# Injections: Drugs R Policy

Page updated: March 2024

This section outlines policy related to billing for injection services, listed in alphabetical order by generic drug name or drug type. For general billing policy information regarding injections services, refer to the *Injections: An Overview* section in this manual. Additional policy information for injection services can be found in the following sections of this manual:

- *Immunizations*
- *Injections: Drugs A Policy*
- *Injections: Drugs B Policy*
- *Injections: Drugs C Policy*
- *Injections: Drugs D Policy*
- *Injections: Drugs E Policy*
- *Injections: Drugs F Policy*
- *Injections: Drugs G Policy*
- *Injections: Drugs H Policy*
- *Injections: Drugs I Policy*
- *Injections: Drugs J-L Policy*
- *Injections: Drugs M Policy*
- *Injections: Drugs N-O Policy*
- *Injections: Drugs P-Q Policy*
- *Injections: Drugs S Policy*
- *Injections: Drugs T Policy*
- *Injections: Drugs U-Z Policy*
- *Injections: Hydration*

# Ranibizumab

Policies for intravitreal ranibizumab (HCPCS codes J2778, J2779, Q5124, and Q5128) are located in the *Ophthalmology* section of the provider manual.

# Ravulizumab-cwvz (Ultomiris®)

Ravulizumab-cwvz is a terminal complement inhibitor that specifically binds to the complement protein C5 with high affinity, thereby inhibiting its cleavage to C5a (the proinflammatory anaphylatoxin) and C5b (the initiating subunit of the terminal complement complex [C5b-9]) and preventing the generation of the terminal complement complex C5b9. ULTOMIRIS inhibits terminal complement-mediated intravascular hemolysis in patients with paroxysmal nocturnal hemoglobinuria (PNH) and complement-mediated thrombotic microangiopathy (TMA) in patients with atypical hemolytic uremic syndrome (aHUS).

## Indications

All FDA-approved indications.

## Dosage

FDA-approved dosages.

## TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

## TAR Criteria

Ravulizumab-cwvz is considered medically necessary in appropriate patients when the following criteria are met:

Universal Criteria

1. Must be used for FDA-approved indications and dosages.
2. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies.

3. Patient must be vaccinated against meningococcal infections within three years prior to, or at the time of initiating ravulizumab (at least two weeks prior to treatment, if not previously vaccinated). In emergent situations, antibiotics may be appropriate with vaccination less than two weeks prior to treatment.
4. Prescriber is enrolled in the ULTOMIRIS REMS program.

A. Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Patient has a documented diagnosis of PNH with granulocyte or monocyte clone size of greater than five percent and:

Treatment Naïve Patients

- Active hemolysis as measured by lactic acid dehydrogenase (LDH) level of 1.5 times the upper limit of normal (ULN) at screening and one of the following within three months of screening:
  - Fatigue, hemoglobinuria, abdominal pain, shortness of breath (dyspnea), anemia (hemoglobin less than10 g/dl), history of MAVE (including thrombosis), dysphagia, or erectile dysfunction; or history of pRBC transfusion due to PNH

Eculizumab Conversion Patients

- Hemolysis as measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal (ULN) at screening AND
- Treatment with eculizumab for at least six months

Initial authorization for up to six months

- Continuation of therapy in appropriate patients is considered medically necessary for the treatment of a patient with documented PNH who is currently receiving treatment with ravulizumab-cwvz and one of the following:
  - Hemolysis control measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal (ULN) or
  - Transfusion avoidance defined as elimination of transfusion requirements or reduced need for transfusions or

- Stabilization of hemoglobin levels or
- Improvement in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT Fatigue) scores

Reauthorization for up to 12 months

B. Atypical Hemolytic Uremic Syndrome (aHUS)

- Confirmed diagnosis of atypical hemolytic uremic syndrome as evidenced by all of the following:
  - Diagnosis of thrombocytopenic purpura (TTP) has been excluded (for example, normal ADAMTS13 activity) OR a trial of plasma exchange did not result in clinical improvement
- ‹‹Patient does not have Shiga toxin-producing Escherichia coli (E. coli) infection.››

Initial authorization for up to six months.

Continuation of Therapy:

- Patient continues to meet initial approval criteria.
- Patient has a documentation of clinical response such as improvement in platelet count and LDH, reduced hemolysis, improved kidney function, reduction in thrombocytopenia, etc.

Reauthorization for up to 12 months.

