Policy Title:	TNF-Alpha Inhibitors		
Policy Number:	*To be determined*	**Department:**	PHA
Effective Date:	09/13/2017		
Review Date:	09/13/2017		
Revision Date:	09/13/2017		

Purpose: To support appropriate use of TNF-alpha inhibitors; and preferred formulary options.

Scope: Medicaid, Exchange

Policy Statement:

TNF-alpha inhibitors will be when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process. This policy applies to TNF-alpha inhibitor therapies including, but not limited to, the following: Humira, Enbrel.

Procedure:

Coverage of TNF-alpha inhibitors will be reviewed based on criteria below. All formulary options are to be tried and failed for adequate duration prior to treatment with non-formulary options. Formulary options include all strengths, dosage forms and packaging of each Humira and Enbrel. Remicade biosimilars (e.g. Inflectra, Renflexis) are to be used in New Starts to therapy prior to Remicade. All infliximab products are covered under the medical benefit.

Coverage Criteria: see attached supplement.

Investigational use: TNF-alpha inhibitors are considered for investigational use when used at a dose and/or for a condition other than those that are recognized as medically accepted indications as defined in one of the above listed resources. Neighborhood does not provide coverage for drugs when used for investigational purses.

Coverage duration: Coverage may be reviewed annually to confirm medical necessity criteria are met and medication is effective in use.

Additional Information:

Product Availability:

Drug Name	Enbrel	Humira	Cimzia	Simponi	Remicade / Inflectra / Renflexis
Generic Name	etanercept	adalimumab	certolizumab pegol	golimumab	infliximab
Dosage Form	vial, pen injector, syringe	pen injector, syringe	Syringe	vial, pen injector, syringe	vial
Strengths	50mg/ml, 25mg/0.5ml	10mg/0.2ml, 20mg/0.4ml, 40mg/0.8ml	400mg, 400mg/2ml	50mg/0.5ml, 100mg/ml, 50mg/0.5ml, 100mg/ml, 50mg/4ml	100mg
Biosimilar Available	N	N	N	N	Y (Inflectra, Renflexis)
Indications	See table on page 3				
Dosing & Administration	SC (for dosing see table on p. 6)	SC (for dosing see table on p. 6)	SC (for dosing see table on p. 6)	SC or IV (for dosing see table on p. 6)	IV (for dosing see table on p. 6)
Boxed Warnings	Increased risk of serious infections leading to hospitalization or death, including tuberculosis, invasive fungal infections, bacterial, viral, and other infections due to opportunistic pathogens including Legionella and Listeria. Lymphoma and other malignancies have been reported in children and adolescent patients treated with TNF blockers. Post-marketing cases of hepatosplenic T-cell lymphoma have been reported in patients treated with TNF-blockers.				
Warnings - additional	Do not use live or live-attenuated vaccines concurrently. Use with other TNF blockers is not recommended. Do not initiate in patients with an active infection				
Contraindications	Enbrel should not be administered to patients with sepsis.	None			Doses > 5 mg/kg should not be administered to patients with moderate to severe heart failure.

FDA-approved Indications:

	Enbrel	Humira	Cimzia	Simponi	Remicade	Inflectra	Renflexis
Moderately to severely active RA	X	X*	X	X	X	X	X
Moderately to severely active polyarticular juvenile idiopathic arthritis (JIA)		X (≥ 2 yrs)					
Juvenile rheumatoid arthritis (JRA)/juvenile idiopathic arthritis (JIA)	X (≥ 2 yrs)						
Active Psoriatic Arthritis (PsA) in adults	X	X*	X	X	X	X	X
Active ankylosing spondylitis (AS) in adults	X	X	X	X	X	X	X
Chronic moderate to severe plaque psoriasis (PsO)	X (≥ 4 yrs)	X			X	X	X
Moderately to severely active Crohn's disease		X (≥ 6 yrs)	X (≥ 18 yrs)		X (≥ 6 yrs)	X (≥ 6 yrs)	X (≥ 6 yrs)
Moderately to severely active ulcerative colitis (UC) in adults		X		X	X	X	X
Moderate to severe hidradenitis suppurativa (HS)		X					
Non-infectious intermediate, posterior, and panuveitis in adults		X					
*May be used in addition to other non-biologic DMARDs							

