylitis (AS) Treatment of patients 4 years or older with chronic moderate to severe plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy Treatment of active juvenile psoriatic arthritis (JPsA) in pediatric patients 2 years of age and older	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	4
Entyvio®	Treatment in adults for moderately to severely active ulcerative colitis (UC)	Integrin receptor antagonist	5

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Agent(s)	FDA Indication(s)	Notes	Ref#
(vedolizumab) Injection for intravenous use Injection for subcutaneous use	Treatment in adults for moderately to severely active Crohn's disease (CD)		
Hadlima™ (adalimumab-bwwd) Subcutaneous Injection	Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA) Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA) Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS) Treatment of moderately to severely active Crohn’s disease (CD) in adults and pediatric patients 6 years of age and older Treatment of moderately to severely active ulcerative colitis (UC) in adult patients • Limitation of use: ○ Effectiveness has not been established in patients with UC who have lost response to or were intolerant to TNF blockers Treatment of adult patients with moderate to severe chronic plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	77
Hulio®/Adalimumab-fkjp Subcutaneous injection	Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA) Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	74

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Agent(s)	FDA Indication(s)	Notes	Ref#
	Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA) Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS) Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older Treatment of moderately to severely active ulcerative colitis (UC) in adult patients • Limitation of use: ○ Effectiveness has not been established in patients with UC who have lost response to or were intolerant to TNF blockers Treatment of adult patients with moderate to severe chronic plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients		
Humira® (adalimumab) Subcutaneous injection	Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA) Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA) Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS) Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older Treatment of moderately to severely active ulcerative colitis (UC) in adults and pediatric patients 5 years of age and older • Limitation of use: ○ The effectiveness of Humira has not been established in patients with UC who have lost response to or were intolerant to TNF blockers Treatment of adult patients with moderate to severe chronic plaque psoriasis (PS) who are candidates for systemic therapy or	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	6

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Agent(s)	FDA Indication(s)	Notes	Ref#
	phototherapy, and when other systemic therapies are medically less appropriate Treatment of moderate to severe hidradenitis suppurativa (HS) in patients 12 years of age and older Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adults and pediatric patients 2 years of age and older		
Hyrimoz®/Adalimumab-adaz Subcutaneous injection	Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA) Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA) Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS) Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older Treatment of moderately to severely active ulcerative colitis (UC) in adult patients • Limitation of use: ○ Effectiveness has not been established in patients with UC who have lost response to or were intolerant to TNF blockers Treatment of adult patients with moderate to severe chronic plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	80
Idacio®/Adalimumab-aacf Subcutaneous injection	Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA) Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	75

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Agent(s)	FDA Indication(s)	Notes	Ref#
	Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA) Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS) Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older Treatment of moderately to severely active ulcerative colitis (UC) in adult patients • Limitation of use: ○ Effectiveness has not been established in patients with UC who have lost response to or were intolerant to TNF blockers Treatment of adult patients with moderate to severe chronic plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adults		
Kevzara® (sarilumab) Subcutaneous injection	Treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs) Treatment of adult patients with polymyalgia rheumatica who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper	Interleukin-6 Inhibitor	7
Kineret® (anakinra) Subcutaneous injection	Reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis (RA), in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs) Treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID)* Treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)*	Interleukin-1 Inhibitor *- approved for use in pediatric patients as young as 1 month of age	8
Litfulo™ (ritlecitinib) Capsule	Treatment of severe alopecia areata in adults and adolescents 12 years and older • Limitations of Use: ○ Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants	Janus Kinase (JAK) inhibitor	81
Olumiant®	Treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) blockers	Janus Kinase (JAK) Inhibitor	9

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Agent(s)	FDA Indication(s)	Notes	Ref#

(baricitinib)
 	
Oral tablet
	• Limitation of Use:
	  ○ Not recommended for use in combination with other JAK inhibitors, biologic disease modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine
	
	Treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)
	
	Treatment of adult patients with severe alopecia areata
	
	• Limitation of Use:
	  ○ Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants		

Omvoh™ (mirikizumab-mrkz) Intravenous injection Subcutaneous injection	Treatment of moderately to severely active ulcerative colitis in adults	Interleukin-23 Inhibitor	86
Orencia® (abatacept) Intravenous infusion Subcutaneous injection	Treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) Treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) Treatment of patients 2 years of age and older with active psoriatic arthritis (PSA) Prophylaxis of acute graft versus host disease (aGVHD), in combination with calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor • Limitation of Use: ○ Concomitant use with other potent immunosuppressants (e.g., biologic disease modifying antirheumatic drugs [bDMARDS], Janus kinase [JAK] inhibitors) is not recommended	T-cell Costimulation Blocker	10
Rinvoq® (upadacitinib extended release) Oral tablet	Treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more TNF blockers • Limitations of Use: ○ Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent	Janus Kinase (JAK) Inhibitor	44

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Agent(s)	FDA Indication(s)	Notes	Ref#
	immunosuppressants such as azathioprine and cyclosporine Treatment of adults with active psoriatic arthritis (PSA) who have had an inadequate response or intolerance to one or more TNF blockers • Limitations of Use: o Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine Treatment of adult and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis (AD) whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable • Limitations of Use: o Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants Treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more TNF blockers • Limitations of Use: o Rinvoq is not recommended for use in combination with other JAK inhibitors, biological therapies for ulcerative colitis, or with potent immunosuppressants such as azathioprine and cyclosporine Treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers • Limitations of Use: o Rinvoq is not recommended for use in combination with other JAK inhibitors, biological therapies for Crohn's disease, or with potent immunosuppressants such as azathioprine and cyclosporine Treatment of adults with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers • Limitations of Use: o Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy • Limitations of Use: o Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent		

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Agent(s)	FDA Indication(s)	Notes	Ref#
	immunosuppressants such as azathioprine and cyclosporine		
Siliq® (brodalumab) Subcutaneous injection	Treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies	Interleukin-17 Receptor Antagonist	11
Simlandi® (adalimumab-ryvk) Subcutaneous injection	Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA) Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years of age and older Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with psoriatic arthritis (PsA) Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS) Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older Treatment of moderately to severely active ulcerative colitis (UC) in adult patients • Limitations of Use: o Effectiveness has not been established in patients who have lost response to or were intolerant to tumor necrosis factor (TNF) blockers Treatment of adult patients with moderate to severe chronic plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	90
Simponi® (golimumab) Subcutaneous injection	Treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate Treatment of adult patients with active psoriatic arthritis (PSA) Treatment of adult patients with active ankylosing spondylitis (AS)	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	12

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Agent(s)	FDA Indication(s)	Notes	Ref#
	Adult patients with moderately to severely active ulcerative colitis with inadequate response or intolerant to prior treatment or requiring continuous steroid therapy • Inducing and maintaining clinical response • Improving endoscopic appearance of the mucosa during induction • Inducing clinical remission • Achieving and sustaining clinical remission in induction responders		
Skyrizi® (risankizumab-rzaa) Subcutaneous injection	Treatment of moderate-to-severe plaque psoriasis (PS) in adults who are candidates for systemic therapy or phototherapy Treatment of active psoriatic arthritis (PSA) in adults Treatment of moderately to severely active Crohn's disease in adults	Interleukin-23 Inhibitor	43
Sotyktu® (deucravacitinib) Tablet	Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy • Limitation of Use: o Not recommended for use in combination with other potent immunosuppressants	Tyrosine Kinase Inhibitor	67
Stelara® (ustekinumab) Intravenous infusion Subcutaneous injection	Treatment of patients 6 years and older with moderate to severe plaque psoriasis (PS) who are candidates for phototherapy for systemic therapy Treatment of patients 6 years and older with active psoriatic arthritis (PSA) Treatment of adult patients with moderately to severely active Crohn's disease (CD) Treatment of adult patients with moderately to severely active ulcerative colitis (UC)	Interleukin-23 Inhibitor	13
Taltz® (ixekizumab) Subcutaneous injection	Treatment of patients 6 years of age and older with moderate-to severe plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy Treatment of adult patients with active psoriatic arthritis (PSA) Treatment of adult patients with active ankylosing spondylitis (AS) Treatment of adult patents with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation	Interleukin-17 Inhibitor	14
Tremfya® (guselkumab) Subcutaneous injection	Treatment of adults with moderate-to-severe plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy Treatment of adult patients with active psoriatic arthritis (PSA)	Interleukin-23 Inhibitor	15

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Agent(s)	FDA Indication(s)	Notes	Ref#
Velsipity™ (etrasimod) Tablets	Treatment of moderately to severely active ulcerative colitis in adults	Sphingosine 1-phosphate (SIP-1) receptor modulator	85
Xeljanz® (tofacitinib) Oral Solution	Treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers • Limitations of use: ○ Use of Xeljanz in combination with biologics DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended	Janus Kinase (JAK) Inhibitor	16

Xeljanz®
 	
(tofacitinib)
 	
Oral tablet
	Treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more TNF blockers
	
	• Limitations of use:
	  ○ Use of Xeljanz in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended
	
	Treatment of adult patients with active psoriatic arthritis (PSA) who have had an inadequate response or intolerance to one or more TNF blockers
	
	• Limitations of use:
	  ○ Use of Xeljanz in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended
	
	Treatment of adult patients with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers
	
	• Limitations of use:
	  ○ Use of Xeljanz in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended
	
	Treatment of adult patients with moderately to severely active ulcerative colitis (UC), who have had an inadequate response or intolerance to one or more TNF blockers
	
	• Limitations of use:
	  ○ Use of Xeljanz in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended
	
	Treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers
	
	• Limitations of use:
		Janus Kinase (JAK) Inhibitor	16

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Agent(s)	FDA Indication(s)	Notes	Ref#
	○ Use of Xeljanz in combination with biologics DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended		
Xeljanz® XR (tofacitinib extended release) Oral tablet	Treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more TNF blockers • Limitations of use: ○ Use of Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended Treatment of adult patients with active psoriatic arthritis (PSA) who have had an inadequate response or intolerance to one or more TNF blockers • Limitations of use: ○ Use of Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended Treatment of adult patients with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers • Limitations of use: ○ Use of Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended Treatment of adult patients with moderately to severely active ulcerative colitis (UC), who have had an inadequate response or intolerance to one or more TNF blockers • Limitations of use: ○ Use of Xeljanz XR in combination with biological therapies for UX or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended	Janus Kinase (JAK) Inhibitor	16
Yuflyma®/Adalimumab-aaty Subcutaneous injection	Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA) Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA) Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS)	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	78

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Agent(s)	FDA Indication(s)	Notes	Ref#
	Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older Treatment of moderately to severely active ulcerative colitis (UC) in adult patients • Limitation of use: o Effectiveness has not been established in patients with UC who have lost response to or were intolerant to TNF blockers Treatment of adult patients with moderate to severe chronic plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients		
Yusimry™ (adalimumab-aqvh) Subcutaneous injection	Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA) Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA) Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS) Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older Treatment of moderately to severely active ulcerative colitis (UC) in adult patients • Limitation of use: o Effectiveness has not been established in patients with UC who have lost response to or were intolerant to TNF blockers Treatment of adult patients with moderate to severe chronic plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	79

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Agent(s)	FDA Indication(s)	Notes	Ref#
Zymfentra™ (infliximab-dyyb) Subcutaneous injection	Maintenance treatment of moderately to severely active ulcerative colitis in adults following treatment with an infliximab product administered intravenously Maintenance treatment of moderately to severely active Crohn's disease in adults following treatment with an infliximab product administered intravenously	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	89

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

RHEUMATOID DISORDERS - Ankylosing spondylitis (AS)	Ankylosing spondylitis (AS) is a form of chronic inflammatory arthritis characterized by sacroiliitis, enthesitis, and a marked propensity for sacroiliac joint and spinal fusion. AS is distinguished by universal involvement with sacroiliac joint inflammation or fusion and more prevalent spinal ankylosis. Goals of treatment for AS are to reduce symptoms, maintain spinal flexibility and normal posture, reduce functional limitations, maintain work ability, and decrease disease complications. The mainstays of treatment have been nonsteroidal anti-inflammatory drugs (NSAIDs) and exercise, with the additional use of disease-modifying antirheumatic drugs (DMARDs) in patients with peripheral arthritis. The American College of Rheumatology (ACR), Spondylitis Association of America (SAA), and Spondyloarthritis Research and Treatment Network (SPARTAN) recommend the following pharmacological treatment for AS:(17,47)
	
	• Stable AS: First line therapy with on demand NSAIDs; there is also a conditional recommendation for continuation of TNF inhibitor as monotherapy
	• Active AS:
	  ○ First line therapy with continuous NSAIDs with physical therapy
	  ○ TNF inhibitor recommended for patients with active AS despite an adequate trial with NSAIDs
	  ▪ Lack of response (or intolerance) to at least 2 different NSAIDs over 1 month or incomplete response to at least 2 different NSAIDs over 2 months would be an adequate NSAID trial to judge response
	  ○ Recommendations for nonresponse to TNF therapy (all conditional):
	  ▪ Primary nonresponse: switch to secukinumab or ixekizumab over another TNF
	  ▪ Secondary nonresponse: switch to another TNF over a non-TNF biologic
	  ▪ Recommend against addition of sulfasalazine or MTX
	  ▪ Recommend against switching to a biosimilar of the failed TNF
	  ○ TNF-inhibitors are conditionally recommended over secukinumab or ixekizumab
	  ○ Secukinumab or ixekizumab are conditionally recommended over DMARDs in patients that have failed NSAIDs and have contraindications to TNF-inhibitors
	  ○ DMARDs (i.e., methotrexate [MTX], sulfasalazine) are only conditionally recommended in patients that have failed NSAIDs and have contraindications to TNF-inhibitors
	  ○ Methotrexate is not recommended as add on therapy to TNF inhibitors in stable and active AS
	  ○ If patient has concomitant inflammatory bowel disease (IBD) or recurrent uveitis, TNF-inhibitors are recommended over other biologics
	  ○ Glucocorticoids are not recommended

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RHEUMATOID DISORDERS - Nonradiographic Axial Spondyloarthritis (nr-axSpA)	Nonradiographic axial spondyloarthritis (nr-axSpA) falls under the same spondyloarthritis family as ankylosing spondylitis (AS). Nr-axSpA includes patients with chronic back pain and features suggestive of spondyloarthritis (SpA), but do not meet the classification of AS. The goals of treatment are to reduce symptoms, maintain spinal flexibility and normal posture, reduce functional limitations, maintain work ability, and decrease disease complications. The mainstays of treatment have been NSAIDs and exercise, with the additional use of DMARDs in patients with peripheral arthritis. The American College of Rheumatology (ACR), Spondylitis Association of America (SAA), and Spondyloarthritis Research and Treatment Network (SPARTAN) recommendation for nr-axSpA are the same as AS:(17,47) • Stable SpA: conditional recommendation for on-demand treatment with NSAIDs • Active SpA: o First line therapy with continuous NSAIDs with physical therapy o TNF inhibitor conditionally recommended for patients with active SpA despite an adequate trial with NSAIDs ▪ Lack of response (or intolerance) to at least 2 different NSAIDs over 1 month or incomplete response to at least 2 different NSAIDs over 2 months would be an adequate NSAID trial to judge response o TNF-inhibitors are conditionally recommended over secukinumab or ixekizumab o Secukinumab or ixekizumab are conditionally recommended over DMARDs in patients that have failed NSAIDs and have contraindications to TNF-inhibitors o Recommendations for nonresponse to TNF therapy (all conditional): ▪ Primary nonresponse: switch to secukinumab or ixekizumab over another TNF ▪ Secondary nonresponse: switch to another TNF over a non-TNF biologic ▪ Recommend against addition of sulfasalazine or MTX ▪ Recommend against switching to a biosimilar of the failed TNF o DMARDs (i.e., methotrexate, sulfasalazine) are only conditionally recommended in patients that have failed NSAIDs and have contraindications to TNF-inhibitors o Methotrexate is not recommended as add on therapy to TNF inhibitors in stable and active AS o If patient has concomitant inflammatory bowel disease or recurrent uveitis, TNF-inhibitors are recommended over other biologics o Glucocorticoids are not recommended
RHEUMATOID DISORDERS - Rheumatoid arthritis (RA)	Rheumatoid arthritis (RA) is the most common inflammatory autoimmune arthritis in adults. The main goal of therapy is to achieve remission, but additional goals include decrease inflammation, relieve symptoms, prevent joint and organ damage, improve physical function/overall well-being, and reduce long term complications.(18,25) The choice of therapy depends on several factors, including the severity of disease activity when therapy is initiated and the response of the patient to prior therapeutic interventions.(18) American College of Rheumatology (ACR) guidelines list the following guiding principles in the treatment of RA:(18) • RA requires early evaluation, diagnosis, and management • Treatment decisions should follow a shared decision-making process • Treatment decisions should be reevaluated within a minimum of 3 months based on efficacy and tolerability of the DMARD(s) chosen • Recommendations are limited to DMARDs approved by the US FDA for treatment of RA: o csDMARDs: hydroxychloroquine, sulfasalazine, methotrexate (MTX), leflunomide

