Samaritan Health Plans

Prior Authorization Criteria

Inter-Community Health Network

PLEASE READ: This document contains information about the criteria for coverage of provider administered drugs for this plan.

Updated on 1/1/2023. For more recent information or other questions, please contact Pharmacy Services at **541-768-4550** or toll free **800-832-4580** (TTY 800-735-2900) or visit **samhealthplans.org**. Pharmacy Services is available Monday through Friday, from 8 a.m. to 5 p.m.

Medically billed drugs

Products Affected

- All physician administered drugs that require authorization, and do not have specific criteria

PA CRITERIA	
Covered Uses	All medically necessary and appropriate conditions
Exclusion Criteria	Investigational/experimental use, or use specifically excluded by the member handbook or Medicaid requirements
Required Medical Information	All requests must contain documentation supporting the medical appropriateness and necessity of the requested medication
Age Restrictions	Per FDA label
Prescriber Restrictions	Specialist prescribing may be required
Other	Renewal Criteria: Documentation or attestation of positive clinical response to therapy.

1. Is the requested medication being used to treat an above the line diagnosis on the OHA Prioritized list OR is the member under 21 years of age with a condition that will limit the ability to grow, develop, or take part in school OR does the member have an above the line comorbid condition that will be treated indirectly by the requested medication? (IHN only question, for SCP/COMM move to question 2)
Yes = Go to Q2 No = Deny The plan does not cover medications that are being used for diagnosis that fall below the line on the OHA Prioritized List unless an above the line comorbid condition will be indirectly treated by the requested medication.
2. Is the requested medication being used for an FDA-approved indication OR being used for an off-label indication with well-established, clinical evidence supporting its use?
Yes = Go to Q3 No = DENY. The plan covers the requested medication when the requested medication is being used for an FDA approved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.
3. Is this an initial or renewal request?
Initial = Go to Q5 Renewal = Go to Q4
4. Does the patient have documentation of continued effectiveness of the requested medication?
Yes = APPROVE X 12 months (or as appropriate)
No = Deny. The plan provides coverage of the requested medication when the patient has documented continued effectiveness. Based on the information provided, this requirement has not been met.

5. Is the request medically necessary and appropriate AND requested by an appropriate specialist?
Yes = Go to Q6 No = DENY.

Acute Infectious Disease Treatments

Products Affected

- Avycaz (ceftazidime/avibactam)
- Cresemba (isavuconazonium sulfate) IV formulation
- Fetroja (cefiderocol)
- Flucytosine
- Kimyrsa (oritavancin)
- Nuzyra (omadacycline)
- Racarbio (imipenem/cilastatin/relebactam)
- Synercid (quinupristin/dalfopristin)
- Vabomere (meropenem/vaborbactam)
- Xenleta (lefamuin)
- Xerava (eravacycline)

PA CRITERIA	
Covered Uses	All FDA and compendia supported uses
Exclusion Criteria	
Required Medical Information	Evidence to support that the use of the anti-infective is medically appropriate and necessary.
Age Restrictions	
Prescriber Restrictions	Infectious disease specialist (or in consultation with)
Coverage Duration	Appropriate duration for given indication

1. Is the requested medication being used to treat an above the line diagnosis on the OHA Prioritized list OR is the member under 21 years of age with a condition that will limit the ability to grow, develop, or take part in school OR does the member have an above the line comorbid condition that will be treated indirectly by the requested medication? (IHN only question, for SCP/COMM move to question 2)

Yes = Go to Q2

No = Deny The plan does not cover medications that are being used for diagnosis that fall below the line on the OHA Prioritized List unless an above the line comorbid condition will be indirectly treated by the requested medication.

2. Is the requested medication being used for an FDA-approved indication OR being used for an off-label indication with well-established, clinical evidence supporting its use?

Yes = Go to Q3

No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

3. Is the requested medication being prescribed by (or in consultation with) an Infectious Disease Specialist?

Yes = Go to Q4

No = Deny. The plan covers the requested medication when the requested medication is being prescribed by or in collaboration with an infectious disease specialist.

4. Is there evidence to support that the use of the anti-infective is medically appropriate and necessary?
Yes = Go to Q5 No = Deny. The plan provides coverage of the requested medication there is evidence to support that the use of the medication is medically appropriate and necessary.
5. Is the request for Kimyrsa (oritavancin)?
Yes = Go to Q6 No = APPROVE for appropriate duration as evidenced by FDA indication or compendia support.
6. Is there a medical reason Orbactiv (oritavancin) cannot be used?
Yes = APPROVE for appropriate duration as evidenced by FDA indication or compendia support. No = DENY. The plan provides coverage of the requested medication when there is a medical reason that Orbactiv (oritavancin) cannot be used.

Lemtrada (alemtuzumab)

Products Affected

- Lemtrada 12mg/1.2mL solution

PA CRITERIA	
Covered Uses	Relapsing Remitting Multiple Sclerosis
Exclusion Criteria	HIV infection (medication causes prolonged CD4 suppression) Current active infection
Required Medical Information	Current neurology chart notes pertaining to MS List of previous medication trials Vaccination records and screenings for infections, HIV, HBV, TB
Age Restrictions	18 years and older
Prescriber Restrictions	Neurology
Coverage Duration	Initial: 12 months; Renewal: 12 months
Other	Renewal Criteria: Documentation of positive clinical response to therapy.

1. Is this an initial or renewal request?

Initial = Go to Q3

Renewal = Go to Q2

2. Have ALL the following criteria been met?

- **Does the patient have documentation of response and disease stability or statement of medical necessity to continue treatment?**
- **Is requested dose: 12mg IV daily x 3 days?**
- **Was previous dose administered at least 12 months prior?**

Yes = APPROVE X 12 months
No = Deny. The plan provides coverage of the requested medication when the patient has documented continued effectiveness and medication is prescribed within FDA indicated uses. Based on the information provided, this requirement has not been met.

3. Is the member under the care of a neurologist?

Yes = Go to Q4
No = DENY. The plan covers the requested medication when it is prescribed by a neurologist. Based on the information provided, this requirement has not been met.

4. Is the medication intended for use for an FDA approved indication:

- **Diagnosis of Relapsing Remitting Multiple Sclerosis**
- **Member age ≥ 18 years old**
- **Prescribed dose 12mg administered daily for 5 days**
- **Patient and provider are enrolled in Lemtrada REMS program**

Yes = Go to Q5
No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

5. Has the following screening for exclusion been met?

- **Female patient: is not pregnant, is consistently using effective means of contraception, or has no childbearing potential**
- **No active infection**
- **No untreated latent or active TB**
- **No HIV or active HBV infection**
- **Varicella-zoster virus immunity status is established**

Yes = Go to Q6

No = DENY. The plan covers the requested medication when the clinical evidence supports its safe use. Certain conditions may increase the risk of serious adverse effects of requested medication. Potential pregnancy and active or dormant infection are exclusions for use of this medication.

6. Is the medication intended for use as monotherapy?

Yes = Go to Q7
No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

7. Has the member failed (continuation of clinical relapses, CNS lesion progression on MRI, or worsening disability) while adherent to therapy on ALL the following? *NOTE: If MS disease is considered "highly active" failure of 2 or more agents is appropriate for approval.*

- **Glatiramer, AND**
- **A fumarate, AND**
- **A sphingosine 1-receptor modulator, AND**
- **An anti-CD20 antibody**

Yes = APPROVE X 12 months
No = DENY. The plan covers the requested medication when there has been a trial and failure of glatiramer, a fumarate, a sphingosine 1-receptor modulator, and anti-CD20 antibody. Based on the information provided, this requirement has not been met.

Apretude (cabotegravir)

Products Affected

- Cabotegravir 200 mg/1 mL IM suspension

PA CRITERIA	
Covered Uses	For use in Pre-Exposure Prophylaxis of HIV (PrEP)
Required Medical Information	**For use in PrEP, all of the following:** • To be used as pre-exposure prophylaxis to reduce the risk for HIV-1 infections • Patient has tested negative for HIV within 1 week of initiation of therapy and has no clinical symptoms; • Patient has had an intolerance or contraindication to generic Truvada (emtricitabine-tenofovir disoproxil) • Dosing is in accordance with FDA approved labeling.
Coverage Duration	Initial: 12 months; Renewal: 12 months
Other	Documentation of continued need for Apretude for PrEP, including a current negative HIV-1 screening test.