Drug Name	Dosing Schedule
Enbrel	• Adult RA, AS, and PsA: 50 mg weekly

Drug Name	Dosing Schedule

	• Adult PsO:
	  ○ Starting Dose: 50 mg twice weekly for 3 months
	  ○ Maintenance Dose: 50 mg once weekly
	• Pediatric PsO or JIA:
	  ○ Weight > 63 kg: 50 mg weekly
	  ○ Weight < 63 kg: 0.8 mg/kg weekly

Humira	• Adult RA, AS, and PsA: 40 mg every other week
	• Adult CD and UC:
	  ○ 160 mg on day 1 followed by 80 mg two weeks later; maintenance dose starting on day 29 of 40 mg every other week
	• Adult PsO and uveitis: 80 mg on day 1 followed by a maintenance dose of 40 mg every other week starting on day 7
	• Adult HS: 160 mg on day 1 followed by 80 mg two weeks later; maintenance dose starting on day 29 of 40 mg weekly
	• Pediatric JIA:
	  ○ Weight 10-14 kg: 10 mg every other week
	  ○ Weight 15-29 kg: 20 mg every other week
	  ○ Weight > 30 kg: 40 mg every other week
	• Pediatric CD:
	  ○ Weight 17-39 kg: 80 mg on day 1 followed by 40 mg two weeks later; maintenance dose starting on day 29 of 20 mg every other week
	  ○ Weight > 40 kg: 160 mg on day 1 followed by 80 mg two weeks later; maintenance dose starting on day 29 of 40 mg every other week

Cimzia	• RA, PsA, AS: Initial dose = two 200 mg injections at weeks 2 and 4; Maintenance dose = 200 mg every other week or 400 mg every 4 weeks • CD: Initial dose = two 200 mg injections at weeks 2 and 4; Maintenance dose = 400 mg every 4 weeks
Simponi	• 2 mg/kg as an IV infusion over 30 minutes at weeks 0 and 4, then every 8 weeks thereafter. • Simponi® should be given in combination with methotrexate.
Remicade Inflectra Renflexis	• CD, UC, PsA, PsO: 5 mg/kg given as an IV infusion at weeks 0, 2, and 6, followed by an every 8 week maintenance regimen. Adult patients with loss of response may receive 10 mg/kg doses. • RA: 3 mg/kg given as an IV infusion at weeks 0, 2, and 6, followed by an every 8 week maintenance regimen; in combination with methotrexate. For patients with an incomplete response, consideration may be given to increasing the dose to 10 mg/kg or treating as often as every 4 weeks. • AS: 5 mg/kg given as an IV infusion at weeks 0, 2, and 6, followed by an every 6 week maintenance regimen

Clinical Evidence:

American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis, 2015: Disease activity is categorized as remission, low, moderate, or high as per validated scales (Patient Activity Scale [PAS or PASII], Routine Assessment of Patient Index Data 3 [RAPID3], Clinical Disease Activity Index [CDAI], Disease Activity Score [DAS], and Simplified Disease Activity Index [SDAI]). The guidelines do not provide recommendations for individual medications (except for patients with previous malignancies) or for use of biosimilars. Authors did not discuss biosimilars due to too little evidence, however, they have provided a position statement saying "…safe and effective treatments should be available to patients at the lowest possible cost…"

Recommendations for the treatment of patients with early RA:

- If disease activity is low, use DMARD monotherapy.
- If disease activity remains moderate or high despite DMARD monotherapy, use combination DMARDs or a TNFi or a non-TNF biologic (with or without methotrexate).