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	○ bDMARDs: TNF inhibitors (etanercept, adalimumab, infliximab, golimumab, certolizumab pegol), T cell costimulatory inhibitor (abatacept), IL-6 receptor inhibitors (tocilizumab, sarilumab), anti-CD20 antibody (rituximab) ○ tsDMARDs: JAK inhibitors (tofacitinib, baricitinib, upadacitinib) • Triple therapy refers to hydroxychloroquine, sulfasalazine, and either methotrexate or leflunomide • Biosimilars are considered equivalent to FDA-approved originator bDMARDs • Recommendations referring to bDMARDs exclude rituximab unless patients have had an inadequate response to TNF inhibitors (in order to be consistent with FDA approval) or have a history of lymphoproliferative disorder for which rituximab is an approved therapy • Treat-to-target refers to a systematic approach involving frequent monitoring of disease activity using validated instruments and modifications of treatment to minimize disease activity with the goal of reaching a predefined target (low disease activity or remission) ACR guidelines are broken down by previous treatment and disease activity:(18) • DMARD-naïve patients with moderate-to-high disease activity initial treatment: ○ MTX monotherapy is strongly recommended over hydroxychloroquine, sulfasalazine, bDMARDs monotherapy, tsDMARD monotherapy, or combination of MTX plus a non-TNF bDMARD or tsDMARD ○ MTX monotherapy is conditionally recommended over leflunomide, dual or triple csDMARD therapy, or combination MTX plus a TNF inhibitor • DMARD-naïve patients with low disease activity initial treatment: ○ Hydroxychloroquine is conditionally recommended over other csDMARDs ○ Sulfasalazine is conditionally recommended over MTX ○ MTX is conditionally recommended over leflunomide • Initial therapy in csDMARD-treated patients, but MTX naïve, with moderate-to high disease activity: ○ MTX monotherapy is conditionally recommended over combination MTX and a bDMARD or tsDMARD • Treatment Modifications in patients treated with DMARDs who are not at target: ○ Addition of a bDMARD or tsDMARD is conditionally recommended over triple therapy for patients taking maximally tolerated doses of MTX who are not at target ○ Switching to a bDMARD or tsDMARD of a different class is conditionally recommended over switching to a bDMARD or tsDMARD belonging to the same class for patients taking a bDMARD or tsDMARD who are not at target Early use of DMARD, particularly MTX, is recommended as soon as possible following diagnosis of RA. Dosing of MTX for RA is once weekly dosing with starting doses at 7.5 mg or 15 mg once weekly.(26,27,28) MTX dose is increased as tolerated and as needed to control symptoms and signs of RA disease. The usual target dose is at least 15 mg weekly and the usual maximum dose is 25 mg weekly.(27,28) ACR defines optimal dosing for RA treatments as 1) dosing to achieve a therapeutic target derived from mutual patient-clinician consideration of patient priorities and 2) given for at least 3 months before therapy escalation or switching. For patients who are unable to take MTX, hydroxychloroquine, sulfasalazine, or leflunomide are other DMARD options. In patients resistant to initial MTX treatment, combination DMARD (e.g., MTX plus sulfasalazine or hydroxychloroquine or a TNF-inhibitor) is recommended.(18) For patients who are resistant to MTX after 3 months of treatment at optimal doses (usually 25 mg per week), it is recommended to either use DMARD triple therapy with MTX plus sulfasalazine and hydroxychloroquine or combination of MTX with TNF

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	inhibitor. Triple therapy regimen has been found to be of similar clinical efficacy to MTX with biologics in several randomized trials, including in patients with high level of disease activity or with adverse prognostic features. The use of triple therapy has been shown to be highly cost-effective compared with combining a biologic with MTX, providing comparable or near comparable clinical benefit. The use of biologic with MTX combination is preferred when patients have high disease activity and clinical benefit from a more rapid response is needed and when patients who do not achieve satisfactory response within 3 months with non-biologic triple therapy following an inadequate response to MTX therapy.(18,28)

RHEUMATOID DISORDERS - Polyarticular Juvenile Idiopathic Arthritis (PJIA)	Juvenile idiopathic arthritis (JIA) is arthritis that begins before the 16th birthday and persists for at least 6 weeks with other known conditions excluded. Polyarticular juvenile idiopathic arthritis (PJIA) is a subset of JIA. The ACR defines PJIA as arthritis in more than 4 joints during their disease course and excludes systemic JIA. Treatment goals are aimed at achieving clinically inactive disease and to prevent long-term morbidities, including growth disturbances, joint contractures and destruction, functional limitations, and blindness or visual impairment from chronic uveitis.(34,35)
	
	The ACR 2019 guidelines recommend the following treatment approach for PJIA:(34,35)
	
	• NSAIDs are conditionally recommended as adjunct therapy
	• DMARD therapy:
	  ○ Methotrexate (MTX) is conditionally recommended over leflunomide and sulfasalazine
	  ○ Subcutaneous MTX is conditionally recommended over oral MTX
	• Intraarticular glucocorticoids are conditionally recommended as adjunct therapy and conditionally recommended for bridging only in patients with moderate to high disease activity
	• Strongly recommend against chronic low-dose glucocorticoid use, irrespective of disease activity and/or risk factors
	• Strongly recommend combination use of a DMARD and infliximab
	• Initial therapy for all patients:
	  ○ DMARD is strongly recommended over NSAID monotherapy
	  ○ MTX monotherapy is conditionally recommended over triple DMARD therapy
	  ○ DMARD is conditionally recommended over a biologic
	  ○ Initial biologic therapy may be considered for patients with risk factors and involvement of high-risk joints (e.g., cervical spine, wrist, hip), high disease activity, and/or those judged by their physician to be at high risk of disabling joint damage
	• Subsequent therapy:
	  ○ Low disease activity:
	  ▪ Escalating therapy (e.g., intraarticular glucocorticoid injections, optimization of DMARD dose, trial of MTX if not already done, and adding or changing biologic agent)
	  ○ Moderate to high disease activity:
	  ▪ Add a biologic to original DMARD over changing to a second DMARD or changing to triple DMARD therapy
	  ▪ Switch to a non-TNF biologic if currently treated with first TNF +/- DMARD over switching to another TNF (unless the patient had good initial response to first TNF)
	  ▪ TNF, abatacept, or tocilizumab (depending on prior biologics received) over rituximab after trial of second biologic

RHEUMATOID DISORDERS - Systemic Juvenile Idiopathic Arthritis (SJIA)	Systemic juvenile idiopathic arthritis (SJIA) is a subset of JIA. SJIA is distinct from all other categories of JIA due to fever, rash, and visceral involvement. Disease pathogenesis and cytokine involvement in SJIA are different than other JIA categories. Up to 40% of cases of SJIA are associated with macrophage activation syndrome (MAS), a secondary hemophagocytic syndrome that is a life-threatening complication requiring urgent recognition and treatment. MAS presents with fevers, high ferritin levels, cytopenias, elevated liver enzyme levels, low fibrinogen levels, and high

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	triglyceride levels. As it may occur at any point during the disease course careful monitoring is necessary for children with or without MAS at presentation. Goals of therapy for SJIA includes control of active inflammation and symptoms, and the prevention of a number of disease and/or treatment related morbidities, such as growth disturbances, joint damage, and functional limitations.(19)
	
	SJIA is defined as:(19)
	
	• Patient age 6 months to 18 years
	• Fever of at least 2 weeks duration (daily fever is not required but at some point exhibit a quotidian (daily) fever pattern, defined as a fever that rises to greater than or equal to 39 degrees Celsius at least once a day and returns to less than or equal to 37 degrees Celsius between fever peaks
	• Arthritis in greater than or equal to 1 joint
	• Accompanied by one or more of the following:
	  ○ Evanescent erythematous rash
	  ○ Generalized lymphadenopathy
	  ○ Hepatomegaly or splenomegaly
	  ○ Pericarditis, pleuritis and/or peritonitis
	
	SJIA without MAS
	
	The American College of Rheumatology conditionally recommends IL-1 or IL-6 inhibitors and/or a brief trial of scheduled non-steroidal anti-inflammatories (NSAIDs) for initial treatment for SJIA without MAS. Studies suggest that a small proportion of patients with systemic JIA will respond to NSAIDs alone. If clinical response is not rapid and complete, rapid escalation of therapy is recommended. There is no consensus on the appropriate duration of initial use of NSAIDs before escalating therapy, as many prescribers prefer that the use of NSAIDs be avoided altogether for SJIA. Oral glucocorticoids are conditionally recommended against use in this population (the recommendation is conditional, as IL-1 or IL-6 inhibitors may not always be immediately available, and glucocorticoids may help control systemic and joint manifestations until IL-1 or IL-6 inhibitors can be started. Conventional synthetic disease modifying antirheumatic drugs (DMARDs) are strongly recommended against as initial therapy in this population. For subsequent therapy IL-1 and IL-6 inhibitors are strongly recommended over a single or combination of conventional synthetic DMARDs for inadequate response to intolerance of NSAIDs and/or glucocorticoids.(19)
	
	SJIA with MAS
	
	The American College of Rheumatology conditionally recommends IL-1 or IL-6 inhibitors over calcineurin inhibitors alone to achieve inactive disease and resolution of MAS. Glucocorticoids are conditionally recommended as part of initial treatment in patients with SJIA with MAS. Systemic glucocorticoids may be necessary for severely ill patients because they can have rapid onset of action. Longer-term glucocorticoids therapy in children is not appropriate because of its effects on bone health and growth.(19)

RHEUMATOID DISORDERS - Enthesitis Related Arthritis	Juvenile idiopathic arthritis (JIA) is a group of heterogenous forms of arthritis characterized by onset before 16 years of age, involving one or more joints, and lasting 6 weeks or more. Enthesitis related arthritis (ERA) is one form of JIA in which patients have predominately enthesitis, enthesitis and arthritis, juvenile ankylosing spondylitis, or inflammatory bowel disease associated arthropathy. The International League Against Rheumatism as arthritis and enthesitis that lasts at least 6 weeks in a child less than 16 years OR arthritis or enthesitis with two of the following features: sacroiliac tenderness or inflammatory spinal pain, HLA-B27 positivity, onset of arthritis in a male patient older than 6 years, and family history of HLA-B27 associated disease. Enthesitis is a distinct feature of ERA and is defined as inflammation of an enthesis, which is a site where a tendon, ligament, or joint capsule attaches to bone. (55)

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	The ACR 2019 guidelines recommend the following treatment approach for ERA: • NSAIDs are strongly recommended over no treatment in children and adolescents (34) • TNF inhibitors are conditionally recommended over methotrexate or sulfasalazine in children and adolescents with active enthesitis despite treatment with NSAIDs (34) • First line therapy with continuous NSAIDs and physical therapy for adult patients (47) • DMARDs (i.e., methotrexate [MTX], sulfasalazine) are only conditionally recommended in patients that have failed NSAIDs and have contraindications to TNF-inhibitors (47) ○ Lack of response (or intolerance) to at least 2 different NSAIDs over 1 month or incomplete response to at least 2 different NSAIDs over 2 months would be an adequate NSAID trial to judge response (17)

RHEUMATOID DISORDERS - Psoriatic Arthritis (PsA)	Psoriatic arthritis (PsA) is a chronic inflammatory musculoskeletal disease associated with psoriasis, most commonly presenting with peripheral arthritis, dactylitis, enthesitis, and spondylitis. Treatment involves the use of a variety of interventions, including many agents used for the treatment of other inflammatory arthritis, particularly spondyloarthritis and RA, and other management strategies of the cutaneous manifestations of psoriasis.(29)
	
	The American Academy of Dermatology (AAD) recommends initiating MTX in most patients with moderate to severe PsA. After 12 to 16 weeks of MTX therapy with appropriate dose escalation, the AAD recommends adding or switching to a TNF inhibitor if there is minimal improvement on MTX monotherapy.(30)
	
	The American College of Rheumatology (ACR) and the National Psoriasis Foundation (NPF) guidelines for PsA recommend a treat-to-target approach in therapy, regardless of disease activity, and the following:(29)
	
	• Active PsA is defined as symptoms at an unacceptably bothersome level as reported by the patient and health care provider to be due to PsA based on the presence of one of the following:
	  ○ Actively inflamed joints
	  ○ Dactylitis
	  ○ Enthesitis
	  ○ Axial disease
	  ○ Active skin and/or nail involvement
	  ○ Extraarticular manifestations such as uveitis or inflammatory bowel disease
	• Disease severity includes level of disease activity at a given time point and the presence/absence of poor prognostic factors and long-term damage
	• Severe PsA disease includes the presence of 1 or more of the following:
	  ○ Erosive disease
	  ○ Elevated markers of inflammation (ESR, CRP) attributable to PsA
	  ○ Long-term damage that interferes with function (i.e., joint deformities)
	  ○ Highly active disease that causes a major impairment in quality of life
	  ○ Active PsA at many sites including dactylitis, enthesitis
	  ○ Function limiting PsA at a few sites
	  ○ Rapidly progressive disease
	• Symptomatic treatments include nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, local glucocorticoid injections
	• Treatment recommendations for active disease:
	  ○ Treatment naïve patients first line options include oral small molecules (OSM), TNF biologics, IL-17 inhibitor, and IL-12/23 inhibitor
	  ▪ OSM (i.e., methotrexate [MTX], sulfasalazine, cyclosporine, leflunomide, apremilast) should be considered if the patient does not have severe PsA, does not have severe psoriasis,

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	prefers oral therapy, has concern over starting a biologic, or has contraindications to TNF inhibitor ▪ Biologics (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) are recommended as a first line option in patients with severe PsA and/or severe psoriasis o Previous treatment with OSM and continued active disease: ▪ Switch to a different OSM (except apremilast) in patients without severe PsA or severe PS, contraindications to TNF biologics, prefers oral therapy OR add on apremilast to current OSM therapy ▪ May add another OSM (except apremilast) to current OSM therapy for patients that have exhibited partial response to current OSM in patients without severe PsA or severe PS, contraindications to TNF biologics, or prefers oral therapy ▪ Biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) monotherapy o Previous treatment with a biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) and continued active disease: ▪ Switch to another biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor, abatacept, or tofacitinib) monotherapy or add MTX to the current TNF biologic
RHEUMATOID DISORDERS - Polymyalgia Rheumatica (PMR)	Polymyalgia rheumatica (PMR) is a rheumatic disorder associated with musculoskeletal pain and stiffness in the neck, shoulder, and hip area. The etiology is not fully understood, but there are associated environmental and genetic factors. The incidence of PMR increases with age and is rarely seen in people under the age of 50. Women are approximately 2-3 times more likely to be affected by PMR than men. A characteristic feature of PMR is a new and relatively acute onset of proximal muscle pain and stiffness in the neck, shoulders, upper arms, hips and thighs. Patients often suffer from a pronounced morning stiffness with difficulty turning in or getting out of bed in the morning with some spontaneous relief of symptoms later in the day. The nonspecific clinical presentation and the absence of specific laboratory findings or serologic features often leads to some diagnostic delay.(72) The American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) guidelines recommend the following for the treatment of PMR: (73) • Strongly recommends using glucocorticoids over NSAIDs for long term care of patients with PMR and used for the minimum effective duration • Conditionally recommends using the minimum effective glucocorticoid dose within a range of 12.5–25 mg prednisone equivalent daily as the initial treatment of PMR. A higher initial prednisone dose within this range may be considered in patients with a high risk of relapse and low risk of adverse events, whereas in patients with relevant comorbidities (e.g., diabetes, osteoporosis, glaucoma, etc.) and other risk factors for glucocorticoid -related side effects, a lower dose may be preferred. The guideline discourages conditionally the use of initial doses less than or equal to 7.5 mg/day and strongly recommends against the use of initial doses greater than 30 mg/day. • Strongly recommends individualizing dose tapering schedules, predicated to regular monitoring of patient disease activity, laboratory markers and adverse events. The following principles of glucocorticoid dose tapering are suggested: o Initial tapering: Taper dose to an oral dose of 10 mg/day prednisone equivalent within 4–8 weeks. o Relapse therapy: Increase oral prednisone to the pre-relapse dose and decrease it gradually (within 4–8 weeks) to the dose at which the relapse occurred. o Tapering once remission is achieved (following initial and relapse therapies): Taper daily oral prednisone by 1 mg every 4 weeks (or by 1.25 mg decrements using schedules such as 10/7.5 mg alternate days, etc.) until discontinuation given that remission is maintained. • Conditionally recommends considering intramuscular (IM) methylprednisolone as an alternative to oral glucocorticoids. The choice between oral

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<table>
<tr><td></td><td>glucocorticoids and IM methylprednisolone remains at the discretion of the prescriber.
• Conditionally recommends using a single rather than divided daily doses of oral glucocorticoids for the treatment of PMR, except for special situations such as prominent night pain while tapering glucocorticoids below the low-dose range (prednisone or equivalent less than 5 mg daily).
• Conditionally recommends considering early introduction of methotrexate (MTX) in addition to glucocorticoids, particularly in patients at a high risk for relapse and/or prolonged therapy as well as in cases with risk factors, comorbidities and/or concomitant medications where glucocorticoid-related adverse events are more likely to occur. MTX may also be considered during follow-up of patients with a relapse, without significant response to glucocorticoid or experiencing glucocorticoid-related adverse events.
• Strongly recommends against the use of TNFa blocking agents for treatment of PMR.</td></tr>
<tr><td>RHEUMATOID DISORDERS - Juvenile Psoriatic Arthritis (JPsA)</td><td>Juvenile psoriatic arthritis (JPsA) is a relatively rare condition in childhood and represents approximately 5% of the whole JIA populations. JPsA is defined by the association of arthritis and psoriasis or, in the absence of typical psoriatic lesions, with at least two of the following:(87)

• Dactylitis
• Nail Pitting
• Onycholysis
• Family history of psoriasis in a first-degree relative.

