Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Complement Inhibitors: Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]	MP-RX-FP-19-23	☒ MMM MA ☐ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of complement inhibitors. Agents addressed in this clinical criteria document include:

- Soliris (eculizumab)
- Ultomiris (ravulizumab-cwvz)

Soliris (eculizumab) and Ultomiris (ravulizumab-cwvz) are monoclonal antibodies that binds to complement protein C5 and inhibits its enzymatic cleavage and blocks formation of the terminal complement complex thereby preventing red cell lysis in PNH and complement-mediated thrombotic microangiopathy in aHUS. Soliris and Ultomiris are approved for the treatment of individuals with paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), and generalized myasthenia gravis (gMG). Soliris is also approved for neuromyelitis optica spectrum disorder (NMOSD).

Background Information

Paroxysmal Nocturnal Hemoglobinuria (PNH): PNH is a rare acquired hematopoietic stem cell disorder associated with a variety of nonspecific clinical features including but not limited to hemolytic anemia, fatigue, smooth muscle dystonia, and atypical venous thrombosis. Treatment options are limited but may include the use of therapeutic anticoagulation, allogeneic hematopoietic cell transplantation and/or complement inhibitors (Soliris or Ultomiris) depending upon symptom severity, degree of hemolysis, and history of thrombosis. Anti-complement therapy is used to reduce intravascular hemolysis, decrease or eliminate the need for blood transfusions, and reduce the risk for thrombosis. If Soliris (eculizumab) or Ultomiris (ravulizumab-cwvz) therapy is discontinued, individuals should be closely monitored for at least 8 weeks after cessation to detect hemolysis.

Atypical Hemolytic Uremic Syndrome (aHUS): aHUS is a rare blood disorder characterized by microangiopathic hemolytic anemia, thrombocytopenia, and acute kidney injury. Treatment options are limited and include plasma therapy (plasma exchange or fresh frozen plasma infusion), renal transplantation, or complement inhibitors. The efficacy of Soliris and Ultomiris in aHUS is based on their ability to inhibit complement-mediated thrombotic microangiopathy (TMA) and thereby improve renal function. If discontinued, close monitoring after cessation of therapy is essential (for example: regular laboratory monitoring including complete blood count, peripheral smear, lactate dehydrogenase, renal function, and

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urine protein beginning the week of the held dose and weekly for 4 weeks, every 2 weeks for 1 month, and then monthly for 3 months at the discretion of the treating clinician).

Myasthenia Gravis (MG): MG is a common disorder of neuromuscular transmission characterized by a variable combination of weakness in ocular, bulbar, limb, and respiratory muscles. Treatment strategies include symptomatic therapy (with anticholinesterase agents such as pyridostigmine), chronic immunotherapy with steroids or other immunosuppressive drugs (such as azathioprine, cyclosporine, or methotrexate), rapid immunotherapy (with plasmapheresis or IV immune globulin), and/or surgical treatment. The Myasthenia Gravis Foundation of America (MGFA) international consensus guidelines recommend immunosuppressive drugs (such as azathioprine or cyclosporine) and/or corticosteroids for individuals who have not met treatment goals after an adequate trial of pyridostigmine. Soliris may be considered in the treatment of severe, refractory MG after trials of other immunotherapies have been unsuccessful. Soliris (eculizumab) was studied in individuals with refractory anti-acetylcholine receptor (AchR) antibody positive generalized MG who had failed an adequate trial of multiple immunosuppressive drugs or a combination of immunosuppressive drugs and rapid immunotherapy. Ultomiris (ravulizumab) is also approved for anti-acetylcholine receptor (AchR) antibody positive generalized MG.

Neuromyelitis optica spectrum disorder (NMOSD): NMOSD is a severe autoimmune disease of the central nervous system caused by immune-mediated demyelination and axonal damage predominantly targeting optic nerves and spinal cord. This damage is triggered by antibodies against aquaporin-4 (AQP4), which are considered diagnostic criteria for NMOSD. The disease is characterized by clusters of attacks of optic neuritis or transverse myelitis with partial recovery between attacks. Progressive visual impairment and paralysis may be caused by repeated attacks. Treatment may include off-label immunosuppressive therapies including rituximab, azathioprine, and mycophenolate. Soliris (eculizumab), Uplizna (inebilizumab), and Enspryng (satralizumab) are FDA-approved for NMOSD and have demonstrated efficacy through a relative reduction in relapse rate compared to placebo.

