Clinical Policy: Biologic and Non-biologic DMARDs

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Coding Implications
Revision Log

See Important Reminder 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-atto (Amjevita™), infliximab-axxq (Avsola™), certolizumab pegol (Cimzia®), secukinumab (Cosentyx®), etanercept (Enbrel®), vedolizumab (Entyvio®), adalimumab (Humira®), tildrakizumab-asmn (Ilumya™), infliximab-dyyb (Inflectra®), sarilumab (Kevzara®), anakinra (Kineret®), baricitinib (Olumiant®), abatacept (Orencia®), apremilast (Otezla®), infliximab (Remicade®), infliximab-abda (Renflexis™), upadacitinib (Rinvoq™), brodalumab (Siliq™), golimumab (Simponi®, Simponi Aria®), risankizumab-rzaa (Skyrizi™), ustekinumab (Stelara®), ixekizumab (Taltz®), guselkumab (Tremfya®), natalizumab (Tysabri®), tofacitinib (Xeljanz®, Xeljanz® XR), ozanimod (Zeposia®).

FDA Approved Indication(s)

	AS	nr-axSpA	CD	UC	PJIA	SJIA	PsO	PsA	RA	Others
Actemra					x#	x#			x#	CRS*, GCA^, SSc-ILD^
Amjevita	x		x	x	x		x	x	x	
Avsola	x		x	x			x	x	x	
Cimzia	x	x	x				x	x	x	
Cosentyx	x	x					x	x		ERA
Enbrel	x				x		x	x	x	
Entyvio			x	x						
Humira	x		x	x	x		x	x	x	HS, UV
Ilumya							x			
Inflectra	x		x	x			x	x	x	
Kevzara									x	
Kineret									x	DIRA, NOMID
Olumiant									x	COVID-19 in the hospitalized setting, alopecia areata
Orencia					x#			x#	x#	aGVHD
Otezla							x	x		BD
Remicade	x		x	x			x	x	x	
Renflexis	x		x	x			x	x	x	
Rinvoq	x	x		x				x	x	AD
Siliq							x			
Simponi	x			x				x	x	
Simponi Aria	x				x			x	x	
Skyrizi			x#				x	x		
Sotyktu							x			
Stelara			x	x			x^	x^		

	AS	nr-axSpA	CD	UC	PJIA	SJIA	PsO	PsA	RA	Others
Taltz	x	x					x	x		
Tremfya							x	x		
Tysabri			x							MS
Xeljanz	x			x	x			x	x	
Xeljanz XR	x			x				x	x	
Zeposia				x						MS

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

Contents:

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 Actemra, Amjevita, Avsola, Cimzia, Cosentyx, Enbrel, Entyvio, Humira, Ilumya, Inflectra, Kevzara, Kineret, Olumiant, Orencia, Otezla, Remicade, Renflexis, Rinvoq, Siliq, Simponi, Simponi Aria, Skyrizi, Stelara, Taltz, Tremfya, Tysabri, Xeljanz, Xeljanz XR, and Zeposia 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 Rinvoq;
3. Prescribed by or in consultation with a dermatologist or allergist;
4. Age ≥ 12 years;
5. Failure of all of the following (a, b, and c), unless contraindicated or clinically significant adverse effects are experienced:
   a. Two formulary medium to very high potency topical corticosteroids, each 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*
   c. One systemic agent used for ≥ 3 months: azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine;
6. Rinvoq is not prescribed concurrently with another biologic medication (e.g., Adbry®, Dupixent®) or a 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.

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: Avsola, Humira, Amjevita, Cimzia, Cosentyx, Enbrel, Inflectra, Remicade, Renflexis, Rinvoq, Simponi, Simponi Aria, Taltz, Xeljanz, or Xeljanz XR;
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 18 years;

5. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for at ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
6. For nr-axSpA for 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:
   a. For Cimzia, Simponi, Simponi Aria, or Taltz: Failure of ALL of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (i, ii, iii, and iv):
      i. **Humira** or **Amjevita**;
      ii. **Enbrel;**
      iii. **Cosentyx;**
      iv. 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;
   b. For Amjevita requests, member must use 40 mg/0.8 mL prefilled SureClick® autoinjector with preferred formulary NDC (72511-0400-01 or 72511-0400-02, *see Appendix N*);
   c. For 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**;
   d. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis;**
   e. 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.

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 ≥ 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;
4. Member is human immunodeficiency virus (HIV)-negative and human herpesvirus 8 (HHV-8)-negative;
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 or to member's renewal date, whichever is longer

E. Crohn's Disease (must meet all)**:**
1. Diagnosis of CD;
2. Request is for one of the following: Avsola, Humira, Amjevita, Cimzia, Entyvio, Inflectra, Remicade, Renflexis, Skyrizi, Stelara, Tysabri;
3. Prescribed by or in consultation with a gastroenterologist;
4. Member meets one of the following (a or b):
   a. Failure of a ≥ 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*);
5. Member meets one of the following (a or b):
   a. For Avsola, Humira, Amjevita, Inflectra, Remicade, Renflexis: age ≥ 6 years;
   b. For Cimzia, Entyvio, Skyrizi, Stelara, Tysabri: age ≥ 18 years;
6. For Amjevita requests, member must use one of the following preferred formulary NDCs (a or b, *see Appendix N*):
   a. 40 mg/0.8 mL prefilled SureClick® autoinjector NDC 72511-0400-01 or 72511-0400-02;
   b. Pediatric only: 20 mg/0.4 mL prefilled syringe NDC 55513-0411-01;
7. For Cimzia, Entyvio, 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):
   a. **Humira** or **Amjevita;**
   b. **Skyrizi;**
   c. **Stelara**;
8. For Stelara: If request is through the pharmacy benefit for 45 mg/0.5 mL vial formulation, member must use **Stelara pre-filled syringe**;

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 and b):
    a. **Inflectra,** and **Renflexis**;
    b. If member has failed Inflectra and Renflexis, then member must use **Avsola**;
11. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis;**
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. Request meets one of the following (a or b):
    a. Dose does not exceed maximum dose indicated in Section V;
    b. For Stelara requests, if request is for a dose that exceeds 90 mg every 8 weeks, all of the following (i, ii, and iii):
        i. Documentation supports inadequate response to a ≥ 3 month trial of the maximum dose indicated in Section V;
        ii. Failure of BOTH of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (1 and 2):
            1) **Humira** or **Amjevita;**
            2) **Skyrizi;**
        iii. Dose does not exceed 90 mg every 4 or 6 weeks.

