Clinical Policy Title:	adalimumab
Policy Number:	RxA.726
Drug(s) Applied:	Humira®
Original Policy Date:	04/18/2022
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Humira® is a tumor necrosis factor (TNF) blocker indicated for:

- **Rheumatoid Arthritis (RA):** 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 RA.
- **Juvenile Idiopathic Arthritis (JIA):** Reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older.
- **Psoriatic Arthritis (PsA):** Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA.
- **Ankylosing Spondylitis (AS):** Reducing signs and symptoms in adult patients with active AS.
- **Crohn's Disease (CD):** Treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.
- **Ulcerative Colitis (UC):** Treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older.
- **Plaque Psoriasis (Ps):** Treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.
- **Hidradenitis Suppurativa (HS):** Treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.
- **Uveitis (UV):** Treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older.

Limitations of Use: For Ulcerative Colitis (UC) Effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
adalimumab (Humira®)	Rheumatoid Arthritis	40 mg subcutaneously every other week Some patients with RA not receiving concomitant methotrexate may benefit from increasing the frequency to 40 mg every Week or 80 mg every other week	40 mg/week

Dosing Information			
Drug Name	**Indication**	**Dosing Regimen**	**Maximum Dose**
	Juvenile Idiopathic Arthritis	Pediatric patients 2 years of age and older: Weight 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg subcutaneously every other week Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg subcutaneously every other week Weight ≥ 30 kg (66 lbs): 40 mg subcutaneously every other week	40 mg every other week
	Psoriatic Arthritis	40 mg subcutaneously every other week	40 mg every other week
	Ankylosing Spondylitis	40 mg subcutaneously every other week	40 mg every other week
	Crohn's Disease	<u>Initial dose:</u> Adults: 160 mg subcutaneously on Day 1, then 80 mg subcutaneously on Day 15 Pediatrics: Weight 17 kg (37 lbs) to < 40 kg (88 lbs): 80 mg subcutaneously on Day 1, then 40 mg Subcutaneously on Day 15 Weight ≥ 40 kg (88 lbs)160 mg subcutaneously on Day 1, then 80 mg Subcutaneously on Day 15 <u>Maintenance dose:</u> Adults: 40 mg subcutaneously every other week starting on Day 29 Pediatrics*:* Weight 17 kg (37 lbs) to < 40 kg (88 lbs): 20 mg Subcutaneously every other week starting on Day 29 Weight ≥ 40 kg (88 lbs): 40 mg subcutaneously every other week starting on Day 29	40 mg every other week
	Ulcerative Colitis	<u>Initial dose:</u> Adults: 160 mg subcutaneously on Day 1 (given in one day or split over two consecutive days), then 80 mg subcutaneously on Day 15 Pediatric patients 5 years or older: Weight 20 kg (44 lbs) to < 40 kg (88 lbs): 80 mg subcutaneously on Day 1, then 40 mg subcutaneously on Day 8, then 40 mg subcutaneously on day Day 15 Weight ≥ 40 kg (88 lbs): 160 mg subcutaneously Day 1, then 80 mg on day 8 and day 15 <u>Maintenance dose:</u> Adults: 40 mg subcutaneously every other week	Age ≥ 18 years :40 mg every other week

Dosing Information			
Drug Name	**Indication**	**Dosing Regimen**	**Maximum Dose**
		starting on Day 29 Pediatrics: Weight 20 kg (44 lbs) to < 40 kg (88 lbs): 40 mg every other week or 20 mg every week starting on day 29 Weight ≥ 40 kg (88 lbs): 80 mg every other week or 40 mg every week starting on day 29	Age ≥ 6 years to 17 years: 80 mg every other week
	Plaque Psoriasis	<u>Initial dose:</u> 80 mg <u>Maintenance dose:</u> 40 mg subcutaneously every other week starting one week after initial dose	40 mg every other week
	Hidradenitis Suppurativa	Adults: Day 1: 160 mg (given in one day or split over two consecutive days) Day 15: 80 mg Day 29 and subsequent doses: 40 mg every week or 80 mg every other week Adolescents: For patients 12 years of age and older: <u>Initial dose:</u> Weight 30 kg (66 lbS) to < 60 kg (132 lbs): 80 mg subcutaneously on Day 1, then 40 mg on Day 8 Weight ≥ 60 kg (132 lbs): 160 mg subcutaneously (given in one day or split over two consecutive days) on Day 1, then 80 mg subcutaneously on Day 15 <u>Maintenance dose:</u> Weight 30 kg (66 lbS) to < 60 kg (132 lbs): 40 mg every other week Weight ≥ 60 kg (132 lbs): 40 mg subcutaneously once weekly or 80 mg every other week starting on Day 29	40 mg/week
	Uveitis	Pediatrics: Weight 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg subcutaneously every other week Weight 15 kg (33 lbs) to < 30 kg (66 lbs):	40 mg every other week