Complement inhibitors have black box warnings for serious meningococcal infections. Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors and meningococcal infection may become rapidly life-threating or fatal if not recognized and treated early. Individuals should be immunized with meningococcal vaccines at least 2 weeks prior to initiation of therapy unless the risks of delaying therapy outweigh the risk of developing a meningococcal infection. The FDA has required the manufacturers to develop comprehensive risk management programs that include the enrollment of prescribers in the Soliris REMS or Ultomiris REMS Programs respectively. Additional information and forms for individuals, prescribers, and pharmacists may be found on the manufacturer's websites: http://www.solirisrems.com or http://www.ultomirisrems.com.

Ultomiris 300 mg/30 mL vial was discontinued by the manufacturer. Criteria will remain active until June 2023 as claims can adjudicate several years after agent discontinuation.

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Approved Indications

A. Paroxysmal Nocturnal Hemoglobinuria (PNH)
B. Atypical Hemolytic Uremic Syndrome (aHUS)
C. Myasthenia Gravis (MG)
D. Neuromyelitis optica spectrum disorder (NMOSD)

Other Uses

A. N/A

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J1300	Injection, eculizumab, 10 mg [Soliris]
J1303	Injection, ravulizumab-cwvz, 10 mg [Ultomiris]

ICD-10	Description
D59.3	Hemolytic-uremic syndrome [when specified as aHUS]
D59.5	Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli]
G36.0	Neuromyelitis optica [Devic]
G70.00-G70.01	Myasthenia gravis

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Clinical *Criteria: Soliris*

A. Criteria For Initial Approval

Soliris (eculizumab)

Requests for initiation of therapy with Soliris (eculizumab) in paroxysmal nocturnal hemoglobinuria (PNH) may be approved if the following criteria are met:

i. Individual has PNH as confirmed by flow cytometry, including the presence of (Parker 2005):
   a. PNH type III red cell clone or a measurable granulocyte or monocyte clone; OR
   b. Glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient polymorphonuclear cells (PMNs);

AND

ii. Individual has been immunized with a meningococcal vaccine at least 2 weeks prior to administration of the first dose of Soliris (eculizumab), unless the clinical record documents the risks of delaying Soliris (eculizumab) outweigh the risk of meningococcal infection;

AND

iii. Individual has no evidence of an active meningococcal infection;

AND

iv. Individual has (Hillmen 2006):
   a. Lactate dehydrogenase greater than 1.5 times the upper limit of normal, and documentation is provided; **AND**
   b. One or more PNH-related sign or symptom (such as but not limited to anemia or history of a major adverse vascular event from thromboembolism).

Requests for initiation of therapy with Soliris (eculizumab) in neuromyelitis optica spectrum disorder (NMOSD) may be approved if the following criteria are met:

i. Individual is 18 years of age or older with NMOSD; **AND**

ii. Documentation is provided that NMOSD is seropositive as confirmed by the presence of anti-aquaporin-4 (AQP4) antibodies;

AND

iii. Documentation is provided that individual has a history of at least 2 acute attacks or relapses in the last 12 months prior to initiation of therapy; **OR**

iv. Documentation is provided that individual has a history of at least 3 acute attacks or relapses in the last 24 months **AND** at least 1 relapse in the 12 months prior to initiation of therapy;

AND

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v. Individual has been immunized with a meningococcal vaccine at least 2 weeks prior to administration of the first dose of Soliris (eculizumab), unless the clinical record documents the risks of delaying Soliris (eculizumab) outweigh the risk of meningococcal infection;

AND

vi. Individual has no evidence of an active meningococcal infection.

Requests for initiation of therapy with Soliris (eculizumab) in atypical hemolytic uremic syndrome (aHUS) may be approved if the following criteria are met:

i. Individual has a diagnosis of aHUS; **AND**

ii. The diagnosis of aHUS is supported by the absence of Shiga toxin-producing E. coli infection; **AND**

iii. Thrombotic thrombocytopenic purpura has been ruled out [for example, normal ADAMTS 13 activity and no evidence of an ADAMTS 13 inhibitor (Loirat 2011, 2016)], or if thrombotic thrombocytopenic purpura cannot be ruled out by laboratory and clinical evaluation, a trial of plasma exchange did not result in clinical improvement; **AND**

iv. Individual has been immunized with a meningococcal vaccine at least 2 weeks prior to administration of the first dose of Soliris (eculizumab), unless the clinical record documents the risks of delaying Soliris (eculizumab) outweigh the risk of meningococcal infection; **AND**

v. Individual has no evidence of an active meningococcal infection.