1. Is this an initial or renewal request?
Initial = Go to Q3 Renewal = Go to Q2
2. Does the patient have documentation of continued need of the requested medication AND a current negative HIV-1 test (a test within the last week)?
Yes = APPROVE X 1 year No = Deny
3. Does the patient weigh at least 35 kg?
Yes = Go to Q4 No = DENY
4. Has the patient tested negative for HIV within 1 week (or the provider attests that they will test for HIV infection 1 week) prior to initiation of Apretude therapy AND patient has no symptoms of HIV?
Yes = Go to Q5 No = DENY
5. Has the patient had an adequate (3 month) trial to generic Truvada (emtricitabine-tenofovir disoproxil) or has a contraindication to generic Truvada?
Yes = APPROVE X 1 year No = DENY

Botulinum Toxins

Products Affected

- Botox (onobotulinumtoxinA)
- Dysport (abobotulinumtoxinA)
- Xeomin (incobotulinumtoxinA)
- Myobloc (rimabotulinumtoxinB)

PA CRITERIA	
Covered Uses	**Abnormal Involuntary Movements**
Required Medical Information	• Diagnosis of: ○ Torsion dystonia ○ Spasmotic torticollis (cervical dystonia) in a member at least 16 years old ○ Blepharospasm in a member at least 12 years old ○ Congenital sternocleidomastoid torticollis ○ Cerebral palsy ○ Chronic limb spasticity from one of the following: ▪ Hereditary spastic paraplegia ▪ Spastic hemiplegia due to stroke ▪ Traumatic brain or spinal cord injury with resultant paraplegia, hemiplegia, or quadriplegia ▪ Multiple sclerosis ▪ Neuromyelitis optica ▪ Other demyelinating diseases of the central nervous system • For all diagnoses ○ The condition is causing functional impairment • For cerebral palsy and chronic limb spasticity ○ Abnormal muscle tone is causing functional impairment or is expected to result in joint contracture • For chronic limb spasticity ○ Abnormal muscle tone is causing functional impairment or is expected to result in joint contracture ○ Trial and failure or contraindications to conventional nonpharmacologic treatment including physical therapy, splinting, bracing, or biofeedback which has been ineffective or cannot be maximized secondary to significant contracture ○ Trial and failure to two oral pharmacologic agents (i.e., baclofen, dantrolene, tizanidine, or benzodiazepines)
Prescriber Restrictions	Neurologist, ophthalmologist, physiatrist, or appropriate specialist for the given condition
Exclusions	• Infection at proposed injection site • Neuromuscular disease (myasthenia gravis)
Coverage Duration	Initial: 12 months; Renewal: 6-12 months

Other	Renewal Criteria:
	• Member has met treatment goals on the current dose, including but not limited to:
	  ○ Decrease in severity of abnormal movements or contractures such as head positioning, improved range of motion, or decreased spasticity
	  ○ Decrease in pain
	  ○ Decrease in disability, such as enhanced motor ability and functional skills, improved execution of tasks, or improvement in activities of daily living
	• Dose optimization or toxin change

1. Is the requested medication being used to treat an above the line diagnosis on the OHA Prioritized list OR is the member under 21 years of age with a condition that will limit the ability to grow, develop, or take part in school OR does the member have an above the line comorbid condition that will be treated indirectly by the requested medication? (IHN only question, for SCP/COMM move to question 2)
Yes = Go to Q2 No = DENY. The plan does not cover medications that are being used for diagnosis that fall below the line on the OHA Prioritized List unless an above the line comorbid condition will be indirectly treated by the requested medication.
2. Is the requested medication being used for an FDA-approved indication OR being used for an off-label indication with well-established, clinical evidence supporting its use?
Yes = Go to Q3 No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.
3. Is this an initial or renewal request?
Initial = Go to Q4 Renewal = Go to Q12
4. Is the requested medication being prescribed or supervised by a neurologist, ophthalmologist, physiatrist, or other appropriate specialist?
Yes = Go to Q5 No = DENY. The plan covers the requested medication when the medication is being prescribed or supervised by a neurologist, ophthalmologist, physiatrist, or other appropriate specialist. Based on the information provided, this requirement has not been met.
5. Does the member have functional impairment from dystonia related to one of the following diagnoses:

a. Torsion dystonia
b. Spasmodic torticollis (cervical dystonia) in a member at least 16 years old

c. Blepharospasm in a member at least 12 years old

d. Congenital sternocleidomastoid torticollis

Yes = Approve x 12 months

No = Go to Q6

6. Does the member have limb spasticity associated with cerebral palsy?

Yes = Go to Q7

No = Go to Q8

7. Is abnormal muscle tone causing functional impairment or expected to result in joint contracture?

Yes = Approve x 12 months
No = Deny. The plan provides coverage of the requested medication when the patient has limb spasticity associated with cerebral palsy and abnormal muscle tone is causing functional impairment or is expected to result in joint contracture. Based on the information provided, this requirement has not been met.

8. Does the member have functional impairment related to chronic limb spasticity from one of the following diagnoses:

a. Hereditary spastic paraplegia

b. Spastic hemiplegia due to stroke
c. Traumatic brain or spinal cord injury with resultant paraplegia, hemiplegia, or quadriplegia d.

Multiple sclerosis

e. Neuromyelitis optica

f. Other demyelinating diseases of the central nervous system

Yes = Go to Q9

No = DENY. The plan covers the requested medication when the member has functional impairment related to chronic limb spasticity from one of the following: hereditary spastic paraplegia, spastic hemiplegia due to stroke, multiple sclerosis, neuromyelitis optica, other demyelinating diseases of the central nervous system, or traumatic brain or spinal cord injury with resultant paraplegia, hemiplegia, or quadriplegia. Based on the information provided, this requirement has not been met.

9. Is abnormal muscle tone causing functional impairment or expected to result in joint contracture?

Yes = Go to Q7

No = DENY. The plan covers the requested medication when abnormal muscle tone is causing functional impairment or is expected to result in joint contracture. Based on the information provided, this requirement has not been met.

10. Has the member trialed and failed or have contraindications to conventional non-pharmacologic treatment including physical therapy, splinting, bracing, or biofeedback which has been ineffective or cannot be maximized secondary to significant contracture?
Yes= Go to Q11 No = DENY. The plan covers the requested medication when the member trialed and failed or have contraindications to conventional non-pharmacologic treatment including physical therapy, splinting, bracing, or biofeedback which has been ineffective or cannot be maximized secondary to significant contracture. Based on the information provided, this requirement has not been met.
11. Has the member tried and failed two oral pharmacologic agents, such as baclofen, dantrolene, tizanidine, and benzodiazepines?
Yes = Approve x 12 months. No = DENY. The plan covers the requested medication when the member tried and failed two oral pharmacologic agents, such as baclofen, dantrolene, tizanidine, and benzodiazepines. Based on the information provided, this requirement has not been met.
12. Has the member met treatment goals on the current dose, including but not limited to the following: **a. Decrease in severity of abnormal movements or contractures such as head positioning, improved range of motion, or decreased spasticity** **b. Decrease in pain** **c. Decrease in disability, such as enhanced motor ability and functional skills, improved execution of tasks, or improvement in activities of daily living**
Yes = Approve x 12 months No = Go to Q13
13. Has the provider requested dose optimization or toxin change?
Yes = Approve x 6 months No = DENY. The plan provides coverage of the requested medication when there is documentation that the member has met treatment goals on the current dose, or the provider has requested dose optimization or toxin change. Based on the information provided, this requirement has not been met.

PA CRITERIA	
Covered Uses	**Chronic Migraine**

Required Medical Information	• Diagnosis of chronic migraine, defined as headaches on at least 15 days per month of which at least 8 days are migraine • Condition has been appropriately managed for medication overuse • No adequate response or contraindication to at least three prior pharmacological prophylaxis therapies: ○ Beta blockers (e.g. propranolol, metoprolol, atenolol, etc.) ○ Anticonvulsants (e.g. divalproex sodium, sodium valproate, topiramate, or carbamazepine) ○ Tricyclic antidepressants (e.g. amitriptyline)
Age Restrictions	18 years old
Prescriber Restrictions	Neurologist, or headache specialist
Exclusions	• Infection at proposed injection site • Neuromuscular disease (myasthenia gravis)
Coverage Duration	Initial: 2 treatments in 6 months; Renewal: 12 months
Other	Renewal Criteria: • Documented positive response to therapy, defined as a reduction of at least 7 headache days per month compared to baseline headache frequency

1. Is the requested medication being used to treat an above the line diagnosis on the OHA Prioritized list OR is the member under 21 years of age with a condition that will limit the ability to grow, develop, or take part in school OR does the member have an above the line comorbid condition that will be treated indirectly by the requested medication? (IHN only question, for SCP/COMM move to question 2)
Yes = Go to Q2 No = Deny The plan does not cover medications that are being used for diagnosis that fall below the line on the OHA Prioritized List unless an above the line comorbid condition will be indirectly treated by the requested medication.
2. Is the requested medication being used for an FDA-approved indication OR being used for an off-label indication with well-established, clinical evidence supporting its use?
Yes = Go to Q3 No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.
3. Is this an initial or renewal request?
Initial = Go to Q4 Renewal = Go to Q9
4. Is the treatment being administered in consultation with a neurologist or headache specialist?

Yes = Go to Q5 No = Deny. The plan provides coverage of the requested medication when it is being administered in consultation with a neurologist or headache specialist. Based on the information provided, this requirement has not been met.
5. Is the member at least 18 years old?
Yes = Go to Q6 No = DENY. The plan covers the requested medication when the member is at least 18 years old. Based on the information provided, this requirement has not been met.
6. Does the member have a diagnosis of chronic migraine, defined as headaches on at least 15 days per month of which at least 8 days are migraines?
Yes = Go to Q7 No = DENY. The plan covers the requested medication when the member has a diagnosis of chronic migraine, defined as headaches on at least 15 days per month of which at least 8 days are migraines. Based on the information provided, this requirement has not been met.
7. Has the condition been appropriately managed for medication overuse?
Yes = Go to Q8 No = DENY. The plan covers the requested medication when the headache condition has been appropriately managed for medication overuse. Based on the information provided, this requirement has not been met.
8. Has the member failed or have contraindications to at least 3 prior prophylaxis therapies (e.g. beta-blocker, anticonvulsant, or tricyclic antidepressant)?
Yes = Approve for 2 treatments in 6 months No= DENY. The plan covers the requested medication when the member failed or have contraindications to at least 3 prior prophylaxis therapies (e.g. beta-blocker, anticonvulsant, or tricyclic antidepressant). Based on the information provided, this requirement has not been met.
9. Is there a documented positive response to therapy, defined as a reduction of at least 7 headache days per month compared to baseline headache frequency?
Yes = Approve x 12 months No = DENY. The plan covers the requested medication when there is a documented positive response to therapy, defined as a reduction of at least 7 headache days per month compared to baseline headache frequency. Based on the information provided, this requirement has not been met.

