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: 04/01/2018
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Important note
Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage or Summary Plan Description to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans.

ABSORICA® (isotretinoin)

1. Diagnosis of either:
    a. severe recalcitrant nodular acne **OR**
    b. compendia-supported off-label use

AND

2. Age 12 years or older **AND**
3. Trial and failure of conventional therapy (Note: including systemic antibiotics if for severe recalcitrant nodular acne) **AND**
4. Failure of an adequate trial of **at least two**, or contraindication or clinically significant intolerance to generic oral isotretinoin products (e.g. Claravis, Myorisan and/or Zenatane) **AND**
5. If request is for second course of therapy, at least 8 weeks has lapsed since completion of first course

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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. Glucocorticoids **AND**
    b. Methotrexate

ADAGEN® (pegademase bovine)

1. Diagnosis of severe combined immunodeficiency disease (SCID) **AND**
2. Member is ≤18 years of age **AND**
3. Member requires enzyme replacement therapy for adenosine deaminase (ADA) deficiency **AND**
    a. Member has failed bone marrow transplantation **OR**
    b. Member is not a suitable candidate for bone marrow transplantation

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ADEMPAS® (riociguat)

INITIAL APPROVAL CRITERIA (3-month approval):

1. Prescribed by one of the following specialists:
    a. Pulmonologist **OR**
    b. Cardiologist

AND

2. Member is 18 years of age or older **AND**

3. One of the following diagnoses:
    a. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO group 4) meeting either criterion (i) or (ii) below:
        i. Recurrent or persistent CTEPH after pulmonary endarterectomy (PEA) **OR**
        ii. Inoperable CTEPH with diagnosis confirmed by **BOTH** of the following:
            a) Perfusion scanning or pulmonary angiography **AND**
            b) Pretreatment right heart catheterization with all of the following:
                1) Mean pulmonary artery pressure (mPAP) ≥ 25 mmHg **AND**
                2) Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg **AND**
                3) Pulmonary vascular resistance (PVR) > 3 Wood units

    OR

    b. Pulmonary arterial hypertension (PAH) (WHO group 1) confirmed by right heart catheterization

AND

4. Member is NOT taking any of the following concomitantly:
    a. nitrates or nitric oxide donors
    b. specific or nonspecific phosphodiesterase-5 (PDE5) inhibitors
    c. theophylline derivatives

AND

5. Nonsmoker **AND**
6. Enrollment in the Adempas REMS program for all females prior to treatment initiation **AND**
7. For women of child-bearing potential, ALL of the following:
    a. Documentation that pregnancy has been excluded before start of treatment **AND**
    b. Pregnancy tests to exclude pregnancy will be conducted monthly during treatment and for one 1 month after treatment discontinuation **AND**
    c. Use of effective forms of contraception to prevent pregnancy during treatment and for one month after treatment discontinuation

AND

8. Clinically appropriate quantity requested (NOTE: quantity will be limited to a 14-day supply during titration period) **AND**
9. Failure of an adequate trial of, contraindication, intolerance to, or persistence of symptoms with preferred formulary agent(s) including:
    a. A calcium channel blocker (if WHO Group 1 and positive vasoreactivity test) **AND**
    b. A phosphodiesterase type 5 inhibitor (e.g. sildenafil) **AND**
    c. An endothelin receptor antagonist (e.g. Letairis OR Tracleer)

<u>CONTINUATION CRITERIA (12-month approval)</u>

1. Member is tolerating treatment **AND**
2. Evidence of continued disease stabilization or improvement **AND**
3. There continues to be a medical need for the medication **AND**
4. Continued enrollment in the Adempas REMS program for all females **AND**

5. For women of child-bearing potential, ALL of the following:
    a. Documentation of monthly pregnancy tests to exclude pregnancy during treatment and for one 1 month after treatment discontinuation **AND**
    b. Use of effective forms of contraception to prevent pregnancy during treatment and for one month after treatment discontinuation

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ADCIRCA® (tadalafil)

1. Diagnosis of pulmonary arterial hypertension **AND**
2. Failure of an adequate trial, intolerance, or contraindication to generic sildenafil

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AMPYRA® (dalfampridine)

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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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 **at least one** 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 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 combination therapy with **at least two** 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 one** 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 **NOT** have:
    a. Severe active lupus nephritis **OR**
    b. Severe active central nervous system lupus **OR**
    c. Concurrent use of other biologic therapies (e.g., tocilizumab, certolizumab, etanercept, abatacept, infliximab, rituximab, golimumab, ustekinumab) **OR**
    d. Concurrent use of intravenous cyclophosphamide

BERINERT® (C1 Esterase Inhibitor, Human)

Initial criteria (6-month approval):

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

AND

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

Continuation criteria (6-month approval):

1. Member is using for treatment of acute HAE attacks **AND**
2. Berinert is the only agent being used for treatment of acute HAE attacks **AND**
3. 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

4. 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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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).

CARBAGLU® (carglumic acid)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

CAYSTON® (aztreonam oral inhalation)

1. Prescribed by one of the following specialists:
    a. Pulmonologist **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*

CERDELGA (eliglustat)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

CHOLBAM® (cholic acid)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

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 one of the following specialists:

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; 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)

Initiation criteria (3-month approval)

1. Prescribed by one of the following specialists:
    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)

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**
c. preferred formulary alternatives (Haegarda)

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. Cinryze is the only injectable medication being used for prophylaxis of HAE attacks **AND**
9. 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

AND

3. Cinryze is the only injectable medication being used for prophylaxis of HAE attacks

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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 **at least one** preferred formulary biologic agent FDA-approved for treatment of plaque psoriasis (i.e. Enbrel OR Humira).

Psoriatic Arthritis:

1. Prescribed by one of the following specialists:
    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 of, clinically significant intolerance, or contraindication to preferred formulary biologic agents FDA-approved for treatment of psoriatic arthritis (i.e. Enbrel, Humira).