Approval duration: 6 months

F. Cytokine Release Syndrome (must meet all)**:**
1. Request is for an intravenous formulation of Actemra;
2. Age ≥ 2 years;
3. Member meets one of the following (a or b):
    a. Member has a scheduled CAR T cell therapy (e.g., Abecma®, Breyanzi®, Carvykti™, Kymriah™, Tecartus®, Yescarta™);
    b. Member has developed refractory CRS related to blinatumomab therapy;
4. 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 ≥ 4 years and < 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;
6. Member meets one of the following (a or b):
   a. Failure of a ≥ 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 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 ≥ 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;
   b. Weight ≥ 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;
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 18 years;
5. Failure of a trial of ≥ 3 consecutive months of a systemic corticosteroid at up to maximally tolerated doses in conjunction with MTX or azathioprine, unless clinically significant adverse effects are experienced or all are contraindicated;
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 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 ≥ 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 Humira;
3. Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist;
4. Age ≥ 12 years;
5. Documentation of Hurley stage II or stage III (*see Appendix D*);
6. 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:
   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);
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: 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 ≥ 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 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. 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: 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 Cimzia, Cosentyx, Enbrel, Humira, Amjevita, Ilumya, Siliq, Skyrizi, Sotyktu, Stelara, Taltz, or Tremfya: PsO is moderate-to-severe as evidenced by involvement of one of the following (i or ii):
      i. ≥ 3% of total body surface area;
      ii. Hands, feet, scalp, face, or genital area;
   b. Request is for Avsola, Inflectra, Remicade, or Renflexis: PsO is chronic-severe as evidenced by involvement of one of the following (i or ii):
      i. ≥ 10% of total body surface area;
      ii. Hands, feet, scalp, face, or genital area;
   c. Request is for Otezla;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Member meets one of the following (a, b, c, or d):
   a. For Avsola, Cimzia, Humira, Amjevita, Ilumya, Inflectra, Otezla, Remicade, Renflexis, Siliq, Skyrizi, Sotyktu, Tremfya: age ≥ 18 years;
   b. For Enbrel: age ≥ 4 years;
   c. For Stelara: age ≥ 6 years;
   d. For Cosentyx and Taltz: age ≥ 6 years;
4. For Amjevita requests, member must use 40 mg/0.8 mL prefilled SureClick® autoinjector with preferred formulary NDC (72511-0400-01 or 72511-0400-02, *see Appendix N*);
5. Member meets one of the following (a or b):
   a. Member has moderate-to-severe disease, and one of the following (i, ii, or iii):
      i. Failure of a ≥ 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 ≥ 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 Otelza;
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, failure of ALL of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated: **Humira** or **Amjevita**, **Skyrizi**, **Stelara, Tremfya, Cosentyx, Enbrel, Otezla**
7. For Cimzia, Siliq, Sotyktu, or Taltz and age ≥ 18 years: Failure of ALL of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated: **Humira** or **Amjevita, Skyrizi**, **Stelara, Tremfya, Cosentyx**;
8. For Stelara: If request is through the pharmacy benefit for 45mg/0.5mL vial formulation, member must use **Stelara pre-filled syringe**;
9. For 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**;
10. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis;**
11. Member meets one of the following (a or b):
a. For Otezla, if request is for concomitant use with biologic DMARD therapy (e.g., Humira, Enbrel, infliximab), member meets one of the following (i or ii):
i. Failure of a ≥ 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*);

12. Request meets one of the following (a or b):
a. Dose does not exceed maximum dose indicated in Section V;
b. For Stelara requests, if request is for a dose that exceeds 90 mg every 12 weeks, all of the following (i, ii, and iii):
i. Documentation supports inadequate response to a ≥ 3 month trial of the maximum dose indicated in Section V;

ii. Failure of ALL of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced (1 or 2):
    1) Adult: **Humira** or **Amjevita, Skyrizi**, **Tremfya, Cosentyx**;
    2) Pediatric: **Cosentyx**;
iii. Dose does not exceed 90 mg every 8 weeks.

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: Actemra, Enbrel, Humira, Amjevita, Orencia, Simponi Aria, or Xeljanz (immediate-release tablets or oral solution);
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 2 years;
5. For Amjevita requests, member must use one of the following preferred formulary NDCs (a or b, *see Appendix N*):
    a. 40 mg/0.8 mL prefilled SureClick® autoinjector NDC 72511-0400-01 or 72511-0400-02;
    b. 20 mg/0.4 mL prefilled syringe NDC 55513-0411-01;
6. Documented baseline 10-joint clinical juvenile arthritis disease activity score (cJADAS-10) (*see Appendix K*);
7. Member meets one of the following (a, b, c, or d):
    a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;
    b. 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 sacroiliitis/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. Documented presence of high disease activity as evidenced by a cJADAS-10 > 8.5 (*see Appendix K*);
8. For Actemra, Orencia, or Simponi Aria: 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):
    a. **Enbrel;**
    b. **Humira** or **Amjevita;**
    c. If member has not responded or is intolerant to one or more TNF blockers, **Xeljanz**, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
9. For 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*

10. 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. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

P. Psoriatic Arthritis (must meet all)**:**

1. Diagnosis of PsA;
2. Request is for one of the following: Avsola, Cimzia, Cosentyx, Enbrel, Humira, Amjevita, Inflectra, Orencia, Otezla, Remicade, Renflexis, Rinvoq, Simponi, Simponi Aria, Skyrizi, Stelara, Taltz, Tremfya, Xeljanz, or Xeljanz XR;
3. Prescribed by or in consultation with a dermatologist or rheumatologist;
4. Member meets one of the following (a or b):
   a. For Cosentyx, Simponi Aria: Age ≥ 2 years;
   b. For Stelara: Age ≥ 6 years;
   c. For Avsola, Humira, Amjevita, Cimzia, Enbrel, Inflectra, Orencia, Otezla, Remicade, Renflexis, Rinvoq, Simponi, Skyrizi, Taltz, Tremfya, Xeljanz, and Xeljanz XR: Age ≥ 18 years;
5. For Amjevita requests, member must use 40 mg/0.8 mL prefilled SureClick® autoinjector with preferred formulary NDC (72511-0400-01 or 72511-0400-02, *see Appendix N*);
6. For Cimzia, Orencia, Simponi, Simponi Aria, or Taltz: Failure of a trial of ALL of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
   a. **Humira** or **Amjevita, Enbrel**, **Otezla**, **Cosentyx, Skyrizi, Stelara, Tremfya;**
   b. If member has not responded or is intolerant to one or more TNF blockers, **Xeljanz/Xeljanz XR or Rinvoq**, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
7. For Stelara: If request is through the pharmacy benefit for 45 mg/0.5 mL vial formulation, member must use **Stelara pre-filled syringe**;
8. For 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**;
9. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis;**
10. For Rinvoq, Xeljanz, Xeljanz XR: Member has not responded or is intolerant to one or more TNF blockers;
    **Prior authorization may be required for TNF blockers*
11. Member meets one of the following (a or b):
    a. For Otezla, if request is for concomitant use with biologic DMARD therapy (e.g., Humira, Enbrel, infliximab), member meets one of the following (i or ii):
       i. Failure of a ≥ 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 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*);

12. Request meets one of the following (a or b):
    a. Dose does not exceed maximum dose indicated in Section V;
    b. For Stelara requests, if request is for a dose that exceeds 45 mg every 12 weeks, all of the following (i, ii, and iii):
        i. Documentation supports inadequate response to a ≥ 3 month trial of the maximum dose indicated in Section V;
        ii. Failure of ALL of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced (1 or 2):
            1) Adult (a and b):
                a) **Humira** or **Amjevita, Enbrel**, **Otezla**, **Cosentyx**, **Skyrizi**, **Tremfya**;
                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;
            2) Pediatric: **Cosentyx**;
        iii. Dose does not exceed 90 mg every 12 weeks.

