Department:	Pharmacy Management	**Original Approval:**	03/12/2025
Policy No:	PM604	**Last Approval:**	03/06/2026
Policy Title:	TNF Inhibitor Clinical Coverage Criteria		
Approved By:	UM Criteria Subcommittee		
Applicable Line(s) of Business:	☒ **Washington Apple Health (Medicaid)** ☐ **Behavioral Health Services Only** ☒ **Apple Health Expansion** ☒ **Medicare Advantage/Special Needs Plan** ☒ **Medicare Advantage Only** ☒ **Cascade Select**		

Required Clinical Documentation for Review

History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: -Diagnosis -Dosing and duration requested -Weight -Age -Medication list (current and past) to include start and end dates of previous trials for all conventional synthetic disease-modifying anti-rheumatic drugs (DMARD)/other small molecule drugs and biologic drugs -Medical records from the last 6 months showing the patient's problems, history, prior treatments, response to treatment, imaging and laboratory studies, details of the skilled needs, details of any specific needs related to risk/trauma/cultural etc., assessment and plan -Prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, neurologist, oncologist, hematologist or other specialist as indicated

Definitions

None.

Indications/Criteria

Medicaid	**The medications listed above are included in WA HCA's Single Preferred Drug List with criteria from WA HCA Cytokine & CAM Antagonists Medical policy no. 66.27.00.AA** ***Preferred Products: Adalimumab biosimilars; Enbrel; Orencia; Otezla; Taltz; Ustekinumab biosimilars; Xeljanz IR***

Individual & Family (Cascade Select) Members	***Preferred Products: Avsola, Cimzia, Entyvio, Ilumya, Inflectra, Simponi AriaNon-preferred Products: Actemra, generic infliximab, Orencia, Remicade, Renflexis***
Medicare Members	***Medicare Criteria is only applicable to the preferred and non-preferred products listed below. For all other drugs, refer to MCG. All other drugs do not require trial of a preferred product.*** ***Preferred Products: Avsola, Cimzia, Entyvio, Ilumya, Inflectra, Simponi Aria*** ***Non-preferred Products: generic infliximab, Remicade, Renflexis***

Shortcuts to Criteria

Medicaid Criteria

Ankylosing Spondylitis

Crohn's Disease

Plaque Psoriasis

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Psoriatic Arthritis

Refractory Sarcoidosis

Rheumatoid Arthritis (RA)

Ulcerative Colitis (UC)

Appendix A

Cascade Select/Medicare Criteria for Infliximab Intravenous Injections

Ankylosing Spondylitis

Crohn's Disease

Plaque Psoriasis

Psoriatic Arthritis

Rheumatoid Arthritis

Ulcerative Colitis

Bechet's Disease

Graft-Versus-Host Disease

Hidradenitis Suppurativa

Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy

Indeterminate Colitis

Juvenile Idiopathic Arthritis (JIA)

Pyoderma Gangrenosum

Sarcoidosis

Scleritis or Sterile Corneal Ulceration

Spondylarthritis, Other Subtypes

Still's Disease

Uveitis

Cascade Select/Medicare Criteria for Golimumab (Simponi Aria)

Ankylosing Spondylitis

Juvenile Idiopathic Arthritis (JIA)

Psoriatic Arthritis

Rheumatoid Arthritis

Medicaid Criteria for Simponi Aria and Infliximab Products (taken from HCA Medical Policy No. 66.27.00.AA)

Clinical Criteria	
Ankylosing Spondylitis (AS) golimumab (Simponi Aria) infliximab (Remicade) infliximab biosimilars	Golimumab (Simponi Aria), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** 2. Prescribed by, or in consultation with a rheumatologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of Ankylosing Spondylitis (AS); **AND**

5. High disease activity as indicated by Bath Ankylosing Disease Activity Index (BASDAI) score of at least 4 or Ankylosing Spondylitis Disease Activity Score (ASDAS) score of at least 2.1; **AND**
6. Treatment with at least two different NSAIDs (e.g., indomethacin, meloxicam, celecoxib, naproxen, nabumetone, etc.) has been ineffective, unless all are contraindicated, or not tolerated [minimum trial of four weeks]; **AND**
7. Disease manifested as either of the following:
    a. Axial disease; **OR**
    b. Peripheral arthritis; **AND**
        i. Treatment with at least one non-Cytokine and CAM disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate, sulfasalazine, leflunomide) has been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 3 months].
8. Treatment with two preferred Cytokine and CAM medications (i.e., adalimumab biosimilars, Enbrel, Xeljanz IR, or Taltz) has each been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 12 weeks].
   Note: Please see **Appendix A** for the list of preferred biosimilars.

If ALL criteria are met, the request will be authorized for **6 months.**

If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.

Criteria (Reauthorization)

Golimumab (Simponi Aria), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met:

1. Not used in combination with another Cytokine and CAM medication; **AND**
2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., decrease in BASDAI or ASDAS score).

If ALL criteria are met, the request will be authorized for **12 months.**

If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.

Crohn's Disease (CD) infliximab (Remicade) infliximab biosimilars	Infliximab (Remicade) or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Patient is 6 years of age or older; **AND** 2. Prescribed by, or in consultation with a gastroenterologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of moderate to severe Crohn's disease (CD); **AND** a. Treatment with conventional therapy has been ineffective, unless all are contraindicated, or not tolerated. Conventional therapy is defined as: i. Oral corticosteroids (e.g., prednisone, methylprednisolone) used short-term to induce remission or alleviate signs/symptoms of disease flare; **AND** ii. At least one immunomodulatory agent (e.g., methotrexate, azathioprine, 6-mercaptopurine) [minimum trial of 12 weeks]; **OR** b. Documentation of high-risk disease (e.g., symptoms despite conventional therapy, obstruction, abscess, stricture, phlegmon, fistulas, resection, extensive bowel involvement, early age of onset, growth retardation, Crohn's Disease Activity Index (CDAI) > 450, Harvey-Bradshaw index > 7). 5. For infliximab and infliximab biosimilar requests, documentation of current weight is provided; **AND** 6. Patient meets one of the following: a. For pediatric infliximab and infliximab biosimilar requests (6-17 years old): treatment with one preferred adalimumab biosimilar has been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 12 weeks]; b. Treatment with two preferred Cytokine and CAM medications (i.e., adalimumab biosimilars, ustekinumab biosimilars) has each been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 12 weeks]. Note: Please see **Appendix A** for the list of preferred biosimilars. If ALL criteria are met, the request will be authorized for **6 months.** If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.
	Criteria (Reauthorization)

	Infliximab (Remicade) or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in endoscopic activity, taper or discontinuation of corticosteroids, reduction in number of liquid stools, decrease in presence and severity of abdominal pain, decrease in CDAI, decrease in Harvey-Bradshaw index). If ALL criteria are met, the request will be authorized for **12 months.** If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.
Plaque Psoriasis infliximab (Remicade) infliximab biosimilars	Infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Prescribed by, or in consultation with a dermatologist; **AND** 2. Not used in combination with another Cytokine and CAM medication; **AND** 3. Diagnosis of moderate to severe plaque psoriasis; **AND** 4. Presence of ongoing disease for greater than 6 months; **AND** 5. The patient meets one of the following: a. Disease affects at least 10% body surface area; **OR** b. Disease affects the face, ears, hands, feet, or genitalia; **AND** 6. Baseline assessments are included (e.g., body surface area (BSA), Psoriasis Area and Severity Index (PASI), Psoriasis Physician's Global Assessment (PGA), itch numeric rating scale, etc.); **AND** 7. History of failure, contraindication, or intolerance to one of the following: a. Phototherapy (UVB or PUVA) [minimum trial of 12 weeks]; **OR** b. Treatment with at least one non-Cytokine and CAM DMARD unless all are contraindicated or not tolerated (e.g., methotrexate, cyclosporine, acitretin, azathioprine, etc.) [minimum trial of 12 weeks]. 8. Patient is 18 years of age or older; **AND** 9. Treatment with two preferred Cytokine and CAM medications (i.e., adalimumab biosimilars, Enbrel, Otezla, Taltz, or ustekinumab biosimilar) has each been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 12 weeks]. Note: Please see **Appendix A** for the list of preferred biosimilars.

