Non- Formulary biologic DMARDs for RA, PsA, AS and JIA

Actemra (tocilizumab)

1. Is the patient being treated for an OHP funded condition?
   a) Yes- Go to question 2
   b) No- Cat 1 denial- Not a covered benefit- Provider submitted diagnosis not for OHP funded condition

2. Is the medication prescribed by, or in consultation with, a rheumatologist?

   a) Yes-go to question 3
   b) No-*Cat 5 denial- All persons with a current rheumatological condition requiring biologic DMARD therapy should be linked to a provider able to provide comprehensive management to reduce risk of adverse outcomes*.

3. Does the member have any of the following exclusions or precautions:

   a) Active infection or history of recurring infection
   b) Pregnant or breastfeeding
   c) Multiple sclerosis
   d) Active malignancy
   e) Concurrent use of another biologic DMARD
   f) ANC less than 2,000 /mm^3
   g) Platelets less than 100,000/mm^3
   h) Uncontrolled or severe hyperlipidemia
   i) History of diverticulitis or GI perforation
   j) Active hepatic disease

   i) Yes- Forward to Medical director for medical appropriateness evaluation
   ii) No- Move to question 4

Rheumatoid Arthritis-Actemra

4. Does the member have diagnosis of rheumatoid arthritis and is 18 or over?
   a) Yes- go to question 5
   b) No- go to question 9

5. Does the member have documentation of moderate to severe disease documented in chart notes within the last 6 months?

- Lab tests confirming RA diagnosis- anti-CCP, RF, CRP, ESR
  AND
- Disease activity evaluated by one of the following-

  - Disease Activity Score for 28 joints (DAS-28) greater than 3.2
  - Simplified Disease Activity Index (SDAI) greater than 11
  - Clinical Disease Activity Index (CDAI) greater than 10

   a) Yes- go to question 6
   b) No- Forward to Medical Director for medical appropriateness evaluation

6. Has the member had inadequate response or contraindication to a minimum of 8 week trial of first line DMARD methotrexate?
   AND
   An inadequate response or contraindication to a minimum 12 week trial of combination (triple) therapy with 3 of the first line DMARDs (methotrexate, sulfasalazine, hydroxychloroquine and/or leflunomide) – with 80 % adherence to therapy or better?
   a) Yes- go to question 7
   b) No- Deny- Cat 5- *Provider submitted documentation does not indicate that member has had inadequate response or has a contraindication to preferred treatment alternatives with demonstrated patient compliance to therapy.*

7. Has member had inadequate response to therapy with TWO formulary TNF inhibitors (Enbrel, Humira, Remicade) combined with non- biologic DMARD for a minimum of 12 weeks trial each and 80% or better adherence to therapy?
   a) Yes –go to question 8
   b) No- Deny Cat 15- *Provider submitted documentation does not indicate that member has had inadequate response to formulary biologic DMARD therapy with demonstrated patient compliance to therapy.*

8. Is dosing appropriate for condition and within FDA guidelines?
   -Note SQ administration is approved for RA only-
   a) Yes- Approve
   IV q 4 weeks- total of 6 doses over 24 weeks
   SQ – Approve for 12 week trial
   b) No-Deny Category 3: *Not a covered benefit. The requested medication dosing is outside the approved dosing established in the FDA approved medication package insert, and therefore safety and efficacy cannot be established*

Renewal Criteria- Actemra

Has member experienced documented improvement in function and reduction in symptoms? (Reduction in swollen joint count, improvement in score of disease assessment) and demonstrated 80% or better compliance to therapy?