‹‹C. Generalized Myasthenia Gravis (gMG)

- Patient is 18 years of age or older.
- Provider must submit documentations for the following:
  - Patient has a documented diagnosis of gMG confirmed by a positive serologic test for anti-AChR antibodies
  - Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV
  - Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score equal to or greater than six
  - Patient has a contraindication, intolerance, or lack of response to any of symptomatic (Pyridostigmine), glucocorticoids (Prednisone), immunosuppressants (Azathioprine, Mycophenolate mofetil, Cyclosporine, Tacrolimus), immunomodulators (Rituximab) therapies or a documented justification why the use of these therapies is not appropriate››

‹‹Initial authorization for up to six months

- Continuation of therapy is considered medically necessary for the treatment of a patient with gMG who is currently receiving treatment with ravulizumab-cwvz and all of the following:
  - There is no evidence of unacceptable toxicity or disease progression while on the current regimen (documentation is required)
  - The patient demonstrates a positive response to therapy (for example), improvement in Myasthenia Gravis Activities of Daily Living (MG-ADL) total score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score) (documentation is required)

Reauthorization for up to 12 months.

D. Neuromyelitis Optica Spectrum Disorder (NMOSD)

- Patient is 18 years of age or older.
- Prescribed by, or in consultation with, a neurologist.
- Provider must submit documentations for the following:
  - Patient has a documented diagnosis of NMOSD confirmed by a positive serologic test for anti-AQP4 antibodies.
  - Patient has at least one core clinical characteristics:
    - ❖ Optic neuritis
    - ❖ Acute myelitis
    - ❖ Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
    - ❖ Acute brainstem syndrome
    - ❖ Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
    - ❖ Symptomatic cerebral syndrome with NMOSD-typical brain lesions
- Patient has at least one relapse/attack in the last 12 months prior to the Screening Period.
- Expanded Disability Status Scale (EDSS) score equal to or less than seven.
- Patient has a contraindication, intolerance, or lack of response to any of immunotherapies (for example: prednisone, azathioprine, rituximab, or a documented justification why the use of these therapies is not appropriate.››

Initial authorization for up to six months

- Continuation of therapy is considered medically necessary for the treatment of a patient with anti-AQP4 antibody-positive NMOSD who is currently receiving treatment with ravulizumab-cwvz and all of the following:
  - There is no evidence of unacceptable toxicity or disease progression while on the current regimen (documentation is required)
  - The patient demonstrates a positive response to therapy (for example: reduction in number of relapses/attacks) (documentation is required)

Reauthorization for up to 12 months.

**REMS**

- Due to the risk of meningococcal infections, ULTOMIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS).
- Prescribers must enroll in the program. Enrollment and additional information are available by telephone: 1-888-765-4747 or through the ULTOMIRIS website.

## Billing

HCPCS code J1303 (injection, ravulizumab-cwvz, 10 mg)

## Suggested Codes

ICD-10 CM Diagnosis code D59.5, D58.8, D59.3, D59.4, D59.8, G36.0, G70.0, G70.01

# Remdesivir (Veklury®)

Veklury is an inhibitor of the SARS-CoV-2 RNA-dependent RNA polymerase (RdRp), which is essential for viral replication. Veklury is an adenosine nucleotide prodrug that is metabolized to the pharmacologically active nucleoside triphosphate metabolite after being distributed into cells. Remdesivir triphosphate (GS-443902) acts as an adenosine triphosphate analog and competes for incorporation into RNA chains by the SARS-CoV-2 RdRp, resulting in delayed chain termination during viral RNA replication. Remdesivir triphosphate can also inhibit viral RNA synthesis due to incorporation into the viral RNA template.

Veklury should be administered in a hospital or a health care setting with immediate access to medications to treat a severe infusion or hypersensitivity reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), if necessary.

## Indications

Veklury is indicated for the treatment of COVID-19 in adults and pediatric patients (at least 28 days old and weighing at least 3 kg) with positive results of SARS-CoV-2 viral testing, who are:

- Hospitalized, or
- Not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.

## Dosages

For adults and pediatric patients weighing 40 kg or more: 200 mg on day one, followed by once-daily maintenance doses of 100 mg from day two, administered only via intravenous infusion.

For pediatric patients at least 28 days old and weighing 3 kg to 40 kg: 5 mg/kg on day one, followed by once-daily maintenance doses of 2.5 mg/kg from day two, administered only via intravenous infusion.

Treatment duration:

Hospitalized Patients:

- For patients not requiring invasive mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO): 5 days; may be extended up to 5 additional days (10 days total) if clinical improvement is not observed.
- For patients requiring invasive mechanical ventilation and/or ECMO: 10 days.
- Initiate treatment as soon as possible after diagnosis of symptomatic COVID-19 is made.

Non-hospitalized Patients:

- For non-hospitalized patients diagnosed with mild-to-moderate COVID-19 who are at high risk for progression to severe COVID-19, including hospitalization or death: three days.
- Initiate as soon as possible and within seven days of symptom onset.

Testing prior to and during treatment: Perform eGFR, hepatic laboratory, and prothrombin time testing prior to initiating Veklury and during use as clinically appropriate.

