Mesalamine Rectal Suppositories (Canasa)

1. Is the patient being treated for a funded condition by the Oregon Health Plan?
    a. Yes; Move to question 2
    b. No; Deny category 1: Not a covered benefit

2. Does member have a diagnosis of active mild to moderate active ulcerative proctitis?
    - Disease is limited to the rectum
    - Mild: ≤ 4 stools per day with or without blood, no signs of systemic toxicity, and a normal erythrocyte sedimentation rate. Mild crampy pain, tenesmus and periods of constipation are also common.
    - Moderate: Frequent, loose, bloody stools (> 4 daily), mild anemia not requiring blood transfusions, and abdominal pain that is not severe. Minimal signs of toxicity, including a low grade fever. Nutrition is maintained and weight loss is not associated.

    a. Yes; Move to question 3
    b. No; Deny category 3: Not a covered benefit

3. Is the medication intended for short-term use? *Rational: Safety and efficacy beyond 6 weeks has not been established*
    a. Yes; move to question 4
    b. No; Deny category 5: Not medically appropriate

4. Has the member tried and failed preferred formulary option mesalamine rectal enema?
    a. Yes; approve for 6 weeks
    b. No; Deny category 5: Not medically appropriate

Tumor Necrosis Factor

Requests for J-code medications in this class with equivalent options for self-administration require trial of self-administered drug first.

New Start

1. Is the patient being treated for a funded condition by the Oregon Health Plan?
    a. Yes; move to question 2
    b. No; Deny category 1: Not a covered benefit

2. Is the medication being prescribed or in consultation with a gastroenterologist?
    a. Yes; Move to question 3
    b. No; Deny category 5: Not medically appropriate

3. Does the member have a history of recurring infections or an active infection?
    a. No; Move to question 4
    b. Yes; Deny category 5: Not medically appropriate

4. Does the member have any of the following exclusions:
    - Pregnant or breastfeeding
    - Multiple sclerosis
    - Active malignance

- Severe CHF

a. No; move to question 5
b. Yes; Deny category 5: Not medically appropriate

5. Have appropriate labs been completed to demonstrate member does not have latent or active tuberculosis or is a carrier of Hepatitis B virus?
    a. Yes; move to question 6
    b. No; Deny category 5: Not medically appropriate

6. Does the member have a diagnosis of severe fistulizing Crohn's Disease?
    a. Yes; Approve for 6 months
    b. No; move to question 7

7. Has the member had a trial and failure or contraindication to an appropriate regimen of first-line therapy based on the indication for treatment?
    Moderate to Severe Ulcerative colitis: symptoms despite treatment for at least 12 weeks with a combination of topical therapy ***and*** the following oral therapies at maximally tolerated doses
    - Oral Aminosalicylates
        - Sulfasalazine 4-6 grams per day
        - Mesalamine 2-4.8 grams per day
        - Basalazine 6.75 grams per day
    - Oral prednisone 40-60mg per day
    - Immunosuppressant
        - Azathioprine 1.5mg/kg/day
        - 6-mercaptopurine 1-1.5mg/kg/day

    Moderate to Severe Crohn's Disease: Symptoms despite treatment with first line therapy with at least one agent from each of the following categories

    - Treatment with any of the following corticosteroid regimens for two weeks has been ineffective or is contraindicated ***or*** member is unable to taper off of one of the following
        - Prednisone 40-60mg daily
        - Oral budesonide 9mg daily
    - Aminosalicylic acid derivatives
        - Sulfasalazine
        - Mesalamine
    - 12 week trial of one of the following therapies
        - Azathioprine 2-3mg/kg/day
        - 6-mercaptopurine 1-1.5mg/kg/day
        - Methotrexate 20mg weekly (GI intolerance requires trial of SQ/IM at 20mg weekly dosing)

    a. Yes; approve for 6 months
    b. No; Deny category 5: Not medically appropriate

Continuation of therapy

1. Is member using biologic for the treatment of Ulcerative Colitis?
    a. Yes; move to question 2
    b. No; move to question 4

2. Has the member demonstrating 80% or greater adherence to biologic and non-biologic therapy for treatment?
    a. Yes; move to question 3
    b. No; Deny category 5: Not medically appropriate

3. Has the member demonstrated a significant response including the following
    - Decrease in bloody stools per day and/or
    - Elimination of signs of toxicity
    a. Yes; approve for 12 months
    b. No; Deny category 5: Not medically appropriate