CORLANOR® (ivabradine)

1. Member has ALL 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

CRESEMBA® (isavuconazonium sulfate)

Initial criteria (12-week approval)

1. Prescribed by an Infectious Disease specialist **AND**
2. Member is at least 18 years old **AND**
3. One of the following:
    a. Diagnosis of invasive aspergillosis **AND**
        i. Failure of an adequate trial of, clinically significant intolerance, or contraindication to voriconazole

    OR

    b. Diagnosis of mucormycosis **AND**
        i. Failure of an adequate trial of, clinically significant intolerance, or contraindication to amphotericin B

AND

4. Fungal culture and other relevant laboratory studies (including histopathology) have been obtained to isolate and identify causative organisms **AND**
5. Member does NOT have any of the following:
    a. Familial short QT syndrome **OR**
    b. Concurrent use of drugs that are strong inducers of CYP3A4 (e.g. phenytoin, carbamazepine, rifampin, St. John's wort) **OR**
    c. Concurrent use of drugs that are strong inhibitors of CYP3A4 (e.g. ketoconazole, high-dose ritonavir)

Continuation criteria

1. Documentation of the following:
    a. Diagnosis of invasive aspergillosis OR mucormycosis **AND**
    b. Culture and sensitivity showing susceptibility to Cresemba **AND**
    c. Need for continuation of therapy:
        i. Radiographic abnormalities have not stabilized **OR**
        ii. Signs of active infection are still present **OR**
        iii. Persistent immune defects present

CUVITRU® (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

DAKLINZA® (daclatasvir)

1. Prescribed by one of the following specialists:
    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:
            a) Metavir score F2 or higher on liver biopsy **OR**
            b) **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. Genotype 3 **AND**
        i. Fibrosis, but not cirrhosis, confirmed by either:
            a) Metavir score F2 or F3 on liver biopsy **OR**
            b) **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

    OR

    c. Genotype 1 OR 3 **AND**
        i. Cryoglobulinemia with end-organ manifestations, defined as one of the following:
            a) Vasculitis **OR**
            b) Peripheral neuropathy **OR**
            c) Raynaud's Phenomenon

        OR

        ii. One of the following extrahepatic manifestations:
            a) Membranoproliferative glomerulonephritis **OR**
            b) 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. Glecaprevir (Mavyret) **OR**
    d. Grazoprevir (Zepatier) **OR**
    e. Ledipasvir (Harvoni) **OR**
    f. Ombitasvir (Technivie, Viekira) **OR**
    g. Paritaprevir (Technivie, Viekira) **OR**
    h. Pibrentasvir (Mavyret) **OR**
    i. Simeprevir (Olysio) **OR**
    j. Sofosbuvir (Epclusa, Harvoni, Sovaldi, Vosevi) **OR**
    k. Velpatasvir (Epclusa, Vosevi) **OR**
    l. Voxilaprevir (Vosevi)

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** **AND**
10. Clinical inappropriateness or inability to tolerate preferred agent(s) (i.e. Mavyret)

**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.*

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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DICLOFENAC 3% GEL

1. Prescribed by a Dermatologist **AND**
2. FDA approved indication **AND**
3. Member is at least 18 years old

DUPIXENT® (dupilumab)

Initial criteria (16-week approval)

1. Prescribed by one of the following specialists:
    a. Dermatologist **OR**
    b. Allergist **OR**
    c. Immunologist

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.)

EMFLAZA® (deflazacort)

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 one of the following specialists:
    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*

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 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 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 a Gastroenterologist **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)

1. Prescribed by one of the following specialists:
    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. **<u>At least TWO</u>** 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. 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. 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. Glecaprevir (Mavyret) **OR**
e. Grazoprevir (Zepatier) **OR**
f. Ledipasvir (Harvoni) **OR**
g. Ombitasvir (Technivie, Viekira) **OR**
h. Paritaprevir (Technivie, Viekira) **OR**
i. Pibrentasvir (Mavyret) **OR**
j. Simeprevir (Olysio) **OR**
k. Sofosbuvir (Epclusa, Harvoni, Sovaldi, Vosevi) **OR**
l. Velpatasvir (Epclusa, Vosevi) **OR**
m. Voxilaprevir (Vosevi)

AND

8. Clinical inappropriateness or inability to tolerate preferred agent(s) (i.e. Mavyret)

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

ESBRIET® (pirfenidone)

Initiation Criteria (12-month approval)

1. Prescribed by a pulmonologist **AND**
2. Diagnosis of mild to moderate Idiopathic Pulmonary Fibrosis (IPF) confirmed by:
    a. Exclusion of other known causes of interstitial lung disease (eg. occupational and domestic environmental causes, connective tissue disease, and drug toxicity) **AND**
    b. Member's baseline forced vital capacity (FVC) is ≥ 50% of predicted value **AND**
    c. **At least one** of the following:
        i. High resolution computed tomography (HRCT) confirming usual interstitial pneumonia (UIP) **OR**
        ii. Surgical lung biopsy confirming UIP

AND

3. Member does NOT have any of the following:
    a. Severe hepatic impairment (Child Pugh class C) **OR**
    b. Concurrent use of Ofev **OR**
    c. Current smoked tobacco use

Continuation Criteria (12-month approval)

1. Demonstrated response to therapy, defined as annual decline in FVC of <10% **AND**
2. Documentation confirming the following:
    a. Lack of moderate (Child Pugh B) or severe hepatic impairment (Child Pugh C) **AND**
    b. Abstinence from smoking

EXJADE™ (deferasirox)

1. Prescribed by one of the following specialists:
    a. Hematologist **OR**
    b. Oncologist

AND

2. One of the following:
    a. Being used for initial therapy in members with chronic iron overload due to blood transfusions with:
        i. Documented serum ferritin levels > 1,000 mcg/L **AND**
        ii. Age 2 years or older

    OR

    b. Being used for treatment of chronic iron overload with non-transfusion dependent thalassemia syndromes (NTDT) with:
        i. A liver iron concentration (LIC) of at least 5 mg iron per gram of liver dry weight (mg Fe/G dw) **AND**
        ii. Serum ferritin greater than 300 mcg/L **AND**
        iii. Age 10 years or older

EYLEA® (aflibercept)

1. Prescribed by an Ophthalmologist **AND**
2. Request is for one of the following FDA-approved or medically-accepted indications:
    a. Branch retinal vein occlusion **OR**
    b. Diabetic macular edema **OR**
    c. Macular edema following central retinal vein occlusion (CRVO) **OR**
    d. Neovascular (wet) age-related macular degeneration **OR**
    e. Retinal edema

FABIOR® (tazarotene) foam

1. FDA approved indication:
    a. Acne

FANAPT® (iloperidone)

1. Prescribed in accordance with product labeling not otherwise excluded from benefit, to include:

a. FDA-approved indication **AND**
b. FDA-approved dose

AND (for new starts only)

2. Failure of an adequate trial of, contraindication or intolerance to **at least two** of the following:
    a. Aripiprazole
    b. Clozapine
    c. Olanzapine
    d. Paliperidone
    e. Quetiapine
    f. Risperidone
    g. Ziprasidone