Requests for initiation of therapy with Soliris (eculizumab) in generalized myasthenia gravis (gMG) may be approved if the following criteria are met:

i. Individual is 18 years of age or older with gMG; **AND**

ii. Individual has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV disease; **AND**

iii. Documentation is provided that individual has a positive serologic test for binding anti-acetylcholine receptor antibodies (AChR-ab); **AND**

iv. Documentation is provided that individual has a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of at least 6 or higher;

AND

v. Documentation is provided that individual has had an inadequate response to, is intolerant of, or has a contraindication to two or more immunosuppressive drug agents (such as azathioprine, cyclosporine, or methotrexate) as monotherapy or in combination therapy for greater than or equal to 12 months;

OR

vi. Documentation is provided that individual has had an inadequate response to, is intolerant of, or has a contraindication to one or more immunosuppressive drug agents as monotherapy or in combination therapy and requires chronic plasma exchange or plasmapheresis or intravenous immunoglobulin therapy;

AND

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vii. Individual has been immunized with a meningococcal vaccine at least 2 weeks prior to administration of the first dose of Soliris (eculizumab), unless the clinical record documents the risks of delaying Soliris (eculizumab) outweigh the risk of meningococcal infection;

AND

viii. Individual has no evidence of an active meningococcal infection.

<u>Ultomiris (ravulizumab-cwvz)</u>

Requests for initiation of therapy with Ultomiris (ravulizumab-cwvz) in paroxysmal nocturnal hemoglobinuria (PNH) may be approved if the following criteria are met:

i. Individual has PNH as documented by flow cytometry, including the presence of (Parker 2005):
   a. PNH type III red cell clone or a measurable granulocyte or monocyte clone; **OR**
   b. Glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient polymorphonuclear cells (PMNs);

AND

ii. Individual has been immunized with a meningococcal vaccine at least 2 weeks prior to administration of the first dose of Ultomiris (ravulizumab-cwvz), unless the clinical record documents the risks of delaying Ultomiris (ravulizumab-cwvz) outweigh the risk of meningococcal infection;

AND

iii. Individual has no evidence of an active meningococcal infection;
   a. Lactate dehydrogenase greater than 1.5 times the upper limit of normal, and documentation is provided; **AND**
   b. One or more PNH-related sign or symptom (such as but not limited to anemia or history of major adverse vascular event from thromboembolism).

Requests for initiation of therapy with Ultomiris (ravulizumab-cwvz) in atypical hemolytic uremic syndrome (aHUS) may be approved if the following criteria are met:

i. Individual has a diagnosis of aHUS; **AND**

ii. The diagnosis of aHUS is supported by the absence of Shiga toxin-producing E. coli infection; **AND**

iii. Thrombotic thrombocytopenic purpura has been ruled out [for example, normal ADAMTS 13 activity and no evidence of an ADAMTS 13 inhibitor (Loirat 2011, 2016)], or if thrombotic thrombocytopenic purpura cannot be ruled out by laboratory and clinical evaluation, a trial of plasma exchange did not result in clinical improvement; **AND**

iv. Individual has been immunized with a meningococcal vaccine at least 2 weeks prior to administration of the first dose of Ultomiris (ravulizumab-cwvz), unless the clinical record documents the risks of delaying Ultomiris (ravulizumab-cwvz) outweigh the risk of meningococcal infection; **AND**

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v. Individual has no evidence of an active meningococcal infection.