Recommendations for the treatment of patients with established RA:

- If disease activity is low use DMARD monotherapy over a TNFi.
- If disease activity remains moderate or high despite DMARD monotherapy, use combination traditional DMARDs or add a TNFi or a non-TNF biologic or tofacitinib (with or without methotrexate).
- If disease activity remains moderate or high despite TNFi therapy in patients who are currently not on DMARDs, add on or two DMARDs to TNFi therapy rather than continuing TNFi therapy alone.
- If the patient's disease is in remission, do not discontinue all RA therapies.

Recommendations in RA patients with high-risk comorbidities:

- For patients with congestive heart failure: use combination DMARDs or non-TNF biologic or tofacitinib over TNFi therapy.
- For patients with hepatitis C infection no receiving antiviral treatment: Use DMARDs over TNFi therapy.
- For patients with past history of malignancy: TNF inhibitors are not recommended.
- For patients with previous serious infections: TNF inhibitors should not be considered first line.

2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: (guidelines were created prior to market entry of Inflectra.)

Recommendations for the treatment of adults with active AS:

- Strongly recommend:
    - Treatment with NSAIDs over no treatment with NSAIDs.
    - Treatment with TNFi over no treatment with TNFi.
    - Treatment with TNFi monoclonal antibodies over treatment with etanercept in patients with AS and inflammatory bowel disease.
    - Against treatment with systemic glucocorticoids
- A particular TNFi is not recommended as the preferred choice except for patients with concomitant inflammatory bowel disease or recurrent iritis in which case infliximab or adalimumab are preferred over etanercept.
- In adults with active nonradiographic axial spondylarthritis despite treatment with NSAIDs, treatment with TNFi is conditionally recommended.

- In active AS despite treatment with the first TNFi used, treatment with a different TNFi is recommended over adding a slow-acting anti-rheumatic drug (e.g. azathioprine, methotrexate) or a non-TNFi biologic agent.
- In patients with stable AS receiving treatment with TNFi and NSAIDs, continuing treatment with TNFi alone is recommended over continuing both treatments.
- In patients with stable AS receiving treatment with TNFi and slow-acting antirheumatic drugs, continuing treatment with TNFi alone is recommended over continuing both treatments.

American Gastroenterological Association Institute Guideline on the use of thiopurines, methotrexate, and anti-TNF-alpha biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease, 2013: (guidelines were created prior to market entry of Simponi and Inflectra.)

Recommendations for induction of remission:

- Thiopurine monotherapy is not recommended to induce remission in patients with moderately severe CD due to their delayed onset of action.
- In patients with moderately severe CD, TNFi monotherapy is not recommended to induce remission, however it would be preferred over thiopurine monotherapy.
- The combination of a TNFi and thiopurine is recommended over using either therapy alone.

Recommendations for maintenance of remission:

- For maintenance of corticosteroid-induced remission, TNFi, thiopurines, or methotrexate may be considered.
- For maintenance of TNFi-induced remission, TNFi therapy should be continued.
- There is conflicting data on the use of combined TNFi and thiopurine maintenance therapy. Combination therapy is associated with an increased risk of lymphoma. The panel does not make a recommendation for or against combination maintenance therapy.

An Evidence-Based Systematic Review on Medical Therapies for Inflammatory Bowel Disease, 2011: (systematic review was conducted prior to market entry of Simponi and Inflectra.) The American College of Gastroenterology IBD Task Force reviewed literature for CD and UC medical therapies to assess the relative efficacy of the various therapies. Regarding the efficacy and safety of biological therapies, the authors focused on randomized, controlled trials. Overall, there were no statistically significant differences in adverse events between the biologic therapies. Major findings for UC: infliximab is effective at inducing remission/improving symptoms in hospitalized patients – there is not enough data available to recommend biological therapy for maintenance. Major findings for CD: TNFi (infliximab, adalimumab, and certolizumab pegol) and natalizumab are effective in inducing remission; TNFi and natalizumab are effective in fistulizing CD and preventing relapse.