Recent studies however have shown that this classification system could conceal more homogeneous subgroups of patients differing by age of onset, clinical characteristics, and prognosis. Little is known about genetic factors and pathogenetic mechanisms which distinguish JPsA from other JIA subtypes or from isolated psoriasis without joint involvement, especially in the pediatric population.(87)

Psoriatic arthritis of adulthood is a well-defined, although phenotypically heterogeneous, clinical condition. In the majority of cases, it is characterized by the onset of arthritis in patients with pre-existing psoriasis. An opposite scenario is seen in children: arthritis complicates only 2% of pediatrics psoriasis, whereas in JPsA skin disease typically occurs up to 10 years after the development of arthritis, making JPsA diagnosis often challenging. JPsA can be differentiated from adult PsA by several factors as follows:(87)

<table>
<tr><th>Clinical feature</th><th>Adult PsA</th><th>JPsA</th></tr>
<tr><td>Timing of psoriasis and arthritis onset</td><td>Psoriasis prior to arthritis</td><td>Arthritis prior to psoriasis</td></tr>
<tr><td>Oligoarticular peripheral arthritis</td><td>20%-55%</td><td>45%-55%</td></tr>
<tr><td>Polyarticular peripheral arthritis</td><td>20%-60%</td><td>33%-55%</td></tr>
<tr><td>Oligo-Extended peripheral arthritis</td><td>NA</td><td>15%-38%</td></tr>
<tr><td>Axial arthritis</td><td>7%-40%</td><td>10%-30%</td></tr>
<tr><td>Radiological damage</td><td>47%</td><td>25%</td></tr>
<tr><td>Enthesitis</td><td>30%-50%</td><td>12%-45%</td></tr>
<tr><td>Dactylitis</td><td>40%-50%</td><td>17%-37%</td></tr>
<tr><td>Nail involvement</td><td>41%-93%</td><td>37%-57%</td></tr>
<tr><td>Uveitis</td><td>8%</td><td>8%-13%</td></tr>
<tr><td>Human Leukocyte antigen (HLA)-B27</td><td>40%-50%</td><td>10%-25%</td></tr>
</table>
</td></tr>
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	<table><tr><td>Antinuclear antibodies (ANA)</td><td>16%</td><td>40%-46%</td></tr></table> Psoriasis occurs in 40%-60% of patients with JPsA, usually the classic vulgaris form, although guttate psoriasis is also observed. Psoriasis in children tends to be subtle with thin, soft plaques that may be similar to atopic eczema. Onychopathy is reported in more than half of patients with JPsA, compared with 30% in childhood psoriasis in general. Onycholysis may also be observed but is much less common than in adults.(87) Nonsteroidal anti-inflammatory drugs and oral glucocorticoids, as well as intra-articular glucocorticoids, are indicated as initial steps for symptom relief and bridge therapies. Disease modifying antirheumatic drugs (DMARDs) represent the mainstay second line treatment of children with polyarthritis. The most used is methotrexate which is recommended over leflunomide or sulfasalazine. Biologic agents should be considered in case of DMARDs failure or intolerance, presence of risk factors, or high disease activities.(87)
DERMATOLOGICAL DISORDERS - Alopecia Areata	Alopecia areata (AA) is a chronic, inflammatory disorder that affects hair follicles and sometimes nails. Initial presentation generally involves patches of hair loss on the scalp, but any hair-bearing skin may be involved. Short broken hairs, also known as exclamation point hairs, may be seen around the margins of the patches. The hair follicles in the growth phase prematurely transition to the non-proliferative involution and resting phases. This leads to hair shedding and inhibition of hair growth. The integrity of hair follicles are preserved, allowing for the potential regrowth of hair even in longstanding disease. Roughly 34-50% of patients will spontaneously recover within a year from symptom onset. AA often remits in patients with almost all patients experiencing multiple episodes of the disease, and roughly 14-50% of patients will progress to total scalp hair loss, known as alopecia totalis (AT), or total loss of scalp and body hair, known as alopecia universalis (AU). Severity at initial presentation is a strong predictor of long-term outcomes of the disease, with more severe disease progressing to AT or AU. Diagnosis is based off of clinical presentation and patient history. Other causes of alopecia need to be ruled out, and some patients may require a biopsy for diagnosis.(65,66) The management of AA involves counseling, and potentially antidepressants, due to the psychological effects associated with hair loss. Pharmacologic treatments are often temporary and do not alter the long-term course of the disease. Spontaneous remission rates also make it difficult to assess treatment efficacy, especially in patients with mild disease. Very potent topical corticosteroids have been used to treat patchy AA spots, but there is limited evidence to support long-term use. Intralesional corticosteroids are also an option for patchy AA spots and have shown more sustained hair growth. Systemic corticosteroids are generally reserved for patients with more extensive hair loss, but adverse effects tend to limit duration of use. Hair loss frequently recurs when these treatments are stopped. Conventional systemic immunomodulators and JAK inhibitors are often used for patients with disease that is refractory to corticosteroids and topical immunotherapy.(65,66)
DERMATOLOGICAL DISORDERS - Psoriasis (PS)	Psoriasis (PS) is a chronic inflammatory skin condition that is often associated with systemic manifestations, especially arthritis. Diagnosis is usually clinical, based on the presence of typical erythematous scaly patches, papules, and plaques that are often pruritic and sometimes painful. Treatment goals for psoriasis include improvement of skin, nail, and joint lesions plus enhanced quality of life.(20) The American Academy of Family Physicians (AAFP) categorizes psoriasis severity into mild to moderate (less than 5% of body surface area [BSA]) and moderate to severe (5% or more of BSA). The AAFP psoriasis treatment guidelines recommend basing treatment on disease severity:(20)

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	• Mild to moderate (less than 5% of BSA and sparing the genitals, hands, feet, and face):
	  ○ Candidate for intermittent therapy: topical corticosteroids, vitamin D analogs (calcipotriene and calcitriol), or tazarotene (Tazorac)
	  ○ Candidate for continuous therapy: calcineurin inhibitors (tacrolimus and pimecrolimus)
	• Severe (5% or more of BSA or involving the genitals, hands, feet, and face):
	  ○ Less than 20% of BSA affected: vitamin D analogs (calcipotriene and calcitriol) with or without phototherapy. These agents have a slower onset of action but a longer disease-free interval than topical corticosteroids
	  ○ 20% or more of BSA affected: systemic therapy with MTX, cyclosporine, acitretin, or biologics. Biologics are recommended for those with concomitant PsA
	• Less commonly used topical therapies include non-medicated moisturizers, salicylic acid, coal tar, and anthralin
	
	The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) categorize psoriasis severity as limited or mild (less than 3% of BSA), moderate (3% to 10% of BSA), or severe (greater than 10% of BSA). The AAD/NPF guidelines also note that psoriasis can be considered severe irrespective of BSA when it occurs in select locations (e.g., hands, feet, scalp, face, or genital area) or when it causes intractable pruritus.(31) The AAD psoriasis treatment guidelines recommend the following*:(30,31,33,88)
	
	• Mild to moderate disease (less than 5% of BSA):
	  ○ Topical corticosteroids (strength of recommendation A)
	  ○ Off-label use of 0.1% tacrolimus for psoriasis involving the face as well as inverse psoriasis (strength of recommendation B)
	  ○ Long-term use (up to 52 weeks) of topical vitamin D analogs including calcipotriene, calcitriol, tacalcitol, and maxacalcitol (strength of recommendation A)
	  ○ Use of calcipotriene foam and calcipotriene plus betamethasone dipropionate gel for the treatment of mild to moderate scalp psoriasis (strength of recommendation A)
	  ○ Use of tacalcitol ointment or calcipotriene combined with hydrocortisone for facial psoriasis (strength of recommendation B)
	  ○ Vitamin D analogs in combination with topical corticosteroids (strength of recommendation A)
	  ○ Topical tazarotene alone or in combination with narrowband ultraviolet B (NB-UVB) (strength of recommendation B), or topical corticosteroids (strength of recommendation A)
	  ○ Topical salicylic acid alone or in combination with topical corticosteroids (strength of recommendation B)
	  ○ Coal tar preparations (strength of evidence A)
	• Moderate to severe disease without PsA (5% or more of BSA or psoriasis in vulnerable areas [e.g., face, genitals, hands, and feet] that adversely affects quality of life):
	  ○ Methotrexate (adults) (strength of evidence A)
	  ○ Methotrexate is less effective than TNF-inhibitors (strength of evidence B)
	  ○ Combination therapy with methotrexate and NB-UVB (adult patients) (strength of evidence B)
	  ○ Cyclosporine for patients with severe, recalcitrant (strength of recommendation A), erythrodermic, generalized pustular, and/or palmoplantar psoriasis (strength of recommendation B)
	  ○ Acitretin as monotherapy or in combination with psoralen plus ultraviolet light (PUVA) or broad band ultraviolet light (BB-UVA [strength of evidence B])
	  ○ If UV-therapy is unavailable, first line therapies include MTX, cyclosporine, acitretin, and biologics
	  ○ Apremilast (strength of recommendation A)

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TNF-α inhibiters monotherapy (strength of evidence A) or in combination with topical corticosteroids with or without a vitamin D analogue (strength of evidence B) or in combination with acitretin (strength of evidence C)
TNF-α inhibitors should be considered as a preferred treatment option for patients with concomitant PsA
Infliximab (strength of evidence A)
IL-12/IL-23 Inhibitors monotherapy (strength of evidence A) or in combination with topical corticosteroids with or without a vitamin D analogue (strength of evidence C) or in combination with acitretin or methotrexate (strength of evidence B)
IL-12/IL-23 inhibitors in combination with apremilast or cyclosporine (strength of evidence C)
IL-17 inhibitors monotherapy (strength of evidence A)
IL-23 inhibitors monotherapy for moderate to severe plaque psoriasis or as monotherapy for generalized pustular psoriasis (strength of evidence B)

* Strength of recommendation and descriptions
<table>
<tr><th>Strength of recommendation</th><th>Description</th></tr>
<tr><td>A</td><td>Recommendation based on consistent and good-quality patient-oriented evidence</td></tr>
<tr><td>B</td><td>Recommendation based on inconsistent or limited-quantity patient-oriented evidence</td></tr>
<tr><td>C</td><td>Recommendation based on consensus, opinion, case studies, or disease-oriented evidence</td></tr>
</table>
Biologics are routinely used when one or more traditional systemic agents fail to produce adequate response, but are considered first line in patients with moderate to severe psoriasis with concomitant severe PsA. Primary failure is defined as initial nonresponse to treatment. Primary failure to a TNF-α inhibitor does not preclude successful response to a different TNF-α inhibitor. Failure of another biologic therapy does not preclude successful response to ustekinumab.(88)

The National Psoriasis Foundation (NPF) medical board recommend a treat-to-target approach to therapy for psoriasis that include the following:(32)

The preferred assessment instrument for determining disease severity is BSA
Target response after treatment initiation should be BSA less than or equal to 1% after 3 months
Acceptable response is either a BSA less than or equal to 3% or a BSA improvement greater than or equal to 75% from baseline at 3 months after treatment initiation

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<td>DERMATOLOGICAL DISORDERS - Hidradenitis Suppurativa (HS)</td>
<td>Hidradenitis suppurativa (HS) is a chronic inflammatory disease causing painful, nodules to form in the folds of the skin and often secrete puss and blood. HS can be described as mild (single or few lesions in one area of the skin, Hurley Stage I), moderate (repeated cycles of enlarged lesions that break open and occur in more than one area of the skin, Hurley Stage II), and severe (widespread lesions, scarring, and chronic pain; Hurley Stage III).(45,46)

Pharmacological treatment for mild HS includes topical clindamycin, oral tetracyclines, hormonal treatment, retinoids, intralesional corticosteroid injections (i.e., triamcinolone), and deroofing. Oral tetracyclines are recommended for mild to moderate HS for at least a 12 weeks course or as long-term maintenance.</td>
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	Combination clindamycin and rifampin is effective second-line therapy for mild to moderate HS, or as first-line or adjunct therapy for severe HS. Combination rifampin, moxifloxacin, and metronidazole are recommended as second or third-line therapy for moderate to severe disease. Dapsone may be effective for a minority of patients with mild to moderate HS as long-term maintenance therapy. Oral retinoids, such as acitretin and isotretinoin, have also been used for mild HS as second or third-line therapy. Hormonal therapy may be considered in female patients for mild to moderate disease as monotherapy, or as adjunct therapy for severe disease. such as hormonal contraceptives, metformin, finasteride, and spironolactone.(45,46) Treatment recommendations for moderate to severe and refractory HS include immunosuppressants (e.g., cyclosporine and low dose systemic corticosteroids) and biologic agents. The TNF-inhibitors that are recommended are adalimumab, at doses within FDA labeling, and infliximab, but optimal doses have not been established. Anakinra and ustekinumab may be effective, but require dose ranging studies to determine optimal doses for management.(45,46)
DERMATOLOGICAL DISORDERS - Atopic Dermatitis	Atopic dermatitis (AD), also known as atopic eczema, is a chronic, pruritic inflammatory dermatosis affecting up to 25% of children and 1-5% of adults. AD follows a relapsing course and is associated with elevated serum immunoglobulin (IgE) levels and a personal or family history of type I allergies, allergic rhinitis, and/or asthma. Onset is most common between 3 and 6 months of age, with approximately 60% of patients developing the eruption in the first year of life and 90% by age 5. While the majority of affected individuals have resolution of disease by adulthood, 10 to 30% do not, and a smaller percentage first develop symptoms as adults. AD has a complex pathogenesis involving genetic, immunologic, and environmental factors, which lead to a dysfunctional skin barrier and dysregulation of the immune system. Clinical findings include erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and lichenification. These clinical findings vary by patient age and chronicity of lesions. Pruritus is a hallmark of the condition that is responsible for much of the disease burden borne by patients and their families. Typical patterns include facial, neck and extensor involvement in infants and children; flexure involvement in any age group, with sparing of groin and axillary regions.(56) Goals of treatment are to reduce symptoms (pruritus and dermatitis), prevent exacerbations, and minimize therapeutics risks.(60) Despite its relapsing and remitting nature, the majority of patients with AD can achieve clinical improvement and disease control with nonpharmacological interventions (e.g., emollient use, wet wrap therapy), conventional topical therapies (including corticosteroids and calcineurin inhibitors) and environmental and occupational modifications, when necessary.(58,60) Topical therapies remain the mainstay of treatment due to their proven track record and generally favorable safety profile. They can be utilized individually or in combination with other topical, physical, and/or systemic treatments; as different classes of treatment have different mechanisms of action, combining therapies allows for the targeting of AD via multiple disease pathways. The American Academy of Dermatology (AAD) strongly recommends the following topical agents:(58) • Calcineurin inhibitors (TCIs) (e.g., tacrolimus, pimecrolimus) • Topical corticosteroids (TCS) • Topical PDE-4 inhibitors (e.g., crisaborole) • Topical JAK inhibitors (e.g., ruxolitinib) Targeting a variety of immune cells and suppressing the release of proinflammatory cytokines, TCS are the most commonly utilized FDA-approved therapies in AD and are commonly used as first-line treatment for mild-to severe dermatitis in all skin regions. When choosing a steroid potency, it is important to consider the anatomical site (i.e., using lower potency agents on the face, neck, genitals, and body folds). Most studies of TCS in AD management involve twice daily application, but some studies (particularly for potent TCS) suggest once daily use may be sufficient. Traditionally, TCS were stopped once AD signs and symptoms of an AD flare were controlled. Maintenance in between AD flares with once to twice weekly use of TCS is another

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	approach. TCIs are a safe anti-inflammatory option for AD, particularly when there is concern for adverse events secondary to corticosteroid use. Topical tacrolimus has shown flare prevention and disease control when used intermittently from 2 to 3 times per week in patients with stable disease.(58) Prescribing information for pimecrolimus cream and tacrolimus ointment indicate evaluation after 6 weeks if symptoms of AD do not improve for adults and pediatrics.(62,63). When AD is more severe or refractory to topical treatment, advanced treatment with phototherapy or systemic medications can be considered. Phototherapy is conditionally recommended by the AAD as a treatment for AD based on low certainty evidence. The AAD strongly recommends the following systemic therapies:(59) • Monoclonal antibodies (biologics) (e.g., dupilumab, tralokinumab) • JAK inhibitors (e.g., upadacitinib, abrocitinib, baricitinib) In a change from the 2014 AAD AD guidelines the use of systemic antimetabolites such as methotrexate, immunosuppressants such as systemic corticosteroids, mycophenolate mofetil, azathioprine, and cyclosporine are now conditionally recommended for AD only in a small number of select patients due to low or very low certainty of evidence and need for monitoring. The most favored first-line systemic is dupilumab.(59) There is no clear consensus on how to operationalize a definition of the FDA indication for treatment of patients with "moderate to severe" AD. The severity of AD can vary substantially over time and, from a patient's perspective, can include a complex combination of intensity of itch, location, body surface area (BSA) involvement, and degree of skin impairment. Given the variability of patient phenotype and lack of familiarity among clinicians with scoring systems used in clinical trials, it is advisable to create a broad clinically relevant definition inclusive of multiple specific measures of disease intensity for example:(82) one of the following: • Affected BSA greater than or equal to 10% • Investigator Global Assessment (IGA) greater than or equal to 3 • Eczema Area and Severity Index (EASI) greater than or equal to 16 OR one of the following: • Affected BSA greater than or equal to 10% • Involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) • Severe itch that has been unresponsive to topical therapies
INFLAMMATORY BOWEL DISEASE - Crohn's Disease (CD)	Crohn’s Disease (CD) is an inflammatory condition that can affect any portion of the gastrointestinal tract from the mouth to the perianal area. Choice of therapy is dependent on the anatomic location of disease, the severity of disease, and whether the treatment goal is to induce remission or maintain remission.(21,36) The American Gastroenterological Association (AGA) 2021 guideline recommends the following:(21) • Biologic therapy: ○ The AGA suggest early introduction with a biologic, with or without an immunomodulator, rather than delaying their use until after failure of 5-aminosalicylates and/or corticosteroids

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	○ Anti-TNF (i.e., infliximab or adalimumab) and ustekinumab are recommended over no treatment for the induction and maintenance of remission ○ Vedolizumab is suggested over no treatment for the induction and maintenance of remission ○ AGA suggests against the use of natalizumab over no treatment for the induction and maintenance of remission ○ Patients naïve to biologic therapy, the AGA recommends infliximab, adalimumab, or ustekinumab over certolizumab pegol and suggests the use of vedolizumab over certolizumab pegol for the induction of remission ○ Patients with primary non-response to anti-TNF, the AGA recommends ustekinumab and suggests vedolizumab for induction of remission ○ Patients with secondary non-response to infliximab, the AGA recommends use of adalimumab or ustekinumab and suggests the use of vedolizumab for the induction of remission (if adalimumab was the first line drug, there is indirect evidence to suggest using infliximab as a second-line agent) • DMARD therapy: ○ Corticosteroids are suggested over no treatment for the induction of remission, and are recommended against for maintenance of remission ○ Patients in corticosteroid induced remission or with quiescent moderate to severe CD, the AGA suggests thiopurines for maintenance of remission ○ Subcutaneous or intramuscular methotrexate are suggested over no treatment for the induction and maintenance of remission ○ The AGA recommends against the use of 5-aminosalicylates or sulfasalazine over no treatment for the induction or maintenance of remission ○ The AGA suggests against the use of thiopurines over no treatment for achieving remission and recommends biologic drug monotherapy over thiopurine monotherapy for induction of remission ○ The AGA suggests against the use of oral methotrexate monotherapy over no treatment for the induction and maintenance of remission • Combination therapy: ○ Patients that are naïve to biologics and immunomodulators, the AGA suggest use of infliximab in combination with thiopurines over infliximab monotherapy for the induction and maintenance of remission (combination infliximab with methotrexate may be more effective over infliximab monotherapy) ○ Patients that are naïve to biologics and immunomodulators, the AGA suggest use of adalimumab in combination with thiopurines over adalimumab monotherapy for the induction and maintenance of remission (combination adalimumab with methotrexate may be more effective over adalimumab monotherapy) ○ No recommendations are being made regarding the use of ustekinumab or vedolizumab in combination with thiopurines or methotrexate over biologic monotherapy for induction or maintenance or remission The 2018 American College of Gastroenterology (ACG) guideline recommends the following(36): • Mild to moderately severe disease/low risk disease: ○ Sulfasalazine (in doses of 3-6 grams daily) is effective in colonic and/or ileocolonic CD, but not those with isolated small bowel disease ○ 5-aminosalicylic (ASA) suppositories and enema preparations are effective for induction and maintenance of remission in rectal and sigmoid disease

