

# Biologic Immunomodulators Prior Authorization with Quantity Limit Program Summary

For BCBS KS, prescription drugs utilized primarily for the stimulation of hair growth are not covered by BCBS KS contracts. This includes coverage of Leqselvi, Litfulto, Olumiant, and other medications used for Alopecia Areata.

## POLICY REVIEW CYCLE

**Effective Date**  
07-01-2025

**Date of Origin**

## FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Abrilada™ (adalimumab-afzb)  Subcutaneous injection	<p>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)</p> <p>Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years of age and older</p> <p>Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with psoriatic arthritis (PsA)</p> <p>Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS)</p> <p>Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older</p> <p>Treatment of moderately to severely active ulcerative colitis (UC) in adult patients</p> <ul style="list-style-type: none"> <li>• Limitations of Use: <ul style="list-style-type: none"> <li>○ Effectiveness has not been established in patients who have lost response to or were intolerant to tumor necrosis factor (TNF) blockers</li> </ul> </li> </ul> <p>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</p> <p>Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients</p> <p>Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients</p>	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	83
Actemra® (tocilizumab)	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)	Interleukin-6 Inhibitor	1

Agent(s)	FDA Indication(s)	Notes	Ref#
Subcutaneous injection	<p>Treatment of giant cell arteritis (GCA) in adult patients</p> <p>Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis associated interstitial lung disease (SSc-ILD)</p> <ul style="list-style-type: none"> <li>Note: <ul style="list-style-type: none"> <li>Subcutaneous administration with the prefilled ACTPen autoinjector has not been studied in SSc-ILD</li> <li>Intravenous administration is not approved for SSc-ILD</li> </ul> </li> </ul> <p>Treatment of active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older</p> <p>Treatment of active systemic juvenile idiopathic arthritis (SJIA) in patients 2 years of age and older</p> <p>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</p> <ul style="list-style-type: none"> <li>Note: Subcutaneous administration is not approved for CRS, use only the intravenous route for treatment of CRS</li> </ul> <p>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)</p> <ul style="list-style-type: none"> <li>Note: Subcutaneous administration is not approved for COVID-19, administer by intravenous infusion only for COVID-19</li> </ul>		
Amjevita® (adalimumab-atto)  Subcutaneous injection	<p>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)</p> <p>Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older</p> <p>Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA)</p> <p>Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS)</p> <p>Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older</p> <p>Treatment of moderately to severely active ulcerative colitis (UC) in adult patients</p> <ul style="list-style-type: none"> <li>Limitation of use:</li> </ul>	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	71

Agent(s)	FDA Indication(s)	Notes	Ref#
	<ul style="list-style-type: none"> <li>The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF blockers</li> </ul> <p>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</p> <p>Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients</p> <p>Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients</p>		
<b>Bimzelx®</b> (bimekizumab-bkzx) Subcutaneous injection	<p>Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy</p> <p>Treatment of adult patients with active psoriatic arthritis (PSA)</p> <p>Treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation</p> <p>Treatment of adult patients with active ankylosing spondylitis (AS)</p> <p>Treatment of adults with moderate to severe hidradenitis suppurativa (HS)</p>	Interleukin-17A and F Antagonist	84
<b>Cimzia®</b> (certolizumab pegol) Subcutaneous injection	<p>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</p> <p>Treatment of adults with moderately to severely active rheumatoid arthritis (RA)</p> <p>Treatment of adult patients with active psoriatic arthritis (PSA)</p> <p>Treatment of adults with active ankylosing spondylitis (AS)</p> <p>Treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation</p> <p>Treatment of adults with moderate-to-severe plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy</p> <p>Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older</p>	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	2
<b>Cosentyx®</b> (secukinumab) Subcutaneous injection	<p>Treatment of moderate to severe plaque psoriasis (PS) in patients 6 years and older who are candidates for systemic therapy or phototherapy</p> <p>Treatment of active psoriatic arthritis (PSA) in patients 2 years of age and older</p> <p>Treatment of adult patients with active ankylosing spondylitis (AS)</p>	Interleukin-17 Inhibitor	3

Agent(s)	FDA Indication(s)	Notes	Ref#
	<p>Treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation</p> <p>Treatment of active enthesitis-related arthritis (ERA) in patients 4 years of age and older</p> <p>Treatment of adults with moderate to severe hidradenitis suppurativa (HS)</p>		
<p>Cyltezo®/Adalimumab-adbm</p> <p>Subcutaneous injection</p>	<p>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)</p> <p>Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older</p> <p>Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA)</p> <p>Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS)</p> <p>Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older</p> <p>Treatment of moderately to severely active ulcerative colitis (UC) in adult patients</p> <ul style="list-style-type: none"> <li>• Limitation of use: <ul style="list-style-type: none"> <li>○ The effectiveness has not been established in patients with UC who have lost response to or were intolerant to TNF blockers</li> </ul> </li> </ul> <p>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</p> <p>Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients</p> <p>Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients</p>	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	76
<p>Enbrel®</p> <p>(etanercept)</p> <p>Subcutaneous injection</p>	<p>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)</p> <p>Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients ages 2 and older</p>	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	4

Agent(s)	FDA Indication(s)	Notes	Ref#
	<p>Reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (PSA)</p> <p>Reducing signs and symptoms in patients with active ankylosing spondylitis (AS)</p> <p>Treatment of patients 4 years or older with chronic moderate to severe plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy</p> <p>Treatment of active juvenile psoriatic arthritis (JPsA) in pediatric patients 2 years of age and older</p>		
<p>Entyvio® (vedolizumab) Subcutaneous injection</p>	<p>Treatment in adults for moderately to severely active ulcerative colitis (UC)</p> <p>Treatment in adults for moderately to severely active Crohn's disease (CD)</p>	Integrin receptor antagonist	5
<p>Hadlima™ (adalimumab-bwwd) Subcutaneous Injection</p>	<p>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)</p> <p>Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older</p> <p>Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA)</p> <p>Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS)</p> <p>Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older</p> <p>Treatment of moderately to severely active ulcerative colitis (UC) in adult patients</p> <ul style="list-style-type: none"> <li>• Limitation of use: <ul style="list-style-type: none"> <li>○ Effectiveness has not been established in patients with UC who have lost response to or were intolerant to TNF blockers</li> </ul> </li> </ul> <p>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</p> <p>Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients</p> <p>Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients</p>	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	77

Agent(s)	FDA Indication(s)	Notes	Ref#
<p>Hulio®/Adalimumab-fkjp</p> <p>Subcutaneous injection</p>	<p>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)</p> <p>Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older</p> <p>Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA)</p> <p>Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS)</p> <p>Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older</p> <p>Treatment of moderately to severely active ulcerative colitis (UC) in adult patients</p> <ul style="list-style-type: none"> <li>• Limitation of use: <ul style="list-style-type: none"> <li>○ Effectiveness has not been established in patients with UC who have lost response to or were intolerant to TNF blockers</li> </ul> </li> </ul> <p>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</p> <p>Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients</p> <p>Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients</p>	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	74
<p>Humira®</p> <p>(adalimumab)</p> <p>Subcutaneous injection</p>	<p>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)</p> <p>Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older</p> <p>Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA)</p> <p>Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS)</p> <p>Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older</p>	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	6

Agent(s)	FDA Indication(s)	Notes	Ref#
	<p>Treatment of moderately to severely active ulcerative colitis (UC) in adults and pediatric patients 5 years of age and older</p> <ul style="list-style-type: none"> <li>Limitation of use: <ul style="list-style-type: none"> <li>The effectiveness of Humira has not been established in patients with UC who have lost response to or were intolerant to TNF blockers</li> </ul> </li> </ul> <p>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</p> <p>Treatment of moderate to severe hidradenitis suppurativa (HS) in patients 12 years of age and older</p> <p>Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adults and pediatric patients 2 years of age and older</p>		
<p>Hyrimoz®/Adalimumab-adaz</p> <p>Subcutaneous injection</p>	<p>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)</p> <p>Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older</p> <p>Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA)</p> <p>Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS)</p> <p>Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older</p> <p>Treatment of moderately to severely active ulcerative colitis (UC) in adult patients</p> <ul style="list-style-type: none"> <li>Limitation of use: <ul style="list-style-type: none"> <li>Effectiveness has not been established in patients with UC who have lost response to or were intolerant to TNF blockers</li> </ul> </li> </ul> <p>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</p> <p>Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients</p> <p>Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients</p>	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	80

Agent(s)	FDA Indication(s)	Notes	Ref#
Idacio®/Adalimumab-aacf  Subcutaneous injection	<p>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)</p> <p>Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older</p> <p>Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA)</p> <p>Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS)</p> <p>Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older</p> <p>Treatment of moderately to severely active ulcerative colitis (UC) in adult patients</p> <ul style="list-style-type: none"> <li>Limitation of use: <ul style="list-style-type: none"> <li>Effectiveness has not been established in patients with UC who have lost response to or were intolerant to TNF blockers</li> </ul> </li> </ul> <p>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</p> <p>Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients</p> <p>Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adults</p>	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	75
Kevzara® (sarilumab)  Subcutaneous injection	<p>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)</p> <p>Treatment of adult patients with polymyalgia rheumatica who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper</p> <p>Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients who weigh 63 kg or greater</p>	Interleukin-6 Inhibitor	7
Kineret® (anakinra)  Subcutaneous injection	<p>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)</p> <p>Treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID)*</p> <p>Treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)*</p>	<p>Interleukin-1 Inhibitor</p> <p>*approved for use in pediatric patients as young as 1 month of age</p>	8



Agent(s)	FDA Indication(s)	Notes	Ref#
Leqselvi™ (deuruxolitinib) Tablet	Treatment of adult patients with severe alopecia areata  Limitation of Use: <ul style="list-style-type: none"> <li>Leqselvi is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants</li> </ul>	Janus Kinase (JAK) Inhibitor	107
Litfulo™ (ritlecitinib) Capsule	Treatment of severe alopecia areata in adults and adolescents 12 years and older <ul style="list-style-type: none"> <li>Limitations of Use: <ul style="list-style-type: none"> <li>Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants</li> </ul> </li> </ul>	Janus Kinase (JAK) Inhibitor	81
Olumiant® (baricitinib) Oral tablet	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 <ul style="list-style-type: none"> <li>Limitation of Use: <ul style="list-style-type: none"> <li>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</li> </ul> </li> </ul> <p>Treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)</p> <p>Treatment of adult patients with severe alopecia areata <ul style="list-style-type: none"> <li>Limitation of Use: <ul style="list-style-type: none"> <li>Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants</li> </ul> </li> </ul> </p>	Janus Kinase (JAK) Inhibitor	9
Omvo® (mirikizumab-mrkz) Subcutaneous injection	Treatment of moderately to severely active ulcerative colitis in adults  Treatment of moderately to severely active Crohn's disease in adults	Interleukin-23 Inhibitor	86
Orencia® (abatacept) 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	T-cell Costimulation Blocker	10

Agent(s)	FDA Indication(s)	Notes	Ref#
	<p>patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor</p> <ul style="list-style-type: none"> <li><u>Note:</u> Subcutaneous administration is not approved for prophylaxis of aGVHD</li> </ul> <p>Limitation of Use:</p> <ul style="list-style-type: none"> <li>Concomitant use with other potent immunosuppressants (e.g., biologic disease modifying antirheumatic drugs [bDMARDs], Janus kinase [JAK] inhibitors) is not recommended</li> </ul>		
<p>Otulf<sup>TM</sup></p> <p>(ustekinumab-aauz)</p> <p>Subcutaneous injection</p>	<p>Treatment of patients 6 years of age and older with moderate to severe plaque psoriasis (PS) who are candidates for phototherapy or systemic therapy</p> <p>Treatment of patients 6 years of age and older with active psoriatic arthritis (PsA)</p> <p>Treatment of adult patients with moderately to severely active Crohn's disease (CD)</p> <p>Treatment of adult patients with moderately to severely active ulcerative colitis (UC)</p>	Interleukin-12 and -23 Antagonist	105
<p>Pyzchiva®/Ustekinumab-ttwe</p> <p>Subcutaneous injection</p>	<p>Treatment of patients 6 years of age and older with moderate to severe plaque psoriasis (PS) who are candidates for phototherapy or systemic therapy</p> <p>Treatment of patients 6 years of age and older with active psoriatic arthritis (PsA)</p> <p>Treatment of adult patients with moderately to severely active Crohn's disease (CD)</p> <p>Treatment of adult patients with moderately to severely active ulcerative colitis (UC)</p>	Interleukin-12 and -23 Antagonist	103
<p>Rinvoq® LQ</p> <p>(upadacitinib)</p> <p>Oral solution</p>	<p>Treatment of adults and pediatric patients 2 years of age and older with active psoriatic arthritis (PSA) who have had an inadequate response or intolerance to one or more TNF blockers</p> <ul style="list-style-type: none"> <li>Limitations of Use: Rinvoq LQ is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine</li> </ul> <p>Treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (PJIA) who have had an inadequate response or intolerance to one or more TNF blockers</p> <ul style="list-style-type: none"> <li>Limitations of Use: Rinvoq LQ is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine</li> </ul>	Janus Kinase (JAK) Inhibitor	44

Agent(s)	FDA Indication(s)	Notes	Ref#
Rinvoq®  (upadacitinib extended release)  Oral tablet	<p>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</p> <ul style="list-style-type: none"> <li>Limitations of Use: <ul style="list-style-type: none"> <li>Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine</li> </ul> </li> </ul> <p>Treatment of adults and pediatric patients 2 years of age and older with active psoriatic arthritis (PSA) who have had an inadequate response or intolerance to one or more TNF blockers</p> <ul style="list-style-type: none"> <li>Limitations of Use: <ul style="list-style-type: none"> <li>Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine</li> </ul> </li> </ul> <p>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</p> <ul style="list-style-type: none"> <li>Limitations of Use: <ul style="list-style-type: none"> <li>Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants</li> </ul> </li> </ul> <p>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</p> <ul style="list-style-type: none"> <li>Limitations of Use: <ul style="list-style-type: none"> <li>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</li> </ul> </li> </ul> <p>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</p> <ul style="list-style-type: none"> <li>Limitations of Use: <ul style="list-style-type: none"> <li>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</li> </ul> </li> </ul> <p>Treatment of adults with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers</p> <ul style="list-style-type: none"> <li>Limitations of Use: <ul style="list-style-type: none"> <li>Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent</li> </ul> </li> </ul>	Janus Kinase (JAK) Inhibitor	44

Agent(s)	FDA Indication(s)	Notes	Ref#
	<p>immunosuppressants such as azathioprine and cyclosporine</p> <p>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</p> <ul style="list-style-type: none"> <li>Limitations of Use: <ul style="list-style-type: none"> <li>Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine</li> </ul> </li> </ul> <p>Treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (PJIA) who have had an inadequate response or intolerance to one or more TNF blockers</p> <ul style="list-style-type: none"> <li>Limitations of Use: <ul style="list-style-type: none"> <li>Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine</li> </ul> </li> </ul> <p>Treatment of adults with giant cell arteritis (GCA)</p> <ul style="list-style-type: none"> <li>Limitations of Use: <ul style="list-style-type: none"> <li>Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine</li> </ul> </li> </ul>		
<p>Selarsdi™</p> <p>Ustekinumab-aekn</p> <p>Subcutaneous injection</p>	<p>Treatment of patients 6 years of age and older with moderate to severe plaque psoriasis (PS) who are candidates for phototherapy or systemic therapy</p> <p>Treatment of patients 6 years of age and older with active psoriatic arthritis (PsA)</p> <p>Treatment of adult patients with moderately to severely active Crohn's disease (CD)</p> <p>Treatment of adult patients with moderately to severely active ulcerative colitis (UC)</p>	Interleukin-12 and -23 Antagonist	104
<p>Siliq®</p> <p>(brodalumab)</p> <p>Subcutaneous injection</p>	<p>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</p>	Interleukin-17 Receptor Antagonist	11
<p>Simlandi®/Adalimumab-ryvk</p> <p>Subcutaneous injection</p>	<p>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)</p>	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	90

Agent(s)	FDA Indication(s)	Notes	Ref#
	<p>Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years of age and older</p> <p>Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with psoriatic arthritis (PsA)</p> <p>Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS)</p> <p>Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older</p> <p>Treatment of moderately to severely active ulcerative colitis (UC) in adult patients</p> <ul style="list-style-type: none"> <li>• Limitations of Use: <ul style="list-style-type: none"> <li>◦ Effectiveness has not been established in patients who have lost response to or were intolerant to tumor necrosis factor (TNF) blockers</li> </ul> </li> </ul> <p>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</p> <p>Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients</p> <p>Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients</p>		
Simponi®  (golimumab)  Subcutaneous injection	<p>Treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate</p> <p>Treatment of adult patients with active psoriatic arthritis (PSA)</p> <p>Treatment of adult patients with active ankylosing spondylitis (AS)</p> <p>Treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for:</p> <ul style="list-style-type: none"> <li>• inducing and maintaining clinical response</li> <li>• improving endoscopic appearance of the mucosa during induction</li> <li>• inducing clinical remission</li> <li>• achieving and sustaining clinical remission in induction responders</li> </ul>	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	12
Skyrizi®  (risankizumab-rzaa)	<p>Treatment of moderate-to-severe plaque psoriasis (PS) in adults who are candidates for systemic therapy or phototherapy</p> <p>Treatment of active psoriatic arthritis (PSA) in adults</p>	Interleukin-23 Inhibitor	43

Agent(s)	FDA Indication(s)	Notes	Ref#
Subcutaneous injection	Treatment of moderately to severely active Crohn's disease in adults  Treatment of moderately to severely active ulcerative colitis in adults		
Sotyktu®  (deucravacitinib)  Tablet	Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy  <ul style="list-style-type: none"> <li>Limitation of Use: <ul style="list-style-type: none"> <li>Not recommended for use in combination with other potent immunosuppressants</li> </ul> </li> </ul>	Tyrosine Kinase Inhibitor	67
Stelara®/Ustekinumab  Subcutaneous injection	Treatment of patients 6 years of age and older with moderate to severe plaque psoriasis (PS) who are candidates for phototherapy or systemic therapy  Treatment of patients 6 years of age 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-12 and -23 Antagonist	13
Steqeyma®  (ustekinumab-stba)  Subcutaneous injection	Treatment of patients 6 years of age and older with moderate to severe plaque psoriasis (PS) who are candidates for phototherapy or systemic therapy  Treatment of patients 6 years of age 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-12 and -23 Antagonist	101
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 patients 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)  Treatment of adult patients with moderately to severely active ulcerative colitis (UC)  Treatment of adult patients with moderately to severely active Crohn's disease (CD)	Interleukin-23 Inhibitor	15

Agent(s)	FDA Indication(s)	Notes	Ref#
Tyenne® (tocilizumab-aazg)  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  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 <ul style="list-style-type: none"> <li>Note: Subcutaneous administration is not approved for CRS, use only the intravenous route for treatment of CRS</li> </ul> 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) <ul style="list-style-type: none"> <li>Note: Subcutaneous administration is not approved for COVID-19, administer by intravenous infusion only for COVID-19</li> </ul>	Interleukin-6 Inhibitor	50
Velsipity® (etrasimod)  Tablets	Treatment of moderately to severely active ulcerative colitis in adults	Sphingosine 1-phosphate (SIP-1) receptor modulator	85
Wezlana™ (ustekinumab-auub)  Subcutaneous injection	Treatment of patients 6 years of age and older with moderate to severe plaque psoriasis (PS) who are candidates for phototherapy or systemic therapy  Treatment of patients 6 years of age 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-12 and -23 Antagonist	91
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 <ul style="list-style-type: none"> <li>Limitations of use: <ul style="list-style-type: none"> <li>Use of Xeljanz in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended</li> </ul> </li> </ul>	Janus Kinase (JAK) Inhibitor	16

Agent(s)	FDA Indication(s)	Notes	Ref#
<p>Xeljanz® (tofacitinib)</p> <p>Oral tablet</p>	<p>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</p> <ul style="list-style-type: none"> <li>Limitations of use: <ul style="list-style-type: none"> <li>Use of Xeljanz in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended</li> </ul> </li> </ul> <p>Treatment of adult patients with active psoriatic arthritis (PSA) who have had an inadequate response or intolerance to one or more TNF blockers</p> <ul style="list-style-type: none"> <li>Limitations of use: <ul style="list-style-type: none"> <li>Use of Xeljanz in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended</li> </ul> </li> </ul> <p>Treatment of adult patients with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers</p> <ul style="list-style-type: none"> <li>Limitations of use: <ul style="list-style-type: none"> <li>Use of Xeljanz in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended</li> </ul> </li> </ul> <p>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</p> <ul style="list-style-type: none"> <li>Limitations of use: <ul style="list-style-type: none"> <li>Use of Xeljanz in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended</li> </ul> </li> </ul> <p>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</p> <ul style="list-style-type: none"> <li>Limitations of use: <ul style="list-style-type: none"> <li>Use of Xeljanz in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended</li> </ul> </li> </ul>	<p>Janus Kinase (JAK) Inhibitor</p>	<p>16</p>
<p>Xeljanz® XR (tofacitinib extended release)</p> <p>Oral tablet</p>	<p>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</p> <ul style="list-style-type: none"> <li>Limitations of use: <ul style="list-style-type: none"> <li>Use of Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended</li> </ul> </li> </ul>	<p>Janus Kinase (JAK) Inhibitor</p>	<p>16</p>



Agent(s)	FDA Indication(s)	Notes	Ref#
	<p>Treatment of adult patients with active psoriatic arthritis (PSA) who have had an inadequate response or intolerance to one or more TNF blockers</p> <ul style="list-style-type: none"> <li>Limitations of use: <ul style="list-style-type: none"> <li>Use of Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended</li> </ul> </li> </ul> <p>Treatment of adult patients with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers</p> <ul style="list-style-type: none"> <li>Limitations of use: <ul style="list-style-type: none"> <li>Use of Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended</li> </ul> </li> </ul> <p>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</p> <ul style="list-style-type: none"> <li>Limitations of use: <ul style="list-style-type: none"> <li>Use of Xeljanz XR in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended</li> </ul> </li> </ul>		
Yesintek™  (ustekinumab-kfce)  Subcutaneous injection	<p>Treatment of patients 6 years of age and older with moderate to severe plaque psoriasis (PS) who are candidates for phototherapy or systemic therapy</p> <p>Treatment of patients 6 years of age and older with active psoriatic arthritis (PsA)</p> <p>Treatment of adult patients with moderately to severely active Crohn's disease (CD)</p> <p>Treatment of adult patients with moderately to severely active ulcerative colitis (UC)</p>	Interleukin-12 and -23 Antagonist	102
Yuflyma®/Adalimumab-aaty  Subcutaneous injection	<p>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)</p> <p>Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older</p> <p>Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA)</p> <p>Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS)</p>	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	78

Agent(s)	FDA Indication(s)	Notes	Ref#
	<p>Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older</p> <p>Treatment of moderately to severely active ulcerative colitis (UC) in adult patients</p> <ul style="list-style-type: none"> <li>Limitation of use: <ul style="list-style-type: none"> <li>Effectiveness has not been established in patients with UC who have lost response to or were intolerant to TNF blockers</li> </ul> </li> </ul> <p>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</p> <p>Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients</p> <p>Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients</p>		
<p>Yusimry® (adalimumab-aqvh)</p> <p>Subcutaneous injection</p>	<p>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)</p> <p>Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older</p> <p>Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PSA)</p> <p>Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS)</p> <p>Treatment of moderately to severely active Crohn's disease (CD) in adults and pediatric patients 6 years of age and older</p> <p>Treatment of moderately to severely active ulcerative colitis (UC) in adult patients</p> <ul style="list-style-type: none"> <li>Limitation of use: <ul style="list-style-type: none"> <li>Effectiveness has not been established in patients with UC who have lost response to or were intolerant to TNF blockers</li> </ul> </li> </ul> <p>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</p> <p>Treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients</p> <p>Treatment of non-infectious intermediate, posterior, and panuveitis (UV) in adult patients</p>	Tumor Necrosis Factor (TNF) -Alpha Inhibitor	79

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)	<p>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/physical therapy.(17,47)</p> <p>NSAIDs are used as first line therapy for patients with active AS, with continuous treatment with NSAIDs being preferred. In patients with stable disease, NSAIDs may be used on-demand to decrease the risk of adverse effects with long term use.(47,61,64) No particular NSAID is recommended as a preferred option.(64) Biologics should be used in patients who continue to have persistently high disease activity despite NSAIDs. Failure of standard treatment with NSAIDs can be defined as a lack of response (or intolerance) to at least 2 NSAIDs after at least a 4-week duration of therapy in total.(47,61)</p> <p>Tumor necrosis factor (TNF) inhibitors or interleukin (IL)-17 inhibitors are recommended as initial biologic therapy.(61,64) Other present comorbidities (e.g., inflammatory bowel disease, psoriasis, uveitis) can help guide selection of the initial biologic agent/drug class.(47,61,64) Patients who have an inadequate response to a TNF inhibitor or IL-17 inhibitor may switch to a biologic of the other drug class, or switch to a Janus kinase (JAK) inhibitor.(61,64) Patients with secondary failure to a biologic (presence of antidrug antibodies) may switch to another biologic of the same or different mode of action.(64)</p> <p>Systemic glucocorticoids should generally not be used in the treatment of AS. Short-term glucocorticoid injections may be used in select patients with peripheral signs and symptoms. Conventional disease-modifying antirheumatic drugs (cDMARDs) (e.g., methotrexate, sulfasalazine, leflunomide) are not recommended as treatment due to their lack of efficacy. However, sulfasalazine may be considered in patients with peripheral arthritis.(47,61,64)</p>
RHEUMATOID DISORDERS - Nonradiographic Axial Spondyloarthritis (nr-axSpA)	<p>Nonradiographic axial spondyloarthritis (nr-axSpA) falls under the same spondyloarthritis family as ankylosing spondylitis (AS). Nr-axSpA is characterized by chronic back pain and features suggestive of spondyloarthritis (SpA), although advanced sacroiliac joint damage and spine ankylosis are absent. The goals of treatment are to reduce symptoms, maintain spinal flexibility and normal posture, reduce functional limitations, maintain work ability, and decrease disease</p>

