

July 8, 2024 - Provider News - LifeWise Washington

Medical Policy and Coding Updates July 8, 2024

Special notices Effective October 20, 2024

Updates to Carelon Medical Benefits Management Clinical Appropriateness Guidelines (formerly AIM Specialty Health).

Effective for dates of service on and after October 20, 2024, the following updates will apply to the Carelon Medical Benefits Management, Inc. Radiology Clinical Appropriateness Guidelines. As part of the Carelon guideline annual review process, these updates are focused on advancing efforts to drive clinically appropriate, safe, and affordable health care services.

Updates by section

Brain Imaging

 Added indications for Magnetic Resonance Imaging (MRI) and amyloid beta positron emission tomography (PET) imaging in Alzheimer disease to address patients considering or receiving lecanemab

Spine Imaging

 Changed "Perioperative and Periprocedural Imaging" to "Postoperative and Postprocedural Imaging;" pre-procedure requests should be reviewed based on more specific indication

Extremity Imaging

- o Separated criteria for osteomyelitis and septic arthritis into separate indications
- Ultrasound or arthrocentesis as preliminary tests were placed only in the "septic arthritis" indication

Vascular Imaging

 Computed tomography angiography (CTA) and magnetic resonance angiography (MRA) Head addition for chronic posterior circulation Stroke/TIA presentations (CTA/MRA neck already allowed, intracranial eval needed for full extent of anatomy)

- Lower Extremity peripheral artery disease: Updated physiologic testing parameters and added allowance for ischemic signs/symptoms at presentation, in alignment with American College of Radiology Appropriateness Criteria
- Suboptimal imaging option downgrades/removals in Brain, Head and Neck and Abdomen/Pelvis

Effective for dates of service on and after October 20, 2024, the following updates will apply to the Carelon Medical Benefits Management, Inc. Cardiology Clinical Appropriateness Guidelines. As part of the Carelon guideline annual review process, these updates are focused on advancing efforts to drive clinically appropriate, safe, and affordable health care services.

Updates by section

Imaging of the Heart

- Resting Transthoracic Echocardiography (TTE)
 - Expanded frequency of echocardiographic evaluation in patients on mavacamten for treatment of hypertrophic obstructive cardiomyopathy
 - Expanded criteria for echocardiographic evaluation to allow a single screening for cardiac disease in patients undergoing evaluation for solid organ or hematopoietic cell transplant

Effective for dates of service on and after October 20, 2024, the following updates will apply to the Carelon Medical Benefits Management, Inc. Genetic Testing Clinical Appropriateness Guidelines. As part of the Carelon guideline annual review process, these updates are focused on advancing efforts to drive clinically appropriate, safe, and affordable health care services.

Updates by section

Chromosomal Microarray Analysis

- o Clarified recommendations for Genetic Counseling
- o Clarified requirements for postnatal evaluation of individuals with:
 - Congenital or early onset epilepsy (before age 3 years) without suspected environmental causes
 - Autism spectrum disorder, developmental delay, or intellectual disability with no identifiable cause (idiopathic)
- Clarified prenatal evaluation of a fetus with a structural fetal anomaly noted on ultrasound

Pharmacogenomic Testing

• Added Apolipoprotein E (APOE) testing

Polygenic Risk Scores renamed Predictive and Prognostic Polygenic Testing

- Broadened guideline scope to include polygenic expression prognostic testing and multivariable prognostic genetic testing (essentially clarifications)
 - Moved these tests to exclusions as they are considered not medically necessary
- Retitled guideline to Predictive and Prognostic Polygenic Testing to address the change in scope

Somatic Testing of Solid Tumors

 Clarified gene expression profiling is to guide adjuvant therapy for localized Breast Cancer

Whole Exome and Whole Genome Sequencing

- Expanded whole exome sequencing (WES) criteria to include congenital or early onset epilepsy (before age 3) without suspected environmental etiology and added other clarifications
- o Clarified well-delineated genetic syndrome in criterion for multiple anomalies
- Clarified Genetic Counseling details for WES

Effective for dates of service on and after October 20, 2024, the following updates will apply to the Carelon Medical Benefits Management, Inc. Radiation Oncology Clinical Appropriateness Guidelines. As part of the Carelon guideline annual review process, these updates are focused on advancing efforts to drive clinically appropriate, safe, and affordable health care services.