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	○ Conventional corticosteroids are primarily used for the treatment of flares, and are often used as a bridge until immunomodulators and/or biologic agents become effective ○ Controlled ileal release budesonide is effective for induction of remission in ileocecal disease • Moderate to severe disease/moderate to high-risk disease ○ Corticosteroids are effective for short-term use in alleviating signs and symptoms of moderate to severely active CD, but do not induce mucosal healing and should be used sparingly ○ Azathioprine, 6-mercaptopurine, or MTX (15 mg once weekly) may be used in treatment of active disease and as adjunctive therapy for reducing immunogenicity against biologic therapy ○ TNF inhibitors should be used to treat CD that is resistant to treatment with corticosteroids and that is refractory to thiopurines or MTX ○ Vedolizumab with or without an immunomodulator should be considered for induction of symptomatic remission for patients with moderate to severely active CD and objective evidence of active disease ○ Ustekinumab should be used in patients that have failed previous treatment with corticosteroids, thiopurines, MTX, or TNF inhibitors, or in patients with no prior TNF inhibitor exposure • Severe/fulminant disease: ○ IV corticosteroids should be used ○ TNF inhibitors can be considered • Maintenance therapy: ○ Thiopurines or methotrexate should be considered once remission is induced with corticosteroids ○ TNF inhibitors, specifically infliximab, adalimumab, and certolizumab pegol, should be used in combination with azathioprine, MTX, or 6-mercaptopurine to maintain remission of TNF induced remission ○ Vedolizumab should be used for maintenance of remission of vedolizumab induced remission ○ Ustekinumab should be used for maintenance of remission of ustekinumab induced remission
INFLAMMATORY BOWEL DISEASE - Ulcerative Colitis (UC)	Ulcerative colitis (UC) is a chronic immune-mediated inflammatory condition affecting the large intestine associated with inflammation of the rectum, but that can extend to involve additional areas of the colon. The American College of Gastroenterology (ACG) recommends a treat-to-target approach and recommend therapeutic management should be guided by diagnosis (i.e., Montreal classification), assessment of disease activity (i.e., mild, moderate, and severe), and disease prognosis. The ACG treatment recommendations are further broken down into induction therapies and maintenance of remission. The 2019 ACG treatment guidelines recommend the following for therapeutic management of UC(37): <u>Induction of remission</u>: • Mildly active disease: ○ Rectal 5-ASA at a dose of 1 g/day with or without oral 5-ASA at a dose of at least 2 g/day for left-sided UC ○ Rectal 5-ASA at a dose of 1 g/day for ulcerative proctitis ○ Oral 5-ASA at a dose of at least 2 g/day for extensive UC ○ Add oral budesonide multi-matrix (MMX) 9 mg/day for patients that are intolerant or non-responsive to oral and/or rectal and oral 5-ASA at appropriate doses • Moderately active disease: ○ Oral budesonide multi-matrix (MMX) 9 mg/day for induction of remission • Moderately to severely active disease:

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	○ Oral systemic corticosteroids, TNF inhibitors (i.e., adalimumab, golimumab, or infliximab), tofacitinib, or vedolizumab to induce remission ○ Combination of infliximab with thiopurine therapy when using infliximab for induction ○ Switch to tofacitinib or vedolizumab for induction in patients that have failed TNF inhibitors ○ Patients with initial response to TNF inhibitors that lose response should have antibody levels and serum drug levels tested to assess reason for loss of response. If serum levels are adequate, use of another TNF inhibitor is not likely to be of benefit. <u>Maintenance of remission</u>: • Previously mildly active disease: ○ Rectal 5-ASA at a dose of 1 g/day in patients with ulcerative proctitis ○ Oral 5-ASA at a dose of at least 2 g/day in patients with left-sided or extensive UC • Previously moderately to severely active disease: ○ Thiopurines in patients that achieved remission due to corticosteroid induction ○ Continue TNF inhibitors (i.e., adalimumab, golimumab, or infliximab) for remission due to TNF induction ○ Continue vedolizumab for remission due to vedolizumab induction ○ Continue tofacitinib for remission due to tofacitinib induction The American Gastroenterology Association (AGA) published recommendations for the management of mild to moderate UC(38): • Use either standard-dose mesalamine (2-3 g/day) or diazo-bonded 5-ASA for patients with extensive UC for induction of remission and maintenance of remission • May add rectal mesalamine to oral 5-ASA in patients with extensive or left-sided UC for induction of remission and maintenance of remission • Use high dose mesalamine (greater than 3 g/day) with rectal mesalamine in patients with suboptimal response to standard-dose mesalamine, diazo-bonded 5-ASA, or with moderate disease activity for induction of remission and maintenance of remission • Add either oral prednisone or budesonide MMX in patients that are refractory to optimized oral and rectal 5-ASA regardless of disease extent The American Gastroenterology Association (AGA) published recommendations for the management of moderate to severe UC(48): • Standard of care is to continue agents initiated for induction therapy as maintenance therapy, if they are effective (excluding corticosteroids and cyclosporine) • Adult outpatients with moderate to severe UC: ○ Infliximab, adalimumab, golimumab, vedolizumab, tofacitinib or ustekinumab are strongly recommended over no treatment ○ Biologic naïve patients: ▪ infliximab or vedolizumab are conditionally recommended over adalimumab for induction of remission ▪ Recommend tofacitinib only be used in the setting of a clinical or registry study ○ Previous exposure to infliximab, particularly those with primary non-response, ustekinumab or tofacitinib are conditionally recommended over vedolizumab or adalimumab for induction of remission

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	○ Conditionally recommend against use of thiopurine monotherapy for induction, but may be used for maintenance of remission over no treatment
OTHER DISORDERS - Uveitis	Uveitis is characterized by inflammation of the uvea, which is the middle portion of the eye; the anterior portion of the uvea includes the iris and ciliary body, and the posterior portion of the uvea is known as the choroid.(39) Treatment of non-infectious uveitis depends on the location of inflammation. Anterior uveitis is generally treated with topical glucocorticoids, such as prednisolone ophthalmic drops.(22,39) Uveitis that is primarily posterior to the lens is generally not responsive to topical medication, although some experts are increasingly using difluprednate.(22) Oral corticosteroids continue to be the mainstay of treatment for noninfectious intermediate, posterior, and pan uveitis. Intraocular and periocular injections of triamcinolone or glucocorticoids are also options, although patients may decline the injections. Systemic treatment is generally reserved for resistant inflammation and may be indicated in patients with glaucoma who cannot be treated with local injection. If remission has been achieved for 6 to 12 months with systemic glucocorticoids, the maintenance dose may be gradually discontinued.(22,42) The American Academy of Ophthalmology recommends the use of immunosuppressive agents, such as methotrexate, azathioprine, mycophenolate, cyclosporine, and tacrolimus, for patients that are intolerant and/or resistant to systemic corticosteroids. TNF-inhibitors, such as adalimumab, are recommended if the patient is inadequately controlled by corticosteroids and non-corticosteroid systemic immunomodulatory therapies.(22,42)
OTHER DISORDERS - Giant Cell Arteritis (GCA)	Giant cell arteritis (GCA) is a blood vessel disease that commonly occurs with polymyalgia rheumatica. It is a type of vasculitis involving mostly the arteries of the scalp and head, especially the arteries over the temples. Eyesight can be affected if GCA spreads to the blood vessels that supply the eye. Treatment should begin as soon as possible to prevent loss of vision.(23) The American College of Rheumatology/Vasculitis Foundation guidelines recommend High-dose systemic glucocorticoids as the mainstay of therapy for GCA. The guidelines provide the following recommendations for the medical management of GCA(40): • Patients with newly diagnosed active GCA with visual symptoms/loss or critical cranial ischemia: ○ High dose IV pulse corticosteroids followed by high dose oral corticosteroids with or without a non-corticosteroid immunosuppressive agent (i.e., methotrexate or tocilizumab) ○ Taper oral corticosteroids in patients that achieve remission ○ Consider adding on or changing non-corticosteroid immunosuppressive agent in patients that have not achieved remission • Patients with newly diagnosed active GCA without visual symptoms/loss or critical cranial ischemia: ○ High dose oral corticosteroids with or without a non-corticosteroid immunosuppressive agent (i.e., methotrexate or tocilizumab) ○ Taper oral corticosteroids in patients that achieve remission ○ Consider adding on or changing non-corticosteroid immunosuppressive agent in patients that have not achieved remission
OTHER DISORDERS - Cryopyrin-Associated Periodic Syndromes (CAPS)/Neonatal-Onset Multisystem Inflammatory Disease	Cryopyrin-associated periodic syndrome (CAPS) is a rare autosomal dominant hereditary autoimmune disorder associated with a defect in the cryopyrin protein. CAPS syndrome is caused by a gain of function mutation in the NLRP3 gene leading to over secretion of fever causing cytokine IL-1B. The CAPS spectrum includes mild, moderate, and severe phenotypes. The mild phenotype is called familial cold autoinflammatory syndrome (FCAS), the moderate phenotype is also known as Muckle-Wells syndrome (MWS), the neonatal-onset multisystem inflammatory disease (NOMID)/chronic infantile neurologic cutaneous articular syndrome (CINCA) describes the severe phenotype. CAPS is diagnosed clinically and genetically. There are more than 240 sequence variants of the NLRP3 gene and mutations in this gene are not

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	inclusive of a CAPS diagnosis. The diagnostic criteria of CAPS recognize that all but a few patients with CAPS have detectable systemic inflammation and use unique CPS-specific clinical features along the whole disease spectrum to achieve reasonable specificity and sensitivity to aid clinicians in making the CAPS diagnosis. These diagnostic criteria do not include genetic confirmation, and therefore can be applied in places where genetic testing is not available. The diagnostic criteria for CAPS are as follows:(24) • Raised inflammatory markers (CRP/SAA) • The presence of at least two of the following signs/symptoms: o Urticaria-like rash o Cold/stress triggered episodes o Sensorineural hearing loss o Musculoskeletal symptoms of arthralgia/arthritis/myalgia o Chronic aseptic meningitis o Skeletal abnormalities of epiphyseal overgrowth/frontal bossing FCAS is characterized by episodes of rash, fever. and joint pain following generalized exposure to cold. Attacks usually occur 1-2 hours after exposure and last less than 24.(49) Patients experience urticaria, arthralgia, fever with chills, severe thirst, red-eyes, and headache after a general cold exposure, including air conditioning. In MWS, inflammation can occur spontaneously as well as from triggers, such as stress, cold, or exercise, with episodes lasting from one to three days. MWS shares the same characteristics as FCAS, but is also characterized by renal amyloidosis, sensorineural hearing loss, and conjunctivitis. Hearing loss, partial or complete, often develop by teenage years.(41) NOMID is a rare chronic inflammatory disease. NOMID is characterized by fever, urticarial rash, aseptic meningitis, deforming arthropathy, hearing loss, and intellectual disability. An urticaria-like rash develops within the first six weeks of life, and a characteristic bony overgrowth predominantly involving the knees develops in most affected children. Therapies are aimed at suppressing inflammation and have included high-dose corticosteroids, disease-modifying antirheumatic drugs, and biologic agent targeting tumor necrosis factor (TNF). Selective blockade of interleukin-1B is effective in the pathophysiology and organ-specific manifestations of NMOSD, in particular the CNS manifestations of the disease.(57) Treatment aims are to suppress systemic inflammation, to improve functionality, to prevent organ damage, and to increase patients' quality of life. To achieve these aims, cytokine targeting drugs are important and evidence-based treatment. Since IL-1 plays a central role in CAPS pathogenesis, the anti-IL1 treatments (anakinra, canakinumab, and rilonacept) are recommended for the whole CAPS spectrum.(24)
OTHER DISORDERS Deficiency of the IL-1 Receptor Antagonist (DIRA)	Systemic autoinflammatory diseases (SAIDs) are a group of multisystem immunodysregulatory disorders caused primarily by the dysfunction of the innate immune system. Currently, SAIDs are comprised of a wide range of disorders with systemic and organ-specific inflammation in the absence of infections or autoimmunity. In a subset of genetically defined SAIDs, the pathogenesis is driven by increased release or signaling of the pro-inflammatory cytokine IL-1.(51) Patients with DIRA present with early-onset pustular rashes that can be triggered by mechanical stress (pathergy), with sterile osteomyelitis, and nail changes (onychomadesis). Although inflammatory markers are typically highly elevated, fever may be absent. Vertebral involvement can include odontoid osteomyelitis resulting in destruction and neck instability, vertebral block formation and gibbus-like spinal changes that need to be screened for by MRI or CT. The differential diagnosis for DIRA includes chronic recurrent multifocal osteomyelitis (CRMO), synovitis, acne, pustulosis, hyperostosis, osteitis (SAPHO) syndrome and pustular psoriasis. Genetic testing for monogenic defects with overlapping clinical features should include *LPIN2, FGR, FBLIM1* for CRMO*, CARD14* for CARD14-Mediated Psoriasis (CAMPS)*, IL36RN* for Deficiency of IL-36 Receptor Antagonist (DITRA)*, AP1S3* for other pustular psoriasis

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	and *MEFV f*or Pyrin-Associated Autoinflammation with Neutrophilic Dermatosis (PAAND).(51) Aims of therapy are early control of disease activity, prevention of disease and treatment related damage, and optimal health-related quality of life. The ultimate goal of a treat-to-target approach is complete remission. In absence of a consensus definition of remission or minimal disease activity for these diseases, remission has been defined for clinical studies and clinical monitoring as an absence of clinical symptoms and normal inflammatory markers. Anakinra and rilonacept both block IL-1α and IL-1β and should be used for DIRA patients.(51)
OTHER DISORDERS- Systemic Sclerosis (Scleroderma)-Associated Interstitial Lung Disease (ILD)	Systemic sclerosis (SSc) is a connective tissue disease (CTD) that affects numerous organ systems, including skin, blood vessels, heart, lungs, kidneys, gastrointestinal, and musculoskeletal. Pulmonary disease is the leading cause of death in patients with systemic sclerosis, and ILD is a common manifestation that tends to occur early in the course of systemic sclerosis.(52) The American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) collaborated on classification criteria for the diagnosis of systemic sclerosis, in which they note that systemic sclerosis-associated ILD is diagnosed when there is radiographic evidence of diffuse parenchymal lung disease in patients with systemic sclerosis. The ACR/EULAR criteria note that ILD is defined as pulmonary fibrosis seen on HRCT or chest radiography, most pronounced in the basilar portions of the lungs.(54) The American College of Rheumatology (ACR) published a treatment algorithm for systemic sclerosis and related conditions. The ACR recommends the following treatment options for ILD associated with systemic sclerosis:(53) Induction therapy: • Mycophenolate mofetil (MMF) as first line therapy • IV cyclophosphamide (CYC) as second line therapy • Rituximab as third line therapy • Lung transplant or hemopoietic stem cell transplant for select patients as fourth line therapy Maintenance therapy: • MMF as first line therapy • Azathioprine as second line therapy • IV or oral CYC as third line therapy Recent recommendations from the American College of Rheumatology suggest early first line treatment with tocilizumab based on the efficacy and safety from phase II and phase III clinical trials. MMF and CYC are alternative options, but do not have clinical trial data showing efficacy and safety for patients with subclinical ILD. Patients that have clinical evidence of skin and/or musculoskeletal manifestations and inactive disease, MMF, CYC, and nintedanib are the preferred first line options for patients with SSc-ILD. Patients with clinical evidence of skin and/or musculoskeletal manifestations and active disease, tocilizumab, MMF, and CYC are suggested as initial therapy. After treatment is initiated, patients should be followed up every 4 months until disease stabilization. Patients that achieve stabilization on first line therapy, should continue first line therapy for maintenance therapy.(70)
Efficacy	**Cosentyx** *Psoriatic Arthritis* The safety and efficacy of Cosentyx were assessed in 1999 patients, in 3 randomized, double-blind, placebo-controlled studies (PsA1, PsA2 and PsA3) in adult patients, age

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18 years and older with active psoriatic arthritis (greater than or equal to 3 swollen and greater than or equal to 3 tender joints) despite non-steroidal anti-inflammatory drug (NSAID), corticosteroid or disease modifying anti-rheumatic drug (DMARD) therapy. In PsA1, patients treated with 150 mg or 300 mg Cosentyx demonstrated a greater clinical response, including ACR20, ACR50, and ACR70 compared to placebo at Week 24 (Table 6). Responses were similar in patients regardless of concomitant methotrexate treatment. Responses were seen regardless of prior anti-TNFα exposure. Patients on placebo who received Cosentyx without a loading regimen achieved similar ACR20 responses over time (data not shown).(3)

In PsA3 Study, inhibition of progression of structural damage was assessed radiographically and expressed by the modified mTSS and its components, the Erosion Score (ES) and Joint Space Narrowing Score (JSN), at Week 24 compared to baseline. Cosentyx 150 mg without load, 150 mg with load and 300 mg with load treatment significantly inhibited progression of peripheral joint damage compared with placebo treatment as measured by change from baseline in mTSS at Week 24. The percentage of patients with no disease progression (defined as a change from baseline in mTSS of less than or equal to 0.0) from randomization to Week 24 was 75.7%, 70.9%, and 76.5% for Cosentyx 150 mg without load, 150 mg, 300 mg, respectively versus 68.2% for placebo. (3)

Future 4 and Future 5 trials assessed the efficacy and safety of Cosentyx 150 mg with or without loading dose in patients with active psoriatic arthritis.(3)

Future 4 trial was a randomized, double-blind, placebo-controlled phase 3 multicenter study of Cosentyx 150 mg, with and without a loading regimen, assessed the efficacy, safety and tolerability in patients with active psoriatic arthritis over 104 weeks. The primary end point was met by both secukinumab treatment regimens (150 mg and 150 mg no-loading dose), demonstrating a significantly higher ACR20 response with secukinumab compared with placebo at week 16. Both secukinumab 150 mg and 150 mg no-loading dose regimens improved other clinically important end points including DAS28-CRP, PASI 75, SF36 PCS, ACR50, ACR70, PASI 90, MDA, FACIT-Fatigue and HAQ-DI response and resolution of enthesitis and dactylitis through 2 years.(3)

Future 4 Trial				
Primary Endpoint	150 mg with loading dose		150 mg without loading dose	
	16 weeks	52 weeks	16 weeks	52 weeks
ACR 20	41.2%	60.5%	39.8%	57.5%
ACR 50	22.8%	40.4%	16.8%	22.8%
ACR 70	7.9%	32.7%	8.8%	18.6%

The Future 4 trial indicated that there was no statistically significant difference between the loading dose and non-loading dose for all primary and secondary endpoints.(68)

Future 5 was a double-blind, placebo-controlled, parallel-group phase III trial of Cosentyx 150 mg, with and without a loading regimen, and Cosentyx 300 mg, to assess the efficacy, safety and tolerability in patients with active psoriatic arthritis over 24 weeks. The primary endpoint, ACR20 response at week 16, was met for all secukinumab regimens, and secondary endpoints were significant for all secukinumab doses except for enthesitis and dactylitis resolution in the 150mg without LD group.