4. Is the member using biologic therapy for the treatment of Crohn's Disease?
    a. Yes; Move to question 5
    b. No; If for the treatment of a condition other than UC or Crohn's, see appropriate criteria

5. Has the member demonstrated adherence to biologic and non-biologic therapy?
    a. Yes; Move to question 6
    b. No; Deny category 5: Not medically appropriate

6. Has the member experienced a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission?
    a. Yes; approve for 12 months
    b. No; Deny category 5: Not medically appropriate

Vedolizumab (Entyvio)—processing under medical benefit: J3380

New Start

1. Is the patient being treated for a funded condition by the Oregon Health Plan?
    a. Yes; move to question 2
    b. No; Deny category 1: Not a covered benefit

2. Is the medication being prescribed or in consultation with a gastroenterologist?
    a. Yes; move to question 3
    b. No; Deny category 5: Not a covered benefit

3. Is the medication intended for the treatment of moderate to severe ulcerative colitis or Crohn's Disease?
    a. Yes; move to question 4
    b. No; Deny category 3: Not a covered benefit

4. Is the member over the age of 18?
    a. Yes; move to question 5
    b. No; category 3 denial: Not a covered benefit

5. Does the member have a history of recurring infections or an active infection?
    a. No; Move to question 6
    b. Yes; Deny category 5: Not medically appropriate

6. Does the member have any evidence of liver injury?
    a. No; Move to question 7
    b. Yes; Deny category 5: Not medically appropriate

7. Member will **not** be on concurrent therapy with another TNF inhibitor: Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria?
    - Antibody testing should be included that shows resistance to TNF-inhibitor options
    a. Yes; Move to question 8
    b. No; Deny category 3: Not a covered benefit

8. Has the member had a trial and failure or contraindication to an appropriate regimen of first-line therapy based on the indication for treatment?
    Moderate to Severe Ulcerative colitis: symptoms despite treatment for at least 12 weeks with a combination of topical therapy ***and*** the following oral therapies at maximally tolerated doses
    - Oral Aminosalicylates
        - Sulfasalazine 4-6 grams per day
        - Mesalamine 2-4.8 grams per day
        - Basalazine 6.75 grams per day
    - Oral prednisone 40-60mg per day
    - Immunosuppressant
        - Azathioprine 1.5mg/kg/day
        - 6-mercaptopurine 1-1.5mg/kg/day

    Moderate to Severe Crohn's Disease: Symptoms despite treatment with first line therapy with at least one agent from each of the following categories

    - Treatment with any of the following corticosteroid regimens for two weeks has been ineffective or is contraindicated ***or*** member is unable to taper off of one of the following
        - Prednisone 40-60mg daily
        - Oral budesonide 9mg daily
    - Aminosalicylic acid derivatives
        - Sulfasalazine
        - Mesalamine
    - 12 week trial of one of the following therapies
        - Azathioprine 2-3mg/kg/day
        - 6-mercaptopurine 1-1.5mg/kg/day
        - Methotrexate 20mg weekly (GI intolerance requires trial of SQ/IM at 20mg weekly dosing)
    a. Yes; move to question 9
    b. No; Deny category 5: Not medically appropriate

9. Member has had an trial and failure to TWO preferred TNF alpha inhibitors (Humira, Remicade) for at least 12 weeks or intolerance or a contraindication to use
    a. Yes; Move to question 10
    b. No; Deny category 5: Not medically appropriate *(medication is not indicated for concomitant use with another biologic)*

10. Prescribed regimen is within the FDA-approved dosing regimen of 300mg at 0, 2, and 6 weeks then every 8 weeks thereafter
    a. Yes; approve for 14 week trial
    b. No; Deny category 3: Not a covered benefit

Continuation of Therapy

1. Is the member using biologic for the treatment of Ulcerative Colitis?
    a. Yes; move to question 2
    b. No; move to question 4

2. Has the member demonstrated adherence to biologic and non-biologic therapy for treatment?
    a. Yes; move to question 3
    b. No; deny category 5: Not medically appropriate

3. Has the member demonstrated a significant response including the following:
    - Decrease in bloody stools per day and/or
    - Elimination of signs of toxicity
    a. Yes; approve for 12 months
    b. No; Deny category 5: not medically appropriate

4. Is the member using biologic therapy for the treatment of Crohn's Disease?
    a. Yes; move the question 5
    b. No; category 3 denial: Not a covered benefit