	If ALL criteria are met, the request will be authorized for **6 months.** If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration. **Criteria (Reauthorization)** Infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in BSA, PASI, Psoriasis PGA, itch numeric rating scale). If ALL criteria are met, the request will be authorized for **12 months.** If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.
Polyarticular Juvenile Idiopathic Arthritis (PJIA) golimumab (Simponi Aria)	Golimumab (Simponi Aria) may be approved when all the following documented criteria are met: 1. Patient is 2 years of age or older; **AND** 2. Prescribed by, or in consultation with a rheumatologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of Polyarticular Juvenile Idiopathic Arthritis (PJIA); **AND** 5. Documentation of current weight is provided; **AND** 6. Treatment with at least one non-Cytokine and CAM DMARD (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine, azathioprine, cyclosporine) have been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 3 months]. 7. Treatment with two preferred Cytokine and CAM medications (i.e., adalimumab biosimilars, Enbrel, Orencia, or Xeljanz IR) has each been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 12 weeks]. Note: Please see **Appendix A** for the list of preferred biosimilars.

	If ALL criteria are met, the request will be authorized for **6 months.** If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.
	Criteria (Reauthorization)
	Golimumab (Simponi Aria) may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in joint pain, swelling, activities of daily living, reduction in diseases flares, etc.). If ALL criteria are met, the request will be authorized for **12 months.**
Psoriatic Arthritis golimumab (Simponi Aria) infliximab (Remicade) infliximab biosimilars	Golimumab (Simponi Aria), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Prescribed by, or in consultation with a dermatologist or rheumatologist; **AND** 2. Not used in combination with another Cytokine and CAM medication; **AND** 3. Diagnosis of Psoriatic Arthritis (PsA); **AND** 4. Patient meets one of the following: a. Treatment with at least one non-Cytokine and CAM DMARD (e.g., methotrexate, sulfasalazine, leflunomide, cyclosporine) have been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 3 months]; **OR** b. Presence of active, severe disease as indicated by provider assessment and the presence of at least ONE of the following: i. Erosive disease ii. Elevated C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR) iii. Long-term damage interfering with function (e.g., joint deformities, vision loss) iv. Major impairment of quality of life due to high disease activity at many sites (including dactylitis, enthesitis) or functionally limiting arthritis at a few sites. 5. The patient meets the appropriate age limit for the requested product: a. For golimumab: 2 years of age or older; **OR** b. For infliximab, and infliximab biosimilars: 18 years of age or older; **AND**

	6. For golimumab, documentation of current weight is provided; **AND** 7. For adult requests, treatment with two preferred Cytokine and CAM medications (i.e., adalimumab biosimilars, Enbrel, Orencia, Otezla, Taltz, ustekinumab biosimilars, or Xeljanz IR) has each been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 12 weeks]. Note: Please see **Appendix A** for the list of preferred biosimilars. If ALL criteria are met, the request will be authorized for **6 months.** If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.
	Criteria (Reauthorization) Golimumab (Simponi Aria), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in joint pain, swelling, activities of daily living, reduction in diseases flares, etc.). If ALL criteria are met, the request will be authorized for **12 months.** If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.
Refractory Sarcoidosis infliximab (Remicade) infliximab biosimilars	Infliximab (Remicade) and infliximab biosimilars may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older; **AND** 2. Prescribed by, or in consultation with a pulmonologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; AND 4. Diagnosis of pulmonary sarcoidosis; **AND** 5. History of failure, contraindication, or intolerance to ALL the following: a. Oral glucocorticoids (e.g., prednisone, prednisolone) [minimum trial of 3 months]; **AND**

	b. Immunosuppressive agents (e.g., methotrexate, azathioprine, leflunomide, mycophenolate) [minimum trial of 3 months]; **AND** 6. Baseline assessments of either of the following: a. Pulmonary function tests; **OR** b. Chest radiograph; **OR** c. Ambulatory oximetry 7. Treatment with one preferred adalimumab biosimilar has each been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 12 weeks]. Note: Please see **Appendix A** for the list of preferred biosimilars. If ALL criteria are met, the request will be authorized for **6 months.** If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.
	Criteria (Reauthorization) Infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g, improvement in pulmonary function tests, chest radiograph, oximetry measurements). If ALL criteria are met, the request will be authorized for **12 months.** If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.
Rheumatoid Arthritis (RA) golimumab (Simponi Aria) infliximab (Remicade) infliximab biosimilars	Golimumab (Simponi Aria), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older; **AND** 2. Prescribed by, or in consultation with a rheumatologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of Rheumatoid Arthritis (RA); **AND** 5. Baseline assessments are included (e.g., Disease Activity Score for 28 joints (DAS28) with the CRP, DAS28 with ESR, Simplified Disease Activity

	Index (SDAI), Clinical Disease Activity Index (CDAI), Routine Assessment of Patient Index Data 3 (RAPID3), Patient Activity Scale (PAS) II; **AND** 6. Treatment with at least one non-Cytokine and CAM DMARD (e.g., methotrexate, sulfasalazine, hydroxychloroquine, leflunomide, cyclosporine, azathioprine) have been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 3 months]. 7. Treatment with two preferred Cytokine and CAM medications (i.e., adalimumab biosimilars, Enbrel, Orencia, or Xeljanz IR) has each been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 12 weeks]. If ALL criteria are met, the request will be authorized for **6 months.** If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.
	Criteria (Reauthorization) Golimumab (Simponi Aria), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g. improvement in DAS28 with CRP/ESR, SDAI, CDAI, RAPID3, PAS II scores). If ALL criteria are met, the request will be authorized for **12 months.** If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.
Ulcerative Colitis (UC) infliximab (Remicade) infliximab biosimilars	Infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Patient is 6 years of age or older; **AND** 2. Prescribed by, or in consultation with a gastroenterologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of moderate-to-severe Ulcerative Colitis (UC); **AND**

5. Baseline assessments are included (e.g., stool frequency, endoscopy results, presence of rectal bleeding, disease activity scoring tool); **AND**
6. Treatment with conventional therapy (e.g., systemic corticosteroids, azathioprine, mesalamine, sulfasalazine) has been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 12 weeks].
7. For infliximab and infliximab biosimilar requests, documentation of current weight is provided; **AND**
8. For pediatric infliximab requests, treatment with one preferred adalimumab biosimilar has been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 12 week]; **OR**
   Note: Please see **Appendix A** for the list of preferred biosimilars.
9. For adult requests, treatment with two preferred Cytokine and CAM medications (i.e., adalimumab biosimilars, ustekinumab biosimilars, or Xeljanz IR) has each been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 12 weeks].
   Note: Please see **Appendix A** for the list of preferred biosimilars.