Future 5 Trial		
Primary Endpoint	150 mg with loading dose	150 mg without loading dose

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	16 weeks	24 weeks	16 weeks	24 weeks
ACR 20	55.5%	53.2%	59.5%	53.2%
ACR 50	35.9%	39%	32.0%	36%
ACR 70	18.2%	24.1%	14.9%	18.5%

The Future 5 trial did not assess if there was statistically significant differences between the loading vs non-loading doses for any endpoints.(69)

Ankylosing Spondylitis

The safety and efficacy of Cosentyx were assessed in 816 patients in three randomized, double-blind, placebo-controlled studies (AS1, AS2, and AS3) in adult patients 18 years of age and older with active ankylosing spondylitis. In AS1, patients treated with 150 mg Cosentyx demonstrated greater improvements in ASAS20 and ASAS40 responses compared to placebo at Week 16. Responses were similar in patients regardless of concomitant therapies. Patients on placebo who received Cosentyx without a loading regimen achieved similar ASAS20 responses over time. At Week 16, the ASAS20 and ASAS40 responses were 58.1% and 40.5% for 150 mg and 60.5% and 42.1% for 300 mg, respectively. Cosentyx treated patients showed improvement compared to placebo-treated patients in health-related quality of life as assessed by ASQoL at Week 16.(3)

Non-Radiographic Axial Spondyloarthritis

The safety and efficacy of Cosentyx were assessed in 555 patients in one randomized, double-blind, placebo-controlled phase 3 study (nr-axSpA1, NCT02696031) in adult patients 18 years of age and older with active non-radiographic axial spondyloarthritis. Patients were treated with Cosentyx 150 mg subcutaneous treatment with load (Weeks 0, 1, 2, 3, and 4) or without a load (Weeks 0 and 4) followed by the same dose every 4 weeks or placebo. In nr-axSpA1 Study, treatment with Cosentyx 150 mg resulted in significant improvements in the measure of disease activity compared to placebo at Week 16 and Week 52.

Number of subjects with ASAS40 response (%)	Cosentyx 150 mg without load (n = 184)	Cosentyx 150 mg with load (n = 185)	Placebo (n = 186)	Difference from Placebo (95% CI)	
				Cosentyx 150 mg without load	Cosentyx 150 mg with load
Week 16	75 (41)	74 (40)	52 (28)	13 (3, 22)	12 (2, 22)
Week 52	70 (38)	62 (34)	36 (19)	19 (10, 28)	14 (5, 23)

COSENTYX treated patients showed improvement in both load and without load arms compared to placebo-treated patients at Week 16 in health-related quality of life as measured by ASQoL (LS mean change: Week 16: -3.5 and -3.6 vs - 1.8, respectively).(3)

Safety

Actemra(1)

Tocilizumab has the following boxed warning:

- Increased risk for developing serious infections that may lead to hospitalization or death, including tuberculosis (TB), bacterial, invasive fungal, viral, and other opportunistic infections. Perform test for latent TB, and if positive, start treatment for TB prior to initiating therapy. Monitor all

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	patients for active TB during treatment, even if initial latent TB test is negative. Tocilizumab is contraindicated in patients with a known hypersensitivity reaction to tocilizumab. *Adalimumab(6,71,74,75,76,77,78,79,80,83,90)* Adalimumab products have the following boxed warnings: • Increased risk for developing serious infections that may lead to hospitalization or death, including tuberculosis (TB), bacterial, invasive fungal, viral, and other opportunistic infections. Perform test for latent TB, and if positive, start treatment for TB prior to initiating therapy. Monitor all patients for active TB during treatment, even if initial latent TB test is negative. • Lymphoma and other malignancies, some fatal have been reported in children and adolescent patients treated with TNF blockers. • Post marketing cases of hepatosplenic T-cell lymphoma have occurred in adolescents and young adults with inflammatory bowel disease treated with TNF blockers *Bimzelx(84)* Bimekizumab-bkzx has no FDA labeled contraindications. *Cimzia(2)* Certolizumab has the following boxed warnings: • Increased risk for developing serious infections that may lead to hospitalization or death, including tuberculosis (TB), bacterial, invasive fungal, viral, and other opportunistic infections. Perform test for latent TB, and if positive, start treatment for TB prior to initiating therapy. Monitor all patients for active TB during treatment, even if initial latent TB test is negative. • Lymphoma and other malignancies, some fatal have been reported in children and adolescent patients treated with TNF blockers. Cimzia is not indicated for use in pediatric patients. Certolizumab is contraindicated in patients with a severe hypersensitivity to certolizumab pegol or to any of the excipients. *Cosentyx(3)* Secukinumab is contraindicated in patients with a serious hypersensitivity reaction to secukinumab or to any of the excipients. *Enbrel(4)* Etanercept has the following boxed warnings: • Increased risk for developing serious infections that may lead to hospitalization or death, including tuberculosis (TB), bacterial, invasive fungal, viral, and other opportunistic infections. Perform test for latent TB, and if positive, start treatment for TB prior to initiating therapy. Monitor all patients for active TB during treatment, even if initial latent TB test is negative.

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	• Lymphoma and other malignancies, some fatal have been reported in children and adolescent patients treated with TNF blockers. Etanercept is contraindicated for use in patients with sepsis. *Entyvio(5)* Vedolizumab is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to Entyvio or any of its excipients. *Kevzara(7)* Sarilumab has the following boxed warning: • Increased risk for developing serious infections that may lead to hospitalization or death, including tuberculosis (TB), bacterial, invasive fungal, viral, and other opportunistic infections. Perform test for latent TB, and if positive, start treatment for TB prior to initiating therapy. Monitor all patients for active TB during treatment, even if initial latent TB test is negative. Sarilumab is contraindicated in patients with a known hypersensitivity to sarilumab or any of the inactive ingredients. *Kineret(8)* Anakinra is contraindicated in patients with a known hypersensitivity to E.coli-derived proteins, anakinra, or any component of the product. *Litfulo(81)* Ritlecitinib is contraindicated in patients with known hypersensitivity to ritlecitinib or any of its excipients. *Olumiant(9)* Baricitinib has the following boxed warnings: • Increased risk of serious bacterial, fungal, viral, and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Interrupt treatment with Olumiant if serious infection occurs until the infection is controlled. Test for latent TB before and during therapy, and if positive, start treatment for TB prior to use. Monitor all patients for active TB during treatment, even if initial latent TB test is negative. • Higher rate of all-cause mortality, including sudden cardiovascular death with another Janus Kinase (JAK) inhibitor vs tumor necrosis factor (TNF) blockers in RA patients • Malignancies have occurred in patients treated with Olumiant. Higher rate of lymphomas and lung cancers with another JAK inhibitor vs TNF blockers in RA patients • Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with another JAK inhibitor vs TNF blockers in RA patients • Thrombosis has occurred in patients treated with Olumiant. Increased incidence of pulmonary embolism, venous and arterial thrombosis with another JAK inhibitor vs TNF blockers. Baricitinib does not have any FDA labeled contraindications for use.

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	Omvoh(86) Mirikizumab is contraindicated in patients with a history of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients. *Orencia(10)* Abatacept does not have any FDA labeled contraindications for use. *Rinvoq(44)* Upadacitinib has the following boxed warnings: • Increased risk of serious bacterial, fungal, viral, and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Interrupt treatment with Rinvoq if serious infection occurs until the infection is controlled. Test for latent TB before and during therapy, and if positive, start treatment for TB prior to use. Monitor all patients for active TB during treatment, even if initial latent TB test is negative. • Higher rate of all-cause mortality, including sudden cardiovascular death with another Janus Kinase (JAK) inhibitor vs tumor necrosis factor (TNF) blockers in RA patients • Malignancies have occurred in patients treated with Rinvoq. Higher rate of lymphomas and lung cancers with another JAK inhibitor vs TNF blockers in RA patients • Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with another JAK inhibitor vs TNF blockers in RA patients • Thrombosis has occurred in patients treated with Rinvoq. Increased incidence of pulmonary embolism, venous and arterial thrombosis with another JAK inhibitor vs TNF blockers. Upadacitinib is contraindicated in patients with known hypersensitivity to upadacitinib or any of its excipients. *Siliq(11)* Brodalumab has the following boxed warning: • Suicidal ideation and behavior, including completed suicides, have occurred in patients. *Simponi(12)* Golimumab has the following boxed warnings: • Increased risk for developing serious infections that may lead to hospitalization or death, including tuberculosis (TB), bacterial, invasive fungal, viral, and other opportunistic infections. Perform test for latent TB, and if positive, start treatment for TB prior to initiating therapy. Monitor all patients for active TB during treatment, even if initial latent TB test is negative. • Lymphoma and other malignancies, some fatal have been reported in children and adolescent patients treated with TNF blockers. *Skyrizi(43)*

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	Risankizumab is contraindicated in patients with a history of serious hypersensitivity reaction to risankizumab-rzaa or any of the excipients. *Sotyktu(67)* Deucravacitinib is contraindicated in patients with a history of hypersensitivity reaction to deucravacitinib or to any of the excipients in Sotyktu. *Stelara(13)* Ustekinumab is contraindicated for use in patients with clinically significant hypersensitivity to ustekinumab or to any of the excipients. *Taltz(14)* Ixekizumab is contraindicated for use in patients with serious hypersensitivity reaction to ixekizumab or to any of the excipients. *Tremfya(15)* Guselkumab is contraindicated for use in patients with serious hypersensitivity reaction to guselkumab or to any of the excipients. *Velsipity(85)* Etrasimod is contraindicated in: • Patient who in the last 6 months, experienced myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure • History or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker *Xeljanz/Xeljanz XR(16)* Tofacitinib has the following boxed warnings: • Increased risk serious bacterial, fungal, viral, and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Interrupt treatment with Xeljanz/Xeljanz XR if serious infection occurs until the infection is controlled. Test for latent TB before and during therapy, and if positive, start treatment for TB prior to initiating therapy. Monitor all patients for active TB during treatment, even if initial latent TB test is negative. • Higher rate of all-cause mortality, including sudden cardiovascular death with Xeljanz vs TNF blockers in RA patients • Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with Xeljanz vs TNF blockers in RA patients. • Thrombosis has occurred in patients treated with Xeljanz. Increased incidence of pulmonary embolism, venous and arterial thrombosis with Xeljanz vs TNF blockers in RA patients. • Malignancies have occurred in patients treated with Xeljanz. Higher rate of lymphomas and lung cancers with Xeljanz vs TNF blockers in RA patients. Tofacitinib does not have any FDA labeled contraindications for use. *Zymfentra(89)*

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	Infliximab has the following boxed warnings: • Increased risk for developing serious infections that may lead to hospitalization or death, including tuberculosis (TB), bacterial, invasive fungal, viral, and other opportunistic infections. Perform test for latent TB, and if positive, start treatment for TB prior to initiating therapy. The risks and benefits of treatment should be carefully considered prior to initiating therapy in patient with chronic or recurrent infection. Monitor all patients for the development of signs and symptoms of infection during and after treatment, including possible development of active TB during treatment, even if initial latent TB test is negative. • Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers. • Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL) have been reported in patients treated with TNF blockers, and almost all patients had received treatment with azathioprine or 6-mercaptopurine concomitantly at or prior to diagnosis. These cases have had a very aggressive disease course and have been fatal. The majority of reported cases have occurred in patients with Crohn's disease or ulcerative colitis and most were in young adult males. Zymfentra is contraindicated in patients with a history of a severe hypersensitivity reaction to infliximab-dyyb, other infliximab products, any of the inactive ingredients in Zymfentra, or any murine proteins. Reactions have included anaphylaxis.

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POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	6627001507F8	Abrilada	adalimumab-afzb prefilled syringe kit	20 MG/0.4ML ; 40 MG/0.8ML	M ; N ; O ; Y				
	6627001507F5	Abrilada 1-pen kit ; Abrilada 2-pen kit	adalimumab-afzb auto-injector kit	40 MG/0.8ML	M ; N ; O ; Y				
	6650007000E5	Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9ML	M ; N ; O ; Y				
	6650007000D5	Actemra actpen	tocilizumab subcutaneous soln auto-injector	162 MG/0.9ML	M ; N ; O ; Y				
	6627001510D5	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.4ML ; 40 MG/0.8ML ; 80 MG/0.8ML	M ; N ; O ; Y				
	6627001510E510	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4ML	M ; N ; O ; Y				

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Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	6627001510E520	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8ML	M ; N ; O ; Y				
	6627001510E5	Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2ML ; 20 MG/0.2ML ; 20 MG/0.4ML ; 40 MG/0.4ML ; 40 MG/0.8ML	M ; N ; O ; Y				
	9025051800D5	Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	160 MG/ML	M ; N ; O ; Y				
	9025051800E5	Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	160 MG/ML	M ; N ; O ; Y				
	525050201064	Cimzia	certolizumab pegol for inj kit	200 MG	M ; N ; O ; Y				
	5250502010F8	Cimzia ; Cimzia starter kit	certolizumab pegol prefilled syringe kit	200 MG/ML	M ; N ; O ; Y				
	9025057500E5	Cosentyx	secukinumab subcutaneous pref syr ; secukinumab subcutaneous soln prefilled syringe	150 MG/ML ; 75 MG/0.5ML	M ; N ; O ; Y				
	9025057500D5	Cosentyx sensoready pen ; Cosentyx unoready	secukinumab subcutaneous auto-inj ; secukinumab subcutaneous soln auto-injector	150 MG/ML ; 300 MG/2ML	M ; N ; O ; Y				
	6627001505F8	Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2ML ; 20 MG/0.4ML ; 40 MG/0.8ML	M ; N ; O ; Y				
	6627001505F5	Cyltezo ; Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	M ; N ; O ; Y				
	662900300021	Enbrel	etanercept for subcutaneous inj	25 MG	M ; N ; O ; Y				
	662900300020	Enbrel	etanercept subcutaneous inj	25 MG/0.5ML	M ; N ; O ; Y				
	6629003000E5	Enbrel	etanercept subcutaneous soln prefilled syringe	25 MG/0.5ML ; 50 MG/ML	M ; N ; O ; Y				
	6629003000E2	Enbrel mini	etanercept subcutaneous solution cartridge	50 MG/ML	M ; N ; O ; Y				
	6629003000D5	Enbrel sureclick	etanercept subcutaneous solution auto-injector	50 MG/ML	M ; N ; O ; Y				
	5250308000D2	Entyvio	vedolizumab soln pen-injector	108 MG/0.68ML	M ; N ; O ; Y				
	6627001520E5	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4ML ; 40 MG/0.8ML	M ; N ; O ; Y				
	6627001520D5	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4ML ; 40 MG/0.8ML	M ; N ; O ; Y				
	6627001535F5	Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8ML	M ; N ; O ; Y				

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Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	6627001535F8	Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4ML ; 40 MG/0.8ML	M ; N ; O ; Y				
	6627001500F8	Humira ; Humira pediatric crohns d	adalimumab prefilled syringe kit	10 MG/0.1ML ; 20 MG/0.2ML ; 40 MG/0.4ML ; 40 MG/0.8ML ; 80 MG/0.8ML ; 80 MG/0.8ML & 40MG/0.4ML	M ; N ; O ; Y				
	6627001500F4	Humira pen ; Humira pen-cd/uc/hs start ; Humira pen-pediatric uc s ; Humira pen-ps/uv starter	adalimumab pen-injector kit	40 MG/0.4ML ; 40 MG/0.8ML ; 80 MG/0.8ML ; 80 MG/0.8ML & 40MG/0.4ML	M ; N ; O ; Y				
	6627001504D5	Hyrimoz ; Hyrimoz crohn's disease a ; Hyrimoz plaque psoriasis ; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	40 MG/0.4ML ; 40 MG/0.8ML ; 80 MG/0.8ML ; 80 MG/0.8ML & 40MG/0.4ML	M ; N ; O ; Y				
	6627001504E5	Hyrimoz ; Hyrimoz pediatric crohn's ; Hyrimoz pediatric crohns	adalimumab-adaz soln prefilled syr ; adalimumab-adaz soln prefilled syringe	10 MG/0.1 ML ; 20 MG/0.2ML ; 40 MG/0.4ML ; 40 MG/0.8ML ; 80 MG/0.8ML ; 80 MG/0.8ML & 40MG/0.4ML	M ; N ; O ; Y				
	6627001502F5	Idacio (2 pen) ; Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	M ; N ; O ; Y				
	6627001502F8	Idacio (2 syringe)	adalimumab-aacf prefilled syringe kit	40 MG/0.8ML	M ; N ; O ; Y				
	6650006000E5	Kevzara	sarilumab subcutaneous soln prefilled syringe	150 MG/1.14ML ; 200 MG/1.14ML	M ; N ; O ; Y				
	6650006000D5	Kevzara	sarilumab subcutaneous solution auto-injector	150 MG/1.14ML ; 200 MG/1.14ML	M ; N ; O ; Y				
	6626001000E5	Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67ML	M ; N ; O ; Y				
	907310601001	Litfulo	ritlecitinib tosylate cap	50 MG	M ; N ; O ; Y				
	666030100003	Olumiant	baricitinib tab	1 MG ; 2 MG ; 4 MG	M ; N ; O ; Y				
	5250405040D5	Omvoh	mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML	M ; N ; O ; Y				