PA CRITERIA	
Covered Uses	**Urinary Incontinence/Overactive Bladder**

Required Medical Information	• Diagnosis of idiopathic detrusor over-activity (overactive bladder) or neurogenic detrusor over-activity (neurogenic bladder) • Failure of at least two anticholinergic medications such as oxybutynin, solifenacin, or tolterodine
Age Restrictions	
Prescriber Restrictions	Neurologist, urologist, or appropriate specialist
Exclusions	• Infection at proposed injection site • Neuromuscular disease (myasthenia gravis)
Coverage Duration	Initial: 3 months; Renewal: 12 months
Other	Renewal Criteria: Documentation of positive clinical response to therapy, defined as a reduction of urinary frequency of 8 episodes per day or urinary incontinence of 2 episodes per day compared to baseline frequency.

1. Is the requested medication being used to treat an above the line diagnosis on the OHA Prioritized list OR is the member under 21 years of age with a condition that will limit the ability to grow, develop, or take part in school OR does the member have an above the line comorbid condition that will be treated indirectly by the requested medication? (IHN only question, for SCP/COMM move to question 2)

Yes = Go to Q2
No = DENY. The plan does not cover medications that are being used for diagnosis that fall below the line on the OHA Prioritized List unless an above the line comorbid condition will be indirectly treated by the requested medication.

2. Is the requested medication being used for an FDA-approved indication OR being used for an off-label indication with well-established, clinical evidence supporting its use?

Yes = Go to Q3
No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

3. Is this an initial or renewal request?

Initial = Go to Q4
Renewal = Go to Q6

4. Does the member have a diagnosis of idiopathic detrusor over-activity (overactive bladder) or neurogenic detrusor over-activity (neurogenic bladder)?

Yes = Go to Q5

No = Deny. The plan covers the requested medication when the member has a diagnosis of idiopathic detrusor over-activity (overactive bladder) or neurogenic detrusor over-activity (neurogenic bladder). Based on the information provided, this requirement has not been met.

5. Has the member failed at least two anticholinergic medications, such as oxybutynin, solifenacin, or tolterodine?
Yes = Approve one treatment in 3 months No = DENY. The plan covers the requested medication when the member has failed at least two anticholinergic medications, such as oxybutynin, solifenacin, or tolterodine. Based on the information provided, this requirement has not been met.
6. Is there a documented positive response to therapy, defined as a reduction of urinary frequency of 8 episodes per day or urinary incontinence of 2 episodes per day compared to baseline frequency?
Yes = Approve x 12 months No = DENY. The plan covers the requested medication when there is a documented positive response to therapy, defined as a reduction of urinary frequency of 8 episodes per day or urinary incontinence of 2 episodes per day compared to baseline frequency. Based on the information provided, this requirement has not been met.

PA CRITERIA	
Covered Uses	**Strabismus**
Required Medical Information	• Diagnosis of strabismus due to other neurologic disorders (H50.89) causing functional impairment
Age Restrictions	
Prescriber Restrictions	Neurologist or ophthalmologist
Exclusions	• Infection at proposed injection site • Neuromuscular disease (myasthenia gravis)
Coverage Duration	Initial: 1 treatment in 3 months
Other	Renewal Criteria: Not approvable

1. Is the requested medication being used to treat an above the line diagnosis on the OHA Prioritized list OR is the member under 21 years of age with a condition that will limit the ability to grow, develop, or take part in school OR does the member have an above the line comorbid condition that will be treated indirectly by the requested medication? (IHN only question, for SCP/COMM move to question 2)
Yes = Go to Q2
No = Deny The plan does not cover medications that are being used for diagnosis that fall below the line on the OHA Prioritized List unless an above the line comorbid condition will be indirectly treated by the requested medication.
2. Is the requested medication being used for an FDA-approved indication OR being used for an off-label indication with well-established, clinical evidence supporting its use?

Yes = Go to Q3

No = DENY. The plan covers the requested medication when it is being used for an FDA-approved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

3. Is the request made by or supervised by an ophthalmologist or neurologist?

Yes = Go to Q4

No = DENY. The plan covers the requested medication when it is being prescribed or supervised by an ophthalmologist or neurologist? Based on the information provided, this requirement has not been met.

4. Does the member have functional impairment related to strabismus due to other neurologic disorders (H50.89)?

Yes = Approve one treatment in 3 months.
No = DENY. The plan covers the requested medication when the member has functional impairment related to strabismus due to other neurologic disorders (H50.89).

PA CRITERIA	
Covered Uses	**Achalasia**
Required Medical Information	• Diagnosis of achalasia • Symptomatic after a prior pneumatic dilation or surgical myotomy • Surgical risk for pneumatic dilation or surgical myotomy ○ High ○ Moderate to low ▪ Presentation with atypical achalasia symptoms and botulinum toxin is needed to help guide therapy or confirm diagnosis
Prescriber Restrictions	Gastroenterologist
Exclusions	• Infection at proposed injection site • Neuromuscular disease (myasthenia gravis)
Coverage Duration	Initial: one treatment in 3 months; Renewal: 12 months
Other	Renewal Criteria: Documentation of response to botulinum toxin, such as reduction in symptoms of dysphagia or reflux

1. Is the requested medication being used to treat an above the line diagnosis on the OHA Prioritized list OR is the member under 21 years of age with a condition that will limit the ability to grow, develop, or take part in school OR does the member have an above the line comorbid condition that will be treated indirectly by the requested medication? (IHN only question, for SCP/COMM move to question 2)

Yes = Go to Q2 No = Deny The plan does not cover medications that are being used for diagnosis that fall below the line on the OHA Prioritized List unless an above the line comorbid condition will be indirectly treated by the requested medication.
2. Is the requested medication being used for an FDA-approved indication OR being used for an off-label indication with well-established, clinical evidence supporting its use?
Yes = Go to Q3 No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.
3. Is this an initial or renewal request?
Initial = Go to Q4 Renewal = Go to Q9
4. Is the request made by or supervised by a gastroenterologist?
Yes = Go to Q5 No = Deny. The plan provides coverage of the requested medication when it is prescribed by or supervised by a gastroenterologist. Based on the information provided, this requirement has not been met.
5. Does the member have a diagnosis of achalasia?
Yes = Go to Q6 No = DENY. The plan covers the requested medication when the member has a diagnosis of achalasia. Based on the information provided, this requirement has not been met.
6. **Has the member remained symptomatic after a prior pneumatic dilation or surgical myotomy?**
Yes = Go to Q7 No = DENY. The plan covers the requested medication when a prior pneumatic dilation or surgical myotomy has failed to improve symptoms. Based on the information provided, this requirement has not been met.
7. Is the member a high surgical risk for pneumatic dilation or surgical myotomy?
Yes = Approve x 3 months. No = Go to Q8
8. Has the member presented with achalasia symptoms and botulinum toxin is needed to help guide therapy or confirm diagnosis?

Yes = Approve x 3 months No = DENY. The plan covers the requested medication when the botulinum toxin is needed to help guide therapy or confirm diagnosis. Based on the information provided, this requirement has not been met.
9. Has there been a positive response to botulinum toxin, such as reduction in symptoms of dysphagia or reflux?
Yes = Approve x 12 months No = DENY. The plan covers the requested medication when there has been a positive response to botulinum toxin. Based on the information provided, this requirement has not been met.

Sublocade (buprenorphine)

Products Affected

- Sublocade 100 mg/0.5 mL
- Sublocade 300 mg/1.5 mL

PA CRITERIA	
Covered Uses	In accordance with Oregon Law, INH would have to cover MAT in the first 30 days without clinical prior authorization. For Sublocade, this applies only through the medical benefit. Sublocade is not indicated for acute opioid withdrawals.
Exclusion Criteria	Documented moderate to severe opiate use disorder (score of 4 or more using DSM-V): • Problematic pattern of opioid use leading to clinically significant impairment or distress • Taking opioids in larger amounts or over a longer period of time than intended • Having a persistent desire or unsuccessful attempts to reduce or control opioid use • Spending excess time obtaining, using or recovering from opioids • Craving for opioids • Continuing opioid use causing inability to fulfill work, home, or school responsibilities • Continuing opioid use despite having persistent social or interpersonal problems • Lack of involvement in social, occupational, or recreational activities • Using opioids in physically hazardous situations • Continuing opioid use in spite of awareness of persistent physical or psychological problems • Tolerance, including need for increased amounts of opioids or diminished effect with continued use at the same amount (as long as the patient is not taking under medical supervision) • Withdrawal manifested by characteristic opioid withdrawal syndrome or taking opioids to relieve or avoid withdrawal symptoms (as long as the patient is not taking under medical supervision) Attestation by provider that patient is interested in treatment with injection and has been informed of all the risks associated with depot buprenorphine **AND** attestation by provider patient has been offered and referred to or is receiving appropriate treatment from an integrated

	behaviorist or external behavioral health services or documentation why that is not appropriate. **AND** documentation that patient is currently stable on SL buprenorphine (8-24mg of SL buprenorphine for at least 7 days) **AND** clear and compelling medical reason SL buprenorphine cannot be continued. Compelling medical reasons include: • Had an overdose in the past 12 months AND at least one trial of Suboxone in the last 12 months. • Had an SUD related hospitalization in the past 12 months AND at least one trial of Suboxone in the last 12 months. • Had recurrence of use on 24 mg oral Suboxone in the past 3 months AND at least 3 total inductions with Suboxone in the previous 3 years. • Repeated incidences of coerced/forced diversion from physical threats or abuse. • Has non-stable housing and inability to safely store/secure personal belongings. Lack of ability to fill monthly mediations due to patient living in a rural area
Age Restrictions	
Prescriber Restrictions	Initial: 6 months; Renewal 6 months
Other	In accordance with Oregon Law, INH would cover MAT in the first 30 days without clinical prior authorization. Authorization would be required after this first injection and approval is not guaranteed. For Sublocade, this applies only through the medical benefit. Sublocade is not indicated for acute opioid withdrawals.

