Prominence® Health Plan

2020 Commercial Prescription Benefit Coverage
Prior Authorization Criteria of Select Specialty Drugs

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Prominence Health Plan

IMMUNOMODULATORY AGENTS FOR AUTOIMMUNE DISORDER TREATMENT

ACTEMRA - SQ (TOCILIZUMAB - SQ)
The guideline named TOCILIZUMAB - SQ (Actemra - SQ) requires a diagnosis of moderate to severe rheumatoid arthritis (RA), giant cell arteritis (GCA), polyarticular juvenile idiopathic arthritis (PJIA), or systemic juvenile idiopathic arthritis (SJIA) for approval. In addition, the following criteria must also be met: For patients with moderate to severe rheumatoid arthritis, approval requires: • Therapy is prescribed by or given in consultation with a rheumatologist • The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine • The patient is 18 years of age or older • The patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Actemra (tocilizumab) or another TNF (tumor necrosis factor) inhibitor: Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria • The patient has had a previous trial and failure of two of the formulary preferred immunomodulators: Enbrel, Humira, Rinvoq, and Xeljianz. For patients with giant cell arteritis, approval requires: • The patient is 18 years of age or older For patients with polyarticular juvenile idiopathic arthritis, approval requires: • Therapy is prescribed by or given in consultation with a rheumatologist • The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine • The patient is 2 years of age or older • The patient has had a previous trial of the formulary preferred immunomodulators: Enbrel For patients with systemic juvenile idiopathic arthritis, approval requires: • Therapy is prescribed by or given in consultation with a rheumatologist • The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine • The patient is 2 years of age or older

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

CIMZIA (CERTOLIZUMAB PEGOL)
Our guideline for **CERTOLIZUMAB PEGOL (Cimzia)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, moderate to severe Crohn's disease, or moderate to severe plaque psoriasis (PsO). The following criteria must also be met. For patients with moderate to severe rheumatoid arthritis (RA), all of the following criteria are required: • Therapy initiated by or in consultation with a rheumatologist • Previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine • 18 years of age or older • Patient will not be on concurrent therapy with another TNF (tumor necrosis factor) inhibitor (Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria) or any other biologic DMARD (disease-modifying antirheumatic drug) agent (Actemra, Kineret, Stelara, Cosentyx, Entyvio, Tysabri, Orencia, or Rituxan) • Previous trial and failure with two of the preferred formulary immunomodulators: Enbrel, Humira, Rinvoq, and Xeljianz. For patients with psoriatic arthritis (PsA), all of the following criteria are required: • Therapy initiated by or in consultation with a rheumatologist or dermatologist • Previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine • 18 years of age or older • Patient will not be on concurrent therapy with another TNF (tumor necrosis factor) inhibitor (Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria) or any other biologic DMARD (disease-modifying antirheumatic drug) agent (Actemra, Kineret, Stelara, Cosentyx, Entyvio, Tysabri, Orencia, or Rituxan) • Previous trial and failure with any two of the following preferred immunomodulators: Enbrel, Humira, Cosentyx, or Otezla For patients with ankylosing spondylitis (AS), all of the following criteria are required: • Therapy initiated by or in consultation with a rheumatologist • 18 years of age or older

- Patient will not be on concurrent therapy with another TNF (tumor necrosis factor) inhibitor (Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria) or any other biologic DMARD (disease-modifying antirheumatic drug) agent (Actemra, Kineret, Stelara, Cosentyx, Entyvio, Tysabri, Orencia, or Rituxan)
- Previous trial and failure with any two of the following preferred immunomodulators: Enbrel, Humira, or Cosentyx

For patients with moderate to severe Crohn's disease (CD), all of the following criteria are required:

- Therapy initiated by or in consultation with a gastroenterologist
- Previous trial or contraindication to one or more of the following conventional agents: corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- 18 years of age or older
- Patient will not be on concurrent therapy with another TNF (tumor necrosis factor) inhibitor (Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria) or any other biologic DMARD (disease-modifying antirheumatic drug) agent (Actemra, Kineret, Stelara, Cosentyx, Entyvio, Tysabri, Orencia, or Rituxan)
- Previous trial and failure with the preferred immunomodulators: Humira and Stelara SC