If ALL criteria are met, the request will be authorized for **6 months.**

If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.

Criteria (Reauthorization)

Adalimumab (Humira), adalimumab biosimilars, golimumab (Simponi), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met:

1. Not used in combination with another Cytokine and CAM medication; **AND**
2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., decreased stool frequency, decreased rectal bleeding, improvement in endoscopic activity, tapering or discontinuation of corticosteroid therapy, or improvement on a disease activity scoring tool).

If ALL criteria are met, the request will be authorized for **12 months.**

If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.

Dosage and quantity limits

golimumab (Simponi Aria®) [billed by mL]		
Dosage Form	**Indication**	**Quantity Limit**
50mg/0.5mL SmartJect autoinjector (#1 per box) 50mg/0.5mL PFS (#1 per box) 100mg/mL SmartJect autoinjector (#1 per box) 100mg/mL PFS (#1 per box)	• Ankylosing Spondylitis • Psoriatic Arthritis • Rheumatoid Arthritis • Ulcerative Colitis	**Ulcerative Colitis:** *Initial PA:* #3 (100mg/mL) autoinjectors or PFS per 28 days for the first month *Maintenance PA:* #1 (100mg/mL) autoinjector or PFS per 28 days for months 2-6 *Renewal PA:* #1 (100mg/mL) autoinjector or PFS per 28 days for one year **All Other Indications:** *Initial PA:* #1 (50mg/0.5mL) autoinjector or PFS per 28 days for six months *Renewal PA:* #1 (50mg/0.5mL) autoinjector or PFS per 28 days for one year
50mg/4mL single-dose vial (Simponi Aria®)	• Ankylosing Spondylitis • Psoriatic Arthritis • Rheumatoid Arthritis	10 vials first 28 days, then 5 vials per 56 days
infliximab (Remicade®) [billed by each]		
Dosage Form	**Indication**	**Quantity Limit**
100 mg single-dose vial	• Ankylosing spondylitis • Crohn's disease • Plaque psoriasis • Psoriatic arthritis • Rheumatoid arthritis • Ulcerative colitis	**Rheumatoid Arthritis** *Initial PA:* 3mg/kg per infusion; 2 infusions per 6 weeks *Renewal PA*: 10mg/kg per infusion; 1 infusion per 8 weeks OR 3mg/kg per infusion; 1 infusion per 4 weeks **All Other Indications:** *Initial PA*: 5mg/kg per infusion; 3 infusions for 6 weeks *Renewal PA*:

		• AS: 5mg/kg per infusion; 1 infusion per 6 weeks • CD: 10mg/kg per infusion; 1 infusion per 8 weeks • Ps/PsA/UC: 5mg/kg per infusion; 1 infusion per 8 weeks
infliximab biosimilars		
infliximab-abda (Renflexis™) [billed by each] **infliximab-dyyb (Inflectra®) [billed by each]** **infliximab-axxq (Avsola®) [billed by each]**		
100 mg single-dose vial	• Ankylosing spondylitis • Crohn's disease • Plaque psoriasis • Psoriatic arthritis • Rheumatoid arthritis • Ulcerative colitis	**Rheumatoid Arthritis** *Initial PA:* 3mg/kg per infusion; 2 infusions per 6 weeks *Renewal PA*: 10mg/kg per infusion; 1 infusion per 8 weeks OR 3mg/kg per infusion; 1 infusion per 4 weeks **All Other Indications:** *Initial PA*: 5mg/kg per infusion; 3 infusions for 6 weeks *Renewal PA*: • AS: 5mg/kg per infusion; 1 infusion per 6 weeks • CD: 10mg/kg per infusion; 1 infusion per 8 weeks • Ps/PsA/UC: 5mg/kg per infusion; 1 infusion per 8 weeks

Individual & Family (Cascade Select) Select and Medicare Criteria

Infliximab Intravenous Injections (Avsola, generic infliximab, Inflectra, Remicade, and Renflexis) Approved Indications

1. **Ankylosing Spondylitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets BOTH of the following criteria (i, ii, and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** The medication is prescribed by or in consultation with a rheumatologist; AND
     - **iii.** For non-preferred products (see **Appendix B)**, the patient meets ONE of the following (a or b):
       - **a)** For Cascade Select patients, patient meets both of the following [(1) and (2)]:
         - **(1)** Patient has tried one of Inflectra or Avsola; AND
         - **(2)** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
       - **b)** For Medicare patients, patient meets one of the following [(1) or (2)]:
         - **(1)** Patient meets both of the following [(a) and (b)]:
           - **(a)** Patient has tried one of Inflectra or Avsola; AND
           - **(b)** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
         - **(2)** The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 days; OR
   - **B)** Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient has been established on therapy for at least 6 months; AND
       Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).
     - **ii.** Patient meets at least one of the following (a or b):
       - **(1)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR

Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

(2) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living; AND

iii. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 6 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

2. Crohn's Disease. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, and iv):

i. Patient is ≥ 6 years of age; AND

ii. Patient meets ONE of the following conditions (a, b, c, or d):

a) Patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient; OR
Note: Examples of corticosteroids are prednisone and methylprednisolone.

b) Patient has tried one other conventional systemic therapy for Crohn's disease; OR
Note: Examples of conventional systemic therapies for Crohn's disease include azathioprine, 6-mercaptopurine, methotrexate, or janus kinase (JAK) inhibitors. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for Crohn's disease. A trial of mesalamine does not count as a systemic therapy for Crohn's disease.

c) Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR

d) Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND

iii. The medication is prescribed by or in consultation with a gastroenterologist; AND

iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR
Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography [MRE], computed tomography enterography [CTE]), endoscopic assessment, and/or reduced dose of corticosteroids.

b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool; AND

iii. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patients, patient meets both of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

3. Plaque Psoriasis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 3 months if the patient meets the following criteria (i, ii, iii and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient meets ONE of the following conditions (a or b):

a) Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
Note: Examples include methotrexate, cyclosporine, or acitretin (Soriatane®, generics). A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient already had a 3-month trial or previous intolerance to at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for psoriasis. A patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.

b) Patient has a contraindication to methotrexate, as determined by the prescriber; AND

iii. The medication is prescribed by or in consultation with a dermatologist; AND

iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the

prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:
(1) Patient meets both of the following [(a) and (b)]:
(a) Patient has tried one of Inflectra or Avsola; AND
(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, iii and iv):
i. Patient has been established on therapy for at least 3 months; AND
Note: A patient who has received < 3 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).
ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an infliximab product) in at least one of the following: estimated body surface area affected, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
iii. Compared with baseline (prior to receiving an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning; AND
iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):
a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:
(1) Patient has tried one of Inflectra or Avsola; AND
(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
b) For Medicare patients, patient meets one of the following [(1) or (2)]:
(1) Patient meets both of the following [(a) and (b)]:
(a) Patient has tried one of Inflectra or Avsola; AND
(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to

the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

4. Psoriatic Arthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets both of the following criteria (i, ii, and iii):

i. Patient is ≥ 18 years of age; AND

ii. The medication is prescribed by or in consultation with a rheumatologist or a dermatologist; AND

iii. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR
Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths; AND

iii. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter.