1. Is this an initial or renewal request?
Initial = Go to Q3 Renewal = Go to Q2
2. Does the patient have documentation of the following: • **No ongoing illicit opioid use (confirmed by urine screen) AND** • **Provider assessment that a transition back to oral meds has been evaluated and deemed clinically inappropriate AND** • **Patient has remained engaged with treatment (adherence, treatment plan)**
Yes = APPROVE X6 months No = Deny
3. Is there documentation of moderate to severe opiate use disorder (score of 4 or more using DSM-V below): • **Problematic pattern of opioid use leading to clinically significant impairment or distress** • **Taking opioids in larger amounts or over a longer period of time than intended**

- **Having a persistent desire or unsuccessful attempts to reduce or control opioid use**
- **Spending excess time obtaining, using or recovering from opioids**
- **Craving for opioids**
- **Continuing opioid use causing inability to fulfill work, home, or school responsibilities**
- **Continuing opioid use despite having persistent social or interpersonal problems**
- **Lack of involvement in social, occupational, or recreational activities**
- **Using opioids in physically hazardous situations**
- **Continuing opioid use in spite of awareness of persistent physical or psychological problems**
- **Tolerance, including need for increased amounts of opioids or diminished effect with continued use at the same amount (as long as the patient is not taking under medical supervision)**
- **Withdrawal manifested by characteristic opioid withdrawal syndrome or taking opioids to relieve or avoid withdrawal symptoms (as long as the patient is not taking under medical supervision)**

Yes = Go to Q4

No = DENY

4. Is there Attestation by provider that patient is interested in treatment with injection and has been informed of all the risks associated with depot buprenorphine?

Yes = Go to Q5

No = DENY

5. Is there attestation by the provider that the patient has been offered and referred to, or is receiving appropriate treatment from an integrated behaviorist or external behavioral health services or documentation why that is not appropriate?

Yes = Go to Q6
No = DENY

6. Is there documentation that patient is currently stable on SL buprenorphine (8-24mg of SL buprenorphine for at least 7 days) AND clear and compelling medical reason SL buprenorphine cannot be continued?

Note: Compelling medical reasons include:

- **Had an overdose in the past 12 months AND at least one trial of Suboxone in the last 12 months.**
- **Had an SUD related hospitalization in the past 12 months AND at least one trial of Suboxone in the last 12 months.**
- **Had recurrence of use on 24 mg oral Suboxone in the past 3 months AND at least 3 total inductions with Suboxone in the previous 3 years.**
- **Repeated incidences of coerced/forced diversion from physical threats or abuse.**
- **Has non-stable housing and inability to safely store/secure personal belongings.**

Yes = Approve x6 months

No = DENY

Cabenuva Drug Name (cabotegravir/rilpivirine)

Products Affected

- Cabenuva 400 mg/600 mg Kit
- Cabenuva 600 mg/900 mg Kit

PA CRITERIA	
Covered Uses	Diagnosis of HIV-1 infection
Exclusion Criteria	Known or suspected treatment failure or resistance to cabotegravir or rilpivirine
Required Medical Information	**For HIV-1 infection treatment, all the following:** • Diagnosis of HIV-1 infection • Patient has no prior virologic failures or baseline resistance to either cabotegravir or rilpivirine AND • Patient is currently on a stable antiretroviral regimen and • Submission of medical records (e.g., chart notes, laboratory results) showing viral suppression (HIV-1 RNA less than 50copies per mL) for at least 6 months prior to initiation of Cabenuva; and • Provider attests that patient demonstrates treatment readiness by both of the following: ○ Patient understands the risks of missed doses of Cabenuva ○ Patient can adhere to the required monthly injection appointments AND • Provider confirms that tolerability will be assessed using a 28-day oral lead-in of Vocabria (cabotegravir) and Edurant®(rilpivirine) tablets prior to the first injection of Cabenuva AND • Dosing is in accordance with the United States Food and Drug Administration approved labeling
Age Restrictions	Age 18 or older
Prescriber Restrictions	Infectious disease
Coverage Duration	Initial: 12 months; Renewal: 12 months
Other	Renewal Criteria: Documentation of positive clinical response to therapy.

1. Is the requested medication being used to treat an above the line diagnosis on the OHA Prioritized list OR is the member under 21 years of age with a condition that will limit the ability to grow, develop, or take part in school OR does the member have an above the line comorbid condition that will be treated indirectly by the requested medication? (IHN only question, for SCP/COMM move to question 2)

Yes = Go to Q2

No = Deny The plan does not cover medications that are being used for diagnosis that fall below the line on the OHA Prioritized List unless an above the line comorbid condition will be indirectly treated by the requested medication.

2. Is the requested medication being used for an FDA-approved indication OR being used for an off-label indication with well-established, clinical evidence supporting its use?
Yes = Go to Q3 No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.
3. Is this an initial or renewal request?
Initial = Go to Q5 Renewal = Go to Q4
4. Does the patient have documentation of continued effectiveness of the requested medication (e.g. patient has achieved and maintained viral suppression (<50 copies of HIV-1 RNA per mL).
Yes = APPROVE X 1 year No = DENY
5. Is the request for the treatment of HIV-1 infection?
Yes = Go to Q6 No = DENY
6. Is the patient currently on a stable antiretroviral regimen and is currently virologically suppressed (e.g. HIV1 RNA < 50 copies per mL) for at least 6 months prior to initiation of Cabenuva?
Yes = Go to Q7 No = DENY
7. Is there documentation that the patient demonstrates treatment readiness by both of the following: **- Patient demonstrates understanding of the risks of missed doses of Cabenuva** **- Patient can adhere to the required monthly injection appointments**
Yes = Go to Q8 No = DENY
8. Is the dosing of Cabenuva within FDA approved dosing?
Yes = APPROVE X 1 year
No = DENY

Eylea (aflibercept)

Products Affected

- Aflibercept 2mg/0.05mL

PA CRITERIA	
Covered Uses	For use in the following FDA approved conditions: • Age-related macular degeneration • Diabetic macular edema • Diabetic retinopathy • Macular edema following retinal vein occlusion

1. Is this an initial or renewal request?
Initial = Go to Q4 Renewal = Go to Q2
2. Has the provider increased the interval between injections to every 8 weeks OR is there documentation that increased intervals have been attempted and failed?
Yes = Go to Q3 No = Deny
3. Has the member demonstrated disease stabilization or clinical response?
Yes = APPROVE X 1 year No = Deny
4. Does the member have one of the following diagnoses: Age-related macular degeneration, Diabetic macular edema, Diabetic retinopathy, or Macular edema following retinal vein occlusion?
Yes = Go to Q5 No = DENY
5. Has the patient tried and failed Avastin?
Yes = Approve x 6 months No = DENY

Interleukin-17 and 23 antagonists: Skyrizi (Risankizumab), Ilumya (tildrakizumab), Stelara (Ustekinumab)

Products Affected

- J3590 Skyrizi (Risankizumab): 600mg/10mL IV Solution
- J3245 Ilumya (tildrakizumab): 100mg/mL solution prefilled syringe
- J3358 Stelara (ustekinumab-Crohn's): 136mg/26mL IV solution

PA CRITERIA	
Covered Uses	Ilumya: moderate to severe plaque psoriasis Skyrizi: Moderately to severely active Crohn's disease, Plaque psoriasis (moderate to severe), psoriatic arthritis Stelara IV: Crohn's disease, ulcerative colitis
Exclusion Criteria	Active serious infection No latent or active TB
Required Medical Information	Clinical documentation pertaining to medication request
Age Restrictions	Review for age appropriate dosing/approval of medication
Prescriber Restrictions	Ilumya: Dermatologist Skyrizi: Dermatologist Stelara: Dermatologist, rheumatologist, gastroenterologist
Coverage Duration	Initial: 6 months; Renewal: 12 months
Other	Renewal Criteria: Documentation of positive clinical response to therapy.

1. Is the requested medication being used to treat an above the line diagnosis on the OHA Prioritized list OR is the member under 21 years of age with a condition that will limit the ability to grow, develop, or take part in school OR does the member have an above the line comorbid condition that will be treated indirectly by the requested medication? (IHN only question, for SCP/COMM move to question 2)

Yes = Go to Q2

No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

2. Is the request for maintenance of remission in a patient who already achieved remission with the requested product or has already initiated therapy?