For patients with moderate to severe plaque psoriasis (PsO), approval requires:

- The patient is 18 years of age or older
- Documentation of the patients current weight
- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
- The patient has had a previous trial of at least one or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient has had a previous trial and failure of any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Otezla, Stelara, Tremfya or Skyrizi (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

KINERET (ANAKINRA)
Our guideline for **ANAKINRA** requires a diagnosis of moderate to severe rheumatoid arthritis or a diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS). The following criteria must also be met. For patients with moderate to severe active rheumatoid arthritis, approval requires all of the following: • Therapy initiated by or in consultation with a rheumatologist • Previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine • 18 years of age or older • Patient will not be on concurrent therapy with a TNF (tumor necrosis factor) inhibitor: Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi AriaPrevious trial and failure with two of the preferred formulary immunomodulators: Enbrel, Humira, Rinvoq, and Xeljianz. For patients with Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS), approval requires the following: • Patient will not be on concurrent therapy with a TNF (tumor necrosis factor) inhibitor: Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria

ORENCIA SQ and ORENCIA CLICKJECT SQ- (ABATACEPT SQ)
Our guideline for **ABATACEPT (SQ)** requires a diagnosis of moderate to severe rheumatoid arthritis, moderate to severe juvenile idiopathic arthritis (JIA) or psoriatic arthritis (PsA). The following criteria must also be met. For patients with moderate to severe rheumatoid arthritis, our guideline requires: • Therapy initiated by or in consultation with a rheumatologist • Previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine • 18 years of age or older • Patient will not be on concurrent therapy with Kineret (anakinra), or a TNF (tumor necrosis factor) inhibitor: Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria • Previous trial and failure with two of the preferred formulary immunomodulators: Enbrel, Humira, Rinvoq, and Xeljanz For patients with moderate to severe juvenile idiopathic arthritis, approval requires all of the following:

- Therapy prescribed by or given in consultation with a rheumatologist
- Previous trial with at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- Patient is 2 years of age or older
- Previous trial and failure of two preferred formulary TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

For patients with psoriatic arthritis (PsA), approval requires all of the following:

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- Previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older
- Previous trial and failure of any two of the following preferred immunomodulators: Enbrel, Humira, Cosentyx,Otezla, Stelara SQ, or Xeljanz

SIMPONI SQ (GOLIMUMAB SQ)

The guideline for **GOLIMUMAB - SQ (Simponi)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe ankylosing spondylitis, or moderate to severe ulcerative colitis. The following criteria must also be met.

For patients with moderate to severe rheumatoid arthritis (RA), approval requires all of the following:

- Therapy initiated by or in consultation with a rheumatologist
- Previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- Concurrent use of methotrexate (unless contraindicated)
- 18 years of age or older
- Patient will not be on concurrent therapy with Kineret (anakinra) or Orencia (abatacept)Previous trial and failure with two of the preferred formulary immunomodulators: Enbrel, Humira, Rinvoq, and Xeljanz.

For patients with psoriatic arthritis (PsA), approval requires all of the following:

- Therapy initiated by or in consultation with a rheumatologist or dermatologist
- Previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

- Concurrent use of methotrexate (unless contraindicated)
- 18 years of age or older
- Patient will not be on concurrent therapy with Kineret (anakinra) or Orencia (abatacept)
- Previous trial and failure with any two of the following preferred formulary immunomodulators: Enbrel, Humira, Cosentyx,Otezla, Stelara SQ, or Xeljanz

For patients with ankylosing spondylitis (AS), approval requires all of the following:

- Therapy initiated by or in consultation with a rheumatologist
- 18 years of age or older
- Patient will not be on concurrent therapy with Kineret (anakinra) or Orencia (abatacept)
- Previous trial and failure with any two of the following preferred formulary immunomodulators: Enbrel, Humira, or Cosentyx

For patients with moderate to severe ulcerative colitis (UC), approval requires all of the following:

- Therapy initiated by or in consultation with a gastroenterologist
- Previous trial with at least one or more of the following conventional agents: corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- 18 years of age or older
- Patient will not be on concurrent therapy with Kineret (anakinra) or Orencia (abatacept)
- Previous trial and failure with both of the preferred immunomodulators: Humira and Xeljanz