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
		20 mg subcutaneously every other week Weight ≥ 30 kg (66 lbs): 40 mg subcutaneously every other week Adults: Initial dose: 80 mg subcutaneously Maintenance dose: 40 mg every other week starting one week after initial dose	

Dosage Forms

- Single-dose prefilled pen: 80 mg/0.8 mL, 40 mg/0.8 mL, 40 mg/0.4 mL
- Single-dose prefilled syringe: 80 mg/0.8 mL, 40 mg/0.8 mL, 40 mg/0.4 mL, 20 mg/0.4 mL, 20 mg/0.2 mL, 10 mg/0.2 mL, 10 mg/0.1 mL
- Single-use vial for institutional use only: 40 mg/0.8 mL

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Rheumatoid Arthritis (must meet all):

1. Diagnosis of Rheumatoid Arthritis (RA);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Trial and failure of a ≥ 3 months of at least one conventional systemic therapy (methotrexate [MTX], sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   *Exception: If one biologic DMARD that is FDA-approved for rheumatoid arthritis has been previously tried, then trial of a conventional systemic agent is not required;
5. Dose does not exceed 40 mg/week.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

B. Juvenile Idiopathic Arthritis (must meet all)**:**

1. Diagnosis of PJIA;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 2 years ;
4. Trial and failure of a ≥ 3 months of at least one (1) conventional systemic therapy (leflunomide [Arava®] or methotrexate)unless contraindicated or clinically significant adverse effects are experienced;

5. Dose does not exceed 40 mg every other week.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

C. Psoriatic Arthritis (must meet all)**:**
1. Diagnosis of Psoriatic Arthritis (PsA);
2. Prescribed by or in consultation with a dermatologist or a rheumatologist;
3. Age ≥ 18 years;
4. Dose does not exceed 40 mg every other week.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

D. Ankylosing Spondylitis (must meet all):
1. Diagnosis of active ankylosing spondylitis (AS);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Trial and failure of at least two (2) non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for at ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 40 mg every other week.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

E. Crohn's Disease (must meet all):
1. Diagnosis of Crohn's Disease (CD);
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 6 years;
4. Member meets one of the following (a or b):
   a. Trial and failure of a ≥ 3 months of at least one (1) conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   a. Trial and failure of corticosteroids (e.g., prednisone, methylprednisolone, budesonide), unless contraindicated or significant adverse effects experienced;
   *Exception: If one biologic DMARD that is FDA-approved for crohn's disease has been previously tried, then trial of a conventional systemic agent is not required;
5. Dose does not exceed 40 mg every other week.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

F. Ulcerative Colitis (must meet all):
1. Diagnosis of Ulcerative Colitis (UC);
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 5 years ;
4. Member meets one of the following (a or b):

a. Trial and failure of ≥ 3 months of at least one (1) conventional agent (azathioprine, 6-mercaptopurine, aminosalicylate) unless contraindicated or clinically significant adverse effects are experienced;
b. Trial and failure of corticosteroids (e.g., prednisone, methylprednisolone, budesonide) unless contraindicated or significant adverse effects experienced;
*Exception: If one biologic DMARD that is FDA-approved for ulcerative colitis has been previously tried, then trial of a conventional systemic agent is not required;

5. Dose does not exceed (a or b):
   a. Age ≥ 18 years: 40 mg every other week;
   b. Age ≥ 6 years to 17 years: 80 mg every other week.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

