

Clinical Policy: Biologic and Non-biologic DMARDs

Reference Number: HIM.PA.SP60

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Line of Business: HIM

Coding Implications
Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

Description

The following are biologic and non-biologic disease-modifying anti-rheumatic drugs (DMARDs) requiring prior authorization: tocilizumab (Actemra®), adalimumab (Humira®), adalimumab-afzb (Abrilada[™]), adalimumab-atto (Amjevita[™]), adalimumab-adbm (Cyltezo[®]), adalimumab-bwwd (Hadlima[™]), adalimumab-fkip (Hulio[®]), adalimumab-adaz (Hyrimoz[®]), adalimumab-aacf (Idacio®), adalimumab-ryvk (Simlandi®), adalimumab-aaty (Yuflyma®), adalimumab-aqvh (Yusimry[™]), infliximab-axxq (Avsola[™]), tocilizumab-anoh (Avtozma[®]), bimekizumab-bkzx (Bimzelx[®]), certolizumab pegol (Cimzia[®]), secukinumab (Cosentyx[®]), etanercept (Enbrel[®]), vedolizumab (Entyvio®), tildrakizumab-asmn (Ilumya™), ustekinumab-srlf (Imuldosa™), infliximab-dyyb (Inflectra®, Zymfentra®), sarilumab (Kevzara®), anakinra (Kineret®), baricitinib (Olumiant[®]), mirikizumab-mrkz (Omvoh[™]), abatacept (Orencia[®]), apremilast (Otezla[®]), ustekinumab-aauz (Otulfi®), ustekinumab-ttwe (Pyzchiva®), infliximab (Remicade®), infliximababda (Renflexis[™]), upadacitinib (Rinvoq[®], Rinvoq LQ[®]), ustekinumab-aekn (Selarsdi[™]), brodalumab (Siliq[™]), golimumab (Simponi[®], Simponi Aria[®]), risankizumab-rzaa (Skyrizi[®]), deucravacitinib (Sotyktu™), ustekinumab (Stelara®), ustekinumab-stba (Steqeyma®), ixekizumab (Taltz[®]), tocilizumab-bavi (Tofidence[™]), guselkumab (Tremfya[®]), tocilizumab-aazg (Tyenne[®]), natalizumab-sztn (Tyruko[®]), natalizumab (Tysabri[®]), etrasimod (Velsipity[™]), ustekinumab-auub (Wezlana[™]), tofacitinib (Xeljanz[®], Xeljanz[®] XR), ustekinumab-kfce (Yesintek[™]). ozanimod (Zeposia[®]).

FDA Approved Indication(s)

TDA Approved Indicati	¥ (*)									
	AS	nr-axSpA	CD	nc	PJIA	SJIA	PsO	P_{SA}	RA	Others
Abrilada	X		X	X	X		X	X	X	HS, UV
Actemra					x [#]	x#			x [#]	CRS*, GCA*, SSc-ILD^, COVID-19 in the hospitalized setting
Amjevita	X		X	X	X		X	X	X	HS, UV
Avsola	X		X	X			X	X	X	
Avtozma					X [#]	$\mathbf{X}^{\#}$			X [#]	COVID-19 in the hospitalized setting, GCA [#]
Bimzelx	X	X					X	X		HS
Cimzia	X	X	X		X		X	X	X	
Cyltezo/adalimumab- adbm	х		X	X	X		X	X	Х	HS, UV
Cosentyx	X	X					X	X		ERA, HS
Enbrel	X				X		X	X	X	



		Y ₀								ø
	AS	nr-axSpA	CD	nc	PJIA	SJIA	PsO	PsA	RA	Others
Entyvio		-	X [#]	X [#]						
Hadlima/adalimumab-	Х		X	X	X		X	X	X	HS, UV
bwwd	74		1	71	1		7.	71	1	115, 5 (
Hulio/adalimumab-fkjp	х		Х	X	X		X	Х	X	HS, UV
Humira	Х		X	X	X		X	X	X	HS, UV
Hyrimoz/adalimumab- adaz	Х		X	X	X		X	X	Х	HS, UV
Idacio/adalimumab-aacf	X		X	X	X		X	X	X	HS, UV
Ilumya							X			
Imuldosa			X #	X [#]			x^	x^		
Inflectra	X		X	X			X	X	X	
Kevzara					X				X	PMR
Kineret									X	DIRA, NOMID
Olumiant									X	COVID-19 in the hospitalized setting, alopecia areata
Omvoh			X #	X [#]						
Orencia					$\mathbf{X}^{\#}$			$\mathbf{X}^{\#}$	$\mathbf{x}^{\#}$	aGVHD
Otezla				.,,			X	X		BD
Otulfi			X#	X#			X^	x ^		
Pyzchiva			X #	X #			x^	x^		
Remicade/unbranded Remicade	Х		X	X			X	X	X	
Renflexis	X		X	X			X	X	X	
Rinvoq	X	X	X	X	X			X	X	AD
Rinvoq LQ				,,	X			X		
Selarsdi			x #	X #			x^	x		
Siliq							X			
Simlandi/adalimumab- ryvk	Х		X	X	X		X	X	X	HS, UV
Simponi	X			X				X	X	
Simponi Aria	X				X			X	X	
Skyrizi			X #	X #			X	X		
Sotyktu			#	#			X	^		
Stelara			X#	X#			X^	x^		
Steqeyma			X #	X #			X [^]	x^		
Taltz Tofidence	X	X			X	X	X	X	х	COVID-19 in the hospitalized
Tremfya			X [#]	X [#]			X	X		setting, GCA
Tyenne					X [#]	X [#]			X [#]	CRS*, COVID-19 in the hospitalized setting, GCA#
Tyruko			X							MS
Tysabri			X							MS
Velsipity				X						
Wezlana			X #	X [#]			x^	x		
Xeljanz	X			X	X			X	X	
Xeljanz XR	X		JI	X			^	X	X	
Yesintek			X [#]	$\mathbf{x}^{\#}$			x^	x		



	AS	nr-axSpA	CD	nc	PJIA	SJIA	PsO	PsA	RA	Others
Yuflyma/adalimumab-	X		X	X	X		X	X	X	HS, UV
aaty										
Yusimry	X		X	X	X		X	X	X	HS, UV
Zeposia				X						MS
Zymfentra			X	X						

If available as IV and SC, then: *=IV only; #=IV/SC; ^= SC only; *=IR only

AD=atopic dermatitis; AS=ankylosing spondylitis; nr-axSpA=non-radiographic axial spondyloarthritis; CD=Crohn's disease; COVID-19=coronavirus disease 2019; UC=ulcerative colitis; GCA = giant cell arteritis; NOMID=neonatal-onset multisystem inflammatory disease; PJIA=polyarticular juvenile idiopathic arthritis; SJIA=systemic juvenile idiopathic arthritis; PsO=plaque psoriasis; PsA=psoriatic arthritis; RA=rheumatoid arthritis; HS=hidradenitis suppurativa, MS=multiple sclerosis, UV=uveitis; CRS=cytokine release syndrome; BD=Behçet's disease; SSc-ILD=systemic sclerosis-associated interstitial lung disease; ERA=enthesitis-related arthritis; aGVHD=acute graft-versus-host disease; PMR=polymyalgia rheumatica

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 - P. Polymyalgia Rheumatica
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VI. Product Availability

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Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Abrilada, Actemra, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Avsola, Avtozma, Bimzelx, Cimzia, Cosentyx, Cyltezo, Enbrel, Entyvio, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Ilumya, Imuldosa, Inflectra, Kevzara, Kineret, Olumiant, Omvoh, Orencia, Otezla, Otulfi, Pyzchiva, Remicade/unbranded Remicade, Renflexis, Rinvoq, Rinvoq LQ, Selarsdi, Siliq, Simlandi, Simponi, Simponi Aria, Skyrizi, Sotyktu, Stelara, Steqeyma, Taltz, Tofidence, Tremfya, Tyenne, Tyruko, Tysabri, Velsipity, Wezlana, Xeljanz, Xeljanz XR, Yesintek, Yuflyma, Yusimry, Zeposia, and Zymfentra are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Atopic Dermatitis (must meet all):

- 1. Diagnosis of atopic dermatitis affecting one of the following (a or b):
 - a. At least 10% of the member's body surface area (BSA);
 - b. Hands, feet, face, neck, scalp, genitals/groin, and/or intertriginous areas;
- 2. Request is for Rinvog;
- 3. Prescribed by or in consultation with a dermatologist or allergist;
- 4. Age \geq 12 years;
- 5. Failure of both of the following (a and b), unless contraindicated or clinically significant adverse effects are experienced:

 †

 | Total Ulinois HIM requests | the step thereon requirements below do not apply as of 1/1/2026 p.

 † For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395

- a. One formulary medium to very high potency topical corticosteroid used for ≥ 2 weeks;
- b. One non-steroidal topical therapy* used for ≥ 4 weeks: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment, pimecrolimus 1% cream) or Eucrisa®; *These agents may require prior authorization
- Rinvoq is not prescribed concurrently with another biologic medication (e.g., Adbry[®], Dupixent[®]) or JAK inhibitors (e.g., Olumiant[®], Cibinqo[®], Opzelura[™]) (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 7. Dose does not exceed maximum dose* indicated in Section V.

 *Maximum dose escalation allowed per prescriber information with documentation of inadequate Speresponse.

Approval duration: 6 months

B. Axial Spondyloarthritis (must meet all):

- 1. Diagnosis of AS or nr-axSpA;
- 2. Request is for one of the following: Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp,



adalimumab-ryvk, Amjevita, Avsola, Bimzelx, Cimzia, Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade/unbranded Remicade, Renflexis, Rinvoq, Simlandi, Simponi, Simponi Aria, Taltz, Xeljanz, Xeljanz XR, Yuflyma, or Yusimry;

- 3. Prescribed by or in consultation with a rheumatologist;
- 4. Age \geq 18 years;
- 5. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;[†]
 [†]For Illinois HIM requests, the step therapy requirements above do not apply to formulary agents as of
 - T For Illinois HIM requests, the step therapy requirements above do not apply to formulary agents as of 1/1/2026 per IL HB 5395
- 6. For nr-axSpA for Bimzelx, Cimzia or Taltz, member meets both of the following (a and b):
 - a. Failure of Cosentyx used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
 - b. If member has not responded or is intolerant to one or more TNF blockers, failure of **Rinvoq**, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
- 7. For AS, one of the following (a, b, c, d, e, or f):
 - a. For Bimzelx, Cimzia, Simponi, Simponi Aria, or Taltz: Member meets ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i, ii, and iii):[†]

[†]For Illinois HIM requests, the step therapy requirements below do not apply to formulary agents as of 1/1/2026 per IL HB 5395

- i. One of the following (1, 2, or 3, see Appendix D):
 - 1) Failure of both of the following, each used for ≥ 3 consecutive months (a and b):
 - a) ONE of the following adalimumab products: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
 - b) Enbrel:
 - 2) If member has had a history of failure of one TNF blocker, then failure of ONE of the following TNF blockers used for ≥ 3 consecutive months: **Enbrel, Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06):
 - 3) History of failure of two TNF blockers and request is not for another TNF blocker;
- ii. Failure of Cosentyx, used for ≥ 3 consecutive months;
- iii. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz®/Xeljanz XR® and Rinvoq each used for ≥ 3 consecutive months, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;



- b. If request is for Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, or Yusimry, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Humira**, **Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), and **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
- c. For Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i, ii, and iii):
 - i. Inflectra and Renflexis;
 - ii. If member has failed Inflectra and Renflexis, then member must use Avsola;
 - iii. If member has failed Inflectra, Renflexis, and Avsola, then member must use **unbranded Remicade**;
- d. For unbranded Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i and ii):
 - i. Inflectra and Renflexis;
 - ii. If member has failed Inflectra and Renflexis, then member must use Avsola;
- e. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis**:
- f. For Rinvoq, Xeljanz, Xeljanz XR: Member has not responded or is intolerant to one or more TNF blockers;
- 8. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 9. Dose does not exceed maximum dose* indicated in Section V.

 *For Cosentyx, maximum dose escalation allowed per prescriber information with documentation of inadequate response.

Approval duration: 6 months

C. Behçet's Disease (must meet all):

- 1. Diagnosis of oral ulcers in members with BD;
- 2. Request is for Otezla;
- 3. Prescribed by or in consultation with a dermatologist or rheumatologist;
- 4. Age \geq 18 years;
- 5. Failure of colchicine at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
- 6. Dose does not exceed 60 mg per day.

Approval duration: 6 months

D. Castleman's Disease (off-label) (must meet all):

- 1. Diagnosis of Castleman's disease;
- 2. Disease is relapsed/refractory or progressive;
- 3. Request is for intravenous Actemra, Avtozma, Tofidence, or Tyenne;



- 4. Member has one of the following (a or b):
 - a. Unicentric disease that is human immunodeficiency virus (HIV)-negative and human herpesvirus 8 (HHV-8)-negative;
 - b. Multicentric disease:
- 5. Prescribed as second-line therapy as a single agent;
- 6. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 7. Request meets one of the following (a or b):*
 - a. Dose does not exceed 8 mg/kg per infusion every 2 weeks;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration: 6 months

E. Crohn's Disease (must meet all):

- 1. Diagnosis of CD;
- 2. Request is for one of the following: Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Avsola, Cyltezo, Cimzia, Entyvio, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Imuldosa, Inflectra, Omvoh, Otulfi, Pyzchiva, Remicade/unbranded Remicade, Renflexis, Rinvoq, Selarsdi, Simlandi, Skyrizi, Stelara, Steqeyma, Tremfya, Tyruko, Tysabri, Wezlana, Yesintek, Yuflyma, Yusimry, or Zymfentra;
- 3. Prescribed by or in consultation with a gastroenterologist;
- 4. Member meets one of the following (a or b):
 - a. For Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Avsola, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra,Remicade/unbranded Remicade, Renflexis, Simlandi, Yuflyma, Yusimry: Age ≥ 6 years;
 - b. For Cimzia, Entyvio, Imuldosa, Omvoh, Otulfi, Pyzchiva, Rinvoq, Selarsdi, Skyrizi, Stelara, Steqeyma, Tremfya, Tyruko, Tysabri, Wezlana, Yesintek, Zymfentra: Age ≥ 18 years;
- 5. If request is for Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, or Yusimry, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), and **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
- 6. Member meets one of the following (a or b):[†]

 †For Illinois HIM requests, the step therapy requirements below do not apply to formulary agents as of 1/1/2026 per IL HB 5395
 - a. Failure of a \geq 3 consecutive month trial of at least ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]) at up to maximally



- indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
- b. Medical justification supports inability to use immunomodulators (*see Appendix E*);
- 7. For Cimzia, Entyvio, Omvoh, Tyruko, or Tysabri: Failure of ALL of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c, see Appendix D):
 - a. ONE of the following adalimumab products, unless the member has had a history of failure of two TNF blockers and request is not for another TNF blocker: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
 - b. Skyrizi, Stelara, and Tremfya;
 - c. If member has not responded or is intolerant to one or more TNF blockers, **Rinvoq**, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
- 8. For Imuldosa, Otulfi, Selarsdi, Steqeyma, Pyzchiva, Wezlana, or Yesintek: Member meets BOTH of the following, used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
 - a. Must use Stelara;
 - b. Failure of all of the following (i, ii, and iii):
 - i. ONE of the following adalimumab products, unless the member has had a history of failure of two TNF blockers and request is not for another TNF blocker: **Humira**, **Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
 - ii. Skyrizi and Tremfya:
 - iii. If member has not responded or is intolerant to one or more TNF blockers, **Rinvoq**, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
- 9. For Skyrizi: Quantity does not exceed one single dose vial or pre-filled cartridge per dose:
- 10. For Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c):
 - a. Inflectra and Renflexis:
 - b. If member has failed Inflectra and Renflexis, then member must use Avsola;
 - c. If member has failed Inflectra, Renflexis, and Avsola, then member must use **unbranded Remicade**;
- 11. For unbranded Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
 - a. Inflectra and Renflexis;
 - b. If member has failed Inflectra and Renflexis, then member must use **Avsola**;
- 12. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis**;



- 13. For Zymfentra, provider attestation that member meets all of the following (a, b, and c, see Appendix D):
 - a. Has received three IV induction doses of an infliximab product prior to initiation;
 - b. Member is responding positively to an IV infliximab product;
 - c. Member is unable to receive continued therapy with IV infliximab due to lack of caregiver or support system for assistance with administration and/or inadequate access to healthcare facility or home care interventions and/or lack of transportation to healthcare facility;
- 14. For Rinvoq*: Member has not responded or is intolerant to one or more TNF blockers:
 - *Prior authorization may be required for TNF blockers
- 15. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 16. Dose does not exceed maximum dose* indicated in Section V.

 *For Avsola, Inflectra, Remicade/unbranded Remicade, Renflexis, maximum dose escalation allowed per prescriber information with documentation of inadequate response.

Approval duration: 6 months

F. Cytokine Release Syndrome (must meet all):

- 1. Request is for Actemra or Tyenne;
- 2. Request is for intravenous formulation;
- 3. Age \geq 2 years;
- 4. Member meets one of the following (a, b, or c):
 - a. Member has a scheduled CAR T cell therapy (e.g., Abecma[®], Breyanzi[®], Carvykti[™], Kymriah[™], Tecartus[®], Yescarta[™]);
 - b. Used as supportive care in severe CRS related to blinatumomab therapy;
 - c. Used as prophylaxis to reduce the risk of CRS when administering teclistamabcqyv;
- 5. Request meets one of the following (a or b):*
 - a. Dose does not exceed 800 mg per infusion for up to 4 total doses;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration: Up to 4 total doses

G. Deficiency of Interleukin-1 Receptor Antagonist (must meet all):

- 1. Diagnosis of DIRA confirmed by presence of loss-of-function *ILRN* mutations;
- 2. Request is for Kineret;
- 3. Prescribed by or in consultation with a rheumatologist;
- 4. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 5. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months



H. Enthesitis-related Arthritis (must meet all):

- 1. Diagnosis of ERA;
- 2. Request is for Cosentyx;
- 3. Prescribed by or in consultation with a rheumatologist;
- 4. Age \geq 4 years and \leq 18 years;
- 5. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless clinically significant adverse effects are experienced or all are contraindicated;[†]
 [†]For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB
- 6. Member meets one of the following (a or b):[†]

 †For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB
 5395
 - a. Failure of $a \ge 3$ consecutive months trial of MTX at up to maximally indicated doses:
 - b. Member has intolerance or contraindication to MTX (see Appendix D), and failure of $a \ge 3$ consecutive month trial of at least ONE conventional disease-modifying anti-rheumatic drug (e.g., sulfasalazine, leflunomide) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
- 7. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 8. Dose does not exceed one of the following (a or b):
 - a. Weight \geq 15 kg and \leq 50 kg: 75 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 75 mg every 4 weeks;
 - b. Weight \geq 50 kg: 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks.