Renal impairment: Veklury is not recommended in individuals with eGFR less than 30 mL/min.

Dose preparation and administration: There are two different formulations of Veklury: Veklury for injection (supplied as 100 mg lyophilized powder in vial), the only approved dosage form of Veklury for pediatric patients weighing 3 kg to less than 40 kg; and Veklury injection (supplied as 100 mg/20 mL [5 mg/mL] solution in vial). See Veklury Package Insert for detailed prescribing information.

## TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

## Billing

HCPCS code: J0248 (injection, remdesivir, 1 mg)

## Important Billing Instructions

DHCS will reimburse Veklury for the treatment of COVID-19 when administered in accordance with FDA approval.

Prior authorization is not required. Provider must meet the following patient selection and monitoring criteria in accordance with FDA approval:

- Patient meets FDA requirements for age and weight.
- Patient has a positive result of direct SARS-CoV-2 viral testing.
- Veklury will be administered in settings where severe hypersensitivity reactions, such as anaphylaxis, can be managed and emergency services activated, such as skilled nursing facilities, home healthcare settings and outpatient facilities such as infusion centers.
- The treatment course is being initiated within 7 days of symptom onset.
- Must comply with the following testing before initiating and during treatment with Veklury:
  - Renal function tests:
    - ❖ Determine estimated glomerular filtration rate (eGFR) before starting Veklury and monitor while receiving Veklury as clinically appropriate.
    - ❖ Monitor serum creatinine and CrCl.
    - ❖ Should not be administered if eGFR is less than 30 mL per minute.
  - Monitor for signs and symptoms of infusion reactions.
  - Hepatic function tests:
    - ❖ Monitor ALT, AST, bilirubin, alkaline phosphatase.
    - ❖ Avoid use if ALT is at least 10 times the upper limit of normal (ULN)
    - ❖ Discontinue use if ALT elevation and signs or symptoms of liver inflammation.
  - Hematology:
    - ❖ Determine prothrombin time and monitor serum chemistries before starting Veklury and monitor while receiving Veklury.

## Suggested ICD-10 Diagnosis Codes

U07.1

## Prescribing Restrictions

Frequency of billing equals 200 mg on day one, followed by 100 mg daily for up to 10 days total.

Maximum billing units equals 200 mg/200 units.

## Resources:

- Veklury Package Insert
- Outpatient Product Information Guide
- NIH COVID-19 Treatment Guidelines
- COVID-19 Treatments

## Veklury Ordering and Access Information

- Hospital ordering process: Hospitals can place orders with any of the following distributors by calling directly:
  - AmerisourceBergen Specialty Distribution, 1-800-746-6273
  - Cardinal Specialty, 1-855-855-0708
  - McKesson Plasma, 1-877-625-2566
- Non-hospital ordering process: Non-hospitals can contact AmerisourceBergen Specialty Distribution by calling 1-800-746-6273 or emailing C19therapies@AmerisourceBergen.com for more information.

# ‹‹Remestemcel-L-rknd (RYONCIL)

## Clinical Use Parameters

Use in accordance with FDA-approved labeling, including indication, dosage, frequency, age and any prescribing limitation.

## TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement

## Billing

HCPCS code J3402 (Injection, remestemcel-l-rknd, per therapeutic dose)

Important Billing Instructions

Due to systems limitations, providers must take the following steps when billing J3402 for appropriate reimbursement:

TAR/SAR Submission

1. Submit and receive back an approved *Treatment Authorization Request* (TAR) or approved product specific Service Authorization Request (SAR).
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line on the TAR/SAR request and enter “2” in the Units box.

Claim Submission

4. Bill using J3402 (injection, remestemcel-l-rknd, per therapeutic dose).
5. Completion of claim forms:
   - Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or UB-04 Medi-Cal claim forms with the following conditions:
     - On the 837I or UB-04 claim form, the provider must submit up to two (2) claim lines to represent a total of one (1) service (for example, one therapeutic dose).››

- ‹‹Each claim line represents one unit with a charge amount up to $99,999.99.
- The sum of the two claim lines (two units) shall equal the total amount billed "per therapeutic dose".

- Providers must submit an invoice for reimbursement.
- This process will ensure that the total reimbursement paid for the submitted claim lines is no more than provider submitted invoice paid price.
- Ryoncil must be billed on its own with no other drug or biologics.