AND

Documentation of laboratory monitoring of neutrophils, platelets, liver enzymes and lipids?

a. Yes- Approve for 12 months
b. No- Forward to Medical Director for evaluation

Juvenile Idiopathic Arthritis- Actemra

9. Is member over age 2 with diagnosis of Juvenile Idiopathic Arthritis?

   a) Yes- go to question 10
   b) No- Deny Cat 3- *Actemra is only FDA approved for use in adults with RA and JIA in patients ages 2 and older*

10. Does the member have moderate to severe disease as documented by physician global assessment and active joint count?
   a) Yes- go to question 11
   b) No- Forward to Medical Director for medical appropriateness evaluation

11. Has the member had inadequate response or contraindications to **ALL** of the following:

- 12 week trial of methotrexate with 80% or better adherence
- Trial of oral corticosteroids and /or glucocorticoid joint injection (if fewer than 4 joints affected)
- **Not required in cases of severe systemic JIA**

a) Yes- continue to question 12

b) No-- Deny Cat 5- - *Provider submitted documentation does not indicate that member has had inadequate response or has a contraindication to preferred treatment alternatives with demonstrated patient compliance*

12. Has the member had inadequate response to 2 formulary TNF inhibitors (Humira, Enbrel or Remicade) combined with non-biologic DMARD following minimum 12 week trials (each) with better than 80% adherence?

** Not required in cases of severe systemic JIA**

a) Yes- continue to question 18

b) No- Deny- Cat 15- *Not a covered benefit- Provider submitted documentation does not indicate that the patient has tried and failed formulary biologic DMARD alternatives etanercept (Enbrel), infliximab (Remicade) or adalimumab (Humira)*

13. Is dosing appropriate for condition and within FDA guidelines?

-Note SQ administration is approved for RA only-

a) Yes- Approve

IV q 4 weeks- total of 6 doses over 24 weeks

b) No-Deny Category 3: *Not a covered benefit. The requested medication dosing is outside the approved dosing established in the FDA approved medication package insert, and therefore safety and efficacy cannot be established*

Renewal Criteria- Actemra

Has member experienced improvement in tender and swollen joint count and is there improvement in functional ability with 80 % or better adherence to therapy?

a) Yes- approve for 1 year

b) No- Forward to Medical Director for evaluation

Orencia (abatacept)

1) Is the patient being treated for an OHP funded condition?
- **a.** Yes- go to question 2
- b. No- Category 1 denial- Not a covered benefit- Provider submitted diagnosis not for OHP funded condition

2) Is the medication prescribed by, or in consultation with, a rheumatologist?
- **a.** Yes- go to question 3
- **b.** No- *Cat 5 denial- All persons with a current rheumatological condition requiring biologic DMARD therapy should be linked to a provider able to provide comprehensive management to reduce risk of adverse outcomes*

3) Does the member have any of the following exclusions or precautions:
- **a.** Active infection or history of recurrent infections
- **b.** Pregnant or breastfeeding
- **c.** Active malignancy
- **d.** Concurrent use of another biologic DMARD
- **e.** History of COPD

i) Yes- Forward to Medical director for medical appropriateness evaluation
ii) No- Move to question 4

Rheumatoid Arthritis- Orencia

4) Does the member have diagnosis of rheumatoid arthritis and is 18 or over?
- a. Yes- go to question 5
- b. No- go to question 10

5) Does the member have documentation of moderate to severe disease documented in chart notes within the last 6 months?

❖ Lab tests confirming RA diagnosis- anti-CCP, RF, CRP, ESR
AND
❖ Disease activity evaluated by one of the following-
- ➢ Disease Activity Score for 28 joints (DAS-28) greater than 3.2
- ➢ Simplified Disease Activity Index (SDAI) greater than 11
- ➢ Clinical Disease Activity Index (CDAI) greater than 10

- **a.** Yes- go to question 6
- **b.** No- Forward to Medical Director for evaluation

6) Has the member had inadequate response or contraindication to a minimum of 8 week trial of first line DMARD methotrexate?

AND

An inadequate response or contraindication to a minimum 12 week trial of triple combination therapy with 3 of the first line DMARDs (methotrexate, sulfasalazine, hydroxychloroquine and/or leflunomide) – All trials with 80% adherence to therapy or better –

- **a.** Yes- go to question 7
- **b.** No- Deny- Cat 5-
- **c.** *Provider submitted documentation does not indicate that member has had inadequate response or has a contraindication to preferred treatment alternatives with demonstrated patient compliance to therapy.*

7) Has member had inadequate response to therapy with TWO formulary TNF inhibitors (Enbrel, Humira, Remicade) combined with non-biologic DMARD for a minimum of 12 week trial for each and 80% or better adherence to therapy?