FASENRA (benralizumab)

Initiation Criteria (3-month approval):

1. Prescribed by one of the following specialists:
    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 ≥150 cells/mcL **AND**
5. One of the following:
    a. Two or more asthma exacerbations (defined as need for systemic corticosteroids or temporary increase in usual maintenance dosages of oral 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. ≥ 500 µg/day inhaled fluticasone propionate or equivalent for ≥3 months **AND**
        ii. Long-acting β-agonist for ≥3 months

    OR

    b. Chronic use of the following:
        i. ≥ 500 µg/day inhaled fluticasone propionate or equivalent for ≥6 months **AND**
        ii. Long-acting β-agonist for ≥6 months **AND**
        iii. Daily oral corticosteroid for ≥6 months

AND

6. Dose will not exceed 30 mg once every 4 weeks **AND**
7. Not being used concomitantly with Cinqair® (reslizumab), Nucala® (mepolizumab), 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. Fasenra **AND**
    b. corticosteroid **AND**
    c. Inhaled Long-acting β-agonist

AND

3. Dose will not exceed 30 mg once every 8 weeks **AND**
4. Not being used concomitantly with Cinqair (reslizumab), Nucala (mepolizumab), or Xolair (omalizumab)

FERRIPROX® (deferiprone)

Initiation Criteria (12-month approval):

1. Prescribed by one of the following specialties:
    a. Hematologist **OR**
    b. Oncologist

AND

2. Member is at least 10 years old **AND**
3. Diagnosed with transfusional iron overload due to thalassemia syndromes **AND**
4. Documented ANC >1.5 x 109/L OR > 1500/mm3 **AND**
5. Weekly ANC evaluation
6. Failure of an adequate trial of OR clinically significant intolerance, or contraindication(s) to the following:
    a. Exjade **AND**
    b. deferoxamine

Continuation Criteria (12-month approval):

1. Documentation of the following:
    a. Serum ferritin > 500 mcg/L **AND**
    b. ≥ 20% decline in serum ferritin within one year of starting therapy **AND**
    c. Weekly ANC evaluation

FIRAZYR® (icatibant)

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

Continuation criteria (6-month approval):

1. Member is using for treatment of acute HAE attacks **AND**
2. Firazyr is the only agent being used for treatment of acute HAE attacks **AND**
3. 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

4. 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

GATTEX® (teduglutide)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

GLUMETZA® (metformin HCL extended release)

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

<u>These criteria apply to the following products:</u>
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

<u>CRITERIA FOR ADULT INDICATIONS:</u>

<u>Adults with growth hormone deficiency (GHD):</u>
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**
    a) low IGF-1 level (e.g. <2.5 percentile or < -2 standard deviations) **AND**
    b) 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

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

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)

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

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 **<u>and</u>** will continue antiretroviral therapy throughout treatment

<u>COVERAGE AUTHORIZATION CRITERIA FOR PEDIATRIC INDICATIONS:</u>

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

<u>For Growth Hormone Deficiency (GHD) Congenital or Acquired:</u>

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**ntil 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)]

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. Haegarda is the only injectable medication being used for prophylaxis of HAE attacks **AND**
9. 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

AND

3. Haegarda is the only injectable medication being used for prophylaxis of HAE attacks

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HARVONI™ (sofosbuvir/ledipasvir)

1. Prescribed by one of the following specialists:
    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:
            a) Metavir score F2 or higher on liver biopsy **OR**
            b) **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. Genotype 4, 5 or 6 chronic HCV **AND**
        i. Fibrosis OR compensated cirrhosis, confirmed by either:
            a) Metavir score F2 or higher on liver biopsy **OR**
            b) **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

c. Genotype 1, 4, 5 or 6 chronic HCV **AND**
    i. Cryoglobulinemia with end-organ manifestations, defined as one of the following:
        a) Vasculitis **OR**
        b) Peripheral neuropathy **OR**
        c) 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. Glecaprevir (Mavyret) **OR**
    e. Grazoprevir (Zepatier) **OR**
    f. Ledipasvir (Harvoni) **OR**
    g. Ombitasvir (Technivie, Viekira) **OR**
    h. Paritaprevir (Technivie, Viekira) **OR**
    i. Pibrentasvir (Mavyret) **OR**
    j. Simeprevir (Olysio) **OR**
    k. Sofosbuvir (Epclusa, Harvoni, Sovaldi, Vosevi) **OR**
    l. Velpatasvir (Epclusa, Vosevi) **OR**
    m. Voxilaprevir (Vosevi)

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

AND

9. Clinical inappropriateness or inability to tolerate preferred agent(s) (i.e. Mavyret)

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

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)

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 one of the following specialists:
    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*

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 one of the following specialists:
    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**

IMPAVIDO® (miltefosine)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

INGREZZA™ (valbenazine)

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 the following:
    a. generic tetrabenazine **AND**
    b. clonazepam

JUBLIA® (efinaconazole)

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.

JUXTAPID® (lomitapide)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

KALBITOR® (ecallantide)

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

9. Failure of, clinically significant intolerance, or contraindication to formulary alternatives (e.g. Berinert, Firazyr)

Continuation criteria (6-month approval):

1. Member is using for treatment of an acute HAE attack **AND**
2. Kalbitor is the only agent being used for treatment of acute attacks **AND**
3. 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

4. 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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KALYDECO® (ivacaftor)

INITIAL APPROVAL CRITERIA (4-month duration):

1. Member is 2 years of age or older **AND**
2. Diagnosis of cystic fibrosis **AND**
3. Confirmed mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or *in vitro* assay data **AND**
4. Baseline AST/ALT < 5 x ULN **AND**
5. If less than 18 years of age, baseline ophthalmic exam to check for lens opacities and cataracts **AND**
6. Member is not/will not be taking the following drugs concomitantly:
    a. Symdeko **OR**
    b. Orkambi **OR**
    c. Strong CYP3A inducers (e.g. barbiturates, carbamazepine, efavirenz, glucocorticoids, modafinil, nevirapine, oxcarbazepine, phenobarbital, phenytoin, pioglitazone, rifabutin, rifampin, St. John's Wort)

CONTINUATION CRITERIA (12-month duration):

