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.
Effective Date: 10/01/2017
Last Updated: 09/07/2017(updated monthly)

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.

ACTEMRA® (tocilizumab) – IV Formulation

Rheumatoid arthritis:

1. Prescribed by a Rheumatologist **AND**
2. Failure of an adequate trial of or clinically significant intolerance to methotrexate **OR**
    a. Contraindication to methotrexate **AND**
    b. Failure of an adequate trial 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 an adequate trial, clinically significant intolerance, or contraindication to preferred anti-TNF agents [i.e. Enbrel AND Humira]

Polyarticular juvenile idiopathic arthritis:

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

AND

3. Failure of an adequate trial of, clinically significant intolerance, or contraindication to preferred anti-TNF agents [i.e. Enbrel AND Humira]

Systemic juvenile idiopathic arthritis:

1. Prescribed by a Rheumatologist **AND**
2. Failure of an adequate trial 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 an adequate trial of or clinically significant intolerance to methotrexate **OR**
    a. Contraindication to methotrexate **AND**
    b. Failure of an adequate trial 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 an adequate trial of, clinically significant intolerance, or contraindication to preferred anti-TNF agents [i.e. Enbrel AND Humira]

Giant Cell Arteritis

1. Prescribed by Rheumatology **AND**
2. Failure of an adequate trial of, clinically significant intolerance, or contraindication to the following:
    a. Glucorticoids **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

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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)

CONTINUTION CRITERIA (duration 12 months):

1. Documentation of clinically significant (≥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

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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

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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. Member has been on the requested product in the past 180 days **OR**
    b. Failure of an adequate trial of <u>at least one</u> OR clinically significant intolerance or contraindication to the following:
        i. Gilenya
        ii. Tecfidera

AUVI-Q® (epinephrine injection)

1. FDA-approved indication **AND**
2. Failure of ALL of the following:
    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 <u>combination therapy</u> with at least **<u>two</u>** other anticonvulsants

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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 **<u>one</u>** standard SLE therapy (e.g., corticosteroids, hydroxychloroquine, NSAIDs, azathioprine, methotrexate, mycophenolate) **OR**
    b. Member has documented clinically significant intolerance, FDA-labeled contraindication, or hypersensitivity to the standard of care drugs listed above

AND

3. Member does **<u>NOT</u>** 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

<u>Initial criteria (6 month approval):</u>

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 **<u>treatment</u>** 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

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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/mm^3 **AND**
5. Neutrophil count is $\geq$1,500 cells/mm^3

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 members 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 OR clinically significant intolerance or contraindication to 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

BRINEURA™ (cerliponase alfa) – NONFORMULARY AGENT

Please refer to medical policy, located here: Brineura (cerliponase alfa) for Batten Disease

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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 an adequate trial of, clinically significant intolerance, or contraindication to tobramycin for oral inhalation **AND**
6. FEV_1 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 an adequate trial of, clinically significant intolerance, 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

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CIMZIA® (certolizumab)

Rheumatoid arthritis:

1. Prescribed by a Rheumatologist **AND**
2. Failure of an adequate trial of or clinically significant intolerance to methotrexate **OR**
    a. Contraindication to methotrexate **AND**
    b. Failure of an adequate trial 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 an adequate trial or, clinically significant intolerance, or contraindication to preferred anti-TNF agents [i.e. Enbrel, Humira]

Crohn's Disease:

1. Prescribed by a Gastroenterologist **AND**
2. Failure of an adequate trial 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 an adequate trial of, clinically significant intolerance, 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. Failure of an adequate trial of or clinically significant intolerance to methotrexate; **OR**
        i. Contraindication to methotrexate **AND**
        ii. Failure of an adequate trial 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 an adequate trial of, clinically significant intolerance, 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 an adequate trial 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 an adequate trial of, clinically significant intolerance, 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. 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 an adequate trial of, clinically significant intolerance, or contraindication 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 ≤35% **AND**
    c. In sinus rhythm **AND**
    d. Resting heart rate of ≥70 bpm

AND

2. Documented failure of an adequate trial of, clinically significant intolerance, or contraindication to maximized beta-blocker therapy

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COSENTYX™ (secukinumab)

Ankylosing spondylitis:

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

AND (for new starts only)

