

SWHP/ICSW (HMO, PPO, Qualified Health Plan) Drug Screening Criteria Guidance

This is a static document and will be revised if there are any prior authorization formulary changes.

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Important note

Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage or Summary Plan Description to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans.

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ACTEMRA® (tocilizumab) – IV Formulation

Rheumatoid arthritis:

1. Prescribed by a Rheumatologist **AND**
2. Failure of methotrexate **OR**
 - a. Contraindication to methotrexate **AND**
 - b. Failure of at least **one** or contraindication(s) to other DMARDs
** The American College of Rheumatology defines DMARDs as:
hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*

AND (for new starts only)

3. Failure of or contraindication to preferred anti-TNF agents [i.e. Enbrel, Humira]

Polyarticular juvenile idiopathic arthritis:

1. Prescribed by a Rheumatologist **AND**
2. Failure of or contraindication(s) to:
 - a. Methotrexate **OR**
 - b. Sulfasalazine **OR**
 - c. Leflunomide

AND

3. Failure of or contraindication to preferred anti-TNF agents [i.e. Enbrel, Humira]

Systemic juvenile idiopathic arthritis:

1. Prescribed by a Rheumatologist **AND**
2. Failure of or contraindication(s) to:
 - a. NSAIDs **OR**
 - b. Glucocorticoids (oral or IV) **OR**
 - c. Anakinra (Kineret®)

ACTEMRA® (tocilizumab) – subcutaneous formulation

Rheumatoid arthritis:

1. Prescribed by a Rheumatologist **AND**
2. Failure of methotrexate **OR**
 - a. Contraindication to methotrexate **AND**
 - b. Failure of at least **one** or contraindication(s) to other DMARDs
** The American College of Rheumatology defines DMARDs as:
hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*

AND (for new starts only)

3. Failure of or contraindication to preferred anti-TNF agents [i.e. Enbrel, Humira]

Giant Cell Arteritis

1. Prescribed by Rheumatology **AND**
2. Failure of, intolerance, or contraindication to the following:
 - a. Glucocorticoids **AND**

b. Methotrexate

AFINITOR® (everolimus)

1. Prescribed by an Oncologist **AND**
 2. Indication is supported by either:
 - a. FDA approved labeling **OR**
 - b. National Comprehensive Cancer Network (NCCN) with a grade 2A or higher recommendation
-

AMPYRA® (dalfampridine) – NONFORMULARY AGENT

INITIAL APPROVAL CRITERIA (duration 12 weeks):

1. Prescribed by a Neurologist **AND**
2. ≥18 years of age **AND**
3. Diagnosis of multiple sclerosis **AND**
4. Currently taking a disease-modifying agent for multiple sclerosis (teriflunomide, interferon beta-1a, interferon beta-1b, glatiramer, fingolimod, dimethyl fumarate, natalizumab) **AND**
5. Documentation of objectively assessed functional impairment related to ambulation **AND**
6. Member does **NOT** have:
 - a. A history of seizures **OR**
 - b. Moderate or severe renal impairment (defined as $Cl_{CR} \leq 50$ mL/min)

CONTINUATION CRITERIA (duration 12 months):

1. Documentation of clinically significant ($\geq 25\%$ improvement from baseline), sustained improvement (based on objective, in-office testing) over the initial 12 weeks of therapy of either:
 - a. Ambulation **OR**
 - b. Functional status measured by objective office testing
-

ARZERRA® (ofatumumab)

1. Prescribed by a:
 - a. Hematologist **OR**
 - b. Oncologist
- AND**
2. Indication is supported by either:

- a. FDA approved labeling **OR**
 - b. National Comprehensive Cancer Network (NCCN) with a grade 2A or higher recommendation
-

AUBAGIO® (teriflunomide)

1. Prescribed by a Neurologist **AND**
 2. Diagnosis of a relapsing form of multiple sclerosis **AND**
 3. ≥18 years of age **AND**
 4. Individual is NOT pregnant **AND**
 5. Individual does NOT have severe hepatic impairment **AND**
 6. Individual is NOT taking in combination with other immunomodulatory agents (interferon beta-1a, glatiramer, interferon beta-1b, natalizumab, fingolimod, dimethyl fumarate or leflunomide), **AND**
 - a. Individual has been on the requested product in the past 180 days **OR**
 - b. Individual has failed, has a contraindication to, or has experienced a clinically significant adverse event with **one** of the following:
 - i. Gilenya **OR**
 - ii. Tecfidera
-

AUVI-Q (epinephrine injection)

1. FDA-approved indication **AND**
 2. Failure of ALL of the following alternatives:
 - a. generic Adrenaclick **AND**
 - b. generic Epipen **AND**
 - c. Adrenaclick **AND**
 - d. Epipen
-

BANZEL® (rufinamide)

1. Prescribed by a Neurologist **AND**
 2. Diagnosis of an epileptic condition **AND**
 3. Refractory to combination therapy with at least **two** other anticonvulsants
-

BENLYSTA® (belimumab)

1. Prescribed by a Rheumatologist
2. Diagnosis of active systemic lupus erythematosus (SLE) **AND**
 - a. Benlysta is being used in combination with at least **one** standard SLE therapy (e.g., corticosteroids, hydroxychloroquine, NSAIDs, azathioprine, methotrexate, mycophenolate) **OR**
 - b. The patient has documented intolerance, FDA-labeled contraindication, or hypersensitivity to the standard of care drugs listed above

AND

3. Member does **NOT** have:
 - a. Severe active lupus nephritis **OR**
 - b. Severe active central nervous system lupus **OR**
 - c. Concurrent use of other biologic therapies (e.g., tocilizumab, certolizumab, etanercept, abatacept, infliximab, rituximab, golimumab, ustekinumab) **OR**
 - d. Concurrent use of intravenous cyclophosphamide

BERINERT® (C1 Esterase Inhibitor, Human) – NONFORMULARY EXCEPT ACA COMPLIANT

Initial criteria (6 month approval):

1. Prescribed by one of the following specialists:
 - a. Allergist **OR**
 - b. Immunology Specialist **OR**
 - c. Hematologist

AND

2. Diagnosis of hereditary angioedema (HAE) with confirming labs and chart notes submitted **AND**
3. Member is using for **treatment** of acute HAE attacks **AND**
4. Member does not have a contraindication to therapy **AND**
5. Member is not using any medications known to cause angioedema (i.e. ACE inhibitor, ARB, or estrogen) **AND**
6. Berinert will be the only medication prescribed for treatment of acute attacks **AND**
7. Request is within FDA-approved labeling **AND**
8. Quantity requested will not result in a supply on hand of more than two doses
 - a. If request is for more than two doses on hand, must supply chart notes confirming anticipated attack frequency requiring treatment

Continuation criteria (6 month approval):

1. Member is using for treatment of acute HAE attacks **AND**
2. Request is for a replacement supply of doses used
 - a. Supply clinical documentation of acute HAE attack(s) requiring treatment including date of attack and number of doses utilized

AND

3. Quantity requested will not result in a supply on hand of more than two doses

- a. If request is for more than two doses on hand, must supply chart notes confirming anticipated attack frequency requiring treatment

NOTE: Safety and efficacy not established for prophylactic therapy

BEXXAR® (tositumomab)

1. Prescribed by a SWHP-approved Interventional Radiologist **AND**
2. Indication is supported by either:
 - a. FDA approved labeling **OR**
 - b. National Comprehensive Cancer Network (NCCN) with a grade 2A or higher recommendation

AND

3. Lymphoma marrow involvement is $\leq 25\%$ **AND**
4. Platelet count is $\geq 100,000$ cells/mm³ **AND**
5. Neutrophil count is $\geq 1,500$ cells/mm³

SWHP Health Services Division (HSD) will not require prior authorization for the use of Bexxar, but reserves the right to obtain a provider audit through the SWHP Provider Audit Committee at any time it deems necessary to check compliance with the clinical requirements.

BONIVA® IV (ibandronate) – INTRAVENOUS FORMULATION

1. Compelling contraindication to oral bisphosphonates such as:
 - a. Active GI bleeding **OR**
 - b. GI ulcers **OR**
 - c. Esophageal motility disorder **OR**
 - d. Esophagitis **OR**
 - e. Inability to sit/stand upright for at least 30 minutes after an oral dose

OR

2. Failure of **two** oral bisphosphonate drugs due to GI intolerance

Note: Must check renal function before starting treatment with Boniva IV. It should not be administered to patients with severe renal impairment (i.e., SrCr > 2.3 mg/dL OR Cl_{CR} < 30 mL/min).

BOTOX® (onabotulinumtoxin A)

1. Member has one of the following diagnoses:

- a. Anal fissures following at least two months of conservative therapy to include trial and failure of the following:
 - i. topical nitroglycerin **AND**
 - ii. topical nifedipine
- OR**
- b. Axillary hyperhidrosis **OR**
 - c. Blepharospasm **OR**
 - d. Cervical dystonia [spasmodic torticollis] **OR**
 - e. Chronic migraine headache **OR**
 - f. Detrusor and sphincter dyssynergia **OR**
 - g. Essential tremor **OR**
 - h. Hemifacial spasm **OR**
 - i. Neurogenic bladder **OR**
 - j. Non-achalasia esophageal motility disorder [dysphagia] **OR**
 - k. Oculomotor nerve injury **OR**
 - l. Oromandibular dystonia **OR**
 - m. Overactive bladder **OR**
 - n. Pelvic floor dyssynergia [anismus] **OR**
 - o. Sialorrhea associated with neurological disorders **OR**
 - p. Spasmodic and laryngeal dysphonia [including post-laryngectomy] **OR**
 - q. Spasticity [post stroke hemiplegia, upper and lower limb spasticity, cerebral palsy] **OR**
 - r. Strabismus
-

CAYSTON® (aztreonam oral inhalation)

- 1. Prescribed by:
 - a. Pulmonology **OR**
 - b. Infectious Disease specialist
- AND**
- 2. Diagnosis of cystic fibrosis **AND**
 - 3. Current, active *Pseudomonas aeruginosa* confirmed by testing **AND**
 - 4. Age ≥ 7 years **AND**
 - 5. Failure of, or contraindication to, tobramycin for oral inhalation **AND**
 - 6. FEV₁ between 25% - 75% of predicted **AND**
 - 7. Member is **NOT** colonized with *Burkholderia cepacia*
-

CIALIS® (tadalafil) – (ACA Compliant/Exchange Only)

- 1. Diagnosis of benign prostatic hyperplasia (BPH) **AND**
- 2. Failure of, or contraindication to:
 - a. One generic formulary alpha-antagonist **AND**
 - b. One generic formulary 5-alpha reductase inhibitor

Note: Drugs used for erectile dysfunction are excluded from coverage for ACA Compliant/Exchange plans

CIMZIA® (certolizumab)

Rheumatoid arthritis:

1. Prescribed by a Rheumatologist **AND**
 2. Failure of methotrexate **OR**
 - a. Contraindication to methotrexate **AND**
 - b. Failure of at least **one** or contraindication(s) to other DMARDs
** The American College of Rheumatology defines DMARDs as:
hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*
- AND (for new starts only; does not apply to ACA Compliant)**
3. Failure of or contraindication to preferred anti-TNF agents [i.e. Enbrel, Humira]

Crohn's Disease:

1. Prescribed by a Gastroenterologist **AND**
 2. Failure of or contraindication(s) to:
 - a. An anti-inflammatory drug (e.g. mesalamine, sulfasalazine) **OR**
 - b. Corticosteroids **OR**
 - c. An immunosuppressive drug (e.g. 6-MP, azathioprine, methotrexate)
- AND (for new starts only; does not apply to ACA Compliant)**
3. Failure of or contraindication to preferred anti-TNF agents [i.e. Humira]

Psoriatic arthritis:

1. Prescribed by a Rheumatologist OR Dermatologist, **AND**
 2. Member has:
 - a. Documented spinal involvement (psoriatic spondylitis); **OR**
 - b. Failed methotrexate; **OR**
 - i. Contraindication to methotrexate **AND**
 - ii. Failure of at least **one** or contraindication(s) to other DMARDs
** The American College of Rheumatology defines DMARDs as:
hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*
- AND (for new starts only; does not apply to ACA Compliant)**
3. Failure of or contraindication to preferred anti-TNF agents [i.e. Enbrel, Humira]

Ankylosing spondylitis:

1. Prescribed by a Rheumatologist **AND**
 2. Member has:
 - a. Documented spinal involvement **OR**
 - b. Failure of at least **one** or contraindication(s) to nonsteroidal anti-inflammatory drugs (NSAIDs)
- AND (for new starts only; does not apply to ACA Compliant)**
3. Failure of or contraindication to preferred anti-TNF agents [i.e. Enbrel, Humira]
-

CINQAIR® (reslizumab) – NONFORMULARY AGENT

Initiation criteria (3 month approval)

1. Prescribed by a(n):

- a. Allergist **OR**
- b. Immunologist **OR**
- c. Pulmonologist

AND

2. Member is at least 18 years old **AND**

3. Diagnosis of severe eosinophilic asthma **AND**

4. A blood eosinophil concentration of ≥ 400 cells/mcL within the last 4 weeks **AND**

5. One of the following:

- a. ≥ 2 asthma exacerbations (defined as need for systemic corticosteroids, ER visit or hospitalization) in the last 12 months despite the use of the following (verified by claims data), unless member is intolerant or has a medical contraindication to these agents:

- i. Inhaled corticosteroid for ≥ 12 months **AND**
- ii. ≥ 1 additional controller for ≥ 3 months

OR

- b. Oral corticosteroid-dependent (verified by claims data), defined as:

- i. daily oral glucocorticoids plus an inhaled corticosteroid for ≥ 6 months **AND**
- ii. ≥ 1 additional controller medication for ≥ 3 months

AND

6. Dose will not exceed 3 mg/kg once every 4 weeks **AND**

7. Not being used concomitantly with Nucala® (mepolizumab) or Xolair® (omalizumab)

Continuation Criteria (12 month approval)

1. Patient has demonstrated response to therapy, defined as:

- a. Decreased asthma exacerbation rate **OR**
- b. Documented improvement in asthma symptoms **OR**
- c. Decreased hospitalizations, emergency department/urgent care visits, or physician visits due to asthma **OR**
- d. Decreased requirement for oral corticosteroids

AND

2. Documented compliance with the following:

- a. Cinqair
- b. Inhaled corticosteroid
- c. ≥ 1 additional controller

CINRYZE® (C1 Esterase Inhibitor, Human) – NONFORMULARY AGENT

Initial criteria (6 month approval):

1. Prescribed by one of the following specialists:
 - a. Allergist **OR**
 - b. Immunology Specialist **OR**
 - c. Hematologist

AND

2. Diagnosis of hereditary angioedema (HAE) with confirming labs and chart notes submitted **AND**
3. Member is using for **prophylaxis** of acute HAE attacks **AND**
4. Member has one of the following, confirmed through chart notes:
 - a. Two or more attacks per month requiring therapy **OR**
 - b. Disabling symptoms 5 or more days per month **OR**
 - c. Laryngeal edema **OR**
 - d. Scheduled major dental work or surgical procedure requiring short term prophylaxis (approval will only be for procedure period)

AND

5. Failure of, contraindication to, or intolerance to:
 - a. attenuated androgens (ex. danazol, stanozolol) **AND**
 - b. antifibrinolytics (ex. aminocaproic acid)

AND

6. Member does not have contraindication to Cinryze therapy **AND**
7. Member is not using any medication known to cause angioedema (i.e. ACE inhibitor, ARB, or estrogen) **AND**
8. Request is within FDA approved labeling

Continuation criteria (6 month approval):

1. Member has shown improvement by:
 - a. Approaching 2 or fewer acute HAE attacks per month while on prophylaxis **OR**
 - b. A decrease in quantity, severity, and length of HAE attacks

AND

2. Submission of chart notes showing:
 - a. Member has documented response **AND**
 - b. Ability to tolerate medication

CORLANOR® (ivabradine)

1. Member has ALL of the following:
 - a. Stable, symptomatic heart failure **AND**
 - b. Left ventricular ejection fraction $\leq 35\%$ **AND**
 - c. In sinus rhythm **AND**
 - d. Resting heart rate of ≥ 70 bpm

AND

2. Documented failure of or intolerance to maximized beta-blocker therapy

COSENTYX™ (secukinumab)

Ankylosing spondylitis:

1. Prescribed by a Rheumatologist **AND**
2. Member has:
 - a. Documented spinal involvement **OR**
 - b. Failure of at least **one** or contraindication(s) to nonsteroidal anti-inflammatory drugs (NSAIDs)

AND (for new starts only)

3. Failure of or contraindication to preferred formulary biologic agents FDA-approved for treatment of ankylosing spondylitis (i.e. Enbrel, Humira).

Plaque Psoriasis:

1. Prescribed by a Dermatologist **AND**
2. Diagnosis of moderate to severe plaque psoriasis affecting:
 - a. greater than 5% of body surface area (BSA); **OR**
 - b. crucial body areas such as hands, feet, face, or genitals

AND

3. Failure of at least two topical treatments [including but not limited to corticosteroids, vitamin D analogues, vitamin D analogue/corticosteroid combinations or tazarotene (Tazorac®)] **AND**
4. Failure of or contraindication to phototherapy (UVB or PUVA) **AND**
5. Failure of or contraindication to methotrexate, cyclosporine, acitretin, leflunomide, sulfasalazine, or tacrolimus **AND**
6. Failure of or contraindication to preferred formulary biologic agents FDA-approved for treatment of plaque psoriasis (i.e. Enbrel, Humira).