- **a.** Yes –go to question 8
- **b.** No- Deny Cat 15- *Provider submitted documentation does not indicate that member has had inadequate response to formulary biologic DMARD therapy with demonstrated patient compliance to therapy.*

8) Is abatacept being prescribed in combination with MTX or another non- biologic DMARD?

- **a.** Yes- go to question 9
- **b.** No- Forward to Medical Director for evaluation- Abatacept is usually given with MTX or another non – biologic DMARD to enhance potency

9) Is dosing appropriate for condition and within FDA guidelines?

- **a.** Yes- Approve for 12 week trial
- **b.** No- Deny- Cat 3- *Not a covered benefit. The requested medication dosing is outside the approved dosing established in the FDA approved medication package insert, and therefore safety and efficacy cannot be established*

Renewal Criteria- Orencia

Has member experienced documented improvement in function and reduction in symptoms? (Reduction in swollen joint count, improvement in score of disease assessment) with 80% or better adherence to Orencia AND non-biologic DMARD therapy?

a. Yes- Approve for 12 months
b. No- Forward to Medical director for evaluation

Juvenile Arthritis- Orencia

10) Is member 6 years of age or older with diagnosis of Juvenile Idiopathic Arthritis?
a. Yes- go to question 11
b. No- Deny Cat 3- Orencia is only FDA approved for use in adults with RA and JIA in patients ages 6 and older

11) Does the member have moderate to severe disease as documented by physician global assessment and active joint count?

a. Yes- go to question 12
b. No- Forward to Medical Director for medical appropriateness evaluation

12) Has the member had inadequate response or contraindications to ALL of the following:
- 12 week trial of methotrexate with 80% or better adherence
- Trial of oral corticosteroids and /or glucocorticoid joint injection (if fewer than 4 joints affected)
  a. Yes- continue to question 13
  b. No-- Deny Cat 5- - *Provider submitted documentation does not indicate that member has had inadequate response or has a contraindication to preferred treatment alternatives with demonstrated patient compliance*

13) Has the member had inadequate response to 2 formulary TNF inhibitors (Humira, Enbrel or Remicade) combined with non- biologic DMARD therapy following a minimum of 12 week trial each with better than 80% adherence?
a. Yes- continue to question 14
b. No- Deny- Cat 15- *Not a covered benefit- Provider submitted documentation does not indicate that the patient has tried and failed formulary biologic DMARD alternatives etanercept (Enbrel), infliximab (Remicade) or adalimumab (Humira)*

14) Is abatacept being prescribed in combination with MTX or another non- biologic DMARD?

- **a.** Yes- go to question 9
- **b.** No- Forward to Medical Director for evaluation- Abatacept is usually given with MTX or another non – biologic DMARD to enhance potency

15) Is dosing appropriate for condition and within FDA guidelines?

- **a.** Yes- Approve for 12 week trial
- **b.** No- Deny- Cat 3- *Not a covered benefit. The requested medication dosing is outside the approved dosing established in the FDA approved medication package insert, and therefore safety and efficacy cannot be established*

Renewal Criteria- Orencia

Has member experienced documented improvement in function and reduction in symptoms? (Reduction in swollen joint count, improvement in score of disease assessment) while demonstrating 80 % or better adherence to Orencia (Abatacept) and concurrent non-biologic DMARD therapy?

- **a.** Yes- Approve for 12 months
- **b.** No- Forward to Medical director for evaluation

Kineret (Anakinra)

1. Is the patient being treated for an OHP funded condition?
    a. Yes- go to question 2
    b. No- Category 1 denial- Not a covered benefit- Provider submitted diagnosis not for OHP funded condition

2. Is the medication prescribed by, or in consultation with, a rheumatologist?
    a. Yes- go to question 3
    b. No- *Cat 5 denial- All persons with a current rheumatological condition requiring biologic DMARD therapy should be linked to a provider able to provide comprehensive management to reduce risk of adverse outcomes*

3. Does the member have any of the following exclusions or precautions:
    a. Active infection or history of recurrent infections
    b. Pregnant or breastfeeding
    c. Active malignancy
    d. Concurrent use of another biologic DMARD
    e. Neutropenia

        i. Yes- Forward to Medical Director for evaluation
        ii. No- Move to question 4

Rheumatoid Arthritis- Kineret

4. Does the member have diagnosis of rheumatoid arthritis and is 18 or over?
    a. Yes- go to question 5
    b. No- go to question 8
5. Does the member have documentation of moderate to severe disease documented in chart notes within the last 6 months?