Updates by section

Radiation Therapy (excludes Proton)

- Removed criteria for hyperthermia
- Clarified inclusion criteria of the RTOG 1112 protocol

Effective for dates of service on and after October 20, 2024, the following updates will apply to the Carelon Medical Benefits Management, Inc. Sleep Clinical Appropriateness Guidelines. As part of the Carelon guideline annual review process, these updates are focused on advancing efforts to drive clinically appropriate, safe, and affordable health care services.

Updates by section

Sleep Disorder Management

- Expanded definitions and terminology
- Expanded documentation of hypoventilation
- Expanded criteria for home and in-lab sleep studies

- Added contraindication to automatic positive airway pressure titration for use of supplemental oxygen
- Removed home sleep apnea testing as an option in medical necessity of multiple sleep latency test/maintenance of wakefulness test for suspected narcolepsy
- Management of obstructive sleep apnea (OSA) using Implanted Hypoglossal Nerve Stimulators (HNS):
 - Narrowed age range (raised lower limit to 13) for HNS in individuals with Down syndrome and OSA to align with age range suggested by Food and Drug Administration (FDA)
- Miscellaneous Devices section added:
 - Electronic positional therapy and neuromuscular electrical training of the tongue musculature are considered not medically necessary due to lack of high-quality evidence

For questions related to guidelines, please contact Carelon via email at <u>MedicalBenefitsManagement.guidelines@Carelon.com</u>. Additionally, you may <u>access and</u> <u>download a copy of the current and upcoming guidelines</u>.

Effective October 8, 2024

Surgical Treatment of Femoral Acetabular Impingement, 7.01.592

New policy

 Surgical treatment of femoral acetabular impingement is considered medically necessary when criteria are met.

Effective August 2, 2024

C3 and C5 Complement Inhibitors, 5.01.571

New policy

 Confirmed granulocyte clone size updated to ≥ 15% for Soliris (eculizumab), Ultomiris (ravulizumab-cwvz), and Empaveli (pegcetacoplan) for the treatment of paroxysmal nocturnal hemoglobinuria (PNH)

Evaluation of Biomarkers for Alzheimer Disease, 2.04.521

New policy

• Measurement of biochemical markers of Alzheimer's disease is considered investigational

Medical policies

New medical policies

No updates this month.

Revised medical policies Effective July 1, 2024

Intraoperative Neurophysiologic Monitoring, 6.01.592

Medically necessary criteria added

 Decompression of facial nerve and resection of tumor involving the facial nerve added as indications

Not medically necessary criteria added

• During removal of spinal cord or dorsal root ganglion stimulators

Note added

 Clarify that when a baseline study is performed for a location that is considered not medically necessary, neither will be covered

Interspinous Fixation (Fusion) Devices, 7.01.591

Renumbered

- Added information within the Appendix previously but policy was not renumbered
- Includes deletion of Intraoperative Monitoring, 7.01.138, as it is renumbered

Minimally Invasive Approaches to Vertebral Fractures and Osteolytic Lesions of the Spine, 6.01.25

Title change

 Policy title updated from "Percutaneous Vertebroplasty and Sacroplasty" to "Minimally Invasive Approaches to Vertebral Fractures and Osteolytic Lesions of the Spine"

Medical necessity criteria updated

• Policy content from Balloon Kyphoplasty, 6.01.38 (deleted) incorporated into this policy with a new title as indicated. There are no changes in criteria.

Psychiatric and Other Specified Evaluations in Inpatient and Residential Behavioral Health Treatment, 3.01.521

Medical necessity criteria removed

- Substance abuse disorder inpatient treatment requirement for a psychiatric evaluation extended from 1 to within 7 days of admission with no required ongoing evaluation
- Policy changes are in alignment with 2024 InterQual

Medical necessity criteria updated

• Substance abuse disorder inpatient treatment requirement for a psychiatric evaluation extended from 1 to within 7 days of admission with no required ongoing evaluation

Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders, 2.01.526

Investigational criteria updated

 Clarified that SAINT is also known as accelerated repetitive high-dose connectivity MRIguided theta-burst stimulation including functional MRI personalized target development and including neuronavigation

Not medically necessary criteria updated

 Contraindications updated to indicate that a brain tumor history, repetitive or severe brain trauma/traumatic brain injury, or an unspecified brain lesion are not contraindications if there is documentation that a neurologist or neurosurgeon evaluated the individual and determined that the individual can safely undergo TMS.