Psoriatic Arthritis:

1. Prescribed by a Rheumatologist OR Dermatologist, **AND**
2. Member has:
 - a. Documented spinal involvement (psoriatic spondylitis); **OR**
 - b. Failed methotrexate; **OR**
 - i. Contraindication to methotrexate **AND**
 - ii. Failure of at least **one** or contraindication(s) to other DMARDs
** The American College of Rheumatology defines DMARDs as: hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*

AND (for new starts only)

3. Failure of or contraindication to preferred formulary biologic agents FDA-approved for treatment of psoriatic arthritis (i.e. Enbrel, Humira).
-

DAKLINZA® (daclatasvir) - NONFORMULARY AGENT

1. Prescribed by a:
 - a. Hepatologist **OR**
 - b. Board Certified Infectious Disease specialist **OR**
 - c. Board Certified Gastroenterologist

AND

2. Must be ≥ 18 years of age

AND

3. Documented diagnosis of:
 - a. Genotype 1 **AND**
 - i. Fibrosis OR compensated cirrhosis, confirmed by either:
 1. Metavir score F2 or higher on liver biopsy**OR**
 2. At least TWO of the following*:
 - a. FIB-4 >1.45
 - b. APRI >0.5
 - c. Fibroscan >7.0
 - d. Fibrosure >0.49
 - e. Radiological imaging consistent with fibrosis and/or cirrhosis (e.g. portal hypertension)

OR

- b. Genotype 3 **AND**
 - i. Fibrosis, but not cirrhosis, confirmed by either:
 1. Metavir score F2 or F3 on liver biopsy**OR**
 2. At least TWO of the following*:
 - a. FIB-4 >1.45
 - b. APRI >0.5
 - c. Fibroscan >7.0
 - d. Fibrosure >0.49
 - e. Radiological imaging consistent with fibrosis

OR

- c. Genotype 1 OR 3 **AND**
 - i. Cryoglobulinemia with end-organ manifestations, defined as one of the following:
 1. Vasculitis **OR**
 2. Peripheral neuropathy **OR**
 3. Raynaud's Phenomenon**OR**
 - ii. One of the following extrahepatic manifestations:
 1. Membranoproliferative glomerulonephritis **OR**
 2. Membranous nephropathy**OR**
 - iii. Prior liver transplant

OR

iv. Currently on liver transplant list

AND

4. Member has been screened for hepatitis B infection prior to initiation of treatment, and will be appropriately monitored and/or treated **AND**
5. Will be used concomitantly with sofosbuvir **AND**
6. Abstinence from alcohol and IV drug use for at least 6 months prior to treatment **AND**
7. Member does NOT have:
 - a. Cirrhosis (if Genotype 3) **OR**
 - b. Decompensated cirrhosis, Child Pugh C (if Genotype 1) **OR**
 - c. Concurrent use of drugs that are strong inducers of CYP3A (e.g. phenytoin, carbamazepine, rifampin, St. John's wort) **OR**
 - d. Any other non-liver related comorbidity resulting in less than a 10-year predicted survival **OR**
 - e. Ongoing non-adherence to prior medications or medical treatment **OR**
 - f. Failure to complete HCV disease evaluation, appointments and procedures (e.g. laboratories)
 - g. Presence of NS5A polymorphisms at amino acid positions M28, Q30, L31, and Y93

AND

8. Member has NOT been previously treated with:
 - a. Elbasvir (Zepatier) OR
 - b. Dasabuvir (Viekira) OR
 - c. Grazoprevir (Zepatier) OR
 - d. Ledipasvir (Harvoni) OR
 - e. Ombitasvir (Technivie, Viekira) OR
 - f. Paritaprevir (Technivie, Viekira) OR
 - g. Simeprevir (Olysio) OR
 - h. Sofosbuvir (Epclusa, Sovaldi, Harvoni) OR
 - i. Velpatasvir (Epclusa)

AND

9. For dose adjustments due to drug interactions, the offending drug(s) is medically necessary and cannot be avoided during the three month hepatitis C treatment period**

**Other non-invasive tests that may be considered include: FibroIndex, Forns Index, HepaScore/FibroScore, ShearWave Elastography, magnetic resonance elastography*

***For 30 mg doses, one 30 mg tablet/day will be authorized; For 60 mg doses, one 60 mg tablet/day will be authorized; For 90 mg doses, one 30 mg tablet/day and one 60 mg tablet/day will be authorized.*

NOTE: Requests for two or more of the following will not be approved: Epclusa (sofosbuvir/velpatasvir), Harvoni (sofosbuvir/ledipasvir), Olysio (simeprevir), Technivie (paritaprevir/ritonavir/ ombitasvir), Sovaldi (sofosbuvir), Victrelis

(boceprevir), Viekira (paritaprevir/ ritonavir/ombitasvir/dasabuvir) or Zepatier (elbasvir/grazoprevir)

DEPEN (d-penicillamine tablets)

1. Diagnosis of Wilson's disease **AND**
 2. Member is using for acute copper toxicity/removal **OR**
 - a. Member is using for maintenance therapy **AND**
 - b. Failure, contraindication or intolerance to zinc acetate
-

DUPIXENT® (dupilumab) – NONFORMULARY

Initial criteria (16 week approval)

1. Prescribed by dermatology or allergy or immunology **AND**
2. Age ≥ 18 years of age **AND**
3. Diagnosis of moderate-to-severe atopic dermatitis affecting ≥ 10% body surface area (BSA) **AND**
4. Member has failed or has a contraindication or intolerance to:
 - a. One topical calcineurin inhibitor (tacrolimus or Elidel) **AND**
 - b. One medium potency to super high potency topical corticosteroid **AND**
 - c. Eucrisa
5. Failure of or contraindication to phototherapy **AND**
6. Failure of or contraindication to one of the following:
 - a. Azathioprine **OR**
 - b. Cyclosporine **OR**
 - c. Methotrexate **OR**
 - d. Mycophenolate mofetil

Continuation criteria

1. Documented positive clinical response to therapy (e.g. reduction in body surface area involvement, reduction in pruritis severity, etc.)
-

DYSPORT (abobotulinumtoxinA) – NONFORMULARY AGENT

1. Failure, contraindication or intolerance to ALL formulary botulinumtoxinA products (Botox **AND** Xeomin) **AND**
2. Member has one of the following diagnoses:
 - a. Anal fissures following at least two months of conservative therapy to include trial and failure of the following:
 - i. topical nitroglycerin **AND**

- ii. topical nifedipine
- OR**
- b. Axillary hyperhidrosis **OR**
 - c. Blepharospasm **OR**
 - d. Cervical dystonia [spasmodic torticollis] **OR**
 - e. Chronic migraine headache **OR**
 - f. Detrusor and sphincter dyssynergia **OR**
 - g. Essential tremor **OR**
 - h. Hemifacial spasm **OR**
 - i. Neurogenic bladder **OR**
 - j. Non-achalasia esophageal motility disorder [dysphagia] **OR**
 - k. Oculomotor nerve injury **OR**
 - l. Oromandibular dystonia **OR**
 - m. Overactive bladder **OR**
 - n. Pelvic floor dyssynergia [anismus] **OR**
 - o. Sialorrhea associated with neurological disorders **OR**
 - p. Spasmodic and laryngeal dysphonia [including post-laryngectomy] **OR**
 - q. Spasticity [post stroke hemiplegia, upper and lower limb spasticity, cerebral palsy] **OR**
 - r. Strabismus
-

EMFLAZA® (deflazacort) – NONFORMULARY AGENT

1. Prescribed by a Neurologist **AND**
 2. Diagnosis of Duchenne muscle dystrophy **AND**
 3. Documented mutation of the dystrophin gene **AND**
 4. Member must be 5 years of age or older **AND**
 5. Onset of weakness before 5 years of age **AND**
 6. Serum creatinine kinase activity at least 10 times the upper limit of normal (ULN) at some stage in their illness **AND**
 7. The patient meets **ONE** of the following conditions:
 - a. The patient has tried prednisone for ≥ 6 months [documentation required] **AND** according to the prescribing physician, the patient has had at least one of the following significant intolerable adverse effects (AEs):
 - i. Cushingoid appearance [documentation required]; **OR**
 - ii. Central (truncal) obesity [documentation required]; **OR**
 - iii. Undesirable weight gain, defined as a $\geq 10\%$ of body weight gain increase over a 6-month period [documentation required]
- AND**
8. A prednisone dose reduction (e.g. 0.3 mg/kg/day) has not resulted in improvement of intolerable adverse effects
-

ENBREL® (etanercept)

Ankylosing spondylitis:

1. Prescribed by a Rheumatologist **AND**
2. Member has:
 - a. Documented spinal involvement **OR**
 - b. Failure of at least **one** or contraindication(s) to nonsteroidal anti-inflammatory drugs (NSAIDs)

Polyarticular juvenile idiopathic arthritis:

1. Prescribed by a Rheumatologist **AND**
2. Failure of or contraindication(s) to:
 - a. Methotrexate, **OR**
 - b. Sulfasalazine, **OR**
 - c. Leflunomide, **OR**
 - d. Another anti-TNF agent

Psoriasis:

1. Prescribed by a Dermatologist **AND**
2. Age \geq 4 years of age **AND**
3. Diagnosis of moderate to severe plaque psoriasis affecting:
 - a. greater than 5% of body surface area (BSA); **OR**
 - b. crucial body areas such as hands, feet, face, or genitals

AND

4. Failure of at least **two** topical treatments [including but not limited to corticosteroids, vitamin D analogues, vitamin D analogue/corticosteroid combinations or tazarotene (Tazorac®)] **AND**
5. Failure of or contraindication to phototherapy (UVB or PUVA) **AND**
6. Failure of or contraindication to methotrexate, cyclosporine, acitretin, leflunomide, sulfasalazine, or tacrolimus

Psoriatic arthritis:

1. Prescribed by a Rheumatologist **OR** Dermatologist; **AND**
2. Member has:
 - a. Documented spinal involvement (psoriatic spondylitis) **OR**
 - b. Failed methotrexate **OR**
 - i. Contraindication to methotrexate **AND**
 - ii. Failure of at least **one** or contraindication(s) to other DMARDs
** The American College of Rheumatology defines DMARDs as: hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*

Rheumatoid arthritis:

1. Prescribed by a Rheumatologist **AND**
2. Failure of methotrexate; **OR**
 - a. Contraindication to methotrexate **AND**

- b. Failure of at least **one** or contraindication(s) to other DMARDs
* *The American College of Rheumatology defines DMARDs as: hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*
-

ENTRESTO™ (sacubitril/valsartan)

1. Member has ALL of the following:
 - a. Chronic stable heart failure (NYHA Class II-IV) **AND**
 - b. Left ventricular ejection fraction <40% **AND**
 - c. Systolic blood pressure >95 mm Hg **AND**
 - d. Baseline serum potassium <5.4 mmol/L
 - AND**
 2. Failure of or contraindication to optimized therapy with ALL of the following:
 - a. Beta-blockers **AND**
 - b. Angiotensin-converting enzyme inhibitors (ACE-I) OR angiotensin receptor blockers (ARBs)
 - AND**
 3. No history of ACE-I or ARB-related angioedema **AND**
 4. No concomitant use of ANY of the following:
 - a. Aliskiren **OR**
 - b. ACE-I (not be used within 36 hours of each other) **OR**
 - c. ARB
-

ENTYVIO® (vedolizumab)

1. Prescribed by Gastroenterology **AND**
 2. Member is >18 years old **AND**
 3. Diagnosis of moderately-to-severely active:
 - a. ulcerative colitis **OR**
 - b. Crohn's disease
 - AND**
 4. Failure of or contraindication to at least **one** anti-TNF agent [Cimzia, Humira (preferred), Remicade or Simponi] **AND**
 5. Member does NOT have a prior history of:
 - a. Progressive multifocal leukoencephalopathy (PML) **OR**
 - b. Other slow-virus infection [e.g. subacute sclerosing panencephalitis (SSPE), progressive rubella panencephalitis (PRP), HIV, AIDS, rabies] **OR**
 - c. Medical condition that significantly compromises the immune system (e.g. leukemia, organ transplant)
-

EPCLUSA® (sofosbuvir/velpatasvir) – NONFORMULARY AGENT

1. Prescribed by a:
 - a. Hepatologist **OR**
 - b. Board Certified Infectious Disease specialist **OR**
 - c. Board Certified Gastroenterologist

AND

2. Must be ≥ 18 years of age

AND

3. Documented diagnosis of Genotype 1, 2, 3, 4, 5 or 6 chronic HCV **AND**
 - a. Fibrosis **OR** cirrhosis, confirmed by either:
 - i. Metavir score F2 or higher on liver biopsy**OR**
 - ii. At least TWO of the following*:
 1. FIB-4 >1.45
 2. APRI >0.5
 3. Fibroscan >7.0
 4. Fibrosure >0.49
 5. Radiological imaging consistent with fibrosis and/or cirrhosis (e.g. portal hypertension)

OR

- a. Cryoglobulinemia with end-organ manifestations, defined as one of the following:
 - i. Vasculitis **OR**
 - ii. Peripheral neuropathy **OR**
 - iii. Raynaud's Phenomenon **OR**

OR

- b. One of the following extrahepatic manifestations:
 - i. Membranoproliferative glomerulonephritis **OR**
 - ii. Membranous nephropathy

OR

- c. Currently on transplant list

AND

4. Member has been screened for hepatitis B infection prior to initiation of treatment, and will be appropriately monitored and/or treated **AND**
5. Abstinence from alcohol and IV drug use for at least 6 months prior to treatment **AND**
6. Member does NOT have:
 - a. Severe renal impairment (eGFR <30 mL/min/1.73m³) or ESRD on hemodialysis **OR**
 - b. Prior organ transplant, currently taking immunosuppressive agents **OR**
 - c. Concomitant use of P-glycoprotein inducers or moderate to potent inducers of CYP2B6, 2C8 or 3A4 (e.g. topotecan, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, efavirenz, tipranavir/ritanovir, St. John's wort) **OR**

- d. Any other non-liver related comorbidity resulting in less than a 10-year predicted survival **OR**
- e. Ongoing non-adherence to prior medications or medical treatment **OR**
- f. Failure to complete HCV disease evaluation, appointments and procedures (e.g. laboratories)

AND

- 7. Member has NOT been previously treated with:
 - a. Daclatasvir (Daklinza) **OR**
 - b. Dasabuvir (Viekira) **OR**
 - c. Elbasvir (Zepatier) **OR**
 - d. Grazoprevir (Zepatier) **OR**
 - e. Ledipasvir (Harvoni) **OR**
 - f. Ombitasvir (Technivie, Viekira) **OR**
 - g. Paritaprevir (Technivie, Viekira) **OR**
 - h. Simeprevir (Olysio) **OR**
 - i. Sofosbuvir (Epclusa, Sovaldi, Harvoni) **OR**
 - j. Velpatasvir (Epclusa)

AND

- 7. Clinical inappropriateness or inability to tolerate preferred agents (i.e. Harvoni, Sovaldi)

**Other non-invasive tests that may be considered include: FibroIndex, Forns Index, HepaScore/FibroScore, ShearWave Elastography, magnetic resonance elastography*

NOTE: Requests for two or more of the following will not be approved: Epclusa (sofosbuvir/velpatasvir), Harvoni (sofosbuvir/ledipasvir), Olysio (simeprevir), Technivie (paritaprevir/ritonavir/ ombitasvir), Sovaldi (sofosbuvir), Victrelis (boceprevir), Viekira (paritaprevir/ ritonavir/ombitasvir/dasabuvir) or Zepatier (elbasvir/grazoprevir)

ERBITUX® (cetuximab)

- 1. Prescribed by a:
 - a. Hematologist **OR**
 - b. Oncologist

AND

- 2. Indication is supported by either:
 - a. FDA approved labeling **OR**
 - b. National Comprehensive Cancer Network (NCCN) with a grade 2A or higher recommendation

NOTE: Genetic testing (including KRAS gene mutation testing) requires prior authorization by the Health Services Division (HSD). Any questions may be directed to HSD by calling 1-888-316-7947.