3. Failure of an adequate trial of, clinically significant intolerance, 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 an adequate trial 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 an adequate trial of, or contraindication to, phototherapy (UVB or PUVA) **AND**
5. Failure of an adequate trial of at least one OR contraindication(s) to:
    a. Methotrexate
    b. Cyclosporine
    c. Acitretin
    d. Leflunomide
    e. Sulfasalazine
    f. Tacrolimus

AND

6. Failure of an adequate trial of, clinically significant intolerance, 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. Failure of an adequate trial of or clinically significant intolerance to methotrexate; **OR**
        i. Contraindication to methotrexate **AND**
        ii. Failure of an adequate trial 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 an adequate trial of, clinically significant intolerance, 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 of an adequate trial of, clinically significant intolerance, or contraindication to zinc acetate

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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. Failure of an adequate trial of, clinically significant intolerance, or contraindication to ALL of the following:
    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 an adequate trial of, or contraindication to, phototherapy **AND**
6. Failure of an adequate trial of at least one OR clinically significant intolerance or contraindication(s) to 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 of an adequate trial of, clinically significant intolerance, or contraindication 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 failure of an adequate trial of, clinically significant intolerance, or contraindication(s) to 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. Member meets ONE of the following conditions:
    a. Trial of prednisone for ≥ 6 months [documentation required] **AND** according to the prescribing physician, member 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 ≥ 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

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ENBREL® (etanercept)

Ankylosing spondylitis:

1. Prescribed by a Rheumatologist **AND**
2. Member has:
    a. Documented spinal involvement **OR**
    b. Failure of an adequate trial 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 an adequate trial of at least one of the following, OR clinically significant intolerance or contraindication(s) to the following:
    a. Methotrexate, **OR**
    b. Sulfasalazine, **OR**
    c. Leflunomide, **OR**
    d. Another anti-TNF agent

Psoriasis:

1. Prescribed by a Dermatologist **AND**
2. Age ≥ 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 an adequate trial 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 an adequate trial of, or contraindication to phototherapy (UVB or PUVA) **AND**
6. Failure of an adequate trial of at least one of the following OR clinically significant intolerance, or contraindication to the following:
    a. Methotrexate
    b. Cyclosporine
    c. Acitretin
    d. Leflunomide
    e. Sulfasalazine
    f. Tacrolimus

Psoriatic arthritis:

1. Prescribed by a Rheumatologist **OR** Dermatologist; **AND**
2. Member has:
    a. Documented spinal involvement (psoriatic spondylitis) **OR**
    b. Failure of an adequate trial of or clinically significant intolerance to methotrexate **OR**
        i. Contraindication to methotrexate **AND**

ii. Failure of an adequate trial 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 an adequate trial of or clinically significant intolerance to methotrexate; **OR**
    a. Contraindication to methotrexate **AND**
    b. Failure of an adequate trial 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 an adequate trial of, clinically significant intolerance, 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 an adequate trial of, clinically significant intolerance, 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/1.73m^3) 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

EXONDYS 51™ (eteplirsen) – NONFORMULARY AGENT

Please refer to medical policy, located here: Eteplirsen (Exondys 51) for Muscular Dystrophy

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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 an adequate trial of, clinically significant intolerance, 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

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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

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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

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GLUMETZA® (metformin HCL extended release) – NONFORMULARY AGENT

1. Failure of an adequate trial of an equivalent dose of ALL of the following:
    a. Metformin immediate-release tablets (generic Glucophage) **AND**
    b. Metformin extended-release tablets (generic Glucophage XR) **AND**
    c. Metformin extended-release tablets OSM (generic Fortamet) **AND**
    d. Fortamet* **AND**
    e. Glucophage IR* **AND**
    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	Nutropin AQ	Tev-Tropin
Humatrope	Saizen	Zomacton
Nutropin	Serostim	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. Adults 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. Adults 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. Member is >18 years old **AND**
3. Dependence 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 IFG-1 or IFGB-3) **OR**
        ii. 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

HAEGARDA® [C1 Esterase Inhibitor, subcutaneous (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 an adequate trial, clinically significant intolerance, or contraindication to:
    a. attenuated androgens (ex. danazol, stanozolol) **AND**
    b. antifibrinolytics (ex. aminocaproic acid)

AND

6. Member does not have contraindication to Haegarda 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

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

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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 (elbasuvir/grazoprevir)

HIZENTRA® (immune globulin, subcutaneous)