Approval duration: 6 months

I. Giant Cell Arteritis (must meet all):

- 1. Diagnosis of GCA;
- 2. Request is for Actemra, Avtozma, Tofidence, or Tyenne;
- 3. Prescribed by or in consultation with a rheumatologist;
- 4. Age \geq 18 years;
- 5. Failure of a systemic corticosteroid at up to maximally tolerated doses, unless clinically significant adverse effects are experienced or all are contraindicated;[†]

 †For Illinois HIM requests, the step therapy requirements above do not apply to formulary agents as of 1/1/2026 per IL HB 5395
- 6. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 7. Dose does not exceed one of the following (a or b):
 - a. 6 mg/kg IV every 4 weeks;
 - b. Actemra, Avtozma, or Tyenne only: 162 mg SC every week.

Approval duration: 6 months



J. Acute Graft-versus-Host Disease (must meet all):

- 1. Prescribed for prophylaxis of aGVHD;
- 2. Request is for intravenous formulation of Orencia;
- 3. Prescribed by or in consultation with an oncologist, hematologist, or bone marrow transplant specialist;
- 4. Age \geq 2 years;
- 5. Member is undergoing HSCT from a matched or 1 allele-mismatched unrelated-donor:
- 6. Prescribed in combination with a calcineurin inhibitor and MTX;
- 7. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 8. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 3 months (4 doses total)

K. Hidradenitis Suppurativa (must meet all):

- 1. Diagnosis of HS;
- 2. Request is for Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Bimzelx, Cosentyx, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Simlandi, Yuflyma, or Yusimry;
- 3. Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist;
- 4. Member meets one of the following (a or b):
 - a. Humira: Age \geq 12 years;
 - b. Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Bimzelx, Cosentyx, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry: Age ≥ 18 years;
- 5. Documentation of Hurley stage II or stage III (see Appendix D);
- 6. If request is for Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, or Yusimry, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), and **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
- 7. For Bimzelx: Failure of both of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
 - a. One of the following, unless the member has had a history of failure of two TNF blockers and request is not for another TNF blocker: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20),



Yuflyma (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);

b. Cosentyx;

- 8. Failure of at least TWO of the following, each tried for ≥ 3 consecutive months from different therapeutic classes, at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated:[†]
 - † For Illinois HIM requests, the step therapy requirements below do not apply to formulary agents as of 1/1/2026 per IL HB 5395
 - a. Systemic antibiotic therapy (e.g., clindamycin, minocycline, doxycycline, rifampin);
 - b. Oral retinoids (e.g., acitretin, isotretinoin);
 - c. Hormonal treatment (e.g., estrogen-containing combined oral contraceptives, spironolactone);
- 9. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 10. Dose does not exceed maximum dose* indicated in Section V.

 *For Cosentyx, maximum dose escalation allowed per prescriber information with documentation of inadequate response.

Approval duration: 6 months

L. Kawasaki Disease (off-label) (must meet all):

- 1. Diagnosis of Kawasaki disease;
- 2. Request is for an infliximab-containing product;
- 3. Prescribed by or in consultation with a cardiologist, allergist, immunologist, infectious disease specialist, or rheumatologist;
- 4. Age \geq 6 years;
- 5. Failure of immune globulins (*Gammagard is preferred*), unless contraindicated or clinically significant adverse effects are experienced;
- 6. If request is for Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c):
 - a. Inflectra and Renflexis:
 - b. If member has failed Inflectra and Renflexis, then member must use Avsola;
 - c. If member has failed Inflectra, Renflexis, and Avsola, then member must use **unbranded Remicade**:
- 7. For unbranded Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
 - a. Inflectra and Renflexis:
 - b. If member has failed Inflectra and Renflexis, then member must use Avsola;
- 8. If request is for Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis**:
- 9. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 10. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 4 weeks (one time approval)



M. Neonatal-Onset Multisystem Inflammatory Disease (must meet all):

- 1. Diagnosis of NOMID or chronic infantile neurological, cutaneous, and articular syndrome (CINCA);
- 2. Request is for Kineret;
- 3. Prescribed by or in consultation with a rheumatologist;
- 4. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 5. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

N. Plaque Psoriasis (must meet all):

- 1. Diagnosis of PsO and one of the following (a, b, or c):
 - a. Request is for Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Bimzelx, Cyltezo, Cimzia, Cosentyx, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Imuldosa, Ilumya, Otulfi, Pyzchiva, Selarsdi, Siliq, Simlandi, Skyrizi, Sotyktu, Stelara, Steqeyma, Taltz, Tremfya, Wezlana, Yesintek, Yuflyma, or Yusimry: PsO is moderate-to-severe as evidenced by involvement of one of the following (i or ii):
 - i. $\geq 3\%$ of total body surface area;
 - ii. Hands, feet, scalp, face, or genital area;
 - b. Request is for Avsola, Inflectra, Remicade/unbranded Remicade, or Renflexis: PsO is chronic-severe as evidenced by involvement of one of the following (i or ii):
 - i. $\geq 10\%$ of total body surface area;
 - ii. Hands, feet, scalp, face, or genital area;
 - c. Request is for Otezla: Member meets one of the following (i or ii):
 - i. Age \geq 18 years;
 - ii. Age 6 years to < 18 years, and both of the following (1 and 2):
 - 1) PsO is moderate-to-severe as evidenced by involvement of one of the following (a or b):
 - a) $\geq 3\%$ of total body surface area;
 - b) Hands, feet, scalp, face, or genital area;
 - 2) Documentation that member weighs $\geq 20 \text{ kg}$;
- 2. Prescribed by or in consultation with a dermatologist or rheumatologist;
- 3. Member meets one of the following (a, b, or c):
 - a. For Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Avsola, Bimzelx, Cimzia, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Ilumya, Inflectra, Remicade/unbranded Remicade, Renflexis, Siliq, Simlandi, Skyrizi, Sotyktu, Tremfya, Yuflyma, Yusimry: Age ≥ 18 years;
 - b. For Enbrel: Age \geq 4 years;
 - c. For Cosentyx, Imuldosa, Otezla, Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Taltz, Wezlana, Yesintek: Age ≥ 6 years;



- 4. If request is for Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, or Yusimry, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Humira**, **Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), and **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
- 5. Member meets one of the following (a or b):[†]

 †For Illinois HIM requests, the step therapy requirements below do not apply to formulary agents as of 1/1/2026 per IL HB 5395
 - a. Member has moderate-to-severe disease, and one of the following (i, ii, or iii):
 - i. Failure of $a \ge 3$ consecutive month trial of methotrexate (MTX) at up to maximally indicated doses;
 - ii. Member has intolerance or contraindication to MTX (see Appendix D), and failure of a \geq 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
 - iii. Member has intolerance or contraindication to MTX, cyclosporine, and acitretin, and failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;
 - b. Member has mild disease, and both of the following (i and ii):
 - i. Request is for Otezla;
 - ii. Failure of one of the following, unless clinically significant adverse effects are experienced or all are contraindicated: calcipotriene, calcitriol, or tazarotene;
- 6. For Ilumya, member meets BOTH of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
 - a. One of the following (i, ii, or iii, see Appendix D):
 - i. Failure of BOTH of the following, each used for ≥ 3 consecutive months (1 and 2):
 - 1) ONE of the following adalimumab products: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
 - 2) Enbrel;
 - ii. If member has had a history of failure of one TNF blocker, then failure of ONE of the following TNF blockers used for ≥ 3 consecutive months: **Enbrel, Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
 - iii. History of failure of two TNF blockers;
 - b. Failure of ALL of the following, each used for ≥ 3 consecutive months: Skyrizi, Stelara, Tremfya, Cosentyx, Otezla;



- 7. For Bimzelx, Cimzia, Siliq, Sotyktu, or Taltz and age ≥ 18 years: Failure of BOTH of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b, see Appendix D):
 - a. ONE of the following, unless the member has had a history of failure of two TNF blockers and request is not for another TNF blocker (i or ii):
 - i. ONE of the following adalimumab products: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
 - ii. Enbrel;
 - b. FOUR of the following: Otezla, Skyrizi, Stelara, Tremfya, Cosentyx;
- 8. For Taltz and age 6 to 17 years: Failure of TWO of the following, both used for \geq 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a d):
 - a. Cosentyx;
 - b. Stelara;
 - c. Otezla;
 - d. Enbrel, unless the member has had a history of failure of two TNF blockers;
- 9. For Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, or Yesintek: Member meets BOTH of the following, used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
 - a. Must use Stelara;
 - b. One of the following (i or ii):
 - i. Age 6 to 17 years: Failure of ONE of the following (1, 2, or 3):
 - 1) Cosentyx;
 - 2) Otezla:
 - 3) **Enbrel**, unless the member has had a history of failure of two TNF blockers:
 - ii. Age \geq 18 years: Failure of BOTH of the following (1 and 2):
 - 1) ONE of the following, unless the member has had a history of failure of two TNF blockers (a or b):
 - a) ONE of the following adalimumab products: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
 - b) Enbrel;
 - 2) THREE of the following: Otezla, Skyrizi, Tremfya, Cosentyx:
- 10. For Imuldosa, Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Wezlana, or Yesintek: Request is for SC formulation;
- 11. For Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c):
 - a. Inflectra and Renflexis:
 - b. If member has failed Inflectra and Renflexis, then member must use Avsola;



- c. If member has failed Inflectra, Renflexis, and Avsola, then member must use unbranded Remicade:
- 12. For unbranded Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
 - a. Inflectra and Renflexis;
 - b. If member has failed Inflectra and Renflexis, then member must use Avsola;
- 13. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis**;
- 14. Member meets one of the following (a or b):
 - a. For Otezla, if request is for concomitant use with biologic DMARD therapy (e.g., adalimumab, Enbrel, infliximab), member meets one of the following (i or ii):[†]

 †For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395
 - i. Failure of $a \ge 3$ consecutive month trial of MTX used in combination with the biologic DMARD at up to maximally indicated doses;
 - ii. Member has intolerance or contraindication to MTX (see Appendix D), and failure of a ≥ 3 consecutive month trial of cyclosporine or acitretin used in combination with the biologic DMARD at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
 - b. For other agents indicated for PsO, member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 15. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

O. Polyarticular Juvenile Idiopathic Arthritis (must meet all):

- 1. Diagnosis of PJIA as evidenced by ≥ 5 joints with active arthritis;
- 2. Request is for one of the following: Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalmumab-ryvk, Actemra, Amjevita, Avtozma, Cimzia, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Kevzara, Orencia, Rinvoq, Rinvoq LQ, Simlandi, Simponi Aria, Tofidence, Tyenne, Xeljanz, Xeljanz XR, Yuflyma, or Yusimry;
- 3. Prescribed by or in consultation with a rheumatologist;
- 4. Age \geq 2 years;
- 5. If request is for Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, or Yusimry, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Humira**, **Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), and **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
- 6. Member meets one of the following (a, b, c, or d):[†]
 [†]For Illinois HIM requests, the step therapy requirements below do not apply to formulary agents as of 1/1/2026 per IL HB 5395



- a. Failure of $a \ge 3$ consecutive month trial of MTX at up to maximally indicated doses:
- b. If member has intolerance or contraindication to MTX (see Appendix D), failure of a ≥ 3 consecutive month trial of leflunomide or sulfasalazine at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
- c. For sacroilitis/axial spine involvement (i.e., spine, hip), failure of a ≥ 4 week trial of an NSAID at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
- d. Documentation of high disease activity;
- 7. For Avtozma, Cimzia, Kevzara, Orencia, Simponi Aria, Tofidence, or Tyenne: Member meets BOTH of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):[†]
 - † For Illinois HIM requests, the step therapy requirements below do not apply to formulary agents as of 1/1/2026 per IL HB 5395
 - a. One of the following (i, ii, or iii, see Appendix D):
 - i. Failure of BOTH of the following, each used for ≥ 3 consecutive months (1 and 2):
 - 1) ONE of the following adalimumab products: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
 - 2) Enbrel;
 - ii. If member has had a history of failure of one TNF blocker, then failure of one of the following TNF blockers used for ≥ 3 consecutive months: **Enbrel, Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
 - iii. History of failure of two TNF blockers and request is not for another TNF blocker;
 - b. If member has not responded or is intolerant to one or more TNF blockers, **Xeljanz** and **Rinvoq/Rinvoq LQ**, used for ≥ 3 consecutive months, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
- 8. For Actemra: Member meets ONE of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a or b):[†]

 †For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395
 - a. One of the following used for ≥ 3 consecutive months, unless the member has had a history of failure of two TNF blockers and request is not for another TNF blocker: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06), or **Enbrel**;



- b. One of the following used for ≥ 3 consecutive months: **Xeljanz** or **Rinvoq/Rinvoq LQ**, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
- 9. For Orencia: For members 2 to 5 years of age, prescribed route of administration is SC:
- 10. For Kevzara: Documentation that member weighs \geq 63 kg;
- 11. For Rinvoq, Rinvoq LQ, Xeljanz, or Xeljanz oral solution: Member has not responded or is intolerant to one or more TNF blockers;

 *Prior authorization may be required for TNF blockers
- 12. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 13. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

P. Polymyalgia Rheumatica (must meet all):

- 1. Diagnosis of PMR per American College of Rheumatology/European Union League Against Rheumatism (ACR/EULAR) criteria as evidenced by both of the following (a and b, *see Appendix N*):
 - a. Documentation that member presents with symptoms of PMR (e.g., bilateral shoulder aching; symmetrical aching; stiffness in shoulders, hip girdle, neck, and torso; morning stiffness);
 - b. Evidence of one of the following (i or ii):
 - i. Baseline erythrocyte sedimentation rate (ESR) \geq 30 mm/hr;
 - ii. Baseline c-reactive protein (CRP) ≥ 10 mg/L;
- 2. Request is for Kevzara;
- 3. Prescribed by or in consultation with a rheumatologist;
- 4. Age > 50 years;
- 5. Member meets one of the following (a or b):
 - a. Failure of a systemic corticosteroid (e.g., prednisone) at maximally tolerated doses for ≥ 2 weeks, unless contraindicated or clinically significant adverse effects are experienced;
 - b. Documentation of one episode of unequivocal PMR flare (e.g., shoulder and/or hip girdle pain associated with inflammatory stiffness) while attempting to taper corticosteroids at a dose ≥ 7.5 mg/day of prednisone equivalent;
- 6. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 7. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

Q. Psoriatic Arthritis (must meet all):

- 1. Diagnosis of PsA or jPsA;
- 2. Request is for one of the following: Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Avsola, Bimzelx, Cimzia, Cosentyx, Cyltezo, Enbrel,



Hadlima, Hulio, Humira, Hyrimoz, Idacio, Imuldosa, Inflectra, Orencia, Otezla, Otulfi, Pyzchiva, Remicade/unbranded Remicade, Renflexis, Rinvoq, Rinvoq LQ, Selarsdi, Simlandi, Simponi, Simponi Aria, Skyrizi, Stelara, Steqeyma, Taltz, Tremfya, Wezlana, Xeljanz, Xeljanz XR, Yesintek, Yuflyma, or Yusimry;

- 3. Prescribed by or in consultation with a dermatologist or rheumatologist;
- 4. Member meets one of the following (a, b, or c):
 - a. For Cosentyx, Enbrel, Orencia, Rinvoq, Rinvoq LQ, or Simponi Aria: Age ≥ 2 vears:
 - b. For Imuldosa, Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Wezlana, or Yesintek: Age ≥ 6 years;
 - c. For Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Avsola, Bimzelx, Cimzia, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Otezla, Remicade/unbranded Remicade, Renflexis, Simlandi, Simponi, Skyrizi, Taltz, Tremfya, Xeljanz, Xeljanz XR, Yuflyma, or Yusimry: Age ≥ 18 years;
- 5. If request is for Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, or Yusimry, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), and **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
- 6. For Cimzia, Bimzelx, Orencia, Simponi, Simponi Aria, or Taltz: If age ≥ 18 years, member meets ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c):[†]

 †For Illinois HIM requests, the step therapy requirements below do not apply to formulary agents as of 1/1/2026 per IL HB 5395
 - a. One of the following (i, ii, or iii, see Appendix D):
 - i. Failure of BOTH of the following, each used for ≥ 3 consecutive months (1 and 2):
 - 1) ONE of the following adalimumab products: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
 - 2) Enbrel;
 - ii. If member has had a history of failure of one TNF blocker, then failure of one of the following TNF blockers used for ≥ 3 consecutive months: **Enbrel, Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
 - iii. History of failure of two TNF blockers and request is not for another TNF blocker;



- b. Failure of a trial of ALL of the following, each used for ≥ 3 consecutive months: Otezla, Cosentyx, Skyrizi, Stelara, Tremfya;
- c. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz/Xeljanz XR and Rinvoq, each used for ≥ 3 consecutive months, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment:
- 7. For Orencia: If member is 2 to 17 years of age, both of the following (a and b):
 - a. Prescribed route of administration is SC;
 - b. Failure of both of the following, used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (i and ii):
 - i. **Enbrel**, unless the member has had a history of failure of two TNF blockers;
 - ii. Cosentyx, Stelara, and Rinvog/Rinvog LQ;
- 8. For Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, or Yesintek: Member meets BOTH of the following, used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
 - a. Must use Stelara;
 - b. One of the following (i or ii):
 - i. Age 6 to 17 years: Failure of both of the following (1 and 2):
 - 1) Cosentyx and Rinvoq/Rinvoq LQ;
 - 2) **Enbrel,** unless the member has had a history of failure of two TNF blockers;
 - ii. Age \geq 18 years: ALL of the following (1, 2, and 3):
 - 1) One of the following (a, b, or c, see Appendix D):
 - a) Failure of BOTH of the following, each used for ≥ 3 consecutive months (i and ii):
 - i) ONE of the following adalimumab products: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
 - ii) Enbrel;
 - b) If member has had a history of failure of one TNF blocker, then failure of one of the following TNF blockers used for ≥ 3 consecutive months: **Enbrel, Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
 - c) History of failure of two TNF blockers and request is not for another TNF blocker;
 - 2) Failure of a trial of ALL of the following, each used for ≥ 3 consecutive months: Otezla, Cosentyx, Skyrizi, Tremfya;
 - 3) If member has not responded or is intolerant to one or more TNF blockers, Xeljanz/Xeljanz XR and Rinvoq, each used for ≥ 3 consecutive months,



unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

- 9. For Imuldosa, Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Wezlana, or Yesintek: Request is for SC formulation;
- 10. For Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c):
 - a. Inflectra and Renflexis:
 - b. If member has failed Inflectra and Renflexis, then member must use Avsola;
 - c. If member has failed Inflectra, Renflexis, and Avsola, then member must use unbranded Remicade:
- 11. For unbranded Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
 - a. Inflectra and Renflexis;
 - b. If member has failed Inflectra and Renflexis, then member must use **Avsola**;
- 12. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis**;
- 13. For Rinvoq, Rinvoq LQ, Xeljanz, or Xeljanz XR: Member has not responded or is intolerant to one or more TNF blockers;
 - *Prior authorization may be required for TNF blockers
- 14. Member meets one of the following (a or b):
 - a. For Otezla, if request is for concomitant use with biologic DMARD therapy (e.g., adalimumab, Enbrel, infliximab), member meets one of the following (i or ii):[†]