Yes = Continue to renewal criteria for the submitted diagnosis

No = Go to Q3

3. Has the risk of infections been addressed by the following?

- **Initial testing for latent TB and treatment, if necessary, before starting treatment**
- **No current active infection at initiation of therapy**
- **Risks and benefits documented in cases of chronic or recurrent infection**

Yes = Go to Q4

No = DENY. The plan covers the requested medication when information from the provider shows the medication is safe for use. Based on the information provided, this requirement has not been met.

4. Has the treatment been initiated by or is an appropriate specialist currently supervising it?

- **Ankylosing Spondylitits and Axial Spondyloarthritis: Rheumatologist**
- **Crohn's Disease: Gastronenterology**
- **Juvenile Idiopathic Arthritis: Rheumatologist**
- **Plaque Psoriasis: Dermatologist**
- **Psoriatic Arthritis: Dermatologist or Rheumatologist**
- **Ulcerative Colitis: Gastroenterologist**

Yes = Go to Q5
No = The plan covers the requested medication when it is prescribed by or in consultation with a specialist. Based on the information provided, this requirement has not been met.

5. Is the requested agent to be used in combination with another biologic or Otezla?

Yes = Continue to specific criteria for the submitted indication.

No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

Crohn's Disease

1. Is this an initial or renewal request?

Initial = Go to Q3
Renewal = Go to Q2

2. Has the member experienced a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission?

Yes = APPROVE X 12 months

No = Deny. The plan provides coverage of the requested medication when the patient has documented continued effectiveness. Based on the information provided, this requirement has not been met.

3. Is the member transitioning to the requested treatment from a different biologic product?

Yes = Go to Q5

No = Go to Q4

4. Does the member have a diagnosis of moderate to severe Crohn's disease?

- **Moderate to severe CD (CDAI score 220-450): failure to respond to treatment for mild to moderate disease, fever, abdominal pain/tenderness, vomiting, weight loss, anemia, intestinal obstruction**
- **Severe to fulminant (CDAI score >450): Persistent symptoms despite outpatient therapy, abdominal pain, rebound tenderness, high temperature, persistent vomiting, possible obstruction, abscess**

Yes = Go to Q5
No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for a moderate to severe Crohn's disease. Based on the information provided, this requirement has not been met.

5. has the member tried and failed ALL of the following?

- **Conventional therapy (at least 1 agent: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate), AND**
- **Infliximab, AND**
- **Humira**

Yes = APPROVE X 6 months

No = DENY. The plan covers the requested medication when there has been trial and failure of conventional therapy (6-mercaptopurine, azathioprine, corticosteroids, methotrexate), Humira, and infliximab. Based on the information provided, this requirement has not been met.

Plaque Psoriasis

1. Is this an initial or renewal request?

Initial = Go to Q2
Renewal = Go to Q3

2. Is there documentation of positive clinical response to therapy as evidenced by ONE of the following:

- **Reduction of body surface area (BSA) involvement from baseline**
- **Improvement in symptoms (e.g. pruritus, inflammation) from baseline**
- **Evidence of functional improvement**

Yes = APPROVE X 12 MONTHS

No = Deny. The plan provides coverage of the requested medication when the patient has documented continued effectiveness. Based on the information provided, this requirement has not been met.

3. Is the member transitioning to the requested treatment from a different biologic product?

Yes = Go to Q5

No = Go to Q4

4. Has the member tried and failed or have contraindications to ALL of the following? •
High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)
- **At least one other topical agent: calcipotriene, tazarotene, anthralin, tar, etc.**
- **PUVA or UVB Phototherapy**
- **Methotrexate**
- **At least 1 other second line systemic agent such as cyclosporine or acitretin**

Yes = Go to Q5

No = DENY. The plan covers the requested medication when there has been a trial and failure of topical highpotency corticosteroids, topical agents such as calcipotriene, tazarotene, etc., UV therapy, methotrexate and at least 1 other agent such as cyclosporine or acitretin. Based on the information provided, this requirement has not been met.

4. Has the member tried and failed biologic therapy with ALL of the following?
- **Infliximab AND**
- **Humira**

Yes = APPROVE X 6 months
No = DENY. The plan covers the requested medication when there is documentation of trial and failure of infliximab and Humira therapy. Based on the information provided, this requirement has not been met.

Psoriatic Psoriasis

1. Is this an initial or renewal request?

Initial = Go to Q2
Renewal = Go to Q3

2. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count?

Yes = APPROVE X 12 months

No = DENY. The plan provides coverage of the requested medication when the patient has documented continued effectiveness. Based on the information provided, this requirement has not been met.

3. Is the member transitioning to the requested treatment from a different biologic product?

Yes = Go to Q6
No = Go to Q4

4. Does the member have psoriatic arthritic based on at least 3 out of 5 of the following?
- **Psoriasis (1 point for personal or family history, 2 points for current) •**
Psoriatic nail dystrophy

- **Negative test result for RF**
- **Dactylitis (current of history)**
- **Radiological evidence of juxta-articular new bone formation**

Yes = Go to Q5

No = DENY. The plan covers the requested medication when there is documentation of moderate to severe psoriatic arthritis. Based on the information provided, this requirement has not been met.

5. Has the member failed of have contraindications to conventional management with all the following?

- **NSAIDs, *AND***
- **Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine**

Yes = Go to Q6

No = DENY. The plan covers the requested medication when there is documented trial and failure of conventional therapy with anti-inflammatory medication and other disease modifying agents such as methotrexate, leflunomide, sulfasalazine or cyclosporine. Based on the information provided, this requirement has not been met.

6. Has the member tried and failed or have contraindication biologic therapy including infliximab and Humira?

Yes = APPROVE X 6 months

No = DENY. The plan covers the requested medication when there is documented trial and failure of biologic therapy with infliximab and Humira. Based on the information provided, this requirement has not been met.

Ulcerative Colitis

1. Is this an initial or renewal request?

Initial = Go to Q2

Renewal = Go to Q3

2. Has the member demonstrated a significant response including the following?

- **Decrease in bloody stools per day and/or**
- **Elimination of signs of toxicity**

Yes = APPROVE X 12 months

No = Deny. The plan provides coverage of the requested medication when the patient has documented continued effectiveness. Based on the information provided, this requirement has not been met.

3. Is the member transitioning to the requested treatment from a different biologic product?

Yes = Go to Q6
No = Go to Q4

4. Does the member have a diagnosis of moderate to severe ulcerative colitis defined by the following criteria?

- **Moderate = greater than or equal to 4 stools daily**
- **Severe = greater than or equal to 6 bloody stools daily and evidence of toxicity such as fever, anemia, elevated ESR, or tachycardia**

Yes = Go to Q5

No = DENY. The plan covers the requested medication when there is documentation of moderate or severe ulcerative colitis. Based on the information provided, this requirement has not been met.

5. Has the member tried and failed to at least 1 of the following conventional immunosuppressive therapies?

- **Mesalamine, olsalazine, sulfasalazine**
- **Mercaptopurine, azathioprine, OR**
- **Corticosteroids (prednisone, methylprednisolone)**

Yes = Go to Q6
No = DENY. The plan covers the requested medication when there is trial and failure of conventional immunosuppressive therapies such as: mesalamine, sulfasalazine, mercaptopurine, azathioprine, and corticosteroids. Based on the information provided, this requirement has not been met.

6. Has the member tried and failed or have contraindication biologic therapy including infliximab and Humira?

Yes = APPROVE X 6 months
No = DENY. The plan covers the requested medication when there has been a trial and failure of preferred biologic therapy with infliximab and Humira. Based on the information provided, this requirement has not been met.

Oncology

Products Affected

- A drug or biological used in an anti-cancer chemotherapeutic regimen

PA CRITERIA	
Covered Uses	For use in cancer treatment
Required Medical Information	- Indication is supported by FDA indication or NCCN guidelines. - Prescribed by an oncologist or hematologist
Coverage Duration	Initial: 6 months; Renewal: 12 months

1. Is the requested medication supported for use by FDA indication OR National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B
Yes = Go to Q2 No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.
2. Is the requested medication being prescribed by an oncologist or hematologist?
Yes = Go to Q3 No = DENY.
3. Is this an initial or renewal request?
Initial = Approve x 6 months Renewal = Go to Q4
4. Is there clinical documentation or attestation of continued efficacy and tolerability?
Yes = APPROVE X 12 months No = Deny. The plan provides coverage of the requested medication when the patient has documented continued effectiveness. Based on the information provided, this requirement has not been met.