G. Plaque Psoriasis (must meet all):
1. Diagnosis of Plaque Psoriasis (PsO);
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Trial and failure of ≥ 3 months of at least one (1) conventional systemic therapy (methotrexate [MTX], cyclosporin, acitretin) or phototherapy (psoralen plus ultraviolet A light [PUVA]) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
*Exception: If one biologic DMARD that is FDA-approved for plaque psoriasis has been previously tried, then trial of a conventional systemic agent or phototherapy is not required;
5. Dose does not exceed 40 mg every other week.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

H. Hidradenitis Suppurativa (must meet all):
1. Diagnosis of Hiradenitis Suppurativa (HS);
2. Prescribed by or in consultation with a dermatologist, a rheumatologist, or a gastroenterologist;
3. Age ≥ 12 years;
4. Documentation of Hurley stage II or stage III (see Appendix D);
5. Trial and failure of at least ≥ 3 months of systemic antibiotic therapy (e.g., clindamycin, minocycline, doxycycline, rifampin) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 40 mg/week.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

I. Uveitis (must meet all):
1. Diagnosis of non-infectious intermediate, posterior, or panuveitis;
2. Age ≥ 2 years;
3. Prescribed by or in consultation with an ophthalmologist or a rheumatologist;
4. Member meets both (a and b):
   a. Trial and failure of at least ≥ 2-week trial of a systemic corticosteroid (e.g., prednisone) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are

experienced;

b. Trial and failure of at least one (1) conventional systemic therapy (e.g., azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, tacrolimus, cyclophosphamide, chlorambucil) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;

5. Dose does not exceed 40 mg every other week.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed maximum dose indicated in dosing information.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

AS: Ankylosing Spondylitis
CD: Crohn's Disease
DMARDs: Disease-Modifying Antirheumatic Drugs
NSAIDs: Non-Steroidal Anti-Inflammatory Drugs
JIA: Juvenile Idiopathic Arthritis
PsO: Plaque Psoriasis
PsA: Psoriatic Arthritis
RA: Rheumatoid Arthritis
UC: Ulcerative Colitis
UV: Uveitis
HS: Hidradenitis Suppurativa
TNF: tumor necrosis factor
PUVA: psoralen plus ultraviolet A light

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
acitretin	**PsO:** 25 or 50 mg orally once daily	50 mg/day
azathioprine (Azasan®, Imuran®)	**RA:** 1 mg/kg/day orally once daily or divided twice daily **CD (off-label), UC (off-label), UV (off-label):** 1.5 – 2 mg/kg/day orally	2.5 mg/kg/day

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
clindamycin (Cleocin®) + rifampin (Rifadin®)	**HS (off-label):** clindamycin 300 mg orally twice daily and rifampin 300 mg orally twice daily	clindamycin: 1,800 mg/day rifampin: 600 mg/day
Corticosteroids	**CD:** prednisone 40 mg orally once daily for 2 weeks or intravenously 50 – 100 mg Q6H for 1 week budesonide (Entocort EC®) 6 – 9 mg orally once daily **UV:** prednisone 5 – 60 mg/day orally in 1 – 4 divided doses	Various
d-penicillamine (Cuprimine®)	**RA(off-label):** Initial dose: 125 or 250 mg orally once daily Maintenance dose: 500 – 750 mg/day orally once daily	1,500 mg/day
cyclophosphamide	**UV (off-label):** 1 – 3 mg/kg/day orally	N/A
cyclosporine (Sandimmune®, Neoral®)	**PsO:** 1 – 4 mg/kg/day orally divided twice daily **RA:** 2.5 – 4 mg/kg/day orally divided twice daily **UV (off-label):** 2.5 – 5 mg/kg/day orally in divided doses	PsO, RA: 4 mg/kg/day UV: 5 mg/kg/day
doxycycline (Acticlate®)	**HS(off-label):** 100 mg orally twice daily	200 mg/day
hydroxychloroquine (Plaquenil®)	**RA (off-label):** Initial dose: 400 – 600 mg/day orally once daily Maintenance dose: 200 – 400 mg/day orally once daily	600 mg/day
leflunomide (Arava®)	**PJIA (off-label):** Weight < 20 kg: 10 mg every other day Weight 20 - 40 kg: 10 mg/day Weight > 40 kg: 20 mg/day **RA:** 100 mg orally once daily for 3 days, then 20 mg orally once daily	PJIA, RA: 20 mg/day SJIA: 10 mg every other day
mercaptopurine (Purixan®)	**C (off-label), UC (off-label):** 50 mg orally once daily or 1 – 2 mg/kg/day orally	2 mg/kg/day
methotrexate	**CD(off-label):** 15 – 25 mg/week intramuscularly or subcutaneously **PsO:** 10 – 25 mg/week orally or 2.5 mg orally Q12 hr for 3 doses/week **PJIA(off-label):** 10 – 20 mg/m^2/week orally, subcutaneously, or intramuscularly	