EXJADE™ (deferasirox)

1. Prescribed by an Oncologist or Hematologist **AND**
 - a. Being used for initial therapy in members with chronic iron overload due to blood transfusions with:
 - i. Documented serum ferritin levels > 1,000 mcg/L **AND**
 - ii. Age 2 years or older
 - OR**
 - b. Being used for treatment of chronic iron overload with non-transfusion dependent thalassemia syndromes (NTDT) with:
 - i. A liver iron concentration (LIC) of at least 5 mg iron per gram of liver dry weight (mg Fe/g dw) **AND**
 - ii. Serum ferritin greater than 300 mcg/L **AND**
 - iii. Age 10 years or older
-

EYLEA® (aflibercept)

1. Prescribed by an Ophthalmologist
 2. FDA approved indication
-

FABIOR® (tazarotene) foam – NONFORMULARY AGENT

1. FDA approved indication:
 - a. Acne
-

FIRAZYR® (icatibant) – NONFORMULARY AGENT

Initial criteria (6 month approval):

1. Prescribed by one of the following specialists:
 - a. Allergist **OR**
 - b. Immunology Specialist **OR**
 - c. Hematologist

AND

2. Diagnosis of hereditary angioedema (HAE) with confirming labs and chart notes submitted **AND**
 3. Member is using for treatment of acute HAE attacks **AND**
 4. Member does not have contraindication to therapy **AND**
 5. Member is not using any medication known to cause angioedema (i.e. ACE inhibitor, ARB, or estrogen) **AND**
 6. Firazyr will be the only medication prescribed for treatment of acute attacks **AND**
 7. Request is within FDA approved labeling **AND**
 8. Quantity requested will not result in a supply on hand of more than two doses
 - a. If request is for more than two doses on hand, must supply chart notes confirming anticipated attack frequency requiring treatment
- AND (ACA Compliant members only)**
9. Failure of, intolerance to, or contraindication to Berinert

Continuation criteria (6 month approval):

1. Member is using for treatment of acute HAE attacks **AND**
 2. Request is for a replacement supply of doses used
 - a. Supply clinical documentation of acute HAE attack(s) requiring treatment including date of attack and number of doses utilized
- AND**
3. Quantity requested will not result in a supply on hand of more than two doses
 - a. If request is for more than two doses on hand, must supply chart notes confirming anticipated attack frequency requiring treatment

NOTE: Safety and efficacy not established for prophylactic therapy

FORTEO® (teriparatide)

1. Initial therapy for severe osteoporosis, defined as:
 - a. osteoporotic fractures **AND**
 - b. a T-score of less than -3.0 in the spine, femoral neck, or total hip
- OR**
2. Second-line for treatment of less severe osteoporosis after failure of an oral bisphosphonate, documented by either:
 - a. A bone mineral density decrease while on bisphosphonate therapy that is significantly greater than the least significant change for the densitometer utilized (i.e. decrease in T-score while on bisphosphonate therapy) **OR**
 - b. New fractures while on bisphosphonate therapy **OR**
 - c. Intolerance of oral bisphosphonates including, but not limited to, abdominal pain, constipation, diarrhea, dyspepsia, headache, musculoskeletal pain, esophagitis, or other esophageal lesions
-

GAZYVA® (obinutuzumab)

1. Prescribed by a:
 - a. Hematologist **OR**
 - b. Oncologist

AND

2. Indication is supported by either:
 - a. FDA approved labeling **OR**

National Comprehensive Cancer Network (NCCN) with a grade 2A or higher recommendation

GLUMETZA® (metformin HCL extended release) – NONFORMULARY AGENT

1. Failure, contraindication or intolerance to an equivalent dose of EACH of the following:
 - a. Metformin immediate-release tablets (generic Glucophage)
 - b. Metformin extended-release tablets (generic Glucophage XR)
 - c. Metformin extended-release tablets OSM (generic Fortamet)
 - d. Fortamet*
 - e. Glucophage IR*
 - f. Glucophage XR*

**Coverage of brand Glucophage IR, brand Glucophage XR, and brand Fortamet requires failure, contraindication or intolerance to an equivalent dose of all generic metformin formulations (generic Glucophage IR, generic Glucophage XR, and generic Fortamet).*

GROWTH HORMONES

These criteria apply to the following products:

Norditropin (preferred product for SWHP Specialty Formulary;

Only product on Exchange formulary – all others will require an exception prior authorization)

Genotropin
Humatrope
Nutropin

Nutropin AQ
Saizen
Serostim

Tev-Tropin
Zomacton
Zorbtive

CRITERIA FOR ADULT INDICATIONS:

Adults with growth hormone deficiency (GHD):

1. Prescribed by an Endocrinologist **AND**
 - a. Initiation/Transition – Documented GHD defined as:
 - i. Adult patient with irreversible hypothalamic-pituitary disease (etiologies may include radiation therapy, surgery or trauma) **AND**
 - 1.) low IGF-1 level (e.g. <2.5 percentile or < -2 standard deviations) **AND**
 - 2.) negative response to GH stimulation testing (peak GH < 5 µg/L) based on insulin tolerance test.
NOTE: Acceptable alternative stimulation tests: growth hormone releasing hormone (GHRH) + arginine (ARG), glucagon or ARG

OR

2. Previously treated with growth hormone for childhood-onset growth hormone deficiency (COGHD) **OR**
3. Adult patient with pan-hypopituitarism (≥3 pituitary hormone deficiencies) **AND**
 - a. low IGF-1 level (e.g. <2.5 percentile or < -2 standard deviations).
NOTE: Pituitary hormones include: thyroid stimulating hormone (TSH), adrenocorticotropin hormone (ACTH), lutenizing hormone (LH), follicle stimulating hormone (FSH) and arginine vasopressin (AVP)

OR

4. Continuation – meets initial use criteria

Adults with short bowel syndrome (Zorbtive ONLY – limited to ONE 4-week course per 12 months)

1. Prescribed by an Endocrinologist **AND**
2. Patient is >18 years old **AND**
3. Patient is dependent on intravenous parenteral nutrition consisting of specialized diet (high carbohydrate, low-fat diet)

Adults with HIV Infection with wasting or cachexia (Serostim ONLY – limited to 12 weeks)

1. Prescribed by an Endocrinologist **AND**
 2. HIV-positive **AND**
 3. Wasting or cachexia; **AND**
 - a. Documented, unintentional weight loss of >10% from baseline **OR**
 - b. Weight <90% of the lower limit of ideal body weight; **OR**
 - c. Body mass index (BMI) <20 kg/m²;
- AND**
4. Able to consume or be fed through parenteral or enteral feeding >75% of maintenance energy requirements based on current body weight **AND**
 5. Currently on antiretroviral therapy for at least 30 days prior to beginning therapy **and** will continue antiretroviral therapy throughout treatment

COVERAGE AUTHORIZATION CRITERIA FOR PEDIATRIC INDICATIONS:

1. Prescribed by a Pediatric Endocrinologist **AND**

For Growth Hormone Deficiency (GHD) Congenital or Acquired:

1. For initiation of therapy:
 - a. Children with any of the following growth patterns:
 - i. Marked short stature defined as height <3rd percentile* (e.g. > 2 standard deviations (SD) below the mean for age and gender) **OR**
 - ii. Growth failure defined as height velocity <3rd percentile (e.g. < 2 SD below mean for age) **OR**
 - iii. Less severe short stature combined with moderate growth failure (e.g. growth velocity <15th percentile or less than 1 SD)
- AND**
- b. Documented GHD as evidenced by:
 - i. Low IGF-1 and/or IGFBP-3 levels (e.g. values > 2 SD below the mean for IGF-1 or IGFBP-3) **OR**
 - ii. The patient must have diminished serum growth hormone level based on TWO of the following stimulation tests: arginine, glucagon, or clonidine
2. For continuation of therapy:
 - a. Until epiphyseal closure† (final height) is documented **OR**
 - b. Growth rate velocity‡ is ≥ 2.5 cm/year (should see a doubling of pre-treatment growth rate or an increase of 3 cm/year or more in the first year and 2.5 cm/year thereafter);

For Turner Syndrome:

1. For initiation of therapy:
 - a. Females with Turner syndrome (diagnosed using chromosome analysis) **AND**
 - b. Short stature
2. For continuation of therapy:
 - a. Continue until a satisfactory height has been attained **OR**
 - b. Until bone age is ≥ 14 years of age

For Small for Gestational Age (SGA)

1. For initiation of therapy:
 - a. Child born SGA who does not have sufficient catch-up growth before age 2 [height remains <3rd percentile (e.g. >2 SDS below the mean for age and sex) at 2 years of age]
2. For continuation of therapy:
 - a. Therapy may be continued if there is accelerated growth rate compared with baseline [growth rate velocity‡ must be ≥ 2.5 cm/year (should see a doubling of pre-treatment growth rate or an increase of 3 cm/year or more in the first year and 2.5 cm/year thereafter)]

For Growth Failure in Children with Chronic Renal Insufficiency:

1. For initiation of therapy:
 - a. Growth failure that persists after other factors contributing to uremic growth failure have been adequately stabilized and prior to kidney transplantation; May also be evaluated by nephrologist

2. For continuation of therapy:
 - a. Until epiphyseal closure is documented **OR**
 - b. Until renal transplantation

For Prader-Willi Syndrome (PWS):

1. For initiation of therapy:
 - a. Child with PWS (diagnosed using chromosome analysis and/or appropriate genetic evaluation) **AND** growth failure. Growth hormone therapy is contraindicated in children with PWS who are severely obese (e. g. weight > 225 % of ideal body weight) or have respiratory impairment or sleep apnea (evaluated by polysomnography)
2. For continuation of therapy:
 - a. Until epiphyseal closure is documented **AND**
 - b. No new onset of sleep apnea **OR** respiratory impairment

For Noonan Syndrome (and other FDA-approved dwarfing syndromes):

1. For initiation of therapy:
 - a. Child with diagnosis of Noonan syndrome **AND**
 - b. Short stature
 2. For continuation of therapy:
 - a. Until satisfactory height has been attained **OR**
 - b. Epiphyseal closure is documented
-

HALAVEN® (eribulin)

1. Prescribed by an Oncologist **AND**
 2. Indication is supported by either:
 - a. FDA approved labeling **OR**
 - b. National Comprehensive Cancer Network (NCCN) with a grade 2A or higher recommendation
-

HARVONI™ (sofosbuvir/ledipasvir)

1. Prescribed by a:
 - a. Hepatologist **OR**
 - b. Board Certified Infectious Disease specialist **OR**
 - c. Board Certified Gastroenterologist

AND

2. Must be ≥ 12 years of age

AND

3. Documented diagnosis of:
 - a. Genotype 1 chronic HCV **AND**

- i. Fibrosis OR cirrhosis, confirmed by either:
 - 1. Metavir score F2 or higher on liver biopsy**OR**
 - 2. At least TWO of the following*:
 - a. FIB-4 >1.45
 - b. APRI >0.5
 - c. Fibroscan >7.0
 - d. Fibrosure >0.49
 - e. Radiological imaging consistent with fibrosis and/or cirrhosis (e.g. portal hypertension)

OR

- b. Genotype 4, 5 or 6 chronic HCV **AND**

- i. Fibrosis OR compensated cirrhosis, confirmed by either:
 - 1. Metavir score F2 or higher on liver biopsy**OR**
 - 2. At least TWO of the following*:
 - a. FIB-4 >1.45
 - b. APRI >0.5
 - c. Fibroscan >7.0
 - d. Fibrosure >0.49
 - e. Radiological imaging consistent with fibrosis and/or cirrhosis (e.g. portal hypertension)

OR

- c. Genotype 1, 4, 5 or 6 chronic HCV **AND**

- i. Cryoglobulinemia with end-organ manifestations, defined as one of the following:
 - 1. Vasculitis **OR**
 - 2. Peripheral neuropathy **OR**
 - 3. Raynaud's Phenomenon

OR

- ii. One of the following extrahepatic manifestations:
 - 1. Membranoproliferative glomerulonephritis **OR**
 - 2. Membranous nephropathy

OR

- iii. Prior liver transplant

OR

- iv. Currently on transplant list

AND

- 4. Member has been screened for hepatitis B infection prior to initiation of treatment, and will be appropriately monitored and/or treated **AND**
- 5. Abstinence from alcohol and IV drug use for at least 6 months prior to treatment

AND

- 6. Member does NOT have:
 - a. Clinically decompensated cirrhosis (allowed if genotype 1) **OR**
 - b. ESRD on hemodialysis **OR**

- c. Any other non-liver related comorbidity resulting in less than a 10-year predicted survival **OR**
- d. Ongoing non-adherence to prior medications or medical treatment **OR**
- e. Failure to complete HCV disease evaluation, appointments and procedures (e.g. laboratories)

AND

- 7. Member has NOT been previously treated with:
 - a. Daclatasvir (Daklinza) **OR**
 - b. Dasabuvir (Viekira) **OR**
 - c. Elbasvir (Zepatier) **OR**
 - d. Grazoprevir (Zepatier) **OR**
 - e. Ledipasvir (Harvoni) **OR**
 - f. Ombitasvir (Technivie, Viekira) **OR**
 - g. Paritaprevir (Technivie, Viekira) **OR**
 - h. Simeprevir (Olysio) **OR**
 - i. Sofosbuvir (Epclusa, Sovaldi, Harvoni)

AND

- 8. For requests of longer treatment duration in lieu of ribavirin use, member must have a documented contraindication or clinically significant intolerance to ribavirin therapy, defined as:
 - a. Women who are pregnant or may become pregnant
 - b. Male whose female partner is or may become pregnant
 - c. Hemoglobinopathy (e.g., thalassemia major or sickle-cell anemia)
 - d. Co-administration with didanosine
 - e. Documented history of clinically significant or unstable cardiac or renal disease
 - f. Documented clinically significant anemia, including clinically significant anemia with prior ribavirin use

**Other non-invasive tests that may be considered include: FibroIndex, Forns Index, HepaScore/FibroScore, ShearWave Elastography, magnetic resonance elastography*

NOTE: Requests for two or more of the following will not be approved: Daklinza (daclatasvir), Epclusa (sofosbuvir/velpatasvir), Harvoni (sofosbuvir/ledipasvir), Olysio (simeprevir), Sovaldi (sofosbuvir), Technivie (paritaprevir/ritonavir/ombitasvir), Victrelis (boceprevir), Viekira (paritaprevir/ritonavir/ombitasvir/dasabuvir), or Zepatier (elbasvir/grazoprevir)

HIZENTRA (immune globulin, subcutaneous)

- 1. Meets Immune Globulin Medical Therapy Medical Policy* **AND**
- 2. Failure of or clinically significant reaction to:
 - a. One formulary IV Immune Globulin product **AND**
 - b. One formulary SQ Immune Globulin product

*Criteria can be found in the Immune Globulin Therapy Medical Policy: <https://swhp.org/en-us/prov/resources/policies#Medical>

HP ACTHAR (corticotropin) – NONFORMULARY AGENT

1. One of the following diagnoses:
 - a. Infantile Spasms (West Syndrome) **AND**
 - i. Patient age less than 24 months (2 years) **AND**
 - ii. Used as monotherapy
 - OR**
 - b. Adults with an FDA labeled, corticosteroid-responsive condition (see list below) and **ALL** of the following:
 - i. Member greater than 18 years **AND**
 - ii. No contraindication to corticosteroid therapy **AND**
 - iii. Clear documentation provided as to why **ALL** other well-established routes for corticosteroid therapy cannot be used (oral and IV steroids) **AND**
 - iv. No contraindications to corticotropin therapy (e.g. scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, hx of PUD, CHF, uncontrolled HTN, primary adrenalcorticol insufficiency, adrenocortical hyperfunction or sensitivity to proteins of porcine origin) **AND**
 - v. Failure, contraindication to, or intolerance to **ALL** formulary alternatives for the specified indication

FDA-labeled, corticosteroid-responsive conditions:

1. Multiple Sclerosis: treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease.
2. Rheumatic Disorders: As adjunctive therapy for short-term administration (e.g during an acute episode or exacerbation) in: psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, or ankylosing spondylitis.
3. Collagen Diseases: During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).
4. Dermatologic Diseases: Severe erythema multiforme, Stevens-Johnson syndrome.
5. Allergic States: Serum sickness.
6. Ophthalmic Diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis; optic neuritis; chorioretinitis; anterior segment inflammation.
7. Respiratory Diseases: Symptomatic sarcoidosis.
8. Edematous State: To induce a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus

HUMIRA® (adalimumab)

Ankylosing spondylitis:

1. Prescribed by a Rheumatologist **AND**
2. Member has:
 - a. Documented spinal involvement **OR**
 - b. Failure of at least **one** or contraindication(s) to nonsteroidal anti-inflammatory drugs (NSAIDs)

Crohn's Disease:

1. Prescribed by a Gastroenterologist **AND**
2. Failure of or contraindication(s) to:
 - a. An anti-inflammatory drug (e.g. mesalamine, sulfasalazine); **OR**
 - b. Corticosteroids; **OR**
 - c. An immunosuppressive drug (e.g. 6-MP, azathioprine, methotrexate)

Hidradenitis suppurativa (acne inversa):

1. Prescribed by a Dermatologist **AND**
2. Diagnosis of severe and/or refractory disease **AND**
3. Failure of or contraindication(s) to ALL of the following:
 - a. Antibiotics **AND**
 - b. Intralesional steroids

Polyarticular juvenile idiopathic arthritis:

1. Prescribed by a Rheumatologist **AND**
2. Failure of or contraindication(s) to:
 - a. Methotrexate, **OR**
 - b. Sulfasalazine, **OR**
 - c. Leflunomide, **OR**
 - d. Another anti-TNF agent

Psoriasis:

1. Prescribed by a Dermatologist **AND**
2. Diagnosis of moderate to severe plaque psoriasis affecting:
 - a. greater than 5% of body surface area (BSA); **OR**
 - b. crucial body areas such as hands, feet, face, or genitals

AND

3. Failure of at least **two** topical treatments [including but not limited to corticosteroids, vitamin D analogues, vitamin D analogue/corticosteroid combinations, Tazorac® (tazarotene)] **AND**

4. Failure of or contraindication to phototherapy (UVB or PUVA) **AND**
5. Failure of or contraindication to methotrexate, cyclosporine, acitretin, leflunomide, sulfasalazine, or tacrolimus.