Humira (adalimumab), Enbrel (etanercept), Simponi Aria (golimumab), Remicade (infliximab), Inflectra (infliximab-dyyb), Renflexis (infliximab-abda), Ixifi (infliximab-qbtx), Avsola (infliximab-axxq),

PA CRITERIA	
Covered Uses	**Adalimumab:** Active Ankylosing spondylitis, Moderate to Severe Crohn's disease, Moderate to Severe Hidradenitis suppurativa, Juvenile idiopathic arthritis, Moderate to Severe plaque psoriasis, Psoriatic arthritis, Moderate to Severe Rheumatoid arthritis, Moderate to Severe ulcerative colitis, Uveitis **Certiolizumab:** ankylosing spondylitis, moderate to severe Crohn's disease, non-radiographic axial spondyloarthritis, moderate to severe plaque psoriasis, psoriatic arthritis, moderate to severe rheumatoid arthritis **Etanercept:** ankylosing spondylitis, moderate to severe plaque psoriasis, psoriatic arthritis, Moderate to severe rheumatoid arthritis **Golimumab:** ankylosing spondylitis, psoriatic arthritis, moderate to severe rheumatoid arthritis (in combination with methotrexate), moderate to severe ulcerative colitis **Infliximab:** ankylosing spondylitis, Fistulizing Crohn's disease, Moderate to severe Crohn's disease (in patients with inadequate response to conventional therapy), severe plaque psoriasis, psoriatic psoriasis, moderate to severe rheumatoid arthritis (in combination with methotrexate), moderate to severe ulcerative colitis (in patients with an inadequate response to conventional therapy)
Exclusion Criteria	Active infection Latent TB infection Class II
Required Medical Information	Pertinent chart notes
Age Restrictions	Dependent on agent
Prescriber Restrictions	Dermatologist Immunologist Gastroenterologist Rheumatologist Ophthamologist
Coverage Duration	Initial: 6 months; Renewal: 12 months
Other	Renewal Criteria: Documentation of positive clinical response to therapy.

All Diagnoses

1. Is the requested medication being used to treat an above the line diagnosis on the OHA Prioritized list OR is the member under 21 years of age with a condition that will limit the ability to grow, develop, or take part in school OR does the member have an above the line comorbid condition that will be treated indirectly by the requested medication? (IHN only question, for SCP/COMM move to question 2)

Yes = Go to Q2

No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

2. Is the request for maintenance of remission in a patient who already achieved remission with the requested product or has already initiated therapy?

Initial = Go to Q3

Renewal = Go to renewal criteria for the submitted diagnosis

3. Has the risk of infections been addressed by the following?

- **Initial testing for latent TB and treatment, if necessary, before starting therapy**
- **No current active infection at initiation of therapy**
- **Risks and benefits documented in cases of chronic or recurrent infection**

Yes = Go to Q4

No = Deny. The plan provides coverage of the requested medication when there is information from your provider that the medication is safe to take.

4. Has the treatment been initiated by or is an appropriate specialist currently supervising it?

- **Ankylosing Spondylitis and Axial Spondyloarthritis: Rheumatologist**
- **Crohn's Disease: Gastroenterologist**
- **Hidradenitis Suppurativa: Dermatologist**
- **Juvenile Idiopathic Arthritis: Rheumatologist**
- **Plaque Psoriasis: Dermatologist**
- **Psoriatic Arthritis: Dermatologist or Rheumatologist**
- **Rheumatoid Arthritis: Rheumatologist**
- **Ulcerative Colitis: Gastroenterologist**
- **Uveitis: Ophthalmologist or Rheumatologist**

Yes = Go to Q5
No = DENY. The plan covers the requested medication when is prescribed by a specialist knowledgeable in managing <list Dx here>. Based on the information provided, this requirement has not been met.

5. Is the requested agent to be used in combination with another biologic or Otezla?

Yes = DENY. The plan covers the requested medication when the requested medication is being used for an FDA-approved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

No = Continue diagnosis specific criteria

Ankylosing Spondylitis and Axial Spondyloarthritis

1. Does the member have ankylosing spondylitis or axial spondyloarthritis (radiographic or nonradiographic)? Diagnosis is definitive if the following are met:

- **Back pain and stiffness for more than 3 months AND**
- **Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive**

Yes = Go to Q2

No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

2. Does the member have moderate to severe active disease at baseline, as evidenced by an objective test such as the BASDAI?

Yes = Go to Q3

No = The plan covers the requested medication when it is used for moderate to severe active ankylosing spondylitis and axial spondyloarthritis confirmed by an objective test (e.g. BASDAI). Based on the information provided, this requirement has not been met.

3. Is the member transitioning to the requested treatment from a different biologic product?

Yes = APPROVE X 6 months

No = Go to Q5

5. has the member tried and failed conventional therapy with both of the following:

- **At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND**
- **Physical therapy/exercise program**

Yes = APPROVE X 6 months

No = DENY. The plan covers the requested medication when there has been a 3-month trial of at least 2 antiinflammatory medication (unless contraindicated) and when the medication will be used in combination with physical therapy or an exercise program. Based on the information provided, this requirement has not been met.

Renewal Criteria

1. Does the member have significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI?

Yes = APPROVE X 12 months

No = Deny. The plan provides coverage of the requested medication when the patient has documented continued effectiveness. Based on the information provided, this requirement has not been met.

Crohn's Disease

1. Is this an initial or renewal request?

Initial = Go to Q2
Renewal = Go to Q5

2. Does the member have moderate to severe Crohn's disease?

- **Moderate to severe CD (CDAI score 220-450): failure to respond to treatment for mild to moderate disease, fever, abdominal pain/tenderness, vomiting, weight loss, anemia, intestinal obstruction**
- **Severe to fulminant (CDAI score >450): Persistent symptoms despite outpatient therapy, abdominal pain, rebound tenderness, high temperature, persistent vomiting, possible obstruction, abscess**

Yes = Go to Q3

No = Deny. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

3. Is the member transitioning from a different biologic product?

Yes = APPROVE X 12 months

No = Go to Q4

4. Has the member tried and failed to respond to at least 1 of the following conventional immunosuppressive therapies for ≥6 months or have moderate/high disease burden risk?

- **Mercaptopurine, azathioprine, or budesonide OR**
- **Have a documented intolerance or contraindication to conventional therapy (corticosteroids, methotrexate, etc.)?**
- **Does member have moderate/high disease burden risk (age <30 at initial diagnosis, extensive anatomic involvement, perianal and/or severe rectal disease, ulcers, prior surgical resection, structuring and/or penetrating behavior)**

Yes = APPROVE X 12 months
No = DENY. The plan covers the requested medication when there has been a trial and failure of conventional therapy, or trial of conventional therapy is not recommended. Based on the information provided, this requirement has not been met.

5. Has the member experienced a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission?

Yes = APPROVE X 12 months

No = Deny. The plan provides coverage of the requested medication when the patient has documented continued effectiveness. Based on the information provided, this requirement has not been met.

Hidradenitis Suppurativa

1. Is this an initial or renewal request?

Initial = Go to Q3

Renewal = Go to Q2

2. Does the patient have documentation of continued effectiveness of the requested medication?

- **A reduction of 25% or more of the total abscess and inflammatory nodule count AND • No increase in abscesses and draining fistulas**

Yes = APPROVE X 12 months

No = DENY. The plan provides coverage of the requested medication when the patient has documented continued effectiveness. Based on the information provided, this requirement has not been met.

3. Does the member have a diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II or Hurley Stage III)*?

Yes = Go to Q4

No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use ***OR (INH ONLY)*** Deny. The plan does not cover medications that are being used for diagnosis that fall below the line on the OHA Prioritized List unless an above the line comorbid condition will be indirectly treated by the requested medication.

4. Has the member tried and failed 90 day trial of conventional therapy (e.g. oral antibiotics), unless such a trial is not tolerated or contraindicated

Yes = APPROVE X 12 months
No = Deny. The plan covers the requested medication when there has been a trial of conventional therapy (such as antibiotic therapy). Based on the information provided, this requirement has not been met.

*For IHN members, condition is funded if it meets the criteria of guideline note 198 for moderate to severe hidradenitis suppurativa.

Juvenile Idiopathic Arthritis

1. Is this an initial or renewal request?

Initial = Go to Q3
Renewal Go to Q2

2. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability?

Yes = APPROVE X 12 months

No = DENY. The plan provides coverage of the requested medication when the patient has documented continued effectiveness. Based on the information provided, this requirement has not been met.

3. Does the member have juvenile idiopathic arthritis with active systemic features of juvenile idiopathic arthritis, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement)?

Yes = Go to Q5
No = Go to Q4

4. Does the member have juvenile idiopathic arthritis without active systemic features of juvenile idiopathic arthritis?

Yes = Go to Q5

No = DENY. The plan covers the requested medication when there are active systemic features of juvenile idiopathic arthritis. Based on the information provided, this requirement has not been met.

5. Is the member transitioning to the requested treatment from a different biologic product?

Yes = APPROVE X 6 months
No = Go to Q6

6. Has the member failed to respond or had inadequate response to NSAID and at least one of the following medications

- **≥6 months Methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, or systemic corticosteroids; OR**
- **Have documented intolerance or contraindication to DMARDs; AND**
- **Member will continue DMARD therapy (unless contraindicated)**

Yes = APPROVED X 6 months
No = DENY. The plan covers the requested medication when there has been trial and failure of medications such as anti-inflammatory agents, methotrexate, leflunomide, sulfasalazine or hydroxychloroquine. Based on the information provided, this requirement has not been met.

Non-infectious Uveitis

1. Is this an initial or renewal request?

Initial = Go to Q3

Renewal = Go to Q2.

2. Is there documentation that disease activity has been controlled, such as a lack of inflammation, no new inflammatory vascular lesions, no vitreous haze or decreases in visual acuity?

Yes = APPROVE X 12 months
No = DENY. The plan provides coverage of the requested medication when the patient has documented continued effectiveness. Based on the information provided, this requirement has not been met.