Pharmacy policies

New pharmacy policies

No updates this month.

Revised pharmacy policies Effective July 1, 2024

Xolair (omalizumab), 5.01.513

Medical necessity criteria added

Treatment of moderate to severe persistent asthma

• May not be used in combination with Tezspire (tezepelumab)

Medical necessity criteria added

Treatment of chronic rhinosinusitis with nasal polyps

• May not be used in combo with Dupixent (dupilumab) or Nucala (mepolizumab)

ALK Tyrosine Kinase Inhibitors, 5.01.538

Medical necessity criteria added

 Coverage of Alecensa (alectinib) expanded to include individuals with non-small cell lung cancer who require adjuvant treatment following tumor resection with tumors ≥ 4 cm or node positive

Pharmacotherapy of Arthropathies, 5.01.550

Drugs added

 Simlandi (adalimumab-ryvk) (SC) and adalimumab-ryvk and (Simlandi unbranded) SC added as first-line agents

Drugs added

o Adalimumab-aaty (Yuflyma unbranded) SC added as a second-line agent

Rituximab: Non-oncologic and Miscellaneous Uses, 5.01.556

Medical necessity criteria updated

• Add preferred agents Simlandi (adalimumab-ryvk) (SC) and Adalimumab-ryvk to the list of those which much be first tried and failed

Pharmacologic Treatment of High Cholesterol, 5.01.558

Policy reformatted with no changes to policy statements except where noted

Repatha (evolocumab)

Medical necessity updated

Heterozygous familial hypercholesterolemia (HeFH)

- Repatha (evolocumab) coverage criteria age requirement changed to 10 years of age or older per the updated prescribing information.
- o Repatha diagnostic criteria now requires the individual to meet specific criteria.

Medical necessity updated

Homozygous familial hypercholesterolemia (HeFH)

- Repatha (evolocumab) coverage criteria age requirement changed to 10 years of age and older per the updated prescribing information.
- Repatha diagnostic criteria now requires the individual to meet specific criteria.

Medical necessity added

Primary hyperlipidemia

• Repatha (evolocumab) coverage criteria now includes treatment of certain adults when all the following criteria are met.

Praluent (alirocumab)

Medical necessity updated

Heterozygous familial hypercholesterolemia (HeFH)

- Praluent (alirocumab) coverage criteria age requirement updated from 18 years to 8 years of age and per the updated prescribing information.
- Praluent diagnostic criteria now requires individual to meet specific criteria.

Medical necessity updated

Homozygous familial hypercholesterolemia (HoFH)

• Praluent diagnostic criteria now requires the individual has to meet specific criteria.

Medical necessity updated

Primary hyperlipidemia

 Praluent (alirocumab) may be considered medically necessary to treat certain adults when prescribed by or in consultation with a cardiologist, endocrinologist, or a physician who focuses on the treatment of cardiovascular risk management and/or lipid disorders and other criteria are met.

Leqvio (inclisiran)

Medical necessity updated

Heterozygous familial hypercholesterolemia (HeFH)

• Leqvio diagnostic criteria now requires individual to meet specific criteria.

Medical necessity updated

Primary hyperlipidemia

 Leqvio (inclisiran) is considered medically necessary to treat certain adults when prescribed by or in consultation with a cardiologist, endocrinologist, or a physician who focuses on the treatment of cardiovascular risk management and/or lipid disorders and other criteria are met.

Nexletol (bempedoic acid) and Nexlizet (bempedoic acid and ezetimibe) Medical necessity criteria updated

Atherosclerotic Cardiovascular Disease (ASCVD)

- Nexletol (bempedoic acid) and Nexlizet (bempedoic acid and ezetimibe) now include age requirement of 18 years or older to the ASCVD criteria per the prescribing information.
- Nexletol and Nexlizet coverage criteria include a quantity limit to the ASCVD criteria per the prescribing information.