6. Providers are advised to take the following steps in order to ensure that Ryoncil claims are identified and processed expeditiously:
   - Paper claims may be identified by notation of "Ryoncil" on the "Remarks" section of the UB-04 claim form (Field #80) and submitted to:

     Attention: Claims Manager
     Medi-Cal Fiscal Intermediary
     P.O. Box 526006
     Sacramento, CA 95852-6006
   - Electronic claims may be identified by notation of "Ryoncil" on the cover sheet, addressed to "Attention: Claims Manager" and submitted with the 837I claim form.››

## Remimazolam (Byfavo®)

Byfavo is a benzodiazepine. Byfavo binds to brain benzodiazepine sites (gamma amino butyric acid type A [GABAA] receptors), while its carboxylic acid metabolite (CNS7054) has a 300 times lower affinity for the receptor. Byfavo, like other benzodiazepines, did not show clear selectivity between subtypes of the GABAA receptor.

### Indications

All FDA-approved indications.

### Dosage

FDA-approved dosages.

## TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

## TAR Criteria

Remimazolam is considered medically necessary when all of the following criteria are met:

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Patient has American Society of Anesthesiologists (ASA) Physical Status Score I-III or III -IV (at the discretion of the physician).
- Drug is being used for the induction and maintenance of procedural sedation.
- Procedure is expected to last 30 minutes or less (for example, colonoscopy, bronchoscopy, etc.).
- Documentation of reason why midazolam or proprofol is not appropriate for patient.
- Patient is not a pregnant or lactating female.
- Patient has no known sensitivity to benzodiazepines, flumazenil, opioids, naloxone, or a medical condition such that the use of these medications is contraindicated.

Authorization is for one procedure.

### Age Limits

Must be 18 years of age or older.

### Billing

HCPCS code J2249 (Injection, remimazolam, 1 mg).

## Reslizumab

Reslizumab is an interleukin-5 antagonist monoclonal antibody (IgG4 kappa) solution for intravenous (IV) administration.

### Indications

Reslizumab is used for the add-on maintenance treatment of severe asthma with an eosinophilic phenotype.

Reslizumab is not indicated for the treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus. Reslizumab is not indicated for use in combination with any of the following: benralizumab, mepolizumab or omalizumab.

### Age

Must be 18 years of age and older.

### Dosage

The recommended dose is 3 mg/kg IV given once every four weeks.

## Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

The TAR must include clinical documentation that demonstrates all of the following:

- The service is medically necessary to treat severe asthma with an eosinophilic type as add-on maintenance therapy:
  - Severe asthma as defined by symptoms that are persistent and uncontrolled despite the use of high dose inhaled corticosteroids combined with a long-acting beta2-agonist, leukotriene receptor agonist, or theophylline for greater than or equal to the previous one year or the use of systemic glucocorticoids for greater than or equal to 50 percent of the previous year‡
  - Persistent uncontrolled asthma as defined by at least one of the following‡:
    - ❖ An ACQ score consistently higher than 1.5 (Asthma Control Questionnaire) or an ACT score lower than 20 (Asthma Control Test)
    - ❖ Two or more exacerbations in the previous year, each requiring 3 or more days of treatment with systemic glucocorticoids
    - ❖ A history of hospitalization, intensive care unit stay, or mechanical ventilation in the previous year
    - ❖ A $FEV_1$ (Forced Expiratory Volume in 1 second) at less than 80 percent of predicted after bronchodilator administration measured by pulmonary function testing or spirometry and documented by report and interpretation
  - Eosinophilia as defined by a blood eosinophil count of greater than or equal to 400 cells/microliter at the initiation of therapy and documented by laboratory report (in the absence of other causes of eosinophilia such as a documented or suspected parasitic infection, neoplastic disease, or hyper-eosinophilic syndromes, etc.)
- For continuation of therapy, documentation of improvement by clinical measurements such as $FEV_1$, asthma control questionnaire, the decreased use of beta-agonists, a decreased incidence of hospitalization, intensive care, or mechanical ventilation, etc.

### Required Codes

The following ICD-10-CM diagnosis code is required for reimbursement:

J82.81 thru J82.89

### Billing

HCPCS code J2786 (injection, reslizumab, 1 mg).

One (1) unit of J2786 equals 1 mg of reslizumab solution.

## Rezafungin (REZZAYO)

Rezafungin is a semi-synthetic echinocandin antifungal drug that inhibits the 1,3-β-D-glucan synthase enzyme complex, which is present in fungal cell walls but not in mammalian cells. This results in inhibition of the formation of 1,3-β-D-glucan, an essential component of the fungal cell wall of many fungi, including *Candida* species (spp.).

### Indications

All FDA-approved indications.

### Dosage

FDA-approved dosages.

### TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

### TAR Criteria

The TAR must include clinical documentation that demonstrates the following:

- Must be used for an FDA-approved indication and dosage.
- Patient must be 18 years of age or older.
- Not used to treat endocarditis, osteomyelitis, and meningitis due to *Candida*.
- Patient had a trial of at least caspofungin, micafungin, anidulafungin, fluconazole, amphotericin B, voriconazole.
- Must show documentation of culture or other laboratory data.