Biologics or tofacitinib for rheumatoid arthritis in incomplete responders to methotrexate or other traditional disease modifying anti-rheumatic drugs: a systematic review and network meta-analysis, 2016: Due to a lack of head-to-head trials, this review aims to summarize all evidence to date. The authors focus on 9 biologics (abatacept, adalimumab, anakinra, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab) and tofacitinib versus traditional treatments such as methotrexate and conventional DMARDs or combination therapy in patients with RA who did not improve with MTX or other DMARDs. Patients were considered inadequate responders due to lack of efficacy, adverse events, patient preference, etc. Authors searched the

Cochrane register, MEDLINE, and EMBASE up to June 2015 and selected a total of 90 randomized, controlled trials (n=32,874). Based on evidence, combination therapy with a biologic + MTX/DMARD was associated with improvement in signs and symptoms of RA (tender or swollen joints), function, chances of remission, and reduced progression (as seen on X-ray). Results for withdrawals due to adverse events and increased risk for malignancy were inconclusive. Combination therapy was associated with an increased risk of serious adverse events.

Efficacy and safety of CT-P13 (biosimilar infliximab) in patients with rheumatoid arthritis: comparison between switching from reference infliximab to CT-P13 and continuing CT-P13 in the PLANETRA extension study: Inflectra is the first monoclonal antibody biosimilar to be approved in the U.S. for use in all indications held by infliximab (Remicade). This open-label extension trial studied the efficacy and safety of switching from infliximab to the biosimilar. Patients were eligible for this study if they completed the 54-week, randomized, parallel-group study comparing Inflectra with Remicade. Overall, 302 patients enrolled and all patients received concomitant methotrexate. There were 158 patients who remained on Inflectra (maintenance group) and 144 patients who switched from Remicade to Inflectra (switch group). Endpoints included: American College of Cardiology 20% response (ACR20), 50% response (ACR50) and 70% response (ACR70), immunogenicity, and safety. ACR20 response rates (week 102) for maintenance and switch groups were, 71.7% vs 71.8%, respectively; ACR50 response rates were 48.0% vs 51.4%, respectively; ACR70 response rates were 24.3% vs 26.1%. The proportion of patients with antidrug antibodies was 40.3% vs 44.8%, respectively. Results of other subjective and objective efficacy metrics did not differ between groups. Treatment-emergent adverse events were similar between both groups (53.5% vs 53.8%, respectively). The biosimilar for infliximab, Inflectra, shows comparable efficacy and tolerability in patients who switched from Remicade and in those who were maintained on Inflectra treatment for 2 years.

References:

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SUPPLEMENT: COVERAGE CRITERIA

Crohn's Disease

CRITERIA FOR INTIATION OF THERAPY:

- The member is (≥6y/o) and has a documented clinical diagnosis of moderate to severely active Crohn's disease.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates and doses) at therapeutic doses or has a documented clinically significant medical reason for not receiving conventional oral therapy (e.g. azathioprine, corticosteroids, 6-mercaptopurine) to manage their medical condition.
- Documentation was submitted indicating that the member was evaluated for active or latent TB infection (i.e. tuberculin skin test) as indicated in package insert.
- The medication requested has an FDA approved indication for use in patients with moderate to severe active Crohn's disease and is being recommended and prescribed by a gastroenterologist at an FDA-approved dosage

If all of the above conditions are met, the request will be approved for up to a 6-month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

CRITERIA FOR CONTINUED COVERAGE:

- The medication is being recommended and prescribed by a gastroenterologist for an FDA-approved indication at an FDA-approved dosage.
- For members who require Humira 40 mg SC weekly, documentation must be submitted indicating that the member was compliant (consistent with pharmacy claims) with receiving at least 16 weeks of continuous Humira therapy every other week prior to the request for weekly dosing of Humira.

If all of the above conditions are met, the request will be approved for a 12 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/Clinical reviewer for medical necessity review.