Medical necessity criteria update

Heterozygous familial hypercholesterolemia (HeFH)

• Nexlizet diagnostic criteria now requires the individual to meet additional criteria.

Medical necessity criteria update

Primary hyperlipidemia

- Nexletol (bempedoic acid) and Nexlizet (bempedoic acid and ezetimibe) may be considered medically necessary for treatment of certain adults when criteria are met.
- Removed the initial authorization requirement for Nexletol (bempedoic acid) and Nexlizet (bempedoic acid and exetimibe) to use in combination with a high-intensity statin per the prescribing information update.

Evkeeza (evinacumab-dgnb)

Medical necessity criteria update

Primary hyperlipidemia

- Evkeeza (evinacumab-dgnb) coverage criteria age requirement changed from 12 years to 5 years of age and older per the prescribing information update.
- Update the step therapy requirement from Praluent (alirocumab) and Repatha (evolocumab) to Repatha only as Repatha is the preferred PCSK9 in the policy for contracting reasons.

Medical necessity criteria update

homozygous familial hypercholesterolemia (HoFH)

- Evkeeza diagnostic criteria now requires the individual to meet one of the following: has an untreated LDL of >400 OR a treated LDL of 300 or greater or has genetic confirmation of two mutant alleles at the LDLR, apoB, PCSK9, or LDLRAP1 gene locus.
- Removed the initial authorization requirement to use in combination with a high-intensity statin per the prescribing information update.

Juxtapid (lomitapide)

Medical necessity criteria update

Homozygous familial hypercholesterolemia (HoFH)

 Juxtapid (lomitapide) diagnostic now requires the individual to meet one of the following: has an untreated LDL of >400; or a treated LDL of 300 or greater; or has genetic confirmation of two mutant alleles at the LDLR, apoB, PCSK9, or LDLRAP1 gene locus.

• Removed the initial authorization requirement to use in combination with a high-intensity statin per the prescribing information update.

Generic pitavastatin

Drug added

Medical necessity criteria added

 Generic pitavastatin added as a preferred alternative option in the HMG-CoA Reductase Inhibitors (statins) coverage criteria.

Roszet (rosuvastatin-ezetimibe), brand rosuvastatin-ezetimibe, and Vytorin (sinvastatin-ezetimibe)

Medical necessity criteria removed

 Removed the requirement from Roszet (rosuvastatin-ezetimibe), brand rosuvastatinezetimibe, and Vytorin (simvastatin-ezetimibe) coverage criteria per the prescribing information expansion.

Evkeeza (evinacumab-dgnb), Juxtapid (lomitapide), Leqvio (inclisiran), Nexletol (bempedoic acid), Nexlizet (bempedoic acid and ezetimibe), Praluent (alirocumab), and Repatha (evolocumab)

Reauthorization requirement removed

 Removed the re-authorization requirement to continue using a maximum tolerated statin from Evkeeza (evinacumab-dgnb), Juxtapid (lomitapide), Leqvio (inclisiran), Nexletol (bempedoic acid), Nexlizet (bempedoic acid and ezetimibe), Praluent (alirocumab), and Repatha (evolocumab) per the prescribing information and guideline recommended use updates.

Pharmacotherapy of Inflammatory Bowel Disorder, 5.01.563

Crohn's disease

Drugs added

 Simlandi (adalimumab-ryvk) (SC) and adalimumab-ryvk and (Simlandi unbranded) SC added as first-line agent

Drug added

o Adalimumab-aaty (Yuflyma unbranded) SC added as a second-line agent

Drug added

Medical necessity criteria added

• Entyvio (vedolizumab) SC is considered medically necessary as a second-line agent when criteria are met

Ulcerative Colitis

Drugs added

 Simlandi (adalimumab-ryvk) (SC) and adalimumab-ryvk (Simlandi unbranded) SC added as first-line agents

Drug added

 $\circ~$ Adalimumab-ryvk (Simlandi unbranded) SC added to the list of second-line TNF- $\alpha~$ Inhibitors