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

5. Rheumatoid Arthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following criteria (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months; AND
Note: Examples include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient already had a 3-month trial of at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for rheumatoid arthritis. A patient who has already tried a biologic is not required to "step back" and try a conventional synthetic DMARD.

iii. The medication is prescribed by or in consultation with a rheumatologist; AND

iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient has been established on therapy for at least 6 months; AND

ii. Patient meets at least one of the following (a or b):

a) Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR

Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).

b) Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths; AND

iii. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 3 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

6. **Ulcerative Colitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   A) Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, and iv):
      i. Patient is ≥ 6 years of age; AND
      ii. Patient meets ONE of the following conditions (a or b):
         a) Patient had a trial of one systemic agent or was intolerant to one of these agents for ulcerative colitis; OR
         Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, a corticosteroid such as prednisone or methylprednisolone, or janus kinase (JAK) inhibitors. A previous trial of one biologic other than the requested medication also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for ulcerative colitis.
         b) Patient meets BOTH of the following [(1) and (2)]:
            (1) Patient has pouchitis; AND
            (2) Patient has tried therapy with an antibiotic, probiotic, corticosteroid enema, or Rowasa® (mesalamine enema); AND
            Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema (Cortenema, generics).
      iii. The medication is prescribed by or in consultation with a gastroenterologist; AND
      iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):
         a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:
            (1) Patient has tried one of Inflectra or Avsola; AND
            (2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
         b) For Medicare patients, patient meets one of the following [(1) or (2)]:
            (1) Patient meets both of the following [(a) and (b)]:
               (a) Patient has tried one of Inflectra or Avsola; AND
               (b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR
Note: Examples of objective measures include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.

b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or rectal bleeding; AND

iii. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

Other Uses with Supportive Evidence

7. Behcet's Disease. Approve for the duration noted if the patient meets ONE of the following criteria (A or B):

A) Initial Therapy. Approve for 3 months if the patient meets ALL of the following conditions (i, ii, iii, and iv):

i. Patient is ≥ 6 years of age; AND

ii. Patient meets ONE of the following (a or b):

a) Patient has tried at least ONE conventional therapy; OR
Note: Examples include systemic corticosteroids (e.g., methylprednisolone), immunosuppressants (azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, tacrolimus, Leukeran® [chlorambucil tablet], cyclophosphamide, interferon alfa), and phosphodiesterase-4 (PDE4) inhibitors. An exception to the requirement for a trial of one conventional therapy can be made if the patient has already had a trial of at least one tumor necrosis factor inhibitor (e.g., an adalimumab product, an etanercept product). A patient who has already tried one biologic other than the requested drug for Behcet's disease is not required to "step back" and try a conventional therapy. A biosimilar of the requested biologic does not count.

b) Patient has ophthalmic manifestations of Behcet's disease; AND

iii. The medication is prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist; AND

iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient has been established on therapy for at least 3 months; AND
Note: A patient who has received < 3 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).

ii. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); AND
Note: Examples of objective measures are dependent upon organ involvement but may include best-corrected visual acuity (if ophthalmic manifestations); serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate); or ulcer depth, number, and/or lesion size

iii. Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain or improved visual acuity (if ophthalmic manifestations); AND

iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, then no more frequently than once every 6 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

8. Graft-Versus-Host Disease. Approve for the duration noted if the patient meets ONE of the following criteria (A or B):

A) Initial Therapy. Approve for 1 month if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient is ≥ 6 years of age; AND

ii. Patient has acute graft-versus-host disease; AND

iii. Patient has tried at least one conventional systemic treatment for graft-versus-host disease; AND

Note: Examples of conventional treatments include corticosteroids (e.g., methylprednisolone), antithymocyte globulin, cyclosporine, tacrolimus, and mycophenolate mofetil.

iv. The medication is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center; AND

v. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):

i. Patient has been established on an infliximab product for at least 1 month; AND
Note: A patient who has received < 1 month of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR
Note: An example of objective measures is normalization of liver function tests, red blood cell count, or platelet count, or resolution of fever or rash.

b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as improvement in skin, oral mucosal, ocular, or gastrointestinal symptoms (e.g., nausea, vomiting, anorexia); AND

iii. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A and B):

A) The dose is up to 10 mg/kg given intravenously; AND

B) Doses are administered no more frequently than once weekly.

9. **Hidradenitis Suppurativa.** Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
   A) Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, iii and iv):
      i. Patient is ≥ 6 years of age; AND
      ii. Patient has tried one other therapy; AND
      Note: Examples include intralesional or oral corticosteroids (e.g., triamcinolone, prednisone), systemic antibiotics (e.g., clindamycin, dicloxacillin, erythromycin), isotretinoin, and Humira.
      iii. The medication is prescribed by or in consultation with a dermatologist; AND
      iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):
         a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:
            (1) Patient has tried one of Inflectra or Avsola; AND
            (2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
         b) For Medicare patients, patient meets one of the following [(1) or (2)]:
            (1) Patient meets both of the following [(a) and (b)]:
               (a) Patient has tried one of Inflectra or Avsola; AND
               (b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
            (2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR
   B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, iii and iv):
      i. Patient has been established on therapy for at least 3 months; AND
      Note: A patient who has received < 3 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).
      ii. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); AND
      Note: Examples of objective measures include Hurley staging, Sartorius score, Physician Global Assessment, and Hidradenitis Suppurativa Severity Index.

iii. Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain or drainage of lesions, nodules, or cysts; AND

iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

10. Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy.
Approve for the duration noted if the patient meets ONE of the following (A or B):
Note: Examples of checkpoint inhibitors include Keytruda (pembrolizumab intravenous [IV] infusion), Opdivo (nivolumab IV infusion), Yervoy (ipilimumab IV infusion), Tecentriq (atezolizumab IV infusion), Bavencio (avelumab IV infusion), or Imfinzi (durvalumab IV infusion).

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):

i. Patient is ≥ 18 years of age; AND

ii. According to the prescriber, patient developed an immunotherapy-related toxicity other than hepatitis; AND

iii. Patient developed this immune-related toxicity while receiving a checkpoint inhibitor; AND

iv. Patient has tried one systemic corticosteroid; AND
Note: Examples include methylprednisolone and prednisone.

v. The medication is prescribed by or in consultation with an oncologist, cardiologist, gastroenterologist, hematologist, nephrologist, pulmonologist, rheumatologist, or ophthalmologist; AND

vi. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least ONE of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR
Note: Examples of objective measures are dependent upon organ involvement but may include clinically significant improvement or normalization of serum

markers (e.g., C-reactive protein, erythrocyte sedimentation rate), fecal markers (e.g., fecal calprotectin), and/or reduced dosage of corticosteroids.

b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness or swelling (if joint symptoms), stool frequency and/or rectal bleeding (if gastrointestinal symptoms), and/or improved function or activities of daily living.

iii. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 10 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, then no more frequently than once every 4 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

11. Indeterminate Colitis. Approve for the duration noted if the patient meets ONE of the following (A or B):

Note: Indeterminate colitis is defined as colitis that cannot be classified with certainty as either ulcerative colitis or Crohn's disease.