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Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	6640001000E5	Orencia	abatacept subcutaneous soln prefilled syringe	125 MG/ML ; 50 MG/0.4ML ; 87.5 MG/0.7ML	M ; N ; O ; Y				
	6640001000D5	Orencia clickject	abatacept subcutaneous soln auto-injector	125 MG/ML	M ; N ; O ; Y				
	666030720075	Rinvoq	upadacitinib tab er	15 MG ; 30 MG ; 45 MG	M ; N ; O ; Y				
	9025052000E5	Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5ML	M ; N ; O ; Y				
	6627001540F5	Simlandi 1-pen kit ; Simlandi 2-pen kit	adalimumab-ryvk auto-injector kit	40 MG/0.4ML	M ; N ; O ; Y				
	6627004000D5	Simponi	golimumab subcutaneous soln auto-injector	100 MG/ML ; 50 MG/0.5ML	M ; N ; O ; Y				
	6627004000E5	Simponi	golimumab subcutaneous soln prefilled syringe	100 MG/ML ; 50 MG/0.5ML	M ; N ; O ; Y				
	9025057070F8	Skyrizi	risankizumab-rzaa sol prefilled syringe	75 MG/0.83ML	M ; N ; O ; Y				
	9025057070E5	Skyrizi	risankizumab-rzaa soln prefilled syringe	150 MG/ML	M ; N ; O ; Y				
	5250406070E2	Skyrizi	risankizumab-rzaa subcutaneous soln cartridge	180 MG/1.2ML ; 360 MG/2.4ML	M ; N ; O ; Y				
	9025057070D5	Skyrizi pen	risankizumab-rzaa soln auto-injector	150 MG/ML	M ; N ; O ; Y				
	902505240003	Sotyktu	deucravacitinib tab	6 MG	M ; N ; O ; Y				
	902505850020	Stelara	ustekinumab inj	45 MG/0.5ML	M ; N ; O ; Y				
	9025058500E5	Stelara	ustekinumab soln prefilled syringe	45 MG/0.5ML ; 90 MG/ML	M ; N ; O ; Y				
	9025055400D5	Taltz	ixekizumab subcutaneous soln auto-injector	80 MG/ML	M ; N ; O ; Y				
	9025055400E5	Taltz	ixekizumab subcutaneous soln prefilled syringe	80 MG/ML	M ; N ; O ; Y				
	9025054200D2	Tremfya	guselkumab soln pen-injector	100 MG/ML	M ; N ; O ; Y				
	9025054200E5	Tremfya	guselkumab soln prefilled syringe	100 MG/ML	M ; N ; O ; Y				
	525045251003	Velsipity	etrasimod arginine tab	2 MG	M ; N ; O ; Y				
	666030651020	Xeljanz	tofacitinib citrate oral soln	1 MG/ML	M ; N ; O ; Y				
	666030651003	Xeljanz	tofacitinib citrate tab	10 MG ; 5 MG	M ; N ; O ; Y				
	666030651075	Xeljanz xr	tofacitinib citrate tab er	11 MG ; 22 MG	M ; N ; O ; Y				
	6627001503F5	Yuflyma 1-pen kit ; Yuflyma 2-pen kit ; Yuflyma cd/uc/hs starter	adalimumab-aaty auto-injector kit	40 MG/0.4ML ; 80 MG/0.8ML	M ; N ; O ; Y				
	6627001503F8	Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	20 MG/0.2ML ; 40 MG/0.4ML	M ; N ; O ; Y				

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Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	6627001509D2	Yusimry	adalimumab-aqvh soln pen-injector	40 MG/0.8ML	M ; N ; O ; Y				
	5250504020F5	Zymfentra 1-pen ; Zymfentra 2-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	M ; N ; O ; Y				
	5250504020F8	Zymfentra 2-syringe	infliximab-dyyb soln prefilled syringe kit	120 MG/ML	M ; N ; O ; Y				

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001507F810	Abrilada	adalimumab-afzb prefilled syringe kit	20 MG/0.4 ML	2	Syringes	28	DAYS				
6627001507F820	Abrilada	adalimumab-afzb prefilled syringe kit	40 MG/0.8 ML	2	Syringes	28	DAYS				
6627001507F520	Abrilada 1-pen kit ; Abrilada 2-pen kit	adalimumab-afzb auto-injector kit	40 MG/0.8 ML	2	Pens	28	DAYS				
6650007000E5	Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9 ML	4	Syringes	28	DAYS				
6650007000D5	Actemra actpen	tocilizumab subcutaneous soln auto-injector	162 MG/0.9 ML	4	Pens	28	DAYS				
6627001510D517	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.4 ML	2	Pens	28	DAYS				
6627001510D520	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8 ML	2	Pens	28	DAYS				
6627001510D537	Amjevita	adalimumab-atto soln auto-injector	80 MG/0.8 ML	2	Pens	28	DAYS				
6627001510E505	Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2 ML	2	Syringes	28	DAYS				
6627001510E508	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.2 ML	2	Syringes	28	DAYS				
6627001510E510	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4 ML	2	Syringes	28	DAYS				
6627001510E517	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.4 ML	2	Syringes	28	DAYS				
6627001510E520	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8 ML	2	Syringes	28	DAYS				

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Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
9025051800D520	Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	160 MG/ML	2	Pens	56	DAYS				
9025051800E520	Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	160 MG/ML	2	Syringes	56	DAYS				
525050201064	Cimzia	certolizumab pegol for inj kit	200 MG	2	Kits	28	DAYS				
5250502010F840	Cimzia	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	2	Kits	28	DAYS				
5250502010F860	Cimzia starter kit	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	1	Kit	180	DAYS				
9025057500E530	Cosentyx	Secukinumab Subcutaneous Pref Syr 150 MG/ML (300 MG Dose)	150 MG/ML	2	Syringes	28	DAYS				
9025057500E510	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe	75 MG/0.5 ML	1	Syringe	28	DAYS				
9025057500E520	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML	150 MG/ML	1	Syringe	28	DAYS				
9025057500D530	Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose)	150 MG/ML	2	Pens	28	DAYS				
9025057500D520	Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	1	Pen	28	DAYS				
9025057500D550	Cosentyx unoready	secukinumab subcutaneous soln auto-injector	300 MG/2ML	1	Pen	28	DAYS				
6627001505F520	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.8 ML	2	Pens	28	DAYS	00597037597 ; 00597054522			
6627001505F805	Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2 ML	2	Syringes	28	DAYS				
6627001505F810	Cyltezo	adalimumab-adbm prefilled syringe kit	20 MG/0.4 ML	2	Syringes	28	DAYS				
6627001505F820	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.8 ML	2	Syringes	28	DAYS				
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS	00597037516 ; 00597054566			
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS	00597037523 ; 00597054544			
662900300021	Enbrel	etanercept for subcutaneous inj	25 MG	8	Vials	28	DAYS				
66290030002015	Enbrel	Etanercept Subcutaneous Inj 25 mg/0.5ml	25 MG/0.5 ML	8	Vials	28	DAYS				
6629003000E525	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML	25 MG/0.5 ML	4	Syringes	28	DAYS				
6629003000E530	Enbrel	Etanercept Subcutaneous Soln	50 MG/ML	4	Syringes	28	DAYS				

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Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		Prefilled Syringe 50 MG/ML									
6629003000E2	Enbrel mini	etanercept subcutaneous solution cartridge	50 MG/ML	4	Cartridges	28	DAYS				
6629003000D5	Enbrel sureclick	etanercept subcutaneous solution auto-injector	50 MG/ML	4	Pens	28	DAYS				
5250308000D220	Entyvio	vedolizumab soln pen-injector	108 MG/0.68 ML	2	Pens	28	DAYS				
6627001520E510	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4 ML	2	Syringes	28	DAYS				
6627001520E520	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.8 ML	2	Syringes	28	DAYS				
6627001520D510	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4 ML	2	Pens	28	DAYS				
6627001520D520	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.8 ML	2	Pens	28	DAYS				
6627001535F520	Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8 ML	2	Pens	28	DAYS				
6627001535F810	Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4 ML	2	Syringes	28	DAYS				
6627001535F820	Hulio	adalimumab-fkjp prefilled syringe kit	40 MG/0.8 ML	2	Syringes	28	DAYS				
6627001500F804	Humira	Adalimumab Prefilled Syringe Kit 10 MG/0.1ML	10 MG/0.1 ML	2	Syringes	28	DAYS				
6627001500F809	Humira	Adalimumab Prefilled Syringe Kit 20 MG/0.2ML	20 MG/0.2 ML	2	Syringes	28	DAYS				
6627001500F830	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.4ML	40 MG/0.4 ML	2	Syringes	28	DAYS				
6627001500F820	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.8ML	40 MG/0.8 ML	2	Syringes	28	DAYS				
6627001500F840	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML	80 MG/0.8 ML	1	Kit	180	DAYS				
6627001500F880	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8 ML & 40MG/0.4ML	1	Kit	180	DAYS				
6627001500F440	Humira pen	adalimumab pen-injector kit	80 MG/0.8 ML	2	Pens	28	DAYS	00074012402 ; 83457012402			
6627001500F430	Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4 ML	2	Pens	28	DAYS				
6627001500F440	Humira pen-cd/uc/hs start	adalimumab pen-injector kit	80 MG/0.8 ML	1	Kit	180	DAYS	00074012403			
6627001500F420	Humira pen-cd/uc/hs start	Adalimumab Pen-injector Kit ;	40 MG/0.8 ML	1	Kit	180	DAYS	00074433906			

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Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		adalimumab pen-injector kit									
6627001500F440	Humira pen-pediatric uc s	adalimumab pen-injector kit	80 MG/0.8 ML	4	Pens	180	DAYS	00074012404			
6627001500F420	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit ; adalimumab pen-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS	00074433907			
6627001500F450	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8 ML & 40MG/0.4ML	1	Kit	180	DAYS				
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4 ML	2	Pens	28	DAYS				
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4 ML	2	Pens	28	DAYS				
6627001504D520	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.8 ML	2	Pens	28	DAYS				
6627001504E508	Hyrimoz	adalimumab-adaz soln prefilled syringe	10 MG/0.1 ML	2	Syringes	28	DAYS				
6627001504E513	Hyrimoz	adalimumab-adaz soln prefilled syringe	20 MG/0.2 ML	2	Syringes	28	DAYS				
6627001504E515	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.4 ML	2	Syringes	28	DAYS				
6627001504E520	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.8 ML	2	Syringes	28	DAYS				
6627001504D540	Hyrimoz ; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8 ML	2	Pens	28	DAYS	61314045420 ; 83457010701			
6627001504D540	Hyrimoz crohn's disease a ; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8 ML	1	Starter Kit	180	DAYS	61314045436 ; 83457011301			
6627001504E560	Hyrimoz pediatric crohn's	adalimumab-adaz soln prefilled syr	80 MG/0.8 ML & 40MG/0.4ML	2	Syringes	180	DAYS				
6627001504E540	Hyrimoz pediatric crohns	adalimumab-adaz soln prefilled syringe	80 MG/0.8 ML	3	Syringes	180	DAYS				
6627001504D560	Hyrimoz plaque psoriasis	adalimumab-adaz soln auto-injector	80 MG/0.8 ML & 40MG/0.4ML	1.6	Starter Kit	180	DAYS				
6627001502F540	Idacio (2 pen)	adalimumab-aacf auto-injector kit	40 MG/0.8 ML	2	Pens	28	DAYS	65219055408 ; 65219061299			
6627001502F840	Idacio (2 syringe)	adalimumab-aacf prefilled syringe kit	40 MG/0.8 ML	2	Syringes	28	DAYS				
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS	65219055438			

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Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS	652190554 28			
6650006000E5	Kevzara	sarilumab subcutaneous soln prefilled syringe	150 MG/1.14 ML ; 200 MG/1.14 ML	2	Syringes	28	DAYS				
6650006000D5	Kevzara	sarilumab subcutaneous solution auto-injector	150 MG/1.14 ML ; 200 MG/1.14 ML	2	Pens	28	DAYS				
6626001000E5	Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67 ML	28	Syringes	28	DAYS				
90731060100120	Litfulo	ritlecitinib tosylate cap	50 MG	28	Capsules	28	DAYS				
666030100003	Olumiant	baricitinib tab	1 MG ; 2 MG ; 4 MG	30	Tablets	30	DAYS				
5250405040D520	Omvoh	mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML	2	Pens	28	DAYS				
6640001000E520	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML	125 MG/ML	4	Syringes	28	DAYS				
6640001000E510	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML	50 MG/0.4 ML	4	Syringes	28	DAYS				
6640001000E515	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7 ML	4	Syringes	28	DAYS				
6640001000D5	Orencia clickject	abatacept subcutaneous soln auto-injector	125 MG/ML	4	Syringes	28	DAYS				
66603072007530	Rinvoq	Upadacitinib Tab ER	30 MG	30	Tablets	30	DAYS				
66603072007540	Rinvoq	Upadacitinib Tab ER	45 MG	84	Tablets	365	DAYS				
66603072007520	Rinvoq	Upadacitinib Tab ER 24HR 15 MG	15 MG	30	Tablets	30	DAYS				
9025052000E5	Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5 ML	2	Syringes	28	DAYS				
6627001540F520	Simlandi 1-pen kit ; Simlandi 2-pen kit	adalimumab-ryvk auto-injector kit	40 MG/0.4 ML	2	Pens	28	DAYS				
6627004000D540	Simponi	Golimumab Subcutaneous Soln Auto-injector 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS				
6627004000D520	Simponi	Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML	50 MG/0.5 ML	1	Syringe	28	DAYS				
6627004000E540	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS				
6627004000E520	Simponi	Golimumab Subcutaneous Soln	50 MG/0.5 ML	1	Syringe	28	DAYS				

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Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		Prefilled Syringe 50 MG/0.5ML									
9025057070F8	Skyrizi	risankizumab-rzaa sol prefilled syringe	75 MG/0.83 ML	1	Box	84	DAYS				
9025057070E5	Skyrizi	risankizumab-rzaa soln prefilled syringe	150 MG/ML	1	Injection Device	84	DAYS				
5250406070E210	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2 ML	1	Cartridges	56	DAY				
5250406070E220	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4 ML	1	Cartridges	56	DAYS				
9025057070D5	Skyrizi pen	risankizumab-rzaa soln auto-injector	150 MG/ML	1	Pen	84	DAYS				
90250524000320	Sotyktu	Deucravacitinib Tab	6 MG	30	Tablets	30	DAYS				
90250585002020	Stelara	Ustekinumab Inj 45 MG/0.5ML	45 MG/0.5 ML	1	Vial	84	DAYS				
9025058500E520	Stelara	Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML	45 MG/0.5 ML	1	Syringe	84	DAYS				
9025058500E540	Stelara	Ustekinumab Soln Prefilled Syringe 90 MG/ML	90 MG/ML	1	Syringe	56	DAYS				
9025055400D5	Taltz	ixekizumab subcutaneous soln auto-injector	80 MG/ML	1	Syringe	28	DAYS				
9025055400E5	Taltz	ixekizumab subcutaneous soln prefilled syringe	80 MG/ML	1	Syringe	28	DAYS				
9025054200D2	Tremfya	guselkumab soln pen-injector	100 MG/ML	1	Pen	56	DAYS				
9025054200E5	Tremfya	guselkumab soln prefilled syringe	100 MG/ML	1	Syringe	56	DAYS				
52504525100350	Velsipity	etrasimod arginine tab	2 MG	30	Tablets	30	DAYS				
66603065102020	Xeljanz	Tofacitinib Citrate Oral Soln	1 MG/ML	240	mLs	30	DAYS				
66603065100330	Xeljanz	Tofacitinib Citrate Tab 10 MG (Base Equivalent)	10 MG	240	Tablets	365	DAYS				
66603065100320	Xeljanz	Tofacitinib Citrate Tab 5 MG (Base Equivalent)	5 MG	60	Tablets	30	DAYS				
66603065107530	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 11 MG (Base Equivalent)	11 MG	30	Tablets	30	DAYS				
66603065107550	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 22 MG (Base Equivalent)	22 MG	120	Tablets	365	DAYS				
6627001503F530	Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4 ML	2	Pens	28	DAYS	72606002209 ; 72606003009			
6627001503F560	Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	80 MG/0.8 ML	2	Pens	28	DAYS	72606002304 ; 72606004004			
6627001503F530	Yuflyma 2-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4 ML	2	Pens	28	DAYS	72606002210 ;			

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Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
								72606003010			
6627001503F820	Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	20 MG/0.2 ML	2	Syringes	28	DAYS				
6627001503F830	Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	40 MG/0.4 ML	1	Kit	28	DAYS				
6627001503F560	Yuflyma cd/uc/hs starter	adalimumab-aaty auto-injector kit	80 MG/0.8 ML	1	Kit	180	DAYS	72606002307			
6627001509D240	Yusimry	adalimumab-aqvh soln pen-injector	40 MG/0.8 ML	2	Pens	28	DAYS				
5250504020F530	Zymfentra 1-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	2	Pens	28	DAYS	726060025001			
5250504020F530	Zymfentra 2-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	2	Pens	28	DAYS	726060025002			
5250504020F830	Zymfentra 2-syringe	infliximab-dyyb soln prefilled syringe kit	120 MG/ML	2	Syringes	28	DAYS				

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Client Formulary
Abrilada	adalimumab-afzb prefilled syringe kit	20 MG/0.4ML ; 40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Abrilada 1-pen kit ; Abrilada 2-pen kit	adalimumab-afzb auto-injector kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Actemra actpen	tocilizumab subcutaneous soln auto-injector	162 MG/0.9ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Amjevita	adalimumab-atto soln auto-injector	40 MG/0.4ML ; 40 MG/0.8ML ; 80 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance

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Target Brand Agent(s)	Target Generic Agent(s)	Strength	Client Formulary
			Marketplace/BasicRx ; KeyRx
Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2ML ; 20 MG/0.2ML ; 20 MG/0.4ML ; 40 MG/0.4ML ; 40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	160 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	160 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cimzia	certolizumab pegol for inj kit	200 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cimzia ; Cimzia starter kit	certolizumab pegol prefilled syringe kit	200 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cosentyx	secukinumab subcutaneous pref syr ; secukinumab subcutaneous soln prefilled syringe	150 MG/ML ; 75 MG/0.5ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cosentyx sensoready pen ; Cosentyx unoready	secukinumab subcutaneous auto-inj ; secukinumab subcutaneous soln auto-injector	150 MG/ML ; 300 MG/2ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2ML ; 20 MG/0.4ML ; 40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cyltezo ; Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Enbrel	etanercept for subcutaneous inj	25 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Enbrel	etanercept subcutaneous inj	25 MG/0.5ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