 †For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395
 - i. Failure of $a \ge 3$ consecutive month trial of MTX used in combination with the biologic DMARD at up to maximally indicated doses;
 - ii. Member has intolerance or contraindication to MTX (see Appendix D), and failure of $a \ge 3$ consecutive month trial of cyclosporine or acitretin used in combination with the biologic DMARD at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
 - b. For other agents indicated for PsA, member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
- 15. Dose does not exceed maximum dose* indicated in Section V.
 - *For Cosentyx, maximum dose escalation allowed per prescriber information with documentation of inadequate response

Approval duration: 6 months

R. Rheumatoid Arthritis (must meet all):

- 1. Diagnosis of RA per ACR criteria (see Appendix H);
- 2. Request is for one of the following: Abrilada, Actemra, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Avsola, Avtozma, Cimzia, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Kevzara, Kineret, Olumiant, Orencia, Remicade/unbranded Remicade, Renflexis, Rinvoq, Simlandi,



- Simponi, Simponi Aria, Tofidence, Tyenne, Xeljanz, Xeljanz XR, Yuflyma, or Yusimry;
- 3. Prescribed by or in consultation with a rheumatologist;
- 4. Age \geq 18 years;
- 5. If request is for Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, or Yusimry, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Humira**, **Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), and **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
- 6. Member meets one of the following (a or b):[†]

 †For Illinois HIM requests, the step therapy requirements below do not apply to formulary agents as of 1/1/2026 per IL HB 5395
 - a. Failure of $a \ge 3$ consecutive month trial of MTX at up to maximally indicated doses;
 - b. Member has intolerance or contraindication to MTX (see Appendix D), and failure of a ≥ 3 consecutive month trial of at least ONE conventional DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated:
- 7. For Kevzara: Member meets TWO of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a d, see Appendix D):[†]

 †For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395
 - a. Failure of \geq 3 consecutive months of ONE of the following adalimumab products: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
 - b. Failure of ≥ 3 consecutive months of **Enbrel**;
 - c. History of failure of two TNF blockers;
 - d. If member has not responded or is intolerant to one or more TNF blockers, failure of ≥ 3 consecutive months of **Xeljanz/Xeljanz XR** or **Rinvoq**, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
- 8. For Avtozma, Cimzia, Kineret, Olumiant, Orencia, Simponi, Simponi Aria, Tofidence, or Tyenne: Member meets BOTH of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):[†]

 †For Illinois HIM requests, the step therapy requirements below do not apply to formulary agents as of 1/1/2026 per IL HB 5395
 - a. One of the following (i, ii, or iii, see Appendix D):
 - i. Failure of both of the following, each used for ≥ 3 consecutive months (1 and 2):
 - 1) ONE of the following adalimumab products: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-



0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);

2) Enbrel;

- ii. If member has had a history of failure of one TNF blocker, then failure of one of the following TNF blockers used for ≥ 3 consecutive months: **Enbrel**, **Humira**, **Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), or **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
- iii. History of failure of two TNF blockers and request is not for another TNF blocker;
- b. If member has not responded or is intolerant to one or more TNF blockers, **Xeljanz/Xeljanz XR** and **Rinvoq**, each used for ≥ 3 consecutive months, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
- 9. For Actemra: Member meets ONE of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a or b):[†]

 †For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395
 - a. One of the following used for ≥ 3 consecutive months, unless the member has had a history of failure of two TNF blockers and request is not for another TNF blocker: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06), or **Enbrel**;
 - b. One of the following used for ≥ 3 consecutive months: **Xeljanz/Xeljanz XR** or **Rinvoq**, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
- 10. For Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a, b and c):
 - a. Inflectra and Renflexis;
 - b. If member has failed Inflectra and Renflexis, then member must use Avsola;
 - c. If member has failed Inflectra, Renflexis, and Avsola, then member must use **unbranded Remicade**:
- 11. For unbranded Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
 - a. Inflectra and Renflexis;
 - b. If member has failed Inflectra and Renflexis, then member must use **Avsola**;
- 12. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis**;
- 13. For Olumiant, Rinvoq, Xeljanz, Xeljanz XR: Member has not responded or is intolerant to one or more TNF blockers, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

 *Prior authorization may be required for TNF blockers
- 14. Documentation of one of the following baseline assessment scores (a or b):
 - a. Clinical disease activity index (CDAI) score (see Appendix I);
 - b. Routine assessment of patient index data 3 (RAPID3) score (see Appendix J);



- 15. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 16. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

S. Systemic Juvenile Idiopathic Arthritis (must meet all):

- 1. Diagnosis of SJIA;
- 2. Request is for Actemra, Avtozma, Tofidence, or Tyenne;
- 3. Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist;
- 4. Age \geq 2 years;
- 5. Member meets one of the following (a, b, or c):[†]

 †For Illinois HIM requests, the step therapy requirements below do not apply to formulary agents as of 1/1/2026 per IL HB 5395
 - a. Failure of an NSAID at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
 - b. Failure of $a \ge 3$ consecutive months trial of MTX or leflunomide at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
 - c. Failure of a \geq 2 week trial of a systemic corticosteroid at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
- 6. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
- 7. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

T. Systemic Sclerosis – Associated Interstitial Lung Disease (must meet all):

- 1. Diagnosis of SSc-ILD;
- 2. Request is for subcutaneous formulation of Actemra;
- 3. Prescribed by or in consultation with a pulmonologist or rheumatologist;
- 4. Member meets both of the following (a and b):
 - a. Pulmonary fibrosis on high-resolution computed tomography (HRCT);
 - b. Additional signs of SSc are identified (see Appendix L);
- 5. Failure of a ≥ 3 consecutive months trial of cyclophosphamide or mycophenolate mofetil, at up to maximally indicated doses, unless both are contraindicated or clinically significant adverse effects are experienced;[†]
 [†]For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB
 5305
- 6. Baseline forced vital capacity (FVC) \geq 40% of predicted;
- 7. Baseline carbon monoxide diffusing capacity (DLCO) \geq 30% of predicted;
- 8. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see *Section III: Diagnoses/Indications for which coverage is NOT authorized*);
- 9. Dose does not exceed 162 mg every week.



Approval duration: 6 months

U. Ulcerative Colitis (must meet all):

- 1. Diagnosis of UC;
- 2. Request is for one of the following: Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Avsola, Cyltezo, Entyvio, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Imuldosa, Inflectra, Omvoh, Otulfi, Pyzchiva, Remicade/unbranded Remicade, Renflexis, Rinvoq, Selarsdi, Simlandi, Simponi, Skyrizi, Stelara, Steqeyma, Tremfya, Velsipity, Wezlana, Xeljanz, Xeljanz XR, Yesintek, Yuflyma, Yusimry, Zeposia, or Zymfentra;
- 3. Prescribed by or in consultation with a gastroenterologist;
- 4. Member meets one of the following (a, b, or c):
 - a. For Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Cyltezo, Entyvio, Hadlima, Hulio, Hyrimoz, Idacio, Imuldosa, Omvoh, Pyzchiva, Rinvoq, Selarsdi, Simlandi, Simponi, Skyrizi, Stelara, Steqeyma, Tremfya, Velsipity, Wezlana, Xeljanz, Xeljanz XR, Yesintek, Yuflyma, Yusimry, Zeposia, Zymfentra: Age ≥ 18 years;
 - b. For Avsola, Inflectra, Remicade/unbranded Remicade, Renflexis: Age ≥ 6 years;
 c. For Humira: Age ≥ 5 years;
- 5. If request is for Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, or Yusimry, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), and **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
- 6. Documentation of a Mayo Score \geq 6 or modified Mayo Score \geq 5 (see Appendix F);
- 7. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;[†]

 †For Illinois HIM requests, the step therapy requirements above do not apply to formulary agents as of 1/1/2026 per IL HB 5395
- 8. For Entyvio, Omvoh, Simponi, Velsipity, Zeposia: Failure of BOTH of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b, see Appendix D):
 - a. THREE of the following: **Skyrizi**, **Stelara**, **Tremfya**, **adalimumab product** [**Humira**/ **Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20)/ **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06)];
 - b. If member has not responded or is intolerant to one or more TNF blockers, **Xeljanz/Xeljanz XR** and **Rinvoq**, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;



- 9. For Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, or Yesintek: Member meets BOTH of the following, used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
 - a. THREE of the following (i iv):
 - i. Must use **Stelara**;
 - ii. Failure of Skyrizi;
 - iii. Failure of Tremfya;
 - iv. Failure of **adalimumab product** [**Humira**/ **Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20)/ **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06)];
 - b. If member has not responded or is intolerant to one or more TNF blockers, **Xeljanz/Xeljanz XR** and **Rinvoq**, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
- 10. For Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c):
 - a. Inflectra and Renflexis:
 - b. If member has failed Inflectra and Renflexis, then member must use Avsola;
 - c. If member has failed Inflectra, Renflexis, and Avsola, then member must use **unbranded Remicade**;
- 11. For unbranded Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
 - a. Inflectra and Renflexis:
 - b. If member has failed Inflectra and Renflexis, then member must use Avsola;
- 12. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis**;
- 13. For Zymfentra, provider attestation that member meets all of the following (a, b, and c, see Appendix D):
 - a. Has received three IV induction doses of an infliximab product prior to initiation;
 - b. Member is responding positively to an IV infliximab product;
 - c. Member is unable to receive continued therapy with IV infliximab due to lack of caregiver or support system for assistance with administration and/or inadequate access to healthcare facility or home care interventions and/or lack of transportation to healthcare facility;
- 14. For Skyrizi: Quantity does not exceed one pre-filled cartridge per dose;
- 15. For Rinvoq and Xeljanz/Xeljanz XR: Member has not responded or is intolerant to one or more TNF blockers;
 - *Prior authorization may be required for TNF blockers
- 16. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see *Section III: Diagnoses/Indications for which coverage is NOT authorized*);
- 17. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months



V. Uveitis (must meet all):

- 1. Diagnosis of non-infectious intermediate, posterior, or panuveitis;
- 2. Request is for Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevtia, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Simlandi, Yuflyma, or Yusimry;
- 3. Prescribed by or in consultation with an ophthalmologist or rheumatologist;
- 4. Member meets one of the following (a or b):
 - a. For Humira: Age ≥ 2 years;
 - b. For Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry: Age ≥ 18 years;
- 5. If request is for Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, or Yusimry, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), and **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
- 6. Failure of a ≥ 2 week trial of a systemic corticosteroid (e.g., prednisone) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;[†]
 [†]For Illinois HIM requests, the step therapy requirements above do not apply to formulary agents as of 1/1/2026 per IL HB 5395
- 7. Failure of a trial of non-biologic immunosuppressive therapy (e.g., azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, tacrolimus, cyclophosphamide, chlorambucil) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;[†]

 †For Illinois HIM requests, the step therapy requirements above do not apply to formulary agents as of 1/1/2026 per IL HB 5395
- 8. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see *Section III: Diagnoses/Indications for which coverage is NOT authorized*);
- 9. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

W. Coronavirus-19 Infection:

1. Initiation of outpatient treatment will not be authorized as Kineret (authorized for emergency use only), Actemra (FDA-approved), Avtozma (FDA-approved), Tofidence (FDA-approved), Tyenne (FDA-approved), and Olumiant (FDA-approved) are authorized for use only in the hospitalized setting (*see Appendix M*).

Approval duration: Not applicable



X. Multiple Sclerosis:

1. For Tyruko, Tysabri, or Zeposia requests, refer to Tyruko, Tysabri, or Zeposia MS criteria, respectively.

Y. Alopecia Areata:

1. Use of Olumiant for the treatment of alopecia areata is a benefit exclusion and will not be authorized because it is considered cosmetic in nature.

Approval duration: Not applicable

Z. Other diagnoses/indications (must meet all):

- 1. If request is for Remicade, unbranded Remicade, or Avsola, member meets one of the following (a, b, or c):
 - a. If request is for Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i, ii, and iii):
 - i. Inflectra and Renflexis;
 - ii. If member has failed Inflectra and Renflexis, then member must use Avsola;
 - iii. If member has failed Inflectra, Renflexis, and Avsola, then member must use **unbranded Remicade**;
 - b. For unbranded Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i and ii):
 - i. Inflectra and Renflexis;
 - ii. If member has failed Inflectra and Renflexis, then member must use Avsola;
 - c. If request is for Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis**;
- 2. Must meet one of the following (a or b):
 - a. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (i or ii):
 - i. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or
 - ii. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; or
 - b. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2a above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace.



II. Continued Therapy

A. Coronavirus-19 Infection:

1. Continuation of therapy in the outpatient setting will not be authorized as Kineret (authorized for emergency use only), Actemra (FDA-approved), Avtozma (FDA-approved), Tofidence (FDA-approved), Tyenne (FDA-approved), and Olumiant (FDA-approved) are authorized for use only in the hospitalized setting (*see Appendix M*).

Approval duration: Not applicable

B. Kawasaki Disease (off-label) (must meet all):

1. Re-authorization for infliximab is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

C. Multiple Sclerosis:

1. For Tyruko, Tysabri, or Zeposia requests, refer to Tyruko, Tysabri, or Zeposia MS criteria, respectively.

D. Alopecia Areata:

1. Use of Olumiant for the treatment of alopecia areata is a benefit exclusion and will not be authorized because it is considered cosmetic in nature.

Approval duration: Not applicable

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

- 1. Member meets one of the following (a, b, or c):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
 - Documentation supports that member is currently receiving IV Actemra or IV
 Tyenne for CAR T cell-induced CRS and member has not yet received 4 total
 doses;
- 2. Member meets one of the following (a, b, c, d, or e):
 - a. For RA: Member is responding positively to therapy as evidenced by one of the following (i or ii):
 - i. A decrease in CDAI (see Appendix I) or RAPID3 (see Appendix J) score from baseline;
 - ii. Medical justification stating inability to conduct CDAI re-assessment, and submission of RAPID3 score associated with disease severity that is similar to initial CDAI assessment or improved;
 - b. For HS: At least a 25% reduction in inflammatory nodules and abscesses;
 - c. For AD: Member is responding positively to therapy as evidenced by, including but not limited to, reduction in itching and scratching;



- d. For PMR: Member is responding positively to therapy as evidenced by both of the following (i and ii):
 - i. Documentation of decrease in signs and symptoms of PMR (e.g., bilateral shoulder aching; symmetrical aching; stiffness in shoulders, hip girdle, neck, and torso; morning stiffness);
 - ii. Evidence of one of the following (1 or 2):
 - 1) Reduction CRP from baseline;
 - 2) Reduction of ESR from baseline;
- e. For all other indications: Member is responding positively to therapy;
- 3. If request is for Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, or Yusimry, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Humira, Cyltezo** (NDC 0597-0375-97, 0597-0375-23, 0597-0375-16, 0597-0400-89, 0597-0405-80, 0597-0370-82, 0597-0495-40, 0597-0495-50, 0597-0495-60, 0597-0485-20), and **Yuflyma** (NDC 72606-030-09, 72606-030-10, 72606-023-04, 72606-023-07, 72606-024-01, 72606-030-06);
- 4. For Skyrizi: If request is for CD or UC, quantity does not exceed 1 pre-filled cartridge every 8 weeks;
- 5. If request is for Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c):
 - a. Inflectra and Renflexis:
 - b. If member has failed Inflectra and Renflexis, then member must use Avsola;
 - c. If member has failed Inflectra, Renflexis, and Avsola, then member must use **unbranded Remicade**;
- 6. For unbranded Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
 - a. Inflectra and Renflexis;
 - b. If member has failed Inflectra and Renflexis, then member must use Avsola;
- 7. If request is for Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis**:
- 8. For Otezla: For PsO, if member is between ages 6 to < 18 years, documentation that member weights ≥ 20 kg;
- 9. For Imuldosa, Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Wezlana, Yesintek: Request is for SC formulation;
- 10. Member meets one of the following (a or b):
 - a. For Otezla, if request is for concomitant use with biologic DMARD therapy (e.g., adalimumab, Enbrel, infliximab) for PsA or PsO, member meets one of the following (i or ii):[†]
 - † For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395
 - i. Failure of $a \ge 3$ consecutive month trial of MTX used in combination with the biologic DMARD at up to maximally indicated doses;
 - ii. Member has intolerance or contraindication to MTX (see Appendix D), and failure of $a \ge 3$ consecutive month trial of cyclosporine or acitretin used in combination with the biologic DMARD at up to maximally indicated doses,



unless clinically significant adverse effects are experienced or both are contraindicated:

- b. For agents other than Otezla, member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see *Section III: Diagnoses/Indications for which coverage is NOT authorized*);
- 11. If request is for a dose increase, new dose does not exceed maximum dose indicated in Section V.

Approval duration: CRS – Up to 4 doses total aGVHD – 3 months (4 doses total) For all other indications – 12 months

F. Other diagnoses/indications (must meet all):

- 1. If request is for Remicade, unbranded Remicade, or Avsola, member meets one of the following (a, b, or c):
 - a. If request is for Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i, ii, and iii):
 - i. Inflectra and Renflexis:
 - ii. If member has failed Inflectra and Renflexis, then member must use Avsola;
 - iii. If member has failed Inflectra, Renflexis, and Avsola, then member must use **unbranded Remicade**;
 - b. For unbranded Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i and ii):
 - i. Inflectra and Renflexis;
 - ii. If member has failed Inflectra and Renflexis, then member must use Avsola;
 - c. If request is for Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis**;
- 2. Must meet one of the following (a or b):
 - a. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (i or ii):
 - i. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or
 - ii. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; or
 - b. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2a above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace.