Duration of approval is for four weeks.

### Age Limits

Must be 18 years of age or older.

### Billing

HCPCS code J0349 (injection, rezafungin, 1 mg).

### Prescribing Restriction(s)

Frequency of billing equals 400 mg/400 units on day 1, then 200 mg/200 units weekly beginning on day eight for up to four doses.

Maximum billing unit(s) equals 400 mg/400 units.

## ‹‹Rifampin (RIFADIN)

### Indications, Dosages and Age

Refer to the FDA-approved labeling.

### TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

### Billing

HCPCS code J2804 (injection, rifampin, 1 mg).

### Prescribing Restriction(s)

Frequency of billing equals 600 mg / 600 units daily.

Maximum billing unit(s) equals 600 mg / 600 units.››

## Rilonacept

Rilonacept is an interleukin-1 blocker and is used in the treatment of Cryopyrin-Associated Periodic Syndrome, including Familial Cold Auto-inflammatory Syndrome and Muckle-Wells Syndrome in adults and children 12 years of age and older.

### Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

### Dosage

In adult patients 18 years of age and older, treatment is initiated with a loading dose of 320 mg, delivered as two subcutaneous injections of 160 mg on the same day at two different sites, then once-weekly injections of 160 mg.

In pediatric patients 12 to 17 years of age, treatment is initiated with a loading dose of 4.4 mg/kg, up to a maximum of 320 mg in either one or two subcutaneous injections on the same day (at two different sites if two injections), then once-weekly injections up to a maximum of 160 mg.

### Billing

HCPCS code J2793 (injection, rilonacept, 1 mg)
One unit equals 1 mg.

## RimabotulinumtoxinB

For detailed billing policy information about rimabotulinumtoxinB, refer to the “Botulinum Toxins A and B” topic in the *Injections: Drugs B Policy* section of the manual.

## Risankizumab-rzaa (SKYRIZI®)

Risankizumab-rzaa is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that selectively binds to the p19 subunit of human interleukin 23 (IL-23) cytokine and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Risankizumab-rzaa inhibits the release of pro-inflammatory cytokines and chemokines.

### Indications

All FDA-approved indications.

### Dosage

FDA approved dosages.

### TAR Requirements

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

### TAR Criteria

TAR Criteria

Must submit clinical documentation to substantiate the following:

Universal Criteria:

- Must be used for FDA-approved indications and dosages.Patient must be 18 years of age or older.
- Patient does not have active infection (including tuberculosis and hepatitis B virus [HBV]) or other serious active infection.
- Patient has baseline liver enzymes and bilirubin levels prior to treatment initiation.
- Patient does not have a known hypersensitivity to risankizumab.
- Must avoid use of live vaccines.

Patient must meet A, B or C below:

A. Plaque Psoriasis (PsO)

- Must be prescribed by or in consultation with a dermatologist.
- Patient must have a diagnosis of plaque psoriasis (with or without psoriatic arthritis) for at least six months before treatment initiation.
- Patient has stable moderate to severe chronic plaque-type psoriasis with or without psoriatic arthritis and meets all of the following:
  - Static Physician Global Assessment (sPGA) score of at least three (moderate)
  - Psoriasis Area and Severity Index (PASI) 12 or more
  - Body Surface Area (BSA) 10 percent or more
- Patient has a history of failure of one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced. Corticosteroids (for example, betamethasone, clobetasol, desonide), Vitamin D analogs (for example, calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (for example, tacrolimus, pimecrolimus), Anthralin, coal tar or phototherapy.
- Patient must have tried and failed one of the preferred products (Remicade, Enbrel or Humira) unless intolerant, inadequate response or contraindication.

B. Psoriatic Arthritis (PsA)

- Must be prescribed by or in consultation with a dermatologist or rheumatologist.
- Patient has a clinical diagnosis of PsA with symptom onset at least six months prior based on the Classification Criteria for PsA (CASPAR).
- Patient has active disease at Baseline defined as five or more tender joints (based on 68 joint counts) and five or more swollen joints (based on 66 joint counts).
- Patient has a diagnosis of active plaque psoriasis with at least one psoriatic plaque of two cm or more in diameter or nail changes consistent with psoriasis at baseline.

- Patient must have a history of failure of a three-month trial of at least one conventional Disease-Modifying Antirheumatic Drug (DMARD) such as methotrexate at maximally indicated doses within the last six months unless intolerant, contraindicated or clinically inappropriate.
- Patient must have tried and failed one of the preferred products (Remicade, Enbrel or Humira) unless intolerant, inadequate response or contraindication.
- Patient has not had a previous treatment with biologic agent.