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, v and vi):

i. Patient is ≥ 6 years of age; AND
ii. Patient has tried one systemic corticosteroid; AND
Note: Examples include prednisone and methylprednisolone.
iii. Patient has tried mesalamine; AND
iv. Patient has tried either azathioprine or 6-mercaptopurine; AND
v. The medication is prescribed by or in consultation with a gastroenterologist; AND
vi. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):
a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:
(1) Patient has tried one of Inflectra or Avsola; AND
(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
b) For Medicare patients, patient meets one of the following [(1) or (2)]:
(1) Patient meets both of the following [(a) and (b)]:
(a) Patient has tried one of Inflectra or Avsola; AND
(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).
ii. Patient meets at least one of the following (a or b):
a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR
Note: Examples of objective measures include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.
b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or rectal bleeding; AND

iii. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):
- **a)** For Cascade Select patients, patient meets both of the following [(1) and (2)]:
  - **(1)** Patient has tried one of Inflectra or Avsola; AND
  - **(2)** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
- **b)** For Medicare patients, patient meets one of the following [(1) or (2)]:
  - **(1)** Patient meets both of the following [(a) and (b)]:
    - **(a)** Patient has tried one of Inflectra or Avsola; AND
    - **(b)** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
  - **(2)** The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

12. Juvenile Idiopathic Arthritis (JIA). Approve for the duration noted if the patient meets ONE of the following (A or B):

Note: This includes JIA regardless of type of onset, including a patient with juvenile spondyloarthropathy/active sacroiliac arthritis. JIA is also referred to as Juvenile Rheumatoid Arthritis.

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following criteria (i, ii, iii, and iv):
- **i.** Patient is ≥ 6 years of age; AND
- **ii.** Patient meets ONE of the following conditions (a or b):
  - **a)** Patient has tried one other systemic medication for this condition; OR
    Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID) [e.g., ibuprofen, naproxen]. A previous trial of one biologic other than the requested medication

also counts as a trial of one medication. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for JIA.

b) Patient has aggressive disease, as determined by the prescriber; AND

iii. The medication is prescribed by or in consultation with a rheumatologist; AND

iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii and iii):

i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR
Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.

b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, or improved function or activities of daily living; AND

iii. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 6 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

13. Pyoderma Gangrenosum. Approve for the duration noted if the patient meets ONE of the following criteria (A or B):

A) Initial Therapy. Approve for 4 months if the patient meets ALL of the following conditions (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient meets ONE of the following conditions (a or b):

a) Patient has tried one systemic corticosteroid; OR

Note: Examples include prednisone and methylprednisolone.

b) Patient has tried one other immunosuppressant for at least 2 months or was intolerant to one of these medications; AND
Note: Examples include mycophenolate mofetil and cyclosporine.

iii. The medication is prescribed by or in consultation with a dermatologist; AND

iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, iii and iv):

i. Patient has been established on therapy for at least 4 months; AND
Note: A patient who has received < 4 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).

ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an infliximab product) in at least one of the following: size, depth, and/or number of lesions; AND

iii. Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain and/or tenderness of affected lesions; AND

iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent,

buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:
- **(1)** Patient meets both of the following [(a) and (b)]:
  - **(a)** Patient has tried one of Inflectra or Avsola; AND
  - **(b)** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
- **(2)** The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

14. Sarcoidosis. Approve for the duration noted if the patient meets ONE of the following criteria (A or B):

A) Initial Therapy. Approve for 3 months if the patient meets ALL of the following conditions (i, ii, iii, iv, and v):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient has tried at least one corticosteroid; AND
  Note: Examples include prednisone and methylprednisolone.
- **iii.** Patient has tried at least one immunosuppressive medication; AND
  Note: Examples include methotrexate, azathioprine, leflunomide, mycophenolate mofetil, hydroxychloroquine, or chloroquine.
- **iv.** The medication is prescribed by or in consultation with a pulmonologist, ophthalmologist, cardiologist, neurologist, or dermatologist; AND
- **v.** For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):
  - **a)** For Cascade Select patients, patient meets both of the following [(1) and (2)]:
    - **(1)** Patient has tried one of Inflectra or Avsola; AND
    - **(2)** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent,

buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient has been established on therapy for at least 3 months; AND
Note: A patient who has received < 3 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).

ii. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); AND
Note: Examples of objective measures are dependent upon organ involvement but may include lung function (e.g., predicted forced vital capacity and/or 6-minute walk distance); serum markers (e.g., C-reactive protein, liver enzymes, N-terminal pro-brain natriuretic peptide [NT-proBNP]); improvement in rash or skin manifestations, neurologic symptoms, or rhythm control; or imaging (e.g., if indicated, chest radiograph, magnetic resonance imaging [MRI], or echocardiography).

iii. Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased cough, fatigue, pain, palpitations, neurologic symptoms, and/or shortness of breath; AND

iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, then no more frequently than once every 6 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

15. Scleritis or Sterile Corneal Ulceration. Approve for the duration noted if the patient meets ONE of the following criteria (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following conditions (i, ii, iii and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient has tried one other therapy for this condition; AND
Note: Examples include oral non-steroidal anti-inflammatory drugs (NSAIDs) such as indomethacin; oral, topical (ophthalmic) or intravenous corticosteroids (such as prednisone, prednisolone, methylprednisolone); methotrexate; cyclosporine; or other immunosuppressants.

iii. The medication is prescribed by or in consultation with an ophthalmologist; AND

iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in

stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR
Note: Examples of objective measures are serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased eye pain, redness, light sensitivity, tearing, and/or improvement in visual acuity; AND

iii. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 10 mg/kg as an intravenous infusion administered at baseline and followed by up to three additional similar doses (for example, up to three additional doses given 2, 6, and 8 weeks after the initial infusion); OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

16. Spondyloarthritis, Other Subtypes Approve for the duration noted if the patient meets ONE of the following criteria (A or B):

Note: Examples of other subtypes include undifferentiated arthritis, non-radiographic axial spondylitis, Reactive Arthritis [Reiter's disease]. For ankylosing spondylitis or psoriatic arthritis, refer to the respective criteria under FDA-approved indications.