Approval duration: 6 months

Q. Rheumatoid Arthritis (must meet all)**:**

1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (*see Appendix H*);
2. Request is for one of the following: Actemra, Avsola, Cimzia, Enbrel, Humira, Amjevita, Inflectra, Kevzara, Kineret, Olumiant, Orencia, Remicade, Renflexis, Rinvoq, Simponi, Simponi Aria, Xeljanz, Xeljanz XR;
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 18 years;
5. For Amjevita requests, member must use 40 mg/0.8 mL prefilled SureClick® autoinjector with preferred formulary NDC (72511-0400-01 or 72511-0400-02, *see Appendix N*);
6. Member meets one of the following (a or b):
    a. Failure of a ≥ 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: Failure of a trial of TWO of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a - c):
   a. **Humira** or **Amjevita;**
   b. **Enbrel;**
   c. If member has not responded or is intolerant to one or more TNF blockers, **Xeljanz/Xeljanz XR** or **Rinvoq**, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
8. For Cimzia, Kineret, Olumiant, Orencia, Actemra, Simponi, or Simponi Aria: Failure of a trial 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):
   a. **Humira** or **Amjevita;**
   b. **Enbrel;**
   c. 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 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**;
10. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis;**
11. 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*
12. 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)*;
13. 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*);
14. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

R. Systemic Juvenile Idiopathic Arthritis (must meet all)**:**
1. Diagnosis of SJIA;
2. Request is for Actemra;
3. Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist;
4. Age ≥ 2 years;
5. Member meets one of the following (a or b):
   a. Failure of a trial of ≥ 3 consecutive months of MTX or leflunomide at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;

b. Failure of a ≥ 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

S. 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 month trial of cyclophosphamide or mycophenolate mofetil, at up to maximally indicated doses, unless both are contraindicated or clinically significant adverse effects are experienced;
6. Baseline forced vital capacity (FVC) ≥ 40% of predicted;
7. Baseline carbon monoxide diffusing capacity (DLCO) ≥ 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

T. Ulcerative Colitis (must meet all)**:**

1. Diagnosis of UC;
2. Request is for one of the following: Avsola, Entyvio, Humira, Amjevita, Inflectra, Remicade, Renflexis, Rinvoq, Simponi, Stelara, Xeljanz, Xeljanz XR, Zeposia;
3. Prescribed by or in consultation with a gastroenterologist;
4. Documentation of a Mayo Score ≥ 6 (*see Appendix F*);
5. Member meets one of the following (a, b, or c):
   a. For Amjevita, Entyvio, Rinvoq, Simponi, Stelara, Xeljanz, Xeljanz XR, Zeposia: age ≥ 18 years;
   b. For Avsola, Inflectra, Remicade, Renflexis: age ≥ 6 years;
   c. For Humira: age ≥ 5 years;
6. For Amjevita requests, member must use 40 mg/0.8 mL prefilled SureClick® autoinjector with preferred formulary NDC (72511-0400-01 or 72511-0400-02, *see Appendix N*);
7. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;

8. For Entyvio, Simponi, Zeposia: 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):
   a. **Humira** or **Amjevita;**
   b. **Stelara;**
   c. 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 Stelara: If request is through the pharmacy benefit for 45mg/0.5mL vial formulation, member must use **Stelara pre-filled syringe**;
10. For 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**;
11. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Inflectra** and **Renflexis;**
12. 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*
13. 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*);
14. Request meets one of the following (a or b):
    a. Dose does not exceed maximum dose indicated in Section V;
    b. For Stelara requests, if request is for a dose that exceeds 90 mg every 8 weeks, all of the following (i, ii, and iii):
       i. Documentation supports inadequate response to a ≥ 3 month trial of the maximum dose indicated in Section V;
       ii. Failure of BOTH of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced (1 and 2):
           1) **Humira** or **Amjevita**;
           2) If member has not responded or is intolerant to one or more TNF blockers, **Xeljanz/Xeljanz XR**, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
       iii. Dose does not exceed 90 mg every 4 or 6 weeks.

Approval duration: 6 months

U. Uveitis (must meet all)**:**
1. Diagnosis of non-infectious intermediate, posterior, or panuveitis;
2. Request is for Humira;
3. Age ≥ 2 years;
4. Prescribed by or in consultation with an ophthalmologist or rheumatologist;
5. 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;

6. 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;
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: 6 months

V. Coronavirus-19 Infection:

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

Approval duration: Not applicable

W. Multiple Sclerosis:

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

X. 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

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

1. If request is for Remicade or Avsola, member meets one of the following (a or b):
   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 and ii):
      i. **Inflectra** and **Renflexis;**
      ii. If member has failed Inflectra and Renflexis, then member must use **Avsola**;
   b. 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 1 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 Actemra (authorized for emergency use only), Kineret (authorized for emergency use only), 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 Tysabri or Zeposia requests, refer to 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);*
   c. Documentation supports that member is currently receiving IV Actemra 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 pJIA: Member is responding positively to therapy as evidenced by a decrease in cJADAS-10 from baseline (*see Appendix K*);

d. For AD: Member is responding positively to therapy as evidenced by, including but not limited to, reduction in itching and scratching;
e. For all other indications: Member is responding positively to therapy;

3. For Amjevita requests, member must use one of the following preferred formulary NDCs (a or b, *see Appendix N*):
   a. 40 mg/0.8 mL prefilled SureClick® autoinjector NDC 72511-0400-01 or 72511-0400-02;
   b. Pediatric only: 20 mg/0.4 mL prefilled syringe NDC 55513-0411-01;
4. For Stelara: If request is through the pharmacy benefit for 45 mg/0.5 mL vial formulation, member must use **Stelara pre-filled syringe**;
5. For Skyrizi: If request is for Crohn's Disease, quantity does not exceed 1 pre-filled cartridge every 8 weeks;
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 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. Member meets one of the following (a or b):
   a. For Otezla, if request is for concomitant use with biologic DMARD therapy (e.g., Humira, Enbrel, infliximab) for PsA or PsO, member meets one of the following (i or ii):
      i. Failure of a ≥ 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 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*);
9. Member meets one of the following (a or b):
   a. If request is for a dose increase, new dose does not exceed maximum dose indicated in Section V;
   b. For Stelara requests, if request is for a dose increase and new maintenance dose exceeds the maximum dose and frequency indicated in Section V, all of the following (i, ii, and iii):
      i. Documentation supports inadequate response to a ≥ 3 month trial of the maximum dose indicated in Section V;
      ii. One of the following (1, 2, 3, or 4):
         1) For CD: Failure of a trial of ≥ 3 consecutive months of BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated (a and b):
            a) **Humira** or **Amjevita;**

b) **Skyrizi;**

2) For UC: Failure of BOTH of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or both are contraindicated (a and b):
   a) **Humira** or **Amjevita;**
   b) If member has not responded or is intolerant to one or more TNF blockers, **Xeljanz/Xeljanz XR,** unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
3) For PsA: Failure of ALL of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a or b):
   a) Adult (both i and ii):
      i) **Humira** or **Amjevita, Enbrel**, **Cosentyx**, **Otezla**, **Skyrizi**, **Tremfya;**
      ii) 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;
   b) Pediatric: **Cosentyx***;*
4) For PsO: Failure of ALL of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a or b):
   a) Adult: **Humira** or **Amjevita, Skyrizi, Tremfya**, **Cosentyx;**
   b) Pediatric: **Cosentyx;**

iii. Dose does not exceed one of the following (1, 2, or 3):
1) CD, UC: 90 mg every 4 or 6 weeks;
2) PsO: 90 mg every 8 weeks;
3) PsA: 90 mg every 12 weeks.