1. Since starting Kalydeco:
    a. Stable or improved FEV1 **OR**
    b. Documented clinical improvement

AND

2. AST/ALT < 5 x ULN, assessed every 3 months during the first year of treatment and then annually thereafter **AND**
3. If less than 18 years of age, baseline and follow-up ophthalmic exams to check for lens opacities and cataracts **AND**
4. Member is not/will not be taking the following drugs concomitantly:
    a. Symdeko **OR**
    b. Orkambi **OR**
    c. Strong CYP3A inducers (e.g. barbiturates, carbamazepine, efavirenz, glucocorticoids, modafinil, nevirapine, oxcarbazepine, phenobarbital, phenytoin, pioglitazone, rifabutin, rifampin, St. John's Wort)

KERYDIN® (tavaborole)

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)

<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 ALL the following:
    a. Enbrel (preferred) **AND**
    b. Humira (preferred) **AND**

c. Actemra **AND**
d. Cimzia **AND**
e. Orencia **AND**
f. Remicade **AND**
g. Simponi

KUVAN® (sapropterin)

INITIAL APPROVAL CRITERIA (8-week approval):
1. Prescribed by a physician knowledgeable in the management of phenylketonuria (PKU) **AND**
2. Prescribed in accordance with product labeling, to include:
    a. FDA-approved indication **AND**
    b. FDA-approved dose

AND
3. Patient does NOT have two null mutations in *trans* **AND**
4. Used in conjunction with phenylalanine (PHE)-restricted diet

CONTINUATION CRITERIA:
1. Dosing within FDA approved labeling **AND**
2. Used in conjunction with PHE-restricted diet **AND**
3. One of the following:
    a. Reduction in blood PHE, defined as 30% or more from baseline **OR**
    b. Increase in dietary PHE tolerance **OR**
    c. Documented improvement in clinical symptoms

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)

Initial criteria (3-month approval):

1. Documentation of FDA-approved indication of chronic refractory gout with hyperuricemia, defined as:
    a. Chronic gouty arthritis with the following:
        i. Two or more gout attacks in the past 12 months **AND**
        ii. Serum uric acid concentrations ≥ 6 mg/dL despite maximized prior therapy

    OR

    b. Tophaceous gout, defined as:
        i. One of the following:
            a) present on the hands **OR**
            b) evidence of bone damage on X-Ray **OR**
            c) significantly impacting quality of life

            AND
        ii. Serum uric acid concentration above 5 mg/dL despite maximized prior therapy

AND

2. Age >18 years **AND**
3. Using in combination with NSAIDS or colchicine for the first 6 months
4. Failure of an adequate trial of, clinically significant intolerance or contraindication to ALL formulary alternatives for gout with hyperuricemia:
    a. Allopurinol 800 mg **AND**
    b. Uloric (febuxostat) 120 mg

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. Serum uric acid concentrations prior to infusion are consistently less than 6 mg/dL

AND

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

LATUDA® (lurasidone)

1. Prescribed in accordance with product labeling not otherwise excluded from benefit, to include:

a. FDA-approved indication **AND**
b. FDA-approved dose

AND (for new starts only)

2. Failure of an adequate trial of, contraindication or intolerance to **at least two** of the following:
    a. Aripiprazole
    b. Clozapine
    c. Olanzapine
    d. Paliperidone
    e. Quetiapine
    f. Risperidone
    g. Ziprasidone

LEMTRADA® (alemtuzumab)

INITIAL DOSE APPROVAL CRITERIA (4-week approval):

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 (4-week approval):

1. Prescribed by a Neurologist **AND**
2. Member is ≥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)

1. Prescribed by one of the following specialists:
    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. <u>At least TWO</u> 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. 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 1, 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. Glecaprevir (Mavyret) **OR**
    v. Grazoprevir (Zepatier) **OR**
    vi. Ledipasvir (Harvoni) **OR**
    vii. Ombitasvir (Technivie, Viekira) **OR**
    viii. Paritaprevir (Technivie, Viekira) **OR**
    ix. Pibrentasvir (Mavyret) **OR**
    x. Simeprevir (Olysio) **OR**
    xi. Sofosbuvir (Epclusa, Harvoni, Sovaldi, Vosevi) **OR**
    xii. Velpatasvir (Epclusa, Vosevi) **OR**
    xiii. Voxilaprevir (Vosevi)

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. Epclusa **OR**
    iii. Pegylated interferon, with or without ribavirin, and one of the following:
        a) Simeprevir (Olysio) **OR**
        b) Sofosbuvir (Sovaldi) **OR**
        c) Boceprevir (Victrelis) **OR**
        d) Telaprevir (Incivek)

    OR

    iv. Ledipasvir/sofosbuvir (Harvoni) **OR**
    v. Daclatasvir (Daklinza) AND one of the following:
        a) Pegylated interferon and ribavirin **OR**
        b) Sofosbuvir (Sovaldi) +/- ribavirin

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

MOZOBIL® (plerixafor)

1. Prescribed by one of the following specialists:
    a. Oncologist **OR**
    b. Hematologist

AND

2. Diagnosis of either:
    a. Non-Hodgkin's lymphoma **OR**
    b. Multiple myeloma

AND

3. Member is undergoing stem cell mobilization for subsequent autologous transplantation **AND**
4. Mozobil is being used in combination with one of the following:
    a. Granulocyte colony stimulating factor (G-CSF) (e.g. filgrastim) **OR**
    b. Granulocyte macrophage colony stimulating factor (GM-CSF) (e.g. sargramostim)

AND

5. One of the following:
    a. Failure of prior standard stem cell mobilization procedures utilizing G-CSF or GM-CSF alone or in combination with chemotherapy **OR**
    b. High risk of poor mobilization (e.g. age > 60, radiation of pelvis, marrow involvement of disease, prior cytotoxic chemotherapy such as lenalidomide or fludarabine, low platelet count prior to mobilization) **OR**
    c. Use with "just-in-time" rescue, or salvage therapy in case of suboptimal peripheral CD34+ count

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MYALEPT® (metreleptin)

Initiation criteria (6-month approval)

1. Prescribed by an Endocrinologist **AND**
2. Confirmed diagnosis of leptin deficiency **AND**
3. Confirmed diagnosed of congenital or acquired generalized lipodystrophy **AND**
4. Confirmed diagnosis of one of the following additional diagnosis:
    a. Diabetes mellitus **OR**
    b. Hypertriglyceridemia

AND

5. Failure of 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)*

NEULASTA® (pegfilgrastim)

1. Request is for one of the following FDA-approved or medically-accepted indications:
    a. Chemotherapy-induced neutropenia
    b. Chronic neutropenia
    c. Drug-induced neutropenia
    d. Mobilization of peripheral blood progenitor cells prior to autologous stem cell transplantation
    e. Myelodysplastic syndrome
    f. Myelosuppressive radiation exposure
2. Drug prescribed in accordance with FDA-approved or medically accepted dosing **AND**
3. Clinically appropriate quantity requested **AND**
4. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