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following conditions (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient meets ONE of the following (a or b):

a) Patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least ONE conventional synthetic disease-modifying antirheumatic drug (DMARD); OR

Note: Examples include methotrexate, leflunomide, and sulfasalazine.

b) Patient has axial spondyloarthritis with objective signs of inflammation, defined as at least one of the following [(1) or (2)]:

(1) C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory; OR

(2) Sacroiliitis reported on magnetic resonance imaging; AND

iii. The medication is prescribed by or in consultation with a rheumatologist; AND

iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to

the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii and iii):

i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS) and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living; AND

iii. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 6 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

17. Still's Disease. Approve for the duration noted if the patient meets ONE of the following criteria (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following conditions (i, ii, iii, iv, and v):

i. Patient is ≥ 18 years of age; AND

ii. Patient has tried one corticosteroid; AND
Note: Examples include prednisone and methylprednisolone.

iii. Patient has tried one conventional synthetic disease-modifying antirheumatic drug (DMARD) given for at least 2 months or was intolerant; AND
Note: An example is methotrexate. A previous trial of one biologic other than the requested drug (e.g., Actemra [tocilizumab intravenous injection, tocilizumab subcutaneous injection], Arcalyst [rilonacept subcutaneous injection], Ilaris [canakinumab subcutaneous injection]) also counts towards this requirement for previous therapy for Still's disease. A biosimilar of the requested biologic does not count.

iv. The medication is prescribed by or in consultation with a rheumatologist; AND

v. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii and iii):

i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR
Note: Examples of objective measures include resolution of fever, improvement in rash or skin manifestations, clinically significant improvement, or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.

b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living; AND

iii. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 6 mg/kg as an intravenous fusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

18. Uveitis. Approve for the duration noted if the patient meets ONE of the following criteria (A or B):

Note: This includes other posterior uveitis and panuveitis syndromes.

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following conditions (i, ii, iii, and iv):

i. Patient is ≥ 6 years of age; AND

ii. Patient has tried one of the following therapies: periocular, intraocular, or systemic corticosteroids, or immunosuppressives; AND
Note: Examples of corticosteroids include prednisolone, triamcinolone, betamethasone, methylprednisolone, prednisone. Examples of immunosuppressives include methotrexate, mycophenolate mofetil, and cyclosporine. An exception to the requirement for a trial of one of these therapies can be made if the patient has already had a trial of an etanercept product or an adalimumab product for uveitis. A patient who has already tried one biologic other than the requested medication also counts. A biosimilar of the requested biologic does not count.

iii. The medication is prescribed by or in consultation with an ophthalmologist; AND

iv. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii and iii):

i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR
Note: Examples of objective measures include best-corrected visual acuity, assessment of chorioretinal and/or inflammatory retinal vascular lesions, or anterior chamber cell grade or vitreous haze grade.

b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased eye pain, redness, light sensitivity, and/or blurred vision; or improvement in visual acuity.

iii. For non-preferred products (see **Appendix B**), the patient meets ONE of the following (a or b):

a) For Cascade Select patients, patient meets both of the following [(1) and (2)]:

(1) Patient has tried one of Inflectra or Avsola; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, patient meets one of the following [(1) or (2)]:

(1) Patient meets both of the following [(a) and (b)]:

(a) Patient has tried one of Inflectra or Avsola; AND

(b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

(2) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 day.

Dosing. Approve the following regimens (A or B):

A) Initial Therapy. Approve up to 10 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, then no more frequently than once every 4 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

Simponi Aria (golimumab) Approved Indications

1. **Ankylosing Spondylitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist; OR
   - **B)** Patient is Currently Receiving Simponi Aria or Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
     - **i.** Patient has been established on therapy for at least 6 months; AND
       Note: A patient who has received < 6 months of therapy or who is restarting therapy with Simponi Aria or subcutaneous is reviewed under criterion A (Initial Therapy).
     - **ii.** Patient meets at least one of the following (a or b):
       - **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Simponi Aria or subcutaneous); OR
         Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
       - **b)** Compared with baseline (prior to initiating Simponi Aria or subcutaneous), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

   Dosing. Approve up to 2 mg/kg as an intravenous infusion at Weeks 0 and 4, then not more frequently than once every 8 weeks thereafter.

2. **Juvenile Idiopathic Arthritis (JIA).** Approve for the duration noted if the patient meets ONE of the following (A or B):

Note: This includes JIA regardless of type of onset, including a patient with juvenile spondyloarthropathy/active sacroiliac arthritis. JIA is also referred to as Juvenile Rheumatoid Arthritis.

A) Initial Therapy. Approve for 6 months if the patient meets the following criteria (i and ii):
- **i.** Patient meets ONE of the following conditions (a or b):
  - **a)** Patient has tried one other medication for this condition; OR
    Note: Examples of other medications for JIA include methotrexate, sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug (NSAID) [e.g., ibuprofen, naproxen]. A previous trial of a biologic other than the requested medication also counts as a trial of one medication. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for JIA.
  - **b)** Patient has aggressive disease, as determined by the prescriber; AND
- **ii.** The medication is prescribed by or in consultation with a rheumatologist; OR

B) Patient is Currently Receiving Simponi Aria or Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
- **i.** Patient has been established on therapy for at least 6 months; AND
  Note: A patient who has received < 6 months of therapy or who is restarting therapy with Simponi Aria or subcutaneous is reviewed under criterion A (Initial Therapy).
- **ii.** Patient meets at least one of the following (a or b):
  - **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Simponi Aria or subcutaneous); OR
    Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
  - **c)** Compared with baseline (prior to initiating Simponi Aria or subcutaneous), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, or improved function or activities of daily living.

Dosing. Approve up to 80 mg/m^2 as an intravenous infusion at Weeks 0 and 4, then not more frequently than once every 8 weeks thereafter.

3. **Psoriatic Arthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist or dermatologist; OR
   - **B)** Patient is Currently Receiving Simponi Aria or Subcutaneous. Approve for 1 year if the patient if the patient meets BOTH of the following (i and ii):
     - **i.** Patient has been established on therapy for at least 6 months; AND
       Note: A patient who has received < 6 months of therapy or who is restarting therapy with Simponi Aria or subcutaneous is reviewed under criterion A (Initial Therapy).
     - **ii.** Patient meets at least one of the following (a or b):
       - **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Simponi Aria or subcutaneous); OR
         Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
       - **b)** Compared with baseline (prior to initiating Simponi Aria or subcutaneous), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.

   Dosing. Approve the following regimens (A or B):
   - **A)** Patient is ≥ 18 years of age: Approve up to 2 mg/kg as an intravenous infusion at Weeks 0 and 4, then not more frequently than once every 8 weeks thereafter; OR
   - **B)** Patient is < 18 years of age: Approve up to 80 mg/m^2 as an intravenous infusion at Weeks 0 and 4, then not more frequently than once every 8 weeks thereafter.

4. **Rheumatoid Arthritis**. Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
     - **i.** Patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months; AND

Note: Examples of conventional synthetic DMARDs include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, sulfasalazine, janus kinase (JAK) inhibitors, and phosphodiesterase-4 (PDE4) inhibitors. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already had a 3-month trial at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for rheumatoid arthritis. A patient who has already tried a biologic for rheumatoid arthritis is not required to "step back" and try a conventional synthetic DMARD.

ii. The medication is prescribed by or in consultation with a rheumatologist; OR

B) Patient is Currently Receiving Simponi Aria or Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on therapy for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with Simponi Aria or subcutaneous is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

a) Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR

Note: Examples of objective measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate or C-reactive protein, Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).

b) Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.

Dosing. Approve up to 2 mg/kg as an intravenous infusion at Weeks 0 and 4, then not more frequently than once every 8 weeks thereafter.