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 or Avsola, member meets one of the following (a or b):
   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 and ii):
      i. **Inflectra** and **Renflexis;**
      ii. If member has failed Inflectra and Renflexis, then member must use **Avsola**;
   b. 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 1 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 of 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, Simponi®, Avsola™, Inflectra™, Remicade®, Renflexis™], interleukin agents [e.g., Arcalyst® (IL-1 blocker), Ilaris® (IL-1 blocker), Kineret® (IL-1RA), Actemra® (IL-6RA), Kevzara® (IL-6RA), Stelara® (IL-12/23 inhibitor), Cosentyx® (IL-17A inhibitor), Taltz® (IL-17A inhibitor), Siliq™ (IL-17RA), Ilumya™ (IL-23 inhibitor), Skyrizi™ (IL-23 inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Xeljanz®/Xeljanz® XR, Cibinqo™, Olumiant™, Rinvoq™], anti-CD20 monoclonal antibodies [Rituxan®, Riabni™, Ruxience™, Truxima®, Rituxan Hycela®], selective co-stimulation modulators [Orencia®], and integrin receptor antagonists [Entyvio®] 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

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
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
FVC: forced vital capacity
GCA: giant cell arteritis
HS: hidradenitis suppurativa,
JAK: Janus kinase
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
PsO: plaque psoriasis
PsA: psoriatic arthritis
RA: rheumatoid arthritis
RAPID3: routine assessment of patient index data 3
SJIA: systemic juvenile idiopathic arthritis
SSc-ILD: systemic sclerosis-associated interstitial lung disease
TNF: tumor necrosis factor
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 (Soriatane®)	**PsO** 25 or 50 mg PO QD	50 mg/day
azathioprine (Azasan®, Imuran®)	**RA** 1 mg/kg/day PO QD or divided BID **CD*, GCA*, UV*** 1.5 – 2 mg/kg/day PO **AD** 1-3 mg/kg/day PO QD	3 mg/kg/day
chlorambucil (Leukeran®)	**UV*** 0.2 mg/kg PO QD, then taper to 0.1 mg/kg PO QD or less	0.2 mg/kg/day
clindamycin (Cleocin®) + rifampin (Rifadin®)	**HS*** clindamycin 300 mg PO BID and rifampin 300 mg PO BID	clindamycin: 1,800 mg/day rifampin: 600 mg/day
corticosteroids Oral: e.g., prednisone, budesonide Medium to very high potency topical:	**CD*** • prednisone 40 mg PO QD for 2 weeks or IV 50 – 100 mg Q6H for 1 week • budesonide (Entocort EC®) 6 – 9 mg PO QD **AD, GCA*** Various **SJIA***	Various

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
e.g., desoximetasone 0.05%, fluocinolone acetonide 0.025%, mometasone 0.1% cream, triamcinolone acetonide 0.1%, augmented betamethasone dipropionate 0.05%, clobetasol propionate 0.05% cream, ointment, gel, or solution, halobetasol propionate 0.05% cream, ointment	< 0.5 mg/kg/day PO of prednisone or equivalent **UC** budesonide (Uceris®) 9 mg PO QD **UV*** prednisone 5 – 60 mg/day PO in 1 – 4 divided doses **PsO** Applied topically to the affected area(s) BID **BD*** • triamcinolone acetonide cream (Orabase® 0.1%): apply topically to the isolated oral ulcer 3 to 4 times daily as needed for pain. • prednisone Initial dose: Week 1: 15 mg PO daily Week 2 onwards: 10 mg PO daily tapered over 2-3 weeks Maintenance dose (if recurrent): 5 mg PO daily	
Cuprimine® (d-penicillamine)	**RA*** Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 – 750 mg/day PO QD	1,500 mg/day
cyclophosphamide (Cytoxan®)	**UV*** 1 – 2 mg/kg/day PO **SSc-ILD*** • PO: 1 – 2 mg/kg/day • IV: 600 mg/m^2/month	PO: 2 mg/kg/day IV: 600 mg/m^2/month
cyclosporine (Sandimmune®, Neoral®)	**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 **AD** 3-6 mg/kg/day PO BID	PsO, RA: 4 mg/kg/day UV: 5 mg/kg/day AD: 300 mg/day
doxycycline (Acticlate®)	**HS*** 50 – 100 mg PO BID	300 mg/day
Hormonal agents	**HS**	varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
(e.g., estrogen-containing combined oral contraceptives, spironolactone)	varies	
hydroxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 – 600 mg/day PO QD Maintenance dose: 200 – 400 mg/day PO QD	600 mg/day
Isotretinoin (Absorica®, Amnesteem®, Claravis®, Myorisan®, Zenatane®)	**HS** varies	varies 1.6 to 2 mg/kg/day
leflunomide (Arava®)	**PJIA*** • Weight < 20 kg: 10 mg every other day • Weight 20 - 40 kg: 10 mg/day • Weight > 40 kg: 20 mg/day **RA** 100 mg PO QD for 3 days, then 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 Weight > 40 kg: 20 mg/day	ERA, PJIA, RA: 20 mg/day SJIA: 10 mg every other day
6-mercaptopurine (Purixan®)	**CD*** 50 mg PO QD or 1 – 2 mg/kg/day PO	2 mg/kg/day
methotrexate (Rheumatrex®)	**AD** 7.5-25 mg/wk PO once weekly **CD*** 15 – 25 mg/week IM or SC **GCA*** 20 – 25 mg/week PO **PsO** 10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week **PJIA*** 10 – 20 mg/m^2/week PO, SC, or IM	30 mg/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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 **UV*** 7.5 – 20 mg/week PO	
minocycline (Minocin®)	**HS*** 50 – 100 mg PO BID	200 mg/day
mycophenolate mofetil (Cellcept®)	**AD** 1-1.5 g PO BID **UV*** 500 – 1,000 mg PO BID **SSc-ILD*** PO: 1 – 3 g/day	3 g/day
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS, nr-axSpA, ERA, PJIA*** Varies	Varies
Pentasa® (mesalamine)	**CD** 1,000 mg PO QID	4 g/day
Ridaura® (auranofin)	**RA** 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine®)	**PJIA*** 30-50 mg/kg/day PO divided BID **RA, ERA** 2 g/day PO in divided doses	PJIA: 2 g/day RA. ERA: 3 g/day UC: 4 g/day
tacrolimus (Prograf®)	**CD*** 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	N/A
Biologics DMARDs (e.g., Humira, Enbrel, Cosentyx, Remicade, Simponi Aria, Otezla, Xeljanz/Xeljanz XR, Kevzara)	See Section V. Dosing and Administration	See Section V. Dosing and Administration
colchicine (Colcrys®)	**BD*** 1.2 to 1.8 mg PO daily	1.8 mg/day
tacrolimus	**AD**	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
(Protopic®), pimecrolimus (Elidel®)	Children ≥ 2 years and adults: Apply a thin layer topically to affected skin BID. Treatment should be discontinued if resolution of disease occurs.	
Eucrisa® (crisaborole)	**AD** Apply to the affected areas BID	Varies
Immune globulin (e.g., Gammagard®)	**Kawasaki disease** Varies based on formulation	Varies based on 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	Known hypersensitivity to Actemra	Risk of serious infections
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. • 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, Amjevita	None reported	• Serious infections • Malignancies
Ilumya	Serious hypersensitivity reaction to tildrakizumab or to any of the excipients	None reported
Avsola, Inflectra,	• Doses > 5 mg/kg in patients with moderate-to-severe heart failure	• Serious infections • Malignancy