SKYRIZI (RISANKIZUMAB)

The guideline named **RISANKIZUMAB (Skyrizi)** requires a diagnosis of moderate to severe plaque psoriasis (PsO). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
- The patient had a previous trial of or contraindication to one or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

STELARA (USTEKINUMAB)
The guideline named **USTEKINUMAB (Stelara)** requires a diagnosis of moderate to severe plaque psoriasis, psoriatic arthritis, or moderately to severely active Crohns disease. The following criteria must also be met. For patients with moderate to severe plaque psoriasis (PsO), approval requires all of the following criteria: • Therapy is initiated by or given in consultation with a dermatologist • Plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, or genital area • Previous trial with at least one or more forms of preferred conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine • The patient is 12 years of age or older • Documentation of the patients current weight For patients with psoriatic arthritis (PsA), approval requires all of the following criteria: • Therapy is initiated by or given in consultation with a rheumatologist or dermatologist • Previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine • The patient is 12 years of age or older For patients with moderately to severely active Crohns disease (CD), approval requires all of the following criteria: • Therapy is initiated by or given in consultation with a gastroenterologist • Previous trial with at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine • The patient is 18 years of age or older • Documentation of the patients current weight

TALTZ (IXEKIZUMAB)
The guideline named **IXEKIZUMAB (Taltz)** requires a diagnosis of moderate to severe plaque psoriasis (PsO). Additional guideline requirements apply. • Therapy prescribed by or in consultation with a dermatologist • Patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, or genital area • Previous trial of at least one or more forms of preferred therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

- The patient is 18 years of age or olderPrevious trial and failure of two of the following preferred formulary agents: Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast),Stelara SQ (ustekinumab), Tremfya (Guselkumab) or Skyrizi (risankizumab)

XELJANZ, XELJANZ XR (TOFACITINIB CITRATE)

The guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis or moderate to severe ulcerative colitis (UC). In addition, the following criteria must also be met.

For patients with moderate to severe rheumatoid arthritis (RA), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

For patients with psoriatic arthritis (PsA), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

For patients with moderate to severe active ulcerative colitis (UC), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient has had a previous trial of at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Prominence Health Plan

ANTIVIRAL AGENTS FOR HEPATITIS C TREATMENT

EPCLUSA (SOFOSBUVIR/VELPATASVIR)
The guideline for **SOFOSBUVIR/VELPATASVIR (Epclusa)** requires a diagnosis of hepatitis C. In addition, the following criteria must also be met. • Patient has genotype 1, 2, 3, 4, 5, or 6 hepatitis C • Patient is at least 18 years old • Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model • Documentation of HCV infection (documented by **TWO** detectable HCV RNA levels separated by 6 months (with one level within the last 6 months) **OR** supported by a past diagnosis of chronic hepatitis C documented with HCV-related chart notes of biopsies, RNA levels, history of diagnosis, other HCV lab work, or HCV prescriptions **AND** the patient has **ONE** detectable HCV RNA level within the last 6 months) • For patients with decompensated cirrhosis, the patient must be using a ribavirin-containing regimen • Treatment naïve patients with genotype 1 infection and without cirrhosis that have a pretreatment HCV RNA level less than 6 million IU/mL must have a trial of Harvoni 8-week regimen or a contraindication to Harvoni Epclusa will not be approved for the following patients: • Patient using any of the following medications concurrently while on Epclusa: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan • Patient with severe renal impairment (estimated glomerular filtration rate (GFR) less than 30mL/min/1.73m^2) or end stage renal disease requiring hemodialysis • Patient with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.