III. Diagnoses/Indications for which coverage is NOT authorized:

- **A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy HIM.PA.154 for health insurance marketplace or evidence of coverage documents;
- B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Remicade® and its biosimilars, Simponi®], interleukin agents [e.g., Actemra® (IL-6RA) and its biosimilars, Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Spevigo® (IL-36 antagonist), Stelara® (IL-12/23 inhibitor) and its biosimilars, Taltz® (IL-17A inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections;
- C. For Siliq: treatment of patients with Crohn's disease;
- **D.** For Xeljanz/Xeljanz XR and Olumiant: alopecia areata (ICD10: L63), also referred to as patchy hair loss.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACR: American College of

Rheumatology

AD: atopic dermatitis

aGVHD: acute graft-versus-host disease

AS: ankylosing spondylitis

BD: Behçet's disease

CAR: chimeric antigen receptor

CD: Crohn's disease

CDAI: clinical disease activity index

CINCA: chronic infantile neurological,

cutaneous, and articular syndrome

cJADAS: clinical juvenile arthritis

disease activity score

COVID-19: coronavirus disease 2019

CRP: c-reactive protein

CRS: cytokine release syndrome

DIRA: deficiency of interleukin-1

receptor antagonist

DLCO: carbon monoxide diffusing

capacity

DMARDs: disease-modifying

antirheumatic drugs

ERA: enthesitis-related arthritis

ESR: erythrocyte sedimentation rate

EULAR: European Union League

Against Rheumatism

FVC: forced vital capacity

GCA: giant cell arteritis

HS: hidradenitis suppurativa,

JAK: Janus kinase

JPsA: juvenile psoriatic arthritis

MS: multiple sclerosis

MTX: methotrexate

NOMID: neonatal-onset multisystem

inflammatory disease

nr-axSpA: non-radiographic axial

spondyloarthritis

NSAIDs: non-steroidal anti-

inflammatory drugs

PJIA: polyarticular juvenile idiopathic

arthritis



PMR: polymyalgia rheumatica SJIA: systemic juvenile idiopathic

PsO: plaque psoriasis arthritis

PsA: psoriatic arthritiss SSc-ILD: systemic sclerosis-associated

RA: rheumatoid arthritis interstitial lung disease RAPID3: routine assessment of patient TNF: tumor necrosis factor

index data 3 UC: ulcerative colitis

UV: uveitis

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/
		Maximum Dose
acitretin	PsO	50 mg/day
(Soriatane®)	25 or 50 mg PO QD	
azathioprine	RA	3 mg/kg/day
(Azasan [®] , Imuran [®])	1 mg/kg/day PO QD or divided BID	
	CD*, GCA*	UV: 4 mg/kg/day
	1.5 – 2 mg/kg/day PO	
	UV*	
	2 - 3 mg/kg/day PO	
chlorambucil	UV*	0.2 mg/kg/day
(Leukeran®)	0.2 mg/kg PO QD, then taper to 0.1	
	mg/kg PO QD or less	
clindamycin	HS*	clindamycin: 600
(Cleocin®) +	clindamycin 300 mg PO BID and	mg/day
rifampin (Rifadin®)	rifampin 300 mg PO BID	rifampin: 600 mg/day
corticosteroids	CD*	Various
	Adult:	
Oral: e.g.,	prednisone 40 mg – 60 mg PO QD for 1	
prednisone,	to 2 weeks, then taper daily dose by 5	
budesonide	mg weekly until 20 mg PO QD, and	
	then continue with $2.5 - 5$ mg	
Medium to very	decrements weekly or IV 50 – 100 mg	
high potency topical:	Q6H for 1 week	
e.g., desoximetasone	_	
0.05%, fluocinolone	budesonide (Entocort EC®) 6 – 9 mg	
acetonide 0.025%,	PO QD	
mometasone 0.1%		
cream,	Pediatric:	
triamcinolone	Prednisone 1 to 2 mg/kg/day PO QD	
acetonide 0.1%,		
augmented	AD, GCA*	
betamethasone	Various	



Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
dipropionate 0.05%, clobetasol propionate 0.05% cream, ointment, gel, or solution, halobetasol propionate 0.05% cream, ointment	SJIA* < 0.5 mg/kg/day PO of prednisone or equivalent UC Adult: Prednisone 40 mg – 60 mg PO QD, then taper dose by 5 to 10 mg/week budesonide (Uceris®) 9 mg PO QD Pediatric: Prednisone 1 to 2 mg/kg/day PO QD UV* prednisone 5 – 60 mg/day PO in 1 – 4 divided doses PsO Applied topically to the affected area(s) BID PMR Prednisone: 7.5 mg to 25 mg PO per day	Maximum Dose
Cuprimine® (d-penicillamine) cyclophosphamide (Cytoxan®)	RA* Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 - 750 mg/day PO QD UV* 1 - 2 mg/kg/day PO SSc-ILD* PO: 1 - 2 mg/kg/day	PO: 2 mg/kg/day IV: 600 mg/m ² /month
cyclosporine (Sandimmune [®] , Neoral [®])	• IV: 600 mg/m²/month PsO 2.5 – 4 mg/kg/day PO divided BID RA 2.5 – 4 mg/kg/day PO divided BID UV* 2.5 – 5 mg/kg/day PO in divided doses	PsO, RA: 4 mg/kg/day UV: 5 mg/kg/day



Drug Name	Dosing Regimen	Dose Limit/
		Maximum Dose
doxycycline	HS*	300 mg/day
(Acticlate®)	50 – 100 mg PO BID	
Hormonal agents	HS	varies
(e.g., estrogen-	varies	
containing combined		
oral contraceptives,		
spironolactone)		
hydroxychloroquine	RA*	600 mg/day
(Plaquenil®)	Initial dose:	
	400 – 600 mg/day PO QD	
	Maintenance dose:	
	200 – 400 mg/day PO QD	
Isotretinoin	HS	varies
(Absorica®,	varies	
Amnesteem®,		
Claravis [®] ,		
Myorisan®,		
Zenatane [®])		
leflunomide	PJIA*	ERA, PJIA, RA: 20
(Arava [®])	• Weight < 20 kg: 10 mg every other	mg/day
	day	
	• Weight 20 - 40 kg: 10 mg/day	SJIA: 10 mg every other
	• Weight > 40 kg: 20 mg/day	day
	Weight > 40 kg. 20 mg/day	
	RA	
	Initial dose (for low risk hepatotoxicity or myelosuppression):	
	100 mg PO QD for 3 days	
	Maintenance dose:	
	'-	
	20 mg PO QD	
	SJIA*	
	100 mg PO every other day for 2 days,	
	then 10 mg every other day	
	ERA	
	Weight < 20 kg: 10 mg every other day	
	Weight 20 - 40 kg: 10 mg/day	
(manage :: t = ::: ;	Weight > 40 kg: 20 mg/day	1.5 ~/1, / 1
6-mercaptopurine	CD*	1.5 mg/kg/day
(Purixan®)	50 mg PO QD or 0.75 – 1.5 mg/kg/day	
.1	PO	
methotrexate	CD*	30 mg/week
$(Trexall^{\mathbb{R}}, Otrexup^{TM},$	15 – 25 mg/week IM or SC	



Drug Name	Dosing Regimen	Dose Limit/
D	CCA+	Maximum Dose
Rasuvo [®] ,	GCA*	
RediTrex [®] ,	20 – 25 mg/week PO	
Xatmep [™] ,	PsO	
Rheumatrex®)	10 to 25 mg/week IM, SC or PO or 2.5	
	mg PO Q12 hr for 3 doses/week	
	PJIA*	
	$10-20 \text{ mg/m}^2/\text{week PO, SC, or IM}$	
	RA	
	7.5 mg/week PO, SC, or IM or 2.5 mg	
	PO Q12 hr for 3 doses/week	
	SJIA*	
	0.5 – 1 mg/kg/week PO or SC	
	7.5 – 20 mg/week PO HS*	200 m = /day
minocycline	, -	200 mg/day
(Minocin®)	50 – 100 mg PO BID UV*	Adulta 2 a/day
mycophenolate		Adult: 3 g/day
mofetil (Cellcept®)	500 – 1,000 mg PO BID	Dadiatuia, 50m a/laa/dass
	CC. H D*	Pediatric: 50mg/kg/day
	SSc-ILD*	
NCAIDa (a. a.	PO: 1 – 3 g/day	Varies
NSAIDs (e.g.,	AS, nr-axSpA, ERA, PJIA*, sJIA* Varies	varies
indomethacin,	varies	
ibuprofen, naproxen,		
celecoxib) Pentasa [®]	CD	4 g/day
(mesalamine)	1,000 mg PO QID	+ g/day
Ridaura®	RA	9 mg/day (3 mg TID)
(auranofin)	6 mg PO QD or 3 mg PO BID	mg/day (3 mg 11D)
sulfasalazine	PJIA*	PJIA, ERA: 2 g/day
(Azulfidine [®])	30-50 mg/kg/day PO divided BID	RA: 3 g/day
(Azumume)	30-30 mg/kg/day i O divided bib	UC: 4 g/day
	RA	OC. 4 g/day
	Initial dose:	
	500 mg to 1,000 mg PO QD for the first	
	week. Increase the daily dose by 500 mg	
	each week up to a maintenance dose of	
	2 g/day.	
	Maintenance dose:	
	2 g/day PO in divided doses	
	2 grady 1 O III divided doses	
	ERA	
	30 to 50 mg/kg/day PO, given in 2	
	divided doses	
	arviaca aoses	



Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
tacrolimus	CD*	N/A
(Prograf [®])	0.27 mg/kg/day PO in divided doses or	
	0.15 - 0.29 mg/kg/day PO	
	UV*	
	0.1-0.15 mg/kg/day PO	
biologic DMARDs	See Section V. Dosing and	See Section V. Dosing
(e.g., Humira,	Administration	and Administration
Enbrel, Cosentyx,		
Remicade, Simponi		
Aria, Otezla,		
Xeljanz/Xeljanz XR,		
Kevzara)		
colchicine	BD*	1.8 mg/day
(Colcrys [®])	1.2 to 1.8 mg PO daily	
tacrolimus	AD	Varies
(Protopic [®]),	Children ≥ 2 years and adults: Apply a	
pimecrolimus	thin layer topically to affected skin BID.	
(Elidel®)	Treatment should be discontinued if	
•	resolution of disease occurs.	
Eucrisa®	AD	Varies
(crisaborole)	Apply to the affected areas BID	
immune globulin	Kawasaki disease	Varies based on
(e.g., Gammagard®)	Varies based on formulation	formulation

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

Appendix C: Contraindications/Boxed Warnings

Drug Name	Contraindication(s)	Boxed Warning(s)
Actemra, Avtozma, Tofidence,	Known hypersensitivity to tocilizumab products	Risk of serious infections
Tyenne Bimzelx	None reported	None reported
Cimzia	None reported	• There is an increased risk of serious infections leading to hospitalization or death including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens.



Drug Name	Contraindication(s)	Boxed Warning(s)
		 Lymphoma and other malignancies have been observed. Epstein Barr Virus-associated post-transplant lymphoproliferative disorder has been observed.
Cosentyx	Serious hypersensitivity reaction to secukinumab or to any of the excipients	None reported
Enbrel	Patients with sepsis	 Serious infections Malignancies
Entyvio	Patients who have had a known serious or severe hypersensitivity reaction to Entyvio or any of its excipients	None reported
Humira and biosimilars (Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, and Yusimry) Ilumya	Serious hypersensitivity reaction to tildrakizumab or to any of the	 Serious infections Malignancies None reported
Avsola, Inflectra, Remicade, Renflexis Zymfentra	 excipients Doses > 5 mg/kg in patients with moderate-to-severe heart failure (Avsola, Inflectra, Remicade, and Renflexis only) Known hypersensitivity to inactive components of the product or to any murine proteins 	• Serious infections • Malignancy
Kevzara	Known hypersensitivity to sarilumab or any of the inactive ingredients	Risk of serious infections



Drug Name	Contraindication(s)	Boxed Warning(s)
Kineret	Known hypersensitivity to <i>E. coli</i> -	None reported
	derived proteins, Kineret, or any	-
	components of the product	
Olumiant	None reported	• Serious infections
	_	• Mortality
		• Malignancies
		Major adverse cardiovascular
		events
		• Thrombosis
Omvoh	History of serious hypersensitivity	None reported
	reaction to mirikizumab-mrkz or	
	any of the excipients	
Orencia	None reported	None reported
Otezla	Known hypersensitivity to	None reported
	apremilast or to any of the	
	excipients in the formulation	
Rinvoq,	Known hypersensitivity to	Serious infections
Rinvoq LQ	upadacitinib or any of the	Mortality
_	excipients in Rinvoq/Rinvoq LQ	Malignancies
		Major adverse cardiovascular
		events
		• Thrombosis
Siliq	Patients with Crohn's disease	Suicidal ideation and behavior
Simponi,	None reported	Serious infections
Simponi	_	• Malignancies
Aria		3
Skyrizi	History of serious hypersensitivity	None reported
	reaction to risankizumab-rzaa or	
	any of the excipients	
Stelara and	Clinically significant	None reported
biosimilars	hypersensitivity to ustekinumab	
(Imuldosa,	products or any of the excipients	
Otulfi,		
Pyzchiva,		
Selarsdi,		
Steqeyma,		
Wezlana,		
Yesintek)	D	N
Taltz	Previous serious hypersensitivity	None reported
	reaction, such as anaphylaxis, to	
	ixekizumab or to any of the	
7E. 4	excipients	N
Tremfya	None reported	None reported



Drug Name	Contraindication(s)	Boxed Warning(s)
Tysabri,	Patients who have or have had	Progressive multifocal
Tyruko	progressive multifocal leukoencephalopathy • Patients who have had a hypersensitivity reaction to natalizumab products or any of its active ingredients	leukoencephalopathy
Velsipity	 In the last 6 months, experienced myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure History or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker 	None reported
Xeljanz/	None reported	Serious infections
Xeljanz XR		Mortality
		MalignanciesMajor adverse cardiovascular eventsThrombosis
Zeposia	 History of any of the following in the last 6 months: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure 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 Severe untreated sleep apnea Concomitant use of a monoamine oxidase inhibitor 	None reported



Appendix D: General Information

- Definition of failure of MTX or DMARDs
 - o Failure of a trial of conventional DMARDs:
 - Child-bearing age is not considered a contraindication for use of MTX. Each drug
 has risks in pregnancy. An educated patient and family planning would allow use
 of MTX in patients who have no intention of immediate pregnancy.
 - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
 - o Reduction in joint pain/swelling/tenderness
 - o Improvement in ESR/CRP levels
 - o Improvements in activities of daily living
- Ulcerative colitis:
 - o For ulcerative colitis maintenance therapy, failure is defined as having two or more exacerbations requiring steroid therapy.
- Neonatal-onset multisystem inflammatory disease:
 - Other names used for NOMID are as follows: chronic infantile neurological, CINCA, chronic neurologic, cutaneous, and articular syndrome, infantile onset multisystem inflammatory disease, IOMID syndrome, and Prieur-Griscelli syndrome.
- Hidradenitis suppurativa:
 - O 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."
 - O 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.
- Ulcerative colitis: There is insufficient evidence to support the off-label weekly dosing of adalimumab for the treatment of moderate-to-severe UC. It is the position of Centene Corporation® that the off-label weekly dosing of adalimumab for the treatment of moderate-to-severe UC is investigational and not medically necessary at this time.
 - O The evidence from the *post hoc* study of the adalimumab pivotal trial suggests further studies are needed to confirm the benefit of weekly adalimumab dosing for the treatment of UC in patients with inadequate or loss of therapeutic response to treatment with adalimumab every other week. No large, randomized, or prospective studies have been published to support the efficacy of the higher frequency of dosing, while national and international treatment guidelines also do not strongly support dose escalation of adalimumab for UC. The current market consensus is that weekly dosing of adalimumab is not medically necessary due to lack of evidence to support its benefit.



- Infliximab used in the treatment of unspecified iridocyclitis (anterior uveitis) has primarily been evaluated in case reports and uncontrolled case series. One phase II clinical trial by Suhler and associates (2009) reported the 2-year follow-up data of patients with refractory uveitis treated with intravenous infliximab as part of a prospective clinical trial. Their 1-year data, published in 2005 (Suhler, 2005) reported reasonable initial success, but an unexpectedly high incidence of adverse events. Of their 23 patients, 7 developed serious adverse events, including 3 thromboses, 1 malignancy, 1 new onset of congestive heart failure, and 2 cases of drug-induced lupus. The American Optometric Association anterior uveitis clinical practice guidelines recommend alternative therapies that include ophthalmic corticosteroids (e.g., prednisolone, dexamethasone, fluoromethalone) and anticholinergics (e.g., atropine, cyclopentolate, homatropine). If the disease has not responded to topical therapy, oral corticosteroids can be considered.
- ERA: Current International League of Associations for Rheumatology (ILAR) classification criteria divide JIA into 7 mutually exclusive categories defined by the number of joints involved, presence or absence of extraarticular manifestations, and presence or absence of additional markers including rheumatoid factor (RF) and HLA—B27. While the current ILAR classification criteria have been useful for identifying homogeneous groups of patients for research, more recent data suggest that these categories may not entirely reflect the underlying genetic and clinical heterogeneity of the disease or be relevant for guiding treatment decisions. According to the 2019 American College of Rheumatology, current treatment guideline focuses treatment approaches based on broad clinical phenotypes rather than ILAR categories.
- TNF blockers:
 - Etanercept (Enbrel®), adalimumab (Humira®) and its biosimilars, infliximab (Remicade®) and its biosimilars (Avsola™, Renflexis™, Inflectra®, Zymfentra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).
- Zymfentra is indicated as maintenance treatment only, starting at week 10 and thereafter.
 All patients must complete an intravenous induction regimen with an infliximab product
 before starting Zymfentra. To switch patients who are responding to maintenance therapy
 with an infliximab product administered intravenously, administer the first subcutaneous
 dose of Zymfentra in place of the next scheduled intravenous infusion and every two
 weeks thereafter.

Appendix E: Immunomodulator Medical Justification

- The following may be considered for medical justification supporting inability to use an immunomodulator for CD:
 - Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids
 - High-risk factors for intestinal complications may include:
 - Initial extensive ileal, ileocolonic, or proximal GI involvement
 - Initial extensive perianal/severe rectal disease
 - Fistulizing disease (e.g., perianal, enterocutaneous, and rectovaginal fistulas)
 - Deep ulcerations
 - Penetrating, stricturing or stenosis disease and/or phenotype
 - Intestinal obstruction or abscess



- o For TNF-inhibitors, high risk factors for postoperative recurrence may include:
 - Less than 10 years duration between time of diagnosis and surgery
 - Disease location in the ileum and colon
 - Perianal fistula
 - Prior history of surgical resection
 - Use of corticosteroids prior to surgery

Appendix F: Mayo Score or Modified Mayo Score

• Mayo Score: evaluates ulcerative colitis stage, based on four parameters: stool frequency, rectal bleeding, endoscopic evaluation and Physician's global assessment. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity) with an overall score of 12.

Score	Decoding
0 - 2	Remission
3 - 5	Mild activity
6 - 10	Moderate activity
>10	Severe activity

Modified Mayo Score: developed from the full Mayo score and evaluates ulcerative
colitis stage, based on three parameters: stool frequency, rectal bleeding, and endoscopic
evaluation. The modified Mayo Score gives a maximum overall score of 9. The FDA
currently accepts the modified Mayo Score for the assessment of disease activity in
pivotal UC clinical trials.