Psoriatic arthritis:

1. Prescribed by a Rheumatologist **OR** Dermatologist **AND**
2. Member has:
 - a. Documented spinal involvement (psoriatic spondylitis); **OR**
 - b. Failed methotrexate; **OR**
 - i. Contraindication to methotrexate **AND**
 - ii. Failure of at least **one** or contraindication(s) to other DMARDs
** The American College of Rheumatology defines DMARDs as: hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*

Rheumatoid arthritis:

1. Prescribed by a Rheumatologist **AND**
2. Failure of methotrexate; **OR**
 - a. Contraindication to methotrexate **AND**
 - b. Failure of at least **one** or contraindication(s) to other DMARDs
** The American College of Rheumatology defines DMARDs as: hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*

Ulcerative Colitis:

1. Prescribed by a Gastroenterologist **AND**
2. Failure of or contraindication(s) to:
 - a. An anti-inflammatory drug (e.g. mesalamine, sulfasalazine); **OR**
 - b. Corticosteroids; **OR**
 - c. An immunosuppressive drug (e.g. 6-MP, azathioprine, methotrexate)

Uveitis:

1. Prescribed by:
 - a. Ophthalmologist **OR**
 - b. Rheumatologist

AND

2. Age >18 years **AND**
3. Diagnosis of non-infectious intermediate, posterior, or panuveitis **AND**
4. Member meets the following criteria:
 - a. Failure of or contraindication to systemic corticosteroids **AND**
 - b. Active inflammation despite \geq 3 month trial of a steroid sparing agent (methotrexate, azathioprine, mycophenolate, cyclosporine, or tacrolimus)

HYQVIA (immune globulin, subcutaneous)

1. Meets Immune Globulin Medical Therapy Medical Policy* **AND**
2. Failure of or clinically significant reaction to:
 - c. One formulary IV Immune Globulin product **AND**
 - d. One formulary SQ Immune Globulin product

*Criteria can be found in the Immune Globulin Therapy Medical Policy: <https://swhp.org/en-us/prov/resources/policies#Medical>

INFLECTRA® (infliximab) – NONFORMULARY AGENT

1. Prescribed in accordance with product labeling, to include:
 - a. FDA-approved indication **AND**
 - b. FDA-approved dose

AND

2. Failure of Remicade, defined as:
 - a. Either of the following:
 - i. Both of the following:
 1. History of a trial of at least 14 weeks of Remicade resulting in minimal clinical response to therapy and residual disease activity **AND**
 2. Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Inflectra or other infliximab biosimilar product, than experienced with Remicade

OR

- ii. Both of the following:
 1. History of intolerance or adverse event to Remicade **AND**
 2. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Inflectra or other infliximab biosimilar product

AND

- b. Both of the following:
 - i. Patient has NOT had a loss of a favorable response after established maintenance therapy with Remicade or other infliximab biosimilar product **AND**
 - ii. Patient has NOT developed neutralizing antibodies to any infliximab biosimilar product that has led to an attenuation of efficacy of therapy

NOTE: Consideration will be given for coverage requests for non-FDA-approved indications upon submission of compelling evidence.

INGREZZA™ (valbenazine) – NONFORMULARY AGENT

1. Prescribed by a Neurologist **AND**
 2. FDA approved indication **AND**
 3. Must be 18 years of age or older **AND**
 4. Failure or intolerance to ALL of the following:
 - a. generic tetrabenazine **AND**
 - b. clonazepam
-

IVIG PRODUCTS

1. Criteria can be found in the Immune Globulin Therapy Medical Policy:
<http://swhp.org/Portals/0/Medical%20Coverage%20Policies/045%20-%20Immune%20Globulin%20Therapy.pdf?ver=2016-10-03-192735-163×tamp=1475524336538>

Applicable to the following drugs:

Bivigam Carimune NF Flebogamma DIF Gammagard S/D Gammagard Liquid Gammaked Gammaplex Gamunex-C Hizentra* Hyqvia* Octagam Privigen
--

**Hizentra and Hyqvia have additional clinical criteria*

JEVTANA® (cabazitaxel)

1. Prescribed by a:
 - a. Hematologist **OR**
 - b. Oncologist
- AND**
2. Indication is supported by either:
 - a. FDA approved labeling **OR**
 - b. National Comprehensive Cancer Network (NCCN) with a grade 2A or higher recommendation
-

JUBLIA® (efinaconazole) – NONFORMULARY AGENT

1. FDA-approved indication **AND**
2. Onychomycosis documented within the last 6 months by one of the following:
 - a. Positive KOH preparation **OR**
 - b. positive periodic-acid-Schiff staining **OR**
 - c. Positive fungal culture

AND

3. One of the following:
 - a. history of cellulitis of the lower extremity, especially if repeated, and ipsilateral toenail onychomycosis **OR**
 - b. diabetes with additional risk factors for cellulitis (ie, prior cellulitis, venous insufficiency, edema) **OR**
 - c. pain associated with infected nails **OR**
 - d. Immunosuppressed

AND

4. Failure of or contraindication to the following:
 - a. oral terbinafine **AND**
 - b. topical ciclopirox

NOTE: FDA-approved indication for Jublia and Kerydin - treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*.

Consideration will be given for coverage requests for other FDA-approved and non-FDA-approved indications upon submission of compelling evidence.

KADCYLA® (trastuzumab emtansine)

1. Prescribed by an Oncologist **AND**
 2. Indication is supported by either:
 - a. FDA approved labeling **OR**
 - b. National Comprehensive Cancer Network (NCCN) with a grade 2A or higher recommendation
-

KALBITOR® (ecallantide) – NONFORMULARY AGENT

Initial criteria (6 month approval):

1. Prescribed by one of the following specialists:
 - a. Allergist **OR**
 - b. Immunology Specialist **OR**
 - c. Hematologist

AND

2. Diagnosis of hereditary angioedema (HAE) with confirming labs and chart notes submitted **AND**
3. Member is using for treatment of acute HAE attacks **AND**
4. Member does not have contraindication to therapy **AND**
5. Member is not using any medication known to cause angioedema (i.e. ACE inhibitor, ARB, or estrogen) **AND**
6. Kalbitor will be the only medication prescribed for treatment of acute attacks **AND**
7. Request is within FDA-approved labeling **AND**
8. Quantity requested will not result in a supply on hand of more than two doses
 - a. If request is for more than two doses on hand, must supply chart notes confirming anticipated attack frequency requiring treatment

AND (ACA Compliant members only)

9. Failure of, intolerance to, or contraindication to Berinert

Continuation criteria (6 month approval):

1. Member is using for treatment of an acute HAE attack **AND**
2. Request is for a replacement supply of doses used
 - a. Supply clinical documentation of acute HAE attack(s) requiring treatment including date of attack and number of doses utilized

AND

3. Quantity requested will not result in a supply on hand of more than two doses
 - a. If request is for more than two doses on hand, must supply chart notes confirming anticipated attack frequency requiring treatment

NOTE: Safety and efficacy not established for prophylactic therapy

KERYDIN® (tavaborole) – NONFORMULARY AGENT

1. FDA-approved indication **AND**
2. Onychomycosis documented within the last 6 months by one of the following:
 - a. Positive KOH preparation **OR**
 - b. positive periodic-acid-Schiff staining **OR**
 - c. Positive fungal culture

AND

3. One of the following:
 - a. history of cellulitis of the lower extremity, especially if repeated, and ipsilateral toenail onychomycosis **OR**
 - b. diabetes with additional risk factors for cellulitis (ie, prior cellulitis, venous insufficiency, edema) **OR**
 - c. pain associated with infected nails **OR**
 - d. Immunosuppressed

AND

4. Failure of or contraindication to the following:
 - a. oral terbinafine **AND**

- b. topical ciclopirox

NOTE: FDA-approved indication for Jublia and Kerydin - treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*.

Consideration will be given for coverage requests for other FDA-approved and non-FDA-approved indications upon submission of compelling evidence.

KEVZARA™ (sarilumab) – NONFORMULARY AGENT

Rheumatoid arthritis

1. Prescribed by a Rheumatologist **AND**

2. Failure of methotrexate; **OR**

a. Contraindication to methotrexate **AND**

b. Failure of at least **one** other DMARD

**The American College of Rheumatology defines DMARDs as:*

hydroxychloroquine, sulfasalazine, methotrexate (oral or Inj), and leflunomide

AND (for new starts only)

3. Failure of, or contraindication to, ALL of the following:

a. Enbrel (preferred) **AND**

b. Humira (preferred) **AND**

c. Actemra **AND**

d. Cimzia **AND**

e. Orencia **AND**

f. Remicade **AND**

g. Simponi

KEYTRUDA® (pembrolizumab)

1. Prescribed by:

a. Hematology **OR**

b. Oncology

AND

2. Indication is:

a. FDA-approved **OR**

b. Supported by the National Comprehensive Cancer Network (NCCN) with a grade 2A or higher recommendation

AND

3. Member does **NOT** have any of the following:

a. Concurrent use of systemic corticosteroids and/or immunosuppressants **OR**

- b. History of a severe immune-mediated adverse reaction from treatment with ipilimumab, requiring use of corticosteroids for 12 weeks or more
-

KINERET® (anakinra)

Cryopyrin-associated periodic syndromes (CAPS)

1. Diagnosis of cryopyrin-associated periodic syndromes (CAPS)

Rheumatoid arthritis

1. Prescribed by a Rheumatologist **AND**
 2. Failure of methotrexate; **OR**
 - a. Contraindication to methotrexate **AND**
 - b. Failure of at least **one** other DMARD

** The American College of Rheumatology defines DMARDs as: hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*
 - AND (for new starts only)**
 3. Failure of or contraindication to preferred formulary biologic agents FDA-approved for treatment of rheumatoid arthritis (i.e. Enbrel, Humira).
-

LEMTRADA® (alemtuzumab) – NONFORMULARY AGENT

INITIAL DOSE APPROVAL CRITERIA (duration 4 weeks):

1. Prescribed by a Neurologist **AND**
2. ≥18 years of age **AND**
3. Diagnosis of a relapsing form of multiple sclerosis **AND**
4. Contraindication to, failure of, or intolerance to at least two of the following disease-modifying therapies:
 - a. Aubagio
 - b. Avonex
 - c. Copaxone or Glatopa
 - d. Extavia
 - e. Gilenya
 - f. Plegridy
 - g. Tecfidera
 - h. Tysabri

AND

5. Other MS therapies have been discontinued, including IVIG **AND**
6. Dose will not exceed maximum allowable quantity of 12 mg x 5 days

CONTINUATION CRITERIA (duration 4 weeks):

1. Prescribed by a Neurologist
 2. ≥18 years of age **AND**
 3. Diagnosis of a relapsing form of multiple sclerosis **AND**
 4. Only one cycle has been previously given **AND**
 5. It has been 365 days since last dose of initial cycle **AND**
 6. Treatment with any other disease-modifying therapy has not been re-initiated during 12 months since first cycle, including IVIG **AND**
 7. Dose will not exceed maximum allowable quantity of 12 mg x 3 days
-

MOZOBIL® (plerixafor)

1. Prescribed by an Oncologist OR Hematologist **AND**
 2. Diagnosis of non-Hodgkin's lymphoma OR multiple myeloma **AND**
 3. Member is undergoing stem cell mobilization for subsequent autologous transplantation **AND**
 4. Being used in combination with:
 - a. Granulocyte colony stimulating factor (G-CSF): Neupogen® (filgrastim) **OR**
 - b. Granulocyte macrophage colony stimulating factor (GM-CSF): Leukine® (sargramostim)
- AND**
5. Failure of prior standard stem cell mobilization procedures utilizing one of the above medications alone or in combination with chemotherapy
-

MYALEPT® (metreleptin) – NONFORMULARY EXCEPT ACA COMPLIANT

Initiation criteria (6 month approval)

1. Prescribed by an Endocrinologist **AND**
 2. Confirmed diagnosis of leptin deficiency **AND**
 3. Confirmed diagnosed of congenital or acquired generalized lipodystrophy **AND**
 4. Confirmed diagnosis of one of the following additional diagnosis:
 - a. Diabetes mellitus **OR**
 - b. Hypertriglyceridemia
- AND**
5. Failure of max tolerable doses of at least **TWO** conventional therapies for each additional diagnosis listed above **AND**
 6. Member has failed lifestyle modification (diet and exercise) and will continue lifestyle modification while on Myalept **AND**
 7. Patient does not have any FDA labeled contraindications* to therapy with Myalept **AND**
 8. Dose is within FDA labeled dosing guidelines **AND**
 9. Myalept is not being used for:

- a. HIV-related lipodystrophy **OR**
- b. Metabolic diseases without concurrent evidence of congenital or acquired lipodystrophy **OR**
- c. Complications from partial lipodystrophy (Barraquer-Simons' syndrome)

AND

10. Member does not have any of the following:

- a. Liver disease including nonalcoholic steatohepatitis (NASH) **OR**
- b. History of lymphoma **OR**
- c. Presence of anti-metresleptin antibodies

Continuation criteria (12 month approval)

- 1. Patient has a documented sustained reduction (from baseline) in at least one of the following parameters: HbA1c or triglycerides **AND**
- 2. Patient will continue with lifestyle modification while on Myalept **AND**
- 3. Patient does not have any FDA labeled contraindications to therapy with Myalept **AND**
- 4. Dose is within FDA labeled dosing guidelines

**Labeled contraindications: Hypersensitivity (e.g, anaphylaxis, urticaria, generalized rash) to metreleptin or any component of the formulation; general obesity (not associated with congenital leptin deficiency)*

MYOBLOC® (rimabotulinumtoxinB)

- 1. Member has one of the following diagnoses:
 - a. Anal fissures following at least two months of conservative therapy to include trial and failure of the following:
 - i. topical nitroglycerin **AND**
 - ii. topical nifedipine
- OR**
- b. Axillary hyperhidrosis **OR**
 - c. Blepharospasm **OR**
 - d. Cervical dystonia [spasmodic torticollis] **OR**
 - e. Chronic migraine headache **OR**
 - f. Detrusor and sphincter dyssynergia **OR**
 - g. Essential tremor **OR**
 - h. Hemifacial spasm **OR**
 - i. Neurogenic bladder **OR**
 - j. Non-achalasia esophageal motility disorder [dysphagia] **OR**
 - k. Oculomotor nerve injury **OR**
 - l. Oromandibular dystonia **OR**
 - m. Overactive bladder **OR**
 - n. Pelvic floor dyssynergia [anismus] **OR**
 - o. Sialorrhea associated with neurological disorders **OR**

- p. Spasmodic and laryngeal dysphonia [including post-laryngectomy] **OR**
 - q. Spasticity [post stroke hemiplegia, upper and lower limb spasticity, cerebral palsy] **OR**
 - r. Strabismus
-

NONFORMULARY DRUGS

Drugs not listed on formulary may be subject to prior authorization to confirm the following:

- 1. Drug used for medically accepted indication and dosage regimen **AND**
 - 2. Requested quantity is clinically appropriate **AND**
 - 3. There are no clinically appropriate formulary alternatives **AND**
 - 4. Drug is not excluded from coverage
-

NOXAFIL® (posaconazole)

A Prior Authorization (PA) is not required for primary prophylaxis prescriptions written by the Department of Hematology/Oncology.

However, a PA, with a Division of Infectious Diseases (ID) consult, is required for all services, including Hematology/Oncology, for use of posaconazole for treatment prescriptions.