NOTE: Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Revision/Review Date: 6/2017

Ulcerative Colitis

PREFERRED STATUS: Preferred Biological Agents- Require Prior Authorization
HUMIRA® (adalimumab)
INFLECTRA (infliximab-dyyb) (Medical Benefit)

CRITERIA FOR INTIATION OF THERAPY:

- The patient is (≥6 y/o) and has moderate to severe active ulcerative colitis.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) treatment failure after receiving an adequate trial of:
    - Sulfasalazine (3 to 6 g/day for 3 months), or mesalamine (1.2 to 2.4 g/day for 3 months), or azathioprine (2 to 2.5 mg/kg/day), or 6-mercaptopurine (1.5 to 2 mg/kg/day), or oral corticosteroids or has a documented medical reason (GI intolerance, hypersensitivity, etc.) for not taking any of these medications to treat their medical condition.
- Documentation was submitted indicating that the member was evaluated for active or latent TB infection (i.e. tuberculin skin test) as indicated in package insert.
- The medication requested has a FDA approved indication for use in patients with moderate to severe active ulcerative colitis and is being prescribed at an FDA-approved dosage and is recommended or prescribed by a gastroenterologist.

If all of the above conditions are met, the request will be approved for up to a 6-month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

CRITERIA FOR CONTINUED COVERAGE:

- The medication is being recommended and prescribed by a gastroenterologist for an FDA-approved indication at an FDA-approved dosage.
- The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy.
- Documentation submitted indicates that the member has obtained clinical benefit from the medication.

If all of the above conditions are met, the request will be approved for a 12 month; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

NOTE: Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Revision/Review Date: 6/2017

Psoriasis

CRITERIA FOR INTIATION OF THERAPY:

- The member is appropriate age per label and has a documented clinical diagnosis of moderate to severe plaque psoriasis.
- Documentation that the patient has had (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trials (including dates and doses) of at least 3 of the treatment bullet points listed below:
    - The use of topical steroids or has a documented medical reason for not using this therapy to manage their medical condition.
    - The use of a topical medication [i.e. Dovonex® (calcipotriene), Tazorac® (tazorotene), anthralin or a coal tar preparation] that is indicated for the treatment of psoriasis or has a documented medical reason for not using any of these therapies to manage their medical condition.
    - The use of methotrexate or has a documented medical reason (e.g. history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism) for not using this therapy to manage their medical condition.
    - The use of cyclosporine or has a documented medical reason for not using this therapy to manage their medical condition.
    - The use of Soriatane® (acitretin) or has a documented medical reason for not using this therapy to manage their medical condition.
    - The use of UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) or has a documented medical reason (e.g. pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g. systemic lupus erythematus, cataracts) for not undergoing UVB phototherapy or PUVA to manage their medical condition.
- Documentation was submitted indicating that the member was evaluated for active or latent TB infection (i.e. tuberculin skin test) as indicated in the package insert.
- The medication requested has an FDA approved indication for use in patients with moderate to severe plaque psoriasis and is being recommended or prescribed by a dermatologist at an FDA-approved dosage.

If all of the above conditions are met, the request will be approved for up to a 6 month duration. If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

CRITERIA FOR CONTINUED COVERAGE:

- The medication is being recommended and prescribed by a dermatologist at an FDA-approved dosage.
- The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy.
- Documentation submitted indicates that the member has obtained clinical benefit from the medication.

If all of the above conditions are met, the request will be approved for a 12 month duration. If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.
NOTE: Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.
Revision/Review Date: 6/2017

Polyarticular Juvenile Idiopathic Arthritis

CRITERIA FOR INTIATION OF THERAPY:

- The patient is a child (< 17 y/o), within the FDA approved age range for the medication requested, and has a documented clinical diagnosis of juvenile idiopathic arthritis.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates and doses) of 2 months or more of therapy with at least one disease-modifying anti-rheumatic drug (DMARD) (e.g. methotrexate), or has a documented medical reason (e.g. intolerance, hypersensitivity) for not utilizing any of these therapies to manage their medical condition.
- Documentation was submitted indicating that the member was evaluated for active or latent TB infection (i.e. tuberculin skin test) as indicated in package insert.
- The medication requested has an FDA approved indication for use in patients with juvenile idiopathic arthritis and is being recommended and prescribed by a rheumatologist or pediatric rheumatologist at an FDA-approved dosage.