3. Does the member have a diagnosis of non-infectious, intermediate, posterior or panuveitis?

Yes = Go to Q4
NO = DENY. The plan provides coverage of the requested medication when the patient has documentation of non-infectious, intermediate, posterior or panuveitis. Based on the information provided, this requirement has not been met.

4. Has the member failed one of each of the following?

- **Topical glucocorticoids for at least 1 month OR periocular steroid injection, AND**
- **Oral corticosteroids, AND**
- **Immunomodulator: mycophenolate, tacrolimus, cyclosporine, azathioprine, or methotrexate**

Yes = APPROVE X 6 months

No = Deny. The plan covers the requested medication when there is documentation of trail and failure of topical glucocorticoids, periocular steroid injections, oral corticosteroids, or immunomodulator (mycophenolate, tacrolimus, cyclosporine, azathioprine, or methotrexate). Based on the information provided, this requirement has not been met.

Plaque Psoriasis

1. Is this an initial or renewal request?

Renewal = Go to Q2
Initial = Go to Q3

2. Is there documentation of positive clinical response to therapy as evidenced by ONE of the following:

- **Reduction of body surface area (BSA) involvement from baseline**
- **Improvement in symptoms (e.g. pruritus, inflammation) from baseline •**
  Evidence of functional improvement

Yes = APPROVE X 12 months

No = Deny. The plan provides coverage of the requested medication when the patient has documented continued effectiveness. Based on the information provided, this requirement has not been met.

3. Does the member have a diagnosis of moderate to severe chronic plaque psoriasis*?

- **Severe symptoms for coverage on Medicaid require: functional impairment as indicated by Dermatology Live Quality Index (DLQI) ≥ 11, Children's Dermatology Life Quality Index (CDLQI) ≥ 13, or score of severity on validated tool AND one or more of the following ○ At least 10% of body surface area involved ○ Hand, foot, face, or mucous membrane involvement**

Yes = Go to Q3
No = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use ***OR (INH Only)*** Deny. The plan does not cover medications that are being used for diagnosis that fall below the line on the OHA Prioritized List unless an above the line comorbid condition will be indirectly treated by the requested medication.

4. Is the member transitioning to the requested treatment from a different biologic product?

Yes = APPROVE X 6 months

No = Go to Q5

5. Has the member tried and failed or have contraindications to ALL of the following?

- **High-potency topical corticosteroids, such as augmented betamethasone cream 0.05%, desoximetasone 0.25% cream, or clobetasol, AND**
- **At least one other topical agent: calcipotriene, tazarotene, anthralin, tar, AND**
- **PUVA or UVB phototherapy, AND**
- **Methotrexate, AND**
- **At least one other second line systemic agent, such as cyclosporine or acitretin**

Yes = APPROVE X 6 months

No = Deny. The plan provides coverage of the requested medication when there has been adequate trial of high potency topical corticosteroids, other topical agents (e.g. calcipotriene, tazarotene, etc.), phototherapy, methotrexate, and at least one other second line systemic agent (e.g. cyclosporine, acitretin, etc.). Based on the information provided, this requirement has not been met.

*IHN members are only eligible for coverage for psoriasis symptoms that are classified as severe in nature per guideline note 21

Psoriatic Arthritis

1. Is this an initial or renewal request?

Initial: Go to Q3

Renewal: Go to Q2

2. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count?

Yes = APPROVE X 12 months

No = Deny. The plan provides coverage of the requested medication when the patient has documented continued effectiveness. Based on the information provided, this requirement has not been met.

3. Does the member have psoriatic arthritic based on at least 3 out of 5 of the following?

- **Psoriasis (1 point for personal or family history, 2 points for current)**
- **Psoriatic nail dystrophy**
- **Negative test result for RF**
- **Dactylitis (current of history)**
- **Radiological evidence of juxta-articular new bone formation**

Yes = Go to Q4
No = DENY. The plan covers the requested medication when there is a confirmed diagnosis of psoriatic arthritis. Based on the information provided, this requirement has not been met.

4. Is the member transitioning to the requested treatment from a different biologic product?

Yes = APPROVE X 12 months

No = Go to Q5

5. Has the member failed of have contraindications to conventional management with all the following?

- **NSAIDs, *AND***
- **Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine**

Yes = APPROVE X 6 months

No = DENY. The plan covers the requested medication when there is documented trial and failure of antiinflammatory medication and methotrexate or other disease modifying drugs such as leflunomide, sulfasalazine, or cyclosporine.

Rheumatoid Arthritis

1. Is this an initial or renewal request?

Initial = Go to Q3

Renewal = Go to Q2

2. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count?

Yes = APPROVE X 12 months
No = Deny. The plan provides coverage of the requested medication when the patient has documented continued effectiveness. Based on the information provided, this requirement has not been met.

3. Does the member have a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)?

Yes = Go to Q4

No = DENY. The plan covers the requested medication when there is a diagnosis of moderate to high disease activity of rheumatoid arthritis. Based on the information provided, this requirement has not been met.

4. Is the member transitioning to the requested treatment from a different biologic product?

Yes = Go to Q

No = Go to Q5

5. Has the member tried and failed or have contraindications to nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine?

YES = APPROVE X 6 months
NO = The plan covers the requested medication when there is documented trial and failure of nonbiologic DMARD therapy. Based on the information provided, this requirement has not been met.

Ulcerative Colitis

1. Is this a renewal or initial request?

Initial = Go to Q3

Renewal = Go to Q2

2. Has the member experienced a significant response to treatment including:

- **Decrease in bloody stools per day and/or**
- **Elimination of signs of toxicity**

Yes = APPROVE X 12 months

No = DENY. The plan covers the requested medication when there is evidence of positive clinical effect from therapy. Based on the information provided, this requirement has not been met.

3. Does the member have a diagnosis of moderate to severe ulcerative colitis defined by the following criteria:

- **Moderate: greater than or equal to 4 stools daily**
- **Severe: ≥6 bloody stools daily AND evidence of toxicity (fever, anemia, elevated ESR, or tachycardia)**

YES = Go to Q4

NO = DENY. The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

4. Has the member tried and failed to at least 1 of the following conventional immunosuppressive therapies?

- **Mesalamine, olsalazine, sulfasalazine**
- **Mercaptopurine, azathioprine, OR**
- **Corticosteroids (prednisone, methylprednisolone)**

Yes = APPROVE X 6 months
No = Deny. The plan provides coverage of the requested medication when the patient has documented continued effectiveness. Based on the information provided, this requirement has not been met.

Recommended therapy to induce remission in members naïve to biologic agents: ***infliximab* or ***vedolizumab*** is preferred over adalimumab for induction of remission. If member has previously been exposed to infliximab (especially those non-responsive to therapy), ***ustekinumab*** or ***tofacitinib*** are preferred over vedolizumab or adalimumab for induction of remission.

Actemra (tocilzumab)

Products Affected

- Actemra IV solution 80mg/4mL, 200mg/10mL, 400mg/20mL

PA CRITERIA	
Covered Uses	• Cytokine release syndrome, Chimeric antigen receptor T-cell induced, severe or life-threatening disease • Juvenile idiopathic arthritis, polyarticular • Lung disease with systemic sclerosis • Rheumatoid arthritis (moderate to severe) • Systemic onset juvenile chronic arthritis • Temporal arteritis
Exclusion Criteria	Concomitant use: Biological DMARD therapy (e.g. TNF inhibitors)
Required Medical Information	Chart notes pertinent to requested therapy
Age Restrictions	Age ≥ 2 years old
Prescriber Restrictions	Rheumatology Pulmonology Cardiology Hematology
Coverage Duration	Initial: 6 months; Renewal: 12 months
Other	Renewal Criteria: Documentation of positive clinical response to therapy.

All Diagnoses
1. Is the requested agent indicated for or supported for use in the submitted diagnosis for the member's age?
Yes = Go to Q2 No = DENY
2. Is the request for maintenance of remission in a patient who already achieved remission with the requested product or has already initiated therapy?
Yes = Continue to renewal criteria for the submitted diagnosis No = Continue to Q3
3. Has the risk of infections been addressed by the following? • **Initial testing for latent TB and treatment, if necessary, before starting therapy** • **No current active infection at initiation of therapy** • **Risks and benefits documented in cases of chronic or recurrent infection**
Yes = Continue to Q4
No = DENY

4. Does the member have medical record documentation of all the following?

- **Absolute neutrophil count (ANC) above 2000/mm3, and**
- **Platelet count above 100,000/mm, and**
- **ALT or ASL below 1.5 times the upper limit of normal (ULN)**

Yes = Go to Q5

No = DENY

5. Has the treatment been initiated by or is an appropriate specialist currently supervising it?

Yes = Continue to 6
No = DENY

6. Is the requested agent to be used in combination with another biologic?

Yes = DENY

No = Continue to diagnosis specific criteria

Giant Cell Arteritis

1. Is this an initial or renewal request?

Renewal = Go to Q2

Initial = Go to Q4

2. Is there clinical documentation of laboratory monitoring of neutrophile, platelets, liver function tests, and lipids?

Yes = Go to Q3
No = DENY

3. Has the member achieved clinical response, including normalization of erythrocyte sedimentation rate and c-reactive protein, successful steroid taper, or sustained absence of signs and symptoms?

Yes = Approve x 12 months
No = Deny

4. Does the member have a diagnosis of giant cell arteritis diagnosed by temporal artery biopsy or imaging?

Yes = Go to Q5

No = DENY

5. Has the member tried high dose steroids (starting with prednisone 60mg per day) to induce remission?

Yes = Go to Q6
No = DENY

6. Is the member currently on steroids and has failed to respond or failed to maintain remission during a taper according to schedule?