- Lab tests confirming RA diagnosis- anti-CCP, RF, CRP, ESR
  AND
- Disease activity evaluated by one of the following-
  - Disease Activity Score for 28 joints (DAS-28) greater than 3.2
  - Simplified Disease Activity Index (SDAI) greater than 11
  - Clinical Disease Activity Index (CDAI) greater than 10

    a. Yes- go to question 6
    b. No- Forward to Medical Director for evaluation

6. Has the member had inadequate response or contraindication to a minimum of 8 week trial of first line DMARD methotrexate?

AND

An inadequate response or contraindication to a minimum 12 week trial of triple combination therapy with 3 of the first line DMARDs (methotrexate, sulfasalazine, hydroxychloroquine and/or leflunomide) – All trials with 80% adherence to therapy or better –

   a. Yes- go to question 7
   b. No- Deny- Cat 5-*Provider submitted documentation does not indicate that member has had inadequate response or has a contraindication to preferred treatment alternatives with demonstrated patient compliance to therapy.*

7. Has member had inadequate response to therapy with TWO formulary TNF inhibitors (Enbrel, Humira, Remicade) in combination with non- biologic DMARD for a minimum of 12 week trial each and 80% or better adherence to therapy?
   a. Yes- go to question 9
   b. No- Deny Cat 15- *Provider submitted documentation does not indicate that member has had inadequate response to formulary biologic DMARD therapy with demonstrated patient compliance to therapy*
8. Does the member have Neonatal Onset Multisystem Inflammatory Disease (NOMID), Chronic Infantile Neurological Cutaneous and Articular Syndrome (CINCA) or Muckle Wells WITH a mutation in the NLRP3 ($CIAS_{1)}$ gene? (Note- this is extremely rare)
   a. Yes- Go to question 9
   b. No- Cat 3 Denial- Anakinra is FDA approved only for use in NOMID and in adults with rheumatoid arthritis

9. Is dosing appropriate for condition and within FDA guidelines?
   a. Yes- Approve for 12 week trial
   b. No- Deny- Cat 3- *Not a covered benefit. The requested medication dosing is outside the approved dosing established in the FDA approved medication package insert, and therefore safety and efficacy cannot be established*

Renewal Criteria – Kineret

Has member experienced documented improvement in function and reduction in symptoms? (Reduction in swollen joint count, improvement in score of disease assessment) while demonstrating 80 % or better adherence to Kineret (Anakinra) therapy?

Yes- Approve for 12 months

No- Forward to Medical director for evaluation

Otezla (Apremilast)

1. Is the patient being treated for an OHP funded condition?
    a. Yes- go to question 2
    b. No- Category 1 denial- Not a covered benefit- Provider submitted diagnosis not for OHP funded condition

2. Is the medication prescribed by, or in consultation with, a rheumatologist?
    a. Yes- go to question 3
    b. No- *Cat 5 denial- All persons with a current rheumatological condition requiring biologic DMARD therapy should be linked to a provider able to provide comprehensive management to reduce risk of adverse outcomes*

3. Does the member have any of the following exclusions or precautions:
    a. Uncontrolled depression or suicidal ideation
    b. Pregnant or breastfeeding
    c. Unexplained or significant weight loss
    d. Concurrent use of another biologic DMARD

        i. Yes- Forward to Medical Director for evaluation
        ii. No- Move to question 4

4. Does member have diagnosis of psoriatic arthritis?
    a. Yes- go to question 2
    b. No- If diagnosis is plaque psoriasis- Go to criteria for psoriasis-

If neither- Deny Category 3- *FDA approved only for treatment of Psoriasis and Psoriatic arthritis*