NEULASTA® ONPRO® (pegfilgrastim)

1. Request is for one of the following FDA-approved or medically-accepted indications:
    a. Chemotherapy-induced neutropenia **OR**
    b. Chronic neutropenia **OR**
    c. Drug-induced neutropenia **OR**
    d. Mobilization of peripheral blood progenitor cells prior to autologous stem cell transplantation **OR**
    e. Myelodysplastic syndrome **OR**
    f. Myelosuppressive radiation exposure

AND

2. Clinically appropriate quantity requested **AND**

3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

NEUPOGEN® (filgrastim)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

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

NORTHERA® (droxidopa)

Initiation Criteria (3-month approval):

1. Prescribed by one of the following specialists:
    a. Cardiologist **OR**
    b. Neurologist

AND

2. FDA-approved diagnosis of symptomatic neurogenic orthostatic hypotension (NOH) caused by at least ONE of the following:
    a. Primary autonomic failure (i.e. Parkinson's disease, multiple system atrophy, or pure autonomic failure) **OR**
    b. Dopamine beta-hydroxylase deficiency **OR**
    c. Nondiabetic autonomic neuropathy

AND

3. Member is at least 18 years old **AND**
4. Failure of an adequate trial of, clinically significant intolerance or contraindication to ALL the following:
    a. Fludrocortisone **AND**
    b. Midodrine

Continuation Criteria (6-month approval):

1. Documented response to therapy, defined as a clinically significant decrease in at least ONE of the following:
    a. Dizziness **OR**
    b. Lightheadedness **OR**
    c. Fainting

AND

2. Member has not experienced supine hypertension during treatment

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NOXAFIL® (posaconazole)

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

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

Primary Prophylaxis

1. 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)

Initiation Criteria (3-month approval):

1. Prescribed by one of the following specialists:
    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

NYMALIZE® (nimodipine)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

OCALIVA® (obeticholic acid)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**

3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

OCREVUS® (ocrelizumab)

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)*

OFEV® (nintedanib)

Initiation Criteria (12-month approval)

1. Prescribed by a pulmonologist **AND**
2. Diagnosis of mild to moderate Idiopathic Pulmonary Fibrosis (IPF) confirmed by:
    a. Exclusion of other known causes of interstitial lung disease (eg. occupational and domestic environmental causes, connective tissue disease, and drug toxicity) **AND**
    b. Baseline forced vital capacity (FVC) is ≥ 50% of predicted value **AND**
    c. **At least one** of the following:
        i. High resolution computed tomography (HRCT) confirming usual interstitial pneumonia (UIP) **OR**
        ii. Surgical lung biopsy confirming UIP

AND

3. Member does NOT have any of the following:
    a. Moderate or severe hepatic impairment (Child Pugh class B or C) **OR**
    b. Concurrent use of Esbriet **OR**
    c. Current smoked tobacco use

Continuation Criteria (12-month approval)

1. Demonstrated response to therapy, defined as annual decline in FVC of <10% **AND**
2. Documentation confirming the following:
    a. Lack of moderate (Child Pugh B) or severe hepatic impairment (Child Pugh C) **AND**
    b. Abstinence from smoking

OFFICE-ADMINISTERED PRODUCTS

1. All Office administered products, where applicable, will be evaluated using:
    a. current medical policy **AND**
    b. medical edit criteria
2. For products without medical policy or prepayment medical edit criteria, product will be evaluated based on the following:
    a. Use in accordance with FDA-approved labeling **AND**
    b. Failure of appropriate preferred formulary alternatives

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OLYSIO® (simeprivir)

INITIATION CRITERIA:

1. Prescribed by one of the following specialists:
    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. **<u>At least TWO</u>** 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. 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. 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. Glecaprevir (Mavyret) **OR**

e. Grazoprevir (Zepatier) **OR**
f. Ledipasvir (Harvoni) **OR**
g. Ombitasvir (Technivie, Viekira) **OR**
h. Paritaprevir (Technivie, Viekira) **OR**
i. Pibrentasvir (Mavyret) **OR**
j. Simeprevir (Olysio) **OR**
k. Sofosbuvir (Epclusa, Harvoni, Sovaldi, Vosevi) **OR**
l. Velpatasvir (Epclusa) **OR**
m. Voxilaprevir (Vosevi)

AND

8. Clinical inappropriateness or inability to tolerate preferred agent(s) (i.e. Mavyret)

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

ONFI® (clobazam)

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

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ORAL ONCOLOGY AGENTS

1. Prescribed by one of the following specialists:
    a. Hematologist **OR**
    b. Oncologist

AND

2. Indication is supported by the National Comprehensive Cancer Network (NCCN) with a grade 1 recommendation

Note: NCCN Category of Evidence and Consensus 2A, a consensus rating supported by low level evidence, will be considered subject to a detailed review of the medical literature. NCCN Categories of Evidence and Consensus 2B and 3 are unproven and considered not medically necessary.

Applicable to the following drugs:

Afinitor® (everolimus)	**Imatinib**	**Tafinlar®** (dabrafenib)
Alacensa® (alectinib)	**Imbruvica®** (ibrutinib)	**Tagrisso®** (osimertinib)
Alunbrig® (brigatinib)	**Inlyta®** (axitinib)	**Tarceva®** (erlotinib)
Bexarotene	**Iressa®** (gefitinib)	**Targretin®** (bexarotene)
Bosulif® (bosutinib)	**Jakafi®** (ruxolitinib)	**Tasigna®** (osimertinib)
Cabometyx™ (cabozantinib)	**Kisqali®** (ribociclib)	**Temozolomide**
Calquence® (acalabrutinib)	**Lenvima®** (lenvatinib)	**Tretinoin**