Pharmacotherapy of Miscellaneous Autoimmune Diseases, 5.01.564

Hidradenitis suppurativa

Drugs added

Medical necessity criteria updated

• Simlandi (adalimumab-ryvk) SC and adalimumab-ryvk (Simlandi unbranded) SC added as first-line agents

Pyoderma gangrenosum

Drugs added

Medical necessity criteria updated

 Simlandi (adalimumab-ryvk) SC and adalimumab-ryvk (Simlandi unbranded) SC added as first-line agents

Uveitis

Drugs added

Medical necessity criteria updated

 Simlandi (adalimumab-ryvk) (SC) and adalimumab-ryvk (Simlandi unbranded) SC added as first-line agents

Drugs added

Medical necessity criteria updated

• Adalimumab-aaty (Yuflyma unbranded) SC added as a second-line agent

Myasthenia Gravis

Medical necessity criteria added

 Added requirement that medication may not be used concurrently with Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Soliris (eculizumab), Ultomiris (ravulizumab-cwvz), or Zilbrysq (zilucoplan)

Pharmacologic Treatment to Reduce Serum Phosphorus, 5.01.598

Title changed from Phosphate Binders

Drug added

Medical necessity criteria added

- Xphozah (tenapanor) is considered medically necessary when an individual is diagnosed with chronic kidney disease, is on dialysis and other policy criteria are met
- Use of Xphozah (tenapanor) is investigational for any application outside of what is outline in the policy

Medical Necessity Criteria for Pharmacy Edits, 5.01.605

Drug added

Medical necessity criteria added

• Libervant (diazepam) may be considered medically necessary for acute treatment of intermittent episodes of frequent seizures for those 2-5 years of age

• The quantity is limited to 10 films per 30 days

Pharmacologic Treatment of Psoriasis, 5.01.629

Drugs added

Plaque psoriasis

Medical necessity criteria updated

 Simlandi (adalimumab-ryvk) SC and adalimumab-ryvk (Simlandi unbranded) SC added to the list of first-line agents

Medical necessity criteria updated

 Use of Otezla (apremilast) oral for expanded from those aged 8 and over to those aged 6 and over

Medical necessity criteria updated

 Simlandi (adalimumab-ryvk) SC and adalimumab-ryvk (Simlandi unbranded) SC added to the list of first-line agents that must be tried and failed to be eligible for a second-line agent

Drug added

Medical necessity criteria updated

• Adalimumab-aaty (Yuflyma unbranded) SC added as a second-line agent

Medical necessity criteria updated

 Simlandi (adalimumab-ryvk) SC and adalimumab-ryvk (Simlandi unbranded) SC added to the list of first-line agents that must be tried and failed to be eligible for a second-line agent

Pharmacologic Treatment of Bladder Cancer, 5.01.632

Title changed from Adstiladrin® (nadofaragene firadenovecvncg) Drug added

Medical necessity criteria added

- Anktiva (nogapendekin alfa inbakicept-pmln) Intravesical to treat non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ is considered medically necessary when criteria are met
- All other uses of not outlined in the policy are investigational

Pharmacologic Treatment of Epidermolysis Bullosa, 5.01.635

Drug added

Medical necessity criteria added

- Filsuvez (birch triterpenes) may be considered medically necessary for the treatment of dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB) when criteria are met
- May not be used concurrently with Vyjuvek (beremagene geperpavec-svdt) Topical
- All other uses of not outlined in the policy are investigational

Chronic Hepatitis B Antiviral Therapy, 5.01.636

Drug added

Medical necessity criteria added

- Viread (tenofovir disoproxil fumarate) oral may be considered medically necessary for the treatment of chronic hepatitis B virus (HBV) infection criteria are met
- All other uses of not outlined in the policy are investigational

Chimeric Antigen Receptor Therapy for Leukemia and Lymphoma, 8.01.63 Drug added

Medical necessity criteria added

- Breyanzi (lisocabtagene maraleucel) IV may be considered medically necessary for the treatment of lymphocytic leukemia (CLL) or small lymphocytic lymphoma, relapsed or refractory mantle cell lymphoma (MCL), or relapsed or refractory follicular lymphoma when criteria are met
- All other uses of not outlined in the policy are investigational