If all of the above conditions are met, the request will be approved for up to a 6 -month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

CRITERIA FOR CONTINUED COVERAGE:

- The medication is being recommended and prescribed by a rheumatologist or pediatric rheumatologist at an FDA-approved dosage.
- The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy.
- Documentation submitted indicates that the member has obtained clinical benefit from the medication.

If all of the above conditions are met, the request will be approved for a 12 month duration. If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

NOTE: Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.
Revision/Review Date: 6/2017

Systemic Juvenile Idiopathic Arthritis

CRITERIA FOR INTIATION OF THERAPY:

- The patient is a child (≤ 17 y/o), within the FDA approved age range for the medication requested, and has a documented clinical diagnosis of systemic juvenile idiopathic arthritis.
- Documentation was submitted indicating that the member was evaluated for active or latent TB infection (i.e. tuberculin skin test) as indicated in the package insert.
- The medication requested has an FDA approved indication for use in patients with systemic juvenile idiopathic arthritis and is being recommended and prescribed by a rheumatologist or a pediatric rheumatologist at an FDA- approved dosage.

If all of the above conditions are met, the request will be approved for a 6-month duration. If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

CRITERIA FOR CONTINUED COVERAGE:

- The medication is being recommended and prescribed by a rheumatologist or pediatric rheumatologist at an FDA-approved dosage.
- The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy.
- Documentation submitted indicates that the member has obtained clinical benefit from the medication.

If all of the above conditions are met, the request will be approved for a 12 month duration. If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

NOTE: Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Revision/Review Date: 6/2017

Rheumatoid Arthritis

CRITERIA FOR INTIATION OF THERAPY:

- The patient is an adult (≥18 y/o) and has a documented clinical diagnosis of rheumatoid arthritis.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates and doses) of 3 months or more of therapy with methotrexate AND then leflunomide (generic Arava®) or another disease-modifying antirheumatic drug (DMARD) option (i.e. combination therapy consisting of methotrexate + sulfasalazine or hydroxychloroquine) or has a documented medical reason (e.g. intolerance, hypersensitivity) for not utilizing any of these therapies to manage their medical condition.
- Documentation was submitted indicating that the member was evaluated for active or latent TB infection (i.e. tuberculin skin test) as indicated in package insert.
- The medication requested has an FDA approved indication for use in patients with rheumatoid arthritis and is being recommended and prescribed by a rheumatologist at an FDA-approved dosage.

If all of the above conditions are met, the request will be approved for up to a 6-month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

CRITERIA FOR CONTINUED COVERAGE:

- The member has been receiving the medication and documentation was provided that a rheumatologist has evaluated the member and recommends continuation of therapy.
- Documentation submitted indicates that the member has obtained clinical benefit from the medication.
- For members who require Humira 40 mg SC weekly documentation must be submitted indicating that the member was compliant (consistent with pharmacy claims) with receiving at least 16 weeks of continuous Humira therapy every other week prior to the request for weekly dosing of Humira AND the member has a medical reason (e.g. intolerance, hypersensitivity, contraindication) for not receiving concomitant methotrexate.
- The medication is being prescribed for an FDA-approved indication at an FDA-approved dosage.