Primary Prophylaxis

- 1. acute leukemia patients undergoing induction/consolidation chemotherapy
- 2. allogeneic hematopoietic transplant patients while receiving immunosuppressive therapy

Treatment

- 1. Fungi (e.g., *Mucor*, *Scedosporium spp*) that are resistant to other formulary agents
-

NUCALA® (mepolizumab) – NONFORMULARY AGENT

Initiation Criteria (3 month approval):

- 1. Prescribed by a:
 - a. Allergist **OR**
 - b. Immunologist **OR**
 - c. Pulmonologist

AND

2. Member is at least 12 years old **AND**
3. Diagnosis of severe eosinophilic asthma **AND**
4. A blood eosinophil concentration of either:
 - a. ≥ 150 cells/mcL within the last 6 weeks **OR**
 - b. >300 cells/mcL in the past 12 months

AND

5. One of the following:
 - a. Two or more asthma exacerbations (defined as need for systemic corticosteroids, ER visit or hospitalization) in the last 12 months despite use of following, unless member is intolerant or has a medical contraindication to these agents:
 - i. ≥ 880 $\mu\text{g/day}$ of inhaled fluticasone propionate or equivalent for ≥ 3 months **AND**
 - ii. ≥ 1 additional controller medication for ≥ 3 months
- OR**
- b. Chronic use of the following:
 - i. daily oral glucocorticoids plus an inhaled corticosteroid for ≥ 6 months **AND**
 - ii. ≥ 1 additional controller medication for ≥ 3 months

AND

6. Dose will not exceed 100 mg once every 4 weeks **AND**
7. Not being used concomitantly with Cinqair[®] (reslizumab) or Xolair[®] (omalizumab)

Continuation Criteria (12 month approval):

1. Patient has demonstrated response to therapy, defined as:
 - a. Decreased asthma exacerbation rate **OR**
 - b. Documented improvement in asthma symptoms **OR**
 - c. Decreased hospitalizations, emergency department/urgent care visits, or physician visits due to asthma **OR**
 - d. Decreased requirement for oral corticosteroids

AND

2. Documented compliance with the following:
 - a. Nucala
 - b. Inhaled corticosteroid
 - c. ≥ 1 additional controller

OCREVUS[®] (ocrelizumab) – NONFORMULARY

Primary progressive multiple sclerosis:

1. Prescribed by a neurologist **AND**
2. Member is at least 18 years old **AND**
3. Member does not have an active Hepatitis B infection

4. Diagnosis of progressive multiple sclerosis as defined by the 2010 McDonald Criteria:
 - a. Disease progression over at least a 12 month time period **AND**
 - b. At least TWO of the following:
 - i. Evidence for dissemination in space (DIS) in the brain based on one or more T2 lesions with at least one that is characteristic for MS (periventricular, juxtacortical, or infratentorial) OR
 - ii. Evidence for DIS in the spinal cord based on \geq two T2 lesions in the cord OR
 - iii. Isoelectric focusing evidence of oligoclonal bands and/or elevated IgG index in the cerebrospinal fluid (CSF)

Relapsing remitting multiple sclerosis:

1. Prescribed by a neurologist **AND**
2. Member is at least 18 years old **AND**
3. Diagnosis of relapsing remitting multiple sclerosis **AND**
4. Member does not have an active Hepatitis B infection
5. Documented failure* of or contraindication to the following disease modifying therapies for multiple sclerosis:
 - a. At least one formulary self-injectable MS therapy (Avonex, Copaxone, Extavia, Glatopa, Plegridy) **AND**
 - b. At least one formulary oral MS therapy (Aubagio, Gilenya, Tecfidera)

AND

6. No concurrent use of any other multiple sclerosis disease modifying agent such as Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Lemtrada, Rebif, Tecfidera, Tysabri, or Zinbryta

***NOTE: Failure is defined as one of the following during treatment with one of these medications:**

1. Continued clinical relapses (at least 1 relapse within the past 12 months)
2. Continued CNS lesion progression as measured by MRI
3. Worsening disability, such as decreased mobility, decreased ability to perform ADLs due to disease progression, or increase in EDSS score)

OLYSIO® (simeprvir) – NONFORMULARY AGENT

INITIATION CRITERIA:

1. Prescribed by a:
 - a. Hepatologist **OR**
 - b. Board Certified Infectious Disease specialist **OR**
 - c. Board Certified Gastroenterologist

AND

2. Must be \geq 18 years of age **AND**
3. Documented diagnosis of Genotype 1 chronic HCV **AND**
 - a. Fibrosis OR compensated cirrhosis, confirmed by either:

- i. Metavir score F2 or higher on liver biopsy

OR

- ii. At least TWO of the following*:
 - 1. FIB-4 >1.45
 - 2. APRI >0.5
 - 3. Fibroscan >7.0
 - 4. Fibrosure >0.49
 - 5. Radiological imaging consistent with fibrosis and/or cirrhosis (e.g. portal hypertension)

OR

- a. Cryoglobulinemia with end-organ manifestations, defined as one of the following:
 - i. Vasculitis **OR**
 - ii. Peripheral neuropathy **OR**
 - iii. Raynaud's Phenomenon

OR

- b. One of the following extrahepatic manifestations:
 - i. Membranoproliferative glomerulonephritis **OR**
 - ii. Membranous nephropathy

OR

- c. Prior liver transplant

OR

- d. Currently on transplant list

AND

- 4. Member has been screened for hepatitis B infection prior to initiation of treatment, and will be appropriately monitored and/or treated **AND**
- 5. Abstinence from alcohol and IV drug use for at least 6 months prior to treatment

AND

- 6. Member does NOT have:
 - a. Clinically decompensated cirrhosis **OR**
 - b. ESRD on hemodialysis **OR**
 - c. Any other non-liver related comorbidity resulting in less than a 10-year predicted survival **OR**
 - d. Ongoing non-adherence to prior medications or medical treatment **OR**
 - e. Failure to complete HCV disease evaluation, appointments and procedures (e.g. laboratories)

AND

- 7. Member has NOT been previously treated with:
 - a. Daclatasvir (Daklinza) **OR**
 - b. Dasabuvir (Viekira) **OR**
 - c. Elbasvir (Zepatier) **OR**
 - d. Grazoprevir (Zepatier) **OR**
 - e. Ledipasvir (Harvoni) **OR**
 - f. Ombitasvir (Technivie, Viekira) **OR**
 - g. Paritaprevir (Technivie, Viekira) **OR**
 - h. Simeprevir (Olysio) **OR**

- i. Sofosbuvir (Epclusa, Sovaldi, Harvoni) OR
- j. Velpatasvir (Epclusa)

AND

- 8. Clinical inappropriateness or inability to tolerate preferred agent(s) (i.e. Harvoni, Sovaldi)

***Other non-invasive tests that may be considered include: FibroIndex, Forns Index, HepaScore/FibroScore, ShearWave Elastography, magnetic resonance elastography*

NOTE: Requests for two or more of the following will not be approved: Epclusa (sofosbuvir/velpatasvir), Harvoni (sofosbuvir/ledipasvir), Olysio (simeprevir), Sovaldi (sofosbuvir), Technivie (paritaprevir/ritonavir/ombitasvir), Victrelis (boceprevir), Viekira (paritaprevir/ritonavir/ombitasvir/dasabuvir), or Zepatier (elbasvir/grazoprevir)

ONFI® (clobazam)

- 1. Prescribed by a Neurologist **AND**
- 2. Diagnosis of an epileptic condition **AND**
- 3. Refractory to combination therapy with at least **two** other anticonvulsants

OPDIVO™ (nivolumab)

- 1. Prescribed by:
 - a. Hematology **OR**
 - b. Oncology

AND

- 2. Indication is:
 - a. FDA-approved **OR**
 - b. Supported by the National Comprehensive Cancer Network (NCCN) with a grade 2A or higher recommendation

AND

- 3. Member does NOT have any of the following:
 - a. Concurrent use of systemic corticosteroids and/or immunosuppressants **OR**
 - b. History of a severe immune-mediated adverse reaction from treatment with ipilimumab, requiring use of corticosteroids for 12 weeks or more

ORAL ONCOLOGY AGENTS

- 1. Prescribed by:
 - a. Hematology **OR**

- b. Oncology

AND

- 2. Indication is:
 - a. FDA-approved **OR**
 - b. Supported by the National Comprehensive Cancer Network (NCCN) with a grade 2A or higher recommendation

Applicable to the following drugs:

Alacensa	Hycamtin	Nexavar	Tarceva	Zydelig
Alunbrig	Ibrance	Nilandron	Targretin	Zykadia
Bosulif	Iclusig	Ninlaro	Tasigna	Zytiga
Cabometyx	Imbruvica	Odomzo	Tykerb	
Capecitabine	Inlyta	Pomalyst	Xtandi	
Cometriq	Iressa	Purixan	Xalkori	
Cotellic	Jakafi	Rubraca	Vandetinib	
Erivedge	Kisqali	Rydapt	Venclexta	
Farydak	Lenvima	Sprycel	Votrient	
Gilotrif	Lonsurf	Stivarga	Zejula	
Gleevec	Lynparza	Tafinlar	Zelboraf	
Hexalen	Mekinist	Tagrisso	Zolinza	

ORENCIA® (abatacept) – IV Formulation

Rheumatoid arthritis

- 1. Prescribed by a Rheumatologist **AND**
- 2. Failure of methotrexate; **OR**
 - a. Contraindication to methotrexate **AND**
 - b. Failure of at least **one** or contraindication(s) to other DMARDs

** The American College of Rheumatology defines DMARDs as: hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*
- AND (for new starts only)**
- 3. Failure of or contraindication to preferred anti-TNF agents (i.e. Enbrel, Humira).

Polyarticular juvenile idiopathic arthritis:

- 1. Prescribed by a Rheumatologist **AND**
- 2. Failure of or contraindication to:
 - a. Methotrexate, **OR**
 - b. Sulfasalazine, **OR**
 - c. Leflunomide
- AND**
- 3. Failure of or contraindication to preferred anti-TNF agents (i.e. Enbrel, Humira)

ORENCIA® (abatacept) – SubQ Formulation

Rheumatoid arthritis

1. Prescribed by a Rheumatologist **AND**
 2. Failure of methotrexate; **OR**
 - a. Contraindication to methotrexate **AND**
 - b. Failure of at least **one** or contraindication(s) to other DMARDs
** The American College of Rheumatology defines DMARDs as:
hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*
- AND (for new starts only)**
3. Failure of or contraindication to preferred anti-TNF agents (i.e. Enbrel, Humira).

ORKAMBI® (lumacaftor/ivacaftor) – NONFORMULARY AGENT

Quantity Limits:

Drug	Strength	Maximum Daily Dose	Quantity Limits
Orkambi	200/125 mg	4 tablets daily	Up to 120 tablets in 30 days

Initial Prior Authorization Criteria (4 month duration):

1. Age 6 or older **AND**
2. Diagnosis of cystic fibrosis **AND**
3. Confirmed homozygous F580del mutation on the CFTR gene using an FDA-approved test **AND**
4. Baseline AST/ALT <5 x ULN, OR if bilirubin elevated must be <2 x ULN with AST/ALT <3 x ULN **AND**
5. If between ages 12-18 years, baseline ophthalmic exam to check for lens opacities and cataracts **AND**
6. If female of child-bearing potential, using non-hormonal contraception **AND**
7. Member is not/will not be taking the following drugs concomitantly:
 - a. Kalydeco **OR**
 - b. Strong CYP3A inducers (e.g., barbiturates, carbamazepine, efavirenz, glucocorticoids, modafinil, nevirapine, oxcarbazepine, phenobarbital, phenytoin, pioglitazone, rifabutin, rifabutin, St. John's Wort)

Continuation Criteria (12 month duration):

1. Since starting Orkambi:
 - a. Stable or improved FEV1 **OR**
 - b. Documented clinical improvement
- AND**
2. AST/ALT <5 x ULN OR if bilirubin elevated must be <2 x ULN with AST/ALT <3 x ULN (every 3 months for first year, then annually thereafter) **AND**

3. If between ages 12-18 years, baseline ophthalmic exam to check for lens opacities and cataracts **AND**
 4. If female of child-bearing potential, using non-hormonal contraception **AND**
 5. Member is not/will not be taking any the following drugs concomitantly:
 - c. Kalydeco **OR**
 - d. Strong CYP3A inducers (e.g., barbiturates, carbamazepine, efavirenz, glucocorticoids, modafinil, nevirapine, oxcarbazepine, phenobarbital, phenytoin, pioglitazone, rifabutin, rifabutin, St. John's Wort)
-

OTEZLA® (apremilast) – NONFORMULARY AGENT

Psoriatic arthritis:

1. Prescribed by a Rheumatologist **OR** Dermatologist **AND**
2. Member has:
 - a. Documented spinal involvement (psoriatic spondylitis); **OR**
 - b. Failed methotrexate; **OR**
 - iii. Contraindication to methotrexate **AND**
 - iv. Failure of at least **one** or contraindication(s) to other DMARDs*
** The American College of Rheumatology defines DMARDs as: hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*

AND

3. Failure of or contraindication to preferred formulary biologic agents FDA-approved for treatment of psoriatic arthritis (i.e. Enbrel, Humira).

Psoriasis:

1. Prescribed by a Dermatologist **AND**
2. Diagnosis of moderate to severe plaque psoriasis affecting:
 - a. greater than 5% of body surface area (BSA); **OR**
 - b. crucial body areas such as hands, feet, face, or genitals

AND

3. Failure of at least **two** topical treatments [including but not limited to corticosteroids, vitamin D analogues, vitamin D analogue/corticosteroid combinations, Tazorac® (tazarotene)] **AND**
4. Failure of or contraindication to phototherapy (UVB or PUVA) **AND**
5. Failure of or contraindication to at least one of the following:
 - a. Methotrexate **OR**
 - b. Cyclosporine **OR**
 - c. Acitretin **OR**

- d. Leflunomide **OR**
- e. Sulfasalazine **OR**
- f. Tacrolimus

AND

- 6. Failure of, contraindication to or intolerance to preferred formulary products FDA-approved for treatment of plaque psoriasis (Humira, Enbrel)
-

PERJETA® (pertuzumab)

- 1. Prescribed by an Oncologist **AND**
- 2. Indication is supported by either:
 - a. FDA approved labeling **OR**
 - b. National Comprehensive Cancer Network (NCCN) with a grade 2A or higher recommendation

AND

- 3. Documented positive laboratory HER2 testing results **AND**
 - 4. Patient has not received prior anti-HER2 therapy for metastatic disease **AND**
 - 5. Must be given in combination with trastuzumab (Herceptin) and taxane therapy
-

PICATO® (ingenol mebutate)

- 1. Diagnosis of actinic keratosis **AND**
- 2. Must be ≥ 18 years old **AND**
- 3. Failure of one of the following:
 - a. a fluorouracil product **OR**
 - b. an imiquimod product **OR**
 - c. a diclofenac gel product

AND

- 4. Women of childbearing potential must use a form of birth control
-

PRADAXA® (dabigatran) – NONFORMULARY AGENT (SWHP)

Prior Authorization Criteria:

- 1. Diagnosis of:
 - a. non-valvular atrial fibrillation OR atrial flutter, **AND**
 - i. Member does **NOT** have a mechanical or prosthetic heart valve**OR**
 - b. treatment and secondary prevention of deep venous thrombosis (DVT) or pulmonary embolism (PE)

AND (for new starts only)

2. Failure of or contraindication to at least one preferred factor Xa inhibitor (Eliquis or Xarelto)

NOTE: Patients may effectively be maintained on warfarin rather than switching to dabigatran, particularly those who are clinically stable and have good INR control. When INR control was within target range at least 66% of the time in the RE-LY study, warfarin therapy was associated with similar rates of stroke and similar or less major bleeding compared to dabigatran.

Patients on warfarin who may be better suited for dabigatran include those who have a high risk of intracranial bleed, difficulty in having INRs monitored regularly, complicated drug regimens, or unstable INRs in the absence of non-adherence.

ADDITIONAL INFORMATION ABOUT DABIGATRAN

- Dabigatran has no antidote. The anticoagulant effect of dabigatran is reduced to about 50% of maximum at 12 hours following a dose.
- Patients should be monitored for adherence, signs and symptoms of bleeding, stroke, GI adverse effects and other adverse effects.
- GI bleeding is greater with dabigatran but warfarin was shown to have a higher rate of intracranial bleeding.
- No routine laboratory monitoring of anticoagulant activity is recommended for dabigatran.
- Dabigatran must remain in the original packaging (e.g., should not be placed in pill reminder boxes), kept tightly closed and away from moisture. Once the package is opened, the product must be used within 60 days.

PRALUENT[®] (alirocumab) – NONFORMULARY AGENT

Initiation Criteria (75 mg dose; initial approval duration 4 months):

1. Prescribed by a:
 - a. Cardiologist OR
 - b. Endocrinologist OR
 - c. a Board Certified Lipidologist

AND

2. Member is ≥ 18 years old **AND**
3. Member has one of the following FDA-approved indications:
 1. Familial hypercholesterolemia (FH) defined as:
 - i. Genetic test confirmation OR a MedPed/WHO score of ≥ 6 per 2011 ESC/EAS guidelines **AND**
 - ii. LDL ≥ 160 mg/dL despite adherence to maximized lipid-lowering therapy (described below)

OR

2. Clinical ASCVD, defined as:
 - i. History of at least one of the following:
 - a) myocardial infarction (MI) **OR**
 - b) acute coronary syndrome (ACS) **OR**
 - c) stable or unstable angina **OR**
 - d) thromboembolic stroke **OR**
 - e) transient ischemic attack (TIA) **OR**
 - f) peripheral artery disease (PAD) **OR**
 - g) coronary or other arterial revascularization

AND

- ii. LDL \geq 130 mg/dL despite adherence to maximized lipid-lowering therapy (described below)

AND

4. Documented adherence to 2013 AHA/ACC Lifestyle Management Guidelines (e.g. heart healthy diet, aerobic exercise three to four times a week, active weight loss if BMI >25 kg/m²)

AND

5. Nonsmoker

AND

6. One of the following:

1. Failure of maximized lipid-lowering therapy, defined as:
 - i. Failure to reach goal LDL concentration despite \geq 80% adherence to a 90-day trial (verified by pharmacy claims) of either:
 - i. Atorvastatin 80 mg/d in combination with Zetia **OR**
 - ii. Rosuvastatin 40 mg/d in combination with Zetia

OR

2. Contraindication to HMG-CoA reductase inhibitor therapy, defined as:
 - i. Immune-mediated hypersensitivity **OR**
 - ii. Active liver disease (*Note: chronic, stable liver disease such as hepatitis B, hepatitis C or non-alcoholic fatty liver do not apply*) **OR**
 - iii. Laboratory-confirmed acute liver injury secondary to HMG-CoA reductase inhibitor therapy **OR**
 - iv. Laboratory-confirmed rhabdomyolysis secondary to HMG-CoA reductase inhibitor therapy **OR**

OR

3. Intolerance to HMG-CoA reductase inhibitor therapy, defined as:
 - i. One of the following:
 - i. Intolerable, persistent, bilateral myalgia (muscle symptoms without creatine kinase elevations) **OR**
 - ii. Myopathy (muscle weakness with creatine kinase elevations >3 x baseline or ULN) **OR**
 - iii. Myositis (creatinine kinase elevations >3 x baseline or ULN without muscle symptoms)

AND

ii. Improvement upon HMG-CoA reductase inhibitor dose decrease or discontinuation

AND

iii. Not attributable to another cause, such as a drug interactions or recognized modifiable conditions that increase risk of statin intolerance