Requests for initiation of therapy with Ultomiris (ravulizumab-cwvz) in generalized myasthenia gravis (gMG) may be approved if the following criteria are met:

i. Individual is 18 years of age or older with gMG; AND
ii. Documentation is provided that individual has a positive serologic test for binding anti-acetylcholine receptor antibodies (AChR-ab); AND
iii. Individual has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV disease; AND
iv. Documentation is provided that individual has a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of at least 6 or higher;

AND

v. Documentation is provided that individual has had an inadequate response to, is intolerant of, or has a contraindication to two or more immunosuppressive drug agents (such as azathioprine, cyclosporine, or methotrexate) as monotherapy or in combination therapy for greater than or equal to 12 months (MGFA 2020);

OR

vi. Documentation is provided that individual has had an inadequate response to, is intolerant of, or has a contraindication to one or more immunosuppressive drug agents as monotherapy or in combination therapy and requires chronic plasma exchange or plasmapheresis or intravenous immunoglobulin therapy (MGFA 2020);

AND

vii. Individual has been immunized with a meningococcal vaccine at least 2 weeks prior to administration of the first dose of Ultomiris (ravulizumab-cwvz), unless the clinical record documents the risks of delaying Ultomiris (ravulizumab-cwvz) outweigh the risk of meningococcal infection;

AND

viii. Individual has no evidence of an active meningococcal infection.

B. Criteria For Continuation of Therapy

<u>Soliris (eculizumab)</u>

Requests for continued use of Soliris (eculizumab) in PNH may be approved if the following criteria are met:

i. Documentation is provided that individual has experienced a clinical response as shown by one of the following:
   a. Stabilization of hemoglobin levels; **OR**
   b. Reduction in number of transfusions required; **OR**
   c. Improvement in hemolysis (for example, normalization or decrease of LDH levels).

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Requests for continued use of Soliris (eculizumab) in NMOSD may be approved if the following criteria are met:

ii. Documentation is provided that individual has experienced a clinical response (for example, a reduction in the frequency of relapse).

Requests for continued use of Soliris (eculizumab) in aHUS may be approved if the following criteria are met:

iii. There is clinical improvement after the initial trial (for example, increased platelet count or laboratory evidence of reduced hemolysis) until an individual becomes a candidate for physician-directed cessation as evidenced by the following (Merrill 2017):
   a. Complete clinical remission has been achieved (that is, resolution of thrombocytopenia and mechanical hemolysis, and normalization or new baseline plateau of renal function) and improvement of precipitating illness is clinically apparent;

   AND

   b. Duration of clinical remission has been stable for 2 months.

Requests for resumption of Soliris (eculizumab) in aHUS may be approved if the following criteria are met (Fakhouri 2017):

iv. Documentation is provided that individual experienced a relapse after discontinuation of therapy as defined by:
   a. Reduction in platelet count to less than 150,000/mm3 or greater than 25% from baseline; **OR**
   b. Mechanical hemolysis (having 2 or more features of hemoglobin less than 10 g/dL, lactate dehydrogenase greater than 2 times upper limit of normal, undetectable haptoglobin, or presence of schistocytes on smear); **OR**
   c. Acute kidney injury with serum creatinine increase greater than 15% from baseline levels.

Requests for continued use of Soliris (eculizumab) in gMG may be approved if the following criteria are met:

v. Individual has experienced a clinical response as evidenced by both of the following:
   a. Reduction in signs or symptoms that impact daily function; AND
   b. Documentation is provided to show at least a 3 point reduction in MG-ADL total score from baseline.

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Ultomiris (ravulizumab-cwvz)

Requests for continued use of Ultomiris (ravulizumab-cwvz) in PNH may be approved if the following criteria are met:

i. Documentation is provided that individual has experienced a clinical response as shown by one of the following:
   a. Stabilization of hemoglobin levels; **OR**
   b. Reduction in number of transfusions required; **OR**
   c. Improvement in hemolysis (for example, normalization or decrease of LDH levels).

Requests for continued use of Ultomiris (ravulizumab-cwvz) in aHUS may be approved if the following criteria are met:

i. There is clinical improvement after the initial trial (for example, increased platelet count or laboratory evidence of reduced hemolysis) until an individual becomes a candidate for physician-directed cessation as evidenced by the following (Merrill 2017):
   a. Complete clinical remission has been achieved (that is, resolution of thrombocytopenia and mechanical hemolysis, and normalization or new baseline plateau of renal function) and improvement of precipitating illness is clinically apparent; **AND**
   b. Duration of clinical remission has been stable for 2 months.

Requests for resumption of Ultomiris (ravulizumab-cwvz) in aHUS may be approved if the following criteria are met (Fakhouri 2017):

i. Documentation is provided that individual experienced a relapse after discontinuation of therapy as defined by:
   a. Reduction in platelet count to less than 150,000/mm3 or greater than 25% from baseline; **OR**
   b. Mechanical hemolysis (having 2 or more features of hemoglobin less than 10 g/dL, lactate dehydrogenase greater than 2 times upper limit of normal, undetectable haptoglobin, or presence of schistocytes on smear); **OR**
   c. Acute kidney injury with serum creatinine increase greater than 15% from baseline levels.