Chimeric Antigen Receptor Therapy for Multiple Myeloma, 8.01.66

Medical necessity criteria updated

- Abecma (idecabtagene vicleucel) coverage criteria updated to include treatment of certain adults with multiple myeloma who have tried two prior therapies.
- Updated Carvykti (ciltacabtagene autoleucel) coverage criteria to include treatment of certain adults with multiple myeloma who have tried one prior therapy and lenalidomide.
- All other uses of not outlined in the policy are investigational

Archived policies

Measurement of Serum Antibodies, 2.04.516

Deleted policies

Balloon Kyphoplasty, 6.01.38

Delete policy

 Policy replaced with Minimally Invasive Approaches to Vertebral Fractures and Osteolytic Lesions of the Spine, 6.01.25 effective July 1, 2024.

Coding updates

Added codes Effective July 1, 2024

Adstiladrin (nadofaragene firadenovec-vncg), 5.01.632

Now requires review for medical necessity and prior authorization.

J9030

Amniotic Membrane and Amniotic Fluid, 7.01.583 Now requires review for investigational.

Q4311, Q4312, Q4313, Q4314, Q4315, Q4316, Q4317, Q4318, Q4319, Q4320, Q4321, Q4322, Q4323, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332, Q4333

ASAM Criteria: Services Reviewed for Medical Necessity, 10.01.532 Now requires review for medical necessity.

H0008, H0009, H0010, H0011

Folate Antimetabolites, 5.01.617 Now requires review for medical necessity and prior authorization.

J8611, J8612

Gene Therapies for Thalassemia, 5.01.42 Now requires review for medical necessity and prior authorization.

J3393

Immune Checkpoint Inhibitors, 5.01.591 Now requires review for medical necessity and prior authorization.

J3263

Laboratory Testing Investigational Services, 2.04.520 Now requires review for investigational.

0450U, 0451U, 0457U, 0458U, 0462U, 0463U, 0468U, 0470U, 0472U

Leadless Cardiac Pacemakers, 2.02.515 Now requires review for investigational.

C1605

Medical Necessity Criteria for Pharmacy Edits, 5.01.605 Now requires review for medical necessity and prior authorization.

J7355

Non-covered Experimental/Investigational Services, 10.01.533

Now requires review for investigational.

0867T, 0868T, 0869T, 0870T, 0871T, 0872T, 0873T, 0874T, 0875T, 0877T, 0878T, 0879T, 0880T, 0881T, 0882T, 0883T, 0887T, 0888T, 0889T, 0890T, 0891T, 0892T, 0893T, 0894T, 0895T, 0896T, 0897T, 0898T, 0899T, 0900T

Non-covered Services and Procedures, 10.01.517 Now covered as part of the standard benefit.

96161

Pharmacologic Treatment of Neuropathy, Fibromyalgia, and Seizure Disorders, 5.01.521 Now requires review for medical necessity and prior authorization.

J7336

Pharmacologic Treatment of Sickle Cell Disease, 5.01.640 Now requires review for medical necessity and prior authorization.

J3394

Pharmacotherapy of Arthropathies, 5.01.550 Now requires review for medical necessity and prior authorization.

J3247

Pharmacotherapy of Inflammatory Bowel Disorder, **5.01.563** Now requires review for medical necessity and prior authorization.

J2267

Pharmacotherapy of Thrombocytopenia, 5.01.566 Now requires review for medical necessity and prior authorization.

J7171

Use of Granulocyte Colony-Stimulating Factors (G-CSF), 5.01.551 Now requires review for medical necessity and prior authorization.

J9361

Carelon Management Genetic Testing

Now reviewed by Carelon for medical necessity and prior authorization.

0020M, 0452U, 0453U, 0454U, 0456U, 0460U, 0461U, 0465U, 0466U, 0467U, 0469U, 0471U, 0473U, 0474U, 0475U

Revised codes Effective July 1, 2024

Pharmacotherapy of Multiple Sclerosis, 5.01.565

Now requires review for medical necessity, including site of service and prior authorization.

J2329

Removed codes Effective July 1, 2024

Laboratory Testing Investigational Services, 2.04.520

No longer requires review.

81382

Measurement of Serum Antibodies to Selected Biologic Agents, 2.04.516 No longer requires review.

80145, 80230, 80280