Drug Name	Contraindication(s)	Boxed Warning(s)
Remicade, Renflexis	• Re-administration to patients who have experienced a severe hypersensitivity reaction to infliximab products • Known hypersensitivity to inactive components of the product or to any murine proteins	
Kevzara	Known hypersensitivity to sarilumab or any of the inactive ingredients	Risk of serious infections
Kineret	Known hypersensitivity to *E. coli*-derived proteins, Kineret, or any components of the product	None reported
Olumiant	None reported	• Serious infections • Malignancies • Thrombosis
Orencia	None reported	None reported
Otezla	Known hypersensitivity to apremilast or to any of the excipients in the formulation	None reported
Rinvoq	None reported	• Serious infections • Malignancies • Thrombosis
Siliq	Patients with Crohn's disease	Suicidal ideation and behavior
Simponi, Simponi Aria	None reported	• Serious infections • Malignancies
Skyrizi	History of serious hypersensitivity reaction to risankizumab-rzaa or any of the excipients	None reported
Stelara	Clinically significant hypersensitivity to ustekinumab or any of its excipients	None reported
Taltz	Previous serious hypersensitivity reaction, such as anaphylaxis, to ixekizumab or to any of the excipients	None reported
Tremfya	None reported	None reported
Tysabri	• Patients who have or have had progressive multifocal leukoencephalopathy • Patients who have had a hypersensitivity reaction to Tysabri	• Progressive multifocal leukoencephalopathy

Drug Name	Contraindication(s)	Boxed Warning(s)
Xeljanz/ Xeljanz XR	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. • Lymphoma and other malignancies have been observed. • Epstein Barr Virus-associated post-transplant lymphoproliferative disorder has been observed. • Rheumatoid arthritis patients with at least one cardiovascular risk factor had a higher rate of all-cause mortality and thrombosis with Xeljanz 10 mg twice daily vs. 5 mg twice daily or TNF blockers.
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
  - 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:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in ESR/CRP levels
  - Improvements in activities of daily living
- Ulcerative Colitis:
  - For Ulcerative Colitis maintenance therapy, failure is defined as having two or more exacerbations requiring steroid therapy.
- Stelara:
  - In the PHOENIX 2 trial, dosing intensification of Stelara to every 8 weeks did not result in greater efficacy compared with continuing treatment every 12 weeks.
  - The approval of Stelara in pediatric PsA is supported by pharmacokinetic data and extrapolation of the efficacy and existing safety profile of Stelara in Phase 3 studies in adult and pediatric patients with moderate to severe PsO (PSTELLAR, CADMUS, and CADMUS Jr trials) and adult patients with active PsA (PSUMMIT-1 and -2 trials).
  - Stelara joins two other biologics approved for use in pediatric PsA: Novartis' Cosentyx (secukinumab) an Janssen's Simponi Aria (golimumab), both of which are indicated to treat patients 2 years of age and older with PsA.
- 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:
  - HS is sometimes referred to as: "acne inversa, acne conglobata, apocrine acne, apocrinitis, Fox-den disease, hidradenitis axillaris, HS, pyodermia sinifica fistulans, Velpeau's disease, and Verneuil's disease."
  - In HS, Hurley stages are used to determine severity of disease. Hurley stage II indicates moderate disease, and is characterized by recurrent abscesses, with sinus tracts and scarring, presenting as single or multiple widely separated lesions. Hurley stage III indicates severe disease, and is characterized by diffuse or near-diffuse involvement presenting as multiple interconnected tracts and abscesses across an entire area.
  - Enbrel has off-label use supported by some efficacy data in severe, refractory HS through retrospective cohort studies and case reports. This off-label indication for Enbrel is recommended by Micromedex with a Class IIa recommendation.
- 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.
  - 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.

- Cimzia:
  - According to the CRADLE, a prospective, postmarketing, multicenter, pharmacokinetic study (n = 17), there were no or minimal certolizumab pegol transfer from the maternal plasma to breast milk, with a relative infant dose of 0.15% of the maternal dose.
- Nr-axSpA: guideline recommendations are largely extrapolated from evidence in AS.
- 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.
- Otezla:
  - PsA:
    - According to the 2018 American College of Rheumatology and National Psoriasis Foundation guidelines, TNF inhibitors or oral small molecules (e.g., methotrexate, sulfasalazine, cyclosporine, leflunomide, apremilast) are preferred over other biologics (e.g., interleukin-17 inhibitors or interleukin-12/23 inhibitors) for treatment-naïve disease. TNF inhibitors are also generally recommended over oral small molecules as first-line therapy unless disease is not severe, member prefers oral agents, or TNF inhibitor therapy is contraindicated. In patients with inadequate response to oral small molecules, the guidelines recommend adding Otezla to the current oral small molecule therapy or switching to a biologic therapy. In patients with inadequate response to biologic monotherapy, the guidelines recommend switching to a different biologic agent over addition of MTX to the current biologic agent; there are no recommendations that address adding or switching to Otezla.
    - The 2019 European League Against Rheumatism guidelines recommend Otezla only in patients with mild disease who have inadequate response to a conventional DMARD and in whom neither biologic DMARDs nor targeted synthetic DMARDs (e.g., Janus kinase inhibitors) are appropriate.
  - PsO: The 2019 American Academy of Dermatology and National Psoriasis Foundation guidelines recommend the combination of a biologic therapy with MTX over combination of a biologic therapy with Otezla, noting that there are limited data and the long-term safety and efficacy of the latter combination is unknown.

- 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.