Limitations/Exclusions

Please see link to member coverage documents below:

Line of Business	Link to Member Coverage Documents
Medicare Advantage Plans (Including D-SNP)	https://medicare.chpw.org/ Select the appropriate plan from the "Plans" drop down on the top navigation bar.

Apple Health	https://www.chpw.org/for-members/benefits-and-coverage-imc/
Cascade Select	https://chnwhealthinsurance.chpw.org/member-center/plan-benefits/

Citations & References

CFR	42 CFR § 438.210	
WAC	WAC 284-43-2050	
RCW		
LOB & Contract Citation	☒ **WAHIMC** ☐ **BHSO** ☐ **Wraparound** ☐ **SMAC** ☐ **HH**	IMC Section 11.3: Medical Necessity Determination
	☒ **AHE**	AHE Section 11.3: Medical Necessity Determination
	☒ **MA/DSNP**	P&P supports all LOB requirements
	☒ **CS**	P&P supports all LOB requirements
Other Requirements		
NCQA Elements		
References	1. Ward, M.M., Deodhar, A., Gensler, L.S, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol, 71: 1599-1613. 2. Ramiro S, Nikiphorou E, Sepriano A, et al. ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. Ann Rheum Dis. Published online October 21, 2022:ard-2022-223296. 3. UpToDate, Inc. Clinical manifestations of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. UpToDate [database online]. Waltham, MA. Last updated November 2, 2022. Available at: http://www.uptodate.com/home/index.html.	

	4. UpToDate, Inc. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondloarthritis) in adults. UpToDate [database online]. Waltham, MA. Last updated August 24, 2022. Available at: http://www.uptodate.com/home/index.html. 5. UpToDate, Inc. Treatment of peripheral spondyloarthritis. UpToDate [database online]. Waltham, MA. Last updated March 17, 2022. Available at: http://www.uptodate.com/home/index.html. 6. Yazici H, Pazarli H, Barnes CG, et al. A controlled trial of azathioprine in Behçet's syndrome. N Engl J Med. 1990;322(5):281-5. 7. Arida A, Fragiadaki K, Giavri E, Sfikakis PP. Anti-TNF agents for Behçet's disease: analysis of published data on 369 patients. Semin Arthritis Rheum. 2011;41(1):61-70. 8. Vallet H, Riviere S, Sanna A, et al. Efficacy of anti-TNF alpha in severe and/or refractory Behçet's disease: Multicenter study of 124 patients. J Autoimmun. 2015;62:67-74. 9. Alpsoy, Erkan, Leccese Pietro, et al. Treatment of Behcet's Disease: An Algorithmic Multidisciplinary Approach. Front. Med., April 2021 10. Hatemi G, Christensen R, Bang D, et al2018 update of the EULAR recommendations for the management of Behçet's syndromeAnnals of the Rheumatic Diseases 2018;77:808-818. 11. Adalimumab (Humira) [Prescribing Information] North Chicago, IL; AbbVie Inc., February 2021. 12. Certolizumab (Cimzia) [Prescribing Information] Smyrna, GA. UCB Inc., September 2019. 13. Singh S, Fumery M, Sandborn WJ, et al. Systematic review and network meta-analysis: first- and second-line biologic therapies for moderate-severe Crohn's disease. Aliment Pharmacol Ther. 2018;48(4):394-409. doi:10.1111/apt.14852 14. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018;113(4):481-517. 15. Lamb, Christopher Andrew et al. "British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults." Gut vol. 68,Suppl 3 (2019): s1-s106. doi:10.1136/gutjnl-2019-318484 16. UpToDate, Inc. Overview of the management of Crohn disease in children and adolescents. UpToDate [database online]. Waltham, MA.

Last updated September 14, 2021. Available at: http://www.uptodate.com/home/index.html.
17. van Rheenen PF, Aloi M, Assa A, et al. The Medical Management of Paediatric Crohn's Disease: an ECCO-ESPGHAN Guideline Update [published online ahead of print, 2020 Oct 7]. J Crohns Colitis. 2020;jjaa161. doi:10.1093/ecco-jcc/jjaa161
18. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022
19. Kimball AB, Okun MM, Williams DA, et al. Two Phase 3 Trials of Adalimumab for Hidradenitis Suppurativa. N Engl J Med. 2016;375(5):422-434.
20. Zouboulis CC, Okun MM, Prens EP, et al. Long-term adalimumab efficacy in patients with moderate-to-severe hidradenitis suppurativa/acne inversa: 3-year results of a phase 3 open-label extension study. J Am Acad Dermatol. 2019;80(1):60-69.e2. doi:10.1016/j.jaad.2018.05.040
21. Ingram JR, Collier F, Brown D, et al. British Association of Dermatologists guidelines for the management of hidradenitis suppurativa (acne inversa) 2018. Br J Dermatol. 2019;180(5):1009-1017.
22. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part II: Topical, intralesional, and systemic medical management. J Am Acad Dermatol. 2019;81(1):91-101. doi:10.1016/j.jaad.2019.02.068
23. UpToDate, Inc. Hidradenitis suppurativa: management. UpToDate [database online]. Waltham, MA. Last updated June 30, 2022. Available at: http://www.uptodate.com/home/index.html.
24. Gulliver W, Zouboulis CC, Prens E, Jemec GB, Tzellos T. Evidence-based approach to the treatment of hidradenitis suppurativa/acne inversa, based on the European guidelines for hidradenitis suppurativa. Rev Endocr Metab Disord. 2016;17(3):343-351.
25. Deodhar A, Gensler LS, Kay J, et al. A 52-Week Randomized Placebo-Controlled Trial of Certolizumab Pegol in Non-Radiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019.
26. Sieper J, Van der heijde D, Dougados M, et al. Efficacy and safety of adalimumab in patients with non-radiographic axial spondyloarthritis:

results of a randomised placebo-controlled trial (ABILITY-1). Ann Rheum Dis. 2013;72(6):815-822.
27. Corbett M, Soares M, Jhuti G, et al. Tumour necrosis factor-α inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis: a systematic review and economic evaluation. Health Technol Assess. 2016;20(9):1-vi. doi:10.3310/hta20090.
28. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072.
29. Menter A, Gelfand JM, Connor C et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Amer Academy of Dermol 2020;82:1445-86.
30. Sbidian E, Chaimani A, Afach Sivem et al. Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis. Cochrane Database Syst Rev 2020;1(1):1-602.
31. Lebwohl M, Blauvelt A, Paul C et al. Certolizumab pegol for the treatment of chronic plaque psoriasis: Results through 48 weeks of a phase 3, multicenter, randomized, double-blind, etanercept- and placebo-controlled study (CIMPACT). Acad Dermatol 2018;79(2):266-276.
32. UpToDate, Inc. Psoriasis: Epidemiology, clinical manifestations, and diagnosis. UpToDate [database online]. Waltham, MA. Last updated December 30, 2019. Available at: http://www.uptodate.com/home/index.html.
33. UpToDate, Inc. Spondyloarthritis in children. UpToDate [database online]. Waltham, MA. Last updated December 4, 2020. Available at uptodate.com. Accessed February 4, 2022.
34. Ringold S, Angeles-han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Care Res (Hoboken). 2019.
35. UpToDate, Inc. Polyarticular juvenile idiopathic arthritis: treatment. UpToDate [database online]. Waltham, MA. Last updated October 19, 2020. Available at: http://www.uptodate.com/home/index.html. Last accessed November 22 ,2021.

36. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
37. Kingsley GH, Scott DL. Assessing the effectiveness of synthetic and biologic disease-modifying antirheumatic drugs in psoriatic arthritis - a systematic review. Psoriasis (Auckl). 2015;5:71-81.
38. Mease PJ, Gladman DD, Samad AS, et al. Design and rationale of the Study of Etanercept and Methotrexate in Combination or as Monotherapy in Subjects with Psoriatic Arthritis (SEAM-PsA). RMD Open. 2018;4(1):e000606.
39. UpToDate, Inc. Treatment of psoriatic arthritis. UpToDate [database online]. Waltham, MA. Last updated November 20, 2018. Available at: http://www.uptodate.com/home/index.html.
40. Gossec L, Baraliakos X, Kerschbaumer A, et alEULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 updateAnnals of the Rheumatic Diseases 2020;79:700-712.
41. Fraenkel L, Bathon JM, England BR, et al. 2021 American college of rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Care Res. 2021;73(7):924-939.
42. Alten R, Mischkewitz M. 2021 ACR guideline reflects changes in RA treatment. Nat Rev Rheumatol. 2021;17(9):513-514. doi:10.1038/s41584-021-00667-2
43. UpToDate, Inc. General principles and overview of management of rheumatoid arthritis in adults . UpToDate [database online]. Waltham, MA. Last updated October 18, 2021. Available at: http://www.uptodate.com/home/index.html.
44. Smolen JS, Landewé RBM, Bijlsma JWJ, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. Ann Rheum Dis. 2020;79:685-699.
45. Golimumab (Simponi) [Prescribing Information] Raritan, NJ; Janssen Biotech, Inc. Updated September 2019.
46. Infliximab (Remicade) [Prescribing Information] Raritan, NJ; Janssen Biotech, Inc. Updated May 2020.
47. Ozanimod (Zeposia) [Prescribing Information] New York, NY; Bristol Myers Squibb Inc., Updated May 2021.

48. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol. 2019;114(3):384-413.
49. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020;158(5):1450-1461. doi:10.1053/j.gastro.2020.01.006
50. Paschos P, Katsoula A, Salanti G, et al. Systematic review with network meta-analysis: the impact of medical interventions for moderate-to-severe ulcerative colitis on health-related quality of life. Aliment Pharmacol Ther. 2018 Dec;48(11-12):1174-1185. doi: 10.1111/apt.15005. Epub 2018 Oct 30. PMID: 30378141.
51. Trigo-Vicente C, Gimeno-Ballester V, García-López S, et al. Systematic review and network meta-analysis of treatment for moderate-to-severe ulcerative colitis. Int J Clin Pharm. 2018 Dec;40(6):1411-1419. doi: 10.1007/s11096-018-0743-4. Epub 2018 Nov 26. PMID: 30478492.
52. Turner et al. Management of Paediatric Ulcerative Colitis, Part 1: Ambulatory Care—An Evidence-based Guideline From European Crohn's and Colitis Organization and European Society of Paediatric Gastroenterology, Hepatology and Nutrition, Journal of Pediatric Gastroenterology and Nutrition: August 2018.
53. Nguyen QD, Merrill PT, Jaffe GJ, et al. Adalimumab for prevention of uveitic flare in patients with inactive non-infectious uveitis controlled by corticosteroids (VISUAL II): a multicentre, double-masked, andomized, placebo-controlled phase 3 trial. Lancet. 2016;388(10050):1183-1192.
54. Jaffe GJ, Dick AD, Brézin AP, et al. Adalimumab in Patients with Active Noninfectious Uveitis. N Engl J Med. 2016;375(10):932-943.
55. Dick AD, Rosenbaum JT, Al-dhibi HA, et al. Guidance on Noncorticosteroid Systemic Immunomodulatory Therapy in Noninfectious Uveitis: Fundamentals Of Care for UveitiS (FOCUS) Initiative. Ophthalmology. 2018;125(5):757-773.
56. Ming S, Xie K, He H, Li Y, Lei B. Efficacy and safety of adalimumab in the treatment of non-infectious uveitis: a meta-analysis and systematic review. Drug Des Devel Ther. 2018;12:2005-2016.

Revision History

Revision Date	Revision Description	Revision Made By
03/11/2025	New Policy	Alan Gabot, PharmD
03/12/2025	Approval	UM Criteria Subcommittee
06/18/2025	Early update. Updated number of preferred products for Crohn's disease, plaque psoriasis, psoriatic arthritis, ankylosing spondyliits, polyarticular juvenile idiopathic arthritis, RA, UC.	Alan Gabot, PharmD
06/24/2025	Approval	UM Criteria Subcommittee
08/12/2025	Early update. For Crohn's disease under Medicaid, updated requirements where pediatric patients require use of at least one adalimumab biosimilar and adult patients require the use of two preferred Cytokine and CAM medications (i.e., adalimumab biosimilar, ustekinumab biosimilar) for at least 12 weeks unless contraindicated or not tolerated. For Cascade Select/Medicare criteria, updated wording for criteria for non-preferred products. Updated criteria for Medicare, where patients can take non-preferred products if the patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 days.	Alan Gabot, PharmD
08/13/2025	Approval	UM Criteria Subcommittee
12/11/2025	Early update. **Graft-versus-Host Disease:** For initial approvals, added the requirement that patient has acute graft-versus-host disease. Modified the requirement that patient has tried at least one conventional systemic treatment to at least one systemic medication. Jakafi (ruxolitinib), Simulect (basiliximab), an etanercept product, sirolimus, Nipent (pentostatin), a tocilizumab product, and Entyvio (vedolizumab) were added to the Note of examples of systemic medications. **Immunotherapy-Related Toxicities Associated with Checkpoint**	Alan Gabot, PharmD

	Inhibitor Therapy: "According to the prescriber" was added to the requirement that patient experienced an immunotherapy-related toxicity while receiving a checkpoint inhibitor and specific examples of immunotherapy-related toxicities were removed. Cardiologist, hematologist, nephrologist, and pulmonologist were added as accepted specialists to the specialist requirement.	
03/05/2026	Early Update. For Medicaid, added generic adalimumab-bwwd, Hadlima, Pyzchiva, Taltz, and Orencia as preferred products for their respective covered indications.	Alan Gabot, PharmD
03/06/2026	Approval	UM Criteria Subcommittee

Appendix A. Preferred Biosimilars for Medicaid

Preferred Adalimumab Biosimilars	Generic adalimumab-aaty, generic adalimumab-adbm, generic adalimumab-adaz, generic adalimumab-bwwd, Hadlima
Preferred Ustekinumab Biosimilars	Pyzchiva, Selarsdi, Steqeyma, Yesintek

Appendix B. Preferred/Non-Preferred Infliximab Products for Cascade Select/Medicare

Preferred Infliximab Products	Avsola, Inflectra
Preferred Infliximab Products	infliximab (authorized generic), Remicade, Renflexis