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Target Brand Agent(s)	Target Generic Agent(s)	Strength	Client Formulary
Enbrel	etanercept subcutaneous soln prefilled syringe	25 MG/0.5ML ; 50 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Enbrel mini	etanercept subcutaneous solution cartridge	50 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Enbrel sureclick	etanercept subcutaneous solution auto-injector	50 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Entyvio	vedolizumab soln pen-injector	108 MG/0.68ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4ML ; 40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4ML ; 40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4ML ; 40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Humira ; Humira pediatric crohns d	adalimumab prefilled syringe kit	10 MG/0.1ML ; 20 MG/0.2ML ; 40 MG/0.4ML ; 40 MG/0.8ML ; 80 MG/0.8ML ; 80 MG/0.8ML & 40MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Humira pen ; Humira pen-cd/uc/hs start ; Humira pen-pediatric uc s ; Humira pen-ps/uv starter	adalimumab pen-injector kit	40 MG/0.4ML ; 40 MG/0.8ML ; 80 MG/0.8ML ; 80 MG/0.8ML & 40MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hyrimoz ; Hyrimoz crohn's disease a ; Hyrimoz plaque psoriasis ; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	40 MG/0.4ML ; 40 MG/0.8ML ; 80 MG/0.8ML ; 80 MG/0.8ML & 40MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hyrimoz ; Hyrimoz pediatric crohn's ; Hyrimoz pediatric crohns	adalimumab-adaz soln prefilled syr ; adalimumab-adaz soln prefilled syringe	10 MG/0.1 ML ; 20 MG/0.2ML ; 40 MG/0.4ML ; 40 MG/0.8ML ; 80 MG/0.8ML ; 80 MG/0.8ML & 40MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Idacio (2 pen) ; Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx

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Target Brand Agent(s)	Target Generic Agent(s)	Strength	Client Formulary
			Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Idacio (2 syringe)	adalimumab-aacf prefilled syringe kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Kevzara	sarilumab subcutaneous soln prefilled syringe	150 MG/1.14ML ; 200 MG/1.14ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Kevzara	sarilumab subcutaneous solution auto-injector	150 MG/1.14ML ; 200 MG/1.14ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Litfulo	ritlecitinib tosylate cap	50 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Olumiant	baricitinib tab	1 MG ; 2 MG ; 4 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Omvoh	mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Orencia	abatacept subcutaneous soln prefilled syringe	125 MG/ML ; 50 MG/0.4ML ; 87.5 MG/0.7ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Orencia clickject	abatacept subcutaneous soln auto-injector	125 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Rinvoq	upadacitinib tab er	15 MG ; 30 MG ; 45 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Simlandi 1-pen kit ; Simlandi 2-pen kit	adalimumab-ryvk auto-injector kit	40 MG/0.4ML	FocusRx; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance

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Target Brand Agent(s)	Target Generic Agent(s)	Strength	Client Formulary
			Marketplace/BasicRx ; KeyRx
Simponi	golimumab subcutaneous soln auto-injector	100 MG/ML ; 50 MG/0.5ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Simponi	golimumab subcutaneous soln prefilled syringe	100 MG/ML ; 50 MG/0.5ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Skyrizi	risankizumab-rzaa sol prefilled syringe	75 MG/0.83ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Skyrizi	risankizumab-rzaa soln prefilled syringe	150 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Skyrizi	risankizumab-rzaa subcutaneous soln cartridge	180 MG/1.2ML ; 360 MG/2.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Skyrizi pen	risankizumab-rzaa soln auto-injector	150 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Sotyktu	deucravacitinib tab	6 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Stelara	ustekinumab inj	45 MG/0.5ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Stelara	ustekinumab soln prefilled syringe	45 MG/0.5ML ; 90 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Taltz	ixekizumab subcutaneous soln auto-injector	80 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Taltz	ixekizumab subcutaneous soln prefilled syringe	80 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Tremfya	guselkumab soln pen-injector	100 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

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Target Brand Agent(s)	Target Generic Agent(s)	Strength	Client Formulary
Tremfya	guselkumab soln prefilled syringe	100 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Velsipity	etrasimod arginine tab	2 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Xeljanz	tofacitinib citrate oral soln	1 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Xeljanz	tofacitinib citrate tab	10 MG ; 5 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Xeljanz xr	tofacitinib citrate tab er	11 MG ; 22 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Yuflyma 1-pen kit ; Yuflyma 2-pen kit ; Yuflyma cd/uc/hs starter	adalimumab-aaty auto-injector kit	40 MG/0.4ML ; 80 MG/0.8ML	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	20 MG/0.2ML ; 40 MG/0.4ML	FocusRx; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Yusimry	adalimumab-aqvh soln pen-injector	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zymfentra 1-pen ; Zymfentra 2-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zymfentra 2-syringe	infliximab-dyyb soln prefilled syringe kit	120 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Abrilada	adalimumab-afzb Injection		FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Abrilada	adalimumab-afzb prefilled syringe kit	20 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Abrilada	adalimumab-afzb prefilled syringe kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Abrilada 1-pen kit ; Abrilada 2-pen kit	adalimumab-afzb auto-injector kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Actemra actpen	tocilizumab subcutaneous soln auto-injector	162 MG/0.9ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Amjevita	adalimumab-atto soln auto-injector	40 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Amjevita	adalimumab-atto soln auto-injector	80 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.2ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	160 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	160 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cimzia	certolizumab pegol for inj kit	200 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cimzia	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cimzia starter kit	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cosentyx	Secukinumab Subcutaneous Pref Syr 150 MG/ML (300 MG Dose)	150 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe	75 MG/0.5ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML	150 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose)	150 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cosentyx unoready	secukinumab subcutaneous soln auto-injector	300 MG/2ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Marketplace/BasicRx ; KeyRx
Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cyltezo	adalimumab-adbm prefilled syringe kit	20 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Enbrel	etanercept for subcutaneous inj	25 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Enbrel	Etanercept Subcutaneous Inj 25 mg/0.5ml	25 MG/0.5ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML	25 MG/0.5ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 50 MG/ML	50 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Enbrel mini	etanercept subcutaneous solution cartridge	50 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Enbrel sureclick	etanercept subcutaneous solution auto-injector	50 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Entyvio	vedolizumab soln pen-injector	108 MG/0.68ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hulio	adalimumab-fkjp prefilled syringe kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Humira	Adalimumab Prefilled Syringe Kit 10 MG/0.1ML	10 MG/0.1ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Humira	Adalimumab Prefilled Syringe Kit 20 MG/0.2ML	20 MG/0.2ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.4ML	40 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.8ML	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML	80 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Humira pen	adalimumab pen-injector kit	80 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Humira pen-cd/uc/hs start	adalimumab pen-injector kit	80 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Humira pen-cd/uc/hs start	Adalimumab Pen-injector Kit ; adalimumab pen-injector kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Humira pen-pediatric uc s	adalimumab pen-injector kit	80 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Humira pen-ps/uv starter	Adalimumab Pen-injector Kit ; adalimumab pen-injector kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Humira pen-ps/uv starter	Adalimumab Pen-injector Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hyrimoz	adalimumab-adaz soln prefilled syringe	10 MG/0.1 ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hyrimoz	adalimumab-adaz soln prefilled syringe	20 MG/0.2ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Marketplace/BasicRx ; KeyRx
Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hyrimoz ; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hyrimoz crohn's disease a ; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hyrimoz pediatric crohn's	adalimumab-adaz soln prefilled syr	80 MG/0.8ML & 40MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hyrimoz pediatric crohns	adalimumab-adaz soln prefilled syringe	80 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Hyrimoz plaque psoriasis	adalimumab-adaz soln auto-injector	80 MG/0.8ML & 40MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Idacio (2 pen)	adalimumab-aacf auto-injector kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Idacio (2 syringe)	adalimumab-aacf prefilled syringe kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Kevzara	sarilumab subcutaneous soln prefilled syringe	150 MG/1.14ML ; 200 MG/1.14ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Kevzara	sarilumab subcutaneous solution auto-injector	150 MG/1.14ML ; 200 MG/1.14ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Litfulo	ritlecitinib tosylate cap	50 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Olumiant	baricitinib tab	1 MG ; 2 MG ; 4 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Omvoh	mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML	125 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML	50 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Orencia clickject	abatacept subcutaneous soln auto-injector	125 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Rinvoq	Upadacitinib Tab ER	30 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Rinvoq	Upadacitinib Tab ER	45 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Rinvoq	Upadacitinib Tab ER 24HR 15 MG	15 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Simlandi 1-pen kit ; Simlandi 2-pen kit	adalimumab-ryvk auto-injector kit	40 MG/0.4ML	Focus Rx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Simponi	Golimumab Subcutaneous Soln Auto-injector 100 MG/ML	100 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Simponi	Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML	50 MG/0.5ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML	100 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML	50 MG/0.5ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Skyrizi	risankizumab-rzaa sol prefilled syringe	75 MG/0.83ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Skyrizi	risankizumab-rzaa soln prefilled syringe	150 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Skyrizi pen	risankizumab-rzaa soln auto-injector	150 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Sotyktu	Deucravacitinib Tab	6 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Stelara	Ustekinumab Inj 45 MG/0.5ML	45 MG/0.5ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Marketplace/BasicRx ; KeyRx
Stelara	Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML	45 MG/0.5ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Stelara	Ustekinumab Soln Prefilled Syringe 90 MG/ML	90 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Taltz	ixekizumab subcutaneous soln auto-injector	80 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Taltz	ixekizumab subcutaneous soln prefilled syringe	80 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Tremfya	guselkumab soln pen-injector	100 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Tremfya	guselkumab soln prefilled syringe	100 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Velsipity	etrasimod arginine tab	2 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Xeljanz	Tofacitinib Citrate Oral Soln	1 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Xeljanz	Tofacitinib Citrate Tab 10 MG (Base Equivalent)	10 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Xeljanz	Tofacitinib Citrate Tab 5 MG (Base Equivalent)	5 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 11 MG (Base Equivalent)	11 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 22 MG (Base Equivalent)	22 MG	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	FocusRx; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	80 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Yuflyma 2-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	20 MG/0.2ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	40 MG/0.4ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Yuflyma cd/uc/hs starter	adalimumab-aaty auto-injector kit	80 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Yusimry	adalimumab-aqvh soln pen-injector	40 MG/0.8ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zymfentra 1-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zymfentra 2-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zymfentra 2-syringe	infliximab-dyyb soln prefilled syringe kit	120 MG/ML	FocusRx ; FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

PREFERRED AGENTS

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td>Option A - FlexRx, GenRx, BasicRx, and KeyRx</td><td>Step Table
<table>
<tr><th rowspan="2">Disease State</th><th colspan="2">Step 1</th><th rowspan="2">Step 2 (Directed to ONE</th><th rowspan="2">Step 3a (Directed to TWO</th><th rowspan="2">Step 3b (Directed to TWO</th><th rowspan="2">Step 3c (Directed to THREE</th></tr>
<tr><th>Step 1a</th><th>Step 1b (Directed</th></tr>
</table></td></tr>
</table>

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Module	Clinical Criteria for Approval						
			to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors	**step 1 agent)**	**step 1 agents)**	**agents from step 1 and/or step 2)**	**step 1 agents)**
	Rheumatoid Disorders						
	Ankylosing Spondylitis (AS)	SQ: Hadlima, Cosentyx, Enbrel, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Nonradiographic Axial Spondyloarthritis (nr-axSpA)	SQ: Cimzia, Cosentyx	Oral: Rinvoq	N/A	SQ: Taltz	N/A	N/A
	Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Enbrel, Hadlima, Humira	Oral: Xeljanz	SQ: Actemra (Hadlima, or Humira is required Step 1 agent)	N/A	SQ: Orencia	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Psoriatic Arthritis (PsA)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Skyrizi,	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**,

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Module	Clinical Criteria for Approval						
		Stelara, Tremfya Oral: Otezla					Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Rheumatoid Arthritis	SQ: Enbrel, Hadlima, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Hadlima, or Humira is required Step 1 agent)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Dermatological Disorder						
	Hidradenitis Suppurativa (HS)	SQ: Cosentyx, Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Psoriasis (PS)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	N/A	Oral: Sotyktu	SQ: Cimzia, Ilumya	N/A	SQ: Abrilada**, Amjevita**, Bimzelx, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Siliq, Simlandi**, Taltz, Yuflyma**

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Module	Clinical Criteria for Approval						
							, Yusimry**
	Inflammatory Bowel Disease						
	Crohn's Disease	SQ: Hadlima, Humira, Skyrizi, Stelara	Oral: Rinvoq	N/A	SQ: Cimzia (Hadlima, or Humira is a required Step 1 agent)	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**, Zymfentra
	Ulcerative Colitis	SQ: Hadlima, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Hadlima, or Humira is required Step 1 agent)	N/A	Zeposia (Hadlima, Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada**, Amjevita**, Cyltezo**, Entyvio, Hulio**, Hyrimoz**, Idacio**, Omvoh, Simlandi**, Yuflyma**, Yusimry**, Zymfentra Oral Velsipity
	Other						
	Uveitis	SQ: Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi*

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Module	Clinical Criteria for Approval						
							*, Yuflyma**, Yusimry**
	Indications Without Prerequisite Biologic Immunomodulators Required						
	Alopecia Areata Atopic Dermatitis Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Juvenile Psoriatic Arthritis (JPsA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Polymyalgia Rheumatica (PMR) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)	N/A	N/A	N/A	N/A	N/A	N/A

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Module	Clinical Criteria for Approval

*Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product
** Note: Hadlima and Humira are required Step1 agents
Note: Branded generic available for Cyltezo, Idacio, Hulio and Hyrimoz and are included as a target at same step level in this program

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The request is NOT for use of Olumiant in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND**
2. If the request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND**
3. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents EXCEPT the following are eligible for continuation of therapy: Abrilada Amjevita Cyltezo, Adalimumab-adbm Hulio, Adalimumab-fkjp Hyrimoz, Adalimumab-adaz Idacio, Adalimumab-aacf Omvoh Simlandi Yuflyma, Adalimumab-aaty Yusimry Zymfentra

      1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
      2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

   B. ALL of the following:
      1. The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration AND **ONE** of the following:

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Module	Clinical Criteria for Approval
	A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) after at least a 3-month duration of therapy **OR** B. The patient has tried and had an inadequate response to another conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA after at least a 3-month duration of therapy **OR** C. The patient has an intolerance or hypersensitivity to ONE of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** D. The patient has an FDA labeled contraindication to ALL of the following conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** E. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of RA **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the request is for Simponi, ONE of the following: A. The patient will be taking the requested agent in combination with methotrexate **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to methotrexate **OR** B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PsA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR** 4. The patient has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable

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Module	Clinical Criteria for Approval
	to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 5. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PsA **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of moderate to severe plaque psoriasis (PS) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS **OR** 4. The patient has severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 5. The patient has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PS **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate,

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Module	Clinical Criteria for Approval
	pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of CD **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of CD **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of CD **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy **OR** 2. The patient has severely active ulcerative colitis **OR** 3. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR** 4. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR** 5. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **OR** 6. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

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Module	Clinical Criteria for Approval
	7. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. The patient has a diagnosis of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following: 1. BOTH of the following: A. ONE of the following: 1. The patient has tried and had an inadequate response to oral corticosteroids used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis after at least a 2-week duration of therapy **OR** 2. The patient has tried and had an inadequate response to periocular or intravitreal corticosteroid injections in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an intolerance or hypersensitivity to oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 4. The patient has an FDA labeled contraindication to BOTH oral corticosteroids and periocular/intravitreal corticosteroids **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that BOTH oral corticosteroids and periocular/intravitreal corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional systemic agent (i.e., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus) used in the treatment of non-infectious intermediate

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Module	Clinical Criteria for Approval
	uveitis, posterior uveitis, or panuveitis after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional systemic agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an FDA labeled contraindication to ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** G. The patient has a diagnosis of giant cell arteritis (GCA) AND ONE of the following: 1. The patient has tried and had an inadequate response to systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA after at least a 7-10 day duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to systemic corticosteroids used in the treatment of GCA **OR** 3. The patient has an FDA labeled contraindication to ALL systemic corticosteroids **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of GCA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL systemic corticosteroids (e.g., prednisone, methylprednisolone) used in

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Module	Clinical Criteria for Approval
	the treatment of GCA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** H. The patient has a diagnosis of active ankylosing spondylitis (AS) AND ONE of the following: 1. The patient has tried and had an inadequate response to TWO different NSAIDs used in the treatment of AS after at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of AS **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of AS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of AS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of AS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** I. The patient has a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) AND ONE of the following: 1. The patient has tried and had an inadequate response to TWO different NSAIDs used in the treatment of nr-axSpA after at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of nr-axSpA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of nr-axSpA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of nr-axSpA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of nr-axSpA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** J. The patient has a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) AND ONE of the following:

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Module	Clinical Criteria for Approval
	1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PJIA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PJIA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PJIA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, leflunomide) used in the treatment of PJIA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** K. The patient has a diagnosis of moderate to severe hidradenitis suppurativa (HS) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of HS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of HS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of HS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS cannot

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Module	Clinical Criteria for Approval
	be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** L. BOTH of the following: 1. The patient has a diagnosis of systemic sclerosis associated interstitial lung disease (SSc-ILD) **AND** 2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **OR** M. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following: 1. The patient has tried and had an inadequate response to TWO different NSAIDs used in the treatment of ERA after at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of ERA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of ERA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of ERA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of ERA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** N. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of the palms and/or soles of the feet **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to at least a mid- potency topical steroid used in the treatment of AD after at least a 4-week duration of therapy **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD after at least a 6-week duration of therapy **OR** B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following:

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Module	Clinical Criteria for Approval
	1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The prescriber has documented the patient's baseline pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND** 4. BOTH of the following: A. The patient is currently treated with topical emollients and practicing good skin care **AND** B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR** O. BOTH of the following: 1. The patient has a diagnosis of severe alopecia areata (AA) **AND** 2. The patient has at least 50% scalp hair loss that has lasted 6 months or more **OR** P. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following: 1. The patient has tried and had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR after at least an 8-week duration of therapy **OR** 2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR** 3. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 4. The prescriber has provided documentation that ALL systemic corticosteroids used in the treatment of PMR cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** Q. The patient has a diagnosis of juvenile psoriatic arthritis (JPsA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide, sulfasalazine) used in the treatment of JPsA after at least a 3-month duration of therapy **OR**