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
  - 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

- 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

- The following may be considered for medical justification supporting inability to use an immunomodulator for ulcerative colitis:
  - Documentation of Mayo Score 6 – 12 indicative of moderate to severe ulcerative colitis.

Appendix G: Dose Rounding Guidelines for Weight-Based Doses

Actemra 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 and Pediatric PsO

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
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
≤ 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

Weight-based Dose Range	Vial Quantity Recommendation
≤ 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 for PsO

Weight-based Dose Range	Quantity Recommendation
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.

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

B	**Serology (at least one test result is needed for classification)**	
	Negative rheumatoid factor (RF) *and* negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF *or* low positive ACPA * *Low: < 3 x upper limit of normal*	2
	High positive RF *or* high positive ACPA * *High: ≥ 3 x upper limit of normal*	3
C	**Acute phase reactants (at least one test result is needed for classification)**	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or abnormal ESR	1
D	**Duration of symptoms**	
	< 6 weeks	0
	≥ 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
≤ 2.8	Remission
> 2.8 to ≤ 10	Low disease activity
> 10 to ≤ 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: Clinical Juvenile Arthritis Disease Activity Score based on 10 joints (cJADAS-10)
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 (FDA Emergency Use Authorization):
- 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).
- Actemra:
  - The EUA was granted, given that there is no adequate, approved and available alternative to Actemra for treatment of adults and pediatric patients (2 years of age and older) hospitalized with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or

ECMO. For information on clinical studies of ACTEMRA and other therapies for the treatment of COVID-19.
    - Actemra is authorized under an EUA as a single 60-minute intravenous infusion, with an optional additional dose if clinical signs or symptoms worsen or do not improve after the first dose.
- Kineret
    - 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]).
    - Available alternatives for the EUA authorized use:
        - Veklury (remdesivir), a SARS-CoV-2 nucleotide analog RNA polymerase inhibitor, is an FDA-approved alternative for the treatment of COVID-19 in hospitalized adults with pneumonia requiring supplemental oxygen (low or high-flow oxygen) who are at risk of progressing to severe respiratory failure.
        - Olumiant (baricitinib), a Janus kinase (JAK) inhibitor, is an FDA-approved alternative for the treatment of COVID-19 in hospitalized adults with pneumonia requiring supplemental oxygen and non-invasive ventilation.
    - Kineret is authorized under an EUA as a 100 mg subcutaneous injection administered daily for 10 days.

Appendix N: Amjevita preferred formulary NDCs

Description	Pack Quantity	NDC
20 mg/0.4 mL prefilled syringe with a fixed 29-gauge needle (used for pediatric indications)	1	55513-0411-01
40 mg/0.8 mL prefilled SureClick® autoinjector	1	72511-0400-01
40 mg/0.8 mL prefilled SureClick® autoinjector	2	72511-0400-02

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Abatacept (Orencia)* **Also see Appendix G: Dose Rounding Guidelines for Weight-Based Doses*	RA PsA	• 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)	IV: 1,000 mg every 4 weeks SC: 125 mg/week

Drug Name	Indication	Dosing Regimen	Maximum Dose
	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 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	1,000 mg/dose
Adalimumab (Humira, Amjevita)	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
	PJIA	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
	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:* Weight 17 kg (37 lbs) to < 40 kg (88 lbs): 80 mg SC on Day 1, then 40 mg SC on Day 15 Weight ≥ 40 kg (88 lbs): 160 mg SC on Day 1, then 80 mg SC on Day 15	40 mg every other week

Drug Name	Indication	Dosing Regimen	Maximum Dose
		Maintenance dose: *Adults:* 40 mg SC every other week starting on Day 29 *Pediatrics:* Weight 17 kg (37 lbs) to < 40 kg (88 lbs): 20 mg SC every other week starting on Day 29 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 Maintenance dose: *Adults:* 40 mg SC every other week starting on Day 29	*Adults:* 40 mg every other week
	PsO	Initial dose: 80 mg SC Maintenance dose: 40 mg SC every other week starting one week after initial dose	40 mg every other week
Adalimumab (Humira)	Pediatric UC	Initial dose: *Pediatrics:* **Weight** / **Days 1 through 15** 20 kg to less than 40 kg: Day 1: 80 mg; Day 8: 40 mg; Day 15: 40 mg 40 kg and greater: Day 1: 160 mg (single dose or split over two consecutive days; Day 8: 80 mg; Day 15: 80 mg *Pediatrics:* **Weight** / **Starting on Day 29*** 20 kg to less than 40 kg: 40 mg every other week or 20 mg every week 40 kg and greater: 80 mg every other week or 40 mg every week **Continue the recommended pediatric dosage in patients who turn 18 years of age and who are well-controlled on Humira regimen.*	*Pediatrics:* 80 mg every other week or 40 mg every week

Drug Name	Indication	Dosing Regimen	Maximum Dose
	UV	*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 *Adults:* Initial dose of 80 mg SC, followed by 40 mg SC every other week starting one week after the initial dose	40 mg every other week
	HS	*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 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 once weekly starting on Day 29	40 mg/week
Anakinra (Kineret)* **Also see Appendix G: Dose Rounding Guidelines for Weight-Based Doses*	RA	100 mg SC QD	100 mg/day
	NOMID	Initial dose: 1 – 2 mg/kg SC QD or divided BID Maintenance dose: 8 mg/kg SC QD or divided BID	8 mg/kg/day
	DIRA	Initial dose: 1 – 2 mg/kg SC QD Maintenance dose: Adjust doses in 0.5 to 1 mg/kg increments.	8 mg/kg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
Apremilast (Otezla)	PsO PsA BD	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	60 mg/day
Baricitinib (Olumiant)	RA	2 mg PO QD	2 mg/day
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
Deucravacitinib (Sotyktu)	PsO	6 mg PO daily	6 mg/day
Etanercept (Enbrel)* **Also see Appendix G: Dose Rounding Guidelines for Weight-Based Doses*	RA PsA	25 mg SC twice weekly or 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	50 mg/week

Drug Name	Indication	Dosing Regimen	Maximum Dose
		Pediatrics: Weight < 63 kg: 0.8 mg/kg SC once weekly Weight ≥ 63 kg: 50 mg SC once weekly	
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
Golimumab (Simponi Aria)* **Also see Appendix G: Dose Rounding Guidelines for Weight-Based Doses*	AS PsA RA	Initial dose: 2 mg/kg IV at weeks 0 and 4 Maintenance dose: 2 mg/kg IV every 8 weeks	2 mg/kg every 8 weeks
	pJIA PsA (pediatric)	Initial dose: 80 mg/m^2 at weeks 0 and 4 Maintenance dose: 80 mg/m^2 IV every 8 weeks	80 mg/m^2 IV every 8 weeks
Guselkumab (Tremfya)	PsA PsO	Initial dose: 100 mg SC at weeks 0 and 4 Maintenance dose: 100 mg SC every 8 weeks	100 mg every 8 weeks
Infliximab (Avsola, Inflectra, Remicade, Renflexis)* **Also see Appendix G: Dose Rounding Guidelines for Weight-Based Doses*	CD, UC	Initial dose: *Adults/Pediatrics:* 5 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: *Adults/Pediatrics:* 5 mg/kg IV every 8 weeks. For CD: Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response	CD, Adults: 10 mg/kg every 8 weeks UC, Adults: 5 mg/kg every 8 weeks Pediatrics: 5 mg/kg 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	10 mg/kg every 4 weeks