	<p>complications. The mainstays of treatment have been NSAIDs and exercise/physical therapy.(17,47)</p> <p>NSAIDs are used as first line therapy for patients with active nr-axSpA, with continuous treatment with NSAIDs being preferred. In patients with stable disease, NSAIDs may be used on-demand to decrease the risk of adverse effects with long term use.(47,61,64) No particular NSAID is recommended as a preferred option.(64) Biologics should be used in patients who continue to have persistently high disease activity despite NSAIDs. Failure of standard treatment with NSAIDs can be defined as a lack of response (or intolerance) to at least 2 NSAIDs after at least a 4-week duration of therapy in total.(47,61)</p> <p>Tumor necrosis factor (TNF) inhibitors or interleukin (IL)-17 inhibitors are recommended as initial biologic therapy.(61,64) Other present comorbidities (e.g., inflammatory bowel disease, psoriasis, uveitis) can help guide selection of the initial biologic agent/drug class.(47,61,64) Patients who have an inadequate response to a TNF inhibitor or IL-17 inhibitor may switch to a biologic of the other drug class, or switch to a Janus kinase (JAK) inhibitor.(61,64) Patients with secondary failure to a biologic (presence of antidrug antibodies) may switch to another biologic of the same or different mode of action.(64)</p> <p>Systemic glucocorticoids should generally not be used in the treatment of nr-axSpA. Short-term glucocorticoid injections may be used in select patients with peripheral signs and symptoms. Conventional disease-modifying antirheumatic drugs (cDMARDs) (e.g., methotrexate, sulfasalazine, leflunomide) are not recommended as treatment due to their lack of efficacy. However, sulfasalazine may be considered in patients with peripheral arthritis.(47,61,64)</p>
<p>RHEUMATOID DISORDERS - Rheumatoid Arthritis (RA)</p>	<p>Rheumatoid arthritis (RA) is an inflammatory autoimmune disease that primarily affects the joints but can also damage extra-articular organs. The main goal of therapy is to achieve remission, but additional goals include decreased disease activity, prevention of systemic complications, and improved physical functioning.(25)</p> <p>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) The American College of Rheumatology (ACR) guidelines (2021) list the following guiding principles in the treatment of RA:(18)</p> <ul style="list-style-type: none"> <li>• RA requires early evaluation, diagnosis, and management</li> <li>• Treatment decisions should follow a shared decision-making process</li> <li>• Treatment decisions should be reevaluated within a minimum of 3 months based on efficacy and tolerability of the disease-modifying antirheumatic drug(s) (DMARDs) chosen</li> <li>• Recommendations are limited to DMARDs approved by the US FDA for treatment of RA: <ul style="list-style-type: none"> <li>○ Conventional synthetic DMARDs (csDMARDs): hydroxychloroquine, sulfasalazine, methotrexate (MTX), leflunomide</li> <li>○ Biologic DMARDs (bDMARDs): Tumor necrosis factor (TNF) inhibitors (e.g., etanercept, adalimumab, infliximab, golimumab, certolizumab), T cell costimulatory inhibitors (e.g., abatacept), Interleukin (IL)-6 inhibitors (e.g., tocilizumab, sarilumab), anti-CD20 antibody* (e.g., rituximab) <ul style="list-style-type: none"> <li>▪ *Recommendations referring to bDMARDs exclude rituximab unless patients have had an inadequate response to TNF</li> </ul> </li> </ul> </li> </ul>

	<p>inhibitors (in order to be consistent with FDA approval) or have a history of lymphoproliferative disorder for which rituximab is an approved therapy</p> <ul style="list-style-type: none"> <li>○ Targeted synthetic DMARDs (tsDMARDs): Janus kinase (JAK) inhibitors (e.g., tofacitinib, baricitinib, upadacitinib)</li> <li>• Triple therapy refers to hydroxychloroquine, sulfasalazine, and either methotrexate or leflunomide</li> <li>• Biosimilars are considered equivalent to FDA-approved originator bDMARDs</li> <li>• 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)</li> </ul> <p>ACR guideline (2021) treatment recommendations are broken down by previous treatment and disease activity:(18)</p> <ul style="list-style-type: none"> <li>• DMARD-naïve patients with moderate-to-high disease activity initial treatment: <ul style="list-style-type: none"> <li>○ MTX monotherapy is strongly recommended over hydroxychloroquine, sulfasalazine, bDMARDs monotherapy, tsDMARD monotherapy, or combination of MTX plus a non-TNF bDMARD or tsDMARD</li> <li>○ MTX monotherapy is conditionally recommended over leflunomide, dual or triple csDMARD therapy, or combination MTX plus a TNF inhibitor</li> </ul> </li> <li>• DMARD-naïve patients with low disease activity initial treatment: <ul style="list-style-type: none"> <li>○ Hydroxychloroquine is conditionally recommended over other csDMARDs</li> <li>○ Sulfasalazine is conditionally recommended over MTX</li> <li>○ MTX is conditionally recommended over leflunomide</li> </ul> </li> <li>• Initial therapy in csDMARD-treated patients, but MTX naïve, with moderate-to high disease activity: <ul style="list-style-type: none"> <li>○ MTX monotherapy is conditionally recommended over combination MTX plus a bDMARD or tsDMARD</li> </ul> </li> <li>• Treatment modifications in patients treated with DMARDs who are not at target: <ul style="list-style-type: none"> <li>○ 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</li> <li>○ 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</li> </ul> </li> </ul> <p>The European Alliance of Associations for Rheumatology (EULAR) guidelines for RA (2022 update) also recommend a treat-to-target approach in therapy. MTX is recommended as first line therapy and should be initiated as soon as the diagnosis of RA is made. If MTX is not clinically appropriate, then an alternative csDMARD should be used as part of the (first) treatment strategy. If initial csDMARD therapy does not produce adequate improvement after 3 months, another csDMARD may be added or switched to as long as poor prognosis factors are absent. In the presence of poor prognosis factors, a bDMARD or JAK inhibitor should be added to csDMARD therapy. If treatment failure occurs with the initial bDMARD or JAK inhibitor, another bDMARD or JAK inhibitor should be considered. If a TNF- or IL-6 receptor inhibitor therapy was</p>
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	<p>initially failed, patients may receive an agent with another mode of action or a second TNF- or IL-6 receptor inhibitor.(26)</p> <p>Initial dosing of MTX for RA should optimally be 15 mg once weekly, with the dose increased as tolerated and as needed to control signs and symptoms. A fast dose escalation of 5 mg/month to 25-30 mg/week has been associated with higher efficacy, but toxicity with this dosing regimen is a limiting factor.(27) In the presence of sufficient folic acid supplementation, the MTX dose can be rapidly escalated to 25 mg once weekly.(26) The MTX target dose is 25 mg weekly, or the highest tolerable dose.(26,27)</p>
RHEUMATOID DISORDERS - Polyarticular Juvenile Idiopathic Arthritis (PJIA)	<p>Juvenile idiopathic arthritis (JIA) is arthritis that begins before the 16<sup>th</sup> 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)</p> <p>The American College of Rheumatology (ACR)/Arthritis Foundation guidelines (2019) recommend the following treatment approach for PJIA:(34)</p> <ul style="list-style-type: none"> <li>• Nonsteroidal anti-inflammatory drugs (NSAIDs) are conditionally recommended as adjunct therapy</li> <li>• Disease modifying antirheumatic drug (DMARD) therapy: <ul style="list-style-type: none"> <li>◦ Methotrexate (MTX) is conditionally recommended over leflunomide and sulfasalazine</li> <li>◦ Subcutaneous MTX is conditionally recommended over oral MTX</li> </ul> </li> <li>• Intraarticular glucocorticoids are conditionally recommended as adjunct therapy and conditionally recommended for bridging only in patients with moderate to high disease activity</li> <li>• Strongly recommend against chronic low-dose glucocorticoid use, irrespective of disease activity and/or risk factors</li> <li>• Strongly recommend combination use of a DMARD and infliximab</li> <li>• Initial therapy for all patients: <ul style="list-style-type: none"> <li>◦ DMARD is strongly recommended over NSAID monotherapy</li> <li>◦ MTX monotherapy is conditionally recommended over triple DMARD therapy</li> <li>◦ DMARD is conditionally recommended over a biologic</li> <li>◦ 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</li> </ul> </li> <li>• Subsequent therapy: <ul style="list-style-type: none"> <li>◦ Low disease activity: <ul style="list-style-type: none"> <li>▪ Escalating therapy (e.g., intraarticular glucocorticoid injections, optimization of DMARD dose, trial of MTX if not already done, and adding or changing biologic agent)</li> </ul> </li> <li>◦ Moderate to high disease activity: <ul style="list-style-type: none"> <li>▪ Add a biologic to original DMARD over changing to a second DMARD or changing to triple DMARD therapy</li> <li>▪ Switch to a non-tumor necrosis factor (TNF)-inhibitor biologic if currently treated with first TNF-inhibitor (+/- DMARD) over switching to another TNF-inhibitor (unless the patient had good initial response to first TNF-inhibitor)</li> <li>▪ TNF-inhibitor, abatacept, or tocilizumab (depending on prior biologics received) over rituximab after trial of second biologic</li> </ul> </li> </ul> </li> </ul>
RHEUMATOID DISORDERS - Systemic Juvenile Idiopathic Arthritis (SJIA)	<p>Systemic juvenile idiopathic arthritis (SJIA) is a subset of juvenile idiopathic arthritis (JIA). SJIA is distinct from all other categories of JIA due to fever, rash, and visceral</p>

	<p>involvement. Disease pathogenesis and cytokine involvement in SJIA are different than other JIA categories.(19) SJIA is now considered to be the same disease as adult onset Still's disease (AOSD) under the umbrella term Still's disease, recognizing that the previous distinction of the two disorders by age of onset (before or after 16 years of age) was mainly artificial.(93)</p> <p>SJIA has been defined as:(28,92)</p> <ul style="list-style-type: none"> <li>• Onset of symptoms occurring before the age of 16 years</li> <li>• Arthritis in greater than or equal to 1 joint for at least 6 weeks' duration</li> <li>• Fever of at least 2 weeks' duration (documented to be daily ["quotidian"] for at least 3 days)</li> <li>• Accompanied by one or more of the following: <ul style="list-style-type: none"> <li>• Evanescent (nonfixed) erythematous rash</li> <li>• Generalized lymphadenopathy (lymph node enlargement)</li> <li>• Hepatomegaly and/or splenomegaly</li> <li>• Serositis (pericarditis, pleuritis, and/or peritonitis)</li> </ul> </li> </ul> <p>The European Alliance of Associations for Rheumatology (EULAR)/Paediatric Rheumatology European Society (PReS) 2024 guidelines strongly recommend that the presence of arthritis not be mandatory for the diagnosis of Still's disease. Arthralgia is commonly present at disease onset, but arthritis often presents later with a median delay of 1 month. Requiring arthritis to make the diagnosis leads to unnecessary treatment delays. Instead, a patient with fever for at least 7 days, rash, arthralgia/myalgia, and elevated inflammatory markers should be sufficient to facilitate rapid diagnosis and initiate early treatment.(93)</p> <p>Macrophage activation syndrome (MAS), a secondary hemophagocytic syndrome, is a life-threatening complication requiring urgent recognition and treatment. MAS presents with fever, high ferritin levels, cytopenia, elevated liver enzyme levels, low fibrinogen levels, and high triglyceride levels. As it may occur at any point during the disease course, including during treatment, careful monitoring is necessary for children with or without MAS at presentation.(19) MAS is the most frequent complication, occurring in 15% to 20% of patients.(93) Goals of therapy for SJIA include 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.(28)</p> <p>An interleukin (IL)-1 or IL-6 inhibitor should be used as initial treatment for SJIA.(19,93) The IL-1/IL-6 should be initiated as early as possible when the diagnosis of SJIA is established or during a flare, irrespective of disease severity. Early initiation of an IL-1 or IL-6 inhibitor has been shown to have favorable outcomes, limit or avoid corticosteroid use, limit a chronic persistent disease course, and also does not interfere with the diagnostic work-up at onset. EULAR/PReS strongly recommends their use based on their efficacy to control all aspects of the disease, including both systemic and joint manifestations.(93)</p> <p>Glucocorticoids can be used short-term in patients with severe symptoms, risk of MAS, and/or severe pericarditis. High dose glucocorticoids are the mainstay of treatment in patients with MAS, being added on to biologic therapy.(93) For some patients with MAS, biologic therapy combined with glucocorticoids and calcineurin inhibitors may be necessary to control the disease.(19,93) Glucocorticoids may also be helpful at disease onset to control systemic and joint manifestations until IL-1 or IL-6 inhibitors can be started.(19)</p> <p>Non-steroidal anti-inflammatory drugs (NSAIDs) are sometimes used as a brief trial for initial treatment for SJIA without MAS. Studies suggest that a small proportion of patients will respond to NSAIDs alone, however many prescribers prefer that the use of NSAIDs be avoided altogether for SJIA.(19) NSAIDs are typically only used to assist in controlling symptoms, such as fever or arthralgia. Conventional synthetic disease-</p>
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	<p>modifying antirheumatic drugs (csDMARDs) have historically been used, but evidence supporting their efficacy is scarce.(93) Methotrexate is sometimes used in patients with arthritis.(19,93)</p>
<p>RHEUMATOID DISORDERS - Enthesitis Related Arthritis (ERA)</p>	<p>Enthesitis related arthritis (ERA) is a form of juvenile idiopathic arthritis (JIA) with an onset at less than 16 years of age. ERA typically presents initially with musculoskeletal pain, followed by signs of inflammation typical of peripheral arthritis. 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) ERA is the pediatric counterpart of adult nonradiographic axial spondyloarthritis (nr-axSpA).(94)</p> <p>The American College of Rheumatology (ACR)/Arthritis Foundation guidelines (2019) recommend the following approach to treatment of children and adolescents with JIA and active enthesitis:(34)</p> <ul style="list-style-type: none"> <li>• Treatment with non-steroidal anti-inflammatory drugs (NSAIDs) is strongly recommended as first-line therapy</li> <li>• If the disease remains active despite treatment with NSAIDs, a tumor necrosis factor (TNF)-inhibitor is conditionally recommended over methotrexate or sulfasalazine</li> <li>• Bridging therapy with a limited course of oral glucocorticoids (less than 3 months) during initiation or escalation of therapy is conditionally recommended</li> </ul> <p>Failure of standard treatment with NSAIDs can be defined as a lack of response (or intolerance) to at least 2 NSAIDs after at least a 4-week duration of therapy in total.(47,61) The interleukin (IL)-17 inhibitor secukinumab is approved by the Food and Drug Administration (FDA) for the treatment of ERA and has been shown to be effective in increasing the time to disease relapse. Studies have shown that the synovial fluid of children with ERA present high levels of IL-17.(55)</p>
<p>RHEUMATOID DISORDERS - Psoriatic Arthritis (PsA)</p>	<p>Psoriatic arthritis (PsA) is a chronic inflammatory musculoskeletal disease associated with psoriasis (PS), most commonly presenting with peripheral arthritis, dactylitis, enthesitis, and spondylitis. Active PsA is defined as symptoms at an unacceptably bothersome level as reported by the patient due to one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement, and/or extraarticular manifestations such as uveitis or inflammatory bowel disease (IBD).(29)</p> <p>Disease severity is based on the assessment of the level of disease activity at a given point in time, and the presence/absence of poor prognostic factors and long-term damage. Severe PsA is defined in the American College of Rheumatology (ACR) and the National Psoriasis Foundation (NPF) guidelines for PsA and includes the presence of one or more of the following:(29)</p> <ul style="list-style-type: none"> <li>• Erosive disease</li> <li>• Elevated markers of inflammation (e.g., erythrocyte sedimentation rate [ESR], C-reactive protein [CRP]) attributable to PsA</li> <li>• Long-term damage that interferes with function (e.g., joint deformities, vision loss)</li> <li>• Highly active disease that causes a major impairment in quality of life, such as: <ul style="list-style-type: none"> <li>○ Active PsA at many sites including dactylitis and enthesitis</li> <li>○ Function-limiting PsA at a few sites</li> </ul> </li> <li>• Rapidly progressive disease</li> </ul> <p>Treatment involves the use of a variety of interventions, including many agents used for the treatment of other inflammatory arthritis disorders, particularly</p>



spondyloarthritis and rheumatoid arthritis, and other management strategies of the cutaneous manifestations of psoriasis. Symptomatic treatments include nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, and local glucocorticoid injections.(29) Only patients with very mild peripheral disease may sufficiently benefit from NSAIDs as monotherapy, and instead patients are typically treated with disease-modifying antirheumatic drugs (DMARDs) and/or biologics. Efficacy of DMARD and biologic therapies should be assessed 3 months after initiation, and if adequate improvement is not seen then the treatment regimen should be updated or changed.(30)

The ACR-NPF guidelines for PsA recommend a treat-to-target approach in therapy, regardless of disease activity, and treatment recommendations for active disease are as follows:(29)

- Treatment naïve patients:
  - First line options include oral small molecules (OSM), tumor necrosis factor (TNF) inhibitors, interleukin (IL)-17 inhibitors, and IL-12/23 inhibitors
    - OSM (i.e., methotrexate [MTX], sulfasalazine, cyclosporine, leflunomide, apremilast) should be considered if the patient does not have severe PsA, does not have severe PS, prefers oral therapy, has concern over starting a biologic, or has contraindications to TNF inhibitors
    - Biologics (e.g., TNF inhibitor, IL-17 inhibitor, IL-12/23 inhibitor) are recommended as a first line option in patients with severe PsA and/or severe PS
- Previous treatment with OSM and continued active disease:
  - Switch to a biologic (i.e., TNF inhibitor, IL-17 inhibitor, IL-12/23 inhibitor); recommended over switching to a different OSM
    - Biologic monotherapy is conditionally recommended over biologic plus MTX combination therapy
  - Switch to a different OSM (except apremilast) OR add on apremilast to current OSM therapy; recommended over adding another OSM
  - Add another OSM (except apremilast) to current OSM therapy; may consider for patients that have exhibited partial response to current OSM
  - Switch to apremilast monotherapy; may be considered instead of adding apremilast to current OSM therapy if the patient has intolerable side effects with the current OSM
- Previous treatment with a biologic and continued active disease:
  - Switch to another biologic (e.g., TNF inhibitor, IL-17 inhibitor, IL-12/23 inhibitor, abatacept, or tofacitinib) as monotherapy
  - Add MTX to the current biologic; may consider adding MTX in patients with a partial response to current biologic therapy

The European Alliance of Associations for Rheumatology (EULAR) guidelines for PsA (2023 update) also recommend a treat-to-target approach in therapy. MTX (preferred) or another conventional synthetic disease-modifying antirheumatic drug (csDMARD) (e.g., sulfasalazine, leflunomide) should be used for initial therapy. If the treatment target is not achieved with a csDMARD, a biologic should be initiated with preference of product being based on patient specific disease characteristics. Biologics include TNF inhibitors, IL-12/23 inhibitors, IL-17A inhibitors, IL-17A/F inhibitors, IL-23 inhibitors, and cytotoxic T-lymphocyte-associated antigen 4 (CTLA4) analogs. No order of preference of biologics is provided since none have demonstrated superiority for joint involvement, however, CTLA4 analogs are least preferred due to limited efficacy in clinical trials. The use of a Janus kinase (JAK) inhibitor (e.g., tofacitinib, upadacitinib) may be used after failure of a biologic or if biologics are not clinically appropriate for the patient. However, careful consideration should be applied prior to using a JAK inhibitor due to the increased risk of cardiovascular and malignancy events in older patients with RA and cardiovascular risk factors. A phosphodiesterase-4 (PDE4) inhibitor (i.e., apremilast) may be considered in patients with mild disease and

	<p>an inadequate response to at least one csDMARD, in whom neither a biologic nor a JAK inhibitor is appropriate. Patients with an inadequate response to a biologic or JAK inhibitor may switch to a different drug within the same class or switch to a different mode of action. Adding MTX to a biologic may increase drug survival by limiting the development of antidrug antibodies, especially for TNF inhibitors.(30)</p>
<p>RHEUMATOID DISORDERS - Polymyalgia Rheumatica (PMR)</p>	<p>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)</p> <p>The American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) guidelines recommend the following for the treatment of PMR:(73)</p> <ul style="list-style-type: none"> <li>• Strongly recommends using glucocorticoids over nonsteroidal anti-inflammatory drugs (NSAIDs) for long term care of patients with PMR and used for the minimum effective duration</li> <li>• 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.</li> <li>• 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: <ul style="list-style-type: none"> <li>○ Initial tapering: Taper dose to an oral dose of 10 mg/day prednisone equivalent within 4–8 weeks.</li> <li>○ 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.</li> <li>○ 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.</li> </ul> </li> <li>• Conditionally recommends considering intramuscular (IM) methylprednisolone as an alternative to oral glucocorticoids. The choice between oral glucocorticoids and IM methylprednisolone remains at the discretion of the prescriber.</li> <li>• 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).</li> <li>• 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.</li> </ul>

	<ul style="list-style-type: none"><li>Strongly recommends against the use of tumor necrosis factor (TNF)-alpha blocking agents for treatment of PMR</li></ul>																																							
RHEUMATOID DISORDERS - Juvenile Psoriatic Arthritis (JPsA)	<p>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)</p> <ul style="list-style-type: none"><li>Dactylitis</li><li>Nail Pitting</li><li>Onycholysis</li><li>Family history of psoriasis in a first-degree relative.</li></ul> <p>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)</p> <p>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 pediatric 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)</p> <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><tr><td>Antinuclear antibodies (ANA)</td><td>16%</td><td>40%-46%</td></tr></table> <p>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)</p> <p>Nonsteroidal anti-inflammatory drugs (NSAIDs) and oral glucocorticoids, as well as intra-articular glucocorticoids, are indicated as initial steps for symptom relief and</p>	Clinical feature	Adult PsA	JPsA	Timing of psoriasis and arthritis onset	Psoriasis prior to arthritis	Arthritis prior to psoriasis	Oligoarticular peripheral arthritis	20%-55%	45%-55%	Polyarticular peripheral arthritis	20%-60%	33%-55%	Oligo-Extended peripheral arthritis	NA	15%-38%	Axial arthritis	7%-40%	10%-30%	Radiological damage	47%	25%	Enthesitis	30%-50%	12%-45%	Dactylitis	40%-50%	17%-37%	Nail involvement	41%-93%	37%-57%	Uveitis	8%	8%-13%	Human Leukocyte antigen (HLA)-B27	40%-50%	10%-25%	Antinuclear antibodies (ANA)	16%	40%-46%
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	<p>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)</p>
DERMATOLOGICAL DISORDERS - Alopecia Areata (AA)	<p>Alopecia areata (AA) is a chronic autoimmune disease characterized by non-scarring hair loss of the scalp.(65) The most common pattern of presentation of hair loss is the patch subtype, with circular patches seen on the scalp or beard areas.(66) Hair loss may also affect other parts of the body, including the eyebrows, eyelashes, beard, and axillary. AA may also affect the nails and cause nail pitting, or in severe cases cause trachyonychia.(97) During early stages of the disease spontaneous hair regrowth is common, but this becomes more rare as the hair loss becomes more extensive. Patients may have a decreased quality-of-life or psychological burden associated with the disease.(65) Patients with AA tend to have a higher risk of both depression and anxiety.(66)</p> <p>AA is diagnosed based off of clinical presentation and patient history, but sometimes a biopsy is required. Active AA can be assessed with a pull test. A pull test involves firmly pulling 50 to 60 hairs close to the scalp, and a positive test is defined as greater than 10% of hairs being pulled out.(66) Severity of the disease is a strong predictor of long-term outcomes of the disease and can assist in guiding treatment.(97) The Severity of Alopecia Tool (SALT) involves splitting the scalp into four quadrants and determining the percentage of scalp area devoid of terminal hairs to provide a total affected area. One limitation of SALT is it does not account for hair loss of facial hair (eyelashes, eyebrows, beard) or body hair.(66) Severity of AA has been defined as follows:(96)</p> <ul style="list-style-type: none"> <li>• Mild AA: 20% or less scalp hair loss</li> <li>• Moderate AA: 21%-49% scalp hair loss</li> <li>• Severe AA: 50%-100% scalp hair loss</li> </ul> <p>Pharmacologic treatment of AA includes topical/intralesional/systemic corticosteroids, systemic immunosuppressants (e.g., cyclosporine, azathioprine, methotrexate), and minoxidil, with the use of each intervention dependent on the severity of the disease and the area of the body affected. Janus kinase (JAK) inhibitors have been shown to be effective in adults and young people with severe AA and are strongly recommended for these patients.(95)</p>
DERMATOLOGICAL DISORDERS - Psoriasis (PS)	<p>Psoriasis (PS) is a chronic inflammatory skin and systemic disorder. It is a complex disease that affects the skin and joints and is associated with numerous comorbidities, including obesity and inflammatory bowel disease. Psoriasis vulgaris, or plaque psoriasis, is a cutaneous form that often presents with pink plaques with silvery scale on the scalp, elbows, knees, or presacral region, but any area of the skin may be involved.(31,33) Plaque psoriasis is the most common form (affecting 90% of adults with psoriasis), but others include guttate, erythrodermic, pustular, inverse, nail, and psoriatic arthritis (PsA). PS is clinically diagnosed based on the presence of cutaneous and systemic symptoms, and treatment is similar for most forms but is guided by the body surface area (BSA) involved.(98)</p> <p>The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) categorize psoriasis severity as 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 causes serious emotional consequences, occurs in select locations (e.g., hands, feet, scalp, face, or genital area), or when it causes intractable pruritus.(31)</p>