Capecitabine	**Lonsurf®** (trifluridine/ tipiracil)	**Tykerb®** (lapatinib)
Caprelsa® (vandetanib)	**Lynparza®** (olaparib)	**Xalkori®** (crizotinib)
Cometriq® (cabozantinib)	**Mekinist®** (trametinib)	**Xeloda®** (capecitabine)
Cotellic® (cobimetinib)	**Nerlynx™** (neratinib)	**Xtandi®** (enzalutamide)
Erivedge® (vismodegib)	**Nexavar®** (sorafenib)	**Vandetanib**
Etoposide	**Nilandron®** (nilutamide)	**Venclexta™** (venetoclax)
Fareston® (toremifene)	**Ninlaro®** (ixazomib)	**Verzenio™** (abemaciclib)
Farydak® (panobinostat)	**Odomzo®** (sonidegib)	**Votrient®** (pazopanib)
Gilotrif® (afatinib)	**Pomalyst®** (pomalidomide)	**Zejula®** (niraparib)
Gleevec® (imatinib)	**Purixan®** (mercaptopurine)	**Zelboraf®** (vemurafenib)
Gleostine	**Revlimid®** (lenalidomide)	**Zolinza®** (vorinostat)
Hexalen® (altretamine)	**Rubraca®** (rucaparib)	**Zydelig®** (idelalisib)
Hycamtin® (topotecan)	**Rydapt®** (midostaurin)	**Zykadia®** (ceritinib)
Ibrance™ (palbociclib)	**Sprycel®** (dasatinib)	**Zytiga®** (abiraterone)
Iclusig® (ponatinib)	**Stivarga®** (regorafenib)	
IDHIFA® (enasidinib)	**Sutent®** (sunitinib)	

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 one of the following specialists:
    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 one of the following specialists:
    a. Dermatologist **OR**

b. Rheumatologist

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 (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)

ORFADIN® (nitisinone)

1. Prescribed by a specialist experienced in the treatment of Hereditary Tyrosinemia type 1 **AND**
2. FDA approved indication **AND**
3. Diagnosis confirmed by laboratory or genetic testing **AND**
4. Used in combination with tyrosine and phenylalanine dietary restrictions **AND**
5. Plasma tyrosine level less than 500 micromol/L **AND**
6. Doses of Orfadin oral suspension above 20 mL will require documentation of either:
    a. clinical inappropriateness **OR**
    b. inability to tolerate Orfadin capsules

ORKAMBI® (lumacaftor/ivacaftor)

<u>Initial Prior Authorization Criteria (4-month duration):</u>

1. Age 6 or older **AND**
2. Diagnosis of cystic fibrosis **AND**
3. Confirmed <u>homozygous</u> F508del mutation on the CFTR gene using an FDA-approved test **AND**
4. One of the following:
    a. Baseline AST/ALT <5 x ULN, **OR**
    b. AST/ALT < 3 x ULN if bilirubin is > 2 x ULN

AND

5. If less than18 years old, 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. Symdeko **OR**
    c. Strong CYP3A inducers (e.g., barbiturates, carbamazepine, efavirenz, glucocorticoids, modafinil, nevirapine, oxcarbazepine, phenobarbital, phenytoin, pioglitazone, rifabutin, rifampin, 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. One of the following, assessed every 3 months for the first year then annually thereafter:
    a. AST/ALT <5 x ULN **OR**
    b. AST/ALT < 3 x ULN if bilirubin is > 2 x ULN

AND

3. If less than 18 years old, follow-up 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:
    a. Kalydeco **OR**
    b. Symdeko **OR**
    c. Strong CYP3A inducers (e.g., barbiturates, carbamazepine, efavirenz, glucocorticoids, modafinil, nevirapine, oxcarbazepine, phenobarbital, phenytoin, pioglitazone, rifabutin, rifampin, St. John's Wort)

OTEZLA® (apremilast)

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

3. Failure of an adequate trial of, clinically significant intolerance, or contraindication to ALL formulary products FDA-approved for treatment of psoriatic arthritis:

a. Enbrel (preferred) **AND**
b. Humira (preferred) **AND**
c. Cimzia **AND**
d. Cosentyx **AND**
e. Orencia **AND**
f. Remicade **AND**
g. Simponi **AND**
h. Stelara

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, 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 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

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)

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 an adequate trial of **at least one** OR clinically significant intolerance or contraindication to the following:
    a. Eliquis **OR**
    b. 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)

Initial Coverage Criteria (initial approval duration 4 months):

1. Prescribed by one of the following specialists:
    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:
    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 (described below)

    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 (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:
    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:
            a) Atorvastatin 80 mg/d in combination with Zetia OR
            b) Rosuvastatin 40 mg/d in combination with Zetia

    OR

    b. 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

c. Intolerance to HMG-CoA reductase inhibitor therapy, defined as:
   i. One of the following:
      a) Intolerable, persistent, bilateral myalgia (muscle symptoms without creatine kinase elevations) **OR**
      b) Myopathy (muscle weakness with creatine kinase elevations >3x baseline or ULN) **OR**
      c) 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 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:
      1) Atorvastatin 10 mg **AND**
      2) Fluvastatin 20 mg **AND**
      3) Lovastatin 20 mg **AND**
      4) Pravastatin 10 mg **AND**
      5) Rosuvastatin 5 mg **AND**
      6) 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

PROCYSBI® (cysteamine bitartrate)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

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. One of the following:
            a) 10-year probability of hip fracture ≥3% **OR**
            b) 10-year probability of any major osteoporosis-related fracture ≥20% based upon the US-adapted WHO algorithm

        AND
        ii. Treatment failure, clinically significant intolerance or contraindication to **<u>at least 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 on</u>**e 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.

RADICAVA™ (edaravone)

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)

RAVICTI® (glycerol phenylbutyrate)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

REMICADE® (infliximab)

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

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

REPATHA® (evolocumab)

Initial Coverage Criteria (initial approval duration 4 months):

1. Prescribed by one of the following specialists:
    a. Cardiologist **OR**
    b. Endocrinologist **OR**
    c. Board Certified Lipidologist

AND

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

    OR

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

        AND

ii. LDL ≥130 mg/dL despite adherence to maximized lipid-lowering therapy

AND

4. Documented adherence to 2013 AHA/ACC Lifestyle Management Guidelines (e.g. heart healthy diet, aerobic exercise three to four times a week, active weight loss if BMI >25 kg/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:
            a) Atorvastatin 80 mg/d in combination with Zetia OR
            b) Rosuvastatin 40 mg/d in combination with Zetia

    OR

    b. 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

    c. Intolerance to HMG-CoA reductase inhibitor therapy, defined as
        i. One of the following:
            a) Intolerable, persistent, bilateral myalgia (muscle symptoms without creatine kinase elevations) **OR**
            b) Myopathy (muscle weakness with creatine kinase elevations >3x baseline or ULN) **OR**
            c) 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 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:
            a) Atorvastatin 10 mg
            b) Fluvastatin 20 mg
            c) Lovastatin 20 mg
            d) Pravastatin 10 mg
            e) Rosuvastatin 5 mg
            f) 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)

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.