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
	RA: 7.5 mg/week orally, subcutaneously, or intramuscularly or 2.5 mg orally Q12 hr for 3 doses/week **UV (off-label):** 15 mg/m^2 once weekly	
minocycline	**HS (off-label):** 50 – 100 mg orally twice daily	200 mg/day
mycophenolate mofetil (Cellcept®)	**UV (off-label):** Oral: Initial: 500 mg twice daily for 2 weeks; increase to a maintenance dose of 1 to 1.5 g twice daily as tolerated	3 g/day
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS:** Varies	Varies
Mesalamine (Pentasa®)	**CD, UC:** 1,000 mg orally four times daily	4 g/day
Ridaura®	**RA:** 6 mg orally once daily or 3 mg orally twice daily	9 mg/day (3 mg Three times daily)
sulfasalazine (Azulfidine®)	**JIA (off-label):** 30-50 mg/kg/day orally divided twice daily **RA:** 2 g/day orally in divided doses **UC:** Initial dose: Adults: 3 – 4 g/day orally in divided doses (not to exceed Q8 hrs) Pediatrics: 40 – 60 mg/kg/day orally in 3 –6 divided doses Maintenance dose: Adults: 2 g orally once daily Pediatrics: 30 mg/kg/day orally in 4 divided doses **UV (off-label):** 0.1-0.15 mg/kg/day orally	PJIA: 2 g/day RA: 3 g/day UC: 4 g/day
tacrolimus (Prograf®)	**CD (off-label):** 0.27 mg/kg/day orally in divided doses or 0.15 – 0.29 mg/kg/day orally	N/A
Biologic DMARDs		
Enbrel®	**RA, PsA:** 25 mg subcutaneously twice weekly or 50 mg subcutaneously once weekly **JIA:** Weight < 63 kg: 0.8 mg/kg subcutaneously once weekly Weight ≥ 63 kg: 50 mg subcutaneously once weekly **PsO:** Adults: Initial dose: 50 mg subcutaneously twice weekly for 3	RA, PsA, JIA, PsO,AS: 50 mg/week

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
	months (Starting doses of 25 mg or 50 mg per week are also shown to be efficacious) Maintenance dose: 50 mg subcutaneously once weekly Pediatrics: Weight < 63 kg: 0.8 mg/kg subcutaneously once weekly Weight ≥ 63 kg: 50 mg subcutaneously once weekly **AS:** 50 mg subcutaneously once weekly	
Cosentyx®	**AS:**With loading dose: 150 mg subcutaneously at weeks 0, 1, 2, 3, and 4, followed by 150 mg subcutaneously every 4 weeks thereafter Without loading dose: 150 mg subcutaneously every 4 weeks If the patient continues to have active ankylosing spondylitis: 300 mg every 4 weeks can be considered **PsO:** Adults:300 mg subcutaneously at weeks 0, 1, 2, 3, and 4, followed by 300 mg subcutaneously every 4 weeks. (For some patients, a dose of 150 mg may be acceptable) Pediatric Patients 6 years of age and older Weight < 50 kg: 75 mg at weeks 0,1,2,4 and 4 followed by dosing every 4 weeks Weight ≥ 50 kg: 150 mg at weeks 0,1,2,3 and 4 followed by dosing every 4 weeks **PsA:** With loading dose: 150 mg subcutaneously at week 0, 1, 2, 3, and 4, followed by 150 mg subcutaneously every 4 weeks Without loading dose: 150 mg subcutaneously every 4 weeks If a patient continues to have active psoriatic arthritis, consider a dosage of 300 mg every 4 weeks. Pediatric Patients 2 years and older: Recommended dosage is administered by subcutaneous injection at weeks 0,1 ,2,3, and 4 and every 4 weeks after: For patients weighing ≥ 15 kg and < 50 kg the dose is 75 mg. For patients weighing ≥ 50 kg the dose is 150 mg.	AS: 300mg every 4 weeks Nr-axSpA: 150 mg every 4 weeks PsO: Adults:300 mg every 4 weeks Pediatrics: Weight < 50 kg: 75 mg every 4 weeks Weight ≥ 50 kg: 150 mg every 4 weeks PsA: 300 mg every 4 weeks
infliximab	**AS:** Initial dose:	AS:

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
(Remicade®), Renflexis®, Inflectra®	5 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg intravenously every 6 weeks **CD, UC:** Initial dose: 5 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg intravenously every 8 weeks.Pediatric UC and CD : ≥ 6 years old For CD: Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response. **PsO, PsA:** Initial dose: 5 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg intravenously every 8 weeks **RA:** In conjunction with MTX Initial dose: 3 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 3 mg/kg intravenously every 8 weeks Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks	5 mg/kg every 6 weeks CD Adults: 10 mg/kg every 8 weeks UC Adults: 5 mg/kg every 8 weeks Pediatrics: 5 mg/kg every 8 weeks PsO, PsA: 5 mg/kg every 8 weeks RA: 10 mg/kg every 4 weeks
Simponi Aria®	**AS, PsA, RA:** Initial dose: 2 mg/kg intravenously at weeks 0 and 4 Maintenance dose: 2 mg/kg intravenously every 8 weeks **JIA:** Initial dose: 80 mg/m^2 at weeks 0 and 4 Maintenance dose: 80 mg/m^2 intravenously every 8 weeks	AS, PsA, RA: 2 mg/kg every 8 weeks JIA: 80 mg/m2 every 8 weeks
Otezla®	**PsO, PsA:** Initial dose: Day 1: 10 mg orally in morning Day 2: 10 mg orally in morning and 10 mg orally in evening Day 3: 10 mg orally in morning and 20 mg orally in evening Day 4: 20 mg orally in morning and 20 mg orally in evening Day 5: 20 mg orally in morning and 30 mg orally in evening Maintenance dose:	PsO, PsA: 60 mg/day

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
	Day 6 and thereafter: 30 mg orally twice daily	
Xeljanz®	**UC:** Induction:10 mg orally twice daily for at least 8 weeks, based on therapeutic response, may continue 10 mg twice daily for a maximum of 16 weeks or transition to maintenance dose. Discontinue after 16 weeks of 10 mg twice daily if adequate therapeutic benefit is not achieved. Maintenance: 5 mg twice daily; if loss of response on 5 mg twice daily, then use 10 mg twice daily after assessing the benefits and risks and use for the shortest duration; use lowest effective dose to maintain response. **AS:** 5 mg orally twice daily **PsA:** use in combination with nonbiologic disease-modifying antirheumatic drugs **RA:** monotherapy or use in combination with nonbiologic disease-modifying antirheumatic drugs **PJIA:** Children 2 years and older weighing 10 to 19 kg: 3.2 mg orally twice daily Children and Adolescents 2 to 17 years weighing 20 to 39 kg: 4 mg orally twice daily Children and Adolescents 2 to 17 years weighing 40 kg or more: 5 mg orally twice daily	UC: 20 mg/day PsA, RA, AS: 10 mg/day PJIA: 5 mg twice daily
Xeljanz® XR/, Xeljanz® oral Solution	**JIA:** 5 mg twice daily or weight-based equivalent twice daily: • 10 kg ≤ body weight <20 kg: 3.2 mg (3.2 mL oral solution) twice daily • 20 kg ≤ body weight <40 kg: 4 mg (4 mL oral solution) twice daily Body weight ≥40 kg: 5 mg (one 5 mg tablet or 5 mL oral solution) twice daily	JIA: 5 mg or 5 ml twice daily
Xeljanz® XR	**PsA, RA, AS:** 11 mg orally once daily **UC:** Induction: 22 mg once daily for at least 8 weeks; may continue 22 mg once daily for a maximum of 16 weeks or transition to maintenance dose. Discontinue therapy if inadequate response achieved after 16 weeks using 22 mg once daily. Maintenance: 11 mg once daily; if loss of response on 11 mg once daily; then use 22 mg once daily for the	PsA, RA, AS: 11 mg/day UC: 22 mg daily