1. Meets Immune Globulin Medical Therapy Medical Policy* **AND**
2. Failure of an adequate trial of, or clinically significant intolerance 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. Member 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 of age **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 of an adequate trial of, clinically significant intolerance, or contraindication 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

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HUMIRA® (adalimumab)

Ankylosing spondylitis:

1. Prescribed by a Rheumatologist **AND**
2. Member has:
    a. Documented spinal involvement **OR**
    b. Failure of an adequate trial 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 an adequate trial of at least one OR clinically significant intolerance, or contraindication(s) to 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)

Hidradenitis suppurativa (acne inversa):

1. Prescribed by a Dermatologist **AND**
2. Diagnosis of severe and/or refractory disease **AND**
3. Failure of an adequate trial of, clinically significant intolerance, 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 an adequate trial of at least one OR clinically significant intolerance, or contraindication(s) to the following:
    a. Methotrexate
    b. Sulfasalazine
    c. Leflunomide

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 an adequate trial 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 an adequate trial of, or contraindication to phototherapy (UVB or PUVA) **AND**
5. Failure of an adequate trial of at least one OR clinically significant intolerance or contraindication to the following:
    a. Methotrexate
    b. Cyclosporine
    c. Acitretin
    d. Leflunomide
    e. Sulfasalazine
    f. Tacrolimus

Psoriatic arthritis:

1. Prescribed by a Rheumatologist **OR** Dermatologist **AND**
2. Member has:
    a. Documented spinal involvement (psoriatic spondylitis); **OR**
    b. Failure of an adequate trial of OR clinically significant intolerance to methotrexate; **OR**
        i. Contraindication to methotrexate **AND**
        ii. Failure of an adequate trial 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 an adequate trial of or clinically significant intolerance to methotrexate; **OR**
    a. Contraindication to methotrexate **AND**
    b. Failure of an adequate trial 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 an adequate trial of at least one OR clinically significant intolerance, or contraindication(s) to the following:
    a. An anti-inflammatory drug (e.g. mesalamine, sulfasalazine)
    b. Corticosteroids
    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 an adequate trial of, clinically significant intolerance, or contraindication to systemic corticosteroids **AND**
    b. Active inflammation despite ≥ 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 an adequate trial of OR clinically significant intolerance to the following:
    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**

INFLECTRA® (infliximab) – NONFORMULARY AGENT

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. Member has NOT had a loss of a favorable response after established maintenance therapy with Remicade or other infliximab biosimilar product **AND**

ii. Member 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 of an adequate trial of, clinically significant intolerance, or contraindication 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&timestamp=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

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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 an adequate trial of, clinically significant intolerance, 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

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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, clinically significant intolerance, 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

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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 an adequate trial of, clinically significant intolerance, 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 an adequate trial of or clinically significant intolerance to methotrexate; **OR**
    a. Contraindication to methotrexate **AND**
    b. Failure of an adequate trial 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 an adequate trial of, clinically significant intolerance, 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

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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 an adequate trial of or clinically significant intolerance to methotrexate; **OR**
    a. Contraindication to methotrexate **AND**
    b. Failure of an adequate trial 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 an adequate trial of, clinically significant intolerance, or contraindication to preferred formulary biologic agents FDA-approved for treatment of rheumatoid arthritis (i.e. Enbrel, Humira).

KRYSTEXXA® (pegloticase) – NONFORMULARY AGENT

Initial criteria (3 month approval):

1. Documentation of FDA-approved indication of chronic symptomatic gout with hyperuricemia **AND**
2. Age >18 years **AND**
3. Using in combination with NSAIDS or colchicine for the first 6 months **AND**
4. Failure of an adequate trial of, clinically significant intolerance, or contraindication to ALL formulary alternatives for gout with hyperuricemia:
    a. Allopurinol **AND**
    b. Probenecid **AND**
    c. Uloric (febuxostat)

AND

5. Use is limited to quantity of 8 mg (1 mL) per 14 days **AND**
6. Member does not have a contraindication to Krystexxa therapy (G6PD deficiency)

Continuation criteria (6 month approval):

1. Request accompanied by documentation of the following:
    a. improvement in frequency and severity of attacks **AND**
    b. urate levels prior to infusion are consistently <6 mg/dL

AND

2. Use is limited to quantity of 8 mg (1 mL) per 14 days

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. Failure of an adequate trial of, clinically significant intolerance or contraindication to at least two of the following:
    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