	<p>Topical therapies are most commonly used to treat mild to moderate PS, but they may be used in combination with phototherapy, systemic, or biologic therapies for the treatment of moderate to severe PS.(88) Topical therapies alone can be sufficient for managing limited disease and also have fewer significant adverse effects compared to systemic treatment options. However, topical therapies may be inadequate to obtain and maintain skin clearance, and systemic therapies may be warranted. Conventional systemic agents are widely used as monotherapy or in combination with biologics for moderate to severe disease, and they are beneficial for widespread disease and ease of administration.(33) Biologics are routinely used when one or more conventional agents fail to produce an adequate response, but are considered first line in patients with severe PS or patients with concomitant severe PsA.(29)</p> <p>The NPF medical board recommends a treat-to-target approach to therapy for psoriasis that includes the following:(32)</p> <ul style="list-style-type: none"> <li>• The preferred assessment instrument for determining treatment response is BSA</li> <li>• The preferred time to perform initial evaluation of treatment response is after 3 months</li> <li>• Target response after treatment initiation should be BSA less than or equal to 1% after 3 months</li> <li>• 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</li> </ul> <p>Selection of treatment is based on several factors including benefit-risk assessment, clinical presentation, disease severity, and comorbidities.(32) The AAD/NPF psoriasis treatment guidelines support the following treatment options:</p> <ul style="list-style-type: none"> <li>• Topical therapies:(88) <ul style="list-style-type: none"> <li>○ Topical corticosteroids (TCS)</li> <li>○ Topical calcineurin inhibitors (TCIs), such as tacrolimus and pimecrolimus</li> <li>○ Vitamin D analogues (e.g., calcipotriene and calcitriol)</li> <li>○ Tazarotene (topical retinoid)</li> <li>○ Coal tar preparations</li> <li>○ Topical anthralin</li> </ul> </li> <li>• Psoralen plus ultraviolet light (PUVA) phototherapy(99)</li> <li>• Systemic non-biologic therapies:(33) <ul style="list-style-type: none"> <li>○ Methotrexate (MTX)</li> <li>○ Cyclosporine</li> <li>○ Acitretin</li> <li>○ Apremilast</li> </ul> </li> <li>• Biologic therapies:(31) <ul style="list-style-type: none"> <li>○ Tumor necrosis factor (TNF)-<math>\alpha</math> inhibitors (e.g., adalimumab, certolizumab, etanercept, infliximab)</li> <li>○ Interleukin (IL)-17 inhibitors (e.g., brodalumab, ixekizumab, secukinumab)</li> <li>○ IL-23 inhibitors (e.g., guselkumab, risankizumab, tildrakizumab)</li> <li>○ IL-12/IL-23 Inhibitors (e.g., ustekinumab)</li> <li>○ *Note: Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics was published in 2019. No specific biologic drug/class is recommended as first-line for all patients with psoriasis, and instead choice of therapy should be individualized based on patient specific factors. Additional biologic drugs have since received FDA approval for psoriasis that are not discussed.</li> </ul> </li> </ul> <p>Primary failure for biologics is defined as initial nonresponse to treatment. Primary failure to a tumor necrosis factor (TNF)-<math>\alpha</math> inhibitor does not preclude successful response to a different TNF-<math>\alpha</math> inhibitor, and failure of another biologic therapy does not preclude successful response to ustekinumab. All biologics may lose efficacy in a</p>
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	<p>patient who initially responds favorably to the medication (secondary failure), and loss of efficacy may be attributed to the presence of antidrug antibodies. The concomitant use of MTX with a biologic may increase drug survival by limiting antibody formation.(31)</p> <p>For the treatment of PS in the pediatric patient population, topical corticosteroids are the mainstay option based on extensive clinical experience that supports efficacy. Topical calcineurin inhibitors are also a treatment option and may be preferred for psoriasis of the face, genitalia, and body folds. Vitamin D analogues are recommended as a treatment option for childhood plaque psoriasis and are considered safe, effective, and generally well tolerated. Other topical therapies that may be used for the treatment of pediatric psoriasis include tazarotene, anthralin, and coal tar. Phototherapy may be efficacious and well tolerated for pediatric patients with generalized psoriasis or localized psoriasis refractory to topical agents. Systemic non-biologic therapies, such as methotrexate, cyclosporine, and acitretin, are options for moderate to severe psoriasis. Biologic therapies (e.g., adalimumab, etanercept, infliximab, ustekinumab) have also shown efficacy in moderate to severe plaque psoriasis in this patient population.(20)</p>
DERMATOLOGICAL DISORDERS - Hidradenitis Suppurativa (HS)	<p>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)</p> <p>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-week course or as long-term maintenance. 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)</p> <p>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)</p>
DERMATOLOGICAL DISORDERS - Atopic Dermatitis (AD)	<p>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,</p>

	<p>neck and extensor involvement in infants and children; flexure involvement in any age group, with sparing of groin and axillary regions.(56)</p> <p>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 topical emollient/moisturizer use and conventional topical therapies (including corticosteroids and calcineurin inhibitors).(59,60) Moisturizers reduce signs, symptoms, and inflammation in AD, and can improve severity while also increasing time between flares. Moisturizers are considered generally safe and are strongly recommended to be used as part of a treatment regimen for AD, either as monotherapy or as concurrent use with pharmacologic treatments.(58)</p> <p>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)</p> <ul style="list-style-type: none"> <li>• Topical corticosteroids (TCS)</li> <li>• Calcineurin inhibitors (TCIs) (e.g., tacrolimus, pimecrolimus)</li> <li>• Topical PDE-4 inhibitors (e.g., crisaborole) [mild to moderate AD]</li> <li>• Topical JAK inhibitors (e.g., ruxolitinib) [mild to moderate AD]</li> </ul> <p>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. TCS target a variety of immune cells and suppress the release of proinflammatory cytokines. High to very high (super) potency TCS can be used to control flares and treat severe disease, while medium potency TCS are utilized for longer courses and as maintenance therapy. Lower potency TCS may be used, and it is important to consider the anatomical site (i.e., using lower potency agents on the face, neck, genitals, and body folds) and severity of the disease when choosing a steroid potency. 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 approach.(58)</p> <p>TCIs are a safe anti-inflammatory option for mild-to-severe AD, particularly when there is concern for adverse events secondary to corticosteroid use. Both tacrolimus and pimecrolimus have been shown to be effective in treating AD, but pimecrolimus may be more appropriate for patients who have milder disease or are sensitive to local reactions.(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).</p> <p>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)</p> <ul style="list-style-type: none"> <li>• Monoclonal antibodies (biologics) (e.g., dupilumab, tralokinumab)</li> <li>• JAK inhibitors (e.g., upadacitinib, abrocitinib, baricitinib)</li> </ul> <p>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</p>
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	<p>certainty of evidence and need for monitoring. The most favored first-line systemic is dupilumab.(59)</p> <p>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)</p> <p>One of the following:</p> <ul style="list-style-type: none"> <li>• Affected BSA greater than or equal to 10%</li> <li>• Investigator Global Assessment (IGA) greater than or equal to 3</li> <li>• Eczema Area and Severity Index (EASI) greater than or equal to 16</li> </ul> <p>OR</p> <p>One of the following:</p> <ul style="list-style-type: none"> <li>• Affected BSA greater than or equal to 10%</li> <li>• 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)</li> <li>• Severe itch that has been unresponsive to topical therapies</li> </ul>
<p>INFLAMMATORY BOWEL DISEASE - Crohn's Disease (CD)</p>	<p>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)</p> <ul style="list-style-type: none"> <li>• Biologic therapy: <ul style="list-style-type: none"> <li>○ The AGA suggests early introduction with a biologic, with or without an immunomodulator, rather than delaying their use until after failure of 5-aminosalicylates and/or corticosteroids</li> <li>○ Anti-tumor necrosis factor (TNF) (i.e., infliximab or adalimumab) and ustekinumab are recommended over no treatment for the induction and maintenance of remission</li> <li>○ Vedolizumab is suggested over no treatment for the induction and maintenance of remission</li> <li>○ AGA suggests against the use of natalizumab over no treatment for the induction and maintenance of remission</li> <li>○ 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</li> <li>○ Patients with primary non-response to anti-TNF, the AGA recommends ustekinumab and suggests vedolizumab for induction of remission</li> <li>○ 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)</li> </ul> </li> <li>• Disease modifying antirheumatic drug (DMARD) therapy:</li> </ul>



- 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 suggests 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 suggests 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
  - 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 methotrexate (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

	<ul style="list-style-type: none"> <li>• Severe/fulminant disease: <ul style="list-style-type: none"> <li>○ Intravenous (IV) corticosteroids should be used</li> <li>○ TNF inhibitors can be considered</li> </ul> </li> <li>• Maintenance therapy: <ul style="list-style-type: none"> <li>○ Thiopurines or methotrexate should be considered once remission is induced with corticosteroids</li> <li>○ 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</li> <li>○ Vedolizumab should be used for maintenance of remission of vedolizumab induced remission</li> <li>○ Ustekinumab should be used for maintenance of remission of ustekinumab induced remission</li> </ul> </li> </ul>
INFLAMMATORY BOWEL DISEASE - Ulcerative Colitis (UC)	<p>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.(37)</p> <p>The American College of Gastroenterology (ACG) recommends a treat-to-target approach and recommends 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)</p> <p><u>Induction of remission:</u></p> <ul style="list-style-type: none"> <li>• Mildly active disease: <ul style="list-style-type: none"> <li>○ Rectal 5-aminosalicylate (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</li> <li>○ Rectal 5-ASA at a dose of 1 g/day for ulcerative proctitis</li> <li>○ Oral 5-ASA at a dose of at least 2 g/day for extensive UC</li> <li>○ 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</li> </ul> </li> <li>• Moderately active disease: <ul style="list-style-type: none"> <li>○ Oral budesonide MMX 9 mg/day for induction of remission</li> </ul> </li> <li>• Moderately to severely active disease: <ul style="list-style-type: none"> <li>○ Oral systemic corticosteroids, tumor necrosis factor (TNF) inhibitors (i.e., adalimumab, golimumab, or infliximab), tofacitinib, or vedolizumab to induce remission</li> <li>○ Combination of infliximab with thiopurine therapy when using infliximab for induction</li> <li>○ Switch to tofacitinib or vedolizumab for induction in patients that have failed TNF inhibitors</li> <li>○ 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.</li> </ul> </li> </ul> <p><u>Maintenance of remission:</u></p> <ul style="list-style-type: none"> <li>• Previously mildly active disease: <ul style="list-style-type: none"> <li>○ Rectal 5-ASA at a dose of 1 g/day in patients with ulcerative proctitis</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ Oral 5-ASA at a dose of at least 2 g/day in patients with left-sided or extensive UC</li> <li>• Previously moderately to severely active disease: <ul style="list-style-type: none"> <li>○ Thiopurines in patients that achieved remission due to corticosteroid induction</li> <li>○ Continue TNF inhibitors (i.e., adalimumab, golimumab, or infliximab) for remission due to TNF induction</li> <li>○ Continue vedolizumab for remission due to vedolizumab induction</li> <li>○ Continue tofacitinib for remission due to tofacitinib induction</li> </ul> </li> </ul> <p>The American Gastroenterology Association (AGA) published recommendations (2018) for the management of mild-to-moderate UC:(38)</p> <ul style="list-style-type: none"> <li>• Use either standard-dose mesalamine (2-3 g/day) or diazo-bonded 5-ASA (e.g., balsalazide) for patients with extensive UC for induction of remission and maintenance of remission</li> <li>• May add rectal mesalamine to oral 5-ASA in patients with extensive or left-sided UC for induction of remission and maintenance of remission</li> <li>• 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</li> <li>• Add either oral prednisone or budesonide MMX in patients that are refractory to optimized oral and rectal 5-ASA regardless of disease extent</li> </ul> <p>The American Gastroenterology Association (AGA) published recommendations (2024) for the management of moderate-to-severe UC:(48)</p> <p><u>General treatment information:</u></p> <ul style="list-style-type: none"> <li>• Suggest <i>against</i> using thiopurine monotherapy for inducing remission <ul style="list-style-type: none"> <li>○ Suggest thiopurine monotherapy may be used for maintaining remission typically induced with corticosteroids</li> </ul> </li> <li>• Suggest early use of advanced therapy (e.g., biologics, ozanimod, etrasimod), with or without immunomodulator therapy (e.g., thiopurines), rather than treatment with 5-ASA and a gradual step up to biologic/immunomodulator therapy after 5-ASA treatment failure <ul style="list-style-type: none"> <li>○ Patients with less severe disease or those who place a higher value on the safety of 5-ASA therapy over the efficacy of immunosuppressives may reasonably choose gradual step therapy with 5-ASA therapy</li> </ul> </li> <li>• Recommend using one of the following advanced therapies over no treatment: <ul style="list-style-type: none"> <li>○ Infliximab, golimumab, vedolizumab, tofacitinib, upadacitinib, ustekinumab, ozanimod, etrasimod, risankizumab, guselkumab</li> </ul> </li> <li>• Suggest using one of the following advanced therapies over no treatment: <ul style="list-style-type: none"> <li>○ Adalimumab, filgotinib*, mirikizumab (*not currently approved by the Food and Drug Administration)</li> </ul> </li> </ul> <p><u>Advanced therapy-naïve patients (first-line therapy):</u></p> <ul style="list-style-type: none"> <li>• Suggest that a higher or intermediate efficacy medication be used rather than a lower efficacy medication <ul style="list-style-type: none"> <li>○ Higher efficacy: infliximab, vedolizumab, ozanimod, etrasimod, upadacitinib, risankizumab, guselkumab</li> </ul> </li> </ul>
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	<ul style="list-style-type: none"> <li>○ Intermediate efficacy: golimumab, ustekinumab, tofacitinib, filgotinib, mirikizumab</li> <li>○ Lower efficacy: adalimumab</li> </ul> <p><u>Prior exposure to one or more advanced therapies, particularly TNF antagonists:</u></p> <ul style="list-style-type: none"> <li>• Suggest that a higher or intermediate efficacy medication be used rather than a lower efficacy medication <ul style="list-style-type: none"> <li>○ Higher efficacy: tofacitinib, upadacitinib, ustekinumab</li> <li>○ Intermediate efficacy: filgotinib, mirikizumab, risankizumab, guselkumab</li> <li>○ Lower efficacy: adalimumab, vedolizumab, ozanimod, etrasimod</li> </ul> </li> </ul>
OTHER DISORDERS - Uveitis	<p>Uveitis is characterized by inflammation of the portion of the eye known as the uvea, with the anterior portion of uvea including the iris and ciliary body and the posterior portion being the choroid. Uveitis can cause redness, pain, decreased or loss of vision, worsening field changes, and floaters involving the eye. Uveitis is subdivided into four types based on the primary anatomical location of the inflammation: anterior, intermediate, posterior, and panuveitis. Intermediate uveitis is defined by inflammation of the vitreous cavity and pars plana, posterior uveitis involves the retina and choroid, and panuveitis includes all layers. Uveitis can be caused by infections, inflammatory diseases, or trauma, or be idiopathic in nature.(22)</p> <p>The goal of treatment in uveitis is to suppress ocular inflammation and achieve an inactive disease state or drug-induced remission.(42) Treatment of non-infectious uveitis (NIU) depends on the location of inflammation. Intermediate, posterior, and panuveitis treatment is complex and should be guided by an ophthalmologist or uveitis specialist.(22) NIU should be treated early and aggressively to prevent complications and preserve sight, with corticosteroids being used initially to suppress inflammation.(39) Oral corticosteroids are the mainstay of treatment, but periocular or intravitreal corticosteroid injections may also be used to limit systemic effects. Treatment with conventional systemic agents (i.e., azathioprine, mycophenolate, methotrexate[MTX], cyclosporine, tacrolimus) may be introduced to control persistent or severe inflammation, or to prevent ocular structural complications. They may also be used if there is a need for a corticosteroid-sparing effect in chronic disease or to maintain disease remission.(42) MTX is used most commonly, with mycophenolate being used if MTX was ineffective, not tolerated, or contraindicated. A conventional immunomodulatory agent should be used for at least three months before assuming that it is not effective.(39)</p> <p>Adalimumab, a tumor necrosis factor (TNF)-inhibitor, is generally considered for treatment in patients whose disease is inadequately controlled by corticosteroids and conventional systemic agents.(42) TNF-inhibitors are effective in most cases, but they may eventually lose their effect and require an escalation in dose.(39) This loss of effect is primarily due to an immune response targeting the drug itself. The concurrent use of an antimetabolite (e.g., MTX or mycophenolate) may prolong the effectiveness of the biologic.(39,100)</p>
OTHER DISORDERS - Giant Cell Arteritis (GCA)	<p>Giant cell arteritis (GCA) is a blood vessel disease that predominantly affects medium to large arteries in individuals older than 50 years of age, causing clinical manifestations in both cranial and extracranial locations. The cranial phenotype is characterized by headache, jaw claudication, and visual disturbance or loss. The extracranial phenotype is characterized by musculoskeletal involvement with symptoms associated with polymyalgia rheumatica, such as pain, stiffness, and limited</p>

	<p>range of motion around the shoulders, neck, and hips. Treatment should begin as soon as the diagnosis is made to prevent loss of vision or blindness.(23)</p> <p>The American College of Rheumatology/Vasculitis Foundation guidelines (2021) recommend high-dose systemic glucocorticoids as the mainstay of therapy for GCA. The guidelines provide the following recommendations for the management of GCA:(40)</p> <ul style="list-style-type: none"> <li>• Patients with newly diagnosed active GCA with visual symptoms/loss or critical cranial ischemia: <ul style="list-style-type: none"> <li>○ High dose IV pulse corticosteroids followed by high dose oral corticosteroids with or without a non-corticosteroid immunosuppressive agent (i.e., methotrexate or tocilizumab)</li> <li>○ Taper oral corticosteroids in patients that achieve remission</li> <li>○ Consider adding on or changing non-corticosteroid immunosuppressive agent in patients that have not achieved remission</li> </ul> </li> <li>• Patients with newly diagnosed active GCA without visual symptoms/loss or critical cranial ischemia: <ul style="list-style-type: none"> <li>○ High dose oral corticosteroids with or without a non-corticosteroid immunosuppressive agent (i.e., methotrexate or tocilizumab)</li> <li>○ Taper oral corticosteroids in patients that achieve remission</li> <li>○ Consider adding on or changing non-corticosteroid immunosuppressive agent in patients that have not achieved remission</li> </ul> </li> </ul>
<p>OTHER DISORDERS - Cryopyrin-Associated Periodic Syndromes (CAPS)/Neonatal-Onset Multisystem Inflammatory Disease (NOMID)</p>	<p>Cryopyrin-associated periodic syndrome (CAPS) is a rare autosomal dominant hereditary autoimmune disorder associated with a defect in the cryopyrin protein. CAPS is caused by a gain-of-function mutation in the <i>NLRP3</i> gene, the gene encoding cryopyrin, leading to over secretion of fever causing cytokine interleukin (IL)-1B. The CAPS spectrum includes mild, moderate, and severe phenotypes. The mild phenotype is familial cold autoinflammatory syndrome (FCAS), the moderate phenotype is Muckle-Wells syndrome (MWS), and 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 <i>NLRP3</i> gene, and mutations in this gene are not inclusive of a CAPS diagnosis. The diagnostic criteria of CAPS recognizes that all but a few patients with CAPS have detectable systemic inflammation and use unique CAPS-specific clinical features along the whole disease spectrum to achieve reasonable specificity and sensitivity to aid clinicians in making the CAPS diagnosis.(24) The diagnostic criteria does not include genetic confirmation and can be applied to all CAPS subtypes regardless of <i>NLRP3</i> mutation. The diagnostic criteria for CAPS are as follows:(49)</p> <ul style="list-style-type: none"> <li>• Raised inflammatory markers (C-reactive protein [CRP]/serum amyloid A [SAA]), AND</li> <li>• The presence of at least two of the following signs/symptoms: <ul style="list-style-type: none"> <li>• Urticaria-like rash</li> <li>• Cold/stress triggered episodes</li> <li>• Sensorineural hearing loss</li> <li>• Musculoskeletal symptoms of arthralgia/arthritis/myalgia</li> <li>• Chronic aseptic meningitis</li> <li>• Skeletal abnormalities of epiphyseal overgrowth/frontal bossing</li> </ul> </li> </ul> <p>Goals of treatment include suppressing systemic inflammation, improving functionality, preventing organ damage, and improving quality of life.(24) IL-1 blocking therapy is the preferred treatment for CAPS and is the recommended</p>

	<p>standard of care. IL-1 blocking therapies control inflammation in the absence of corticosteroids. Current IL-1 blocking therapies include anakinra, canakinumab, and rilonacept. Each of these drugs blocks the effect of IL-1B on the IL-1 receptor and downstream signaling.(51)</p>
OTHER DISORDERS - Deficiency of IL-1 Receptor Antagonist (DIRA)	<p>Deficiency of interleukin (IL)-1 receptor antagonist (DIRA) is a very rare, autosomal recessive inflammatory disease caused by biallelic deleterious loss-of-function mutations in the <i>IL1RN</i> gene, which encodes the IL-1 receptor antagonist (IL-1Ra). These mutations lead to the absence of IL-1Ra, which allows unopposed action of IL-1 and an increased response to proinflammatory cytokines IL-1<math>\alpha</math> and IL-1<math>\beta</math> stimulation. This results in life-threatening systemic inflammation and marked skin and bone involvement.(57)</p> <p>DIRA presents in early childhood, sometimes at birth, with pustular rashes, osteomyelitis, and/or nail changes (onychomadesis). Which features a patient may present with is dependent on the domain affected by the mutation, with some patients presenting primarily with skin involvement and minimal bone involvement, or vice versa. Although inflammatory markers are typically highly elevated, patients rarely present with flare-associated fever unless an infection is present. The diagnosis of DIRA is typically suspected based on clinical features and confirmed on subsequent genetic testing. DIRA can only be diagnosed by genetic analysis and detection of mutations in the <i>IL1RN</i> gene. If untreated, DIRA can result in multiorgan failure and death in early childhood.(57)</p> <p>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, with remission defined as an absence of clinical symptoms and normal inflammatory markers. In patients with DIRA, treatment with agents that block both IL-1<math>\alpha</math> and IL-1<math>\beta</math> is recommended and includes anakinra and rilonacept. Both drugs have shown benefit in controlling disease flares and in preventing long-term complications. Anakinra is typically used initially in all patients with DIRA to achieve disease control, while rilonacept is used to maintain remission.(51)</p>
OTHER DISORDERS - Systemic Sclerosis-Associated Interstitial Lung Disease (SScILD)	<p>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 interstitial lung disease (ILD) is a common manifestation that tends to occur early in the course of systemic sclerosis.(52)</p> <p>SSc-associated ILD (SSc-ILD) is diagnosed when there is radiographic evidence of diffuse parenchymal lung disease in patients with systemic sclerosis. ILD is defined as pulmonary fibrosis seen on high-resolution computed tomography (HRCT) or chest radiography, most pronounced in the basilar portions of the lungs.(54) All patients with suspected SSc-ILD should undergo HRCT of the chest at initial evaluation. HRCT is preferred over pulmonary function tests (PFTs) since patients with ILD can have normal PFTs or have difficulty performing them due to cough or microstomia. HRCT is also preferred over chest radiography due to its low sensitivity, which limits its use as a screening test for ILD.(41)</p> <p>The American College of Rheumatology (ACR) and American College of Chest Physicians (CHEST) guidelines (2023) recommend the following treatment options for SSc-ILD:(53)</p> <ul style="list-style-type: none"> <li>• <i>Note: Treatments are listed in order based on a hierarchy established by the voting panel, but it is noted that the decision on which first-line therapy to use is dependent on specific situations and patient factors</i></li> <li>• Preferred therapies: mycophenolate, tocilizumab, rituximab</li> </ul>

	<ul style="list-style-type: none"><li>Additional options: cyclophosphamide, nintedanib, azathioprine</li></ul> <p>The American Thoracic Society (ATS) guidelines (2023) state the following for the treatment of SSc-ILD:(70)</p> <ul style="list-style-type: none"><li>Recommends the use of [strong in favor]: mycophenolate</li><li>Suggests the use of [conditional in favor]: cyclophosphamide, rituximab, tocilizumab, nintedanib, nintedanib plus mycophenolate</li></ul>																			
Efficacy	<p><b>Cosentyx</b></p> <p><i>Psoriatic Arthritis</i></p> <p>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 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)</p> <p>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)</p> <p>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)</p> <p>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)</p> <table><tr><th colspan="5">Future 4 Trial</th></tr><tr><th rowspan="2">Primary Endpoint</th><th colspan="2">150 mg with loading dose</th><th colspan="2">150 mg without loading dose</th></tr><tr><th>16 weeks</th><th>52 weeks</th><th>16 weeks</th><th>52 weeks</th></tr><tr><td>ACR 20</td><td>41.2%</td><td>60.5%</td><td>39.8%</td><td>57.5%</td></tr></table>	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%
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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.(69)

Future 5 Trial				
Primary Endpoint	150 mg with loading dose		150 mg without loading dose	
	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 were 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.(3)