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
	shortest duration;use lowest effective dose to maintain response.	
Kevzara®	**RA:** 200 mg subcutaneously once every two weeks	200 mg/2 Weeks
Actemra®	**JIA:** Weight < 30 kg: 10 mg/kg intravenously every 4 weeks or 162 mg subcutaneously every 3 weeks. Weight ≥ 30 kg: 8 mg/kg intravenously every 4 weeks or 162 mg subcutaneously every 2 weeks. **RA:** Intravenously: 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response. Subcutaneously: Weight < 100 kg: 162 mg every other week, followed by an increase to every week based on clinical response. Weight ≥ 100 kg: 162 mg every week.	JIA: Intravenously: 10 mg/kg every 4 weeks Subcutaneously: 162 mg every 2 weeks RA: Intravenously: 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response. Subcutaneously: Weight < 100 kg: 162 mg every other week, followed by an increase to every week based on clinical response. Weight ≥ 100 kg: 162 mg every week.
Cimzia®	**AS, PsA:** **RA:** Initial dose: 400 mg subcutaneously at 0, 2, and 4 weeks. Maintenance dose: 200 mg subcutaneously every other week (or 400 mg subcutaneous every 4 weeks) **CD:** Initial dose: 400 mg subcutaneously at 0, 2, and 4 weeks Maintenance dose: 400 mg subcutaneously every 4 weeks **PsO:** 400 mg subcutaneously every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg subcutaneously at 0, 2 and 4 weeks, followed by 200 mg subcutaneously every other week may be considered.	AS, nr-axSpA, PsA: RA: 400 mg every 4 weeks CD: 400 mg every 4 weeks Pso: 400 mg every other week
Entyvio®	**CD, UC:** Initial dose: 300 mg intravenously at weeks 0, 2, and 6 Maintenance dose: 300 mg intravenously every 8 weeks	CD, UC: 300 mg every 8 weeks
Ilumya®	**PsO:** Initial dose: 100 mg subcutaneously at weeks 0 and 4 Maintenance dose: 100 mg subcutaneously every 12 weeks	PsO: 100 mg every 12 weeks

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
	Tildrakizumab should only be administered by a healthcare professional.	
Kineret®	**RA:** 100 mg subcutaneously once daily	RA: 100 mg/day
Olumiant®	**RA:** 2 mg orally once daily	RA: 2 mg/day
Orencia®	**JIA:** Intravenously: in pediatric patients ≥ 6 years old weight-based dose at weeks 0, 2, and 4, followed by every 4 weeks Weight < 75 kg: 10 mg/kg per dose Weight 75 to 100 kg: 750 mg per dose Weight >100 kg: 1,000 mg per dose Subcutaneously: In pediatric patients ≥ 2 years old weight-based dose once weekly Weight 10 to < 25 kg: 50 mg per dose Weight 25 to < 50 kg: 87.5 mg per dose Weight ≥ 50 kg: 125 mg per dose **RA, PsA:** Intravenously: weight-based dose at weeks 0, 2, and 4, followed by every 4 weeks Weight < 60 kg: 500 mg per dose Weight 60 to 100 kg: 750 mg per dose Weight > 100 kg: 1,000 mg per dose Subcutaneously: 125 mg once weekly **RA and PsA:** Patients switching from intravenous use to subcutaneous use, administer first subcutaneous dose instead of next scheduled intravenous dose. (For RA: Prior to the first subcutaneous dose, may administer an optional loading dose as a single intravenous infusion as per body weight categories above.) For PsA: Intravenous loading dose is not recommended	JIA: Intravenously: 1,000 mg every 4 weeks Subcutaneously: 125 mg/week RA, PsA: Intravenously: 1,000 mg every 4 weeks Subcutaneously: 125 mg/week
Rinvoq®	**RA and PsA:** 15 mg orally once daily Can be used as monotherapy or in combination with methotrexate or other non-biologic DMARDs. *For use in adults who have had an inadequate response or intolerance to one or more TNF blockers	RA and PsA: 15 mg/day
Siliq®	**PsO:** Initial dose: 210 mg subcutaneously at weeks 0, 1, and 2 Maintenance dose: 210 mg subcutaneously every 2 weeks	PsO: 210 mg every 2 weeks