C. Crohn’s Disease (CD)

- Must be prescribed by or in consultation with a gastroenterologist.
- Patient has a diagnosis of CD for at least three months prior to baseline.
- Patient has a confirmed diagnosis of moderate to severe CD as assessed by stool frequency (SF), abdominal pain (AP) score, and Simple Endoscopic Score for Crohn's Disease (SES-CD).
- Patient has Crohn's disease activity index (CDAI) score 220 to 450 at baseline.
- Patient had inadequate response, intolerance or contraindication to at least one conventional therapy option such as corticosteroids (for example, prednisone, methylprednisolone, budesonide), mercaptopurine (Purinethol), azathioprine (Imuran) or methotrexate (Rheumatrex, Trexall).
- Patient must have tried and failed one of the preferred products (Remicade or Humira, unless intolerant, inadequate response or contraindication.
- If female, participant must meet the contraception recommendations.
- Patient does not have a current diagnosis of ulcerative colitis or indeterminate colitis.
- Patient has not received Crohn's disease approved biologic agents (Remicade, Humira, Cimzia, Entyvio, Tysabri within eight weeks prior to Baseline or Stelara within 12 weeks prior to baseline).

Initial authorization is for 12 months.

Continued therapy

- Patient continues to meet initial approval criteria.
- Patient has experienced positive clinical response as evidenced by disease improvement or stabilization compared to baseline.
- Liver enzymes and bilirubin levels are being monitored up to at least 12 weeks of treatment and thereafter as needed.

Reauthorization is for 12 months.

### Age Limits

Must be 18 years of age or older.

### Billing

HCPCS code J2327, (injection, risankizumab-rzaa, intravenous, 1 mg).

### Prescribing Restriction(s)

Frequency of billing equals 600 mg/600 units every four weeks.

Maximum billing unit(s) equals 600 mg/600 units.

## Risperidone ER (RYKINDO®)

The mechanism of action of risperidone in schizophrenia is unclear. The drug's therapeutic activity could be mediated through a combination of dopamine Type 2 (D2) and serotonin Type 2 (5HT2) receptor antagonism. The clinical effect from risperidone results from the combined concentrations of risperidone and its major active metabolite, 9-hydroxyrisperidone (paliperidone). Antagonism at receptors other than D2 and 5HT2 may explain some of the other effects of risperidone.

### Indications

All FDA-approved indications.

## Dosage

FDA-approved dosages.

## TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

## TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Must be prescribed by or in consultation with a psychiatrist.
- Patient must have a diagnosis of schizophrenia or bipolar I disorder based on DSM criteria.

Drug is used under the following conditions:

  - Treatment of Schizophrenia.
  - As monotherapy for the maintenance treatment of bipolar I disorder
  - As adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder
- Patient has an established stability and tolerability of oral risperidone.
- Patient meets one of the following conditions:
  - Has a history of non-adherence, refuses to take oral medication or oral medication is clinically inappropriate
  - Treatment was initiated in inpatient during a recent hospitalization, within the last 60 days

- Must provide documentation justifying why formulary alternative injections such as Risperdal Consta is not clinically appropriate.
- Patient has no history of hypersensitivity (for example, anaphylaxis, angioedema) to risperidone, paliperidone, or any component of the formulation.

Initial authorization is for six months.

Continued Therapy

- Patient continues to meet initial approval criteria.
- Patient has experienced documented positive clinical response from baseline.

Reauthorization is for 12 months.

## Age Limits

Must be 18 years of age or older.

## Billing

HCPCS code J2801 (injection, risperidone [rykindo], 0.5 mg).

## Suggested ICD-10-CM Diagnosis Codes

F20.0 thru F20.9, F25.0 thru F25.9 (Schizophrenia), F31.0 thru F31.31 (Bipolar Disorder)

## Prescribing Restrictions

Frequency of billing equals 50 mg / 100 units every two weeks.
Maximum billing units equals 50 mg / 100 units.

# Risperidone ER SQ Injection (Perseris)

Perseris is an atypical antipsychotic with an unclear mechanism of action in schizophrenia. Its therapeutic activity in schizophrenia could be mediated through a combination of dopamine Type 2 (D2) and serotonin Type 2 (5HT2) receptor antagonism. The clinical effect from risperidone results from the combined concentrations of risperidone and its major metabolite, 9-hydroxyrisperidone (paliperidone). Antagonism at receptors other than D2 and 5HT2 may explain some of the other effects of risperidone.

## Indications

All FDA-approved indications.

## Dosage

FDA-approved dosages.

## TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must meet the following criteria for approval:

- Must be for FDA-approved indications.
- The patient must be 18 to 65 years of age.
- The patient must have a documented history of poor adherence to oral risperidone.
- The patient must be able to tolerate at least 3 mg/day of oral risperidone.