Yes = Go to Q7

No = Deny

7. Will the requested product be initiated in conjunction with a steroid taper?

Yes = Approve for 6 months
No = DENY

Juvenile Idiopathic Arthritis

1. Is this an initial or renewal request?

Yes = Go to Q2
No = Go to Q3

2. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count or stabilization of active systemic activity?

Yes = Approve x 12 months

No = Deny

3. Does the member have juvenile idiopathic arthritis with active systemic features of JIA , with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement)?

Yes = Go to Q4
No = DENY

4. Does the member have juvenile idiopathic arthritis without active systemic features of JIA?

Yes = Go to Q5

No = DENY

5. Has the member tried and failed systemic corticosteroids?

Yes = Go to Q6
No = DENY

6. Has the member tried and failed methotrexate or leflunomide for at least 3 months (or have a contraindication to both)?

Yes = APPROVE X 6 months

No = Deny

Rheumatoid Arthritis

1. Is this an initial or renewal request?

Renewal = Go to Q2 Initial
= Go to Q4.

2. Is there documentation of laboratory monitoring of neutrophils, platelets, liver function tests, and lipids?

Yes = Go to Q3
No = DENY

3. has the member experienced 20% or greater improvement in tender joint count and swollen joint?

Yes = APPROVE x 12 months

No = Deny

4. Does the member have a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)?

Yes = Go to Q5
No = Deny

5. Is the member transitioning to the requested treatment from a different biologic product?

Yes = Go to Q7

No = Go to Q6

6. Has the member tried and failed or have contraindications to all of the following:

- **Methotrexate dosed at least 20mg per week for 8 weeks**
- **Leflunomide (exclude if member is on methotrexate)**
- **Hydroxychloroquine**
- **sulfasalazine**

Yes = Go to Q7
No = DENY

7. Has the member tried and failed or have contraindication to infliximab?

Yes = APPROVE X 6 months

No = DENY

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)

Is this an initial or renewal request?

Initial = Go to Q3

Renewal = Go to Q2

2. Has the provider documented a decrease in decline in lung function?

Yes = APPROVE X 12 months
No = DENY

3. Does the member have a confirmed diagnosis of SSc-ILD?

Yes = Go to Q5

No = DENY

Has the member failed mycophenolate mofetil (or cyclophosphamide if unable to take mycophenolate)?

Yes = APPROVE X 6 months

No = Deny

Thyroid Eye Disease

1. Does the member have a diagnosis of Graves' Disease?

Yes = Go to Q2

No = DENY

2. Is the patient pregnant?

Yes = DENY
No = Go to Q3

3. Has the patient been assessed by a specialized ophthalmologist (neuro-ophthalmologist or other facial plastic surgeon)?

Yes = Go to Q4 No = DENY
4. Does the patient have immediate sight-threatening disease?
Yes = DENY No = Go to Q5
5. Is the patient euthyroid?
Yes = Go to Q6 No = DENY
6. Does the member have active thyroid eye disease defined as a CAS of 4 or higher within the past 3 months?
Yes = Go to Q7 No = DENY
7. Does the member have moderate to severe TED?
Yes = Go to Q8 No = DENY
8. Does the patient have diabetes and an HbA1c of over 9%?
Yes = DENY No = Continue to Q9
9. Has the member failed, or the provider submitted an acceptable statement to avoid 3 weeks of high dose corticosteroids?
Yes = APPROVE FOR REQUESTED DOSE AND DURATION No = DENY

Entyvio (vedolizumab)

Products Affected

- Entyvio Intravenous solution 300mg

PA CRITERIA	
Covered Uses	Moderate to severe Crohn's disease Moderate to severe ulcerative colitis
Exclusion Criteria	Active, severe infection or opportunistic infection
Required Medical Information	Current chart notes related to CD or UD diagnosis
Age Restrictions	Age ≥ 18
Prescriber Restrictions	Gastroenterology
Coverage Duration	Initial: 6 months; Renewal: 12 months
Other	Renewal Criteria: Documentation of positive clinical response to therapy.

Ulcerative Colitis

1. Is this an initial or renewal request?

Initial = Go to Q3

Renewal = Go to Q2

2. Has the member experienced a significant response to treatment including:

- **Decrease in bloody stools per day and/or**
- **Elimination of signs of toxicity**

Yes = APPROVE X 12 months

No = The plan covers the requested medication when there is evidence of positive clinical effect from therapy. Based on the information provided, this requirement has not been met.

3. Is the member under the care of a gastroenterologist?

Yes = Go to Q4
No = DENY. The plan covers the requested medication when it is prescribed by a gastroenterologist. Based on the information provided, this requirement has not been met.

4. Is the member ≥18 years old?

Yes = Go to Q5

No = The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

5. Does the member have a diagnosis of moderate to severe ulcerative colitis defined by the following criteria:

- **Moderate: greater than or equal to 4 stools daily**
- **Severe: ≥6 bloody stools daily AND evidence of toxicity (fever, anemia, elevated ESR, or tachycardia)**

Yes = Go to Q6
No = The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

6. Has the following screening for exclusion been met?

- **No severe, active infection**
- **No opportunistic Infection**
- **No untreated latent or active TB**
- **No active HBV infection**

Yes = Go to Q7
No = Deny. The plan covers the requested medication when the clinical evidence supports its safe use. Certain conditions may increase the risk of serious adverse effects of requested medication. Potential pregnancy and active or dormant infection are exclusions for use of this medication.

7. Has the member tried and failed or have contraindication to at least 2 TNF inhibitors? Adequate trial of therapy is 3 months of continuous therapy with adherence based on fill history**

Yes = APPROVE X 6 months

No = DENY. The plan covers the requested medication when there has been an adequate trial or contraindication of TNF therapy. Based on the information provided, this requirement has not been met.

Recommended therapy to induce remission in members naïve to biologic agents: ***infliximab* or ***vedolizumab*** is preferred over adalimumab for induction of remission. If member has previously been exposed to infliximab (especially those non-responsive to therapy), ***ustekinumab*** or ***tofacitinib*** are preferred over vedolizumab or adalimumab for induction of remission.

Crohn's Disease

1. Is this an initial or renewal request?

Initial = Go to Q
Renewal = Go to Q

2. Has the member experienced a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission?

Yes = APPROVE X 12 months

No = DENY. The plan covers the requested medication when there is evidence of positive clinical effect from therapy. Based on the information provided, this requirement has not been met.

3. Is the member under the care of a gastroenterologist?

Yes = Go to Q4
No = DENY. The plan covers the requested medication when it is prescribed by a gastroenterologist. Based on the information provided, this requirement has not been met.

4. Is the member ≥18 years old

Yes = Go to Q5
No = The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

5. **Does the member have moderate to severe Crohn's disease?**

- **Moderate to severe CD (CDAI score 220-450): failure to respond to treatment for mild to moderate disease, fever, abdominal pain/tenderness, vomiting, weight loss, anemia, intestinal obstruction**
- **Severe to fulminant (CDAI score >450): Persistent symptoms despite outpatient therapy, abdominal pain, rebound tenderness, high temperature, persistent vomiting, possible obstruction, abscess**

Yes = Go to Q6
No = The plan covers the requested medication when the requested medication is being used for an FDAapproved indication or being used for an off-label indication with well- established, or clinical evidence supporting its use.

6. Has the following screening for exclusion been met?

- **No active infection**
- **No opportunistic infection**
- **No untreated latent or active TB**
- **No active HBV infection**

Yes = Go to Q7

No = Deny. The plan covers the requested medication when the clinical evidence supports its safe use. Certain conditions may increase the risk of serious adverse effects of requested medication. Potential pregnancy and active or dormant infection are exclusions for use of this medication.

7. Is the member transitioning from a different biologic product?

Yes = Go to Q9
No = Go to Q8

8. has the member tried and failed to respond to at least 1 of the following conventional immunosuppressive therapies for ≥6 months or have moderate/high disease burden risk?

- **Mercaptopurine, azathioprine, or budesonide OR**

- **Have a documented intolerance or contraindication to conventional therapy?**
- **Does member have moderate/high disease burden risk (age <30 at initial diagnosis, extensive anatomic involvement, perianal and/or severe rectal disease, ulcers, prior surgical resection, structuring and/or penetrating behavior)**

Yes = Go to Q9
No = DENY. The plan covers the requested medication when there is documentation of failure of preferred therapies and moderate/high disease burden risk. Based on the information provided, this requirement has not been met.

9. Has the member tried and failed or have contraindication to at least 2 TNF inhibitors?

- **Adequate trial of therapy is 3 months of continuous therapy with adherence based on fill history**
- **TNF drug concentrations are therapeutic, low/undetectable antibody concentrations are present, and inflammation is present***

Yes = APPROVE X 6 months
No = DENY. The plan covers the requested medication when there has been an adequate trial or contraindication of TNF therapy. Based on the information provided, this requirement has not been met.

*If disease fails to respond to TNF therapy assess drug and TNF antibody concentrations

- If low/undetectable drug and antibody concentrations: Increase drug dose
- If low/undetectable drug and high antibody concentrations: Change within drug class
- If drug concentration is therapeutic with low/undetectable antibody concentrations: Assess inflammation