Requests for continued use of Ultomiris (ravulizumab-cwvz) in gMG may be approved if the following criteria are met:

i. Individual has experienced a clinical response as evidenced by both of the following:
   a. Reduction in signs or symptoms that impact daily function; **AND**
   b. Documentation is provided showing at least a 3-point reduction in MG-ADL total score from baseline.

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C. Authorization Duration

i. Soliris (eculizumab)
   a. Initial Approval Duration: **PNH** 6 months
   b. Initial Approval Duration: **NMOSD** 1 year
   c. Initial Approval Duration: **aHUS** 12 weeks
   d. Initial Approval Duration: **gMG** 26 weeks
   e. Reauthorization Approval Duration: Up to 12 months depending on clinical indications.

ii. Ultomiris (ravulizumab-cwvz)
   a. Initial Approval Duration: **PNH** 6 months
   b. Initial Approval Duration: **aHUS** 6 months
   c. Initial Approval Duration: **gMG** 26 weeks
   d. Reauthorization Approval Duration: Up to 6 months.

D. **Conditions Not Covered**

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Requests for Soliris (eculizumab) may not be approved for the following:
   a. Individual is using in combination with efgartigimod alfa, ravulizumab, rituximab, inebilizumab, or satralizumab; **OR**
   b. Individual is using in combination with pegcetacoplan for more than 4 weeks for PNH; **OR**
   c. When the above criteria are not met and for all other indications.

ii. Requests for Ultomiris (ravulizumab-cwvz) may not be approved for the following:
   a. Individual is using in combination with efgartigimod alfa, eculizumab, pegcetacoplan, or rituximab; **OR**
   b. When the above criteria are not met and for all other indications.

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Limits or Restrictions

A. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Soliris (eculizumab) Quantity Limit

Drug	Limit
Soliris 300 mg/30 mL vial*	8 vials per 28 days
Exceptions	
*Initiation of therapy for Atypical Hemolytic Uremic Syndrome (aHUS), generalized Myasthenia Gravis (MG), or neuromyelitis optica spectrum disorder (NMOSD) : May approve 4 (four) additional vials (300 mg/mL) in the first 28 days (4 weeks) of treatment. If individual receives plasma exchange [PE], plasmapheresis [PP], or fresh frozen plasma infusion during therapy, supplemental doses of Soliris (up to 600 mg following each PE or PP intervention or up to 300 mg following fresh frozen plasma) may be approved.	

Ultomiris (ravulizumab-cwvz) Quantity Limit

Drug	Limit
Ultomiris 300 mg/30 mL vial*; 300mg/3 mL vial*	12 vials per 56 days
Ultomiris 1100 mg/11 mL vial^	3 vials per 56 days
Ultomiris 245 mg/3.5 mL prefilled cartridge with on-body injector	2 cartons [with 1 prefilled cartridge and 1 on-body injector each per week
Exceptions	
Initiation of therapy: *May approve 10 (ten) additional vials (300 mg/30mL or 300mg/3mL) in the first 28 days (4 weeks) of treatment; **OR** ^May approve 3 (three) additional 1100 mg vials (1100 mg/11 mL) in the first 28 days (4 weeks) of treatment. *^If individual receives plasma exchange [PE], plasmapheresis [PP], or intravenous immunoglobulin [IVIg] interventions during therapy, supplemental intravenous doses of Ultomiris (up to 1800 mg following each PE or PP intervention or up to 600 mg following completion of an IVIg cycle) may be approved.	

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Reference Information

1. Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2019.
2. Ultomiris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2018.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
4. Centers for Medicare and Medicaid Services (2023, February 09). Local Coverage Determination (LCD). CMS. Retrieved July 10, 2023, from https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=59074&ver=28&keyword=Soliris&keywordType=starts&areaId=s46&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1
5. Welcome to the Clinical Criteria Page (2022, December 21). Anthem. Retrieved July 10, 2023, from https://www.anthem.com/ms/pharmacyinformation/clinicalcriteria/Complement-Inhibitors.pdf

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023

Revised: 08/18/2023