**Note:** Neither a loading dose nor an overlap with oral risperidone is necessary.

## Age Limits

Must be 18 to 65 years of age.

## Billing

HCPCS code J2798 (injection, risperidone, (Perseris), 0.5 mg)

### Prescribing Restrictions

Frequency of billing equals every month.

Maximum billing units equals 120 mg equals 240 units.

## Risperidone Injection (Risperdal Consta)

Risperdal Consta is an atypical, antipsychotic with an unclear mechanism of action in schizophrenia. Its therapeutic activity in schizophrenia could be mediated through a combination of dopamine Type 2 (D2) and serotonin Type 2 ($5HT_2$) receptor antagonism. The clinical effect from risperidone results from the combined concentrations of risperidone and its major active metabolite, 9hydroxyrisperidone (paliperidone). Antagonism at receptors other than D2 and $5HT_2$ may explain some of the other effects of risperidone.

### Indications

All FDA-approved indications

### Dosage

FDA-approved dosages.

### TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must meet the following criteria for approval:

- FDA-approved indications.
- Must be 18 years of age or older.
- Must be able to tolerate at least 2 mg/day of oral risperidone.
- Must have a documented history of poor adherence to oral risperidone.
- Oral risperidone or other antipsychotics administered with Risperdal Consta should be tapered off after three (3) weeks.

### Age Limits

Must be 18 years of age or older.

### Billing

HCPCS code J2794 (injection, risperidone [Risperdal Consta], 0.5 mg).

### Prescribing Restrictions

Frequency of billing equals every 14 days.

Maximum billing units equals 50 mg equals 100 units.

## Risperidone (UZEDY)

Risperidone is a benzisoxazole atypical antipsychotic with high 5-HT2 and dopamine-D2 receptor antagonist activity. Alpha1, alpha2 adrenergic, and histaminergic receptors are also antagonized with high affinity. Risperidone has low to moderate affinity for 5-HT1C, 5-HT1D, and 5-HT1A receptors, weak affinity for D1 and no affinity for muscarinics or beta1 and beta2 receptors.

### Indications

All FDA-approved indications.

### Dosage

FDA-approved dosages.

### TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

## TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Must be prescribed by or in consultation with a psychiatrist.
- Patient must have a diagnosis of schizophrenia based on DSM-5 criteria for more than one year and has had 1 or more episodes of relapse in the last 24 months.
- Patient has an established stability and tolerability of oral risperidone.
  - Neither a loading dose nor overlap with oral risperidone is needed. Initiate Uzedy the day after the last dose of oral therapy.
- The patient must have a documented history of poor adherence to oral risperidone or has relapsed due to medication nonadherence or other reason why an oral formulation is clinically inappropriate.
- Must provide documentation justifying why formulary alternative injections such as Perseris or Risperdal Consta are not clinically appropriate.
- Patient has no history of hypersensitivity (eg, anaphylaxis, angioedema) to risperidone, paliperidone, or any component of the formulation.

Initial authorization is for six months.

Continued Therapy

- Patient continues to meet initial approval criteria.
- Patient has experienced documented positive clinical response from baseline.

Reauthorization is for 12 months.

## Age Limits

Must be 18 years of age or older.

## Billing

HCPCS code J2799, (injection, risperidone, [uzedy], 1 mg).

## Prescribing Restrictions

Frequency of billing equals 50 mg/50 units to 125 mg/125 units once monthly or 100 mg/100 units to 250 mg/250 units every two months.

Maximum billing units equals 250 mg/250 units.

# Rituximab

Rituximab is a CD20-directed cytolytic antibody for intravenous (IV) administration.

## Indications

Rituximab is used to treat both oncologic and non-oncologic diseases including the following conditions:

- Non-Hodgkin's Lymphoma
- Chronic Lymphocytic Leukemia
- Rheumatoid Arthritis
- Granulomatosis with polyangiitis (Wegener's Granulomatosis)
- Microscopic Polyangiitis

For the use of rituximab in oncologic conditions, refer to the *Chemotherapy: Drugs R-S Policy* section in the appropriate Part 2 Medi-Cal manual.

## Age Limits

Must be 18 years of age and older.

## Dosage

The recommended dosage varies based on the treatment condition, the use of rituximab as a single agent or in combination with other agents, the use of rituximab for induction or maintenance therapy, and the patient's response to treatment.

## Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

The TAR must include clinical documentation that demonstrates the following:

- The service is medically necessary.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/order for rituximab.

## Billing

HCPCS code J9312 (injection, rituximab, 10 mg)
One (1) unit of J9312 equals 10 mg of rituximab injection solution.