HARVONI (LEDIPASVIR/SOFOSBUVIR)
Our guideline for **LEDIPASVIR/SOFOSBUVIR (Harvoni)** requires a diagnosis of hepatitis C. In addition, the following criteria must also be met: • Has genotype 1, genotype 4, genotype 5, or 6 hepatitis C • Patient is at least 18 years old or request is for a pediatric patient (12-17 years old or weighs at least 77 pounds (35kg))

- Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- Documentation of HCV infection (e.g., at least two detectable HCV RNA levels separated by 6 months OR evidence of chronic HCV (prior to the last 6 months) supported by a past diagnosis of hepatitis C documented with HCV-related chart notes of biopsies, RNA levels, history of diagnosis, other HCV lab work, or HCV prescription and the patient has documentation of one detectable HCV RNA level within the last 6 months
- For treatment-experienced patients with genotype 1 (no cirrhosis or compensated cirrhosis), previous dual therapy with 1) Sovaldi/ribavirin with or without peginterferon, 2) peginterferon and ribavirin or 3) triple therapy with HCV protease inhibitor, peginterferon and ribavirin is required
- For patients with decompensated cirrhosis or those who are post-liver transplant (without cirrhosis or compensated cirrhosis), the patient must be at least 18 years old, have genotype 1 or genotype 4 infection, and will be using a ribavirin-containing regimen

The medication will not be approved for the following patients:

- Patient using any of the following medications concurrently while on Harvoni: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, rosuvastatin, simeprevir, sofosbuvir, Stribild (elvitegravir/cobicistat/emtricitabine/ tenofovir), or tipranavir/ritonavir
- Patient with end stage renal disease
- Patient on dialysis
- Patient with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.
- Patient using any of the following medications concurrently while on Sovaldi: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, or tipranavir/ritonavir, and for requests for Sovaldi when used with another direct acting antiviral (e.g., Olysio or Daklinza), patients must not be on concurrent amiodarone

For requests for interferon-free Sovaldi/Olysio regimen for genotype 1, the following criteria must be met:

- Patient is at least 18 years old
- Patient must have a trial of or contraindication to Vosevi, Harvoni or Epclusa
- Must not have genotype 1a and NS3 Q80K polymorphism

- No previous failure of a prior full course of therapy with any HCV protease inhibitor OR regimen containing NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)

For patients using Sovaldi with Daklinza, the following criteria must be met:

- Patient is at least 18 years old
- Genotype 1 or 3 hepatitis C
- Patient must not have concurrent use with any of the following medications (contraindicated or not recommended by the manufacturer, or agents that require Daklinza 90mg dosage, except for specified HIV medications): amiodarone, carbamazepine, phenytoin, rifampin, rifapentine, bosentan, dexamethasone, modafinil, or nafcillin
- Concurrent ribavirin use required for the following patients:
  - Those with genotype 1 infection 1) with decompensated cirrhosis or 2) post-transplant
  - Those with genotype 3 infection 1) with compensated or decompensated cirrhosis or 2) post-transplant
- For genotype 1, previous trial of Vosevi, Harvoni or Epclusa (e.g., adverse effect early in therapy or contraindication to therapy); an individual who has completed a full course of therapy that did not achieve SVR will not be approved
- For adults with genotype 3, previous trial of Vosevi or Epclusa (e.g., adverse effect early in therapy or contraindication to therapy); an individual who has completed a full course of therapy that did not achieve SVR will not be approved

MAVYRET (GLECAPREVIR/PIBRENTASVIR)

The guideline named **GLECAPREVIR/PIBRENTASVIR (Mavyret)** requires a diagnosis of genotype 1, 2, 3, 4, 5, or 6 hepatitis C. The following criteria must also be met:

- The patient is at least 18 years old
- The medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- Evidence of current HCV infection and chronic HCV infection as documented by:
- at least two detectable HCV RNA levels separated by 6 months, or
- documentation of current, chronic hepatitis C (with at least one detectable HCV RNA level within past 6 months) and a past diagnosis of chronic hepatitis C infection documented by chart notes of biopsy, elevated liver enzymes or evidence of fibrosis or cirrhosis related to HCV, and/or previous HCV prescriptions. Patient is 1) treatment naïve (genotype 1-6), OR 2) treatment experienced with regimens containing

interferon, peginterferon, ribavirin, and/or sofosbuvir (genotype 1-6), OR 3) treatment experienced with NS5A inhibitor or NS3/4A protease inhibitor (genotype 1)

The medication will not be approved for the following:

- Patient is concurrently taking: rifampin, atazanavir, carbamazepine, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin (at doses greater than 10mg), cyclosporine (for patients requiring stable cyclosporine doses greater than 100mg/day) or medications containing ethinyl estradiol
- Patient has moderate or severe liver impairment (Child-Pugh B or C)
- Patients with prior failure of a direct-acting antiviral (DAA) regimen that contains NS5A inhibitor AND NS3/4A protease inhibitor (e.g., Technivie, Viekira, Vosevi, Zepatier) or previous concurrent treatments containing a NS5A inhibitor AND NS3/4A protease inhibitor
- Patient with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

SOVALDI (SOFOSBUVIR)

The guideline for **SOFOSBUVIR (Sovaldi)** requires a diagnosis of chronic hepatitis C. In addition, the following criteria must also be met.

- Patient is at least 18 years old with a diagnosis of chronic hepatitis C genotype 1, 2, 3, or 4 OR patient is under age 18 (ages 12-17 or weighing at least 77lb (35kg)) with a diagnosis of chronic hepatitis C genotype 2 or 3
- Currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- 1) Evidence of current HCV infection and chronic HCV infection as documented by two detectable HCV RNA levels separated by 6 months **OR** 2) documentation of current chronic HCV infection (one detectable HCV RNA level within the last 6 months) **AND** past diagnosis of chronic hepatitis C infection documented by chart notes of a biopsy, elevated liver enzymes, or evidence of liver fibrosis or cirrhosis related to HCV, or previous HCV prescriptions
- Adults: Concurrent use of Olysio (genotype 1 only) or Daklinza (genotype 3 only)
- Concurrent use of ribavirin (genotypes 2 and 3) for pediatric patients (under age 18)
- Requests for pediatric patients must meet the FDA-approved indication (treatment naïve or treatment experienced patient with compensated cirrhosis (Child-Pugh A))
- Patients with genotype 1 or 4 infection: requires a previous trial of Vosevi, Harvoni or Epclusa (short trial, contraindication and/or intolerance) for patients with decompensated cirrhosis

- Adult patients with genotype 2 or 3 infection: requires a previous trial of Vosevi or Epclusa (short trial, contraindication and/or intolerance) for patients with decompensated cirrhosis
- Patients with genotype 1 or 4 infections: requires a previous trial of Mavyret, Vosevi, Harvoni or Epclusa (short trial, contraindication and/or intolerance) for patients without decompensated cirrhosis
- Adult patients with genotype 2 or 3 infection: requires a previous trial of Mavyret, Vosevi or Epclusa (short trial, contraindication and/or intolerance) for patients without decompensated cirrhosis

The medication will not be approved for the following:

- Patient with severe renal impairment (GRF <30), end stage renal disease, and/or those requiring dialysis
- Patient with a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
- Patients with decompensated cirrhosis, unless patient meets criteria for Sovaldi/Daklinza use for genotype 1 or 3
- Patient using any of the following medications concurrently while on Sovaldi: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, or tipranavir/ritonavir, and for requests for Sovaldi when used with another direct acting antiviral (e.g., Olysio or Daklinza), patients must not be on concurrent amiodarone

For requests for interferon-free Sovaldi/Olysio regimen for genotype 1, the following criteria must be met:

- Patient is at least 18 years old
- Patient must have a trial of or contraindication to Vosevi, Harvoni or Epclusa
- Must not have genotype 1a and NS3 Q80K polymorphism
- No previous failure of a prior full course of therapy with any HCV protease inhibitor OR regimen containing NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)

For patients using Sovaldi with Daklinza, the following criteria must be met:

- Patient is at least 18 years old
- Genotype 1 or 3 hepatitis C
- Patient must not have concurrent use with any of the following medications (contraindicated or not recommended by the manufacturer, or agents that require Daklinza 90mg dosage, except for specified HIV medications): amiodarone, carbamazepine, phenytoin, rifampin, rifapentine, bosentan, dexamethasone, modafinil, or nafcillin
- Concurrent ribavirin use required for the following patients:

- Those with genotype 1 infection 1) with decompensated cirrhosis or 2) post-transplant
- Those with genotype 3 infection 1) with compensated or decompensated cirrhosis or 2) post-transplant