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
Simponi®	**AS, PsA, RA:** 50 mg subcutaneously once monthly **UC:** Initial dose: 200 mg subcutaneously at week 0, then 100 mg subcutaneoulys at week 2 Maintenance dose: 100 mg subcutaneously every 4 weeks	AS, PsA, RA: 50 mg/month UC: 100 mg every 4 weeks
Simponi Aria®	**JIA:** Initial dose: 80 mg/m^2 at weeks 0 and 4 Maintenance dose: 80 mg/m^2 intravenously every 8 weeks **AS, PsA, RA:** Initial dose: 2 mg/kg IV at weeks 0 and 4 Maintenance dose: 2 mg/kg intravenously every 8 weeks	JIA: 80 mg/m^2 every 8 weeks AS, PsA, RA: 2 mg/kg every 8 weeks
Skyrizi®	**PsO:** 150 mg subcutaneously at weeks 0, 4, and every 12 weeks thereafter	PsO: 150 mg/12 Weeks
Stelara®	**CD, UC:** Weight based dosing intravenously at initial dose, followed by 90 mg subcutaneously every 8 weeks Weight ≤ 55 kg: 260 mg Weight 55 kg to 85 kg: 390 mg Weight > 85 kg: 520 mg **PsO:** Weight based dosing subcutaneously at weeks 0 and 4, followed by maintenance dose every 12 weeks Adult: Weight ≤ 100 kg: 45 mg (some patients may require doses of 90 mg or maintenance dosing of every 8 weeks) Weight > 100 kg: 90 mg (some patients may require maintenance dosing of every 8 weeks) Pediatrics (Age 6 years and older): Weight < 60 kg: 0.75 mg/kg Weight ≥ 60 to ≤100 kg: 45 mg Weight > 100kg: 90 mg **PsA:** 45 mg subcutaneously at weeks 0 and 4, followed by 45 mg every 12 weeks	CD, UC: 90 mg every 8 weeks PsO: 90 mg every 8 weeks PsA: 45 mg every 12 weeks
Taltz®	**PsO:** Adult Plaque Psoriasis: Recommended dose is 160 mg subcutaneously (two 80 mg injections) at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks Pediatric Plaque Psoriasis (age 6 years or older):	nr-axSpA: 80 mg every 4 weeks PsO: 80 mg every 4 weeks

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
	For patients weighing greater than 50 kg:160 mg subcutaneously (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks. For patients weighing 25-50 kg: 80 mg subcutaneously at Week 0, followed by 40 mg every 4 weeks. For patients weighing less than 25 kg:40 mg subcutaneously at Week 0, followed by 20 mg every 4 weeks **AS, PsA:** Initial dose: 160 mg (two 80 mg injections) subcutaneously Maintenance dose: 80 mg subcutaneously every 4 weeks	AS, PsA: 80 mg every 4 weeks
Tremfya®	**PsO, PsA:** Initial dose: 100 mg subcutaneously at weeks 0 and 4 Maintenance dose: 100 mg subcutaneously every 8 weeks Can be used alone or in combination with conventional DMARD e.g. methotrexate	PsO, PsA: 100 mg every 8 weeks
Tysabri®	**CD:** 300 mg intravenously every 4 weeks	CD: 300 mg every 4 Weeks
Avsola®	**AS:** 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 6 weeks thereafter. **CD:** 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 8 weeks thereafter; dose may be increased to 10 mg/kg every 8 weeks in patients who respond but then lose their response **UC, PsO, PsA:** 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 8 weeks thereafter **RA:** 3 mg/kg at 0, 2, and 6 weeks, followed by a maintenance regimen of 3 mg/kg every 8 weeks thereafter	AS, CD, UC, PsO, PsA: 5 mg/kg RA: 3 mg/kg