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Module	Clinical Criteria for Approval
	2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of JPsA **OR** 3. The patient has an FDA labeled contraindication to methotrexate **OR** 4. The patient has severe active JPsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to JPsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 5. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of JPsA **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agent (i.e., methotrexate, leflunomide, sulfasalazine) used in the treatment of JPsA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** R. The patient has a diagnosis not mentioned previously **AND** 2. ONE of the following (reference Step Table): A. The requested indication does NOT require any prerequisite biologic immunomodulator agents **OR** B. The requested agent is a Step 1a agent for the requested indication **OR** C. If the requested agent is a Step 1b agent for the requested indication, then ONE of the following: 1. The patient has tried and had an inadequate response to ONE Tumor Necrosis Factor (TNF) inhibitor for the requested indication after at least a 3-month duration of therapy (See Step 1a for preferred TNF inhibitors) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to therapy with a TNF inhibitor for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL TNF inhibitors for the requested indication **OR** 4. BOTH of the following: A. ALL TNF inhibitors are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND**

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Module	Clinical Criteria for Approval
	B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL TNF inhibitors for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. If the requested agent is a Step 2 agent for the requested indication, then ONE of the following: 1. The patient has tried and had an inadequate response to ONE of the required Step 1 agents for the requested indication after at least a 3-month duration of therapy (See Step 2) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE of the required Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL required Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. ALL of the required Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL required Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. If the requested agent is a Step 3a agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to TWO of the Step 1 agents for the requested indication after at least a 3-month trial per agent (See Step 3a) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration or hypersensitivity to TWO of the Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. ALL of the Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**

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Module	Clinical Criteria for Approval
	5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. If the requested agent is a Step 3b agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to TWO agents from Step 1 and/or Step 2 for the requested indication after at least a 3-month trial per agent (See Step 3b) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to TWO agents from Step 1 and/or Step 2 for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 AND Step 2 agents for the requested indication **OR** 4. BOTH of the following: A. ALL of the Step 1 AND Step 2 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 AND Step 2 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** G. If the requested agent is a Step 3c agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to THREE of the Step 1 agents for the requested indication after at least a 3-month trial per agent (See Step 3c) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to THREE of the Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR** 4. BOTH of the following:

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Module	Clinical Criteria for Approval
	A. ALL of the Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. If Cosentyx 300 mg is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy **AND** 4. If Omvoh is requested for the treatment of ulcerative colitis, ONE of the following: A. the patient has received Omvoh IV for induction therapy **OR** B. The patient is new to therapy and will receive Omvoh IV for induction therapy **AND** 5. If Entyvio is requested for the treatment of ulcerative colitis, ONE of the following: A. The patient has received at least 2 doses of Entyvio IV therapy **OR** B. The patient is new to therapy and will receive 2 doses of Entyvio IV therapy **AND** 6. If Skyrizi is requested for the treatment of Crohn's disease, ONE of the following A. The patient received Skyrizi IV for induction therapy **OR** B. The patient is new to therapy and will receive Skyrizi IV for induction therapy **AND** 7. If Stelara is requested for the treatment of Crohn's disease or ulcerative colitis, ONE of the following: A. The patient received Stelara IV for induction therapy **OR** B. The patient is new to therapy and will receive Stelara IV for induction therapy **AND** 8. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND**

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Module	Clinical Criteria for Approval
	4. If Stelara 90 mg is requested, ONE of the following: A. The patient has a diagnosis of psoriasis AND weighs >100kg **OR** B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg **OR** C. The patient has a diagnosis of Crohn's disease or ulcerative colitis **AND** 5. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or has consulted with a specialist in the area of the patient's diagnosis **AND** 7. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 9. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks. **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The request is NOT for use of Olumiant or Actemra in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND** 2. The request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND** 3. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note Stelara renewal must be for the same strength as the initial approval) [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 4. ONE of the following:

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Module	Clinical Criteria for Approval
	A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of polymyalgia rheumatica AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. If the requested agent is Kevzara, the patient does NOT have any of the following: A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND** B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND** C. AST or ALT elevations 3 times the upper limit of normal **OR** C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica AND the patient has had clinical benefit with the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): 1. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** 2. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 7. If Cosentyx 300 mg is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy **AND** 8. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

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Module	Clinical Criteria for Approval
Option B - Focus Rx	**Step Table**

Disease State	Step 1		Step 2 (Directed to ONE step 1 agent)	Step 3a (Directed to TWO step 1 agents)	Step 3b (Directed to TWO agents from step 1 and/or step 2)	Step 3c (Directed to THREE step 1 agents)
	Step 1a	Step 1b (Directed to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors				
Rheumatoid Disorders						
Ankylosing Spondylitis (AS)	SQ: Cyltezo, Cosentyx, Enbrel, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
Nonradiographic Axial Spondyloarthritis (nr-axSpA)	SQ: Cimzia, Cosentyx	Oral: Rinvoq	N/A	SQ: Taltz	N/A	N/A
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Cyltezo, Enbrel, Humira	Oral: Xeljanz	SQ: Actemra (Cyltezo, or Humira is required Step 1 agent)	N/A	SQ: Orencia	SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**

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Module	Clinical Criteria for Approval						
	Psoriatic Arthritis (PsA)	SQ: Cyltezo, Cosentyx, Enbrel, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita*, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Rheumatoid Arthritis	SQ: Cyltezo, Enbrel, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Cyltezo, or Humira is required Step 1 agent)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Dermatological Disorder						
	Hidradenitis Suppurativa (HS)	SQ: Cosentyx, Cyltezo, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Psoriasis (PS)	SQ: Cyltezo, Cosentyx, Enbrel, Humira, Skyrizi,	N/A	Oral: Sotyktu	SQ: Cimzia, Ilumya	N/A	SQ: Abrilada**, Amjevita**, Bimzelx, Hadlima**

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Module	Clinical Criteria for Approval						
		Stelara, Tremfya Oral: Otezla					, Hulio**, Hyrimoz**, Idacio**, Siliq, Simlandi**, Taltz, Yuflyma**, Yusimry**
	Inflammatory Bowel Disease						
	Crohn's Disease	SQ: Cyltezo, Humira, Skyrizi, Stelara	Oral: Rinvoq	N/A	SQ: Cimzia (Cyltezo, or Humira is a required Step 1 agent)	N/A	SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**, Zymfentra
	Ulcerative Colitis	SQ: Cyltezo, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Cyltezo, or Humira is required Step 1 agent)	N/A	Zeposia (Cyltezo, Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada**, Amjevita**, Entyvio, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Omvoh, Simlandi**, Yuflyma**, Yusimry**, Zymfentra Oral Velsipity
	Other						

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Module	Clinical Criteria for Approval						
	Uveitis	SQ: Cyltezo, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Indications Without Prerequisite Biologic Immunomodulators Required						
	Alopecia Areata Atopic Dermatitis Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Juvenile Psoriatic Arthritis (JPsA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Polymyalgia Rheumatica (PMR)	N/A	N/A	N/A	N/A	N/A	N/A

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Module	Clinical Criteria for Approval

Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)						

*Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product
**Note: Cyltezo and Humira are required Step 1 agents
Note: Branded generic available for Cyltezo, Idacio, Hulio and Hyrimoz and are included as a target at same step level in this program

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The request is NOT for use of Olumiant in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND**
2. If the request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND**
3. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents EXCEPT the following are eligible for continuation of therapy: Abrilada Amjevita Hadlima Hulio, Adalimumab-fkjp Hyrimoz, Adalimumab-adaz Idacio, Adalimumab-aacf Omvoh Simlandi Yuflyma, Adalimumab-aaty

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Module	Clinical Criteria for Approval
	Yusimry Zymfentra 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. ALL of the following: 1. The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration AND **ONE** of the following: A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) after at least a 3-month duration of therapy **OR** B. The patient has tried and had an inadequate response to another conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA after at least a 3-month duration of therapy **OR** C. The patient has an intolerance or hypersensitivity to ONE of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** D. The patient has an FDA labeled contraindication to ALL of the following conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** E. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of RA **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the request is for Simponi, ONE of the following:

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Module	Clinical Criteria for Approval
	A. The patient will be taking the requested agent in combination with methotrexate **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to methotrexate **OR** B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PsA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR** 4. The patient has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 5. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PsA **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of moderate to severe plaque psoriasis (PS) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS **OR** 4. The patient has severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 5. The patient has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that

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Module	Clinical Criteria for Approval
	interferes with function [i.e., joint deformities], rapidly progressive) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PS **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of CD **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of CD **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of CD **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy **OR**

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Module	Clinical Criteria for Approval
	2. The patient has severely active ulcerative colitis **OR** 3. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR** 4. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR** 5. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **OR** 6. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 7. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. The patient has a diagnosis of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following: 1. BOTH of the following: A. ONE of the following: 1. The patient has tried and had an inadequate response to oral corticosteroids used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis after at least a 2-week duration of therapy **OR** 2. The patient has tried and had an inadequate response to periocular or intravitreal corticosteroid injections in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an intolerance or hypersensitivity to oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 4. The patient has an FDA labeled contraindication to BOTH oral corticosteroids and periocular/intravitreal corticosteroids **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**

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Module	Clinical Criteria for Approval
	C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that BOTH oral corticosteroids and periocular/intravitreal corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional systemic agent (i.e., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus) used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional systemic agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an FDA labeled contraindication to ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** G. The patient has a diagnosis of giant cell arteritis (GCA) AND ONE of the following: 1. The patient has tried and had an inadequate response to systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA after at least a 7-10 day duration of therapy **OR**

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Module	Clinical Criteria for Approval
	2. The patient has an intolerance or hypersensitivity to systemic corticosteroids used in the treatment of GCA **OR** 3. The patient has an FDA labeled contraindication to ALL systemic corticosteroids **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of GCA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** H. The patient has a diagnosis of active ankylosing spondylitis (AS) AND ONE of the following: 1. The patient has tried and had an inadequate response to TWO different NSAIDs used in the treatment of AS after at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of AS **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of AS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of AS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of AS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** I. The patient has a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) AND ONE of the following: 1. The patient has tried and had an inadequate response to TWO different NSAIDs used in the treatment of nr-axSpA after at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of nr-axSpA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of nr-axSpA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of nr-axSpA **OR**

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Module	Clinical Criteria for Approval
	5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of nr-axSpA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** J. The patient has a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PJIA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PJIA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PJIA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, leflunomide) used in the treatment of PJIA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** K. The patient has a diagnosis of moderate to severe hidradenitis suppurativa (HS) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of HS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of HS **OR**

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Module	Clinical Criteria for Approval
	4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of HS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** L. BOTH of the following: 1. The patient has a diagnosis of systemic sclerosis associated interstitial lung disease (SSc-ILD) **AND** 2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **OR** M. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following: 1. The patient has tried and had an inadequate response to TWO different NSAIDs used in the treatment of ERA after at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of ERA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of ERA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of ERA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of ERA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** N. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR**

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Module	Clinical Criteria for Approval
	B. The patient has involvement of the palms and/or soles of the feet **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to at least a mid- potency topical steroid used in the treatment of AD after at least a 4-week duration of therapy **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD after at least a 6-week duration of therapy **OR** B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The prescriber has documented the patient's baseline pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND** 4. BOTH of the following: 1. The patient is currently treated with topical emollients and practicing good skin care **AND** 2. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR** O. BOTH of the following: 1. The patient has a diagnosis of severe alopecia areata (AA) **AND** 2. The patient has at least 50% scalp hair loss that has lasted 6 months or more **OR** P. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following: 1. The patient has tried and had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR after at least an 8-week duration of therapy **OR** 2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR** 3. The patient is currently being treated with the requested agent as indicated by ALL of the following:

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Module	Clinical Criteria for Approval
	A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 4. The prescriber has provided documentation that ALL systemic corticosteroids used in the treatment of PMR cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** Q. The patient has a diagnosis of juvenile psoriatic arthritis (JPsA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide, sulfasalazine) used in the treatment of JPsA after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of JPsA **OR** 3. The patient has an FDA labeled contraindication to methotrexate **OR** 4. The patient has severe active JPsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to JPsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 5. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of JPsA **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents used in the treatment of JPsA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** R. The patient has a diagnosis not mentioned previously **AND** 2. ONE of the following (reference Step Table): A. The requested indication does NOT require any prerequisite biologic immunomodulator agents **OR** B. The requested agent is a Step 1a agent for the requested indication **OR** C. If the requested agent is a Step 1b agent for the requested indication, then ONE of the following: 1. The patient has tried and had an inadequate response to ONE Tumor Necrosis Factor (TNF) inhibitor for the requested

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Module	Clinical Criteria for Approval
	indication after at least a 3-month duration of therapy (See Step 1a for preferred TNF inhibitors) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to therapy with a TNF inhibitor for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL TNF inhibitors for the requested indication **OR** 4. BOTH of the following: A. ALL TNF inhibitors are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL TNF inhibitors for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. If the requested agent is a Step 2 agent for the requested indication, then ONE of the following: 1. The patient has tried and had an inadequate response to ONE of the required Step 1 agents for the requested indication after at least a 3-month duration of therapy (See Step 2) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE of the required Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL required Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. ALL of the required Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL required Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

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Module	Clinical Criteria for Approval
	E. If the requested agent is a Step 3a agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to TWO of the Step 1 agents for the requested indication after at least a 3-month trial per agent (See Step 3a) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration or hypersensitivity to TWO of the Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. ALL of the Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. If the requested agent is a Step 3b agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to TWO agents from Step 1 and/or Step 2 for the requested indication after at least a 3-month trial per agent (See Step 3b) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to TWO agents from Step 1 and/or Step 2 for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 AND Step 2 agents for the requested indication **OR** 4. BOTH of the following: A. ALL of the Step 1 AND Step 2 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 AND Step 2 agents for the requested indication cannot be used due to a documented medical condition or comorbid

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Module	Clinical Criteria for Approval
	condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** G. If the requested agent is a Step 3c agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to THREE of the Step 1 agents for the requested indication after at least a 3-month trial per agent (See Step 3c) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to THREE of the Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. ALL of the Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. If Cosentyx 300 mg is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy **AND** 4. If Omvoh is requested for the treatment of ulcerative colitis ONE of the following: A. The patient has received Omvoh IV for induction therapy **OR** B. The patient is new to therapy and will receive Omvoh IV for induction therapy **AND** 5. If Entyvio is requested for the treatment of ulcerative colitis, ONE of the following: A. The patient has received at least 2 doses of Entyvio IV therapy **OR**

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Module	Clinical Criteria for Approval
	B. The patient is new to therapy and will receive at least 2 doses of Entyvio IV therapy **AND** 6. If Skyrizi is requested for the treatment of Crohn's disease, ONE of the following: A. The patient received Skyrizi IV for induction therapy **OR** B. The patient is new to therapy and will receive Skyrizi IV for induction therapy **AND** 7. If Stelara is requested for the treatment of Crohn's disease or ulcerative colitis, ONE of the following: 1. The patient received Stelara IV for induction therapy **OR** 2. The patient is new to therapy and will receive Stelara IV for induction therapy **AND** 8. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 4. If Stelara 90 mg is requested, ONE of the following: A. The patient has a diagnosis of psoriasis AND weighs >100kg **OR** B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg **OR** C. The patient has a diagnosis of Crohn's disease or ulcerative colitis **AND** 5. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or has consulted with a specialist in the area of the patient's diagnosis **AND** 7. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 9. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks. **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

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Module	Clinical Criteria for Approval
	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The request is NOT for use of Olumiant or Actemra in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND** 2. The request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND** 3. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note Stelara renewal must be for the same strength as the initial approval) [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 4. ONE of the following: A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of polymyalgia rheumatica AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. If the requested agent is Kevzara, the patient does NOT have any of the following: A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND** B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND** C. AST or ALT elevations 3 times the upper limit of normal **OR** C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica AND the patient has had clinical benefit with the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): 1. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** 2. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 7. If Cosentyx 300 mg is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR**

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Module	Clinical Criteria for Approval
	2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy **AND** 8. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL All Program Type	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. The requested agent is Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis, AND BOTH of the following: 1. There is support for therapy for the dose exceeding the quantity limit [e.g., patient has lost response to the FDA labeled maintenance dose (i.e., 5 mg twice daily or 11 mg once daily) during maintenance treatment; requires restart of induction therapy] (medical records required) **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **OR** B. The requested agent is Xeljanz oral solution for a diagnosis of polyarticular course juvenile idiopathic arthritis, AND ONE of the following: 1. BOTH of the following: A. The requested quantity (dose) does not exceed the maximum FDA labeled dose (i.e., 5 mg twice daily) NOR the maximum compendia supported dose **AND** B. There is support why the patient cannot take Xeljanz 5 mg tablets **OR** 2. The requested quantity (dose) exceeds the maximum FDA labeled dose but does NOT exceed the maximum compendia supported dose for the requested indication **OR** 3. BOTH of the following: A. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND** B. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** C. The requested agent is NOT Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis or polyarticular course juvenile idiopathic arthritis, AND ONE of the following: 1. The patient has an FDA labeled indication for the requested agent, AND ONE of the following: A. BOTH of the following:

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Module	Clinical Criteria for Approval
	1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does NOT exceed the program quantity limit **OR** B. ALL of the following: 1. The requested quantity (dose) exceeds the FDA maximum labeled dose **AND** 2. The patient has tried and had an inadequate response to at least a 3 month duration of therapy at the maximum FDA labeled dose (medical records required) **AND** 3. ONE of the following: A. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does NOT exceed the program quantity limit **OR** B. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND** 2. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** 2. The patient has a compendia supported indication for the requested agent, AND ONE of the following: A. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does NOT exceed the program quantity limit **OR** B. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication **AND** 2. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** 3. The patient does NOT have an FDA labeled indication NOR a compendia supported indication for the requested agent AND BOTH of the following: A. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **AND** B. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

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Module	Clinical Criteria for Approval
	Length of Approval: Initial Approval with PA: up to 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for up to 12 weeks, Rinvoq for AD may be approved for up to 6 months, Siliq for PS may be approved for up to 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for up to 16 weeks. **Renewal Approval with PA:** up to 12 months **Standalone QL approval:** up to 12 months or through the remainder of an existing authorization, whichever is shorter **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable.

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab)

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Contraindicated as Concomitant Therapy
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)

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Contraindicated as Concomitant Therapy
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

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POLICY REVIEW CYCLE

Effective Date	Date of Origin	Status
07-01-2024	01-01-2018	Draft

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