Appendix G: Dose Rounding Guidelines for Weight-Based Doses

Actemra, Avtozma, Tofidence, and Tyenne for Intravenous Use for PJIA and SJIA

Weight-based Dose Range	Vial Quantity Recommendation
≤ 83.99 mg	1 vial of 80 mg/4 mL
84 to 209.99 mg	1 vial of 200 mg/10 mL
210 to 419.99 mg	1 vial of 400 mg/20 mL
420 to 503.99 mg	1 vial of 80 mg/4 mL and 1 vial 400 mg/20 mL
504 to 629.99 mg	1 vial of 200 mg/10 mL and 1 vial 400 mg/20 mL
630 to 839.99 mg	2 vials 400 mg/20 mL
840 to 923.99 mg	1 vial of 80 mg/4 mL and 2 vials 400 mg/20 mL
924 to 1,049.99 mg	1 vial of 200 mg/10 mL and 2 vials 400 mg/20 mL
1050 to 1,259.99 mg	3 vials 400 mg/20 mL

Enbrel for PJIA, Pediatric PsO, and JPsA

Weight-based Dose Range	Vial Quantity Recommendation
≤ 25.99 mg	1 vial of 25 mg/0.5 mL
26 to 52.49 mg	1 vial of 50 mg/mL

Infliximab for All Indications

Weight-based Dose Range	Vial Quantity Recommendation
≤ 104.99 mg	1 vial of 100 mg/20 mL
105 to 209.99 mg	2 vials of 100 mg/20 mL



Weight-based Dose Range	Vial Quantity Recommendation
210 to 314.99 mg	3 vials of 100 mg/20 mL
315 to 419.99 mg	4 vials of 100 mg/20 mL
420 to 524.99 mg	5 vials of 100 mg/20 mL
525 to 629.99 mg	6 vials of 100 mg/20 mL
630 to 734.99 mg	7 vials of 100 mg/20 mL
735 to 839.99 mg	8 vials of 100 mg/20 mL

Kineret for NOMID

Weight-based Dose Range	Vial Quantity Recommendation
≤ 104.99 mg	1 syringe of 100 mg/0.67 mL
105 to 209.99 mg	2 syringes of 100 mg/0.67 mL
210 to 314.99 mg	3 syringes of 100 mg/0.67 mL
315 to 419.99 mg	4 syringes of 100 mg/0.67 mL
420 to 524.99 mg	5 syringes of 100 mg/0.67 mL
525 to 629.99 mg	6 syringes of 100 mg/0.67 mL
630 to 734.99 mg	7 syringes of 100 mg/0.67 mL
735 to 839.99 mg	8 syringes of 100 mg/0.67 mL

Orencia for Intravenous Use PJIA and SJIA

Weight-based Dose Range	Vial Quantity Recommendation
\leq 262.49 mg	1 vial of 250 mg
262.50 mg to524.99 mg	2 vials of 250 mg
525 to 787.49 mg	3 vials of 250 mg
787.50 mg to 1,049.99 mg	4 vials of 250 mg

Orencia for Subcutaneous Use for PJIA and SJIA

Weight-based Dose Range	Prefilled Syringe Quantity Recommendation
10 to 24.99 kg	1 syringe of 50 mg/0.4 mL
25 to 49.99 kg	1 syringe of 87.5 mg/0.7 mL
> 50 kg	1 syringe of 125 mg/mL

Simponi Aria for All Indications

Simponi iti ia 101 itii inaications		
Weight-based Dose Range	Vial Quantity Recommendation	
\leq 52.49 mg	1 vial of 50 mg/4 mL	
52.5 to 104.99 mg	2 vials of 50 mg/4 mL	
105 to 157.49 mg	3 vials of 50 mg/4 mL	
157.5 to 209.99 mg	4 vials of 50 mg/4 mL	
210 to 262.49 mg	5 vials of 50 mg/4 mL	



Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, and Yesintek for PsO

Weight-based Dose Range	Quantity Recommendation			
Subcutaneous, Syringe	Subcutaneous, Syringe			
≤ 46.99 mg	1 syringe of 45 mg/0.5 mL			
47 to 94.49 mg	1 syringe of 90 mg/1 mL			
94.5 to 141.49 mg	1 syringe of 45 mg/0.5 mL and 1 syringe of 90 mg/1 mL			
Subcutaneous, Vial				
≤ 46.99 mg	1 vial of 45 mg/0.5 mL			
47 to 94.49 mg	2 vials of 45 mg/0.5 mL			

Appendix H: The 2010 ACR Classification Criteria for RA

Add score of categories A through D; a score of ≥ 6 out of 10 is needed for classification of a

patient as having definite RA.

patici	it as having definite RA.	
A	Joint involvement	Score
	1 large joint	0
	2-10 large joints	1
	1-3 small joints (with or without involvement of large joints)	2
	4-10 small joints (with or without involvement of large joints)	3
	> 10 joints (at least one small joint)	5
В	Serology (at least one test result is needed for classification)	
	Negative rheumatoid factor (RF) and negative anti-citrullinated protein	0
	antibody (ACPA)	
	Low positive RF <i>or</i> low positive ACPA	2
	*Low: < 3 x upper limit of normal	
	High positive RF or high positive ACPA	3
	* High: $\geq 3 x$ upper limit of normal	
C	Acute phase reactants (at least one test result is needed for classification)	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate	0
	(ESR)	
	Abnormal CRP or abnormal ESR	1
D	Duration of symptoms	
	< 6 weeks	0
	\geq 6 weeks	1

Appendix I: Clinical Disease Activity Index (CDAI) Score

The Clinical Disease Activity Index (CDAI) is a composite index for assessing disease activity in RA. CDAI is based on the simple summation of the count of swollen/tender joint count of 28 joints along with patient and physician global assessment on VAS (0–10 cm) Scale for estimating disease activity. The CDAI score ranges from 0 to 76.

CDAI Score	Disease state interpretation
\leq 2.8	Remission
$> 2.8 \text{ to} \le 10$	Low disease activity
$> 10 \text{ to } \le 22$	Moderate disease activity
> 22	High disease activity



Appendix J: Routine Assessment of Patient Index Data 3 (RAPID3) Score The Routine Assessment of Patient Index Data 3 (RAPID3) is a pooled index of the three patient-reported ACR core data set measures: function, pain, and patient global estimate of status. Each of the individual measures is scored 0-10, and the maximum achievable score is 30.

RAPID3 Score	Disease state interpretation
≤ 3	Remission
3.1 to 6	Low disease activity
6.1 to 12	Moderate disease activity
> 12	High disease activity

Appendix K: Polyarticular Juvenile Idiopathic Arthritis Disease Activity
According to 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis, disease activity (moderate/high and low) as defined by the clinical Juvenile Disease Activity score based on 10 joints (cJADAS-10) is provided as a general parameter and should be interpreted within the clinical context.

The cJADAS10 is a continuous disease activity score specific to JIA and consisting of the following three parameters totaling a maximum of 30 points:

- Physician's global assessment of disease activity measured on a 0-10 visual analog scale (VAS), where 0 = no activity and 10 = maximum activity;
- Parent global assessment of well-being measured on a 0-10 VAS, where 0 = very well and 10 = very poor;
- Count of joints with active disease to a maximum count of 10 active joints*

 *ACR definition of active joint: presence of swelling (not due to currently inactive synovitis or to bony enlargement) or, if swelling is not present, limitation of motion accompanied by pain, tenderness, or both

cJADAS-10	Disease state interpretation
≤1	Inactive disease
1.1 to 2.5	Low disease activity
2.51 to 8.5	Moderate disease activity
> 8.5	High disease activity

Appendix L: American College of Rheumatology (ACR) 2013 SSc Classification Criteria While the majority of patients with SSc experience skin thickening and variable involvement of internal organs, there is no one confirmatory test for SSc. Similar to the IPF guidelines above, ACR lists HRCT as a diagnostic method for determining pulmonary fibrosis in SSc-ILD. The other diagnostic parameters below are drawn from ACR's scoring system purposed for clinical trials. While informative, ACR cautions that the scoring system parameters are not all inclusive of the myriad of SSc manifestations that may occur across musculoskeletal, cardiovascular, renal, neuromuscular, and genitourinary systems.

Examples of SSc skin/internal organ manifestations and associated laboratory tests:

- Skin thickening of the fingers
- Fingertip lesions
- Telangiectasia
- Abnormal nailfold capillaries
- Raynaud's phenomenon



- SSc-ILD
- Pulmonary arterial hypertension
- SSc-related autoantibodies
- Anticentromere
- Anti-topoisomerase I (anti-Scl-70)
- Anti-RNA polymerase III

Appendix M: Coronavirus-19 Infection:

• An EUA is an FDA authorization for the emergency use of an unapproved product or unapproved use of an approved product (i.e., drug, biological product, or device) in the United States under certain circumstances including, but not limited to, when the Secretary of HHS declares that there is a public health emergency that affects the national security or the health and security of United States citizens living abroad, and that involves biological agent(s) or a disease or condition that may be attributable to such agent(s).

Kineret

o The EUA decision was based on the results of the SAVE-MORE trial, which was a randomized, double-blinded, placebo-controlled study to evaluate the safety and efficacy of Kineret in adult patients with COVID-19 pneumonia who were at risk of developing severe respiratory failure (SRF). The primary endpoint of the study was the 11-point WHO Clinical Progressional ordinal Scale (CPS) which was compared between the two arms of treatment by Day 28. Patients treated with Kineret had lower odds of more severe disease according to the WHO-CPS at Day 28 compared to placebo (odds ratio: 0.37 [95% CI 0.26 to 0.50]).

Appendix N: PMR Classification Criteria Scoring Algorithm

Per 2012 EULAR/ACR Provisional Classification Criteria for PMR required criteria: age ≥ 50 years, bilateral shoulder aching, and abnormal CRP and/or ESR. A score of 4 or more is categorized a PMR in the algorithm without ultrasound (US) and a score of 5 or more is categorized as PMR in the algorithm with US.

Category	Points without US (0-6)	Points with US (0-8)
Morning stiffness duration > 45 minutes	2	2
Hip pain or limited range of motion	1	1
Absence of rheumatoid factor (RA) or anti-citrullinated protein antibody (ACPA)	2	2
Absence of other joint involvement	1	1
At least 1 shoulder with subdeltoid bursitis and/or biceps tenosynovitis and/or glenohumeral synovitis (either posterior or axillary) and at least 1 hip with synovitis and/or trochanteric bursitis	N/A	1
Both shoulders with subdeltoid bursitis, biceps tenosynovitis, or glenohumeral synovitis	N/A	1



V. Dosage and Administration

Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber information with documentation of inadequate response	Maximum Dose
Abatacept (Orencia)*	RA	• IV: weight-based dose at weeks 0, 2, and 4, followed by every 4 weeks	IV: 1,000 mg every 4
*Also see Appendix G: Dose Rounding Guidelines for Weight-Based Doses		Weight < 60 kg: 500 mg per dose Weight 60 to 100 kg: 750 mg per dose Weight > 100 kg: 1,000 mg per dose • SC: 125 mg once weekly (For RA: if single IV loading dose is given, start first SC injection within one day of IV dose)	weeks SC: 125 mg/week
	PsA	 Adult: IV: 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 SC: 125 mg once weekly (For RA: if single IV loading dose is given, start first SC injection within one day of IV dose) Pediatric: SC: Weight 10 kg to < 25 kg: 50 mg once weekly Weight 25 to < 50 kg: 87.5 mg once weekly Weight ≥ 50 kg: 125 mg once weekly 	IV: 1,000 mg every 4 weeks SC: 125 mg/week
	PJIA	 • IV: 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 • SC: 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 	IV: 1,000 mg every 4 weeks SC: 125 mg/week
	aGVHD	• Age ≥ 2 years and < 6 years: 15 mg/kg on day before transplantation, followed by 12	1,000 mg/dose



Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber information with documentation of inadequate response	Maximum Dose
		 mg/kg on Days 5, 14, and 28 after transplantation Age ≥ 6 years: 10 mg/kg (up to 1,000 mg maximum dose) on day before transplantation, followed by 10 mg/kg (up to 1,000 mg maximum dose) on Days 5, 14, and 28 after transplantation 	
Adalimumab and biosimilars (Humira, Abrilada, Amjevita, Cyltezo,	RA	40 mg SC every other week Some patients with RA not receiving concomitant methotrexate may benefit from increasing the frequency to 40 mg every week.	40 mg/week
Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry)	PJIA	Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hyrimoz, Idacio: Weight 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg SC every other week Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Idacio, Simlandi, Yuflyma: Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg SC every other week Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry: Weight ≥ 30 kg (66 lbs): 40 mg SC every other week	40 mg every other week
	PsA AS	40 mg SC every other week	40 mg every other week
	CD	Initial dose: Adults: 160 mg SC on Day 1, then 80 mg SC on Day 15 Pediatrics: Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Idacio, Simlandi, Yuflyma:	40 mg every other week
		Weight 17 kg (37 lbs) to < 40 kg (88 lbs): 80 mg SC on Day 1, then 40 mg SC on Day 15	



Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber	Maximum Dose
		information with documentation of inadequate response	Dose
		Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry: Weight ≥ 40 kg (88 lbs): 160 mg SC on Day 1, then 80 mg SC on Day 15	
		Maintenance dose: Adults: 40 mg SC every other week starting on Day 29	
		Pediatrics: Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Idacio, Simlandi, Yuflyma:	
		Weight 17 kg (37 lbs) to < 40 kg (88 lbs): 20 mg SC every other week starting on Day 29 Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio,	
		Simlandi, Yuflyma, Yusimry: Weight ≥ 40 kg (88 lbs): 40 mg SC every other week starting on Day 29	
	UC	Initial dose: Adults: 160 mg SC on Day 1, then 80 mg SC on Day 15	Adults: 40 mg every other week
		Maintenance dose: Adults: 40 mg SC every other week starting on Day 29	
	PsO	Initial dose: 80 mg SC	40 mg every other week
		Maintenance dose: 40 mg SC every other week starting one week after initial dose	
	HS	Humira: For patients 12 years of age and older weighing at least 30 kg: Initial dose: Weight 30 kg (66 lbs) to < 60 kg (132 lbs): 80 mg SC on Day 1, then 40 mg on Day 8 Weight ≥ 60 kg (132 lbs): 160 mg SC on Day 1, then 80 mg SC on Day 15	40 mg/week



Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber information with documentation of inadequate response	Maximum Dose
		Maintenance dose: Weight 30 kg (66 lbs) to < 60 kg (132 lbs): 40 mg every other week Weight ≥ 60 kg (132 lbs): 40 mg SC every week or 80 mg SC every other week starting on Day 29	
		Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry: Initial dose: Adults: 160 mg SC on day 1, then 80 mg SC on Day 15	
		Maintenance dose: Adults: 40 mg SC every week or 80 mg SC every other week starting on Day 29	
	UV	Humira: Pediatrics: Weight 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg SC every other week Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg SC every other week Weight ≥ 30 kg (66 lbs): 40 mg SC every other week	40 mg every other week
		Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry: Adults: Initial dose of 80 mg SC, followed by 40 mg SC every other week starting one week after	
Adalimumab (Humira)	Pediatric UC	the initial dose Initial dose: Pediatrics:	Pediatrics: 80 mg every other week or 40 mg every week



Drug Name	Indication	*Maximum dose	Dosing Regimen* *Maximum dose escalation allowed per prescriber information with documentation of inadequate response		
		Weight	Days 1 through 15		
		20 kg to less	Day 1: 80 mg		
		than 40 kg	Day 8: 40 mg		
			Day 15: 40 mg		
		40 kg and	Day 1: 160 mg (single		
		greater	dose or split over two		
			consecutive days		
			Day 8: 80 mg		
			Day 15: 80 mg		
		Dadiatuias			
		Pediatrics:	Starting on Day 20*		
		Weight 20 kg to less	Starting on Day 29* 40 mg every other week		
			or 20 mg every week		
		than 40 kg 40 kg and	80 mg every other week		
		greater *Continue the rece	or 40 mg every week		
			18 years of age and who are well-		
		controlled on Hun			
Anakinra (Kineret)*	RA	100 mg SC QD		100 mg/day	
*Also see	NOMID	Initial dose:		8 mg/kg/day	
Appendix G:	NOMB		C QD or divided BID	o mg/kg/day	
Dose Rounding		Maintenance do	=		
Guidelines for			O or divided BID		
Weight-Based	DIRA	Initial dose:		8 mg/kg/day	
Doses		1-2 mg/kg SC	CQD		
		Maintenance de	~		
			0.5 to 1 mg/kg increments.		
Apremilast	PsA	Initial dose:		60 mg/day	
(Otezla)	BD	Day 1: 10 mg F	PO QAM		
			PO QAM and 10 mg PO QPM		
		Day 3: 10 mg F	PO QAM and 20 mg PO QPM		
		Day 4: 20 mg F	PO QAM and 20 mg PO QPM		
		Day 5: 20 mg F	PO QAM and 30 mg PO QPM		
		Maintenance de	ose:		
			eafter: 30 mg PO BID		



Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber information with documentation of inadequate response	Maximum Dose
	PsO	Initial dose: Day 1: 10 mg PO QAM Day 2: 10 mg PO QAM and 10 mg PO QPM Day 3: 10 mg PO QAM and 20 mg PO QPM Day 4: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 30 mg PO QPM Maintenance dose: Day 6 and thereafter: 30 mg PO BID Pediatric: Weight ≥ 50 kg: Initial dose: Day 1: 10 mg PO QAM and 10 mg PO QPM Day 3: 10 mg PO QAM and 20 mg PO QPM Day 4: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 30 mg PO QPM Maintenance dose: Day 6 and thereafter: 30 mg PO BID Weight 20 kg to < 50 kg: Initial dose: Day 1: 10 mg PO QAM Day 2: 10 mg PO QAM Day 3: 10 mg PO QAM Maintenance dose: Day 6 and thereafter: 30 mg PO BID Weight 20 kg to < 50 kg: Initial dose: Day 1: 10 mg PO QAM Day 2: 10 mg PO QAM Day 3: 10 mg PO QAM and 20 mg PO QPM Day 3: 10 mg PO QAM and 20 mg PO QPM Day 4: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 20 mg PO QPM Maintenance dose: Day 1 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 20 mg PO QPM	Adults: 60 mg/day Pediatric: Weight ≥ 50 kg: 60 mg/day Weight 20 kg to < 50 kg: 40 mg/day
Baricitinib (Olumiant)	RA	Day 6 and thereafter: 20 mg PO BID 2 mg PO QD	2 mg/day
Bimekizumab- bkzx (Bimzelx)	PsO (with or without coexist PsA)	320 mg (given as 2 SC injections of 160 mg each) at Weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter For patients weighing \geq 120 kg, consider a	320 mg/8 weeks (after loading doses)
		dosage of 320 mg every 4 weeks after Week 16.	Weight ≥ 120 kg: 320 mg/4 weeks (after



Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber information with documentation of inadequate response	Maximum Dose
	AS nr-axSpA	160 mg SC every 4 weeks	loading doses) 160 mg/4 weeks
	PsA HS	320 mg SC at Weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16, then every 4 weeks thereafter	320 mg/4 weeks (after loading doses)
Brodalumab (Siliq)	PsO	Initial dose: 210 mg SC at weeks 0, 1, and 2 Maintenance dose: 210 mg SC every 2 weeks	210 mg every 2 weeks
Certolizumab (Cimzia)	CD	Initial dose: 400 mg SC at 0, 2, and 4 weeks Maintenance dose: 400 mg SC every 4 weeks	400 mg every 4 weeks
	RA PsA AS nr-axSpA	Initial dose: 400 mg SC at 0, 2, and 4 weeks Maintenance dose: 200 mg SC every other week (or 400 mg SC every 4 weeks)	400 mg every 4 weeks
	PsO	400 mg SC every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg SC at 0, 2 and 4 weeks, followed by 200 mg SC every other week may be considered.	400 mg every other week
	pJIA	Loading dose: • Weight 10 kg (22 lbs) to < 20 kg (44 lbs): 100 mg SC at week 0, 2, and 4 • Weight 20 kg (44 lbs) to < 40 kg (88 lbs): 200 mg SC at week 0, 2, and 4 • Weight ≥ 40 kg (88 lbs): 400 mg SC at week 0, 2, and 4 Maintenance dose: • Weight 10 kg (22 lbs) to < 20 kg (44 lbs):	200 mg every 2 weeks
		 Weight 10 kg (22 los) to < 20 kg (44 los). 50 mg SC at week 6 and every 2 weeks thereafter Weight 20 kg (44 lbs) to < 40 kg (88 lbs): 100 mg SC at week 6 and every 2 weeks thereafter 	



Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber information with documentation of inadequate response	Maximum Dose
		Weight ≥ 40 kg (88 lbs): 200 mg SC at week 6 and every 2 weeks thereafter	
Deucravacitinib (Sotyktu)	PsO	6 mg PO daily	6 mg/day
Etanercept (Enbrel)*	RA	25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
*Also see Appendix G: Dose Rounding Guidelines for Weight-Based Doses	PsA	Adults: 25 mg SC twice weekly or 50 mg SC once weekly Pediatrics: Weight < 63 kg: 0.8 mg/kg SC once weekly Weight ≥ 63 kg: 50 mg SC once weekly	50 mg/week
	AS	50 mg SC once weekly	50 mg/week
	PJIA*	Weight < 63 kg: 0.8 mg/kg SC once weekly Weight ≥ 63 kg: 50 mg SC once weekly	50 mg/week
	PsO*	Adults: Initial dose: 50 mg SC twice weekly for 3 months Maintenance dose: 50 mg SC once weekly Pediatrics: Weight < 63 kg: 0.8 mg/kg SC once weekly Weight ≥ 63 kg: 50 mg SC once weekly	50 mg/week
Etrasimod (Velsipity)	UC	2 mg PO QD	2 mg/day
Golimumab (Simponi)	AS PsA RA	50 mg SC once monthly	50 mg/month
	UC	Initial dose: 200 mg SC at week 0, then 100 mg SC at week 2 Maintenance dose: 100 mg SC every 4 weeks	100 mg every 4 weeks



Drug Name	Indication	Dosing Regimen*	Maximum
		*Maximum dose escalation allowed per prescriber information with documentation of inadequate response	Dose
Golimumab	AS	Initial dose:	2 mg/kg
(Simponi	PsA	2 mg/kg IV at weeks 0 and 4	every 8
Aria)*	RA	Maintenance dose:	weeks
		2 mg/kg IV every 8 weeks	
*Also see	pJIA	Initial dose:	$80 \text{ mg/m}^2 \text{ IV}$
Appendix G:	PsA	80 mg/m^2 at weeks 0 and 4	every 8
Dose Rounding	(pediatric)	Maintenance dose:	weeks
Guidelines for		80 mg/m ² IV every 8 weeks	
Weight-Based			
Doses	CD	T 1	200 /4
Guselkumab	CD	Induction:	200 mg/4
(Tremfya)		200 mg IV at weeks 0, 4, and 8, or	weeks
		400 mg SC at weeks 0, 4, and 8	
		Maintenance:	
		100 mg SC at week 16, and every 8 weeks	
		thereafter, or	
		200 mg SC at week 12, and every 4 weeks	
		thereafter	
	PsA	Initial dose:	100 mg every
	PsO	100 mg SC at weeks 0 and 4	8 weeks
		Maintenance dose:	
		100 mg SC every 8 weeks	
	UC	Induction:	200 mg/4
		200 mg IV at weeks 0, 4, and 8	weeks
		Maintenance:	
		100 mg SC at week 16, and every 8 weeks	
		thereafter or	
		200 mg SC at week 12, and every 4 weeks	
Infliximab	CD LIC	thereafter	CD Adulta.
(Avsola,	CD, UC	Initial dose: Avsola, Inflectra, Remicade, Renflexis:	CD, Adults: 10 mg/kg IV
Inflectra,		Adults/Pediatrics: 5 mg/kg IV at weeks 0, 2	every 8
Remicade,		and 6	weeks or 120
Renflexis,		and o	mg SC every
Zymfentra)*		Maintenance dose:	2 weeks
		Avsola, Inflectra, Remicade, Renflexis:	
*Also see		Adults/Pediatrics: 5 mg/kg IV every 8	UC, Adults: 5
Appendix G:		weeks.	mg/kg IV
Dose Rounding		For CD: Some adult patients who initially	every 8
Guidelines for		respond to treatment may benefit from	weeks or 120



Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber information with documentation of inadequate response	Maximum Dose
Weight-Based Doses		increasing the dose to 10 mg/kg if they later lose their response*	mg SC every 2 weeks
		Zymfentra: Adults: 120 mg SC every 2 weeks starting at week 10	Pediatrics: 5 mg/kg IV every 8 weeks
	PsA PsO	Initial dose: 5 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg IV every 8 weeks	5 mg/kg every 8 weeks
	RA	In conjunction with MTX Initial dose: 3 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: 3 mg/kg IV every 8 weeks Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks*	10 mg/kg every 4 weeks
	AS	Initial dose: 5 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg IV every 6 weeks	5 mg/kg every 6 weeks
	Kawasaki disease (off-label)	Single infusion of 10 mg/kg given over 2 hours	10 mg/kg
Ixekizumab (Taltz)	PsO (with or without coexistent PsA)	Adults: Initial dose: 160 mg (two 80 mg injections) SC at week 0, then 80 mg SC at weeks 2, 4, 6, 8, 10, and 12 Maintenance dose: 80 mg SC every 4 weeks Pediatrics (ages 6 to 17 years):	80 mg every 4 weeks



Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber information with documentation of inadequate response			Maximum Dose
		Pediatric Patient's Weight	Starting Dose (Week 0)	Dose every 4 weeks (Q4W) Thereafter	
		> 50 kg	160 mg (two 80 mg injections)	80 mg	
		25 to 50 kg < 25 kg	80 mg 40 mg	40 mg 20 mg	
	PsA, AS	Initial dose: SC at week Maintenance	160 mg (two 80 mg)		80 mg every 4 weeks
	nr-axSpA	80 mg SC ev	very 4 weeks		80 mg every 4 weeks
Mirikizumab- mrkz (Omvoh)	CD	Maintenance	t Weeks 0, 4, and		300 mg/4 weeks (after loading doses)
	UC	Induction do 300 mg IV a	ose: at Weeks 0, 4, and	18	200 mg/4 weeks (after loading doses)
Natalizumab (Tysabri) and its biosimilar natalizumab- sztn (Tyruko)	MS, CD		very 4 weeks	,	300 mg/4 weeks
Ozanimod (Zeposia)	MS, UC	Days 5-7: 0.	23 mg PO QD 46 mg PO QD nereafter: 0.92 mg	g PO QD	0.92 mg/day
Risankizumab- rzaa (Skyrizi)	PsO, PsA		at weeks 0, 4, and		150 mg/12 weeks
	CD	Induction: 6 and Week 8	00 mg IV at Wee	k 0, Week 4	IV: 600 mg/dose
		T	e: 180 mg or 360 y 8 weeks thereaf	_	SC: 360 mg every 8 weeks



Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber information with documentation of inadequate response	Maximum Dose
	UC	Induction: 1,200 mg IV at Week 0, Week 4 and Week 8	IV: 1,200 mg/dose
		Maintenance: 180 mg or 360 mg SC at Week 12 and every 8 weeks thereafter	SC: 360 mg every 8 weeks
Sarilumab (Kevzara)	RA, PMR, pJIA	200 mg SC once every two weeks	200 mg/2 weeks
Secukinumab (Cosentyx)	PsO (with or without PsA)	Adults: 300 mg SC at weeks 0, 1, 2, 3, and 4, followed by 300 mg SC every 4 weeks. (for some patients, a dose of 150 mg may be acceptable)	Adults: 300 mg every 4 weeks
		Pediatric patients age 6 to 17 years and weight < 50 kg (PsO only): 75 mg SC at weeks 0, 1, 2, 3 and 4, followed by maintenance dose of 75 mg every 4 weeks	Pediatric patients: 150 mg every 4 weeks
		Pediatric patients age 6 to 17 years and weight ≥ 50 kg (PsO only): 150 mg SC at weeks 0, 1, 2, 3 and 4, followed by maintenance dose of 150 mg every 4 weeks	
	PsA	Adults: SC: • With loading dose: 150 mg SC at week 0, 1, 2, 3, and 4, followed by 150 mg SC	Adults: 300 mg every 4 weeks
		 1, 2, 3, and 4, followed by 150 hig SC every 4 weeks Without loading dose: 150 mg SC every 4 weeks. If a patient continues to have active psoriatic arthritis: 300 mg every 4 weeks and documentation supports inadequate response to a ≥ 3 consecutive month trial of 150 mg every 4 weeks or member has coexistent PsO* 	Pediatric patients: 150 mg every 4 weeks
		 IV: With loading dose: 6 mg/kg IV at week 0, followed by 1.75 mg/kg IV every 4 weeks. Without loading dose: 1.75 mg/kg IV every 4 weeks. 	



Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber information with documentation of inadequate response	Maximum Dose
		 Pediatric: SC: Pediatric patients age 2 to 17 years and weight ≥ 15 kg and < 50 kg: 75 mg SC at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 75 mg every 4 weeks. Pediatric patients age 2 to 17 years old and weight ≥ 50 kg: 150 mg SC at weeks 0, 1, 2, 3, and 4, followed by a maintenance dose of 150 mg every 4 weeks. 	
	AS, nr-axSpA	 SC: With loading dose: 150 mg SC at weeks 0, 1, 2, 3, and 4, followed by 150 mg SC every 4 weeks thereafter. Without loading dose: 150 mg SC every 4 weeks. For AS only: 300 mg every 4 weeks, if documentation supports inadequate response to a ≥ 3 consecutive month trial of 150 mg every 4 weeks* IV: With loading dose: 6 mg/kg IV at week 0, followed by 1.75 mg/kg IV every 4 weeks. Without loading dose: 1.75 mg/kg IV every 	300 mg every 4 weeks nr-axSpA (SC): 150 mg every 4 weeks (after loading doses)
	ERA	 4 weeks. Weight > 15 kg and < 50 kg: 75 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 75 mg every 4 weeks Weight ≥ 50 kg: 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks 	Maintenance: • weight < 50 kg: 75 mg every 4 weeks • weight ≥ 50 kg: 150 mg every 4 weeks
	HS	300 mg SC at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 300 mg every 4 weeks	300 mg every 2 weeks



Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber	Maximum Dose
		information with documentation of inadequate response	Dose
		Consider increasing the dosage to 300 mg	
		every 2 weeks if patient does not adequately	
		respond*	
Tildrakizumab-	PsO	Initial dose:	100 mg every
asmn (Ilumya)		100 mg SC at weeks 0 and 4	12 weeks
		Maintenance dose:	
		100 mg SC every 12 weeks	
		Ilumya should only be administered by a	
		healthcare professional.	
Tocilizumab	PJIA	Actemra, Avtozma, Tofidence, Tyenne:	IV: 10 mg/kg
(Actemra)* and		• Weight < 30 kg: 10 mg/kg IV every 4	every 4
biosimilars		weeks	weeks
(Avtozma, Tofidence,		• Weight \geq 30 kg: 8 mg/kg IV every 4 weeks	SC: 162 mg
Tyenne)*		See Appendix G for dose rounding guidelines	SC: 162 mg every 2
		Actemra, Avtozma, Tyenne:	weeks
*Also see		• Weight < 30 kg: 162 mg SC every 3 weeks	
Appendix G:		• Weight ≥ 30 kg: 162 mg SC every 2 weeks	
Dose Rounding	RA	Actemra, Avtozma, Tofidence, Tyenne:	IV: 800 mg
Guidelines for Weight-Based		IV: 4 mg/kg every 4 weeks followed by an	every 4
Doses		increase to 8 mg/kg every 4 weeks based on	weeks
Doses		clinical response	SC: 162
		Actemra, Avtozma, Tyenne:	SC: 162 mg every week
		SC:	every week
		• Weight < 100 kg: 162 mg SC every other	
		week, followed by an increase to every	
		week based on clinical response	
		• Weight ≥ 100 kg: 162 mg SC every week	
	SJIA	Actemra, Avtozma, Tofidence, Tyenne:	IV: 12 mg/kg
		IV:	every 2
		• Weight < 30 kg: 12 mg/kg IV every 2 weeks	weeks
		• Weight ≥ 30 kg: 8 mg/kg IV every 2 weeks	SC: 162 mg
		See Appendix G for dose rounding	every week
		guidelines	
		Actemra, Avtozma, Tyenne: SC:	
		• Weight < 30 kg: 162 mg SC every 2 weeks	
		• Weight ≥ 30 kg: 162 mg SC every	



Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber information with documentation of inadequate response	Maximum Dose
	GCA	Actemra, Avtozma, Tofidence, Tyenne: IV: 6 mg/kg every 4 weeks in combination with a tapering course of glucocorticoids	IV: 6 mg/kg every 4 weeks
		Actemra, Avtozma, Tyenne: SC: 162 mg SC every week (every other week may be given based on clinical considerations)	SC: 162 mg every week
Tocilizumab (Actemra) and biosimilar	CRS	Weight < 30 kg: 12 mg/kg IV per infusion Weight ≥ 30 kg: 8 mg/kg IV per infusion	IV: 800 mg/infusion, up to 4 doses
(Tyenne)		If no clinical improvement in the signs and symptoms of CRS occurs after the first dose, up to 3 additional doses of tocilizumab may be administered. The interval between consecutive doses should be at least 8 hours.	
Tocilizumab (Actemra)	SSc-ILD	162 mg SC once weekly	SC: 162 mg every week
Tofacitinib (Xeljanz)	pJIA	 10 kg ≤ body weight < 20 kg: 3.2 mg (3.2 mL oral solution) PO BID 20 kg ≤ body weight < 40 kg: 4 mg (4 mL oral solution) PO BID Body weight ≥ 40 kg: 5 mg PO BID 	10 mg/day
	PsA RA AS	5 mg PO BID	
	UC	Induction: 10 mg PO BID for 8 weeks, up to 16 weeks Maintenance: 5 mg PO BID	Induction: 20 mg/day
			Maintenance: 10 mg/day
Tofacitinib extended- release (Xeljanz XR)	PsA RA AS	11 mg PO QD	11 mg/day
	UC	Induction: 22 mg PO QD for 8 weeks, up to 16 weeks Maintenance: 11 mg PO QD	Induction: 22 mg/day Maintenance:
			11 mg/day
Upadacitinib (Rinvoq)	AS, nr- axSpA, RA	15 mg PO QD	15 mg/day



Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber information with documentation of inadequate response	Maximum Dose
	AD	Age ≥ 12 years and ≥ 40 kg but < 65 years: 15 mg PO QD; if an adequate response is not achieved, consider increasing the dosage to 30 mg PO QD	$\frac{\text{Age} \ge 12}{\text{years and} \ge}$ $\frac{40 \text{ kg but} <}{65 \text{ years:}}$ 30 mg/day
		Age ≥ 65 years: 15 mg PO QD If member's age < 65 years: if an adequate response is not achieved, consider increasing the dosage to 30 mg PO QD*	$\frac{\text{Age} \ge 65}{\text{years}}$ 15 mg/day
	UC	 Induction: 45 mg PO Q for 8 weeks Maintenance: 15 mg PO QD A dosage of 30 mg PO QD may be considered for patients with refractory, severe, or extensive disease.* 	30 mg/day
	CD	 Induction: 45 mg PO Q for 12 weeks Maintenance: 15 mg PO QD A dosage of 30 mg PO QD may be considered for patients with refractory, severe, or extensive disease.* 	30 mg/day
	PsA	Age ≥ 18 years: 15 mg PO QD Age ≥ 2 years but < 18 years: Weight ≥ 30 kg: 15 mg PO QD	15 mg/day
	pJIA	$\frac{\text{Age} \ge 2 \text{ years:}}{\text{Weight} \ge 30 \text{ kg: } 15 \text{ mg PO QD}}$	15 mg/day
Upadacitinib (Rinvoq LQ)	PsA	Age ≥ 2 years but < 18 years: • Weight 10 kg to < 20 kg: 3 mg (3 mL oral solution) PO BID • Weight 20 kg to < 30 kg: 4 mg (4 mL oral solution) PO BID • Weight ≥ 30 kg: 6 mg (6 mL oral solution) PO BID	12 mg/day
	рЛА	Age ≥ 2 years: • Weight 10 kg to < 20 kg: 3 mg (3 mL oral solution) PO BID	12 mg/day



Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber information with documentation of inadequate response	Maximum Dose
		 Weight 20 kg to < 30 kg: 4 mg (4 mL oral solution) PO BID Weight ≥ 30 kg: 6 mg (6 mL oral solution) PO BID 	
Ustekinumab (Stelara), ustekinumab- srlf (Imuldosa), ustekinumab- aauz (Otulfi), ustekinumab- ttwe (Pyzchiva), ustekinumab- aekn (Selarsdi), ustekinumab- stba (Steqeyma), ustekinumab- auub (Wezlana),	PsO	Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks Adult: Weight ≤ 100 kg: 45 mg Weight > 100 kg: 90 mg Pediatrics (age 6 years to 17 years): Stelara, Otulfi, Pyzchiva, Wezlana, Yesintek: Weight < 60 kg: 0.75 mg/kg Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, Yesintek: Weight 60 to 100 kg: 45 mg Weight > 100 kg: 90 mg	90 mg every 12 weeks
ustekinumab- kfce (Yesintek) *Also see Appendix G: Dose Rounding Guidelines for Weight-Based Doses	PsA	Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks **Adult: 45 mg SC at weeks 0 and 4, followed by 45 mg every 12 weeks **Pediatrics (age 6 years to 17 years): Weight based dosing SC at weeks 0 and 4, then every 12 weeks thereafter. **Stelara, Otulfi, Pyzchiva, Wezlana, Yesintek: Weight < 60 kg: 0.75 mg/kg **Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, Yesintek: Weight ≥ 60 kg: 45 mg	45 mg every 12 weeks



Drug Name	Indication	Dosing Regimen* *Maximum dose escalation allowed per prescriber information with documentation of inadequate response	Maximum Dose
	PsA with co-existent PsO	Weight > 100 kg: 90 mg SC at weeks 0 and 4, followed by 90 mg every 12 weeks	90 mg every 12 weeks
	CD, UC	Weight based dosing IV at initial dose: Weight ≤ 55 kg: 260 mg Weight > 55 kg to 85 kg: 390 mg Weight > 85 kg: 520 mg	90 mg every 8 weeks
		Maintenance dose: 90 mg SC every 8 weeks	
Vedolizumab (Entyvio)	CD, UC	Initial dose: 300 mg IV at weeks 0 and 2, followed by 300 mg IV or 108 mg SC at week 6	IV: 300 mg every 8 weeks
		Maintenance dose: 300 mg IV every 8 weeks or 108 mg SC every 2 weeks	SC: 108 mg every 2 weeks

VI. Product Availability

Drug Name	Availability
Abatacept (Orencia)	Single-use vial: 250 mg
	Single-dose prefilled syringe: 50 mg/0.4 mL, 87.5 mg/0.7 mL, 125
	mg/mL
	Single-dose prefilled ClickJect [™] autoinjector: 125 mg/mL
Adalimumab (Humira)	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
Adalimumab-afzb	Single-dose prefilled pen (Abrilada Pen): 40 mg/0.8 mL
(Abrilada)	Single dose prefilled syringe: 40 mg/0.8 mL, 20 mg/0.4 mL, 10
	mg/0.2 mL
	Single-dose glass vial for institutional use only: 40 mg/0.8 mL
Adalimumab-atto	Single-dose prefilled SureClick autoinjector: 80 mg/0.8 mL, 40
(Amjevita)	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
Adalimumab-adbm	Single-dose prefilled syringe: 40 mg/0.4 mL, 40 mg/0.8 mL, 20
(Cyltezo)	mg/0.4 mL, 10 mg/ 0.2 mL
	Single-dose prefilled pen (Cyltezo Pen): 40 mg/0.4 mL, 40 mg/0.8
	mL



Drug Name	Availability
Adalimumab-bwwd	Single-dose prefilled autoinjector (Hadlima PushTouch): 40
(Hadlima)	mg/0.8 mL, 40 mg/0.4 mL (citrate-free)
	Single-dose prefilled syringe: 40 mg/0.8 mL, 40 mg/0.4 mL
	(citrate-free)
	Single-dose glass vial for institutional use only: 40 mg/0.8 mL
Adalimumab-fkjp	Single-dose prefilled pen (Hulio Pen): 40 mg/0.8 mL
(Hulio)	Single-dose prefilled syringe: 40 mg/0.8 mL, 20 mg/0.4 mL
Adalimumab-adaz	Single-dose prefilled glass syringe (with BD UltraSafe Passive [™]
(Hyrimoz)	Needle Guard): 20 mg/0.4 mL, 40 mg/0.8 mL, 40 mg/0.4 mL, 80
	mg/0.8 mL
	Single-dose prefilled pen (Sensoready® Pen): 40 mg/0.8 mL, 40
	mg/0.4 mL, 80 mg/0.8 mL
	Single-dose prefilled glass syringe: 10 mg/0.2 mL, 10 mg/0.1 mL,
	20 mg/0.2 mL
Adalimumab-aacf	Single-dose prefilled pen (Idacio Pen): 40 mg/0.8 mL
(Idacio)	Single-dose prefilled glass syringe: 40 mg/0.8 mL
(1440-15)	Single-dose institutional use vial kit: 40 mg/0.8 mL
Adalimumab-ryvk	Single-dose autoinjector: 40 mg/0.4 mL, 80 mg/0.8 mL
(Simlandi)	Single-dose prefilled glass syringe: 20 mg/0.2 mL, 40 mg/0.4 mL,
(Simular)	80 mg/0.8 mL
Adalimumab-aaty	Single-dose prefilled auto-injector (Yuflyma AI): 40 mg/0.4 mL,
(Yuflyma)	80 mg/0.8 mL
(1 4/11/1144)	Single-dose prefilled syringe with safety guard: 40 mg/0.4 mL, 80
	mg/0.8 mL
	Single-dose prefilled syringe: 20 mg/0.2 mL, 40 mg/0.4 mL, 80
	mg/0.8 mL
Adalimumab-aqvh	Single-dose prefilled pen (Yusimry Pen): 40 mg/0.8 mL
(Yusimry)	Single-dose prefilled glass syringe: 40 mg/0.8 mL
Anakinra (Kineret)	Single-use prefilled syringe: 100 mg/0.67 mL
Apremilast (Otezla)	Tablets : 10 mg, 20 mg, 30 mg
Baricitinib (Olumiant)	Tablet: 1 mg, 2 mg
Bimekizumab-bkzx	Single-dose prefilled syringe: 160 mg/mL, 320 mg/2 mL
(Bimzelx)	Single-dose prefilled autoinjector: 160 mg/mL, 320 mg/2 mL
Brodalumab (Siliq)	Single-dose prefilled syringe: 210 mg/1.5 mL
Certolizumab pegol	Lyophilized powder in a single-use vial for reconstitution: 200 mg
(Cimzia)	Single-use prefilled syringe: 200 mg/mL
Deucravacitinib	Tablet: 6 mg
(Sotyktu)	
Etanercept (Enbrel)	Single-dose prefilled syringe: 25 mg/0.5 mL, 50 mg/mL
	Single-dose prefilled SureClick® Autoinjector: 50 mg/mL
	Single-dose vial: 25 mg/0.5 mL
	Multi-dose vial for reconstitution: 25 mg
	Enbrel Mini TM single-dose prefilled cartridge for use with
	AutoTouch™ reusable autoinjector : 50 mg/mL



Drug Name	Availability
Etrasimod (Velsipity)	Tablet: 2 mg
Golimumab (Simponi)	Single-dose prefilled SmartJect® autoinjector: 50 mg/0.5 mL, 100
, ,	mg/1 mL
	Single-dose prefilled syringe: 50 mg/0.5 mL, 100 mg/1 mL
Golimumab (Simponi	Single-use vial: 50 mg/4 mL
Aria)	
Infliximab-axxq	Single-use vial: 100 mg/20 mL
(Avsola)	
Infliximab-dyyb	Single-use vial: 100 mg/20 mL
(Inflectra)	
Infliximab-dyyb	Single-dose prefilled syringe: 120 mg/mL
(Zymfentra)	Single-dose prefilled syringe with needle shield: 120 mg/mL
	Single-dose prefilled pen: 120 mg/mL
Infliximab (Remicade)	Single-use vial: 100 mg/20 mL
Infliximab-abda	Single-use vial: 100 mg/20 mL
(Renflexis)	
Ixekizumab	Single-dose prefilled autoinjector: 80 mg/mL
(Taltz)	Single-dose prefilled syringe: 20 mg/0.25 mL, 40 mg/0.5 mL, 80
	mg/mL
Guselkumab	Single-dose prefilled syringe for SC: 100 mg/mL, 200 mg/2 mL
(Tremfya)	Single-dose One-Press pen-injector for SC: 100 mg/mL
	Single-dose prefilled pen (Tremfya Pen) for SC: 100 mg/mL, 200
	mg/2 mL
	Single-dose vial for IV: 200 mg/20 mL
Mirikizumab-mrkz	Single-dose vial (for intravenous infusion): 300 mg/15 mL (20
(Omvoh)	mg/mL)
	Single-dose prefilled pen (for subcutaneous use): 100 mg/mL, 200
	mg/2 mL
	Single-dose prefilled syringe (for subcutaneous use): 100 mg/mL,
NY . 12	200 mg/2 mL
Natalizumab-sztn	Single-dose vial: 300 mg/15 mL
(Tyruko)	
Natalizumab-sztn	Single-dose vial: 300 mg/15 mL
(Tyruko)	C: 1 .1.200 /15 I
Natalizumab (Tysabri)	Single-use vial: 300 mg/15 mL
Ozanimod (Zeposia)	Oral capsules: 0.23 mg, 0.46 mg, 0.92 mg
Risankizumab-rzaa	Subcutaneous injection
(Skyrizi)	Single-dose prefilled syringe: 90 mg/mL, 150 mg/mL
	Single-dose prefilled pen: 150 mg/mL
	Single-dose prefilled cartridge: 180 mg/1.2 mL, 360 mg/2.4 mL
	Intravenous infusion Single dose viol: 600 mg/10 ml
Sorilymah (Varyzana)	Single-dose vial: 600 mg/10 mL
Sarilumab (Kevzara)	Single-dose prefilled syringes/pens: 150 mg/1.14 mL, 200 mg/1.14
	mL



Drug Name	Availability
Secukinumab	Single-dose UnoReady pen: 300 mg/2 mL
(Cosentyx)	Single-dose Sensoready® pen: 150 mg/mL
3 /	Single-dose prefilled syringe: 75 mg/0.5 mL, 150 mg/mL, 300 mg/2
	mL
	Single-dose vial (for IV infusion): 125 mg/5 mL
Tildrakizumab-asmn	Single-dose prefilled syringe: 100 mg/1 mL
(Ilumya)	
Tocilizumab	Single-use vial : 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL
(Actemra)	Single-dose prefilled syringe: 162 mg/0.9 mL
	Single-dose prefilled autoinjector: 162 mg/0.9 mL
Tocilizumab-aazg	Single-use vial: 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL
(Tyenne)	Single-dose prefilled syringe: 162 mg/0.9 mL
	Single-dose prefilled autoinjector: 162 mg/0.9 mL
Tocilizumab-anoh	Single-dose vial: 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL
(Avtozma)	Single-dose prefilled syringe: 162 mg/0.9 mL
	Single-dose prefilled autoinjector: 162 mg/0.9 mL
Tocilizumab-bavi	Single-dose vial: 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL
(Tofidence)	
Tofacitinib (Xeljanz)	Tablets : 5 mg, 10 mg
	Oral solution: 1 mg/mL
Tofacitinib extended-	Tablets: 11 mg, 22 mg
release (Xeljanz XR)	
Upadacitinib (Rinvoq)	Tablets, extended-release: 15 mg, 30 mg, 45 mg
Upadacitinib (Rinvoq LQ)	Oral solution: 1 mg/mL
Ustekinumab (Stelara)	Single-use prefilled syringe: 45 mg/0.5 mL, 90 mg/mL
	Single-dose vial for SC: 45 mg/0.5 mL
	Single-dose vial for IV: 130 mg/26 mL (5 mg/mL)
Ustekinumab-aauz	Single-dose prefilled syringe for SC injection: 45 mg/0.5 mL, 90
(Otulfi)	mg/mL
	Single-dose vial for SC injection: 45 mg/0.5 mL
	Single-dose vial for IV infusion: 130 mg/26 mL
Ustekinumab-aekn	Single-dose prefilled syringe for SC injection: 45 mg/0.5 mL, 90
(Selarsdi)	mg/mL
TT . 1 . 4 . 4	Single-dose vial for IV infusion: 130 mg/26 mL
Ustekinumab-auub	Single-dose prefilled syringe for SC injection: 45 mg/0.5 mL, 90
(Wezlana)	mg/mL
	Single-dose vial for SC injection: 45 mg/0.5 mL
	Single-dose prefilled autoinjector (ConfiPen) for SC injection: 45
	mg/0.5 mL, 90 mg/mL
Hatalringumals 1-fac	Single-dose vial for IV infusion: 130 mg/26 mL
Ustekinumab-kfce	Single-dose prefilled syringe for SC injection: 45 mg/0.5 mL, 90
(Yesintek)	mg/mL Single does yiel for SC injection: 45 mg/0.5 ml
	Single-dose vial for SC injection: 45 mg/0.5 mL
	Single-dose vial for IV infusion: 130 mg/26 mL



Drug Name	Availability
Ustekinumab-srlf	Single-dose prefilled syringe for SC injection: 45 mg/0.5 mL, 90
(Imuldosa)	mg/mL
	Single-dose vial for IV infusion: 130 mg/26 mL
Ustekinumab-stba	Single-dose prefilled syringe for SC injection: 45 mg/0.5 mL, 90
(Steqeyma)	mg/mL
	Single-dose vial for IV infusion: 130 mg/26 mL
Ustekinumab-ttwe	Single-dose prefilled syringe for SC injection: 45 mg/0.5 mL, 90
(Pyzchiva)	mg/mL
	Single-dose vial for SC injection: 45 mg/0.5 mL
	Single-dose vial for IV infusion: 130 mg/26 mL
Vedolizumab	Lyophilized powder in a single-dose vial for reconstitution for IV
(Entyvio)	infusion: 300 mg
	Single-dose prefilled syringe for SC injection: 108 mg/0.68 mL
	Single-dose prefilled Entyvio Pen for SC injection: 108 mg/0.68
	mL

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Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS	Description
Codes	
J0129	Injection, abatacept, 10 mg
J0139	Injection, adalimumab, 1 mg
J0717	Injection, certolizumab pegol, 1 mg
J1438	Injection, etanercept, 25 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J1628	Injection, guselkumab, 1 mg



HCPCS	Description
Codes	
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J2267	Injection, mirikizumab-mrkz, 1 mg
J2323	Injection, natalizumab, 1 mg
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg
J3245	Injection, tildrakizumab, 1 mg
J3247	Injection, secukinumab, intravenous, 1 mg
J3262	Injection, tocilizumab, 1 mg
J3357	Ustekinumab, for subcutaneous injection,1 mg
J3358	Ustekinumab, for intravenous injection, 1 mg
J3380	Injection, vedolizumab, intravenous, 1 mg
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg
Q5140	Injection, adalimumab-fkjp, biosimilar, 1 mg
Q5141	Injection, adalimumab-aaty, biosimilar, 1 mg
Q5142	Injection, adalimumab-ryvk biosimilar, 1 mg
Q5143	Injection, adalimumab-adbm, biosimilar, 1 mg
Q5144	Injection, adalimumab-aacf (idacio), biosimilar, 1 mg
Q5145	Injection, adalimumab-afzb (abrilada), biosimilar, 1 mg
Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg
Q5135	Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg
Q5134	Injection, natalizumab-sztn (tyruko), biosimilar, 1 mg
Q5137	Injection, ustekinumab-auub (wezlana), biosimilar, subcutaneous, 1 mg
Q5138	Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg
Q9996	Injection, ustekinumab-ttwe (pyzchiva), subcutaneous, 1 mg
Q9997	Injection, ustekinumab-ttwe (pyzchiva), intravenous, 1 mg
Q9998	Injection, ustekinumab-aekn (selarsdi), 1 mg
Q9999	Injection, ustekinumab-aauz (otulfi), biosimilar, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2021 annual review: added criteria for new indication of DIRA for Kineret; added additional criteria related to diagnosis of PsO per 2019 AAD/NPF guidelines specifying involvement of areas that severely impact daily function OR at least 3% BSA involvement for moderate-to-severe, at least 10% BSA involvement for chronic-severe; added biosimilar redirection to other diagnoses/indications; added alopecia areata as indication not coverable for Xeljanz/Xeljanz XR requests (cosmetic); updated CDAI table with ">" to prevent overlap in classification of severity; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); clarified that different therapeutic classes must be tried for HS, each for 3 months; references reviewed and updated.	05.04.21	05.21



Reviews, Revisions, and Approvals	Date	P&T
		Approval Date
RT4: updated criteria to reflect pediatric extension for UC to include		Date
patients 5 years of age and older.		
RT4: added criteria for new FDA indication, SSc-ILD		
RT4: updated Cosentyx PsO age requirement from ≥ 18 years to ≥ 6	06.04.21	
years per FDA pediatric expansion; added new 75 mg/0.5 mL		
prefilled syringe for pediatric patients. RT4: added new Skyrizi 150		
mg/mL prefilled pen and syringe formulations.		
RT4: added Zeposia to the policy for its newly FDA-approved	06.14.21	08.21
indication for ulcerative colitis.		
SSc-ILD: added rheumatologist prescriber option per specialist		
feedback and added baseline FVC/DLCO requirements.		
Per June SDC and prior clinical guidance, modified Avsola to parity		
status with Inflectra and Renflexis; added Avsola to list of biosimilar		
infliximab products that must be used prior to Remicade.		
RT4: added information regarding Actemra and Olumiant EUA for		
COVID-19 hospitalized patients.	00.00.01	11.01
Added requirement of concomitant treatment with MTX and	08.23.21	11.21
bDMARD if request is for concomitant treatment with Otezla and		
bDMARD; added dose escalation guideline on Stelara for CD, UC,		
PsO and PsA; revised place in therapy for Xeljanz per FDA		
announcement and allowed bypassing Xeljanz if member had		
cardiovascular risk and benefits do not outweigh the risk of treatment.	05.02.22	05.22
2Q 2022 annual review: added newly FDA-approved indications:	05.02.22	05.22
AD, AS, UC, and PsA for Rinvoq, aGVHD for IV Orencia, ERA for		
Cosentyx, PsA for Skyrizi, AS for Xeljanz/Xeljanz XR, IV formulation for Actemra for GCA; FDA use extension to mild PsO for		
Otezla after failure of at least one topical therapy; pediatric use		
extension down to 2 years and older for PsA for Cosentyx; removed		
oral and topical steroid requirement for Behçet's disease; added off-		
label use for Kawasaki disease for infliximab; for moderate-to-severe		
PsO, allowed phototherapy as alternative to systemic conventional		
DMARD if contraindicated or clinically significant adverse effects are		
experienced; for Olumiant, Rinvoq, and Xeljanz, updated place in		
therapy after TNFi per FDA labeling; revised redirection from		
Remicade to biosimilars to "must use" language; for Stelara requests		
via the pharmacy benefit, added that member must use prefilled		
syringe formulation if request is for the 45 mg vial; reiterated		
requirement against combination biologic DMARD use from Section		
III to Sections I and II; removed unspecified iridocyclitis (ICD10		
H20.9) from Section III; clarified other diagnoses/indications section		
to enforce biosimilar redirection intent; references reviewed and		
updated.		