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - Serious infections;
  - Malignancies

APPENDIX D: General Information

- Ankylosing Spondylitis:
  - Several AS treatment guidelines call for a trial of 2 or 3 NSAIDs prior to use of an anti- TNF agent. A two year trial showed that continuous NSAID use reduced radiographic progression of AS versus on demand use of NSAID.
- Polyarticular Juvenile Idiopathic Arthritis:
  - Failure of MTX in PJIA is defined as disease activity remaining moderate to high despite treatment with MTX.
  - In PJIA, response to treatment is reflected by improvement of disease activity level and poor prognostic features including: reduction in the number of active joints, ESR or CRP, Physician global assessment, patient/parent global assessment, arthritis of the hip or cervical spine, positive RF or ACPA, radiographic damage.
- Hidradenitis suppurativa:
  - HS is sometimes referred to as: "acne inversa, acne conglobata, apocrine acne, apocrinitis, Fox-den disease, hidradenitis axillaris, HS, pyodermia sinifica fistulans, Velpeau's disease, and Verneuil's disease."
  - In HS, Hurley stages are used to determine severity of disease. Hurley stage II indicates moderate disease, and is characterized by recurrent abscesses, with sinus tracts and scarring, presenting as single or multiple widely separated lesions. Hurley stage III indicates severe disease, and is characterized by diffuse or near-diffuse involvement presenting as multiple interconnected tracts and abscesses across an entire area.

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Review/Revision History	Review/Revision Date	P&T Approval Date
RxA.592.Biologic_DMARDs was last reviewed and updated on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Biologics_DMARDs.	01/05/2022	4/18/2022
Drug specific policy for Humira® was created based on RxA.592.Biologics_DMARDs: 1. Initial Approval Criteria, I.A.5, I.H.6: Updated dosing criteria from Dose does not exceed maximum dose indicated in background to Dose does not exceed 40 mg/week. *Enter quantity limit for the dose of the indication consistent with FDA approved labeling. 2. Initial Approval Criteria, I.B.4: Updated to include new trial and failure criteria Trial and failure of a ≥ 3 months of at least one (1) conventional systemic therapy (leflunomide [Arava®] or methotrexate)unless contraindicated or clinically significant adverse effects are experienced; 3. Initial Approval Criteria, I.B.5, I.C.4, I.D.5, I.E.5, I.G.5, I.I.5: Updated dosing criteria from Dose does not exceed maximum dose indicated in background to Dose does not exceed 40 mg every other week. *Enter quantity limit for the dose of the indication consistent with FDA approved labeling. 4. Initial Approval Criteria, I.E.4: Updated to remove Medical justification supports inability to use immunomodulators (see Appendix D). 5. Initial Approval Criteria, I.F.5:	02/11/2022	4/18/2022

Updated dosing criteria from Dose does not exceed maximum dose indicated in background to Dose does not exceed (a or b): 6. Age ≥ 18 years: 40 mg every other week; 7. Age ≥ 6 years to 17 years: 80 mg every other week. *Enter quantity limit for the dose of the indication consistent with FDA approved labeling. 8. Initial Approval Criteria, I.G.4: Updated trial and failure criteria to rephrase and include phototherapy (psoralen plus ultraviolet A light [PUVA]). 9. Continued Therapy Approval Criteria II.A.3 was updated to include *Enter quantity limit for the dose of the indication consistent with FDA approved labeling. 10. Appendix A: Updated to include abbreviations PUVA. 11. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative Soriatane®. 12. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs. 13. Appendix D, General Information: Updated to remove information regarding: (a, b, c, d, e, f, g and h) a. Rheumatoid Arthritis; b. Ulcerative Colitis; c. Medical justification supporting inability to use an immunomodulator for Crohn's disease; d. Definition of failure of MTX or DMARDs; e. Examples of positive response to therapy.		

f. Psoriatic Arthritis; g. The American Academy of Neurology (2018) Guidelines h. For female patients who are actively attempting to conceive. 14. References were reviewed and updated.		