5. Is the diagnosis based on:
    Documentation within last 6 months of active, inflammatory arthritis present with elevated ESR or CRP, swollen joints, radiographic findings consistent with PsA and personal or family history of psoriasis
    a. Yes- Go to question 12
    b. No- Forward to Medical director for medical appropriateness evaluation

6. Has the member had an inadequate response or contraindication to ALL of the following with 80 % or better adherence to therapy for a total of at least 12 weeks?
    a. Methotrexate
    b. Alternate DMARDs- sulfasalazine, leflunomide, hydroxychloroquine or azathioprine (Only in cases where psoriasis is not active)

        i. Yes- go to question 16
        ii. No- Deny Cat 5- - *Provider submitted documentation does not indicate that member has had inadequate response or has a contraindication to preferred treatment alternatives with demonstrated patient compliance*

7. Has the member had inadequate response to 2 formulary TNF inhibitors (Humira, Enbrel or Remicade) combined with a non- biologic DMARD following minimum of 12 week trial of EACH with better than 80% adherence to therapy?

    a. Yes- continue to question 7

    b. No- Deny- Cat 15- *Not a covered benefit- Provider submitted documentation does not indicate that the patient has tried and failed formulary biologic DMARD alternatives etanercept (Enbrel), infliximab (Remicade) or adalimumab (Humira)*

8. Is dosing appropriate for condition and within FDA guidelines?
    a. Yes- Approve for 12 week trial
    b. No- Deny- Cat 3- *Not a covered benefit. The requested medication dosing is outside the approved dosing established in the FDA approved medication package insert, and therefore safety and efficacy cannot be established*

Renewal Criteria- Otezla

Has member shown documented improvement in function and reduction in symptoms while demonstrating 80% or better compliance with Otezla therapy?

Yes- Approve for 1 year
No- Forward to Medical Director for evaluation of medical appropriateness

Xeljanz (Tofacitinib)

1. Is the patient being treated for an OHP funded condition?
    a. Yes- go to question 2
    b. No- Category 1 denial- Not a covered benefit- Provider submitted diagnosis not for OHP funded condition

2. Is the medication prescribed by, or in consultation with, a rheumatologist?
    a. Yes- go to question 3
    b. No- *Cat 5 denial- All persons with a current rheumatological condition requiring biologic DMARD therapy should be linked to a provider able to provide comprehensive management to reduce risk of adverse outcomes*

3. Does the member have any of the following exclusions or precautions:
    a. Active infection or history of recurrent infections
    b. Pregnant or breastfeeding
    c. Active malignancy
    d. Concurrent use of another biologic DMARD
    e. Neutropenia (ANC < 1000 cells/mm^3 or lymphocytes < 500 cells/mm^3)
    f. Anemia- (Hgb < 9g/dL)
    g. Conduction abnormalities, arrhythmias or HR < 60 bpm
    h. Uncontrolled hyperlipidemia
    i. Hepatic or renal impairment (dose reduction required)
    j. H/O diverticulitis or Gi perforation

        i. Yes- Forward to Medical Director for evaluation
        ii. No- Move to question 4

Rheumatoid Arthritis- Xeljanz

4. Does the member have diagnosis of rheumatoid arthritis and is 18 or over?
    a. Yes- go to question 5
    b. No- go to question 8
5. Does the member have documentation of moderate to severe disease documented in chart notes within the last 6 months?

❖ Lab tests confirming RA diagnosis- anti-CCP, RF, CRP, ESR

AND

- ❖ Disease activity evaluated by one of the following-
  - ➢ Disease Activity Score for 28 joints (DAS-28) greater than 3.2
  - ➢ Simplified Disease Activity Index (SDAI) greater than 11
  - ➢ Clinical Disease Activity Index (CDAI) greater than 10

a. Yes- go to question 6

b. No- Forward to Medical Director for evaluation

6. Has the member had inadequate response or contraindication to a minimum of 8 week trial of first line DMARD methotrexate?