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)
	<p>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)</p>					
Safety	<p><i>Adalimumab</i>(6,71,74,75,76,77,78,79,80,83,90)</p> <p>Adalimumab products have the following boxed warnings:</p> <ul style="list-style-type: none"> <li>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.</li> <li>Lymphoma and other malignancies, some fatal have been reported in children and adolescent patients treated with TNF blockers.</li> <li>Post marketing cases of hepatosplenic T-cell lymphoma have occurred in adolescents and young adults with inflammatory bowel disease treated with TNF blockers</li> </ul> <p><i>Bimzelx</i>(84)</p> <p>Bimekizumab-bkzx has no FDA labeled contraindications for use.</p> <p><i>Cimzia</i>(2)</p> <p>Certolizumab has the following boxed warnings:</p> <ul style="list-style-type: none"> <li>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.</li> <li>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.</li> </ul> <p>Certolizumab is contraindicated in patients with a severe hypersensitivity to certolizumab pegol or to any of the excipients.</p> <p><i>Cosentyx</i>(3)</p> <p>Secukinumab is contraindicated in patients with a serious hypersensitivity reaction to secukinumab or to any of the excipients. Cases of anaphylaxis and angioedema have been reported during treatment with secukinumab.</p> <p><i>Enbrel</i>(4)</p> <p>Etanercept has the following boxed warnings:</p> <ul style="list-style-type: none"> <li>Increased risk for developing serious infections that may lead to hospitalization or death, including tuberculosis (TB), bacterial, invasive</li> </ul>					

	<p>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.</p> <ul style="list-style-type: none"> <li>• Lymphoma and other malignancies, some fatal have been reported in children and adolescent patients treated with TNF blockers.</li> </ul> <p>Etanercept is contraindicated for use in patients with sepsis.</p> <p><i>Entyvio</i>(5)</p> <p>Vedolizumab is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to Entyvio or any of its excipients.</p> <p><i>Kevzara</i>(7)</p> <p>Sarilumab has the following boxed warning:</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p>Sarilumab is contraindicated in patients with a known hypersensitivity to sarilumab or any of the inactive ingredients.</p> <p><i>Kineret</i>(8)</p> <p>Anakinra is contraindicated in patients with a known hypersensitivity to E.coli-derived proteins, anakinra, or any component of the product.</p> <p><i>Leqselvi</i>(107)</p> <p>Leqselvi has the following boxed warnings:</p> <ul style="list-style-type: none"> <li>• Increased risk of serious bacterial, fungal, viral and opportunistic infections, including tuberculosis (TB), that may lead to hospitalization or death. Interrupt treatment if a serious infection occurs until the infection is controlled. Treatment is not recommended in patients with active tuberculosis. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test.</li> <li>• Higher rate of all-cause mortality, including sudden cardiovascular death, was observed with another Janus kinase (JAK) inhibitor vs. tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients. Leqselvi is not approved for use in RA patients.</li> <li>• Malignancies were reported in patients treated with Leqselvi. Higher rate of lymphomas and lung cancers was observed with another JAK inhibitor vs. TNF blockers in RA patients.</li> <li>• Higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke) was observed with another JAK inhibitor vs. TNF blockers in RA patients.</li> <li>• Thrombosis, including cerebral venous sinus thrombosis (CVT), deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients treated with Leqselvi. Increased incidence of pulmonary embolism,</li> </ul>
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	<p>venous and arterial thrombosis was observed with another JAK inhibitor vs. TNF blockers.</p> <p>Leqselvi is contraindicated in patients who are:</p> <ul style="list-style-type: none"> <li>• CYP2C9 poor metabolizers</li> <li>• On concomitant moderate or strong CYP2C9 inhibitors</li> </ul> <p><i>Litfulo(81)</i></p> <p>Ritlecitinib has the following boxed warnings:</p> <ul style="list-style-type: none"> <li>• Increased risk of serious bacterial, fungal, viral, and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Interrupt treatment 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.</li> <li>• 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. Litfulo (ritlecitinib) is not approved for use in RA patients.</li> <li>• Malignancies have occurred in patients treated with Litfulo. Higher rate of lymphomas and lung cancers with another JAK inhibitor vs TNF blockers in RA patients.</li> <li>• Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with another JAK inhibitor vs TNF blockers in RA patients</li> <li>• Thrombosis has occurred in patients treated with Litfulo. Increased incidence of pulmonary embolism, venous and arterial thrombosis with another JAK inhibitor vs TNF blockers.</li> </ul> <p>Ritlecitinib is contraindicated in patients with known hypersensitivity to ritlecitinib or any of its excipients.</p> <p><i>Olumiant(9)</i></p> <p>Baricitinib has the following boxed warnings:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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</li> <li>• 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</li> <li>• Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with another JAK inhibitor vs TNF blockers in RA patients</li> <li>• Thrombosis has occurred in patients treated with Olumiant. Increased incidence of pulmonary embolism, venous and arterial thrombosis with another JAK inhibitor vs TNF blockers.</li> </ul> <p>Baricitinib has no FDA labeled contraindications for use.</p>
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	<p><i>Omvo</i>(86)</p> <p>Mirikizumab is contraindicated in patients with a history of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients.</p> <p><i>Orencia</i>(10)</p> <p>Abatacept has no FDA labeled contraindications for use.</p> <p><i>Rinvoq</i>(44)</p> <p>Upadacitinib has the following boxed warnings:</p> <ul style="list-style-type: none"> <li>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.</li> <li>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</li> <li>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</li> <li>Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with another JAK inhibitor vs TNF blockers in RA patients</li> <li>Thrombosis has occurred in patients treated with Rinvoq. Increased incidence of pulmonary embolism, venous and arterial thrombosis with another JAK inhibitor vs TNF blockers.</li> </ul> <p>Upadacitinib is contraindicated in patients with known hypersensitivity to upadacitinib or any of its excipients.</p> <p><i>Siliq</i>(11)</p> <p>Brodalumab has the following boxed warning:</p> <ul style="list-style-type: none"> <li>Suicidal ideation and behavior, including completed suicides, have occurred in patients.</li> </ul> <p><i>Simponi</i>(12)</p> <p>Golimumab has the following boxed warnings:</p> <ul style="list-style-type: none"> <li>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.</li> <li>Lymphoma and other malignancies, some fatal have been reported in children and adolescent patients treated with TNF blockers.</li> </ul> <p><i>Skyrizi</i>(43)</p>
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	<p>Risankizumab is contraindicated in patients with a history of serious hypersensitivity reaction to risankizumab-rzaa or any of the excipients.</p> <p><i>Sotyktu</i>(67)</p> <p>Deucravacitinib is contraindicated in patients with a history of hypersensitivity reaction to deucravacitinib or to any of the excipients in Sotyktu.</p> <p><i>Taltz</i>(14)</p> <p>Ixekizumab is contraindicated for use in patients with serious hypersensitivity reaction to ixekizumab or to any of the excipients.</p> <p><i>Tocilizumab</i>(1,50)</p> <p>Tocilizumab has the following boxed warning:</p> <ul style="list-style-type: none"> <li>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.</li> </ul> <p>Tocilizumab is contraindicated in patients with a known hypersensitivity reaction to tocilizumab.</p> <p><i>Tremfya</i>(15)</p> <p>Guselkumab is contraindicated for use in patients with serious hypersensitivity reaction to guselkumab or to any of the excipients.</p> <p><i>Ustekinumab</i>(13,91,101,102,103,104,105)</p> <p>Ustekinumab is contraindicated for use in patients with clinically significant hypersensitivity to ustekinumab or to any of the excipients.</p> <p><i>Velsipity</i>(85)</p> <p>Etrasimod is contraindicated in:</p> <ul style="list-style-type: none"> <li>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</li> <li>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</li> </ul> <p><i>Xeljanz/Xeljanz XR</i>(16)</p> <p>Tofacitinib has the following boxed warnings:</p> <ul style="list-style-type: none"> <li>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.</li> </ul>
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	<ul style="list-style-type: none"> <li>Higher rate of all-cause mortality, including sudden cardiovascular death with Xeljanz vs TNF blockers in RA patients</li> <li>Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with Xeljanz vs TNF blockers in RA patients.</li> <li>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.</li> <li>Malignancies have occurred in patients treated with Xeljanz. Higher rate of lymphomas and lung cancers with Xeljanz vs TNF blockers in RA patients.</li> </ul> <p>Tofacitinib has no FDA labeled contraindications for use.</p> <p><i>Zymfentra</i>(89)</p> <p>Infliximab has the following boxed warnings:</p> <ul style="list-style-type: none"> <li>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.</li> <li>Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers.</li> <li>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.</li> </ul> <p>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.</p>
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## REFERENCES

Number	Reference
1	Actemra prescribing information. Genentech, Inc. September 2024.
2	Cimzia prescribing information. UCB, Inc. September 2024.
3	Cosentyx prescribing information. Novartis Pharmaceuticals Corp. October 2024.
4	Enbrel prescribing information. Immunex Corporation. October 2023.
5	Entyvio prescribing information. Takeda Pharmaceuticals U.S.A., Inc. April 2024.
6	Humira prescribing information. AbbVie, Inc. November 2023.
7	Kevzara prescribing information. Regeneron Pharmaceuticals, Inc/ Sanofi-Aventis U.S. LLC. June 2024.
8	Kineret prescribing information. Swedish Orphan Biovitrum. December 2020.
9	Olumiant prescribing information. Eli Lilly and Company. June 2022.
10	Orencia prescribing information. Bristol-Myers Squibb. May 2024.
11	Siliq prescribing information. Bausch Health US LLC. June 2020.
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## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Orencia clickject	abatacept subcutaneous soln auto-injector	125 MG/ML	M ; N ; O ; Y	N		
Orencia	abatacept subcutaneous soln prefilled syringe	125 MG/ML ; 50 MG/0.4ML ; 87.5 MG/0.7ML	M ; N ; O ; Y	N		
Humira ; Humira pediatric crohns d ; Humira pen ; Humira pen-cd/uc/hs start ; Humira pen-pediatric uc s ; Humira pen-ps/uv starter	adalimumab auto-injector kit ; 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	N		
Adalimumab-aacf (2 pen) ; Adalimumab-aacf starter p ; Idacio (2 pen) ; Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	M ; N ; O ; Y	N		
Adalimumab-aacf (2 syring ; Idacio (2 syringe)	adalimumab-aacf prefilled syringe kit	40 MG/0.8ML	M ; N ; O ; Y	N		
Adalimumab-aaty 1-pen kit ; Adalimumab-aaty 2-pen kit ; Adalimumab-aaty cd/uc/hs ; 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	N		
Adalimumab-aaty 2-syringe ; Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	20 MG/0.2ML ; 40 MG/0.4ML	M ; N ; O ; Y	N		
Adalimumab-adaz ; Hyrimoz ; Hyrimoz crohn's disease a ; Hyrimoz plaque psoriasis ; 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	N		

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Adalimumab-adaz ; Hyrimoz ; Hyrimoz pediatric crohn's ; Hyrimoz pediatric crohns	adalimumab-adaz soln prefilled syr ; adalimumab-adaz soln prefilled syringe	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	N		
Adalimumab-adbm ; Adalimumab-adbm crohns/uc ; Adalimumab-adbm psoriasis ; Adalimumab-adbm starter p ; Cyltezo ; Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.4ML ; 40 MG/0.8ML	M ; N ; O ; Y	N		
Adalimumab-adbm ; Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2ML ; 20 MG/0.4ML ; 40 MG/0.4ML ; 40 MG/0.8ML	M ; N ; O ; Y	N		
Abrilada 1-pen kit ; Abrilada 2-pen kit	adalimumab-afzb auto-injector kit	40 MG/0.8ML	M ; N ; O ; Y	N		
Abrilada	adalimumab-afzb prefilled syringe kit	20 MG/0.4ML ; 40 MG/0.8ML	M ; N ; O ; Y	N		
Yusimry	adalimumab-aqvh soln auto-injector	40 MG/0.8ML	M ; N ; O ; Y	N		
Amjevita	adalimumab-atto soln auto-injector	40 MG/0.4ML ; 40 MG/0.8ML ; 80 MG/0.8ML	M ; N ; O ; Y	N		
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	N		
Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4ML ; 40 MG/0.8ML	M ; N ; O ; Y	N		
Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4ML ; 40 MG/0.8ML	M ; N ; O ; Y	N		
Adalimumab-fkjp ; Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8ML	M ; N ; O ; Y	N		
Adalimumab-fkjp ; Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4ML ; 40 MG/0.8ML	M ; N ; O ; Y	N		
Adalimumab-ryvk (2 pen) ; Simlandi 1-pen kit ; Simlandi 2-pen kit	adalimumab-ryvk auto-injector kit	40 MG/0.4ML ; 80 MG/0.8ML	M ; N ; O ; Y	N		
Adalimumab-ryvk ; Simlandi	adalimumab-ryvk prefilled syringe kit	20 MG/0.2ML ; 40 MG/0.4ML ; 80 MG/0.8ML	M ; N ; O ; Y	N		
Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67ML	M ; N ; O ; Y	N		
Olumiant	baricitinib tab	1 MG ; 2 MG ; 4 MG	M ; N ; O ; Y	N		
Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	160 MG/ML ; 320 MG/2ML	M ; N ; O ; Y	N		
Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	160 MG/ML ; 320 MG/2ML	M ; N ; O ; Y	N		
Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5ML	M ; N ; O ; Y	N		
Cimzia ; Cimzia starter kit	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	M ; N ; O ; Y	N		
Sotyktu	deucravacitinib tab	6 MG	M ; N ; O ; Y	N		
Leqselvi	deuruxolitinib phosphate tab	8 MG	M ; N ; O ; Y	N		
Enbrel ; Enbrel mini ; Enbrel sureclick	etanercept subcutaneous inj ; etanercept subcutaneous soln prefilled syringe ; etanercept	25 MG/0.5ML ; 50 MG/ML	M ; N ; O ; Y	N		

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
	subcutaneous solution auto-injector ; etanercept subcutaneous solution cartridge					
Velsipity	etrasimod arginine tab	2 MG	M ; N ; O ; Y	N		
Simponi	Golimumab Subcutaneous Soln Auto-injector 100 MG/ML	100 MG/ML	M ; N ; O ; Y	N		
Simponi	Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML	50 MG/0.5ML	M ; N ; O ; Y	N		
Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML	100 MG/ML	M ; N ; O ; Y	N		
Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML	50 MG/0.5ML	M ; N ; O ; Y	N		
Tremfya ; Tremfya induction pack fo	guselkumab soln auto- injector	200 MG/2ML	M ; N ; O ; Y	N		
Tremfya ; Tremfya pen	guselkumab soln auto- injector	100 MG/ML	M ; N ; O ; Y	N		
Tremfya	guselkumab soln prefilled syringe	200 MG/2ML	M ; N ; O ; Y	N		
Tremfya	guselkumab soln prefilled syringe	100 MG/ML	M ; N ; O ; Y	N		
Zymfentra 1-pen ; Zymfentra 2-pen	infliximab-dyyb soln auto- injector kit	120 MG/ML	M ; N ; O ; Y	N		
Zymfentra 2-syringe	infliximab-dyyb soln prefilled syringe kit	120 MG/ML	M ; N ; O ; Y	N		
Taltz	ixekizumab subcutaneous soln auto-injector ; ixekizumab subcutaneous soln prefilled syringe	20 MG/0.25ML ; 40 MG/0.5ML ; 80 MG/ML	M ; N ; O ; Y	N		
Omvoh	mirikizumab-mrkz subcutaneous auto-inj ; mirikizumab-mrkz subcutaneous soln auto- injector	100 MG/ML ; 100 MG/ML & 200 MG/2ML	M ; N ; O ; Y	N		
Omvoh	mirikizumab-mrkz subcutaneous pref syr ; mirikizumab-mrkz subcutaneous sol prefill syringe	100 MG/ML ; 100 MG/ML & 200 MG/2ML	M ; N ; O ; Y	N		
Skyrizi ; Skyrizi pen	risankizumab-rzaa soln auto-injector ; risankizumab-rzaa soln prefilled syringe	150 MG/ML	M ; N ; O ; Y	N		
Skyrizi	risankizumab-rzaa subcutaneous soln cartridge	180 MG/1.2ML ; 360 MG/2.4ML	M ; N ; O ; Y	N		
Litfulo	ritlectinib tosylate cap	50 MG	M ; N ; O ; Y	N		
Kevzara	sarilumab subcutaneous soln prefilled syringe ; sarilumab subcutaneous solution auto-injector	150 MG/1.14ML ; 200 MG/1.14ML	M ; N ; O ; Y	N		
Cosentyx sensoready pen ; Cosentyx unoready	secukinumab subcutaneous auto-inj ; secukinumab subcutaneous soln auto- injector	150 MG/ML ; 300 MG/2ML	M ; N ; O ; Y	N		
Cosentyx	secukinumab subcutaneous pref syr ; secukinumab subcutaneous soln prefilled syringe	150 MG/ML ; 75 MG/0.5ML	M ; N ; O ; Y	N		
Actemra actpen	tocilizumab subcutaneous soln auto-injector	162 MG/0.9ML	M ; N ; O ; Y	N		

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9ML	M ; N ; O ; Y	N		
Tyenne	tocilizumab-aazg subcutaneous soln auto-inj	162 MG/0.9ML	M ; N ; O ; Y	N		
Tyenne	tocilizumab-aazg subcutaneous soln pref syr	162 MG/0.9ML	M ; N ; O ; Y	N		
Xeljanz ; Xeljanz xr	tofacitinib citrate oral soln ; tofacitinib citrate tab ; tofacitinib citrate tab er	1 MG/ML ; 10 MG ; 11 MG ; 22 MG ; 5 MG	M ; N ; O ; Y	N		
Rinvoq lq	upadacitinib oral soln	1 MG/ML	M ; N ; O ; Y	N		
Rinvoq	upadacitinib tab er	15 MG ; 30 MG ; 45 MG	M ; N ; O ; Y	N		
Stelara ; Ustekinumab	ustekinumab inj ; ustekinumab soln prefilled syringe	45 MG/0.5ML ; 90 MG/ML	M ; N ; O ; Y	N		
Otulf	ustekinumab-aazg soln prefilled syringe	45 MG/0.5ML ; 90 MG/ML	M ; N ; O ; Y	N		
Selarsdi ; Ustekinumab-aekn	ustekinumab-aekn soln prefilled syringe	45 MG/0.5ML ; 90 MG/ML	M ; N ; O ; Y	N		
Wezlana	ustekinumab-auub inj ; ustekinumab-auub soln prefilled syringe	45 MG/0.5ML ; 90 MG/ML	M ; N ; O ; Y	N		
Yesintek	ustekinumab-kfce soln prefilled syringe ; ustekinumab-kfce subcutaneous soln	45 MG/0.5ML ; 90 MG/ML	M ; N ; O ; Y	N		
Steqeyma	ustekinumab-stba soln prefilled syringe	45 MG/0.5ML ; 90 MG/ML	M ; N ; O ; Y	N		
Pyzchiva ; Ustekinumab-ttwe	ustekinumab-ttwe soln prefilled syringe	45 MG/0.5ML ; 90 MG/ML	M ; N ; O ; Y	N		
Entyvio pen	vedolizumab soln auto-injector	108 MG/0.68ML	M ; N ; O ; Y	N		

## POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
		40 MG/0.8 ML	1	Kit	180	DAYS			
Abrilada	adalimumab-afzb prefilled syringe kit	20 MG/0.4 ML	2	Syringes	28	DAYS			
Abrilada	adalimumab-afzb prefilled syringe kit	40 MG/0.8 ML	2	Syringes	28	DAYS			
Abrilada 1-pen kit ; Abrilada 2-pen kit	adalimumab-afzb auto-injector kit	40 MG/0.8 ML	2	Pens	28	DAYS			
Actemra	Tocilizumab Subcutaneous Soln Prefilled Syringe 162 MG/0.9ML	162 MG/0.9 ML	4	Syringes	28	DAYS			
Actemra actpen	Tocilizumab Subcutaneous Soln Auto-injector 162 MG/0.9ML	162 MG/0.9 ML	4	Pens	28	DAYS			
Adalimumab-aacf (2 pen) ; Idacio (2 pen)	adalimumab-aacf auto-injector kit	40 MG/0.8 ML	1	Kit	28	DAYS			652190 55408 ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
									652190 61299
Adalimumab-aacf (2 syringe ; Idacio (2 syringe)	adalimumab-aacf prefilled syringe kit	40 MG/0.8 ML	1	Kit	28	DAYS			
Adalimumab-aacf starter p ; Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS			652190 55438 ; 652190 61289
Adalimumab-aacf starter p ; Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS			652190 55428 ; 652190 61269
Adalimumab-aaty 1-pen kit ; Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4 ML	2	Pens	28	DAYS			726060 02209 ; 726060 03009
Adalimumab-aaty 1-pen kit ; Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	80 MG/0.8 ML	2	Pens	28	DAYS			726060 02304 ; 726060 04004
Adalimumab-aaty 2-pen kit ; Yuflyma 2-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4 ML	2	Pens	28	DAYS			726060 02210 ; 726060 03010
Adalimumab-aaty 2-syringe ; Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	20 MG/0.2 ML	2	Syringes	28	DAYS			
Adalimumab-aaty 2-syringe ; Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	40 MG/0.4 ML	2	Syringes	28	DAYS			
Adalimumab-aaty cd/uc/hs ; Yuflyma cd/uc/hs starter	adalimumab-aaty auto-injector kit	80 MG/0.8 ML	1	Kit	180	DAYS			726060 02307 ; 726060 04006
Adalimumab-adaz ; Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4 ML	2	Pens	28	DAYS			
Adalimumab-adaz ; Hyrimoz	adalimumab-adaz soln prefilled syringe	10 MG/0.1 ML	2	Syringes	28	DAYS			
Adalimumab-adaz ; Hyrimoz	adalimumab-adaz soln prefilled syringe	20 MG/0.2 ML	2	Syringes	28	DAYS			
Adalimumab-adaz ; Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.4 ML	2	Syringes	28	DAYS			
Adalimumab-adaz ; Hyrimoz ; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8 ML	2	Pens	28	DAYS			613140 32520 ; 613140 45420 ; 834570 10701
Adalimumab-adbm ; Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.4 ML	2	Pens	28	DAYS			005970 49550 ; 005970 57550;8 200901 4422
Adalimumab-adbm ; Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.8 ML	2	Pens	28	DAYS			005970 37597 ; 005970 54522;8 200901 4822

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Adalimumab-adbm ; Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2 ML	2	Syringes	28	DAYS			
Adalimumab-adbm ; Cyltezo	adalimumab-adbm prefilled syringe kit	20 MG/0.4 ML	2	Syringes	28	DAYS			
Adalimumab-adbm ; Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.4 ML	2	Syringes	28	DAYS			
Adalimumab-adbm ; Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.8 ML	2	Syringes	28	DAYS			
Adalimumab-fkjp ; Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8 ML	2	Pens	28	DAYS			
Adalimumab-fkjp ; Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4 ML	2	Syringes	28	DAYS			
Adalimumab-fkjp ; Hulio	adalimumab-fkjp prefilled syringe kit	40 MG/0.8 ML	2	Syringes	28	DAYS			
Adalimumab-ryvk (2 pen) ; Simlandi 1-pen kit ; Simlandi 2-pen kit	adalimumab-ryvk auto-injector kit	40 MG/0.4 ML	2	Pens	28	DAYS			
Adalimumab-ryvk ; Simlandi	adalimumab-ryvk prefilled syringe kit	40 MG/0.4 ML	2	Syringes	28	DAYS			
Amjevita	adalimumab-atto soln auto-injector	40 MG/0.4 ML	2	Pens	28	DAYS			
Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8 ML	2	Pens	28	DAYS			
Amjevita	adalimumab-atto soln auto-injector	80 MG/0.8 ML	2	Pens	28	DAYS			
Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2 ML	2	Syringes	28	DAYS			
Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.2 ML	2	Syringes	28	DAYS			
Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4 ML	2	Syringes	28	DAYS			
Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.4 ML	2	Syringes	28	DAYS			
Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8 ML	2	Syringes	28	DAYS			
Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	160 MG/ML	2	Pens	56	DAYS			
Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	320 MG/2ML	1	Pen	28	DAYS			
Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	160 MG/ML	2	Syringes	56	DAYS			
Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	320 MG/2ML	1	Syringe	28	DAYS			



Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Cimzia	certolizumab pegol prefilled syringe kit	200 MG/ML	2	Kits	28	DAYS			504740 71079;
Cimzia starter kit	certolizumab pegol prefilled syringe kit	200 MG/ML	1	Kit	180	DAYS			504740 71081;
Cosentyx	Secukinumab Subcutaneous Pref Syr 150 MG/ML (300 MG Dose)	150 MG/ML	2	Syringes	28	DAYS			
Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe	75 MG/0.5 ML	1	Syringe	28	DAYS			
Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML	150 MG/ML	1	Syringe	28	DAYS			
Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose)	150 MG/ML	2	Pens	28	DAYS			
Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	1	Pen	28	DAYS			
Cosentyx unoready	secukinumab subcutaneous soln auto-injector	300 MG/2ML	1	Pen	28	DAYS			
Cyltezo starter package for Crohn's disease, ulcerative colitis, or hidradenitis	adalimumab-adbm auto-injector kit	40 MG/0.4 ML	1	Kit	180	DAYS			005970 49560 ; 005970 57560;
Cyltezo starter package for Crohn's disease, ulcerative colitis, or hidradenitis	adalimumab-adbm auto-injector kit	40 MG/0.8 ML	1	Kits	180	DAYS			005970 37516 ; 005970 54566;
Cyltezo starter package for psoriasis/uveitis	adalimumab-adbm auto-injector kit	40 MG/0.4 ML	1	Kit	180	DAYS			005970 49540 ; 005970 57540;
Cyltezo starter package for psoriasis/uveitis	adalimumab-adbm auto-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS			005970 37523 ; 005970 54544;
Enbrel	Etanercept Subcutaneous Inj 25 mg/0.5ml	25 MG/0.5 ML	4	Vials	28	DAYS			
Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML	25 MG/0.5 ML	4	Syringes	28	DAYS			
Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 50 MG/ML	50 MG/ML	4	Syringes	28	DAYS			
Enbrel mini	Etanercept Subcutaneous Solution Cartridge 50 MG/ML	50 MG/ML	4	Cartridges	28	DAYS			
Enbrel sureclick	Etanercept Subcutaneous Solution Auto-injector 50 MG/ML	50 MG/ML	4	Pens	28	DAYS			
Entyvio pen	vedolizumab soln pen-injector 108 mg/0.68ml	108 MG/0.68 ML	2	Pens	28	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Hadlima	adalimumab-bwvd soln prefilled syringe	40 MG/0.4 ML	2	Syringes	28	DAYS			
Hadlima	adalimumab-bwvd soln prefilled syringe	40 MG/0.8 ML	2	Syringes	28	DAYS			
Hadlima pushtouch	adalimumab-bwvd soln auto-injector	40 MG/0.4 ML	2	Pens	28	DAYS			
Hadlima pushtouch	adalimumab-bwvd soln auto-injector	40 MG/0.8 ML	2	Pens	28	DAYS			
Humira	Adalimumab Prefilled Syringe Kit 10 MG/0.1ML	10 MG/0.1 ML	2	Syringes	28	DAYS			
Humira	Adalimumab Prefilled Syringe Kit 20 MG/0.2ML	20 MG/0.2 ML	2	Syringes	28	DAYS			
Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.4ML	40 MG/0.4 ML	2	Syringes	28	DAYS			
Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.8ML	40 MG/0.8 ML	2	Syringes	28	DAYS			
Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML	80 MG/0.8 ML	1	Kit	180	DAYS			
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			
Humira pen	adalimumab auto-injector kit	40 MG/0.8 ML	2	Pens	28	DAYS			000744 33902;
Humira pen	adalimumab auto-injector kit	80 MG/0.8 ML	2	Pens	28	DAYS			000740 12402;8 345701 2402
Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4 ML	2	Pens	28	DAYS			
Humira pen-cd/uc/hs start	adalimumab auto-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS			000744 33906;
Humira pen-cd/uc/hs start	adalimumab auto-injector kit	80 MG/0.8 ML	1	Kit	180	DAYS			000740 12403;
Humira pen-pediatric uc s	adalimumab auto-injector kit	80 MG/0.8 ML	1	Kit	180	DAYS			000740 12404;
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			
Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.8 ML	2	Pens	28	DAYS			
Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.8 ML	2	Syringes	28	DAYS			
Hyrimoz crohn's disease a	adalimumab-adaz soln auto-injector	80 MG/0.8 ML	1	Kit	180	DAYS			613140 45436

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Hyrimoz pediatric crohn's	adalimumab-adaz soln prefilled syr	80 MG/0.8 ML & 40MG/0.4ML	1	Kit	180	DAYS			
Hyrimoz pediatric crohns	adalimumab-adaz soln prefilled syringe	80 MG/0.8 ML	1	Kit	180	DAYS			
Hyrimoz plaque psoriasis ; Hyrimoz plaque psoriasis/	adalimumab-adaz soln auto-injector	80 MG/0.8 ML & 40MG/0.4ML	1	Kit	180	DAYS			
Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8 ML	3	Pens	180	DAYS			834570 11301
Kevzara	Sarilumab Subcutaneous Soln Prefilled Syringe 150 MG/1.14ML	150 MG/1.14 ML	2	Syringes	28	DAYS			
Kevzara	Sarilumab Subcutaneous Soln Prefilled Syringe 200 MG/1.14ML	200 MG/1.14 ML	2	Syringes	28	DAYS			
Kevzara	Sarilumab Subcutaneous Solution Auto-injector 150 MG/1.14ML	150 MG/1.14 ML	2	Pens	28	DAYS			
Kevzara	Sarilumab Subcutaneous Solution Auto-injector 200 MG/1.14ML	200 MG/1.14 ML	2	Pens	28	DAYS			
Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67 ML	28	Syringes	28	DAYS			
Kineret	Anakinra Subcutaneous Soln Prefilled Syringe 100 MG/0.67ML	100 MG/0.67 ML	28	Syringes	28	DAYS			
Leqselvi	deuruxolitinib phosphate tab	8 MG	60	Tablets	30	DAYS			
Litfulo	ritlecitinib tosylate cap	50 MG	28	Capsules	28	DAYS			
Olumiant	baricitinib tab	1 MG ; 2 MG ; 4 MG	30	Tablets	30	DAYS			
OmvoH	mirikizumab-mrkz subcutaneous auto-inj	100 MG/ML & 200 MG/2ML	2	Pens	28	DAYS			
OmvoH	mirikizumab-mrkz subcutaneous pref syr	100 MG/ML & 200 MG/2ML	2	Syringes	28	DAYS			
OmvoH	mirikizumab-mrkz subcutaneous sol prefill syringe	100 MG/ML	2	Syringes	28	DAYS			
OmvoH	mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML	2	Pens	28	DAYS			
Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML	125 MG/ML	4	Syringes	28	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML	50 MG/0.4 ML	4	Syringes	28	DAYS			
Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7 ML	4	Syringes	28	DAYS			
Orencia clickject	Abatacept Subcutaneous Soln Auto-Injector 125 MG/ML	125 MG/ML	4	Pens	28	DAYS			
Otulf	ustekinumab-aauz soln prefilled syringe	45 MG/0.5 ML	1	Syringe	84	DAYS			
Otulf	ustekinumab-aauz soln prefilled syringe	90 MG/ML	1	Syringe	56	DAYS			
Pyzchiva ; Ustekinumab-ttwe	ustekinumab-ttwe soln prefilled syringe	45 MG/0.5 ML	1	Syringe	84	DAYS			
Pyzchiva ; Ustekinumab-ttwe	ustekinumab-ttwe soln prefilled syringe	90 MG/ML	1	Syringe	56	DAYS			
Rinvoq	Upadacitinib Tab ER	45 MG	84	Tablets	365	DAYS			
Rinvoq	Upadacitinib Tab ER 24HR 15 MG	15 MG	30	Tablets	30	DAYS			
Rinvoq lq	upadacitinib oral soln	1 MG/ML	360	mLs	30	DAYS			
Selarsdi ; Ustekinumab-aekn	ustekinumab-aekn soln prefilled syringe	45 MG/0.5 ML	1	Syringe	84	DAYS			
Selarsdi ; Ustekinumab-aekn	ustekinumab-aekn soln prefilled syringe	90 MG/ML	1	Syringe	56	DAYS			
Siliq	Brodalumab Subcutaneous Soln Prefilled Syringe 210 MG/1.5ML	210 MG/1.5 ML	2	Syringes	28	DAYS			
Simlandi	adalimumab-ryvk prefilled syringe kit	20 MG/0.2 ML	2	Syringes	28	DAYS			
Simlandi	adalimumab-ryvk prefilled syringe kit	80 MG/0.8 ML	2	Syringes	28	DAYS			
Simlandi 1-pen kit	adalimumab-ryvk auto-injector kit	80 MG/0.8 ML	2	Pens	28	DAYS			
Simponi	Golimumab Subcutaneous Soln Auto-injector 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS			
Simponi	Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML	50 MG/0.5 ML	1	Syringe	28	DAYS			
Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS			
Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML	50 MG/0.5 ML	1	Syringe	28	DAYS			
Skyrizi	Risankizumab-rzaa Soln Prefilled Syringe	150 MG/ML	1	Syringe	84	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2 ML	1	Cartridge	56	DAYS			
Skyrizi pen	Risankizumab-rzaa Soln Auto-injector	150 MG/ML	1	Pen	84	DAYS			
Sotyktu	Deucravacitinib Tab	6 MG	30	Tablets	30	DAYS			
Stelara ; Ustekinumab	Ustekinumab Inj 45 MG/0.5ML	45 MG/0.5 ML	1	Vial	84	DAYS			
Stelara ; Ustekinumab	Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML	45 MG/0.5 ML	1	Syringe	84	DAYS			
Stelara ; Ustekinumab	Ustekinumab Soln Prefilled Syringe 90 MG/ML	90 MG/ML	1	Syringe	56	DAYS			
Steqeyma	ustekinumab-stba soln prefilled syringe	45 MG/0.5 ML	1	Syringe	84	DAYS			
Steqeyma	ustekinumab-stba soln prefilled syringe	90 MG/ML	1	Syringe	56	DAYS			
Taltz	Ixekizumab Subcutaneous Soln Auto-injector 80 MG/ML	80 MG/ML	1	Syringe	28	DAYS			
Taltz	ixekizumab subcutaneous soln prefilled syringe	20 MG/0.25 ML	1	Syringe	28	DAYS			
Taltz	ixekizumab subcutaneous soln prefilled syringe	40 MG/0.5 ML	1	Syringe	28	DAYS			
Taltz	Ixekizumab Subcutaneous Soln Prefilled Syringe 80 MG/ML	80 MG/ML	1	Syringe	28	DAYS			
Tremfya	guselkumab soln auto-injector	200 MG/2ML	1	Pen	28	DAYS			578940 65101 ; 578940 65102;
Tremfya	guselkumab soln prefilled syringe	200 MG/2ML	1	Syringe	28	DAYS			
Tremfya	Guselkumab Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	56	DAYS			
Tremfya ; Tremfya pen	Guselkumab Soln Pen-Injector 100 MG/ML	100 MG/ML	1	Pen	56	DAYS			
Tremfya induction pack fo	guselkumab soln auto-injector	200 MG/2ML	3	Kits	180	DAYS			578940 65104;
Tyenne	tocilizumab-aazg subcutaneous soln auto-inj	162 MG/0.9 ML	4	Pens	28	DAYS			
Tyenne	tocilizumab-aazg subcutaneous soln pref syr	162 MG/0.9 ML	4	Syringes	28	DAYS			
Velsipity	etrasimod arginine tab	2 MG	30	Tablets	30	DAYS			
Wezlana	ustekinumab-auub inj	45 MG/0.5 ML	1	Vial	84	DAYS			
Wezlana	ustekinumab-auub soln prefilled syringe	45 MG/0.5 ML	1	Syringe	84	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Wezlana	ustekinumab-auub soln prefilled syringe	90 MG/ML	1	Syringe	56	DAYS			
Xeljanz	Tofacitinib Citrate Oral Soln	1 MG/ML	240	mLs	30	DAYS			
Xeljanz	Tofacitinib Citrate Tab 10 MG (Base Equivalent)	10 MG	240	Tablets	365	DAYS			
Xeljanz	Tofacitinib Citrate Tab 5 MG (Base Equivalent)	5 MG	60	Tablets	30	DAYS			
Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 11 MG (Base Equivalent)	11 MG	30	Tablets	30	DAYS			
Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 22 MG (Base Equivalent)	22 MG	120	Tablets	365	DAYS			
Yesintek	ustekinumab-kfce soln prefilled syringe	45 MG/0.5 ML	1	Syringe	84	DAYS			
Yesintek	ustekinumab-kfce soln prefilled syringe	90 MG/ML	1	Syringe	56	DAYS			
Yesintek	ustekinumab-kfce subcutaneous soln	45 MG/0.5 ML	1	Vial	84	DAYS			
Yusimry	adalimumab-aqvh soln pen-injector 40 mg/0.8ml	40 MG/0.8 ML	2	Pens	28	DAYS			
Zymfentra 1-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	2	Pens	28	DAYS			726060 02501
Zymfentra 2-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	2	Pens	28	DAYS			726060 02502
Zymfentra 2-syringe	infliximab-dyyb soln prefilled syringe kit	120 MG/ML	2	Syringes	28	DAYS			
Rinvoq	Upadacitinib Tab ER	30 MG	30	Tablets	30	DAYS			
Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4 ML	1	Cartridge	56	DAYS			

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Abrilada	adalimumab-afzb prefilled syringe kit	20 MG/0.4ML ; 40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Abrilada 1-pen kit ; Abrilada 2-pen kit	adalimumab-afzb auto-injector kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9ML	Commercial ; HIM ; ResultsRx
Actemra actpen	tocilizumab subcutaneous soln auto-injector	162 MG/0.9ML	Commercial ; HIM ; ResultsRx
Adalimumab-aacf (2 pen) ; Adalimumab-aacf starter p ; Idacio (2 pen) ; Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-aacf (2 syring ; Idacio (2 syringe)	adalimumab-aacf prefilled syringe kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-aaty 1-pen kit ; Adalimumab-aaty 2-pen kit ; Adalimumab-aaty cd/uc/hs ; 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	Commercial ; HIM ; ResultsRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Adalimumab-aaty 2-syringe ; Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	20 MG/0.2ML ; 40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Adalimumab-adaz ; Hyrimoz ; Hyrimoz crohn's disease a ; Hyrimoz plaque psoriasis ; 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	Commercial ; HIM ; ResultsRx
Adalimumab-adaz ; Hyrimoz ; Hyrimoz pediatric crohn's ; Hyrimoz pediatric crohns	adalimumab-adaz soln prefilled syr ; adalimumab-adaz soln prefilled syringe	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	Commercial ; HIM ; ResultsRx
Adalimumab-adbm ; Adalimumab-adbm crohns/uc ; Adalimumab-adbm psoriasis ; Adalimumab-adbm starter p ; Cyltezo ; Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.4ML ; 40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-adbm ; Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2ML ; 20 MG/0.4ML ; 40 MG/0.4ML ; 40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-fkjp ; Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-fkjp ; Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4ML ; 40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-ryvk (2 pen) ; Simlandi 1-pen kit ; Simlandi 2-pen kit	adalimumab-ryvk auto-injector kit	40 MG/0.4ML ; 80 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-ryvk ; Simlandi	adalimumab-ryvk prefilled syringe kit	20 MG/0.2ML ; 40 MG/0.4ML ; 80 MG/0.8ML	Commercial ; HIM ; ResultsRx
Amjevita	adalimumab-atto soln auto-injector	40 MG/0.4ML ; 40 MG/0.8ML ; 80 MG/0.8ML	Commercial ; HIM ; ResultsRx
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	Commercial ; HIM ; ResultsRx
Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	160 MG/ML ; 320 MG/2ML	Commercial ; HIM ; ResultsRx
Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	160 MG/ML ; 320 MG/2ML	Commercial ; HIM ; ResultsRx
Cimzia ; Cimzia starter kit	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	Commercial ; HIM ; ResultsRx
Cosentyx	secukinumab subcutaneous pref syr ; secukinumab subcutaneous soln prefilled syringe	150 MG/ML ; 75 MG/0.5ML	Commercial ; HIM ; ResultsRx
Cosentyx sensoready pen ; Cosentyx unoready	secukinumab subcutaneous auto-inj ; secukinumab subcutaneous soln auto-injector	150 MG/ML ; 300 MG/2ML	Commercial ; HIM ; ResultsRx
Enbrel ; Enbrel mini ; Enbrel sureclick	etanercept subcutaneous inj ; etanercept subcutaneous soln prefilled syringe ; etanercept subcutaneous solution auto-injector ; etanercept subcutaneous solution cartridge	25 MG/0.5ML ; 50 MG/ML	Commercial ; HIM ; ResultsRx
Entyvio pen	vedolizumab soln auto-injector	108 MG/0.68ML	Commercial ; HIM ; ResultsRx
Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4ML ; 40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4ML ; 40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Humira ; Humira pediatric crohns d ; Humira pen ; Humira pen-cd/uc/hs start ; Humira pen-pediatric uc s ; Humira pen-ps/uv starter	adalimumab auto-injector kit ; 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	Commercial ; HIM ; ResultsRx
Kevzara	sarilumab subcutaneous soln prefilled syringe ; sarilumab subcutaneous solution auto-injector	150 MG/1.14ML ; 200 MG/1.14ML	Commercial ; HIM ; ResultsRx
Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67ML	Commercial ; HIM ; ResultsRx
Leqselvi	deuruxolitinib phosphate tab	8 MG	Commercial ; HIM ; ResultsRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Litfulo	ritlecitinib tosylate cap	50 MG	Commercial ; HIM ; ResultsRx
Olumiant	baricitinib tab	1 MG ; 2 MG ; 4 MG	Commercial ; HIM ; ResultsRx
OmvoH	mirikizumab-mrkz subcutaneous auto-inj ; mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML ; 100 MG/ML & 200 MG/2ML	Commercial ; HIM ; ResultsRx
OmvoH	mirikizumab-mrkz subcutaneous pref syr ; mirikizumab-mrkz subcutaneous sol prefill syringe	100 MG/ML ; 100 MG/ML & 200 MG/2ML	Commercial ; HIM ; ResultsRx
Orencia	abatacept subcutaneous soln prefilled syringe	125 MG/ML ; 50 MG/0.4ML ; 87.5 MG/0.7ML	Commercial ; HIM ; ResultsRx
Orencia clickject	abatacept subcutaneous soln auto-injector	125 MG/ML	Commercial ; HIM ; ResultsRx
Otulf	ustekinumab-aaaz soln prefilled syringe	45 MG/0.5ML ; 90 MG/ML	Commercial ; HIM ; ResultsRx
Pyzchiva ; Ustekinumab-ttwe	ustekinumab-ttwe soln prefilled syringe	45 MG/0.5ML ; 90 MG/ML	Commercial ; HIM ; ResultsRx
Rinvoq	upadacitinib tab er	15 MG ; 30 MG ; 45 MG	Commercial ; HIM ; ResultsRx
Rinvoq lq	upadacitinib oral soln	1 MG/ML	Commercial ; HIM ; ResultsRx
Selarsdi ; Ustekinumab-aekn	ustekinumab-aekn soln prefilled syringe	45 MG/0.5ML ; 90 MG/ML	Commercial ; HIM ; ResultsRx
Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5ML	Commercial ; HIM ; ResultsRx
Simponi	Golimumab Subcutaneous Soln Auto-injector 100 MG/ML	100 MG/ML	Commercial ; HIM ; ResultsRx
Simponi	Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML	50 MG/0.5ML	Commercial ; HIM ; ResultsRx
Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML	100 MG/ML	Commercial ; HIM ; ResultsRx
Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML	50 MG/0.5ML	Commercial ; HIM ; ResultsRx
Skyrizi	risankizumab-rzaa subcutaneous soln cartridge	180 MG/1.2ML ; 360 MG/2.4ML	Commercial ; HIM ; ResultsRx
Skyrizi ; Skyrizi pen	risankizumab-rzaa soln auto-injector ; risankizumab-rzaa soln prefilled syringe	150 MG/ML	Commercial ; HIM ; ResultsRx
Sotyktu	deucravacitinib tab	6 MG	Commercial ; HIM ; ResultsRx
Stelara ; Ustekinumab	ustekinumab inj ; ustekinumab soln prefilled syringe	45 MG/0.5ML ; 90 MG/ML	Commercial ; HIM ; ResultsRx
Steqeyma	ustekinumab-stba soln prefilled syringe	45 MG/0.5ML ; 90 MG/ML	Commercial ; HIM ; ResultsRx
Taltz	ixekizumab subcutaneous soln auto-injector ; ixekizumab subcutaneous soln prefilled syringe	20 MG/0.25ML ; 40 MG/0.5ML ; 80 MG/ML	Commercial ; HIM ; ResultsRx
Tremfya	guselkumab soln prefilled syringe	200 MG/2ML	Commercial ; HIM ; ResultsRx
Tremfya	guselkumab soln prefilled syringe	100 MG/ML	Commercial ; HIM ; ResultsRx
Tremfya ; Tremfya induction pack fo	guselkumab soln auto-injector	200 MG/2ML	Commercial ; HIM ; ResultsRx
Tremfya ; Tremfya pen	guselkumab soln auto-injector	100 MG/ML	Commercial ; HIM ; ResultsRx
Tyenne	tocilizumab-aazg subcutaneous soln auto-inj	162 MG/0.9ML	Commercial ; HIM ; ResultsRx
Tyenne	tocilizumab-aazg subcutaneous soln pref syr	162 MG/0.9ML	Commercial ; HIM ; ResultsRx
Velsipity	etrasimod arginine tab	2 MG	Commercial ; HIM ; ResultsRx
Wezlana	ustekinumab-auub inj ; ustekinumab-auub soln prefilled syringe	45 MG/0.5ML ; 90 MG/ML	Commercial ; HIM ; ResultsRx



Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Xeljanz ; Xeljanz xr	tofacitinib citrate oral soln ; tofacitinib citrate tab ; tofacitinib citrate tab er	1 MG/ML ; 10 MG ; 11 MG ; 22 MG ; 5 MG	Commercial ; HIM ; ResultsRx
Yesintek	ustekinumab-kfce soln prefilled syringe ; ustekinumab-kfce subcutaneous soln	45 MG/0.5ML ; 90 MG/ML	Commercial ; HIM ; ResultsRx
Yusimry	adalimumab-aqvh soln auto-injector	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Zymfentra 1-pen ; Zymfentra 2-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	Commercial ; HIM ; ResultsRx
Zymfentra 2-syringe	infliximab-dyyb soln prefilled syringe kit	120 MG/ML	Commercial ; HIM ; ResultsRx

## CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
		40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Abrilada	adalimumab-afzb prefilled syringe kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Abrilada	adalimumab-afzb prefilled syringe kit	20 MG/0.4ML	Commercial ; HIM ; ResultsRx
Abrilada 1-pen kit ; Abrilada 2-pen kit	adalimumab-afzb auto-injector kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Actemra	Tocilizumab Subcutaneous Soln Prefilled Syringe 162 MG/0.9ML	162 MG/0.9ML	Commercial ; HIM ; ResultsRx
Actemra actpen	Tocilizumab Subcutaneous Soln Auto-injector 162 MG/0.9ML	162 MG/0.9ML	Commercial ; HIM ; ResultsRx
Adalimumab-aacf (2 pen) ; Idacio (2 pen)	adalimumab-aacf auto-injector kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-aacf (2 syringe) ; Idacio (2 syringe)	adalimumab-aacf prefilled syringe kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-aacf starter p ; Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-aacf starter p ; Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-aaty 1-pen kit ; Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Adalimumab-aaty 1-pen kit ; Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	80 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-aaty 2-pen kit ; Yuflyma 2-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Adalimumab-aaty 2-syringe ; Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Adalimumab-aaty 2-syringe ; Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	20 MG/0.2ML	Commercial ; HIM ; ResultsRx
Adalimumab-aaty cd/uc/hs ; Yuflyma cd/uc/hs starter	adalimumab-aaty auto-injector kit	80 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-adaz ; Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Adalimumab-adaz ; Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Adalimumab-adaz ; Hyrimoz	adalimumab-adaz soln prefilled syringe	20 MG/0.2ML	Commercial ; HIM ; ResultsRx
Adalimumab-adaz ; Hyrimoz	adalimumab-adaz soln prefilled syringe	10 MG/0.1ML	Commercial ; HIM ; ResultsRx
Adalimumab-adaz ; Hyrimoz ; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-adbm ; Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Adalimumab-adbm ; Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-adbm ; Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Adalimumab-adbm ; Cyltezo	adalimumab-adbm prefilled syringe kit	20 MG/0.4ML	Commercial ; HIM ; ResultsRx
Adalimumab-adbm ; Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2ML	Commercial ; HIM ; ResultsRx
Adalimumab-adbm ; Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Adalimumab-fkjp ; Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-fkjp ; Hulio	adalimumab-fkjp prefilled syringe kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Adalimumab-fkjp ; Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4ML	Commercial ; HIM ; ResultsRx
Adalimumab-ryvk (2 pen) ; Simlandi 1-pen kit ; Simlandi 2-pen kit	adalimumab-ryvk auto-injector kit	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Adalimumab-ryvk ; Simlandi	adalimumab-ryvk prefilled syringe kit	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Amjevita	adalimumab-atto soln auto-injector	80 MG/0.8ML	Commercial ; HIM ; ResultsRx
Amjevita	adalimumab-atto soln auto-injector	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.2ML	Commercial ; HIM ; ResultsRx
Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2ML	Commercial ; HIM ; ResultsRx
Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4ML	Commercial ; HIM ; ResultsRx
Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	320 MG/2ML	Commercial ; HIM ; ResultsRx
Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	160 MG/ML	Commercial ; HIM ; ResultsRx
Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	320 MG/2ML	Commercial ; HIM ; ResultsRx
Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	160 MG/ML	Commercial ; HIM ; ResultsRx
Cimzia	certolizumab pegol prefilled syringe kit	200 MG/ML	Commercial ; HIM ; ResultsRx
Cimzia starter kit	certolizumab pegol prefilled syringe kit	200 MG/ML	Commercial ; HIM ; ResultsRx
Cosentyx	Secukinumab Subcutaneous Pref Syr 150 MG/ML (300 MG Dose)	150 MG/ML	Commercial ; HIM ; ResultsRx
Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe	75 MG/0.5ML	Commercial ; HIM ; ResultsRx
Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML	150 MG/ML	Commercial ; HIM ; ResultsRx
Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose)	150 MG/ML	Commercial ; HIM ; ResultsRx
Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	Commercial ; HIM ; ResultsRx
Cosentyx unoready	secukinumab subcutaneous soln auto-injector	300 MG/2ML	Commercial ; HIM ; ResultsRx
Cyltezo starter package for Crohn's disease, ulcerative colitis, or hidradenitis	adalimumab-adbm auto-injector kit	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Cyltezo starter package for Crohn's disease, ulcerative colitis, or hidradenitis	adalimumab-adbm auto-injector kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Cyltezo starter package for psoriasis/uveitis	adalimumab-adbm auto-injector kit	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Cyltezo starter package for psoriasis/uveitis	adalimumab-adbm auto-injector kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Enbrel	Etanercept Subcutaneous Inj 25 mg/0.5ml	25 MG/0.5ML	Commercial ; HIM ; ResultsRx
Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML	25 MG/0.5ML	Commercial ; HIM ; ResultsRx
Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 50 MG/ML	50 MG/ML	Commercial ; HIM ; ResultsRx
Enbrel mini	Etanercept Subcutaneous Solution Cartridge 50 MG/ML	50 MG/ML	Commercial ; HIM ; ResultsRx
Enbrel sureclick	Etanercept Subcutaneous Solution Auto-injector 50 MG/ML	50 MG/ML	Commercial ; HIM ; ResultsRx
Entyvio pen	vedolizumab soln pen-injector 108 mg/0.68ml	108 MG/0.68ML	Commercial ; HIM ; ResultsRx
Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Humira	Adalimumab Prefilled Syringe Kit 10 MG/0.1ML	10 MG/0.1ML	Commercial ; HIM ; ResultsRx
Humira	Adalimumab Prefilled Syringe Kit 20 MG/0.2ML	20 MG/0.2ML	Commercial ; HIM ; ResultsRx
Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.4ML	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.8ML	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML	80 MG/0.8ML	Commercial ; HIM ; ResultsRx
Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	Commercial ; HIM ; ResultsRx
Humira pen	adalimumab auto-injector kit	80 MG/0.8ML	Commercial ; HIM ; ResultsRx
Humira pen	adalimumab auto-injector kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4ML	Commercial ; HIM ; ResultsRx
Humira pen-cd/uc/hs start	adalimumab auto-injector kit	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Humira pen-cd/uc/hs start	adalimumab auto-injector kit	80 MG/0.8ML	Commercial ; HIM ; ResultsRx
Humira pen-pediatric uc s	adalimumab auto-injector kit	80 MG/0.8ML	Commercial ; HIM ; ResultsRx
Humira pen-ps/uv starter	Adalimumab Pen-injector Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	Commercial ; HIM ; ResultsRx
Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Hyrimoz crohn's disease a	adalimumab-adaz soln auto-injector	80 MG/0.8ML	Commercial ; HIM ; ResultsRx
Hyrimoz pediatric crohn's	adalimumab-adaz soln prefilled syr	80 MG/0.8ML & 40MG/0.4ML	Commercial ; HIM ; ResultsRx
Hyrimoz pediatric crohns	adalimumab-adaz soln prefilled syringe	80 MG/0.8ML	Commercial ; HIM ; ResultsRx
Hyrimoz plaque psoriasis ; Hyrimoz plaque psoriasis/	adalimumab-adaz soln auto-injector	80 MG/0.8ML & 40MG/0.4ML	Commercial ; HIM ; ResultsRx
Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	Commercial ; HIM ; ResultsRx
Kevzara	Sarilumab Subcutaneous Soln Prefilled Syringe 150 MG/1.14ML	150 MG/1.14ML	Commercial ; HIM ; ResultsRx
Kevzara	Sarilumab Subcutaneous Soln Prefilled Syringe 200 MG/1.14ML	200 MG/1.14ML	Commercial ; HIM ; ResultsRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Kevzara	Sarilumab Subcutaneous Solution Auto-injector 150 MG/1.14ML	150 MG/1.14ML	Commercial ; HIM ; ResultsRx
Kevzara	Sarilumab Subcutaneous Solution Auto-injector 200 MG/1.14ML	200 MG/1.14ML	Commercial ; HIM ; ResultsRx
Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67ML	Commercial ; HIM ; ResultsRx
Kineret	Anakinra Subcutaneous Soln Prefilled Syringe 100 MG/0.67ML	100 MG/0.67ML	Commercial ; HIM ; ResultsRx
Leqselvi	deuruxolitinib phosphate tab	8 MG	Commercial ; HIM ; ResultsRx
Litfulo	ritlecitinib tosylate cap	50 MG	Commercial ; HIM ; ResultsRx
Olumiant	baricitinib tab	1 MG ; 2 MG ; 4 MG	Commercial ; HIM ; ResultsRx
OmvoH	mirikizumab-mrkz subcutaneous auto-inj	100 MG/ML & 200 MG/2ML	Commercial ; HIM ; ResultsRx
OmvoH	mirikizumab-mrkz subcutaneous pref syr	100 MG/ML & 200 MG/2ML	Commercial ; HIM ; ResultsRx
OmvoH	mirikizumab-mrkz subcutaneous sol prefill syringe	100 MG/ML	Commercial ; HIM ; ResultsRx
OmvoH	mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML	Commercial ; HIM ; ResultsRx
Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML	125 MG/ML	Commercial ; HIM ; ResultsRx
Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML	50 MG/0.4ML	Commercial ; HIM ; ResultsRx
Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7ML	Commercial ; HIM ; ResultsRx
Orencia clickject	Abatacept Subcutaneous Soln Auto-Injector 125 MG/ML	125 MG/ML	Commercial ; HIM ; ResultsRx
Otulf	ustekinumab-aaaz soln prefilled syringe	90 MG/ML	Commercial ; HIM ; ResultsRx
Otulf	ustekinumab-aaaz soln prefilled syringe	45 MG/0.5ML	Commercial ; HIM ; ResultsRx
Pyzchiva ; Ustekinumab-ttwe	ustekinumab-ttwe soln prefilled syringe	90 MG/ML	Commercial ; HIM ; ResultsRx
Pyzchiva ; Ustekinumab-ttwe	ustekinumab-ttwe soln prefilled syringe	45 MG/0.5ML	Commercial ; HIM ; ResultsRx
Rinvoq	Upadacitinib Tab ER	45 MG	Commercial ; HIM ; ResultsRx
Rinvoq	Upadacitinib Tab ER 24HR 15 MG	15 MG	Commercial ; HIM ; ResultsRx
Rinvoq lq	upadacitinib oral soln	1 MG/ML	Commercial ; HIM ; ResultsRx
Selarsdi ; Ustekinumab-aekn	ustekinumab-aekn soln prefilled syringe	90 MG/ML	Commercial ; HIM ; ResultsRx
Selarsdi ; Ustekinumab-aekn	ustekinumab-aekn soln prefilled syringe	45 MG/0.5ML	Commercial ; HIM ; ResultsRx
Siliq	Brodalumab Subcutaneous Soln Prefilled Syringe 210 MG/1.5ML	210 MG/1.5ML	Commercial ; HIM ; ResultsRx
Simlandi	adalimumab-ryvk prefilled syringe kit	20 MG/0.2ML	Commercial ; HIM ; ResultsRx
Simlandi	adalimumab-ryvk prefilled syringe kit	80 MG/0.8ML	Commercial ; HIM ; ResultsRx
Simlandi 1-pen kit	adalimumab-ryvk auto-injector kit	80 MG/0.8ML	Commercial ; HIM ; ResultsRx
Simponi	Golimumab Subcutaneous Soln Auto-injector 100 MG/ML	100 MG/ML	Commercial ; HIM ; ResultsRx
Simponi	Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML	50 MG/0.5ML	Commercial ; HIM ; ResultsRx
Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML	100 MG/ML	Commercial ; HIM ; ResultsRx
Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML	50 MG/0.5ML	Commercial ; HIM ; ResultsRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Skyrizi	Risankizumab-rzaa Soln Prefilled Syringe	150 MG/ML	Commercial ; HIM ; ResultsRx
Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2ML	Commercial ; HIM ; ResultsRx
Skyrizi pen	Risankizumab-rzaa Soln Auto-injector	150 MG/ML	Commercial ; HIM ; ResultsRx
Sotyktu	Deucravacitinib Tab	6 MG	Commercial ; HIM ; ResultsRx
Stelara ; Ustekinumab	Ustekinumab Inj 45 MG/0.5ML	45 MG/0.5ML	Commercial ; HIM ; ResultsRx
Stelara ; Ustekinumab	Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML	45 MG/0.5ML	Commercial ; HIM ; ResultsRx
Stelara ; Ustekinumab	Ustekinumab Soln Prefilled Syringe 90 MG/ML	90 MG/ML	Commercial ; HIM ; ResultsRx
Steqeyma	ustekinumab-stba soln prefilled syringe	90 MG/ML	Commercial ; HIM ; ResultsRx
Steqeyma	ustekinumab-stba soln prefilled syringe	45 MG/0.5ML	Commercial ; HIM ; ResultsRx
Taltz	Ixekizumab Subcutaneous Soln Auto-injector 80 MG/ML	80 MG/ML	Commercial ; HIM ; ResultsRx
Taltz	ixekizumab subcutaneous soln prefilled syringe	20 MG/0.25ML	Commercial ; HIM ; ResultsRx
Taltz	ixekizumab subcutaneous soln prefilled syringe	40 MG/0.5ML	Commercial ; HIM ; ResultsRx
Taltz	Ixekizumab Subcutaneous Soln Prefilled Syringe 80 MG/ML	80 MG/ML	Commercial ; HIM ; ResultsRx
Tremfya	guselkumab soln auto-injector	200 MG/2ML	Commercial ; HIM ; ResultsRx
Tremfya	guselkumab soln prefilled syringe	200 MG/2ML	Commercial ; HIM ; ResultsRx
Tremfya	Guselkumab Soln Prefilled Syringe 100 MG/ML	100 MG/ML	Commercial ; HIM ; ResultsRx
Tremfya ; Tremfya pen	Guselkumab Soln Pen-Injector 100 MG/ML	100 MG/ML	Commercial ; HIM ; ResultsRx
Tremfya induction pack fo	guselkumab soln auto-injector	200 MG/2ML	Commercial ; HIM ; ResultsRx
Tyenne	tocilizumab-aazg subcutaneous soln auto-inj	162 MG/0.9ML	Commercial ; HIM ; ResultsRx
Tyenne	tocilizumab-aazg subcutaneous soln pref syr	162 MG/0.9ML	Commercial ; HIM ; ResultsRx
Velsipity	etrasimod arginine tab	2 MG	Commercial ; HIM ; ResultsRx
Wezlana	ustekinumab-auub inj	45 MG/0.5ML	Commercial ; HIM ; ResultsRx
Wezlana	ustekinumab-auub soln prefilled syringe	90 MG/ML	Commercial ; HIM ; ResultsRx
Wezlana	ustekinumab-auub soln prefilled syringe	45 MG/0.5ML	Commercial ; HIM ; ResultsRx
Xeljanz	Tofacitinib Citrate Oral Soln	1 MG/ML	Commercial ; HIM ; ResultsRx
Xeljanz	Tofacitinib Citrate Tab 10 MG (Base Equivalent)	10 MG	Commercial ; HIM ; ResultsRx
Xeljanz	Tofacitinib Citrate Tab 5 MG (Base Equivalent)	5 MG	Commercial ; HIM ; ResultsRx
Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 11 MG (Base Equivalent)	11 MG	Commercial ; HIM ; ResultsRx
Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 22 MG (Base Equivalent)	22 MG	Commercial ; HIM ; ResultsRx
Yesintek	ustekinumab-kfce soln prefilled syringe	90 MG/ML	Commercial ; HIM ; ResultsRx
Yesintek	ustekinumab-kfce soln prefilled syringe	45 MG/0.5ML	Commercial ; HIM ; ResultsRx
Yesintek	ustekinumab-kfce subcutaneous soln	45 MG/0.5ML	Commercial ; HIM ; ResultsRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Yusimry	adalimumab-aqvh soln pen-injector 40 mg/0.8ml	40 MG/0.8ML	Commercial ; HIM ; ResultsRx
Zymfentra 1-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	Commercial ; HIM ; ResultsRx
Zymfentra 2-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	Commercial ; HIM ; ResultsRx
Zymfentra 2-syringe	infliximab-dyyb soln prefilled syringe kit	120 MG/ML	Commercial ; HIM ; ResultsRx
Rinvoq	Upadacitinib Tab ER	30 MG	Commercial ; HIM ; ResultsRx
Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4ML	Commercial ; HIM ; ResultsRx

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval																												
1. Adalimumab and Adalimumab Biosimilars	<table> <tr> <th>Preferred Target Agent(s)</th><th>Non-Preferred Target Agent(s)</th></tr> <tr> <td><b>Adalimumab-aaty</b></td><td><b>Abrilada</b> (adalimumab-afzb)</td></tr> <tr> <td><b>Adalimumab-adaz</b></td><td><b>Adalimumab-aacf</b></td></tr> <tr> <td><b>Hadlima</b> (adalimumab-bwwd)</td><td><b>Adalimumab-adbm</b></td></tr> <tr> <td><b>Simlandi</b> (adalimumab-ryvk)</td><td><b>Adalimumab-fkjp</b></td></tr> <tr> <td></td><td><b>Adalimumab-ryvk</b></td></tr> <tr> <td></td><td><b>Amjevita</b> (adalimumab-atto)</td></tr> <tr> <td></td><td><b>Cyltezo</b> (adalimumab-adbm)</td></tr> <tr> <td></td><td><b>Hulio</b> (adalimumab-fkjp)</td></tr> <tr> <td></td><td><b>Humira</b> (adalimumab)</td></tr> <tr> <td></td><td><b>Hyrimoz</b> (adalimumab-adaz)</td></tr> <tr> <td></td><td><b>Idacio</b> (adalimumab-aacf)</td></tr> <tr> <td></td><td><b>Yuflyma</b> (adalimumab-aaty)</td></tr> <tr> <td></td><td><b>Yusimry</b> (adalimumab-aqvh)</td></tr> </table> <p><b>Initial Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>ONE of the following: <ol style="list-style-type: none"> <li>The requested agent is eligible for continuation of therapy AND ONE of the following:</li> </ol> </li> </ol> <div style="border: 1px solid black; padding: 5px; text-align: center;"> <b>Agents Eligible for Continuation of Therapy</b> </div>	Preferred Target Agent(s)	Non-Preferred Target Agent(s)	<b>Adalimumab-aaty</b>	<b>Abrilada</b> (adalimumab-afzb)	<b>Adalimumab-adaz</b>	<b>Adalimumab-aacf</b>	<b>Hadlima</b> (adalimumab-bwwd)	<b>Adalimumab-adbm</b>	<b>Simlandi</b> (adalimumab-ryvk)	<b>Adalimumab-fkjp</b>		<b>Adalimumab-ryvk</b>		<b>Amjevita</b> (adalimumab-atto)		<b>Cyltezo</b> (adalimumab-adbm)		<b>Hulio</b> (adalimumab-fkjp)		<b>Humira</b> (adalimumab)		<b>Hyrimoz</b> (adalimumab-adaz)		<b>Idacio</b> (adalimumab-aacf)		<b>Yuflyma</b> (adalimumab-aaty)		<b>Yusimry</b> (adalimumab-aqvh)
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Module	Clinical Criteria for Approval
	<div data-bbox="479 184 1174 919" style="border: 1px solid black; padding: 10px; margin-bottom: 20px;"> <p>All target agents EXCEPT the following are eligible for continuation of therapy:</p> <p>Abrilada</p> <p>Adalimumab-ryvk</p> <p>Amjevita</p> <p>Cyltezo, Adalimumab-adbm</p> <p>Hulio, Adalimumab-fkjp</p> <p>Humira</p> <p>Hyrimoz</p> <p>Idacio, Adalimumab-aacf</p> <p>Yuflyma</p> <p>Yusimry</p> </div> <ol style="list-style-type: none"> <li>1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days <b>OR</b></li> <li>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 <b>OR</b></li> </ol> <p>B. ALL of the following:</p> <ol style="list-style-type: none"> <li>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: <ol style="list-style-type: none"> <li>A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has ONE of the following: <ol style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has tried and had an inadequate response to ONE conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA after at least a 3-month duration of therapy <b>OR</b></li> <li>C. Has an intolerance or hypersensitivity to ONE conventional agent (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA <b>OR</b></li> </ol> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA <b>OR</b></li> <li>3. 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 <b>OR</b></li> </ol> </li> <li>B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following:</li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> <li>1. The patient has ONE of the following: <ol style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PsA <b>OR</b></li> </ol> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PsA <b>OR</b></li> <li>3. 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, vision loss], rapidly progressive) <b>OR</b></li> <li>4. 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) <b>OR</b></li> <li>5. 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 <b>OR</b></li> </ol> <p>C. The patient has a diagnosis of moderate to severe plaque psoriasis (PS) AND ONE of the following:</p> <ol style="list-style-type: none"> <li>1. The patient has ONE of the following: <ol style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS <b>OR</b></li> </ol> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS <b>OR</b></li> <li>3. 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) <b>OR</b></li> <li>4. 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, vision loss], rapidly progressive) <b>OR</b></li> <li>5. 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 <b>OR</b></li> </ol> <p>D. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following:</p> <ol style="list-style-type: none"> <li>1. The patient has ONE of the following: <ol style="list-style-type: none"> <li>A. 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 <b>OR</b></li> </ol> </li> </ol>



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	<ul style="list-style-type: none"> <li> <ul style="list-style-type: none"> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of CD <b>OR</b></li> </ul> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of CD <b>OR</b></li> <li>3. 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 <b>OR</b></li> <li>E. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ONE of the following: <ul style="list-style-type: none"> <li>1. The patient has ONE of the following: <ul style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of UC <b>OR</b></li> </ul> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of UC <b>OR</b></li> <li>3. The patient has severely active ulcerative colitis <b>OR</b></li> <li>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 UC <b>OR</b></li> </ul> </li> <li>F. The patient has a diagnosis of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following: <ul style="list-style-type: none"> <li>1. BOTH of the following: <ul style="list-style-type: none"> <li>A. ONE of the following: <ul style="list-style-type: none"> <li>1. The patient has ONE of the following: <ul style="list-style-type: none"> <li>A. Has tried and had an inadequate response to ONE oral corticosteroid used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis after at least a 2-week duration of therapy <b>OR</b></li> <li>B. Has tried and had an inadequate response to ONE periocular or intravitreal corticosteroid injection used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis <b>OR</b></li> <li>C. Has an intolerance or hypersensitivity to ONE oral corticosteroid or periocular/intravitreal corticosteroid injection used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis <b>OR</b></li> </ul> </li> <li>2. The patient has an FDA labeled contraindication to ALL oral corticosteroids and periocular/intravitreal corticosteroids used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis <b>AND</b></li> </ul> </li> <li>B. ONE of the following: <ul style="list-style-type: none"> <li>1. The patient has ONE of the following: <ul style="list-style-type: none"> <li>A. Has tried and had an inadequate response to ONE conventional systemic agent (i.e., azathioprine,</li> </ul> </li> </ul> </li> </ul> </li> </ul> </li> </ul>

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	<p>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 <b>OR</b></p> <p>B. Has an intolerance or hypersensitivity to ONE conventional systemic agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis <b>OR</b></p> <p>2. 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 <b>OR</b></p> <p>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 <b>OR</b></p> <p>G. The patient has a diagnosis of active ankylosing spondylitis (AS) AND ONE of the following:</p> <p>1. The patient has ONE of the following:</p> <p>A. Has tried and had an inadequate response to TWO different nonsteroidal anti-inflammatory drugs (NSAIDs) used in the treatment of AS after at least a 4-week TOTAL duration of therapy <b>OR</b></p> <p>B. Has tried and had an inadequate response to ONE NSAID used in the treatment of AS after at least a 4-week duration of therapy and an intolerance or hypersensitivity to ONE additional NSAID used in the treatment of AS <b>OR</b></p> <p>C. Has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of AS <b>OR</b></p> <p>2. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of AS <b>OR</b></p> <p>3. 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 <b>OR</b></p> <p>H. The patient has a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) AND ONE of the following:</p> <p>1. The patient has ONE of the following:</p> <p>A. 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 duration of therapy <b>OR</b></p> <p>B. Has tried and had an inadequate response to ONE NSAID used in the treatment of nr-axSpA after at least a 4-week duration of therapy and an intolerance or hypersensitivity to ONE additional NSAID used in the treatment of nr-axSpA <b>OR</b></p> <p>C. Has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of nr-axSpA <b>OR</b></p> <p>2. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of nr-axSpA <b>OR</b></p>

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	<ul style="list-style-type: none"> <li>3. 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 <b>OR</b></li> <li>I. The patient has a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) AND ONE of the following: <ul style="list-style-type: none"> <li>1. The patient has ONE of the following: <ul style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PJIA <b>OR</b></li> </ul> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PJIA <b>OR</b></li> <li>3. 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 <b>OR</b></li> </ul> </li> <li>J. The patient has a diagnosis of moderate to severe hidradenitis suppurativa (HS) AND ONE of the following: <ul style="list-style-type: none"> <li>1. The patient has ONE of the following: <ul style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of HS <b>OR</b></li> </ul> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of HS <b>OR</b></li> <li>3. 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 <b>OR</b></li> </ul> </li> <li>K. The patient has a diagnosis not mentioned previously <b>AND</b></li> <li>2. If the client has preferred agents, then ONE of the following (reference preferred agents table): <ul style="list-style-type: none"> <li>A. The requested agent is a preferred agent <b>OR</b></li> <li>B. The patient has ONE of the following (medical records required): <ul style="list-style-type: none"> <li>1. Has tried and had an inadequate response to THREE preferred agents after at least a 3-month duration of therapy per agent <b>OR</b></li> <li>2. Has tried and had an inadequate response to TWO preferred agents after at least a 3-month duration of therapy per agent and an intolerance or hypersensitivity to ONE preferred agent that is not expected to occur with the requested agent <b>OR</b></li> <li>3. Has tried and had an inadequate response to ONE preferred agent after at least a 3-month duration of therapy and an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent <b>OR</b></li> </ul> </li> </ul> </li> </ul>

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> <li>4. Has an intolerance or hypersensitivity to THREE preferred agents that is not expected to occur with the requested agent <b>OR</b></li> <li>C. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent (medical records required) <b>OR</b></li> <li>D. BOTH of the following (medical records required): <ol style="list-style-type: none"> <li>1. ALL of the preferred agents are not clinically appropriate for the patient <b>AND</b></li> <li>2. The prescriber has provided a complete list of previously tried agents for the requested indication <b>AND</b></li> </ol> </li> <li>3. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> <li>A. The patient's age is within FDA labeling for the requested indication for the requested agent <b>OR</b></li> <li>B. There is support for using the requested agent for the patient's age for the requested indication <b>AND</b></li> </ol> </li> <li>2. 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), or has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></li> <li>3. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table): <ol style="list-style-type: none"> <li>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) <b>OR</b></li> <li>B. The patient will be using the requested agent in combination with another immunomodulatory agent <b>AND</b> BOTH of the following: <ol style="list-style-type: none"> <li>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent <b>AND</b></li> <li>2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) <b>AND</b></li> </ol> </li> </ol> </li> <li>4. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>5. The patient has been tested for latent tuberculosis (TB) <b>AND</b> if positive the patient has begun therapy for latent TB</li> </ol> <p><b>Compendia Allowed:</b> AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use</p> <p><b>Length of Approval:</b> 12 months for all indications EXCEPT:</p> <ul style="list-style-type: none"> <li>• Ulcerative colitis (UC): 12 weeks.</li> </ul> <p>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p><b>Renewal Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] <b>AND</b></li> <li>2. The patient has had clinical benefit with the requested agent <b>AND</b></li> <li>3. If the client has preferred agents, then ONE of the following (reference preferred agents table): <ol style="list-style-type: none"> <li>A. The requested agent is a preferred agent <b>OR</b></li> <li>B. The patient has ONE of the following (medical records required): <ol style="list-style-type: none"> <li>1. Has tried and had an inadequate response to THREE preferred agents after at least a 3-month duration of therapy per agent <b>OR</b></li> </ol> </li> </ol> </li> </ol>

Module	Clinical Criteria for Approval																
	<ol style="list-style-type: none"> <li>2. Has tried and had an inadequate response to TWO preferred agents after at least a 3-month duration of therapy per agent and an intolerance or hypersensitivity to ONE preferred agent that is not expected to occur with the requested agent <b>OR</b></li> <li>3. Has tried and had an inadequate response to ONE preferred agent after at least a 3-month duration of therapy and an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent <b>OR</b></li> <li>4. Has an intolerance or hypersensitivity to THREE preferred agents that is not expected to occur with the requested agent <b>OR</b></li> <li>C. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent (medical records required) <b>OR</b></li> <li>D. BOTH of the following (medical records required): <ol style="list-style-type: none"> <li>1. ALL of the preferred agents are not clinically appropriate for the patient <b>AND</b></li> <li>2. The prescriber has provided a complete list of previously tried agents for the requested indication <b>AND</b></li> </ol> </li> <li>4. 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), or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></li> <li>5. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table): <ol style="list-style-type: none"> <li>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) <b>OR</b></li> <li>B. The patient will be using the requested agent in combination with another immunomodulatory agent <b>AND</b> BOTH of the following: <ol style="list-style-type: none"> <li>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent <b>AND</b></li> <li>2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) <b>AND</b></li> </ol> </li> </ol> </li> <li>6. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Length of Approval:</b> 12 months</p> <p>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria.</p>																
2. Ustekinumab and Ustekinumab Biosimilars	<table border="1" data-bbox="233 1230 1229 1692"> <thead> <tr> <th data-bbox="233 1230 646 1264">Preferred Target Agent(s)</th><th data-bbox="646 1230 1229 1264">Non-Preferred Target Agent(s)</th></tr> </thead> <tbody> <tr> <td data-bbox="233 1264 646 1318"><b>Selarsdi</b> (ustekinumab-aekn)</td><td data-bbox="646 1264 1229 1318"><b>Otulfi</b> (ustekinumab-aauz)</td></tr> <tr> <td data-bbox="233 1318 646 1373"><b>Steqeyma</b> (ustekinumab-stba)</td><td data-bbox="646 1318 1229 1373"><b>Pyzchiva</b> (ustekinumab-ttwe)</td></tr> <tr> <td data-bbox="233 1373 646 1428"><b>Yesintek</b> (ustekinumab-kfce)</td><td data-bbox="646 1373 1229 1428"><b>Stelara</b> (ustekinumab)</td></tr> <tr> <td data-bbox="233 1428 646 1482"></td><td data-bbox="646 1428 1229 1482"><b>Ustekinumab</b></td></tr> <tr> <td data-bbox="233 1482 646 1537"></td><td data-bbox="646 1482 1229 1537"><b>Ustekinumab-aekn</b></td></tr> <tr> <td data-bbox="233 1537 646 1591"></td><td data-bbox="646 1537 1229 1591"><b>Ustekinumab-ttwe</b></td></tr> <tr> <td data-bbox="233 1591 646 1646"></td><td data-bbox="646 1591 1229 1646"><b>Wezlana</b> (ustekinumab-auub)</td></tr> </tbody> </table> <p><b>Initial Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. ONE of the following:</li> </ol>	Preferred Target Agent(s)	Non-Preferred Target Agent(s)	<b>Selarsdi</b> (ustekinumab-aekn)	<b>Otulfi</b> (ustekinumab-aauz)	<b>Steqeyma</b> (ustekinumab-stba)	<b>Pyzchiva</b> (ustekinumab-ttwe)	<b>Yesintek</b> (ustekinumab-kfce)	<b>Stelara</b> (ustekinumab)		<b>Ustekinumab</b>		<b>Ustekinumab-aekn</b>		<b>Ustekinumab-ttwe</b>		<b>Wezlana</b> (ustekinumab-auub)
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	<b>Ustekinumab-ttwe</b>																
	<b>Wezlana</b> (ustekinumab-auub)																