If all of the above conditions are met, the request will be approved for a 12 month duration. if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

NOTE: Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Revision/Review Date: 6/2017

Ankylosing Spondylitis

CRITERIA FOR INTIATION OF THERAPY:

- The patient is an adult (≥18 y/o) and has documented ankylosing spondylitis.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial of or has a documented medical reason for not taking at least two nonsteroidal anti-inflammatory drugs (NSAIDS) to manage their medical condition.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial of or has a documented medical reason for not taking a cyclo-oxygenase (COX)-2-selective inhibitors to manage their medical condition.
- Documentation was submitted indicating that the member was evaluated for active or latent TB infection (i.e. tuberculin skin test) as indicated in package insert.
- The medication requested has an FDA approved indication for use in patients with ankylosing spondylitis and is being recommended and prescribed by a rheumatologist at an FDA approved dosage.

If all of the above conditions are met, the request will be approved for up to a 6-month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

CRITERIA FOR CONTINUED COVERAGE:

- The medication is being recommended and prescribed by a rheumatologist at an FDA-approved dosage.
- The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy.
- Documentation submitted indicates that the member has obtained clinical benefit from the medication.

If all of the above conditions are met, the request will be approved for a 12 month. If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.
NOTE: Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.
Revision/Review Date: 6/2017

Psoriatic Arthritis (PsA)

CRITERIA FOR INTIATION OF THERAPY:

- The patient is an adult (≥18 y/o) and has documented psoriatic arthritis.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial of 2 g/day for 3 months of sulfasalazine or has a documented medical reason for not taking sulfasalazine (e.g. predominantly axial symptoms, hepatotoxicity, GI intolerance) to manage their medical condition.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (3 months without any improvement at maximum doses) of methotrexate or has another documented medical reason for not taking methotrexate (e.g. predominantly axial symptoms, liver toxicity) to manage their medical condition.
- Documentation was submitted indicating that the member was evaluated for active or latent TB infection (i.e. tuberculin skin test), as indicated in the package insert.
- The medication requested has a FDA approved indication for use in patients with psoriatic arthritis and is being recommended and prescribed by a rheumatologist or a dermatologist at an FDA-approved dosage.

If all of the above conditions are met, the request will be approved for up to a 6-month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

CRITERIA FOR CONTINUED COVERAGE:

- The medication is being recommended and prescribed by a rheumatologist or dermatologist at an FDA-approved dosage.
- The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy.
- Documentation submitted indicates that the member has obtained clinical benefit from the medication.

If all of the above conditions are met, the request will be approved for a 12 month duration. If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.
NOTE: Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.
Revision/Review Date 6/2017

FDA (if no indication specific criteria) and NON-FDA Approved Medically Accepted Indications

CRITERIA FOR INTIATION OF THERAPY FOR OTHER FDA or NON-FDA APPROVED MEDICALLY ACCEPTED INDICATIONS:

- The medication is prescribed for a non-FDA approved indication that is considered a medically accepted use of the medication per the medical compendia (i.e. Micromedex, DrugPoints, AHFS drug information) as defined by the Social Security Act.
- The medication is prescribed at a medically accepted dose per the medical compendia as defined by the Social Security Act.
- The medication is recommended and prescribed by a specialist in the field to treat the member's respective medical condition.
- Documentation was submitted indicating that the member has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates, doses of medications) of all first line medical therapies as recommended by the medical compendia and standard of care guidelines or has another documented medical reason (e.g. intolerance, contraindications) for not receiving or trying all first line medical treatment(s).
- Documentation was submitted indicating that the member was evaluated for active or latent TB infection (i.e. tuberculin skin test) as indicated in package insert.

If all of the above conditions are met, the request will be approved for up to a 6 month duration. If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

CRITERIA FOR CONTINUED COVERAGE FOR OTHER NON-FDA APPROVED MEDICALLY ACCEPTED INDICATIONS:

- The medication is prescribed at a medically accepted dose per the medical compendia as defined by the Social Security Act.
- The medication is recommended and prescribed by a specialist in the field to treat the member's respective medical condition.
- Documentation submitted indicates that the member has obtained clinical benefit from the medication.

If all of the above conditions are met, the request will be approved for a 6-month duration. If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

NOTE: Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Revision/Review Date: 6/2017