AND

An inadequate response or contraindication to a minimum 12 week trial of triple combination therapy with 3 first line DMARDs (methotrexate, sulfasalazine, hydroxychloroquine and/or leflunomide)? All trials with 80% adherence to therapy or better

a. Yes- go to question 7

b. No- Deny- Cat 5-*Provider submitted documentation does not indicate that member has had inadequate response or has a contraindication to preferred treatment alternatives with demonstrated patient compliance to therapy.*

7. Has member had inadequate response to therapy with TWO formulary TNF inhibitors (Enbrel, Humira, Remicade) combined with non-biologic DMARD for a minimum of 12 week trial for each and 80% or better adherence to therapy?

a. Yes- go to question 9

b. No- Deny Cat 15- *Provider submitted documentation does not indicate that member has had inadequate response to formulary biologic DMARD therapy with demonstrated patient compliance to therapy*

8. Is dosing appropriate for condition and within FDA guidelines? (Xeljanz- 1 bid- XR- 1 qd)

a. Yes- Approve for 12 week trial

b. No- Deny- Cat 3- *Not a covered benefit. The requested medication dosing is outside the approved dosing established in the FDA approved medication package insert, and therefore safety and efficacy cannot be established*

Renewal Criteria- Xeljanz

Has member shown documented improvement in function and reduction in symptoms while demonstrating 80% or better compliance with Xeljanz therapy?

Yes- Approve for 1 year

No- Forward to Medical Director for evaluation of medical appropriateness

Cosentyx (Secukinumab)

1. Is the patient being treated for an OHP funded condition?
    a. Yes- go to question 2
    b. No- Category 1 denial- Not a covered benefit- Provider submitted diagnosis not for OHP funded condition

2. Is the medication prescribed by, or in consultation with, a rheumatologist?
    a. Yes- go to question 3
    b. No- *Cat 5 denial- All persons with a current rheumatological condition requiring biologic DMARD therapy should be linked to a provider able to provide comprehensive management to reduce risk of adverse outcomes*

3. Does the member have any of the following exclusions or precautions:
    a. Chronic or current infection or h/o recurrent infection
    b. Pregnant or breastfeeding
    c. Concurrent use of another biologic DMARD

        i. Yes- Forward to Medical Director for evaluation
        ii. No- Move to question 4

4. Does member have diagnosis of psoriatic arthritis?
    a. Yes- go to question 5
    b. No- go to question 7

    (If diagnosis is plaque psoriasis- Go to criteria for psoriasis)

5. Is the diagnosis based on:
    Documentation within last 6 months of active, inflammatory arthritis present with elevated ESR or CRP, swollen joints, radiographic findings consistent with PsA and personal or family history of psoriasis
    a. Yes- Go to question 6
    b. No- Forward to Medical director for medical appropriateness evaluation

6. Has the member had an inadequate response or contraindication to **ALL** of the following with 80 % or better adherence to a minimum of 12 weeks total of therapy
    - **a.** Methotrexate
    - **b.** Alternate DMARDs- sulfasalazine, leflunomide, hydroxychloroquine or azathioprine (Only in cases where psoriasis is not active)
        - **i.** Yes- go to question 10
        - **ii.** No- Deny Cat 5- - *Provider submitted documentation does not indicate that member has had inadequate response or has a contraindication to preferred treatment alternatives with demonstrated patient compliance*

Ankylosing Spondylitis- Cosentyx

7. Does the member have diagnosis of Ankylosing Spondylitis?
    - **a**. Yes- go to question 8
    - **b**. No- If member has Psoriasis- go to psoriasis criteria-
    - If not, Cat 3 denial-*Cosnetyx is FDA approved only for the treatment of Psoriatic Arthritis, Ankylosing Spondylitis and Psoriasis.*

8. Does the member have moderate to severe active disease as defined by:
   Bath AS Disease Activity Index (BASDAI) score of 4 or greater **OR**
   Physician Global Assessment of 2 or greater
    - **a.** Yes- go to question 9
    - **b.** No- Forward to Medical Director for medical appropriateness evaluation

9. Has the member had inadequate response to 2 formulary TNF inhibitors (Humira, Enbrel or Remicade) combined with physical therapy/ exercise program following minimum of 12 week trials of EACH with better than 80% adherence to therapy?