RUCONEST® (C1 Esterase Inhibitor, Recombinant)

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

9. Failure of an adequate trial of, contraindication or clinically significant intolerance to formulary alternatives (e.g. Berinert, Firazyr)

Continuation criteria (6-month approval):
1. Member is using for treatment of acute HAE attacks **AND**
2. Ruconest is the only agent being used for acute attacks **AND**
3. 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

4. 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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SABRIL® (vigabatrin)

1. Prescribed by a Neurologist **AND**
2. One of the following:
    a. Diagnosis of an epileptic condition **AND**
        i. Refractory to combination therapy with **at least two** other anticonvulsants

    OR

    b. Diagnosis of infantile spasms **AND**:
        i. Member between ages 1 month to 2 years **AND**
        ii. Potential benefits outweigh potential risk of vision loss

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SAPHRIS® (asenapine)

1. Prescribed in accordance with product labeling not otherwise excluded from benefit, to include:
    a. FDA-approved indication **AND**
    b. FDA-approved dose

AND (for new starts only)

2. Failure of an adequate trial of, contraindication or intolerance to **at least two** of the following:
    a. Aripiprazole
    b. Clozapine
    c. Olanzapine
    d. Paliperidone
    e. Quetiapine
    f. Risperidone
    g. Ziprasidone

SAVAYSA® (edoxaban)

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 an adequate trial of **at least one** OR clinically significant intolerance or contraindication to the following:

a. Eliquis **OR**
b. Xarelto

SENSIPAR® (cinacalcet)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

SIGNIFOR® (pasireotide)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

SILIQ™ (brodalumab)

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 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

SIRTURO® (bedaquiline)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

SIMPONI® (golimumab)

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, Humira).

Psoriatic arthritis:

1. Prescribed by one of the following specialists:
    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 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)

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 one of the following specialists:
    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. **<u>At least TWO</u>** 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. 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. Glecaprevir (Mavyret) **OR**
e. Grazoprevir (Zepatier) **OR**
f. Ledipasvir (Harvoni) **OR**
g. Ombitasvir (Technivie, Viekira) **OR**
h. Paritaprevir (Technivie, Viekira) **OR**
i. Pibrentasvir (Mavyret) **OR**
j. Simeprevir (Olysio) **OR**
k. Sofosbuvir (Epclusa, Harvoni, Sovaldi, Vosevi) **OR**
l. Velpatasvir (Epclusa) **OR**
m. Voxilaprevir (Vosevi)

AND

8. Clinical inappropriateness or inability to tolerate preferred agent(s) (i.e. Mavyret)

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

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. Member is ≥12 years of age
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 <u>at least two</u> topical treatments [including but not limited to corticosteroids, Vitamin D analogues, Vitamin D analogue/corticosteroid combinations, Tazorac® (tazarotene)] **AND**
5. Failure of an adequate trial of, or contraindication to, phototherapy (UVB or PUVA) **AND**
6. Failure of an adequate trial of <u>at least one</u> **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 one of the following specialists:
    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)

STRENSIQ® (asfotase alfa)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

SUBSYS® (fentanyl sublingual spray)

1. Prescribed by one of the following specialists:
    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

SYLATRON™ (peginterferon alfa-2b)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

SYMDEKO™ (tezacaftor/ivacaftor)

INITIAL APPROVAL CRITERIA (4-month duration):

1. Member is 12 years of age or older **AND**
2. Diagnosis of cystic fibrosis **AND**
3. One of the following:
    a. Confirmed homozygous F508del mutation on the cystic fibrosis transmembrane conductance regulator (CFTR) gene using an FDA-approved test **OR**
    b. At least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence

AND

4. One of the following:
    a. Baseline AST/ALT < 5 x ULN **OR**
    b. AST/ALT < 3 x ULN if bilirubin is > 2 x ULN

AND

5. If between 12-18 years of age, baseline ophthalmic exam to check for lens opacities and cataracts **AND**
6. Member is not/will not be taking the following drugs concomitantly:
    a. Kalydeco **OR**
    b. Orkambi **OR**
    c. Strong CYP3A inducers (e.g. barbiturates, carbamazepine, efavirenz, glucocorticoids, modafinil, nevirapine, oxcarbazepine, phenobarbital, phenytoin, pioglitazone, rifabutin, rifampin, St. John's Wort)

CONTINUATION CRITERIA (12-month duration):

1. Since starting Symdeko:
    a. Stable or improved FEV1 **OR**
    b. Documented clinical improvement

AND

2. One of the following, assessed every 3 months during the first year of treatment and then annually thereafter:
    a. AST/ALT < 5 x ULN **OR**
    b. AST/ALT < 3 x ULN if bilirubin is > 2 x ULN

AND

3. If between 12-18 years of age, baseline and follow-up ophthalmic exams to check for lens opacities and cataracts **AND**
7. Member is not/will not be taking the following drugs concomitantly:
    a. Kalydeco **OR**
    b. Orkambi **OR**
    c. Strong CYP3A inducers (e.g. barbiturates, carbamazepine, efavirenz, glucocorticoids, modafinil, nevirapine, oxcarbazepine, phenobarbital, phenytoin, pioglitazone, rifabutin, rifampin, St. John's Wort)

SYNRIBO® (omacetaxine)

1. Prescribed by one of the following specialists:
    a. Hematologist **OR**
    b. Oncologist

AND

2. Indication is supported by the National Comprehensive Cancer Network (NCCN) with a grade 1 recommendation

Note: NCCN Category of Evidence and Consensus 2A, a consensus rating supported by low level evidence, will be considered subject to a detailed review of the medical literature. NCCN Categories of Evidence and Consensus 2B and 3 are unproven and considered not medically necessary.

SYPRINE® (trientine)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

TALTZ™ (ixekinumab)

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)

1. Prescribed by one of the following specialists:
    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*:
            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. 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, Harvoni, Sovaldi, Vosevi) **OR**
    j. Velpatasvir (Epclusa) **OR**
    k. Voxilaprevir (Vosevi)

AND

9. Clinical inappropriateness or inability to tolerate preferred agent(s) (i.e. Mavyret)

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

TETRABENAZINE

1. Prescribed by a Neurologist **AND**
2. One of the following:
    a. FDA approved indication **OR**
    b. Medically accepted indication

AND

3. Member is at least 18 years old **AND**
4. Dosing regimen is medically accepted **AND**
5. If diagnosis is:
    a. Tourette's syndrome OR tic disorder:
        i. Failure of an adequate trial, intolerance or contraindication to ALL of the following:
            a) clonidine **AND**
            b) guanfacine **AND**
            c) haloperidol **AND**
            d) pimozide **AND**
            e) risperidone
    b. Tardive dyskinesia:
        i. Failure of an adequate trial, intolerance or contraindication to clonazepam

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TREMFYA™ (guselkumab)

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.