AND

iv. Adequate trial resulting in intolerance to ALL formulary statins at lowest FDA-approved dose:

i. Atorvastatin 10 mg

ii. Fluvastatin 20 mg

iii. Lovastatin 20 mg

iv. Pravastatin 10 mg

v. Rosuvastatin 5 mg

vi. Simvastatin 10 mg

AND

7. Continuation of highest tolerated dose of HMG-CoA reductase inhibitor therapy AND other lipid lowering therapies

Dose Escalation Criteria (150 mg dose; initial approval duration of 4 months)

1. Inadequate response to an 8-week trial of the 75 mg dose, defined as <50% reduction in LDL from baseline (non-treated) OR not achieving pre-specified goal LDL

AND

2. Documentation of adherence to ALL of the following:

a. Praluent therapy, verified by claims history **AND**

b. Concomitant lipid lowering therapies, verified by claims history **AND**

c. 2013 AHA/ACC Lifestyle Management Guidelines (e.g. heart healthy diet, aerobic exercise three to four times a week, active weight loss if BMI >25 kg/m²) **AND**

d. Nonsmoker

Continuation Criteria (approval duration of 12 months):

1. Medical record documentation of:

a. A clinically significant decrease in LDL since initiation, defined as:

i. >50% reduction in baseline (non-treated) LDL **OR**

ii. reaching prespecified goal LDL concentration **OR**

iii. ≥35% reduction in LDL concentration since starting Praluent

AND

b. Documented adherence to ALL of the following:

i. Praluent therapy, verified by claims history **AND**

ii. Concomitant cholesterol lowering therapies, verified by claims history

AND

- iii. 2013 AHA/ACC Lifestyle Management Guidelines (e.g. heart healthy diet, aerobic exercise three to four times a week, active weight loss if BMI >25 kg/m²) **AND**
- iv. Nonsmoker

The following must be submitted with each request:

- baseline (non-treated) LDL if available;
- pre-Praluent LDL, if applicable;
- LDL within the last 30 days; and
- Target LDL

MedPed/WHO Heterozygous Familial Hypercholesterolemia Clinical Diagnostic Criteria:

Criteria	Score
First-degree relative known with premature CAD and/or first-degree relative with LDL-C >95 th centile	1
First-degree relative with tendon xanthomata and/or children <18 with LDL-C >95 th centile	2
Patient has premature CAD (male<55 yo; female <60 yo)	2
Patient has premature cerebral/peripheral vascular disease	1
Tendon xanthomata	6
Arcus cornealis below the age of 45 years	4
LDL-C >330 mg/dL	8
LDL-C 250 – 329 mg/dL	5
LDL-C 190 – 249 mg/dL	3
LDL-C 155 – 189 mg/dL	1

PROLIA® (denosumab)

1. At least 18 years old **AND**
2. Osteoporosis or high risk for osteoporosis, as evidenced by:
 - a. History of osteoporotic fracture **OR**
 - b. Bone Mineral Density (BMD) T-score of ≤ -2.5 **OR**
 - c. BMD T-score between -1.0 and -2.5 **AND**
 - i. 10-year probability of hip fracture ≥3% **OR**
 - ii. 10-year probability of any major osteoporosis-related fracture ≥20% based upon the US-adapted WHO algorithm

AND

 - iii. Treatment failure, intolerance or contraindication to at least **one** oral bisphosphonate

AND

3. One of the following populations:
 - a. Males age 50 and older **OR**
 - b. Post-menopausal females **OR**

- c. Males receiving androgen deprivation therapy for nonmetastatic prostate cancer **OR**
 - d. Females receiving adjuvant aromatase inhibitor therapy for breast cancer
-

PROMACTA® (eltrombopag)

Chronic immune thrombocytopenia (ITP)

INITIATION CRITERIA (approve for 3 months):

- 1. FDA approved indication **AND**
- 2. Previous failure of:
 - a. Corticosteroids **OR**
 - b. Immunoglobulins **OR**
 - c. Splenectomy

AND

- 3. Platelet count < 30,000/mcL

CONTINUATION CRITERIA (approve for 12 months):

- 1. Demonstrated response to treatment with a platelet count of at least 50,000/mcL but less than 200,000/mcL.

For chronic hepatitis C virus (HCV) associating with thrombocytopenia

INITIATION CRITERIA (approve for 2 months):

- 1. FDA approved indication **AND**
- 2. Platelet count < 75,000/mcL

CONTINUATION CRITERIA (approve for 12 months):

- 1. Demonstrated response to treatment with an improved platelet count from baseline.
-

PROVENGE® (sipuleucel-T)

- 1. FDA approved labeling

OR

- 2. Prescribed by an Oncologist OR Hematologist, **AND**
 - a. Documented metastatic prostate cancer with radiologic evidence of metastatic disease in the lymph nodes and/or bone. *NOTE: Patient may not have visceral metastasis (metastases to liver, lung or brain), pathologic bone fractures or spinal cord compression.*

AND

- b. Hormone refractory (castrate resistant or androgen-independent) disease with a testosterone level of <50 ng/mL **AND**
- c. Asymptomatic or minimally symptomatic disease **AND**
- d. Life expectancy of greater than 6 months **AND**

- e. Either:
 - i. ECOG performance status of 0-1 **OR**
 - ii. Karnofsky score of 80-100
- AND**
- f. No simultaneous chemotherapy or immunosuppressive therapy
-

RADICAVA™ (edaravone) – NONFORMULARY AGENT

1. Prescribed by a Neurologist **AND**
 2. FDA approved indication, defined as definite or probable Amyotrophic lateral sclerosis (ALS), based on El Escorial revised criteria **AND**
 3. 18 years of age or older **AND**
 4. Functionality retained for most activities of daily living, as demonstrated by a score of 2 or more on each item of the ALS Functional Rating Scale- revised (ALSFRS-R) **AND**
 5. Normal respiratory function, defined as an FVC of at least 80% **AND**
 6. Disease duration of two years or less **AND**
 7. Failure of, intolerance to, or continuation of riluzole
-

RALOXIFENE (generic only)

As required by health care reform (PPACA) per the U.S. Preventive Services Task Force (USPSTF) for women who are at increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications.

Medications Included: raloxifene, tamoxifen

Coverage Criteria:

1. Indicated for PRIMARY PREVENTION of invasive breast cancer in women considered high risk (high risk defined by prescribing physician to include risk assessment and counseling) **AND**
 2. Age \geq 35 years old **AND**
 3. Female gender **AND**
 4. Post-menopausal (ONLY applies to raloxifene use) **AND**
 5. Member does **NOT** have a prior history of:
 - a. a diagnosis of breast cancer, ductal carcinoma in situ (DCIS), or lobular carcinoma in situ (LCIS) **OR**
 - b. thromboembolic events (deep venous thrombosis, pulmonary embolus, stroke or transient ischemic attack)
-

REMICADE® (infliximab)

1. Prescribed in accordance with product labeling, to include:
 - a. FDA-approved indication **AND**
 - b. FDA-approved dose

NOTE: Consideration will be given for coverage requests for non-FDA-approved indications upon submission of compelling evidence.

REPATHA® (evolocumab) – NONFORMULARY AGENT

Initiation Criteria (approval duration 4 months):

1. Prescribed by a:
 - a. Cardiologist **OR**
 - b. Endocrinologist **OR**
 - c. Board Certified Lipidologist
- AND**
2. Member is ≥ 18 years old **AND**
 3. Member has one of the following FDA-approved indications:
 - a. Familial hypercholesterolemia (FH) defined as:
 - i. Genetic test confirmation **OR** a MedPed/WHO score of ≥ 6 per 2011 ESC/EAS guidelines **AND**
 - ii. LDL ≥ 160 mg/dL despite adherence to maximized lipid-lowering therapy
- OR**
- b. Clinical ASCVD, defined as:
 - i. History of at least one of the following:
 - a) myocardial infarction (MI) **OR**
 - b) acute coronary syndrome (ACS) **OR**
 - c) stable or unstable angina **OR**
 - d) thromboembolic stroke **OR**
 - e) transient ischemic attack (TIA) **OR**
 - f) peripheral artery disease (PAD) **OR**
 - g) coronary or other arterial revascularization
- AND**
- ii. LDL ≥ 130 mg/dL despite adherence to maximized lipid-lowering therapy
- AND**
4. Documented adherence to 2013 AHA/ACC Lifestyle Management Guidelines (e.g. heart healthy diet, aerobic exercise three to four times a week, active weight loss if BMI >25 kg/m²)
- AND**
5. Nonsmoker

AND

6. One of the following:

- a. Failure of maximized lipid-lowering therapy, defined as:
 - i. Failure to reach goal LDL concentration despite $\geq 80\%$ adherence to a 90-day trial (verified by pharmacy claims) of either:
 - 1. Atorvastatin 80 mg/d in combination with Zetia OR
 - 2. Rosuvastatin 40 mg/d in combination with Zetia

OR

- a. Contraindication to HMG-CoA reductase inhibitor therapy, defined as:
 - i. Immune-mediated hypersensitivity **OR**
 - ii. Active liver disease (*Note: chronic, stable liver disease such as hepatitis B, hepatitis C or non-alcoholic fatty liver do not apply*) **OR**
 - iii. Laboratory-confirmed acute liver injury secondary to HMG-CoA reductase inhibitor therapy **OR**
 - iv. Laboratory-confirmed rhabdomyolysis secondary to HMG-CoA reductase inhibitor therapy **OR**

OR

- b. Intolerance to HMG-CoA reductase inhibitor therapy, defined as
 - i. One of the following:
 - 1. Intolerable, persistent, bilateral myalgia (muscle symptoms without creatine kinase elevations) **OR**
 - 2. Myopathy (muscle weakness with creatine kinase elevations $>3x$ baseline or ULN) **OR**
 - 3. Myositis (creatinine kinase elevations $>3x$ baseline or ULN without muscle symptoms)

AND

- ii. Improvement upon HMG-CoA reductase inhibitor dose decrease or discontinuation

AND

- iii. Not attributable to another cause, such as a drug interactions or recognized modifiable conditions that increase risk of statin intolerance

AND

- iv. Adequate trial resulting in intolerance to ALL formulary statins at lowest FDA-approved dose:
 - i. Atorvastatin 10 mg
 - ii. Fluvastatin 20 mg
 - iii. Lovastatin 20 mg
 - iv. Pravastatin 10 mg
 - v. Rosuvastatin 5 mg
 - vi. Simvastatin 10 mg

AND

7. Continuation of highest tolerated dose of HMG-CoA reductase inhibitor therapy AND other lipid lowering therapies

Continuation Criteria (approval duration of 12 months):

- 1. Medical record documentation of:

- a. A clinically significant decrease in LDL since initiation, defined as:
 - i. >50% reduction in baseline (non-treated) LDL **OR**
 - ii. reaching prespecified goal LDL concentration **OR**
 - iii. \geq 35% reduction in LDL concentration since starting Repatha

AND

- b. Documented adherence to ALL of the following:
 - i. Repatha therapy, verified by claims history **AND**
 - ii. Concomitant cholesterol lowering therapies, verified by claims history **AND**
 - iii. 2013 AHA/ACC Lifestyle Management Guidelines (e.g. heart healthy diet, aerobic exercise three to four times a week, active weight loss if BMI >25 kg/m²) **AND**
 - iv. Nonsmoker

Dosing:

Clinical ASCVD and HeFH: 140 mg sq every 2 weeks (2 injections/28 ds) OR 420 mg sq every 4 weeks (using Pushtronix system)

HoFH: 420 mg sq every 4 weeks (using Pushtronix system)

The following must be submitted with each request: baseline (non-treated) LDL if available; pre-Repatha LDL, if applicable; LDL within the last 30 days; and Target LDL

MedPed/WHO Heterozygous Familial Hypercholesterolemia Clinical Diagnostic Criteria:

Criteria	Score
First-degree relative known with premature CAD and/or first-degree relative with LDL-C >95 th centile	1
First-degree relative with tendon xanthomata and/or children <18 with LDL-C >95 th centile	2
Patient has premature CAD (male<55 yo; female <60 yo)	2
Patient has premature cerebral/peripheral vascular disease	1
Tendon xanthomata	6
Arcus cornealis below the age of 45 years	4
LDL-C >330 mg/dL	8
LDL-C 250 – 329 mg/dL	5
LDL-C 190 – 249 mg/dL	3
LDL-C 155 – 189 mg/dL	1

RETIN-A[®] MICRO (tretinoin)

- 5. Diagnosis of:
 - a. acne vulgaris **OR**
 - b. acne rosacea **OR**
 - c. actinic keratosis

NOTE: Consideration will be given for coverage requests for other FDA-approved and non-FDA-approved indications upon submission of compelling evidence.

RUCONEST® (C1 Esterase Inhibitor, Recombinant) – NONFORMULARY AGENT

Initial criteria (6 month approval):

1. Prescribed by one of the following specialists:
 - a. Allergist **OR**
 - b. Immunology Specialist **OR**
 - c. Hematologist

AND

2. Diagnosis of hereditary angioedema (HAE) with confirming labs and chart notes submitted **AND**
3. Member is using for **treatment** of acute HAE attacks **AND**
4. Member does NOT have contraindication to therapy **AND**
5. Member is NOT using any medication known to cause angioedema (i.e. ACE inhibitor, ARB, or estrogen) **AND**
6. Ruconest will be the only medication prescribed for treatment of acute attacks **AND**
7. Request is within FDA-approved labeling **AND**
8. Quantity requested will not result in a supply on hand of more than two doses
 - a. If request is for more than two doses on hand, must supply chart notes confirming anticipated attack frequency requiring treatment

AND (ACA Compliant members only)

9. Failure of, intolerance to, or contraindication to Berinert.

Continuation criteria (6 month approval):

1. Member is using for treatment of acute HAE attacks **AND**
2. Request is for a replacement supply of doses used
 - a. Supply clinical documentation of acute HAE attack(s) requiring treatment including date of attack and number of doses utilized

AND

3. Quantity requested will not result in a supply on hand of more than two doses
 - a. If request is for more than two doses on hand, must supply chart notes confirming anticipated attack frequency requiring treatment

NOTE: Safety and efficacy not established for prophylactic therapy

SAVAYSA® (edoxaban) – NONFORMULARY AGENT

Prior Authorization Criteria:

1. Diagnosis of:

- a. non-valvular atrial fibrillation OR atrial flutter, **AND**
 - i. Member does **NOT** have a mechanical or prosthetic heart valve
- OR**
- b. treatment and secondary prevention of deep venous thrombosis (DVT) or pulmonary embolism (PE)

AND (for new starts only)

2. Failure of or contraindication to at least one preferred factor Xa inhibitor (Eliquis or Xarelto)
-

SILIQ™ (brodalumab) – NONFORMULARY AGENT

Plaque Psoriasis:

1. Prescribed by a Dermatologist **AND**
2. Diagnosis of moderate to severe plaque psoriasis affecting:
 - a. greater than 10% of body surface area (BSA); **OR**
 - b. crucial body areas such as hands, feet, face, or genitals

AND

3. Failure of at least two topical treatments [including but not limited to corticosteroids, vitamin D analogues, vitamin D analogue/corticosteroid combinations or tazarotene (Tazorac®)] **AND**
 4. Failure of or contraindication to phototherapy (UVB or PUVA) **AND**
 5. Failure of or contraindication to methotrexate, cyclosporine, acitretin, leflunomide, sulfasalazine, or tacrolimus **AND**
 6. Failure, contraindication to or intolerance to ALL formulary biologic products FDA-approved for treatment of plaque psoriasis:
 - a. Enbrel (preferred) **AND**
 - b. Humira (preferred) **AND**
 - c. Cosentyx **AND**
 - d. Remicade **AND**
 - e. Stelara
-

SIMPONI® (golimumab)

Rheumatoid arthritis

1. Prescribed by a Rheumatologist **AND**
2. Failure of methotrexate; **OR**
 - a. Contraindication to methotrexate **AND**
 - b. Failure of at least **one** other DMARD
 - * *The American College of Rheumatology defines DMARDs as: hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*

AND (for new starts only)

3. Failure of or contraindication to preferred anti-TNF agents (i.e. Enbrel, Humira).

Psoriatic arthritis:

1. Prescribed by a Rheumatologist **OR** Dermatologist **AND**
2. Member has:
 - a. Documented spinal involvement (psoriatic spondylitis); **OR**
 - b. Failed methotrexate; **OR**
 - i. Contraindication to methotrexate **AND**
 - ii. Failure of at least **one** or contraindication(s) to other DMARDs
** The American College of Rheumatology defines DMARDs as: hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*

AND (for new starts only)

3. Failure of or contraindication to preferred anti-TNF agents (i.e. Enbrel, Humira).

Ankylosing spondylitis:

1. Prescribed by a Rheumatologist **AND**
2. Member has:
 - a. Documented spinal involvement **OR**
 - b. Failure of at least **one** or contraindication(s) to nonsteroidal anti-inflammatory drugs (NSAIDs)

AND (for new starts only)

3. Failure of or contraindication to preferred anti-TNF agents (i.e. Enbrel, Humira).

Ulcerative Colitis:

1. Prescribed by a Gastroenterologist **AND**
2. Failure of or contraindication(s) to:
 - a. An anti-inflammatory drug (e.g. mesalamine, sulfasalazine); **OR**
 - b. Corticosteroids; **OR**
 - c. Immunosuppressive drug (e.g. 6-MP, azathioprine, methotrexate)

AND (for new starts only)