Reviews, Revisions, and Approvals	Date	P&T
		Approval Date
Per May SDC and prior clinical guidance, modified Kevzara redirection in RA from all to two of the following: Humira, Enbrel, Xeljanz/Xeljanz XR, Rinvoq; revised Rinvoq lower age limit for AD from 18 to 12 years per PI; RT4: revised FDA approved indications to include treatment of alopecia and hospitalized COVID-19; reiterated that Olumiant is not covered for COVID-19 since it is FDA-approved for use only in the hospital setting; added alopecia areata to the list of indications for which coverage is NOT authorized, since its use is cosmetic in nature and thus a benefit exclusion; RT4: updated Skyrizi with Crohn's disease indication along with new vial and prefilled cartridge formulations and new contraindication; references reviewed and updated.	07.07.22	Date
RT4: for Stelara for PsA, updated criteria and dosing per FDA approved pediatric extension. Template changes applied to other diagnoses/indications and continued therapy section.	09.09.22	
Per August SDC and prior clinical guidance, modified Remicade redirection to be stepwise, first requiring Inflectra and Renflexis, then if member has failed Inflectra and Renflexis member must use Avsola; for Avsola added redirection to Inflectra and Renflexis; RT4: for Skyrizi, added new 180 mg/1.2 mL single-dose prefilled cartridge dosage form and quantity limit stating that only one single dose vial or pre-filled cartridge is allowed per dose for CD; RT4: added Sotyktu to the policy for its newly FDA-approved indication for PsO; RT4: criteria added for new FDA indication for Rinvoq: nr-axSpA.	08.23.22	11.22
RT4: added information regarding Kineret EUA for COVID-19 hospitalized patients; added HCPCS code: [J2327].	12.02.22	
Per February SDC, added Amjevita to policy with criteria requiring use of preferred formulary NDCs along with reference to Appendix N; added Amjevita as an alternative option to Humira for applicable indications.	02.13.23	
For PsO, added requirement of preferred biologic agents before trial of Sotyktu.	03.10.23	
2Q 2023 annual review: RT4: for Actemra, revised criteria for COVID-19 emergency authorized use to FDA-approved indication; updated off-label dosing for Appendix B; removed Actemra from Appendix M since Actemra does not have EUA and is now approved for COVID-19; for AS, pJIA, PsO, PsA, RA, CD, and UC, added TNFi criteria to allow bypass if member has had history of failure of two TNF blockers; references reviewed and updated. For PsA, updated criteria from "Xeljanz/Xeljanz XR or Rinvoq" to "Xeljanz/Xeljanz XR and Rinvoq" to align with commercial policy and to allow trial of both JAK inhibitors after trial of TNF-blockers.	04.19.23	05.23



Reviews, Revisions, and Approvals	Date	P&T
		Approval Date
RT4: for Kevzara, added criteria for newly approved PMR indication		Date
to policy and added Appendix O for PMR Classification Criteria		
Scoring Algorithm; for Amjevita, updated FDA approved indications		
to reflect new HS indication, added Amjevita to HS criteria, updated		
biosimilar dosing in section V, and added 10 mg/0.2 mL prefilled		
glass syringe dosage form; for PsO, corrected Otezla misspelling for		
"request is for Otezla" criteria.		
RT4: for Rinvoq, criteria added for new FDA indication: Crohn's	05.25.23	
disease; updated Appendix C to align boxed warnings among JAK		
inhibitors and to align with individual prescriber information; RT4:		
for Cosentyx, added new dosage forms (UnoReady Pen and 300 mg/2		
mL dose of pre-filled syringe) to policy.		
Added Humira biosimilars Abrilada, unbranded adalimumab-adaz,	07.25.23	
unbranded adalimumab-fkjp, Cyltezo, Hadlima, Hulio, Hyrimoz,		
Idacio, Yuflyma, and Yusimry to policy; for Amjevita request criteria,		
removed "preferred formulary" language; added HCPCS codes		
[Q5131] and [C9399].		
Per July SDC: for AS, CD, PsO, pJIA, PsA, RA, and UC, modified		
redirection from "Humira or Amjevita" to "one of the following		
adalimumab products: Humira, Hadlima, or adalimumab-adaz"; added		
requirement for Humira biosimilars that member must use all		
preferred adalimumab products: Humira, Hadlima, and unbranded		
adalimumab-adaz (NDC 61314-0327-20, 61314-0327-96, 61314-		
0327-64, 61314-0327-94); removed criteria requiring use of preferred		
Amjevita NDCs and Appendix with Amjevita NDC references.		
Per August SDC: for Stelara, removed redirection criteria for requests	08.22.23	
that are above the labeled maximum dose.		
RT4: for Amjevita, added new strengths for prefilled autoinjector 40	09.19.23	
mg/0.4 mL, 80 mg/0.8 mL and prefilled syringe 20 mg/0.2 mL, 40		
mg/0.4 mL, 80 mg/0.8 mL in section VI; RT4: for Abrilada, Hulio/		
adalimumab-fkjp, Hyrimoz/ adalimumab-adaz, and Yusimry, updated		
FDA approved indications, approval criteria, and dosing in section V		
to reflect new UV indication; RT4: for Entyvio, added new dosage		
forms (prefilled syringe and Entyvio Pen) for SC injection to sections		
V and VI; for section VI, revised Entyvio formulation from "single-		
use vial" to "lyophilized powder in a single-dose vial for		
reconstitution for IV infusion: 300 mg" per PI; for Entyvio: for CD,		
added "request is for IV formulation" in initial approval and continued		
therapy sections; RT4: added newly approved biosimilar Tofidence to		
FDA approved indication section, pJIA, RA, sJIA criteria, and section		
V; RT4: Tyruko (a Tysabri biosimilar) added to FDA approved indications, approved eritoria, and section V to reflect new CD and MS		
indications, approval criteria, and section V to reflect new CD and MS		
indication; RT4: for Yuflyma, added new strengths for auto-injector		



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		Date
80 mg/0.8 mL, prefilled syringe with safety guard 80 mg/0.8 mL, and prefilled syringe 20 mg/0.2 mL and 80 mg/0.8 mL and updated Yuflyma pediatric weight base dosing for pJIA and CD in section V; RT4: for Idacio, updated FDA approved indications, approval criteria, and dosing in section V to reflect new HS indication; RT4: for Cosentyx, added new dosage form single-dose vial 125 mg/5 mL for intravenous infusion, added IV specific dosing for AS, nr-axSpA and PsA; RT4: for PsA, added newly approved JPsA indication for Enbrel;		
added Tofidence to section III.B; added HCPCS code [Q5132].	00.00.00	12.22
Per August SDC: for CD, PsO, PsA, UC, and continued therapy, removed criteria "for Stelara: if request is through the pharmacy benefit for 45 mg/0.5 mL vial formulation, member must use Stelara pre-filled syringe"; RT4: for PsO, added Bimzelx to criteria; RT4: for CD and UC, added Zymfentra to criteria; RT4: for UC, added Velsipity to criteria; RT4: for UC, added Omvoh to criteria.	08.22.23	12.23
Per December SDC, added Cyltezo with specific NDCs to list of	02.12.24	02.24
preferred adalimumab products. RT4: for Orencia, updated PsA criteria with pediatric extension to include ages 2 years and older; for pJIA, added "for Orencia: members 2 to 17 years of age, prescribed route of administration is SC" to align with Medicaid criteria; RT4: for Cosentyx, added newly approved HS indication to criteria; RT4: for Idacio, added newly approved UV indication to criteria; RT4: for Idacio, added new dosage formulation [single-dose institutional use vial kit: 40 mg/0.8 mL]; for CD and pJIA, updated Idacio pediatric dosing in section V; RT4: added newly approved biosimilar Wezlana to criteria; added Wezlana to section III.B; for AD initial criteria, removed systemic immunosuppressant therapy step criterion per updated guideline and competitor analysis and in alignment with previously P&T approved approach; for Appendix B, removed AD systemic immunosuppressant therapy therapeutic alternatives.		02.27
Revised HCPCS code description [J3380] and add HCPCS codes [C9166, C9168, Q5133, Q5134].	02.22.24	
2Q 2024 annual review: RT4: for UV, added Yuflyma to criteria; for Castleman's disease, added member has either unicentric disease with HIV-negative and HHV-8-negative or multicentric disease as supported by NCCN compendium and updated duration from "6 months or to member's renewal date, whichever is longer" to "6 months"; for cytokine release syndrome, added "i.e., inadequate response to steroids, vasopressors" as examples for refractory CRS; for Appendix D, removed AS and nr-axSpA guideline, CRADLE trial for Cimzia, and pediatric pharmacokinetic studies for Stelara; for Appendix M, added Actemra information as an FDA-approved	03.25.24	05.24



Reviews, Revisions, and Approvals	Date	P&T
		Approval
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alternative for COVID-19; for Renflexis, removed "re-administration		
to patients who have experienced severe hypersensitivity reaction to infliximab products" in contraindications section; for Cosentyx,		
Rinvoq, Avsola, Inflectra, Remicade, and Renflexis, added "maximum		
dose escalation allowed per prescriber information with		
documentation of inadequate response" in criteria and section V;		
added Bimzelx, Zymfentra, Omvoh, Sotyktu, Tofidence, and Velsipity		
to section III.B; references reviewed and updated.		
Per March SDC: for Rinvoq in Atopic Dermatitis, modified		
requirement of two topical corticosteroids to require only one,		
removed requirement for use of one systemic agent.		
RT4: added newly approved Humira biosimilar Simlandi to criteria;		
RT4: added newly approved Actemra biosimilar Tyenne to RA, GCA,		
pJIA, and sJIA criteria; added Sotyktu to description section and		
"medically necessary" section.		
Per SDC: for PsO, added redirection to Enbrel and Otezla as	05.09.24	06.24
alternative option with "or" instead of "and" language to list of		
preferred redirected agents.		
Added branded Cyltezo 40 mg/0.4 mL specific NDCs [0597-0495-40,		
0597-0495-50, 0597-0495-60, 0597-0485-20] to list of preferred		
adalimumab products; for PsA and pJIA, added redirection to		
preferred agent Rinvoq LQ.		
RT4: for Entyvio, added new dosage form (subcutaneous injection)		
and removed "request is for IV formulation" for CD criteria; RT4: for		
PsA and PsO, added newly approved biosimilar Selarsdi to criteria;		
for PsO, updated Wezlana age requirement from ≥ 18 years to ≥ 6		
years; RT4: for Otezla, added newly approved pediatric extension to 6		
years and older for PsO criteria; RT4: for Rinvoq, updated criteria to		
reflect pediatric extension to 2 years and older for PsA; for Rinvoq,		
added new FDA approved pJIA indication and added redirection to		
preferred agent Rinvoq LQ; for PsA and pJIA, added new oral		
solution dosage form [Rinvoq LQ] to criteria; for PsA, added		
redirection to preferred agent Stelara for pediatric Orencia requests;		
RT4: for Omvoh, added new dosage form [single-dose prefilled		
syringe 100 mg/mL]; RT4: for Cyltezo, added new 40 mg/0.4 mL		
dosage strengths for single-dose pen and single-dose prefilled syringe; for Appendix D, removed supplemental information on DIRA		
indication and PHOENIX 2 trial for Stelara.		
Added HCPCS codes [J3247, Q5137, Q5138, J2267] and removed		
HCPCS codes [C9166, C9168].		
Per June SDC: modified Remicade stepwise redirection by adding if	07.15.24	08.24
member has failed Inflectra, Renflexis, and Avsola, member must use	U / .1 J . 2 T	00.2T
unbranded Remicade; for unbranded Remicade, member must use		



Reviews, Revisions, and Approvals	Date	P&T
		Approval Date
Inflectra and Renflexis, then if member has failed Inflectra and Renflexis, member must use Avsola; for CD and UC, added additional requirement for Zymfentra requests requiring provider attestation that "member is unable to receive continued therapy with IV infliximab due to lack of caregiver or support system for assistance with administration and/or inadequate access to healthcare facility or home care interventions and/or lack of transportation to healthcare facility." RT4: for Kevzara, added newly approved polyarticular juvenile idiopathic arthritis indication to criteria; RT4: for Skyrizi, added newly approved Ulcerative Colitis indication to criteria; RT4: for CD, UC, PsO, PsA: added newly approved biosimilar Pyzchiva to criteria. For PsA: added Rinvoq to list of agents for ages ≥ 2 years and older; for Orencia requests for ages 2 to 17 years and Selarsdi/Wezlana requests for ages 6 to 17 years, added Rinvoq to list of redirected agents.		
RT4: for Simlandi, added new prefilled syringe formulation and strengths [20 mg/0.2 mL, 40 mg/0.4 mL, 80 mg/0.8 mL]; for section V, added Simlandi pediatric dose for pJIA [15 kg to less than 30 kg: 20 mg every other week] and pediatric dose for CD [17 kg to less than 40 kg: 80 mg SC on Day 1, 40 mg SC on Day 15, then 20 mg SC every other week starting on Day 29]; RT4: for Tofidence, added coverage for COVID-19 and GCA; for section V, added Tofidence dosing for GCA; for Appendix M, added supplemental information for Tofidence; added HCPCS code [Q5135] for Tyenne; RT4: for Taltz: added new strengths for single-dose prefilled syringe [20 mg/0.25 mL, 40 mg/0.5 mL].	08.13.24	
RT4: for Tremfya, added criteria for newly approved indication for UC; added new subcutaneous formulations [single-dose prefilled syringe 200 mg/2 mL; single-dose prefilled pen (Tremfya Pen) 200 mg/2 mL] and intravenous formulation [single-dose vial 200 mg/20 mL]; RT4: for Cimzia, added criteria for newly approved indication for PJIA; RT4: for Bimzelx, added criteria for newly approved indications for PsA, AS, and nr-axSpA; RT4: added newly approved biosimilar Otulfi to criteria.	09.19.24	11.24
Per August SDC, added Yuflyma with specific NDCs to list of preferred adalimumab products; removed Hadlima and adalimumabadaz from list of preferred adalimumab products. RT4: for Bimzelx, added new strength [320 mg/2 mL] for single-dose prefilled syringe and single-dose prefilled autoinjector; RT4: added newly approved biosimilar Imuldosa to criteria; RT4: for Selarsdi, added newly approved indications for CD and UC; added new dosage formulation [single-dose vial for IV infusion 130 mg/26 mL]; for	11.04.24	12.24



Reviews, Revisions, and Approvals	Date	P&T
		Approval
continued therapy, removed redirection to Stelara for Stelara biosimilars. Added HCPCS codes [J0139, Q5140, Q5141, Q5142, Q5143, Q5144, Q5145, Q9996, Q9997, Q9998] and removed [J0135, Q5131, Q5132]. For Stelara, added "#" superscript to include IV induction for CD and UC indications in FDA Approved Indications table.		Date
Per December SDC: for RA and pJIA, revised Actemra redirection to require only a single step through preferred formulary products. RT4: for Bimzelx, added criteria for newly approved indication for HS; RT4: added newly approved biosimilar Yesintek to criteria; RT4: for Pyzchiva, added new dosage formulation [single-dose vial for SC injection 45 mg/0.5 mL]; added Pyzchiva to "weight < 60 kg: 0.75 mg/kg per dose" pediatric dosing for PsO and PsA; RT4: for Wezlana, added new dosage formulation [single-dose prefilled autoinjector (ConfiPen) 45 mg/0.5 mL, 90 mg/mL]; RT4: added newly approved biosimilar Steqeyma to criteria; for AS, CD, HS, PsO, pJIA, PsA, RA, UC, and UV, added adalimumab-aacf, adalimumab-aaty, adalimumab-bwwd, and adalimumab-ryvk to criteria; per SDC: for GCA, removed criteria for failure of "≥ 3 consecutive month trial" of a systemic corticosteroid and "in conjunction with methotrexate or azathioprine"; for pJIA: removed criteria for minimum cJADAS-10 score ≥ 8.5 for documentation of high disease activity and "baseline 10-joint clinical juvenile arthritis disease activity score" in initial criteria; removed criteria for "member is responding positively to therapy as evidenced by a decrease in cJADAS-10 from baseline" in continued therapy; for Appendix K, added pJIA disease activity information per 2019 ACR guidelines.	01.13.25	02.25
2Q 2025 annual review: for UC initial criteria, added option for documentation of modified Mayo Score ≥ 5; removed redirection to preferred adalimumab products as adalimumab is not recommended due to low efficacy per 2024 AGA guidelines; for Appendix F, added supplemental information on modified Mayo Score; RT4: for Omvoh, added criteria for newly approved indication for CD and added new dosage forms [single-dose prefilled pen 200 mg/2 mL and single-dose syringe 200 mg/2 mL]; RT4: added newly approved biosimilar Avtozma to criteria; RT4: for Simlandi, added new single-dose autoinjector strength [80 mg/0.8 mL]; for sJIA, added redirection to NSAID as an option per clinical practice guidelines and competitor analysis; for CD, allowed redirection to preferred agent Rinvoq after TNF blocker per FDA labeling; for CRS, revised criteria from "member has developed refractory CRS related to blinatumomab therapy" to "used as supportive care in severe CRS related to blinatumomab therapy" and added criteria "used as prophylaxis to	04.07.25	05.25



Reviews, Revisions, and Approvals	Date	P&T Approval Date
reduce the risk of CRS when administering teclistamab-cqyv" per NCCN compendium; added HCPCS code [Q9999]; for Appendix D,		
removed supplemental information on Enbrel in HS; updated section		
III.B with Spevigo and biosimilar verbiage; ; for Kawasaki disease,		
updated dose in section V from 5 mg/kg given over 2 hours to 10		
mg/kg given over 2 hours; for Appendix M, removed supplemental		
information on COVID-19 therapeutic alternatives; references reviewed and updated.		
RT4: for Tyenne, added newly approved CRS and COVID-19		
indications to criteria; for Appendix D, removed PsA and PsO		
supplemental information on Otezla; RT4: for Tremfya, added criteria		
for newly approved indication for CD; RT: for Tremfya, added new		
strength [100 mg/mL] for single-dose prefilled pen (Tremfya Pen);		
RT4: for Otulfi, added new dosage formulation [single-dose vial for SC injection: 45 mg/0.5 mL]; added Otulfi to "weight < 60 kg: 0.75		
mg/kg per dose" pediatric dosing in section V for PsA and PsO; per		
SDC: for UC, revised redirection to include adalimumab product in		
criteria for "three of the following: Stelara, Skyrizi, Tremfya,		
adalimumab product [Humira/Cyltezo/Yuflyma]"; added step therapy		
bypass for IL HIM per IL HB 5395.		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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