Module	Clinical Criteria for Approval
	<p>A. The requested agent is eligible for continuation of therapy AND ONE of the following:</p> <div data-bbox="479 279 1174 724" style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p style="text-align: center;"><b>Agents Eligible for Continuation of Therapy</b></p> <p>All target agents EXCEPT the following are eligible for continuation of therapy:</p> <p>Otulfi</p> <p>Pyzchiva, Ustekinumab-ttwe</p> <p>Stelara, Ustekinumab</p> <p>Ustekinumab-aekn</p> <p>Wezlana</p> </div> <ol style="list-style-type: none"> <li>1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days <b>OR</b></li> <li>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 <b>OR</b></li> </ol> <p>B. ALL of the following:</p> <ol style="list-style-type: none"> <li>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: <ol style="list-style-type: none"> <li>A. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has ONE of the following: <ol style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PsA <b>OR</b></li> </ol> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PsA <b>OR</b></li> <li>3. 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, vision loss], rapidly progressive) <b>OR</b></li> <li>4. 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) <b>OR</b></li> <li>5. 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 <b>OR</b></li> </ol> </li> <li>B. The patient has a diagnosis of moderate to severe plaque psoriasis (PS) AND ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has ONE of the following:</li> </ol> </li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<ul style="list-style-type: none"> <li> <ul style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS <b>OR</b></li> </ul> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS <b>OR</b></li> <li>3. 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) <b>OR</b></li> <li>4. 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, vision loss], rapidly progressive) <b>OR</b></li> <li>5. 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 <b>OR</b></li> <li>C. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following: <ul style="list-style-type: none"> <li>1. The patient has ONE of the following: <ul style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of CD <b>OR</b></li> </ul> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of CD <b>OR</b></li> <li>3. 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 <b>OR</b></li> </ul> </li> <li>D. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ONE of the following: <ul style="list-style-type: none"> <li>1. The patient has ONE of the following: <ul style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of UC <b>OR</b></li> </ul> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of UC <b>OR</b></li> <li>3. The patient has severely active ulcerative colitis <b>OR</b></li> <li>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 UC <b>OR</b></li> </ul> </li> <li>E. The patient has a diagnosis not mentioned previously <b>AND</b></li> </ul>

Module	Clinical Criteria for Approval
	<p>2. If the client has preferred agents, then ONE of the following (reference preferred agents table):</p> <ul style="list-style-type: none"> <li>A. The requested agent is a preferred agent <b>OR</b></li> <li>B. The patient has ONE of the following (medical records required): <ul style="list-style-type: none"> <li>1. Has tried and had an inadequate response to THREE preferred agents after at least a 6-month duration of therapy per agent <b>OR</b></li> <li>2. Has tried and had an inadequate response to TWO preferred agents after at least a 6-month duration of therapy per agent and an intolerance or hypersensitivity to ONE preferred agent that is not expected to occur with the requested agent <b>OR</b></li> <li>3. Has tried and had an inadequate response to ONE preferred agent after at least a 6-month duration of therapy and an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent <b>OR</b></li> <li>4. Has an intolerance or hypersensitivity to THREE preferred agents that is not expected to occur with the requested agent <b>OR</b></li> </ul> </li> <li>C. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent (medical records required) <b>AND</b></li> </ul> <p>3. If an ustekinumab product is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following:</p> <ul style="list-style-type: none"> <li>A. The patient received an ustekinumab IV product for induction therapy <b>OR</b></li> <li>B. The patient is new to therapy and will receive an ustekinumab IV product for induction therapy <b>AND</b></li> </ul> <p>4. If the patient has an FDA labeled indication, then ONE of the following:</p> <ul style="list-style-type: none"> <li>A. The patient's age is within FDA labeling for the requested indication for the requested agent <b>OR</b></li> <li>B. There is support for using the requested agent for the patient's age for the requested indication <b>AND</b></li> </ul> <p>2. If an ustekinumab 90 mg product is requested, then ONE of the following:</p> <ul style="list-style-type: none"> <li>A. The patient has a diagnosis of psoriasis AND weighs &gt;100kg <b>OR</b></li> <li>B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient weighs &gt;100kg <b>OR</b></li> <li>C. The patient has a diagnosis of Crohn's disease or ulcerative colitis <b>AND</b></li> </ul> <p>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for PsA; gastroenterologist for CD, UC; dermatologist for PS), or has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></p> <p>4. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table):</p> <ul style="list-style-type: none"> <li>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) <b>OR</b></li> <li>B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: <ul style="list-style-type: none"> <li>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent <b>AND</b></li> <li>2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) <b>AND</b></li> </ul> </li> </ul> <p>5. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></p> <p>6. The patient has been tested for latent tuberculosis (TB) AND if positive the patient has begun therapy for latent TB</p> <p><b>Compendia Allowed:</b> AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use</p>



Module	Clinical Criteria for Approval									
	<p><b>Length of Approval:</b> 12 months</p> <p>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p><b>Renewal Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"><li>The patient has been previously approved for the requested agent through the plan’s Prior Authorization process (*NOTE: ustekinumab product 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] <b>AND</b></li><li>The patient has had clinical benefit with the requested agent <b>AND</b></li><li>If the client has preferred agents, then ONE of the following (reference preferred agents table):<ol style="list-style-type: none"><li>The requested agent is a preferred agent <b>OR</b></li><li>The patient has ONE of the following (medical records required):<ol style="list-style-type: none"><li>Has tried and had an inadequate response to THREE preferred agents after at least a 6-month duration of therapy per agent <b>OR</b></li><li>Has tried and had an inadequate response to TWO preferred agents after at least a 6-month duration of therapy per agent and an intolerance or hypersensitivity to ONE preferred agent that is not expected to occur with the requested agent <b>OR</b></li><li>Has tried and had an inadequate response to ONE preferred agent after at least a 6-month duration of therapy and an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent <b>OR</b></li><li>Has an intolerance or hypersensitivity to THREE preferred agents that is not expected to occur with the requested agent <b>OR</b></li></ol></li><li>The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent (medical records required) <b>AND</b></li></ol></li><li>The prescriber is a specialist in the area of the patient’s diagnosis (e.g., rheumatologist for PsA; gastroenterologist for CD, UC; dermatologist for PS), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis <b>AND</b></li><li>ONE of the following (please refer to “Agents NOT to be used Concomitantly” table):<ol style="list-style-type: none"><li>The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) <b>OR</b></li><li>The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:<ol style="list-style-type: none"><li>The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent <b>AND</b></li><li>There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) <b>AND</b></li></ol></li></ol></li><li>The patient does NOT have any FDA labeled contraindications to the requested agent</li></ol> <p><b>Length of Approval:</b> 12 months</p> <p>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria.</p>									
3. All other Target Agents	<p><b>Step Table</b></p> <table><tr><th rowspan="2">Disease State</th><th colspan="2">Step 1</th><th rowspan="2">Step 2 (Directed to ONE step 1 agent)</th><th rowspan="2">Step 3a (Directed to TWO step 1 agents)</th><th rowspan="2">Step 3b (Directed to TWO agents from step 1 and/or step 2)</th><th rowspan="2">Step 3c (Directed to THREE step 1 agents)</th></tr><tr><th>Step 1a</th><th>Step 1b (Directed to ONE TNF inhibitor)</th></tr></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)
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)								

Module	Clinical Criteria for Approval						
			<b>NOTE: Please see Step 1a for preferred TNF inhibitors</b>				
	Rheumatoid Disorders						
Ankylosing Spondylitis (AS)	SC: adalimum ab product(s) **, Cosentyx, Enbrel	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SC: Cimzia, Simponi, Taltz	N/A	SC: Bimzelx	
Nonradiographic Axial Spondyloarthritis (nr- axSpA)	SC: Cimzia, Cosentyx	Oral: Rinvoq	N/A	SC: Taltz	N/A	SC: Bimzelx	
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SC: adalimum ab product(s) **, Enbrel	Oral: Rinvoq, Rinvoq LQ, Xeljanz	SC: Tyenne (an adalimumab product** is a required Step 1 agent)	SC: Cimzia	SC: Actemra (an adalimumab product** AND Tyenne are required Step agents)  Orencia	SC: Kevzara	
Psoriatic Arthritis (PsA)	SC: adalimum ab product(s) **, Cosentyx, Enbrel, Skyrizi, Tremfya, ustekinumab product(s) ^^  Oral: Otezla	Oral: Rinvoq, Rinvoq LQ, Xeljanz, Xeljanz XR	N/A	SC: Cimzia, Orencia, Simponi, Taltz	N/A	SC: Bimzelx	
Rheumatoid Arthritis (RA)	SC: adalimum ab product(s) **, Enbrel	Oral: Rinvoq, Xeljanz, Xeljanz XR	SC: Tyenne (an adalimumab product** is a required Step 1 agent)	Oral: Olumiant  SC: Cimzia, Kevzara, Orencia, Simponi	SC: Actemra (an adalimumab product** AND Tyenne are required Step agents)	SC: Kineret	

Module	Clinical Criteria for Approval						
	Systemic Juvenile Idiopathic Arthritis (SJIA)	SC: Tyenne	N/A	SC: Actemra	N/A	N/A	N/A
	Dermatological Disorder						
	Hidradenitis Suppurativa (HS)	SC: adalimumab product(s) **, Cosentyx	N/A	N/A	N/A	N/A	SC: Bimzelx
	Psoriasis (PS)	SC: adalimumab product(s) **, Cosentyx, Enbrel, Skyrizi, Tremfya, ustekinumab product(s) ^^  Oral: Otezla, Sotyktu	N/A	N/A	SC: Cimzia, Ilumya	N/A	SC: Bimzelx, Siliq, Taltz
	Inflammatory Bowel Disease						
	Crohn's Disease (CD)	SC: adalimumab product(s) **, Entyvio, Skyrizi, Tremfya, ustekinumab product(s) ^^	Oral: Rinvoq	SC: Omvoh	SC: Cimzia Zymfentra	N/A	N/A
	Ulcerative Colitis (UC)	SC: adalimumab product(s) **, Entyvio, Skyrizi, Tremfya, ustekinumab product(s) ^^	Oral: Rinvoq, Xeljanz, Xeljanz XR	SC: Omvoh  Simponi (an adalimumab product**) is a required Step 1 agent)	SC: Zymfentra  Oral: Zeposia	N/A	Oral: Velsipity
	Other						

Module	Clinical Criteria for Approval						
	Giant Cell Arteritis (GCA)	SC: Tyenne Oral: Rinvoq	N/A	SC: Actemra	N/A	N/A	N/A
	Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)	SC: Tyenne	N/A	SC: Actemra	N/A	N/A	N/A
	Uveitis	SC: adalimumab product(s) **	N/A	N/A	N/A	N/A	N/A
	Indications Without Prerequisite Biologic Immunomodulators Required						
	Alopecia Areata (AA)						
	Atopic Dermatitis (AD)						
	Deficiency of IL-1 Receptor Antagonist (DIRA)						
	Enthesitis Related Arthritis (ERA)	N/A	N/A	N/A	N/A	N/A	N/A
	Juvenile Psoriatic Arthritis (JPsA)						
	Neonatal-Onset Multisystem Inflammatory Disease (NOMID)						
	Polymyalgia Rheumatica (PMR)						
	<b>**Allowable preferred adalimumab product(s)</b>						
	Adalimumab-aaty, Adalimumab-adaz, Hadlima, Simlandi						

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	<table><tr><td>^^Allowable preferred ustekinumab product(s)</td></tr><tr><td>Selarsdi, Steqeyma, Yesintek</td></tr></table> <p><u>Note:</u> For Xeljanz products (Xeljanz and Xeljanz XR) and Rinvoq products (Rinvoq and Rinvoq LQ), a trial of either or both dosage forms collectively counts as ONE product</p> <p><b>Initial Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"><li>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] <b>AND</b></li><li>If the request is for use in alopecia areata <b>AND</b> alopecia areata is NOT restricted from coverage under the patient's benefit <b>AND</b></li><li>ONE of the following:<ol style="list-style-type: none"><li>The requested agent is eligible for continuation of therapy <b>AND</b> ONE of the following:<table><tr><td><b>Agents Eligible for Continuation of Therapy</b></td></tr><tr><td>All target agents EXCEPT the following are eligible for continuation of therapy:</td></tr><tr><td>Actemra</td></tr></table></li></ol></li></ol> <ol style="list-style-type: none"><li><ol style="list-style-type: none"><li><ol style="list-style-type: none"><li>The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days <b>OR</b></li><li>The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days <b>AND</b> is at risk if therapy is changed <b>OR</b></li></ol></li><li>ALL of the following:<ol style="list-style-type: none"><li>The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration <b>AND</b> ONE of the following:<ol style="list-style-type: none"><li>The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) <b>AND</b> BOTH of the following:<ol style="list-style-type: none"><li>ONE of the following:<ol style="list-style-type: none"><li>The patient has ONE of the following:<ol style="list-style-type: none"><li>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 <b>OR</b></li><li>Has tried and had an inadequate response to ONE conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA after at least a 3-month duration of therapy <b>OR</b></li><li>Has an intolerance or hypersensitivity to ONE conventional agent (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA <b>OR</b></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol>	^^Allowable preferred ustekinumab product(s)	Selarsdi, Steqeyma, Yesintek	<b>Agents Eligible for Continuation of Therapy</b>	All target agents EXCEPT the following are eligible for continuation of therapy:	Actemra
^^Allowable preferred ustekinumab product(s)						
Selarsdi, Steqeyma, Yesintek						
<b>Agents Eligible for Continuation of Therapy</b>						
All target agents EXCEPT the following are eligible for continuation of therapy:						
Actemra						

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	<ul style="list-style-type: none"> <li> <ul style="list-style-type: none"> <li> <ul style="list-style-type: none"> <li>B. The patient has an FDA labeled contraindication to ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA <b>OR</b></li> <li>C. 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 <b>AND</b></li> </ul> </li> <li>2. If the request is for Simponi, then ONE of the following:               <ul style="list-style-type: none"> <li>A. The patient will be using methotrexate in combination with the requested agent <b>OR</b></li> <li>B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to methotrexate <b>OR</b></li> </ul> </li> </ul> </li> <li>B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following:           <ul style="list-style-type: none"> <li>1. The patient has ONE of the following:               <ul style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PsA <b>OR</b></li> </ul> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PsA <b>OR</b></li> <li>3. 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, vision loss], rapidly progressive) <b>OR</b></li> <li>4. 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) <b>OR</b></li> <li>5. 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 <b>OR</b></li> </ul> </li> <li>C. The patient has a diagnosis of moderate to severe plaque psoriasis (PS) AND ONE of the following:           <ul style="list-style-type: none"> <li>1. The patient has ONE of the following:               <ul style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS <b>OR</b></li> </ul> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS <b>OR</b></li> <li>3. 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) <b>OR</b></li> <li>4. The patient has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of</li> </ul> </li> </ul>

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	<p>inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities, vision loss], rapidly progressive) <b>OR</b></p> <p>5. The patient's medication history indicates use of another biologic immunomodulator agent <b>OR</b> Otezla that is FDA labeled or supported in compendia for the treatment of PS <b>OR</b></p> <p>D. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) <b>AND</b> ONE of the following:</p> <ol style="list-style-type: none"> <li>1. The patient has ONE of the following: <ol style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of CD <b>OR</b></li> </ol> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of CD <b>OR</b></li> <li>3. 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 <b>OR</b></li> </ol> <p>E. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) <b>AND</b> ONE of the following:</p> <ol style="list-style-type: none"> <li>1. The patient has ONE of the following: <ol style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of UC <b>OR</b></li> </ol> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of UC <b>OR</b></li> <li>3. The patient has severely active ulcerative colitis <b>OR</b></li> <li>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 UC <b>OR</b></li> </ol> <p>F. The patient has a diagnosis of non-infectious intermediate uveitis, posterior uveitis, or panuveitis <b>AND</b> ONE of the following:</p> <ol style="list-style-type: none"> <li>1. BOTH of the following: <ol style="list-style-type: none"> <li>A. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has ONE of the following: <ol style="list-style-type: none"> <li>A. Has tried and had an inadequate response to ONE oral corticosteroid used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis after at least a 2-week duration of therapy <b>OR</b></li> <li>B. Has tried and had an inadequate response to ONE periocular or intravitreal corticosteroid injection used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis <b>OR</b></li> <li>C. Has an intolerance or hypersensitivity to ONE oral</li> </ol> </li> </ol> </li> </ol> </li> </ol>

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	<p>corticosteroid or periocular/intravitreal corticosteroid injection used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis <b>OR</b></p> <p>2. The patient has an FDA labeled contraindication to ALL oral corticosteroids and periocular/intravitreal corticosteroids used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis <b>AND</b></p> <p>B. ONE of the following:</p> <p>1. The patient has ONE of the following:</p> <p>A. 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 <b>OR</b></p> <p>B. Has an intolerance or hypersensitivity to ONE conventional systemic agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis <b>OR</b></p> <p>2. 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 <b>OR</b></p> <p>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 <b>OR</b></p> <p>G. The patient has a diagnosis of giant cell arteritis (GCA) AND ONE of the following:</p> <p>1. The patient has ONE of the following:</p> <p>A. Has tried and had an inadequate response to ONE systemic corticosteroid (e.g., prednisone, methylprednisolone) used in the treatment of GCA after at least a 7-day duration of therapy <b>OR</b></p> <p>B. Has an intolerance or hypersensitivity to ONE systemic corticosteroid used in the treatment of GCA <b>OR</b></p> <p>2. The patient has an FDA labeled contraindication to ALL systemic corticosteroids used in the treatment of GCA <b>OR</b></p> <p>3. 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 <b>OR</b></p> <p>H. The patient has a diagnosis of active ankylosing spondylitis (AS) AND ONE of the following:</p> <p>1. The patient has ONE of the following:</p> <p>A. Has tried and had an inadequate response to TWO different nonsteroidal anti-inflammatory drugs (NSAIDs) used in the treatment of AS after at least a 4-week TOTAL duration of therapy <b>OR</b></p>



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	<ul style="list-style-type: none"> <li> <ul style="list-style-type: none"> <li> <ul style="list-style-type: none"> <li>B. Has tried and had an inadequate response to ONE NSAID used in the treatment of AS after at least a 4-week duration of therapy and an intolerance or hypersensitivity to ONE additional NSAID used in the treatment of AS <b>OR</b></li> <li>C. Has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of AS <b>OR</b></li> </ul> </li> <li>2. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of AS <b>OR</b></li> <li>3. 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 <b>OR</b></li> </ul> </li> <li>I. The patient has a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) AND ONE of the following: <ul style="list-style-type: none"> <li>1. The patient has ONE of the following: <ul style="list-style-type: none"> <li>A. 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 duration of therapy <b>OR</b></li> <li>B. Has tried and had an inadequate response to ONE NSAID used in the treatment of nr-axSpA after at least a 4-week duration of therapy and an intolerance or hypersensitivity to ONE additional NSAID used in the treatment of nr-axSpA <b>OR</b></li> <li>C. Has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of nr-axSpA <b>OR</b></li> </ul> </li> <li>2. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of nr-axSpA <b>OR</b></li> <li>3. 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 <b>OR</b></li> </ul> </li> <li>J. The patient has a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) AND ONE of the following: <ul style="list-style-type: none"> <li>1. The patient has ONE of the following: <ul style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PJIA <b>OR</b></li> </ul> </li> <li>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PJIA <b>OR</b></li> <li>3. 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 <b>OR</b></li> </ul> </li> <li>K. The patient has a diagnosis of moderate to severe hidradenitis suppurativa (HS) AND ONE of the following: <ul style="list-style-type: none"> <li>1. The patient has ONE of the following: <ul style="list-style-type: none"> <li>A. 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;</li> </ul> </li> </ul> </li> </ul>

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	<p>cyclosporine; oral retinoids) used in the treatment of HS after at least a 3-month duration of therapy <b>OR</b></p> <p>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of HS <b>OR</b></p> <p>2. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of HS <b>OR</b></p> <p>3. 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 <b>OR</b></p> <p>L. BOTH of the following:</p> <p>1. The patient has a diagnosis of systemic sclerosis associated interstitial lung disease (SSc-ILD) <b>AND</b></p> <p>2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans <b>OR</b></p> <p>M. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following:</p> <p>1. The patient has ONE of the following:</p> <p>A. Has tried and had an inadequate response to TWO different NSAIDs used in the treatment of ERA after at least a 4-week TOTAL duration of therapy <b>OR</b></p> <p>B. Has tried and had an inadequate response to ONE NSAID used in the treatment of ERA after at least a 4-week duration of therapy and an intolerance or hypersensitivity to ONE additional NSAID used in the treatment of ERA <b>OR</b></p> <p>C. Has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of ERA <b>OR</b></p> <p>2. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of ERA <b>OR</b></p> <p>3. 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 <b>OR</b></p> <p>N. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following:</p> <p>1. ONE of the following:</p> <p>A. The patient has at least 10% body surface area involvement <b>OR</b></p> <p>B. The patient has 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) <b>OR</b></p> <p>C. The patient has an Eczema Area and Severity Index (EASI) score greater than or equal to 16 <b>OR</b></p> <p>D. The patient has an Investigator Global Assessment (IGA) score greater than or equal to 3 <b>AND</b></p> <p>2. ONE of the following:</p> <p>A. BOTH of the following:</p> <p>1. ONE of the following:</p> <p>A. The patient has ONE of the following:</p> <p>1. Has tried and had an inadequate response to ONE at least medium-potency topical corticosteroid used in the</p>

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	<p>treatment of AD after at least a 4-week duration of therapy <b>OR</b></p> <p>2. Has an intolerance or hypersensitivity to ONE at least medium-potency topical corticosteroid used in the treatment of AD <b>OR</b></p> <p>B. The patient has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of AD <b>AND</b></p> <p>2. ONE of the following:</p> <p>A. The patient has ONE of the following:</p> <p>1. Has tried and had an inadequate response to ONE topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD after at least a 6-week duration of therapy <b>OR</b></p> <p>2. Has an intolerance or hypersensitivity to ONE topical calcineurin inhibitor used in the treatment of AD <b>OR</b></p> <p>B. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD <b>OR</b></p> <p>B. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of AD <b>AND</b></p> <p>3. The prescriber has documented the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) <b>OR</b></p> <p>O. BOTH of the following:</p> <p>1. The patient has a diagnosis of severe alopecia areata (AA) <b>AND</b></p> <p>2. The patient has at least 50% scalp hair loss that has lasted 6 months or more <b>OR</b></p> <p>P. The patient has a diagnosis of polymyalgia rheumatica (PMR) <b>AND</b> ONE of the following:</p> <p>1. The patient has tried and had an inadequate response to ONE systemic corticosteroid 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 <b>OR</b></p> <p>2. The patient is currently treated with systemic corticosteroid therapy at a dose equivalent to at least 7.5 mg/day of prednisone <b>AND</b> cannot tolerate a corticosteroid taper <b>OR</b></p> <p>Q. The patient has a diagnosis of juvenile psoriatic arthritis (JPsA) <b>AND</b> ONE of the following:</p> <p>1. The patient has ONE of the following:</p>

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	<ul style="list-style-type: none"> <li> <ul style="list-style-type: none"> <li>A. 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 <b>OR</b></li> <li>B. Has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of JPsA <b>OR</b></li> </ul> </li> <li>2. The patient has an FDA labeled contraindication to methotrexate <b>OR</b></li> <li>3. 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, vision loss], rapidly progressive) <b>OR</b></li> <li>4. 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) <b>OR</b></li> <li>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 JPsA <b>OR</b></li> <li>R. The patient has a diagnosis not mentioned previously <b>AND</b></li> <li>2. ONE of the following (reference Step Table): <ul style="list-style-type: none"> <li>A. The requested indication does NOT require any prerequisite biologic immunomodulator agents <b>OR</b></li> <li>B. The requested agent is a Step 1a agent for the requested indication <b>OR</b></li> <li>C. If the requested agent is a Step 1b agent for the requested indication, then ONE of the following: <ul style="list-style-type: none"> <li>1. The patient has ONE of the following: <ul style="list-style-type: none"> <li>A. 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) <b>OR</b></li> <li>B. Has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE TNF inhibitor for the requested indication <b>OR</b></li> </ul> </li> <li>2. The patient has an FDA labeled contraindication to ALL TNF inhibitors for the requested indication <b>OR</b></li> <li>3. BOTH of the following: <ul style="list-style-type: none"> <li>A. ALL TNF inhibitors are not clinically appropriate for the patient <b>AND</b></li> <li>B. The prescriber has provided a complete list of previously tried agents for the requested indication <b>OR</b></li> </ul> </li> </ul> </li> <li>D. If the requested agent is a Step 2 agent for the requested indication, then ONE of the following: <ul style="list-style-type: none"> <li>1. The patient has ONE of the following: <ul style="list-style-type: none"> <li>A. 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) <b>OR</b></li> <li>B. 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 <b>OR</b></li> </ul> </li> </ul> </li> </ul> </li> </ul>