3. Failure of or contraindication to preferred anti-TNF agents (i.e. Humira).

SOMATULINE DEPOT (lanreotide) – COMMERCIAL ONLY

1. One of the following indications:
 - a. Acromegaly **OR**
 - b. Carcinoid tumor **OR**
 - c. Unresectable, asymptomatic, somatostatin-receptor positive, well-differentiated GINET with high tumor burden **OR**
 - d. Vasoactive intestinal peptide tumors (VIPoma)

AND

2. Failure of, contraindication to, or intolerance to octreotide

SOVALDI® (sofosbuvir)

1. Prescribed by a:
 - a. Hepatologist **OR**
 - b. Board Certified Infectious Disease specialist **OR**
 - c. Board Certified Gastroenterologist

AND

2. Must be ≥ 12 years of age

AND

3. Documented diagnosis of Genotype 1, 2, 3 or 4 chronic HCV **AND**
 - a. Fibrosis **OR** compensated cirrhosis, confirmed by either:
 - i. Metavir score F2 or higher on liver biopsy

OR

 - ii. At least TWO of the following*:
 1. FIB-4 >1.45
 2. APRI >0.5
 3. Fibroscan >7.0
 4. Fibrosure >0.49
 5. Radiological imaging consistent with fibrosis and/or cirrhosis (e.g. portal hypertension)

OR

- b. Cryoglobulinemia with end-organ manifestations, defined as one of the following:
 - i. Vasculitis **OR**
 - ii. Peripheral neuropathy **OR**
 - iii. Raynaud's Phenomenon **OR**

OR

- c. One of the following extrahepatic manifestations:
 - i. Membranoproliferative glomerulonephritis **OR**
 - ii. Membranous nephropathy

OR

- d. Prior liver transplant

OR

- e. Currently on transplant list

AND

4. Member has been screened for hepatitis B infection prior to initiation of treatment, and will be appropriately monitored and/or treated **AND**
5. Abstinence from alcohol and IV drug use for at least 6 months prior to treatment

AND

6. Member does NOT have:
 - a. Clinically decompensated cirrhosis **OR**
 - b. ESRD on hemodialysis **OR**
 - c. Any other non-liver related comorbidity resulting in less than a 10-year predicted survival **OR**

- d. Ongoing non-adherence to prior medications or medical treatment **OR**
- e. Failure to complete HCV disease evaluation, appointments and procedures (e.g. laboratories)

AND

- 7. Member has NOT been previously treated with:
 - a. Daclatasvir (Daklinza) **OR**
 - b. Dasabuvir (Viekira) **OR**
 - c. Elbasvir (Zepatier) **OR**
 - d. Grazoprevir (Zepatier) **OR**
 - e. Ledipasvir (Harvoni) **OR**
 - f. Ombitasvir (Technivie, Viekira) **OR**
 - g. Paritaprevir (Technivie, Viekira) **OR**
 - h. Simeprevir (Olysio) **OR**
 - i. Sofosbuvir (Epclusa, Sovaldi, Harvoni) **OR**
 - j. Velpatasvir (Epclusa)

AND

- 8. If genotype 1, clinical inappropriateness or inability to tolerate preferred agent (i.e. Harvoni)

***Other non-invasive tests that may be considered include: FibroIndex, Forns Index, HepaScore/FibroScore, ShearWave Elastography, magnetic resonance elastography*

NOTE: Requests for two or more of the following will not be approved: Epclusa (sofosbuvir/velpatasvir), Harvoni (sofosbuvir/ledipasvir), Olysio (simeprevir), Sovaldi (sofosbuvir), Technivie (paritaprevir/ritonavir/ombitasvir), Victrelis (boceprevir), Viekira (paritaprevir/ritonavir/ombitasvir/dasabuvir) or Zepatier (elbasvir/grazoprevir)

SPINRAZA™ (nusinersin) – NONFORMULARY

Initial treatment (4 loading doses):

- 1. Prescribed by a neurologist with expertise in the diagnosis and/or treatment of spinal muscular atrophy (SMA) **AND**
- 2. Diagnosis of SMA type I, confirmed by the following:
 - a. 5q SMA homozygous gene deletion or homozygous mutation, OR compound heterozygous mutation **AND**
 - b. Presence of no more than 2 copies of survival motor neuron 2 (SMN2)

AND

- 3. Onset of disease before 6 months of age
- 4. Member is NOT dependent on either:
 - a. Invasive ventilation or tracheostomy **OR**
 - b. Non-invasive ventilation for more than 6 hours per day

AND

5. Request accompanied by baseline motor ability testing using either:
 - a. Hammersmith Infant Neurological Exam (HINE) **OR**
 - b. Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP INTEND)

AND

6. Dosing is in accordance with FDA labeling

Continuation criteria (prior to each maintenance dose, every 4 months):

1. All of above criteria met **AND**
2. Request accompanied by assessment of motor ability testing using either HINE or CHOP INTEND that shows improvement in at least one of the following:
 - a. HINE:
 - i. Improvement or maintenance of previous improvement of at least 2 point (or maximum score) increase in ability to kick **OR**
 - ii. Improvement or maintenance of previous improvement of at least 1 point increase in motor milestones of head control, rolling, sitting, crawling, standing, or walking **OR**
 - iii. Improvement in more categories of motor milestones than worsening

OR

 - b. CHOP-INTEND:
 - i. Improvement or maintenance of previous improvement of at least a 4 point increase in score from pretreatment baseline

STELARA® (ustekinumab)

Crohn’s Disease – initiation criteria (one time approval for IV loading dose):

1. Prescribed by a Gastroenterologist **AND**
2. Failure of, or contraindication(s) to, at least one of the following:
 - a. An anti-inflammatory drug (e.g. mesalamine, sulfasalazine) **OR**
 - b. Corticosteroids **OR**
 - c. An immunosuppressive drug (e.g. 6-MP, azathioprine, methotrexate)

AND (for new starts)

3. Failure of or contraindication to preferred formulary biologic agents FDA-approved for treatment of Crohn’s disease (i.e. Humira)

Crohn’s Disease - continuation criteria

1. Prescribed by a Gastroenterologist **AND**
2. Documented clinical response

Psoriasis:

1. Prescribed by a Dermatologist **AND**
2. Diagnosis of moderate to severe plaque psoriasis affecting:

- a. greater than 5% of body surface area (BSA); **OR**
- b. crucial body areas such as hands, feet, face, or genitals

AND

3. Failure of at least two topical treatments [including but not limited to corticosteroids, Vitamin D analogues, Vitamin D analogue/corticosteroid combinations, Tazorac® (tazarotene)] **AND**
4. Failure of or contraindication to phototherapy (UVB or PUVA) **AND**
5. Failure of or contraindication to methotrexate, cyclosporine, acitretin, leflunomide, sulfasalazine, or tacrolimus **AND**
6. If prescription is for Stelara 90 mg, documented weight of >100 kg (220 lbs).
AND (for new starts)
7. Failure of or contraindication to preferred formulary biologic agents FDA-approved for treatment of psoriasis (i.e. Enbrel, Humira) **AND**
8. Failure of Cosentyx

Psoriatic arthritis:

1. Prescribed by a:
 - a. Rheumatologist **OR**
 - b. Dermatologist

AND

2. Member has:
 - a. Documented spinal involvement (psoriatic spondylitis); **OR**
 - b. Failed methotrexate; **OR**
 - i. Contraindication to methotrexate **AND**
 - ii. Failure of at least one or contraindication(s) to other DMARDs
** The American College of Rheumatology defines DMARDs as: hydroxychloroquine, sulfasalazine, methotrexate (oral or inj), and leflunomide*

AND

3. If prescription is for Stelara 90 mg:
 - a. documented weight of >100 kg (220 lbs) **AND**
 - b. concomitant diagnosis of plaque psoriasis

AND (for new starts only)

4. Failure of or contraindication to preferred formulary biologic agents FDA-approved for treatment of psoriatic arthritis (i.e. Enbrel, Humira)

SUBSYS® (fentanyl sublingual spray) – NONFORMULARY AGENT

1. Prescribed by:
 - a. Oncologist **OR**
 - b. Pain specialist

AND

2. Diagnosis is an FDA-approved use:

- a. Management of breakthrough cancer pain **AND**
- b. Member is already receiving and is tolerant to opioid therapy (defined as 60 mg morphine/day or an equianalgesic dose of another opioid for a week or longer) for underlying persistent cancer pain

AND

3. Must be 18 years of age or older **AND**
4. Failure or intolerance to adequate doses of a formulary immediate release narcotic for breakthrough pain **AND**
5. Must be on an adequate dose of a long-acting (maintenance, around-the-clock) opioid **AND**
6. Member does NOT have any of the following:
 - a. Use of an MAO-I within 14 days **OR**
 - b. Known past or current substance abuse potential **OR**
 - c. Currently being treated for substance abuse (including treatment with buprenorphine or buprenorphine-naloxone)

SUPPRELIN® LA (histrelin acetate)

1. Prescribed by an Endocrinologist **AND**
2. Age \geq 2 years old **AND**
3. Clinically diagnosed with central precocious puberty

TALTZ™ (ixekinumab) – NONFORMULARY AGENT

Plaque Psoriasis:

1. Prescribed by a Dermatologist **AND**
2. Diagnosis of moderate to severe plaque psoriasis affecting:
 - a. greater than 10% of body surface area (BSA); **OR**
 - b. crucial body areas such as hands, feet, face, or genitals

AND

3. Failure of at least two topical treatments [including but not limited to corticosteroids, vitamin D analogues, vitamin D analogue/corticosteroid combinations or tazarotene (Tazorac®)] **AND**
4. Failure of or contraindication to phototherapy (UVB or PUVA) **AND**
5. Failure of or contraindication to methotrexate, cyclosporine, acitretin, leflunomide, sulfasalazine, or tacrolimus **AND**
6. Failure of or contraindication to ALL formulary products FDA-approved for treatment of plaque psoriasis:
 - a. Enbrel (preferred) **AND**
 - b. Humira (preferred) **AND**

- c. Cosentyx **AND**
 - d. Remicade **AND**
 - e. Stelara
-

TAMOXIFEN (GENERIC ONLY)

As required by health care reform (PPACA) per the U.S. Preventive Services Task Force (USPSTF) for women who are at increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications.

Medications Included: raloxifene, tamoxifen

Coverage Criteria:

1. Indicated for PRIMARY PREVENTION of invasive breast cancer in women considered high risk (high risk defined by prescribing physician to include risk assessment and counseling) **AND**
 2. Greater than or equal to 35 years old **AND**
 3. Female gender **AND**
 4. Post-menopausal (ONLY applies to raloxifene use) **AND**
 5. Member does **NOT** have a prior history of:
 - a. a diagnosis of breast cancer, ductal carcinoma in situ (DCIS), or lobular carcinoma in situ (LCIS) **OR**
 - b. thromboembolic events (deep venous thrombosis, pulmonary embolus, stroke or transient ischemic attack)
-

TAZORAC® (tazarotene)

1. FDA-approved indications:
 - a. plaque psoriasis
 - b. acne vulgaris.

NOTE: Consideration will be given for coverage requests for other FDA-approved and non-FDA-approved indications upon submission of compelling evidence.

TECHNIVIE® (paritaprevir/ombitasvir/ritonavir) – NONFORMULARY AGENT

1. Prescribed by a:
 - a. Hepatologist **OR**
 - b. Board Certified Infectious Disease specialist **OR**

c. Board Certified Gastroenterologist

AND

2. Must be ≥ 18 years of age

AND

3. Documented diagnosis of Genotype 4 chronic HCV **AND**

a. Fibrosis, but not cirrhosis, confirmed by either:

i. Metavir score F2 or F3 on liver biopsy

OR

ii. At least TWO of the following*:

1. FIB-4 >1.45

2. APRI >0.5

3. Fibroscan >7.0

4. Fibrosure >0.49

5. Radiological imaging consistent with fibrosis and/or cirrhosis (e.g. portal hypertension)

OR

b. Cryoglobulinemia with end-organ manifestations, defined as one of the following:

i. Vasculitis **OR**

ii. Peripheral neuropathy **OR**

iii. Raynaud's Phenomenon

OR

c. One of the following extrahepatic manifestations:

i. Membranoproliferative glomerulonephritis **OR**

ii. Membranous nephropathy

OR

d. Prior liver transplant

OR

e. Currently on transplant list

AND

4. Member has been screened for hepatitis B infection prior to initiation of treatment, and will be appropriately monitored and/or treated **AND**

5. Abstinence from alcohol and IV drug use for at least 6 months prior to treatment

AND

6. Ribavirin will be used concomitantly, unless contraindicated, defined as:

a. Women who are pregnant or may become pregnant

b. Male whose female partner is or may become pregnant

c. Hemoglobinopathy (e.g., thalassemia major or sickle-cell anemia)

d. Co-administration with didanosine

e. Documented history of clinically significant or unstable cardiac or renal disease

f. Documented clinically significant anemia, including clinically significant anemia with prior ribavirin use

AND

7. Member does NOT have:

a. Cirrhosis **OR**

- b. Moderate or severe hepatic impairment (Child-Pugh class B or C) **OR**
 - c. ESRD on hemodialysis **OR**
 - d. Concurrent use of drugs that are:
 - i. highly dependent on CYP3A for clearance **OR**
 - ii. moderate and strong inducers of CYP3A
- OR**
- e. Any other non-liver related comorbidity resulting in less than a 10-year predicted survival **OR**
 - f. Ongoing non-adherence to prior medications or medical treatment **OR**
 - g. Failure to complete HCV disease evaluation, appointments and procedures (e.g. laboratories)

AND

8. Member has NOT been previously treated with:
- a. Daclatasvir (Daklinza) **OR**
 - b. Dasabuvir (Viekira) **OR**
 - c. Elbasvir (Zepatier) **OR**
 - d. Grazoprevir (Zepatier) **OR**
 - e. Ledipasvir (Harvoni) **OR**
 - f. Ombitasvir (Technivie, Viekira) **OR**
 - g. Paritaprevir (Technivie, Viekira) **OR**
 - h. Simeprevir (Olysio) **OR**
 - i. Sofosbuvir (Epclusa, Sovaldi, Harvoni) **OR**
 - j. Velpatasvir (Epclusa)

AND

9. Clinical inappropriateness or inability to tolerate preferred agent(s) (i.e. Harvoni, Sovaldi)

***Other non-invasive tests that may be considered include: FibroIndex, Forns Index, HepaScore/FibroScore, ShearWave Elastography, magnetic resonance elastography*

NOTE: Requests for two or more of the following will not be approved: Epclusa (sofosbuvir/velpatasvir), Harvoni (sofosbuvir/ledipasvir), Olysio (simeprevir), Technivie (paritaprevir/ritonavir/ ombitasvir), Sovaldi (sofosbuvir), Victrelis (boceprevir), Viekira (paritaprevir/ ritonavir/ombitasvir/dasabuvir), or Zepatier (elbasvir/grazoprevir)

TRETINOIN

1. Diagnosis of:
- a. Acne vulgaris **OR**
 - b. Acne rosacea **OR**
 - c. Actinic keratosis

NOTE: Consideration will be given for coverage requests for other FDA-approved and non-FDA-approved indications upon submission of compelling evidence.

TYSABRI® (natalizumab)

For Multiple Sclerosis:

1. Prescribed by Neurology **AND**
2. Diagnosis of relapsing multiple sclerosis **AND**
3. Failure of or contraindication to:
 - a. Avonex **OR**
 - b. Glatiramer (Copaxone)

AND

4. Member has **NOT** received:
 - a. An immunosuppressant in the last three months; **OR**
 - b. An antineoplastic in the last three months; **OR**
 - c. Interferon beta **OR** glatiramer (Copaxone) in the last 2 weeks

AND

5. No prior history of:
 - a. Progressive multifocal leukoencephalopathy (PML); **OR**
 - b. Other slow-virus infection [e.g. subacute sclerosing panencephalitis (SSPE), progressive rubella panencephalitis (PRP), HIV, AIDS, rabies]; **OR**
 - c. Medical condition that significantly compromises the immune system (e.g. leukemia, organ transplant)

** Services must be provided by a TOUCH Prescribing Program provider

For Crohn's disease

1. Prescribed by Gastroenterology **AND**
2. Diagnosis of moderate to severe Crohn's disease **AND**
3. Evidence of active inflammation (e.g., elevated C-reactive protein) **AND**
4. Failure of or contraindication to at least one anti-TNF agent (e.g. Humira, Cimzia, Remicade) **AND**
5. Member has NOT received:
 - a. An immunosuppressant in the last three months; **OR**
 - b. An antineoplastic in the last three months; **OR**
 - c. An anti-TNF agent in the last four weeks

AND

6. No prior history of:
 - d. Progressive multifocal leukoencephalopathy (PML); **OR**
 - e. Other slow-virus infection [e.g. subacute sclerosing panencephalitis (SSPE), progressive rubella panencephalitis (PRP), HIV, AIDS, rabies]; **OR**
 - f. Medical condition that significantly compromises the immune system (e.g. leukemia, organ transplant)

** Services must be provided by a TOUCH Prescribing Program provider

UPTRAVI (selexipag) – NONFORMULARY AGENT

1. Diagnosis of WHO functional class II or III Pulmonary arterial hypertension (PAH)
AND
 2. Failure of, contraindication, or intolerance to BOTH of the following:
 - a. An endothelin receptor antagonist (Letairis, Tracleer OR Opsumit) **AND**
 - b. A phosphodiesterase type 5 inhibitor (sildenafil OR Adcirca)
-

VECTIBIX® (panitumumab)

1. Prescribed by a:
 - c. Hematologist **OR**
 - d. Oncologist
- AND**
2. Indication is supported by either:
 - a. FDA approved labeling **OR**
 - b. National Comprehensive Cancer Network (NCCN) with a grade 2A or higher recommendation

NOTE: Genetic testing (including KRAS gene mutation testing) requires prior authorization by the Health Services Division (HSD). Any questions may be directed to HSD by calling 1-888-316-7947.