Drug Name	Indication	Dosing Regimen	Maximum Dose
		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	
	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 5 mg/kg given over 2 hours	5 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 between ages of 6 and 18 years: **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 / 80 mg / 40 mg < 25 kg / 40 mg / 20 mg	80 mg every 4 weeks
	PsA, AS	Initial dose: 160 mg (two 80 mg injections) SC at week 0 Maintenance dose: 80 mg SC every 4 weeks	80 mg every 4 weeks
	nr-axSpA	80 mg SC every 4 weeks	80 mg every 4 weeks
Natalizumab (Tysabri)	MS, CD	300 mg IV every 4 weeks	300 mg/4 weeks
Ozanimod (Zeposia)	MS, UC	Days 1-4: 0.23 mg PO QD Days 5-7: 0.46 mg PO QD	0.92 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		Day 8 and thereafter: 0.92 mg PO QD	
Risankizumab-rzaa (Skyrizi)	PsO, PsA	150 mg SC at weeks 0, 4, and every 12 weeks thereafter	150 mg/12 weeks
	CD	Induction: 600 mg IV at Week 0, Week 4 and Week 8 Maintenance: 180 mg or 360 mg SC at Week 12 and every 8 weeks thereafter	IV: 600 mg/dose SC: 360 mg every 8 weeks
Sarilumab (Kevzara)	RA	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) 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 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	Adults: 300 mg every 4 weeks Pediatric patients: 150 mg every 4 weeks
	PsA	Adult: With loading dose: 150 mg SC at week 0, 1, 2, 3, and 4, followed by 150 mg SC every 4 weeks Without loading dose: 150 mg SC every 4 weeks If a patient continues to have active psoriatic arthritis, consider a dosage of 300 mg. 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.	Adults: 300 mg every 4 weeks Pediatric patients: 150 mg every 4 weeks

Drug Name	Indication	Dosing Regimen	Maximum Dose
	AS, nr-axSpA	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: if a patient continues to have active ankylosing spondylitis, consider a dosage of 300 mg SC every 4 weeks.	AS: 300 mg every 4 weeks nr-axSpA: 150 mg every 4 weeks
	ERA	• 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
Tildrakizumab-asmn (Ilumya)	PsO	Initial dose: 100 mg SC at weeks 0 and 4 Maintenance dose: 100 mg SC every 12 weeks Ilumya should only be administered by a healthcare professional.	100 mg every 12 weeks
Tocilizumab (Actemra)* **Also see Appendix G: Dose Rounding Guidelines for Weight-Based Doses*	RA	IV: 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response SC: 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	IV: 800 mg every 4 weeks SC: 162 mg every week
	GCA	IV: 6 mg/kg every 4 weeks in combination with a tapering course of glucocorticoids SC: 162 mg SC every week (every other week may be given based on clinical considerations)	IV: 6 mg/kg every 4 weeks SC: 162 mg every week
	PJIA	Weight < 30 kg: 10 mg/kg IV every 4 weeks or 162 mg SC every 3 weeks Weight ≥ 30 kg: 8 mg/kg IV every 4 weeks or 162 mg SC every 2 weeks	IV: 10 mg/kg every 4 weeks

Drug Name	Indication	Dosing Regimen	Maximum Dose
			SC: 162 mg every 2 weeks
	SJIA	IV: Weight < 30 kg: 12 mg/kg IV every 2 weeks Weight ≥ 30 kg: 8 mg/kg IV every 2 weeks SC: Weight < 30 kg: 162 mg SC every 2 weeks Weight ≥ 30 kg: 162 mg SC every week	IV: 12 mg/kg every 2 weeks SC: 162 mg every week
	CRS	Weight < 30 kg: 12 mg/kg IV per infusion Weight ≥ 30 kg: 8 mg/kg IV per infusion If no clinical improvement in the signs and symptoms of CRS occurs after the first dose, up to 3 additional doses of Actemra may be administered. The interval between consecutive doses should be at least 8 hours.	IV: 800 mg/infusion, up to 4 doses
	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	15 mg PO QD	RA, PsA, AS, nr-axSpA:

Drug Name	Indication	Dosing Regimen	Maximum Dose
	RA PsA AD	For AD only, if member's age < 65 years: if an adequate response is not achieved, consider increasing the dosage to 30 mg PO QD	15 mg/day AD: 30 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
Ustekinumab (Stelara)* **Also see Appendix G: Dose Rounding Guidelines for Weight-Based Doses*	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):* Weight < 60 kg: 0.75 mg/kg Weight 60 to 100 kg: 45 mg Weight > 100kg: 90 mg	90 mg every 12 weeks
	PsA	*Adult:* 45 mg SC at weeks 0 and 4, followed by 45 mg every 12 weeks *Pediatric (age 6 years to 17 years):* Weight based dosing SC at weeks 0 and 4, then every 12 weeks thereafter. Weight < 60 kg: 0.75 mg/kg Weight ≥ 60 kg: 45 mg	45 mg every 12 weeks
	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, followed by 90 mg SC every 8 weeks Weight ≤ 55 kg: 260 mg Weight > 55 kg to 85 kg: 390 mg Weight > 85 kg: 520 mg	90 mg every 8 weeks
Vedolizumab (Entyvio)	CD UC	Initial dose: 300 mg IV at weeks 0, 2, and 6 Maintenance dose: 300 mg IV every 8 weeks	300 mg every 8 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-atto (Amjevita)	**Single-dose prefilled SureClick autoinjector:** 40 mg/0.8 mL **Single-dose prefilled syringe:** 40 mg/0.8 mL, 20 mg/0.4 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
Brodalumab (Siliq)	**Single-dose prefilled syringe:** 210 mg/1.5 mL
Certolizumab pegol (Cimzia)	**Lyophilized powder in a single-use vial for reconstitution**: 200 mg **Single-use prefilled syringe**: 200 mg/mL
Deucravacitinib (Sotyktu)	**Tablet:** 6 mg
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™ single-dose prefilled cartridge for use with AutoTouch™ reusable autoinjector**: 50 mg/mL
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 Aria)	**Single-use vial:** 50 mg/4 mL
Infliximab-axxq (Avsola)	**Single-use vial**: 100 mg/20 mL
Infliximab-dyyb (Inflectra)	**Single-use vial**: 100 mg/20 mL
Infliximab (Remicade)	**Single-use vial**: 100 mg/20 mL
Infliximab-abda (Renflexis)	**Single-use vial:** 100 mg/20 mL
Ixekizumab (Taltz)	**Single-dose prefilled autoinjector**: 80 mg/mL **Single-dose prefilled syringe**: 80 mg/mL
Guselkumab (Tremfya)	**Single-dose prefilled syringe:** 100 mg/mL **Single-dose One-Press pen-injector**: 100 mg/mL