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MAVYRET™ (glecaprevir/pibrentasvir) - 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 compensated cirrhosis (Child-Pugh A), 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. Either of the following:
    a. Member has genotype 2, 3, 4 5, or 6 HCV and has NOT been previously treated with:
        i. Daclatasvir (Daklinza) **OR**
        ii. Dasabuvir (Viekira) **OR**
        iii. Elbasvir (Zepatier) **OR**
        iv. Grazoprevir (Zepatier) **OR**
        v. Ledipasvir (Harvoni) **OR**
        vi. Ombitasvir (Technivie, Viekira) **OR**
        vii. Paritaprevir (Technivie, Viekira) **OR**
        viii. Simeprevir (Olysio) **OR**

ix. Sofosbuvir (Epclusa, Sovaldi, Harvoni) **OR**
x. Velpatasvir (Epclusa)

OR

b. Member is genotype 1 and has been previously treated with ONE of the following regimens (not more than one):
i. Sofosbuvir (Sovaldi) and simeprevir (Olysio) **OR**
ii. Pegylated interferon and ribavirin PLUS
1. Simeprevir (Olysio) **OR**
2. Boceprevir (Victrelis) **OR**
3. Telaprevir (Incivek)

OR

iii. Ledipasvir/sofosbuvir (Harvoni) **OR**
iv. Daclatasvir (Daklinza) PLUS pegylated interferon and ribavirin

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)

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

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MYALEPT® (metreleptin) – NONFORMULARY EXCEPT ACA COMPLIANT

<u>Initiation criteria (6 month approval)</u>

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 maximum tolerable doses of at least **TWO** conventional therapies for each additional diagnosis listed above **AND**
6. Failure of lifestyle modification (diet and exercise) and will continue lifestyle modification while on Myalept **AND**
7. Member 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-metreleptin antibodies

Continuation criteria (12 month approval)

1. Member has a documented sustained reduction (from baseline) in at least one of the following parameters: HbA1c or triglycerides **AND**
2. Member will continue with lifestyle modification while on Myalept **AND**
3. Member 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, or clinically significant intolerance or contraindication to, ALL 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 <u>primary prophylaxis</u> 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 <u>treatment</u> prescriptions.

<u>Primary Prophylaxis</u>

1. Members with acute leukemia undergoing induction/consolidation chemotherapy

2. Members with allogeneic hematopoietic transplant that are receiving immunosuppressive therapy

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

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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 µg/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. Member 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 ≥ 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 an adequate trial of, clinically significant intolerance or contraindication to the following:
    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® (simeprivir) – 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 ≥ 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 <u>combination therapy</u> with at least **<u>two</u>** other anticonvulsants

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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

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

ORENCIA® (abatacept) – IV Formulation

Rheumatoid arthritis

1. Prescribed by a Rheumatologist **AND**
2. Failure of an adequate trial of or clinically significant intolerance to methotrexate, **OR**
    a. Contraindication to methotrexate **AND**
    b. Failure of an adequate trial 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 an adequate trial, clinically significant intolerance, or contraindication to ALL preferred anti TNF agents (i.e. Enbrel AND Humira)

Polyarticular juvenile idiopathic arthritis:

1. Prescribed by a Rheumatologist **AND**
2. Member is at least 6 years old **AND**
3. Failure of an adequate trial of at least one OR clinically significant intolerance or contraindication to the following:
    a. Methotrexate **OR**
    b. Sulfasalazine **OR**
    c. Leflunomide

AND

4. Failure of an adequate trial, clinically significant intolerance, or contraindication to ALL preferred anti-TNF agents (i.e. Enbrel AND Humira)

Psoriatic arthritis:

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

AND

2. Member has:
    a. Documented spinal involvement (psoriatic spondylitis) **OR**
    b. Failure of an adequate trial of or clinically significant intolerance to methotrexate **OR**
        i. Contraindication to methotrexate **AND**
        ii. Failure of an adequate trial 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 an adequate trial, clinically significant intolerance, or contraindication to ALL preferred anti-TNF agents (i.e. Enbrel AND Humira)

ORENCIA® (abatacept) – SubQ Formulation

Rheumatoid arthritis

1. Prescribed by a Rheumatologist **AND**
2. Failure of an adequate trial of or clinically significant intolerance to methotrexate, **OR**
    a. Contraindication to methotrexate **AND**

b. Failure of an adequate trial 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 an adequate trial, clinically significant intolerance, or contraindication to ALL preferred anti-TNF agents (i.e. Enbrel, Humira).