VIEKIRA®/VIEKIRA® PAK/VIEKIRA XR™ (paritaprevir/ombitasvir/ritonavir/dasabuvir) - NONFORMULARY AGENT

1. Prescribed by a:
 - a. Hepatologist **OR**
 - b. Board Certified Infectious Disease specialist **OR**
 - c. Board Certified Gastroenterologist
- AND**
2. Must be ≥ 18 years of age **AND**
 3. Documented diagnosis of Genotype 1 chronic HCV **AND**
 - a. Fibrosis OR compensated cirrhosis, confirmed by either:
 - i. Metavir score F2 or higher on liver biopsy
 - OR**
 - ii. At least TWO of the following*:
 1. FIB-4 >1.45

2. APRI >0.5
3. Fibroscan >7.0
4. Fibrosure >0.49
5. Radiological imaging consistent with fibrosis and/or cirrhosis (e.g. portal hypertension)

OR

- b. Cryoglobulinemia with end-organ manifestations, defined as one of the following:
 - i. Vasculitis **OR**
 - ii. Peripheral neuropathy **OR**
 - iii. Raynaud's Phenomenon

OR

- c. One of the following extrahepatic manifestations:
 - i. Membranoproliferative glomerulonephritis **OR**
 - ii. Membranous nephropathy

OR

- d. Prior liver transplant

OR

- e. Currently on transplant list

AND

4. Member has been screened for hepatitis B infection prior to initiation of treatment, and will be appropriately monitored and/or treated **AND**
5. Abstinence from alcohol and IV drug use for at least 6 months prior to treatment

AND

6. Member does NOT have:
 - a. Clinically decompensated cirrhosis **OR**
 - b. Any other non-liver related comorbidity resulting in less than a 10-year predicted survival **OR**
 - c. Ongoing non-adherence to prior medications or medical treatment **OR**
 - d. Failure to complete HCV disease evaluation, appointments and procedures (e.g. laboratories)

AND

7. Member has NOT been previously treated with:
 - a. Daclatasvir (Daklinza) **OR**
 - b. Dasabuvir (Viekira) **OR**
 - c. Elbasvir (Zepatier) **OR**
 - d. Grazoprevir (Zepatier) **OR**
 - e. Ledipasvir (Harvoni) **OR**
 - f. Ombitasvir (Technivie, Viekira) **OR**
 - g. Paritaprevir (Technivie, Viekira) **OR**
 - h. Simeprevir (Olysio) **OR**
 - i. Sofosbuvir (Epclusa, Sovaldi, Harvoni) **OR**
 - j. Velpatasvir (Epclusa)

AND

8. Clinical inappropriateness or inability to tolerate preferred agent(s) (i.e. Harvoni, Sovaldi)

***Other non-invasive tests that may be considered include: FibroIndex, Forns Index, HepaScore/FibroScore, ShearWave Elastography, magnetic resonance elastography*

NOTE: Requests for two or more of the following will not be approved: Epclusa (sofosbuvir/velpatasvir), Harvoni (sofosbuvir/ledipasvir), Olysio (simeprevir), Sovaldi (sofosbuvir), Technivie (paritaprevir/ritonavir/ombitasvir), Victrelis (boceprevir), Viekira (paritaprevir/ritonavir/ombitasvir/dasabuvir), or Zepatier (elbasvir/grazoprevir)

XADAGO™ (safinamide) – NONFORMULARY AGENT

1. Prescribed by a Neurologist **AND**
 2. FDA approved indication **AND**
 3. 18 years of age or older **AND**
 4. Concomitant use of levodopa/carbidopa **AND**
 5. "Off" time (time when medication effect has worn off and parkinsonian features, including bradykinesia and rigidity, return) of greater than 1.5 hours per day, excluding morning akinesia **AND**
 6. Member does NOT have any of the following:
 - a. Concomitant use of ANY of the following:
 - i. Other monoamine oxidase inhibitors or other drugs that are potent inhibitors of monoamine oxidase (e.g., linezolid) **OR**
 - ii. Opioid drugs (e.g., tramadol, meperidine and related derivatives) **OR**
 - iii. Selective norepinephrine reuptake inhibitors **OR**
 - iv. Tri-or tetra-cyclic or triazolopyridine antidepressants **OR**
 - v. Cyclobenzaprine **OR**
 - vi. Methylphenidate, amphetamine, and their derivatives **OR**
 - vii. St. John's wort **OR**
 - viii. Dextromethorphan
 - OR**
 - b. Severe hepatic impairment (Child-Pugh C:10-15)
- AND**
7. Failure of, or contraindication to, ALL of the following:
 - a. Entacapone **AND**
 - b. Pramipexole **AND**
 - c. Rasagiline **AND**
 - d. Ropinirole **AND**
 - e. Tocapone **AND**
 - f. Selegiline

XELJANZ® (tofacitinib) – NONFORMULARY EXCEPT ACA COMPLIANT

Rheumatoid arthritis

1. Prescribed by a Rheumatologist **AND**
 2. Failure of methotrexate; **OR**
 - a. Contraindication to methotrexate **AND**
 - b. Failure of at least **one** other DMARD
**The American College of Rheumatology defines DMARDs as:
hydroxychloroquine, sulfasalazine, methotrexate (oral or Inj), and leflunomide*
- AND (for new starts only)**
3. Failure of or contraindication to preferred anti-TNF agents (i.e. Enbrel, Humira).

XENAZINE® (tetrabenazine) – NONFORMULARY AGENT

1. Prescribed by a Neurologist **AND**
 2. One of the following indications:
 - a. FDA approved indication **OR**
 - b. Tourette's syndrome
- AND**
3. Must be 18 years of age or older **AND**
 4. Failure or intolerance to generic tetrabenazine

XEOMIN® (incobotulinumtoxinA)

1. Member has one of the following diagnoses:
 - a. Anal fissures following at least two months of conservative therapy to include trial and failure of the following:
 - iii. topical nitroglycerin **AND**
 - iv. topical nifedipine
- OR**
- b. Axillary hyperhidrosis **OR**
 - c. Blepharospasm **OR**
 - d. Cervical dystonia [spasmodic torticollis] **OR**
 - e. Chronic migraine headache **OR**
 - f. Detrusor and sphincter dyssynergia **OR**
 - g. Essential tremor **OR**
 - h. Hemifacial spasm **OR**

- i. Neurogenic bladder **OR**
 - j. Non-achalasia esophageal motility disorder [dysphagia] **OR**
 - k. Oculomotor nerve injury **OR**
 - l. Oromandibular dystonia **OR**
 - m. Overactive bladder **OR**
 - n. Pelvic floor dyssynergia [anismus] **OR**
 - o. Sialorrhea associated with neurological disorders **OR**
 - p. Spasmodic and laryngeal dysphonia [including post-laryngectomy] **OR**
 - q. Spasticity [post stroke hemiplegia, upper and lower limb spasticity, cerebral palsy] **OR**
 - r. Strabismus
-

XGEVA® (denosumab)

- 1. Prescribed by an Oncologist OR Hematologist **AND**
 - 2. FDA-approved indication **AND**
 - 3. Member does **NOT** have multiple myeloma
-

XIAFLEX® (collagenase clostridium histolyticum)

Duputren's contracture

- 1. Administered by:
 - a. An orthopedic surgeon **OR**
 - b. Hand surgeon **OR**
 - c. Plastic surgeon
- AND**
- 2. At least 18 years of age **AND**
 - 3. Diagnosis of Dupuytren's contracture with ALL of the following:
 - a. A palpable cord **AND**
 - b. Fixed-flexion contracture of 20 degrees or more of either:
 - i. The metacarpophalangeal joint **OR**
 - ii. Proximal interphalangeal joint (excludes thumb)

AND

- 4. Maximum of two injections per treatment session:
 - a. Two palpable cords affecting two joints may be injected **OR**
 - b. One palpable cord affecting two joints in the same finger may be injected at two locations

Peyronie's disease

- 1. Administered by a Urologist **AND**
- 2. At least 18 years of age **AND**
- 3. Diagnosis of Peyronie's disease **AND**

4. A palpable plaque that can be felt causing greater than 30 degree penile curvature at treatment initiation
-

XIFAXAN® (rifaximin)

1. FDA-approved indications **AND**
 2. If indication is hepatic encephalopathy, then patient must meet the following circumstances:
 - a. Encephalopathy with admission to hospital while on lactulose; OR
 - b. Encephalopathy with diarrhea uncontrolled; OR
 - c. Encephalopathy with intolerance to lactulose; OR
 - d. Encephalopathy that is not improving with lactulose alone
-

XOLAIR® (omalizumab)

For IgE-Mediated Allergic Asthma

1. Age ≥6 years **AND**
2. Diagnosis of IgE-mediated allergic asthma **AND**
3. Diagnosis confirmed by an allergist within the prior year **AND**
4. Patient is following allergen and irritant avoidance **AND**
5. Xolair is used as adjunct and not replacing immunotherapy or other forms of treatment in this patient **AND**
6. Patient is demonstrably complying with fuller controller pharmacotherapy including inhaled corticosteroid and long-acting bronchodilator therapy **AND**
7. Dose of Xolair will be the first to be reduced or discontinued when this patient become well-controlled **AND**
8. Patient has had a pulmonary profile that demonstrated evidence of reversible airways obstruction within the prior year **AND**
9. Patient demonstrates poor control with **at least one** of the following:
 - a. One hospital admission in the prior six months **OR**
 - b. Two emergency room or urgent care visits in the prior six months **OR**
 - c. Two months of daily oral corticosteroid use without significant tapering **OR**
 - d. Other events which are felt to indicate poor control (if this option is chosen, please elaborate in the Additional Comment field)

NOTE: SWHP will also request baseline IgE level and expected dose of Xolair for diagnosis of IgE-mediated allergic asthma

For Chronic Idiopathic Urticaria (CIU)

1. Age ≥12 years **AND**

2. Diagnosis of chronic idiopathic urticaria (CIU) **AND**
 3. Patient continues to be symptomatic despite H1 antihistamine therapy **AND**
 4. Diagnosis confirmed by an allergist within the prior year **AND**
 5. Patient is following allergen and irritant avoidance
-

YERVOY® (ipilimumab)

1. Prescribed by an Oncologist OR Hematologist **AND**
 2. Indication is:
 - a. FDA-approved labeling **OR**
 - b. Supported by the National Comprehensive Cancer Network (NCCN) with a grade 2A or higher recommendation
- AND**
3. Member does NOT have any of the following:
 - a. Concurrent use of systemic corticosteroids and/or immunosuppressants
-

ZALTRAP® (ziv-aflibercept)

1. Prescribed by a:
 - a. Hematologist **OR**
 - b. Oncologist
- AND**
2. Indication is supported by either:
 - a. FDA approved labeling **OR**
 - b. National Comprehensive Cancer Network (NCCN) with a grade 2A or higher recommendation
-

ZEMPLAR® (paricalcitol)

1. Prescribed by a Nephrologist **AND**
 - a. Diagnosis of stage 5 chronic kidney disease **OR**
 - b. Chronic Kidney Disease (CKD) Stage 3-4 **AND**
 - i. A normal 25(OH) level (normal level is 16-60 ng/ml) **AND**
 - ii. An elevated intact parathyroid hormone (PTH) serum concentration (normal level is 10-60 pg/ml),, depending on the patient's CKD stage (noted in the Kidney Disease Outcomes Quality Initiative (K-DOQI) guidelines below)
-

ZEPATIER® (elbasvir/grazoprevir) - NONFORMULARY AGENT

1. Prescribed by a:

- a. Hepatologist **OR**
- b. Board Certified Infectious Disease specialist **OR**
- c. Board Certified Gastroenterologist

AND

2. Must be \geq 18 years of age

AND

3. Documented diagnosis of Genotype 1 or 4 chronic HCV **AND**

a. Fibrosis **OR** cirrhosis, confirmed by either:

i. Metavir score F2 or higher on liver biopsy

OR

ii. At least TWO of the following*:

1. FIB-4 >1.45

2. APRI >0.5

3. Fibroscan >7.0

4. Fibrosure >0.49

5. Radiological imaging consistent with fibrosis and/or cirrhosis (e.g. portal hypertension)

OR

b. Cryoglobulinemia with end-organ manifestations, defined as one of the following:

i. Vasculitis **OR**

ii. Peripheral neuropathy **OR**

iii. Reynaud's Phenomenon

OR

c. One of the following extrahepatic manifestations:

i. Membranoproliferative glomerulonephritis **OR**

ii. Membranous nephropathy

OR

d. Currently on transplant list

AND

4. If Genotype 1a:

- a. Confirmation via FDA-approved test of the presence or absence of baseline NS5A treatment resistance-associated polymorphisms (M28, Q30, L31 or Y93)

AND

5. Baseline liver function tests **AND**

6. Abstinence from alcohol and IV drug use for at least 6 months prior to treatment

AND

7. Member does NOT have:

- a. Genotype 1a HCV with baseline NS5A treatment resistance-associated polymorphisms, with prior protease inhibitor treatment experience (e.g. boceprevir, telaprevir) **OR**

- b. Moderate or severe hepatic impairment (Child-Pugh class B or C) **OR**
- c. Prior organ transplant, currently taking immunosuppressive agents **OR**
- d. Concurrent use of ANY of the following:
 - i. efavirenz **OR**
 - ii. strong inducers of CYP3A (e.g. carbamazepine, phenytoin, rifampin, St. John's Wort) **OR**
 - iii. OATP1B1/3 inhibitors (e.g. atazanavir, cyclosporine, darunavir, lopinavir, saquinavir, tipranavir)

OR

- e. Any other non-liver related comorbidity resulting in less than a 10-year predicted survival **OR**
- f. Ongoing non-adherence to prior medications or medical treatment **OR**
- g. Failure to complete HCV disease evaluation, appointments and procedures (e.g. laboratories)

AND

- 8. Member has NOT been previously treated with:
 - a. Elbasvir (Zepatier) **OR**
 - b. Daclatasvir (Daklinza) **OR**
 - c. Dasabuvir (Viekira) **OR**
 - d. Grazoprevir (Zepatier) **OR**
 - e. Ledipasvir (Harvoni) **OR**
 - f. Ombitasvir (Technivie, Viekira) **OR**
 - g. Paritaprevir (Technivie, Viekira) **OR**
 - h. Simeprevir (Olysio) **OR**
 - i. Sofosbuvir (Epclusa, Sovaldi, Harvoni) **OR**
 - j. Velpatasvir (Epclusa)

AND

- 9. Clinical inappropriateness or inability to tolerate preferred agent(s) (i.e. Harvoni, Sovaldi)

***Other non-invasive tests that may be considered include: FibroIndex, Forns Index, HepaScore/FibroScore, ShearWave Elastography, magnetic resonance elastography*

NOTE: Requests for two or more of the following will not be approved: Epclusa (sofosbuvir/velpatasvir), Harvoni (sofosbuvir/ledipasvir), Olysio (simeprevir), Technivie (paritaprevir/ritonavir/ ombitasvir), Sovaldi (sofosbuvir), Victrelis (boceprevir), Viekira (paritaprevir/ ritonavir/ombitasvir/dasabuvir) or Zepatier (elbasvir/grazoprevir)

ZEVALIN® (ibritumomab tiuxetan)

Scott & White Health Plan (SWHP) will provide coverage under the terms and limitations of the Evidence of Coverage (EOC)/Standard Plan Document (SPD) for the use of Zevalin when the following criteria are met:

1. Prescribed by a SWHP –approved Interventional Radiologist AND
 - a. Diagnosis of CD20 antigen-expressing, relapsed or refractory, low grade follicular or transformed, Non-Hodgkin’s Lymphoma, including patients with rituximab-refractory lymphoma **AND**
 - i. Marrow involvement is < 26%; **AND**
 - ii. Platelet count is $\geq 100,000$ cells/mm³ **AND**
 - iii. Neutrophil count is $\geq 1,500$ cells/mm³
 - OR**
 - b. FDA approve labeling

SWHP Health Services Division (HSD) will not require prior authorization for the use of Zevalin, but reserves the right to obtain a Provider audit through the SWHP Provider Audit Committee at any time it deems necessary to check compliance with the clinical requirements.

ZINBRYTA™ (daclizumab) – NONFORMULARY AGENT

APPROVAL CRITERIA (duration 12 months):

1. Prescribed by a Neurologist **AND**
 2. ≥ 18 years of age **AND**
 3. Diagnosis of a relapsing form of multiple sclerosis **AND**
 4. Contraindication to, failure of, or intolerance to at least two of the following disease-modifying therapies:
 - a. Aubagio
 - b. Avonex
 - c. Copaxone or Glatopa
 - d. Extavia
 - e. Gilenya
 - f. Plegridy
 - g. Tecfidera
 - h. Tysabri
 - AND**
 5. Other MS therapies have been discontinued, including IVIG
-