- For genotype 1, previous trial of Vosevi, Harvoni or Epclusa (e.g., adverse effect early in therapy or contraindication to therapy); an individual who has completed a full course of therapy that did not achieve SVR will not be approved
- For adults with genotype 3, previous trial of Vosevi or Epclusa (e.g., adverse effect early in therapy or contraindication to therapy); an individual who has completed a full course of therapy that did not achieve SVR will not be approved

VOSEVI (SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR)

The guideline named **SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR** requires a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 infection. The following criteria must also be met:

- Patient is at least 18 years old
- Evidence of current HCV infection and chronic HCV infection as documented by:
  - At least two detectable HCV RNA levels separated by 6 months, or
  - Documentation of current, chronic hepatitis C (with at least one detectable HCV RNA level within past 6 months) and a past diagnosis of chronic hepatitis C infection documented by chart notes of biopsy, elevated liver enzymes or evidence of fibrosis or cirrhosis related to HCV, and/or previous HCV prescriptions.
- Medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- Patient meets one of the following:
  - Genotype 1 infection previous treatment failure with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both
  - Genotype 1-6 infection and previous treatment failure with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir
- Patient has failed a full course of therapy with a DAA regimen that includes NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza/Sovaldi combination) OR patient has genotype 1a or genotype 3 with previously failed a full course of therapy with DAA regimen that includes sofosbuvir without NS5A inhibitor (e.g., Sovaldi/ribavirin, Sovaldi/peginterferon/ribavirin, Olysio/Sovaldi (or other HCV protease inhibitor in combination with Sovaldi))

The medication will not be approved for the following:

- Patient has severe renal impairment (estimated glomerular filtration rate (GFR) less than 30mL/min/1.73m^2) or end stage renal disease requiring dialysis
- Patient is concurrently taking any of the following medications: amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifapentine, HIV regimen containing atazanavir, lopinavir, tipranavir/ritonavir, or efavirenz, rosuvastatin, pitavastatin, pravastatin (at doses above 40mg), cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, or topotecan
- Patients has moderate or severe hepatic impairment (Child-Pugh B or C)
- Patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)

ZEPATIER (ELBASVIR/GRAZOPREVIR)

The guideline for **ELBASVIR/GRAZOPREVIR (Zepatier)** requires a diagnosis of hepatitis C. In addition, the following criteria must also be met:

- Patient has genotype 1 or genotype 4 hepatitis C
- Patient is at least 18 years old
- Patient must have a trial of (or contraindication to) Mavyret, Harvoni, Epclusa, or Vosevi prior to approval
- Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- Documentation of HCV infection (e.g., at least two detectable HCV RNA levels separated by 6 months OR evidence of chronic HCV (prior to the last 6 months) supported by a past diagnosis of hepatitis C documented with HCV-related chart notes of biopsies, RNA levels, history of diagnosis, other HCV lab work, or HCV prescription and the patient has documentation of one detectable HCV RNA level within the last 6 months
- Testing for baseline NS5A polymorphisms is required for patients with genotype 1a infection
- Ribavirin use is required for certain treatment-experienced patients or for treatment naïve patients with genotype 1a infection and baseline NS5A polymorphisms (per product labeling)
- Treatment experienced patients will be approved per product labeling (previous failure of peginterferon/ribavirin for genotype 1a, 1b or 4; previous failure of HCV protease inhibitor triple therapy regimen for genotype 1a or 1b infection)
- Patient must be evaluated for (and absent of) current alcohol and other substance abuse (physician attestation or validated screening instruments such as AUDIT or AUDIT-C) and have a urine toxicology screen at baseline

Zepatier will not be approved for the following patients:

- Patients using any of the following interacting medications concurrently while on elbasvir/grazoprevir: phenytoin, carbamazepine, rifampin, efavirenz (e.g., Atripla, Sustiva), atazanavir (e.g., Evotaz, Reyataz), darunavir (e.g., Prezcobix, Prezista), lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (e.g., Stribild, Genvoya), atorvastatin at doses higher than 20mg daily, or rosuvastatin at doses greater than 10mg daily
- Patient taking Sovaldi (sofosbuvir) with Zepatier
- Patients with moderate or severe hepatic impairment (Child-Pugh B or C)
- Patients with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.