Polyarticular juvenile idiopathic arthritis:

1. Prescribed by a Rheumatologist AND
2. Member is at least 2 years old AND
3. Failure of an adequate trial of at least one OR clinically significant intolerance or contraindication to the following:
    a. Methotrexate
    b. Sulfasalazine
    c. Leflunomide

AND

4. Failure of an adequate trial, clinically significant intolerance, or contraindication to ALL preferred anti-TNF agents (i.e. Enbrel AND Humira)

Psoriatic arthritis:

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

AND

2. Member has:
    a. Documented spinal involvement (psoriatic spondylitis) **OR**
    b. Failure of an adequate trial of or clinically significant intolerance to methotrexate **OR**
        i. Contraindication to methotrexate **AND**
        ii. Failure of an adequate trial 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 an adequate trial, clinically significant intolerance, or contraindication to ALL preferred anti-TNF agents (i.e. Enbrel AND 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. Failure of an adequate trial of or clinically significant intolerance to methotrexate; **OR**
   iii. Contraindication to methotrexate **AND**
   iv. Failure of an adequate trial 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 an adequate trial of, clinically significant intolerance, 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 an adequate trial 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 an adequate trial of, or contraindication to phototherapy (UVB or PUVA) **AND**
5. Failure of an adequate trial of at least one OR clinically significant intolerance or contraindication to the following:
   a. Methotrexate
   b. Cyclosporine
   c. Acitretin
   d. Leflunomide
   e. Sulfasalazine
   f. Tacrolimus

AND

6. Failure of, clinically significant intolerance, or contraindication 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. Member has not received prior anti-HER2 therapy for metastatic disease **AND**
5. Must be given in combination with trastuzumab (Herceptin) and taxane therapy

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PICATO® (ingenol mebutate)

1. Diagnosis of actinic keratosis **AND**
2. Must be ≥ 18 years old **AND**
3. Failure of an adequate trial of at least one OR clinically significant intolerance or contraindication to the following:
    a. a fluorouracil product
    b. an imiquimod product
    c. a diclofenac gel product

AND

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

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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: Members 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.

Members 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.*
- *Members 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 ≥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/m^2)

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 ≥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 >3x baseline or ULN) **OR**
            iii. Myositis (creatine 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

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 >95th centile	1
First-degree relative with tendon xanthomata and/or children <18 with LDL-C >95th 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, clinically significant intolerance or contraindication to at least **<u>one</u>** 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

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PROMACTA® (eltrombopag)

<u>Chronic immune thrombocytopenia (ITP)</u>
INITIATION CRITERIA (approve for 3 months):
1. FDA approved indication **AND**

2. Failure of an adequate trial of <u>at least one</u> of the following:
    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.

<u>For chronic hepatitis C virus (HCV) associating with thrombocytopenia</u>

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: Member may <u>not</u> 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

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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 an adequate trial of, clinically significant intolerance or contraindication to, or continuation of riluzole

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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 ≥ 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.

RENFLEXIS™ (infliximab-abda) – 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 Renflexis 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 Renflexis or other infliximab biosimilar product

    AND

    b. Both of the following:
        iii. Member has NOT had a loss of a favorable response after established maintenance therapy with Remicade or other infliximab biosimilar product **AND**
        iv. Member 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.

REPATHA® (evolocumab) – NONFORMULARY AGENT

<u>Initiation Criteria (approval duration 4 months)</u>:

1. Prescribed by a:
    a. Cardiologist **OR**
    b. Endocrinologis**t 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/m^2)

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 ≥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 (creatine 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. ≥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 >95th centile	1
First-degree relative with tendon xanthomata and/or children <18 with LDL-C >95th 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, clinically significant 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

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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, clinically significant intolerance, 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 an adequate trial of <u>at least two</u> topical treatments [including but not limited to corticosteroids, vitamin D analogues, vitamin D analogue/corticosteroid combinations or tazarotene (Tazorac®)] **AND**
4. Failure of an adequate trial of, or contraindication to, phototherapy (UVB or PUVA) **AND**
5. Failure of an adequate trial of at least one OR clinically significant intolerance or contraindication to the following:
    a. Methotrexate
    b. Cyclosporine
    c. Acitretin
    d. Leflunomide
    e. Sulfasalazine
    f. Tacrolimus

AND

6. Failure of an adequate trial of, clinically significant intolerance, or contraindication 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)

<u>Rheumatoid arthritis</u>

1. Prescribed by a Rheumatologist **AND**
2. Failure of an adequate trial of or clinically significant intolerance to methotrexate; **OR**
    a. Contraindication to methotrexate **AND**
    b. Failure of an adequate trial of <u>at least one</u> 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 an adequate trial of, clinically significant intolerance, or contraindication to preferred anti-TNF agents (i.e. Enbrel, Humira).