Drug Name	Availability
Natalizumab (Tysabri)	**Single-use vial**: 300 mg/15 mL
Ozanimod (Zeposia)	**Oral capsules:** 0.23 mg, 0.46 mg, 0.92 mg
Risankizumab-rzaa (Skyrizi)	*Subcutaneous injection* **Single-dose prefilled syringe:** 75 mg/0.83 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 vial:** 600 mg/10 mL
Sarilumab (Kevzara)	**Single-dose prefilled syringe:** 150 mg/1.14 mL, 200 mg/1.14 mL
Secukinumab (Cosentyx)	**Single-dose Sensoready® pen:** 150 mg/mL **Single-dose prefilled syringe:** 75 mg/0.5 mL, 150 mg/mL **Single-use vial:** 150 mg
Tildrakizumab-asmn (Ilumya)	**Single-dose prefilled syringe:** 100 mg/1 mL
Tocilizumab (Actemra)	**Single-use vial**: 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL **Single-dose prefilled syringe:** 162 mg/0.9 mL **Single-dose prefilled autoinjector:** 162 mg/0.9 mL
Tofacitinib (Xeljanz)	**Tablets**: 5 mg, 10 mg **Oral solution**: 1 mg/mL
Tofacitinib extended-release (Xeljanz XR)	**Tablets**: 11 mg, 22 mg
Upadacitinib (Rinvoq)	**Tablets, extended-release:** 15 mg, 30 mg, 45 mg
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)
Vedolizumab (Entyvio)	**Single-use vial:** 300 mg/20 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 Codes	Description
J0129	Injection, abatacept, 10 mg
J0135	Injection, adalimumab, 20 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
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J2323	Injection, natalizumab, 1 mg
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg
J3590	Unclassified biologics
J3245	Injection, tildrakizumab, 1 mg
J3262	Injection, tocilizumab, 1 mg
J3357	Ustekinumab, for subcutaneous injection,1 mg
J3358	Ustekinumab, for intravenous injection, 1 mg
J3380	Injection, vedolizumab, 1 mg
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created; per SDC and prior clinical guidance adapted from CP.CPA.194; replaces the following policies where HIM line of business has been removed: CP.PHAR.241, CP.PHAR.242, CP.PHAR.244, CP.PHAR.247, CP.PHAR.250, CP.PHAR.253, CP.PHAR.254, CP.PHAR.257, CP.PHAR.261, CP.PHAR.263, CP.PHAR.264, CP.PHAR.267, CP.PHAR.346, CP.PHAR.364, CP.PHAR.375, CP.PHAR.386; the following HIM policies are being retired: HIM.PA.SP17, HIM.PA.SP38.	12.11.19	02.20
Criteria added for new FDA indication for Taltz: ankylosing spondylitis; criteria added for new FDA indication for Stelara: ulcerative colitis; removed redirection to azathioprine, 6-mercaptopurine, or aminosalicylate for UC per 2019 ACG guidelines; references reviewed and updated. RT4: added Xeljanz XR 22 mg dose form and updated to indicate FDA approved use and dosing in UC with similar redirection as Xeljanz immediate release; added Tremfya pen-injector dose form. Added unspecified iridocyclitis to Section III as an excluded use for Inflectra, Remicade, and Renflexis. Added Coding Implications table.	12.03.19	02.20
2Q 2020 annual review: for RA, added specific diagnostic criteria for definite RA, baseline CDAI score requirement, and decrease in CDAI score as positive response to therapy; for UC, added Mayo score requirement of at least 6; allowed IV Actemra for refractory CRS	04.23.20	05.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
related to blinatumomab therapy per NCCN; added dose rounding guidelines for agents (i.e., Actemra, Enbrel, infliximab, Kineret, Orencia, Stelara, Simponi Aria) with weight-based doses; added NCCN supported off-label uses for Actemra; added age limit of 2 year or older for Actemra for CRS; added requirement for redirection to Inflectra and Renflexis to Section II for Remicade; for HS, revised requirement from systemic antibiotics to additionally require oral retinoids or hormonal therapy, and required at least a 25% reduction in inflammatory nodules and abscesses for reauthorization; added pediatric age extension for Taltz from age 18 years down to 6 years old; removed criteria set for Tysabri for MS; refer to HIM.PA.SP17; references reviewed and updated.		
Per April SDC and prior clinical guidance, added Skyrizi as a preferred product for PsO, added Rinvoq as a preferred product for RA.	04.22.20	
Per July SDC and prior clinical guidance, added Stelara and Tremfya as preferred products for their respective indications; revised redirection for AS, PsA, PsO, and RA to require ALL among the list of preferred products; for Stelara off-label dosing added requirement for documentation of inadequate response on a 3 month trial of maximum indicated dose and redirection to alternative preferred products; for SC Actemra RA requests, removed existing redirection to Kevzara; for Cimzia, Entyvio, or Tysabri CD requests revised redirection to require Humira and Stelara; for Entyvio and Simponi UC request revised redirection to require Humira, Stelara, and Xeljanz/Xeljanz XR.	07.09.20	
RT2: Added newly FDA-approved indication for Cosentyx and Taltz for nr-axSpA to the policy, including requiring redirection only to Cosentyx based on contracting (no redirection to Humira and Enbrel as these are off-label for nr-axSpA), while allowing for redirection to Cosentyx, Humira, and Enbrel when the diagnosis is AS; added new FDA indication for Tremfya: PsA; RT4: updated Enbrel new dosage form: single-dose vial AND updated Stelara PsO criteria and dosing information in response to pediatric extension to be used in patients 6yo+; references reviewed and updated.	08.25.20	11.20
Per November SDC and prior clinical guidance, added redirection to Inflectra and Renflexis for Avsola; Revised typo in Appendix E from “normal ESR” to “abnormal ESR” for a point gained for ACR Classification Criteria.	11.22.20	
RT2: Added newly FDA-approved indication for Simponi Aria: pJIA and Xeljanz: pcJIA; removed duplication of information included in Appendix D: General Information as well as information that did not aid in decision-making;	11.23.20	02.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
RT4: updated Xeljanz new dosage form: oral solution; updated Simponi for PsA given age extension to pediatrics; references reviewed and updated. Added criteria for RAPID3 assessment for RA given limited in-person visits during COVID-19 pandemic, updated appendices.		
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. RT4: updated criteria to reflect pediatric extension for UC to include patients 5 years of age and older. RT4: added criteria for new FDA indication, SSc-ILD	05.04.21	05.21
RT4: updated Cosentyx PsO age requirement from ≥ 18 years to ≥ 6 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.	06.04.21	
RT4: added Zeposia to the policy for its newly FDA-approved 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.	06.14.21	08.21
Added requirement of concomitant treatment with MTX and 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.	08.23.21	11.21
2Q 2022 annual review: added newly FDA-approved indications: 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	05.02.22	05.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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.		
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	
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	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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	

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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