Prominence Health Plan

PCSK9 INHIBITOR AGENTS

PRALUENT (ALIROCUMAB)
Our guideline for **ALIROCUMAB** requires that the patient is at least 18 years of age, has a LDL cholesterol level of greater than 70mg/dL while on maximally tolerated statin therapy, and has a diagnosis of heterozygous familial hypercholesterolemia or history of atherosclerotic cardiovascular disease. Praluent must be prescribed by, or in consultation with a cardiologist, endocrinologist, or lipidologist. Diagnosis must include documentation as follows: For the patients with heterozygous familial hypercholesterolemia, diagnosis must be determined by meeting ONE of the following criteria: • Simon Broome diagnostic criteria for HeFH (definite) [example: genetic testing consistent with HeFH and pretreatment baseline LDL cholesterol is greater than 190 mg/dL] • Dutch Lipid Network criteria for HeFH with a score of at least 6 For patients with atherosclerotic cardiovascular disease, • Diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) (e.g., history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis) For statin tolerant patients, ALL of the following criteria must also be met: • **ONE** of the following criteria: ○ The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks, **OR** ○ The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) • Patient must continue therapy with maximally tolerated statin while using Praluent For statin intolerant patients, ONE of the following criteria must also be met: • The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction) • The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than 10 times the upper limit of normal, liver function test elevation greater than 3-times the upper limit of normal,

rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

REPATHA (EVOLOCUMAB)

The guideline named **EVOLOCUMAB (Repatha)** requires a diagnosis of heterozygous familial hypercholesterolemia (HeFH), clinical atherosclerotic cardiovascular disease (ASCVD), or homozygous familial hypercholesterolemia (HoFH). The agent must also be prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist, **AND** the patient must have a LDL-cholesterol level greater than 70 mg/dL while on maximally tolerated statin treatment. The following criteria must also be met:
 	
For statin-tolerant patients:
• **ONE** of the following criteria:
  ○ The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks, **OR**
  ○ The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
• The patient continue statin treatment as described above in combination with Repatha
 	
For statin-intolerant patients or those with contraindication to statins:
• The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
• The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than 10 times the upper limit of normal, liver function test elevation greater than 3-times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin
 	
For patients with heterozygous familial hypercholesterolemia (HeFH), ALL of the following criteria must also be met:
• The patient is 18 years of age or older, **AND**
• Diagnosis of heterozygous familial hypercholesterolemia (HeFH) as determined by meeting **ONE** of the following criteria:
  ○ Simon Broome diagnostic criteria for HeFH (definite)
  ○ Dutch Lipid Network criteria for HeFH with a score of at least 6

- Patient intends to continue statin once Repatha is started unless the patient has complete intolerance or is absolutely contraindicated to statin
- Patient has tried and failed the preferred PCSK9: Praluent

For patients with clinical atherosclerotic cardiovascular disease (ASCVD), ALL of the following criteria must also be met:

- The patient is 18 years of age or older, **AND**
- Diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) (e.g., history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis)

For patients with homozygous familial hypercholesterolemia (HoFH), ALL of the following criteria must also be met:

- The patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by meeting **ONE** of the following criteria:
  - Simon Broome diagnostic criteria (definite)
  - Dutch Lipid Network criteria with a score of at least 8
  - A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

INTERFERON AGENTS FOR MULTIPLE SCLEROSIS TREATMENT

AVONEX, AVONEX PEN (INTERFERON BETA-1A), AVONEX ADMINISTRATION PACK, REBIF (INTERFERON BETA-1A/ALBUMIN), BETASERON, EXTAVIA (INTERFERON BETA-1B), PLEGRIDY, PLEGRIDY PEN (PEGINTERFERON BETA-1A) AND REBIF
Our guideline for **INTERFERONS FOR MULTIPLE SCLEROSIS** requires a diagnosis of a relapsing form of multiple sclerosis. In addition**,** approval for **EXTAVIA** requires a trial of at least two of the following preferred interferons: Tecfidera, Copaxone, Rebif, Gilenya, or Betaseron, Aubagio where indication is applicable