<u>Psoriatic arthritis:</u>

1. Prescribed by a Rheumatologist **OR** Dermatologist **AND**
2. Member has:
    a. Documented spinal involvement (psoriatic spondylitis); **OR**
    b. Failure of an adequate trial of, or clinically significant intolerance to, methotrexate; **OR**
        i. Contraindication to methotrexate **AND**

ii. Failure of an adequate trial 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 an adequate trial of, clinically significant intolerance, 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 an adequate trial of at least one or contraindication(s) to nonsteroidal anti-inflammatory drugs (NSAIDs)

AND (for new starts only)

3. Failure of an adequate trial of, clinically significant intolerance, or contraindication to preferred anti-TNF agents (i.e. Enbrel AND Humira).

Ulcerative Colitis:

1. Prescribed by a Gastroenterologist **AND**
2. Failure of an adequate trial of, clinically significant intolerance, 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 an adequate trial of, clinically significant intolerance, 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 an adequate trial of, clinically significant intolerance, or contraindication to octreotide

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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

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STELARA® (ustekinumab)

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

1. Prescribed by a Gastroenterologist **AND**
2. Failure of an adequate trial of at least one OR clinically significant intolerance or contraindication(s) to 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 an adequate trial of, clinically significant intolerance, 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 an adequate trial of at least <u>two</u> topical treatments [including but not limited to corticosteroids, Vitamin D analogues, Vitamin D analogue/corticosteroid combinations, Tazorac® (tazarotene)] **AND**
4. Failure of an adequate trial of, or contraindication to, phototherapy (UVB or PUVA) **AND**
5. Failure of an adequate trial of at least one OR clinically significant intolerance or contraindication to the following:
    a. Methotrexate
    b. Cyclosporine
    c. Acitretin
    d. Leflunomide
    e. Sulfasalazine
    f. Tacrolimus

AND

6. If prescription is for Stelara 90 mg, documented weight of >100 kg (220 lbs).

AND (for new starts)

7. Failure of an adequate trial of, clinically significant intolerance, or contraindication to the following:
    a. Preferred formulary biologic agents FDA-approved for treatment of psoriasis (i.e. Enbrel AND Humira) **AND**
    b. Cosentyx

<u>Psoriatic arthritis:</u>

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

AND

2. Member has:
    a. Documented spinal involvement (psoriatic spondylitis); **OR**
    b. Failure of an adequate trial of or clinically significant intolerance to methotrexate; **OR**
        i. Contraindication to methotrexate **AND**
        ii. Failure of an adequate trial of <u>at least one</u> 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 an adequate trial of, clinically significant intolerance, 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 of an adequate trial of, or clinically significant 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 ≥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 an adequate trial 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 an adequate trial of, or contraindication to, phototherapy (UVB or PUVA) **AND**
5. Failure of an adequate trial of at least one OR clinically significant intolerance or contraindication to the following:
    a. Methotrexate
    b. Cyclosporine
    c. Acitretin
    d. Leflunomide
    e. Sulfasalazine
    f. tacrolimus

AND

6. Failure of an adequate trial of, clinically significant intolerance, 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)

TREMFYA™ (guselkumab) – 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 an adequate trial 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 an adequate trial of, or contraindication to phototherapy (UVB or PUVA) **AND**
5. Failure of an adequate trial of at least one OR clinically significant intolerance or contraindication to the following:
    a. Methotrexate
    b. Cyclosporine
    c. Acitretin
    d. Leflunomide
    e. Sulfasalazine
    f. Tacrolimus

AND

6. Failure of an adequate trial of, clinically significant intolerance, 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

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 an adequate trial of, clinically significant intolerance, 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 an adequate trial of at least one OR clinically significant intolerance or contraindication to the following:
    a. Humira
    b. Cimzia
    c. 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

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UPTRAVI® (selexipag) – NONFORMULARY AGENT