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	<ol style="list-style-type: none"> <li>2. The patient has an FDA labeled contraindication to ALL required Step 1 agents for the requested indication <b>OR</b></li> <li>3. BOTH of the following: <ol style="list-style-type: none"> <li>A. ALL of the required Step 1 agents are not clinically appropriate for the patient <b>AND</b></li> <li>B. The prescriber has provided a complete list of previously tried agents for the requested indication <b>OR</b></li> </ol> </li> <li>E. If the requested agent is a Step 3a agent for the requested indication, then ONE of the following (medical records required): <ol style="list-style-type: none"> <li>1. The patient has ONE of the following: <ol style="list-style-type: none"> <li>A. Has tried and had an inadequate response to TWO Step 1 agents for the requested indication after at least a 3-month duration of therapy per agent (See Step 3a) <b>OR</b></li> <li>B. Has tried and had an inadequate response to ONE Step 1 agent for the requested indication after at least a 3-month duration of therapy per agent and an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE Step 1 agent for the requested indication <b>OR</b></li> <li>C. Has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to TWO Step 1 agents for the requested indication <b>OR</b></li> </ol> </li> <li>2. The patient has an FDA labeled contraindication to ALL Step 1 agents for the requested indication <b>OR</b></li> <li>3. BOTH of the following: <ol style="list-style-type: none"> <li>A. ALL of the Step 1 agents are not clinically appropriate for the patient <b>AND</b></li> <li>B. The prescriber has provided a complete list of previously tried agents for the requested indication <b>OR</b></li> </ol> </li> </ol> </li> <li>F. If the requested agent is a Step 3b agent for the requested indication, then ONE of the following (medical records required): <ol style="list-style-type: none"> <li>1. The patient has ONE of the following: <ol style="list-style-type: none"> <li>A. 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 duration of therapy per agent (See Step 3b) <b>OR</b></li> <li>B. Has tried and had an inadequate response to ONE agent from Step 1 or Step 2 for the requested indication after at least a 3-month duration of therapy per agent and an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE agent from Step 1 or Step 2 for the requested indication <b>OR</b></li> <li>C. 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 <b>OR</b></li> </ol> </li> <li>2. The patient has an FDA labeled contraindication to ALL of the Step 1 AND Step 2 agents for the requested indication <b>OR</b></li> <li>3. BOTH of the following: <ol style="list-style-type: none"> <li>A. ALL of the Step 1 AND Step 2 agents are not clinically appropriate for the patient <b>AND</b></li> </ol> </li> </ol> </li> </ol>

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	<p data-bbox="760 180 1360 264">B. The prescriber has provided a complete list of previously tried agents for the requested indication <b>OR</b></p> <p data-bbox="568 268 1393 323">G. If the requested agent is a Step 3c agent for the requested indication, then ONE of the following (medical records required):</p> <ol data-bbox="643 327 1414 1251" style="list-style-type: none"> <li data-bbox="643 327 1159 354">1. The patient has ONE of the following: <ol data-bbox="760 359 1414 1020" style="list-style-type: none"> <li data-bbox="760 359 1403 470">A. Has tried and had an inadequate response to THREE Step 1 agents for the requested indication after at least a 3-month duration of therapy per agent (See Step 3c) <b>OR</b></li> <li data-bbox="760 474 1414 669">B. Has tried and had an inadequate response to TWO Step 1 agents for the requested indication after at least a 3-month duration of therapy per agent and an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE Step 1 agent for the requested indication <b>OR</b></li> <li data-bbox="760 674 1414 900">C. Has tried and had an inadequate response to ONE Step 1 agent for the requested indication after at least a 3-month duration of therapy and an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to TWO Step 1 agents for the requested indication <b>OR</b></li> <li data-bbox="760 905 1403 1020">D. Has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to THREE Step 1 agents for the requested indication <b>OR</b></li> </ol> </li> <li data-bbox="643 1024 1370 1079">2. The patient has an FDA labeled contraindication to ALL Step 1 agents for the requested indication <b>OR</b></li> <li data-bbox="643 1083 1360 1251">3. BOTH of the following: <ol data-bbox="760 1108 1360 1251" style="list-style-type: none"> <li data-bbox="760 1108 1305 1163">A. ALL of the Step 1 agents are not clinically appropriate for the patient <b>AND</b></li> <li data-bbox="760 1167 1360 1251">B. The prescriber has provided a complete list of previously tried agents for the requested indication <b>AND</b></li> </ol> </li> </ol> <p data-bbox="472 1255 1393 1310">3. If Omvoh is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following:</p> <ol data-bbox="568 1314 1349 1398" style="list-style-type: none"> <li data-bbox="568 1314 1349 1341">A. The patient has received Omvoh IV for induction therapy <b>OR</b></li> <li data-bbox="568 1346 1338 1398">B. The patient is new to therapy and will receive Omvoh IV for induction therapy <b>AND</b></li> </ol> <p data-bbox="472 1402 1393 1457">4. If Entyvio is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following:</p> <ol data-bbox="568 1461 1393 1587" style="list-style-type: none"> <li data-bbox="568 1461 1273 1524">A. The patient has received at least 2 doses of Entyvio IV therapy <b>OR</b></li> <li data-bbox="568 1528 1393 1587">B. The patient is new to therapy and will receive at least 2 doses of Entyvio IV therapy <b>AND</b></li> </ol> <p data-bbox="472 1591 1386 1646">5. If Skyrizi is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following:</p> <ol data-bbox="568 1650 1330 1745" style="list-style-type: none"> <li data-bbox="568 1650 1292 1682">A. The patient received Skyrizi IV for induction therapy <b>OR</b></li> <li data-bbox="568 1686 1330 1745">B. The patient is new to therapy and will receive Skyrizi IV for induction therapy <b>AND</b></li> </ol> <p data-bbox="472 1749 1305 1803">6. If Zymfentra is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following:</p> <ol data-bbox="568 1808 1317 1934" style="list-style-type: none"> <li data-bbox="568 1808 1317 1871">A. The patient received an infliximab IV product for induction therapy <b>OR</b></li> <li data-bbox="568 1875 1360 1934">B. The patient is new to therapy and will receive an infliximab IV product for induction therapy <b>AND</b></li> </ol> <p data-bbox="472 1938 1414 1992">7. If Tremfya is requested for the treatment of ulcerative colitis, then ONE of the following:</p>

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	<div data-bbox="565 180 1349 268"> <ul style="list-style-type: none"> <li>A. The patient received Tremfya IV for induction therapy <b>OR</b></li> <li>B. The patient is new to therapy and will receive Tremfya IV for induction therapy <b>AND</b></li> </ul> </div> <div data-bbox="469 275 1377 415"> <ul style="list-style-type: none"> <li>8. If the patient has an FDA labeled indication, then ONE of the following:               <ul style="list-style-type: none"> <li>A. The patient's age is within FDA labeling for the requested indication for the requested agent <b>OR</b></li> <li>B. There is support for using the requested agent for the patient's age for the requested indication <b>AND</b></li> </ul> </li> </ul> </div> <div data-bbox="280 422 1409 1833"> <ul style="list-style-type: none"> <li>4. If Cosentyx 300 mg is requested as maintenance dosing, then ONE of the following:               <ul style="list-style-type: none"> <li>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 <b>OR</b></li> <li>B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following:                   <ul style="list-style-type: none"> <li>1. The requested dose is 300 mg every 4 weeks <b>OR</b></li> <li>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 <b>OR</b></li> </ul> </li> <li>C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND BOTH of the following:                   <ul style="list-style-type: none"> <li>1. The requested dose is 300 mg every 4 weeks <b>AND</b></li> <li>2. The patient has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy <b>AND</b></li> </ul> </li> </ul> </li> <li>5. If Tremfya 200 mg is requested, the patient has a diagnosis of Crohn's disease or ulcerative colitis <b>AND</b></li> <li>6. 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) <b>AND</b></li> <li>7. If Kevzara is requested for a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA), the patient weighs 63 kg or greater <b>AND</b></li> <li>8. If the patient has a diagnosis of moderate-to-severe atopic dermatitis (AD), then BOTH of the following:               <ul style="list-style-type: none"> <li>A. The patient is currently treated with topical emollients and practicing good skin care <b>AND</b></li> <li>B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent <b>AND</b></li> </ul> </li> <li>9. 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 <b>AND</b></li> <li>10. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table):               <ul style="list-style-type: none"> <li>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) <b>OR</b></li> <li>B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:                   <ul style="list-style-type: none"> <li>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent <b>AND</b></li> <li>2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) <b>AND</b></li> </ul> </li> </ul> </li> <li>11. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>12. ONE of the following:               <ul style="list-style-type: none"> <li>A. The prescribing information for the requested agent requires testing for latent tuberculosis (TB) AND the patient has been tested for latent TB AND if positive the patient has begun therapy for latent TB <b>OR</b></li> <li>B. The prescribing information for the requested agent does NOT require testing for latent tuberculosis (TB)</li> </ul> </li> </ul> </div> <div data-bbox="232 1871 1401 1927"> <p><b>Compendia Allowed:</b> AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use</p> </div>

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	<p><b>Length of Approval:</b> 12 months for all agents EXCEPT:</p> <ul style="list-style-type: none"> <li>• Rinvoq for atopic dermatitis (AD): 6 months</li> <li>• Siliq for plaque psoriasis (PS): 16 weeks</li> <li>• Xeljanz and Xeljanz XR for induction therapy for ulcerative colitis (UC): 16 weeks</li> </ul> <p>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p><b>Renewal Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>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] <b>AND</b></li> <li>2. If the request is for use in alopecia areata AND alopecia areata is NOT restricted from coverage under the patient's benefit <b>AND</b></li> <li>3. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] <b>AND</b></li> <li>4. ONE of the following: <ol style="list-style-type: none"> <li>A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following: <ol style="list-style-type: none"> <li>1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: <ol style="list-style-type: none"> <li>A. Affected body surface area <b>OR</b></li> <li>B. Flares <b>OR</b></li> <li>C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification <b>OR</b></li> <li>D. A decrease in the Eczema Area and Severity Index (EASI) score <b>OR</b></li> <li>E. A decrease in the Investigator Global Assessment (IGA) score <b>AND</b></li> </ol> </li> <li>2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent <b>OR</b></li> </ol> </li> <li>B. The patient has a diagnosis of polymyalgia rheumatica AND BOTH of the following: <ol style="list-style-type: none"> <li>1. The patient has had clinical benefit with the requested agent <b>AND</b></li> <li>2. If the requested agent is Kevzara, the patient does NOT have any of the following: <ol style="list-style-type: none"> <li>A. Neutropenia (ANC less than 1,000 per mm<sup>3</sup> at the end of the dosing interval) <b>AND</b></li> <li>B. Thrombocytopenia (platelet count is less than 100,000 per mm<sup>3</sup>) <b>AND</b></li> <li>C. AST or ALT elevations 3 times the upper limit of normal <b>OR</b></li> </ol> </li> </ol> </li> <li>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 <b>AND</b></li> </ol> </li> <li>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 <b>AND</b></li> <li>6. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table): <ol style="list-style-type: none"> <li>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) <b>OR</b></li> </ol> </li> </ol>



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	<p data-bbox="354 180 1380 239">B. The patient will be using the requested agent in combination with another immunomodulatory agent <b>AND BOTH</b> of the following:</p> <ol data-bbox="469 239 1380 352" style="list-style-type: none"> <li data-bbox="469 239 1380 298">1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent <b>AND</b></li> <li data-bbox="469 298 1380 352">2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) <b>AND</b></li> </ol> <p data-bbox="280 352 584 382">7. ONE of the following:</p> <ol data-bbox="354 382 1170 411" style="list-style-type: none"> <li data-bbox="354 382 1170 411">A. The requested agent is eligible for continuation of therapy <b>OR</b></li> </ol> <div data-bbox="469 449 1182 623" style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p data-bbox="469 457 1050 487"><b>Agents Eligible for Continuation of Therapy</b></p> <p data-bbox="469 493 1117 552">All target agents <b>EXCEPT</b> the following are eligible for continuation of therapy:</p> <p data-bbox="469 588 573 617">Actemra</p> </div> <p data-bbox="354 661 953 690">B. ONE of the following (reference Step table):</p> <ol data-bbox="469 690 1421 1967" style="list-style-type: none"> <li data-bbox="469 690 1338 749">1. The requested indication does NOT require any prerequisite biologic immunomodulator agents <b>OR</b></li> <li data-bbox="469 749 1386 779">2. The requested agent is a Step 1a agent for the requested indication <b>OR</b></li> <li data-bbox="469 779 1369 837">3. If the requested agent is a Step 1b agent for the requested indication, then ONE of the following: <ol data-bbox="565 837 1403 1094" style="list-style-type: none"> <li data-bbox="565 837 1065 867">A. The patient has ONE of the following: <ol data-bbox="641 867 1403 1094" style="list-style-type: none"> <li data-bbox="641 867 1403 980">1. 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) <b>OR</b></li> <li data-bbox="641 980 1403 1094">2. Has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE TNF inhibitor for the requested indication <b>OR</b></li> </ol> </li> <li data-bbox="565 1094 1330 1152">B. The patient has an FDA labeled contraindication to ALL TNF inhibitors for the requested indication <b>OR</b></li> <li data-bbox="565 1152 1369 1299">C. BOTH of the following: <ol data-bbox="641 1182 1369 1299" style="list-style-type: none"> <li data-bbox="641 1182 1369 1241">1. ALL TNF inhibitors are not clinically appropriate for the patient <b>AND</b></li> <li data-bbox="641 1241 1369 1299">2. The prescriber has provided a complete list of previously tried agents for the requested indication <b>OR</b></li> </ol> </li> </ol> </li> <li data-bbox="469 1299 1421 1358">4. If the requested agent is a Step 2 agent for the requested indication, then ONE of the following: <ol data-bbox="565 1358 1403 1791" style="list-style-type: none"> <li data-bbox="565 1358 1403 1589">A. The patient has ONE of the following: <ol data-bbox="641 1388 1403 1589" style="list-style-type: none"> <li data-bbox="641 1388 1403 1476">1. 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) <b>OR</b></li> <li data-bbox="641 1476 1403 1589">2. 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 <b>OR</b></li> </ol> </li> <li data-bbox="565 1589 1383 1648">B. The patient has an FDA labeled contraindication to ALL required Step 1 agents for the requested indication <b>OR</b></li> <li data-bbox="565 1648 1396 1791">C. BOTH of the following: <ol data-bbox="641 1677 1396 1791" style="list-style-type: none"> <li data-bbox="641 1677 1321 1736">1. ALL of the required Step 1 agents are not clinically appropriate for the patient <b>AND</b></li> <li data-bbox="641 1736 1396 1791">2. The prescriber has provided a complete list of previously tried agents for the requested indication <b>OR</b></li> </ol> </li> </ol> </li> <li data-bbox="469 1791 1369 1850">5. If the requested agent is a Step 3a agent for the requested indication, then ONE of the following (medical records required): <ol data-bbox="565 1850 1403 1967" style="list-style-type: none"> <li data-bbox="565 1850 1065 1879">A. The patient has ONE of the following: <ol data-bbox="641 1879 1403 1967" style="list-style-type: none"> <li data-bbox="641 1879 1403 1967">1. Has tried and had an inadequate response to TWO Step 1 agents for the requested indication after at least a 3-month duration of therapy per agent (See Step 3a) <b>OR</b></li> </ol> </li> </ol> </li> </ol>

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	<ul style="list-style-type: none"> <li>2. Has tried and had an inadequate response to ONE Step 1 agent for the requested indication after at least a 3-month duration of therapy per agent and an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE Step 1 agent for the requested indication <b>OR</b></li> <li>3. Has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to TWO Step 1 agents for the requested indication <b>OR</b></li> <li>B. The patient has an FDA labeled contraindication to ALL Step 1 agents for the requested indication <b>OR</b></li> <li>C. BOTH of the following: <ul style="list-style-type: none"> <li>1. ALL of the Step 1 agents are not clinically appropriate for the patient <b>AND</b></li> <li>2. The prescriber has provided a complete list of previously tried agents for the requested indication <b>OR</b></li> </ul> </li> <li>6. If the requested agent is a Step 3b agent for the requested indication, then ONE of the following (medical records required): <ul style="list-style-type: none"> <li>A. The patient has ONE of the following: <ul style="list-style-type: none"> <li>1. 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 duration of therapy per agent (See Step 3b) <b>OR</b></li> <li>2. Has tried and had an inadequate response to ONE agent from Step 1 or Step 2 for the requested indication after at least a 3-month duration of therapy per agent and an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE agent from Step 1 or Step 2 for the requested indication <b>OR</b></li> <li>3. 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 <b>OR</b></li> </ul> </li> <li>B. The patient has an FDA labeled contraindication to ALL of the Step 1 AND Step 2 agents for the requested indication <b>OR</b></li> <li>C. BOTH of the following: <ul style="list-style-type: none"> <li>1. ALL of the Step 1 AND Step 2 agents are not clinically appropriate for the patient <b>AND</b></li> <li>2. The prescriber has provided a complete list of previously tried agents for the requested indication <b>OR</b></li> </ul> </li> </ul> </li> <li>7. If the requested agent is a Step 3c agent for the requested indication, then ONE of the following (medical records required): <ul style="list-style-type: none"> <li>A. The patient has ONE of the following: <ul style="list-style-type: none"> <li>1. Has tried and had an inadequate response to THREE Step 1 agents for the requested indication after at least a 3-month duration of therapy per agent (See Step 3c) <b>OR</b></li> <li>2. Has tried and had an inadequate response to TWO Step 1 agents for the requested indication after at least a 3-month duration of therapy per agent and an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE Step 1 agent for the requested indication <b>OR</b></li> <li>3. Has tried and had an inadequate response to ONE Step 1 agent for the requested indication after at least a 3-month duration of therapy and an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to TWO Step 1 agents for the requested indication <b>OR</b></li> <li>4. Has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or</li> </ul> </li> </ul> </li> </ul>

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	<p>hypersensitivity to THREE Step 1 agents for the requested indication <b>OR</b></p> <p>B. The patient has an FDA labeled contraindication to ALL Step 1 agents for the requested indication <b>OR</b></p> <p>C. BOTH of the following:</p> <ol style="list-style-type: none"> <li>ALL of the Step 1 agents are not clinically appropriate for the patient <b>AND</b></li> <li>The prescriber has provided a complete list of previously tried agents for the requested indication <b>AND</b></li> </ol> <p>8. If Cosentyx 300 mg is requested as maintenance dosing, then ONE of the following:</p> <ol style="list-style-type: none"> <li>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 <b>OR</b></li> <li>The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: <ol style="list-style-type: none"> <li>The requested dose is 300 mg every 4 weeks <b>OR</b></li> <li>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 <b>OR</b></li> </ol> </li> <li>The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND BOTH of the following: <ol style="list-style-type: none"> <li>The requested dose is 300 mg every 4 weeks <b>AND</b></li> <li>The patient has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy <b>AND</b></li> </ol> </li> </ol> <p>9. If Tremfya 200 mg is requested, the patient has a diagnosis of Crohn's disease or ulcerative colitis <b>AND</b></p> <p>10. 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) <b>AND</b></p> <p>11. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p><b>Length of Approval:</b> 12 months</p> <p>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

## QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL All Program Type	<p><b>Quantity limit for the Target Agent(s)</b> will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> <li>The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></li> <li>The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> <li>The requested agent is Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis (UC), AND BOTH of the following: <ol style="list-style-type: none"> <li>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) <b>AND</b></li> <li>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 <b>OR</b></li> </ol> </li> <li>The requested agent is Xeljanz oral solution for a diagnosis of polyarticular course juvenile idiopathic arthritis (pcJIA), AND ONE of the following: <ol style="list-style-type: none"> <li>BOTH of the following: <ol style="list-style-type: none"> <li>The requested quantity (dose) does NOT exceed the maximum FDA labeled dose (i.e., 5 mg twice daily) for the requested indication <b>AND</b></li> <li>There is support for why the patient cannot take Xeljanz 5 mg tablets <b>OR</b></li> </ol> </li> <li>ALL of the following:</li> </ol> </li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<ul style="list-style-type: none"> <li>A. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication <b>AND</b></li> <li>B. The patient has tried and had an inadequate response to at least a 3-month duration of therapy at the maximum FDA labeled dose for the requested indication (medical records required) <b>AND</b></li> <li>C. ONE of the following: <ul style="list-style-type: none"> <li>1. BOTH of the following: <ul style="list-style-type: none"> <li>A. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication <b>AND</b></li> <li>B. 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 <b>OR</b></li> </ul> </li> <li>2. BOTH of the following: <ul style="list-style-type: none"> <li>A. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication <b>AND</b></li> <li>B. There is support for therapy with a higher dose for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) <b>OR</b></li> </ul> </li> </ul> </li> <li>C. The requested agent is NOT Xeljanz/Xeljanz XR for a diagnosis of UC or pcJIA, AND ONE of the following: <ul style="list-style-type: none"> <li>1. The patient has an FDA labeled indication for the requested agent, AND ONE of the following: <ul style="list-style-type: none"> <li>A. BOTH of the following: <ul style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>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 <b>OR</b></li> </ul> </li> <li>B. ALL of the following: <ul style="list-style-type: none"> <li>1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication <b>AND</b></li> <li>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 for the requested indication (medical records required) <b>AND</b></li> <li>3. ONE of the following: <ul style="list-style-type: none"> <li>A. BOTH of the following: <ul style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication <b>AND</b></li> <li>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 <b>OR</b></li> </ul> </li> <li>B. BOTH of the following: <ul style="list-style-type: none"> <li>1. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication <b>AND</b></li> <li>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) <b>OR</b></li> </ul> </li> </ul> </li> </ul> </li> </ul> </li> </ul> </li></ul>

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> <li>2. The patient has a compendia supported indication for the requested agent, AND ONE of the following: <ol style="list-style-type: none"> <li>A. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication <b>AND</b></li> <li>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 <b>OR</b></li> </ol> </li> <li>B. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication <b>AND</b></li> <li>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) <b>OR</b></li> </ol> </li> </ol> </li> <li>3. The patient does NOT have an FDA labeled indication NOR a compendia supported indication for the requested agent AND BOTH of the following: <ol style="list-style-type: none"> <li>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 <b>AND</b></li> <li>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)</li> </ol> </li> </ol> <p><b>Compendia Allowed:</b> AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use</p> <p><b>Length of Approval:</b> up to 12 months</p> <p><u>Note:</u> For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling, followed by the maintenance dose for the remainder of the length of approval.</p> <p><b>**NOTE:</b> Cosentyx loading doses for the diagnoses of AS, nr-axSpA, and PSA are NOT approvable.</p>

## CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
<p><b>Agents NOT to be used Concomitantly</b></p> <p> 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)  Ebglyss (lebrikizumab-lbkz) </p>

**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)  
Imuldosa (ustekinumab-srlf)  
Inflectra (infliximab-dyyb)  
Infliximab  
Kevzara (sarilumab)  
Kineret (anakinra)  
Leqselvi (deuruxolitinib)  
Litfulo (ritlecitinib)  
Nemluvio (nemolizumab-ilto)  
Nucala (mepolizumab)  
Olumiant (baricitinib)  
Omvoh (mirikizumab-mrkz)  
Opzelura (ruxolitinib)  
Orencia (abatacept)  
Otezla (apremilast)  
Otulfi (ustekinumab-aauz)  
Pyzchiva (ustekinumab-ttwe)  
Remicade (infliximab)  
Renflexis (infliximab-abda)  
Riabni (rituximab-arrx)  
Rinvoq (upadacitinib)  
Rituxan (rituximab)  
Rituxan Hycela (rituximab/hyaluronidase human)  
Ruxience (rituximab-pvvr)  
Saphnelo (anifrolumab-fnia)  
Selarsdi (ustekinumab-aekn)  
Siliq (brodalumab)  
Simlandi (adalimumab-ryvk)  
Simponi (golimumab)  
Simponi ARIA (golimumab)  
Skyrizi (risankizumab-rzaa)  
Sotyktu (deucravacitinib)  
Spevigo (spesolimab-sbzo) subcutaneous injection  
Stelara (ustekinumab)  
Steqeyma (ustekinumab-stba)  
Taltz (ixekizumab)  
Tezspire (tezepelumab-ekko)  
Tofidence (tocilizumab-bavi)  
Tremfya (guselkumab)  
Truxima (rituximab-abbs)  
Tyenne (tocilizumab-aazg)  
Tysabri (natalizumab)  
Ustekinumab  
Velsipity (etrasimod)  
Wezlana (ustekinumab-auub)  
Xeljanz (tofacitinib)  
Xeljanz XR (tofacitinib extended release)  
Xolair (omalizumab)  
Yesintek (ustekinumab-kfce)  
Yuflyma (adalimumab-aaty)  
Yusimry (adalimumab-aqvh)  
Zeposia (ozanimod)  
Zymfentra (infliximab-dyyb)