    a. Yes- continue to question 11

    b. No- Deny- Cat 15- *Not a covered benefit- Provider submitted documentation does not indicate that the patient has tried and failed formulary biologic DMARD alternatives etanercept (Enbrel), infliximab (Remicade) or adalimumab (Humira)*

10. Is medication being prescribed in combination with physical therapy and plan to keep active/ exercise?
    - **a.** Yes- continue to question 11
    - **b.** No- Deny Cat 5- *Exercise and physical therapy are recommended for all patients with AS to preserve spinal mobility and function and is a necessary component of treatment program.*

11. Is dosing appropriate for condition and within FDA guidelines?

a. Yes- Approve for 12 week trial

b. No- Deny- Cat 3- *Not a covered benefit. The requested medication dosing is outside the approved dosing established in the FDA approved medication package insert, and therefore safety and efficacy cannot be established*

Renewal Criteria- Cosentyx

Has member shown documented improvement in function and reduction in symptoms while demonstrating 80% or better compliance with Cosentyx and exercise/PT therapy?

Yes- Approve for 1 year

No- Forward to Medical Director for evaluation of medical appropriateness

Stelara (Ustekinumab) – Formulary Biologic

1. Is the patient being treated for an OHP funded condition?
    a. Yes- go to question 2
    b. No- Category 1 denial- Not a covered benefit- Provider submitted diagnosis not for OHP funded condition

2. Is the medication prescribed by, or in consultation with, a rheumatologist?
    a. Yes- go to question 3
    b. No- *Cat 5 denial- All persons with a current rheumatological condition requiring biologic DMARD therapy should be linked to a provider able to provide comprehensive management to reduce risk of adverse outcomes*

3. Does the member have any of the following exclusions or precautions:
    a. Chronic or current infection or h/o recurrent infection
    b. Pregnant or breastfeeding
    c. Concurrent use of another biologic DMARD (non- biologic DMARD recommended with Stelara to reduce risk of antibody formation)

        i. Yes- Forward to Medical Director for evaluation
        ii. No- Move to question 4

4. Does member have diagnosis of psoriatic arthritis?
    a. Yes- go to question 5
    b. No- If diagnosis is plaque psoriasis- Go to criteria for psoriasis *Stelara is FDA approved for psoriatic arthritis and psoriasis only*

5. Is the diagnosis based on:
   Documentation within last 6 months of active, inflammatory arthritis present with elevated ESR or CRP, swollen joints, radiographic findings consistent with PsA and personal or family history of psoriasis
    a. Yes- Go to question 6
    b. No- Forward to Medical director for medical appropriateness evaluation

6. Has the member had an inadequate response or contraindication to ALL of the following with 80 % or better adherence to a minimum of 12 weeks of therapy with:
    a. Methotrexate
    b. Alternate DMARDs- sulfasalazine, leflunomide, hydroxychloroquine or azathioprine (Only in cases where psoriasis is not active)
        i. Yes- go to question 10
        ii. No- Deny Cat 5- - *Provider submitted documentation does not indicate that member has had inadequate response or has a contraindication to preferred treatment alternatives with demonstrated patient compliance*

7. Has the member had inadequate response to 2 TNF inhibitors (Humira, Enbrel or Remicade) following minimum of 12 week trials of EACH with better than 80% adherence to therapy?
    a. Yes- continue to question 11
    b. No- Deny- Cat 15- *Not a covered benefit- Provider submitted documentation does not indicate that the patient has tried and failed preferred biologic DMARD alternatives etanercept (Enbrel), infliximab (Remicade) or adalimumab (Humira)*

8. Is dosing appropriate for condition and within FDA guidelines?
    a. Yes- Approve for 12 week trial
    b. No- Deny- Cat 3- *Not a covered benefit. The requested medication dosing is outside the approved dosing established in the FDA approved medication package insert, and therefore safety and efficacy cannot be established*

Renewal Criteria- Stelara

Has member shown documented improvement in function and reduction in symptoms while demonstrating 80% or better compliance with Stelara therapy?

Yes- Approve for 1 year

No- Forward to Medical Director for evaluation of medical appropriateness