1. Diagnosis of WHO functional class II or III Pulmonary arterial hypertension (PAH) **AND**
2. Failure of an adequate trial of, clinically significant intolerance, or contraindication to 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

    f. Cryoglobulinemia with end-organ manifestations, defined as one of the following:
        iv. Vasculitis **OR**
        v. Peripheral neuropathy **OR**
        vi. Raynaud's Phenomenon

    OR

    g. One of the following extrahepatic manifestations:
        iii. Membranoproliferative glomerulonephritis **OR**
        iv. Membranous nephropathy

    OR

    h. Prior liver transplant

    OR

    i. 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:
    e. Daclatasvir (Daklinza) **OR**

f. Dasabuvir (Viekira) **OR**
g. Elbasvir (Zepatier) **OR**
h. Grazoprevir (Zepatier) **OR**
i. Ledipasvir (Harvoni) **OR**
j. Ombitasvir (Technivie, Viekira) **OR**
k. Paritaprevir (Technivie, Viekira) **OR**
l. Simeprevir (Olysio) **OR**
m. Sofosbuvir (Epclusa, Sovaldi, Harvoni) **OR**
n. 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)

VOSEVI™ (sofosbuvir/velpatasvir/voxilaprevir) - 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, 2, 3, 4,5 or 6 **AND**
        i. Fibrosis OR compensated cirrhosis (Child Pugh A), 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

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

OR

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

OR

iv. Prior liver transplant

OR

v. Currently on liver transplant list

AND

4. Failure of prior treatment with either:
    a. A regimen containing an NS5A inhibitor:
        i. Daklinza **OR**
        ii. Epclusa **OR**
        iii. Harvoni **OR**
        iv. Technivie **OR**
        v. Viekira Pak **OR**
        vi. Viekira XR **OR**
        vii. Zepatier **OR**

    OR

    b. A regimen containing sofosbuvir WITHOUT an NS5A inhibitor, ONLY if member has genotype 1a or 3:
        i. Sofosbuvir + interferon +/- ribavirin
        ii. Sofosbuvir + ribavirin
        iii. Sofosbuvir + NS 3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir)

AND

5. Member has been screened for hepatitis B infection prior to initiation of treatment, and will be appropriately monitored and/or treated **AND**
6. Abstinence from alcohol and IV drug use for at least 6 months prior to treatment **AND**
7. Member does NOT have:
    a. Decompensated cirrhosis **OR**
    b. Concurrent use of drugs that are:
        i. moderate or strong inducers of CYP2B6, CYP2C8, or CYP3A **OR**
        ii. inducers of P-gp (e.g., rifampin or St. John's wort) **OR**
        iii. OATP inhibitors (e.g. cyclosporine)

    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)

**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)

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 an adequate trial of, clinically significant intolerance, 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 an adequate trial of or clinically significant intolerance to methotrexate; **OR**
    a. Contraindication to methotrexate **AND**
    b. Failure of an adequate trial 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 an adequate trial of, clinically significant intolerance, or contraindication to preferred anti-TNF agents (i.e. Enbrel AND 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 of an adequate trial of, or clinically significant intolerance to, generic tetrabenazine

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XEOMIN® (incobotulinumtoxinA)

1. Member has one of the following diagnoses:
    a. Anal fissures following at least two months of conservative therapy with OR clinically significant intolerance, or contraindication to 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 of 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

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XIFAXAN® (rifaximin)

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

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XOLAIR® (omalizumab)

<u>For IgE-Mediated Allergic Asthma</u>

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. Compliance with allergen and irritant avoidance **AND**
5. Xolair is used as adjunct and not replacing immunotherapy or other forms of treatment **AND**
6. Demonstrable compliance 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 asthma becomes well-controlled **AND**
8. Pulmonary profile demonstrating evidence of reversible airways obstruction within the prior year **AND**
9. Poor control, defined as experiencing **at least <u>one</u>** 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. Continued symptoms despite H1 antihistamine therapy **AND**
4. Diagnosis confirmed by an allergist within the prior year **AND**
5. Compliance with 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

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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

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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 member'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 ≥ 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**
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 ≤ 25% **AND**
4. Platelet count is ≥100,000 cells/mm^3 **AND**
5. Neutrophil count is ≥1,500 cells/mm^3

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. Failure of an adequate trial of at least two OR clinically significant intolerance or contraindication to the following:
    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