5. Has the member demonstrated 80% or greater adherence to biologic and non-biologic therapy?
    a. Yes; move to question 6
    b. No; Deny category 5: not medically appropriate

6. Has the member experienced a decrease in symptoms, reduction in entercutaneous fistulas or clinical remission?
    a. Yes; approve for 12 months
    b. No; deny category 5: Not medically appropriate

Natalizumab (Tysabri)—processing under medical benefit J2323

New Start Criteria

1. Is the patient being treated for a funded condition by the Oregon Health Plan?
    a. Yes; move to question 2
    b. No; category 1 denial: Not a covered benefit

2. Is the medication being prescribed by or in consultation with a gastroenterologist?
    a. Yes; move to question 3
    b. No; Deny category 5: Not medically appropriate

3. Is the medication intended for the treatment of Crohn's Disease?
    a. Yes; move to question 4

b. No; category 3 denial: Not a covered benefit *(exception: for the treatment of MS)*

4. Is the member over the age of 18?
    a. Yes; move to question 5
    b. No; category 3 denial: Not a covered benefit

5. Are the member and provider enrolled in the Tysabri Outreach Unified Commitment to Health (TOUCH) Prescribing Program?
    a. Yes, move to question 6
    b. No; category 5 denial: Not medically appropriate

6. Does the member have a history of recurring infectious or an active infection?
    a. No; Move to question 7
    b. Yes; category 5 denial: not medically appropriate

7. Does the member have any evidence of liver injury?
    a. No; Move to question 8
    b. Yes; category 5 denial: not medically appropriate

8. Does member have current or history of progressive multifocal leukoencephalopathy?
    a. No; move to question 9
    b. Yes; category 5 denial: Not medically appropriate (contraindication for use)

9. Member will **not** be on concurrent therapy with a TNF inhibitor: Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria?
    - Antibody testing should be included that shows resistance to TNF-inhibitor options

    a. Yes; move to question 10
    b. No; Category 3 denial: Not a covered benefit

10. Has the member had a trial and failure of contraindication to an appropriate regimen of first-line therapy based on the indication for treatment?
    Moderate to Severe Crohn's Disease: Symptoms despite treatment with first line therapy with at least one agent from each of the following categories
    - Treatment with any of the following corticosteroid regimens for two weeks has been ineffective or is contraindicated ***or*** member is unable to taper off of one of the following
        - Prednisone 40-60mg daily
        - Oral budesonide 9mg daily
    - Aminosalicylic acid derivatives
        - Sulfasalazine
        - Mesalamine
    - 12 week trial of one of the following therapies
        - Azathioprine 2-3mg/kg/day
        - 6-mercaptopurine 1-1.5mg/kg/day
        - Methotrexate 20mg weekly (GI intolerance requires trial of SQ/IM at 20mg weekly dosing)

    a. Yes; move to question 11
    b. No; category 5 denial: Not medically appropriate

11. Member has had an trial and failure to TWO preferred TNF alpha inhibitors (Humira, Remicade) for at least 12 weeks or intolerance or a contraindication to use
    a. Yes; move to question 12
    b. No; Deny category 5: Not medically appropriate

12. Prescribed regimen is within the FDA dosing
    a. Yes; approved for 12 weeks trial with a QL of 15 mL per 28 days
    b. No; category 3 denial: Not a covered benefit

Continuation of therapy

1. Is the member using biologic therapy for the treatment of moderate to severe Crohn's Disease?
    a. Yes; move to question 2
    b. No; category 3 denial: Not a covered benefit

2. Has the member demonstrated 80% or greater adherence to biologic therapy?
    a. Yes; move to question 3
    b. No; deny category 5: Not medically appropriate

3. Is member currently on chronic oral corticosteroids?
    a. Yes; move to question 5
    b. No; move to question 4

4. Has the member experienced a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission? *Rational: Member and provider must be enrolled in REMS program (Tysabri Outreach Unified Commitment to Health—TOUCH) and treatment must be reauthorized every 6 months)*
    a. Yes; approved for 6 months
    b. No; deny category 5: not medically appropriate

5. Is there a plan in place to taper oral corticosteroids within 6 months of therapy initiation **or** concomitant corticosteroid therapy required does not exceed 3 months per year (in addition to initial corticosteroid taper)?
    a. Yes; approve for 3 months
    b. No; deny category 5: not medically appropriate