# Romosozumab-aqqg (Evenity®)

Evenity® inhibits the action of sclerostin, a regulatory factor in bone metabolism. Evenity increases bone formation and, to a lesser extent, decreases bone resorption. Animal studies showed that romosozumab-aqqg stimulates new bone formation on trabecular and cortical bone surfaces by stimulating osteoblastic activity resulting in increases in trabecular and cortical bone mass and improvements in bone structure and strength.

## Indications

All FDA-approved indications

## Dosage

FDA-approved dosages

## TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include clinical documentation that demonstrates the following:

- For FDA-approved indications and dosages
- Treatment of osteoporosis in postmenopausal women at high risk of fracture

- Bone mineral density (BMD) T-score of less than or equal to -2.5 or FRAX Score indicating major fracture risk greater than 20 percent or HIP Fracture greater than three percent, or non-traumatic fracture.
- Patient has tried and failed, or is intolerant, or has a contraindication to bisphosphonate therapy.
- Patient has tried and failed, or is intolerant, or has a contraindication to injectable osteoporosis treatment drugs such as teriparatide, denosumab and abaloparatide.
- Must correct pre-existing hypocalcemia prior to initiation of therapy.
- Patient had no myocardial infarction or stroke within one year of starting Evenity.
- Patient is taking a minimum 500 mg calcium and 600 IU vitamin D daily or contraindication.
- Patient is not using Evenity in combination with denosumab, bisphosphonates, calcitonin, raloxifene, zolendronic acid, teriparatide or abaloparatide.
- Must be limited to 12 monthly doses only.

## Age Limits

Must be 18 years of age or older.

## Billing

HCPCS code J3111 (injection, romosozumab-aqqg, 1 mg).

## Prescribing Restrictions

Frequency of billing equals every month.

Maximum billing units equals 210 mg (two syringes) equals 210 units.

# Rozanolixizumab-noli Injection (RYSTIGGO®)

Rozanolixizumab-noli is a humanized IgG4 monoclonal antibody that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG.

## Indications

All FDA-approved indications.

## Dosage

FDA-approved dosages.

## TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

## TAR Criteria

The TAR must include clinical documentation that demonstrates all of the following:

- Must be used for FDA-approved indications and dosages.
- Must be prescribed by or in consultation with a neurologist.
- Patient is at least 18 years of age.
- Patient is up to date with all vaccination according to vaccination guidelines prior to initiation of therapy.
- Patient is not currently on other immunomodulatory biologic therapy (for example, efgartigimod, ravulizumab, rituximab, etc.).
- Patient will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (for example, hydroxychloroquine, botulinum toxins, beta-blockers, etc.).
- Patient will not be administered live attenuated or live vaccine during treatment.

- Patient does not have a deficiency of immunoglobulin G (IgG).
- Patient does not have an active infection.
- Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease.
- Patient has a positive serologic test for anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibodies.
- Physician has assessed objective signs of neurological weakness and fatiguability on a baseline neurological examination (for example, including, but not limited to, the Quantitative Myasthenia Gravis (QMG) score, etc.).
- Patient had an inadequate response to initial therapy based on their antibodies:
  - AChR+ disease: a minimum one-year trial of concurrent use with two or more immunosuppressive therapies (for example, corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, etc.); OR
  - MuSK+ disease: a minimum one-year trial with immunosuppressive therapy (for example, corticosteroids, azathioprine, or mycophenolate) and rituxumab; OR
  - Patient required at least one acute or chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to their background therapy above.

Initial approval is for 16 weeks.

Continued Therapy:

- Patient meets the initial criteria described above.
- A minimum of 63 days must have elapsed from the start of the previous treatment cycle.
- Absence of unacceptable toxicity from the drug.
- Patient has had improvement in muscle strength and at least 1 point from baseline in the MG-ADL total score.

Reauthorization is for six months.

## Age Limits

Must be 18 years of age or older.

## Billing

HCPCS code J9333 (injection, rozanolixizumab-noli, 1 mg.

## Required ICD-10-CM Diagnosis Codes

G70.00, G70.01

## Prescribing Restriction(s)

Frequency of billing equals 850 mg/850 units once weekly for six weeks.

Maximum billing unit(s) equals 850 mg/850 units.

## Legend

Symbols used in the document above are explained in the following table.

| Symbol | Description |
|---|---|
| ‹‹ | This is a change mark symbol. It is used to indicate where on the page the most recent change begins. |
| ›› | This is a change mark symbol. It is used to indicate where on the page the most recent change ends. |
| ‡ | References: 1) The 2014 ERS/ATS (European Respiratory Society/ American Thoracic Society) Task Force Report Guidelines on Severe Asthma and 2) The 2007 NAEPP (National Asthma Education and Prevention Program) Expert Panel Report 3, U.S. Department of Health and Human Services National Institutes of Health. |