TYMLOS® (abaloparitide)

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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TYSABRI® (natalizumab)

<u>For Multiple Sclerosis:</u>

1. Prescribed by a Neurologist **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 a Gastroenterologist **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:
    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

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UPTRAVI® (selexipag)

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)

VALCHLOR® (mechlorethamine)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

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

1. Prescribed by one of the following specialists:
    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. **<u>At least TWO</u>** 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. Cryoglobulinemia with end-organ manifestations, defined as one of the following:
        i. Vasculitis **OR**
        ii. Peripheral neuropathy **OR**
        iii. Raynaud's Phenomenon

    OR

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

OR

d. Prior liver transplant **OR**
e. Currently on transplant list

AND

4. Member has been screened for hepatitis B infection prior to initiation of treatment, and will be appropriately monitored and/or treated **AND**
5. Abstinence from alcohol and IV drug use for at least 6 months prior to treatment **AND**
6. Member does NOT have:
    a. Clinically decompensated cirrhosis **OR**
    b. Any other non-liver related comorbidity resulting in less than a 10-year predicted survival **OR**
    c. Ongoing non-adherence to prior medications or medical treatment **OR**
    d. Failure to complete HCV disease evaluation, appointments and procedures (e.g. laboratories)

AND

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

AND

8. Clinical inappropriateness or inability to tolerate preferred agent(s) (i.e. Mavyret)

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

VOSEVI™ (sofosbuvir/velpatasvir/voxilaprevir)

1. Prescribed by one of the following specialists:
    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:
            a) Metavir score F2 or higher on liver biopsy **OR**
            b) **<u>At least TWO</u>** 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

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

        OR

        iii. One of the following extrahepatic manifestations:
            a) Membranoproliferative glomerulonephritis **OR**
            b) 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*

VRAYLAR™ (cariprazine)

1. Prescribed in accordance with product labeling not otherwise excluded from benefit, to include:
    a. FDA-approved indication **AND**
    b. FDA-approved dose

AND (for new starts only)

2. Failure of an adequate trial of, contraindication or intolerance to **at least two** of the following:
    a. Aripiprazole
    b. Clozapine
    c. Olanzapine
    d. Paliperidone
    e. Quetiapine
    f. Risperidone
    g. Ziprasidone

XADAGO™ (safinamide)

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)

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)

1. Prescribed by a Neurologist **AND**
2. One of the following:
    a. FDA approved indication **OR**
    b. Medically accepted indication

AND

3. Member is at least 18 years old **AND**
4. Dosing regimen is medically accepted **AND**
5. If diagnosis is:
    a. Tourette's syndrome **OR** tic disorder:
        i. Failure of an adequate trial of, intolerance or contraindication to ALL the following:
            a) clonidine **AND**
            b) guanfacine **AND**
            c) haloperidol **AND**
            d) pimozide **AND**
            e) risperidone

    OR

    b. Tardive dyskinesia:
        i. Failure of an adequate trial of, intolerance or contraindication to clonazepam

AND

6. Failure of an adequate trial of, or clinically significant intolerance to, generic tetrabenazine

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XERMELO™ (telotristat ethyl)

1. Drug prescribed in accordance with FDA-approved or medically accepted indication and dosing **AND**
2. Clinically appropriate quantity requested **AND**
3. Failure of an adequate trial of, contraindication or intolerance to preferred formulary agent(s)

XGEVA® (denosumab)

1. Prescribed by one of the following specialists:
    a. Hematologist **OR**
    b. Oncologist

AND

2. FDA-approved indication

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)

For IgE-Mediated Allergic Asthma

1. Age ≥6 years **AND**

2. Diagnosis of IgE-mediated allergic asthma **AND**
3. Diagnosis confirmed by an allergist within the prior year **AND**
4. 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 **<u>at least 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

<u>For Chronic Idiopathic Urticaria (CIU)</u>

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

XYREM® (sodium oxybate)

1. Prescribed by a Board Certified Sleep Medicine Specialist **AND**
2. Diagnosis of either:
    a. Moderate to severe cataplexy associated with narcolepsy **AND**
        i. Failure of an adequate trial, intolerance, or contraindication to the following:
            a) **<u>At least one</u>** selective serotonin reuptake inhibitor (SSRI) **OR** serotonin/norepinephrine reuptake inhibitor (SNRI) **AND**
            b) **<u>At least one</u>** tricyclic antidepressant

    OR

    b. Narcolepsy without cataplexy **AND**
        i. Failure of an adequate trial, intolerance, or contraindication to ALL of the following:
            a) Amphetamine/dextroamphetamine **AND**

b) Armodafinil **AND**
c) Dextroamphetamine **AND**
d) Methylphenidate **AND**
e) Modafinil

ZAVESCA® (miglustat)

1. Prescribed by a specialist experienced in the treatment of Gaucher disease **AND**
2. Diagnosis of mild to moderate Type 1 Gaucher disease **AND**
3. Diagnosis confirmed by one of the following:
    a. enzyme assay **OR**
    b. DNA testing

AND

4. No concomitant use of other enzyme replacement or substrate reduction therapies for Gaucher's disease **AND**
5. Documentation confirming an adequate trial of, intolerance or contraindication to formulary enzyme replacement therapies (e.g. Cerezyme)

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)

K-DOQI link: http://www.kidney.org/professionals/kdoqi/guidelines_bone/guide8a.htm

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ZEPATIER® (elbasvir/grazoprevir)

1. Prescribed by one of the following specialists:
    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. **<u>At least TWO</u>** 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. 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. Glecaprevir (Mavyret) **OR**
    e. Grazoprevir (Zepatier) **OR**
    f. Ledipasvir (Harvoni) **OR**
    g. Ombitasvir (Technivie, Viekira) **OR**
    h. Paritaprevir (Technivie, Viekira) **OR**
    i. Pibrentasvir (Mavyret) **OR**
    j. Simeprevir (Olysio) **OR**
    k. Sofosbuvir (Epclusa, Harvoni, Sovaldi, Vosevi) **OR**
    l. Velpatasvir (Epclusa, Vosevi) **OR**
    m. Voxilaprevir (Vosevi)

AND

9. Clinical inappropriateness or inability to tolerate preferred agent(s) (i.e. Mavyret)

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

ZINBRYTA™ (daclizumab)

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
