Medical and Behavioral Health Policy Activity

Policies Effective: January 6, 2025 Notification Posted: November 1, 2024

Policies Developed

- **Spinal Fusion: Cervical, IV-181**

I. Cervical Spinal Fusion for Emergent Conditions

Cervical spinal fusion may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- ONE OR MORE of the following emergent conditions:
  - Unstable traumatic spinal fractures, traumatic ligamentous disruption, or dislocations with neural compression when instability is present, or decompression is anticipated to result in instability; OR
  - Central cord syndrome; OR
  - Epidural hematoma; OR
  - Infection (e.g., discitis, epidural abscess, osteomyelitis) when instability is present, or debridement and/or decompression is anticipated to result in instability; OR
  - Occipitocervical and/or atlantoaxial (C1-C2) nontraumatic instability; OR
  - Rapid progressive or profound neurological deficit; OR
  - Tumor involving the spine or spinal canal when instability is present, or resection and/or decompression is anticipated to result in instability;

  AND
- Confirmatory imaging studies within the last 6 months.

II. Cervical Spinal Fusion for Instability

Cervical spinal fusion may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Recent (within 6 months) MRI/CT identifies spinal cord compression and/or subluxation that is concordant with the patient's symptoms and physical examination findings of instability; **AND**
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.

III. Cervical Spinal Fusion for Radiculopathy

Cervical spinal fusion may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of radiculopathy with unremitting radicular pain to shoulder girdle and/or upper extremity resulting in disability; **AND**
- Significant level of daily pain resulting in functional impairment as defined by ONE of the following:
  - Visual Analog Scale (VAS)/ Numeric Rating Scale (NRS) ≥ 7; OR
  - Oswestry Disability Index (ODI) ≥ 25; OR
  - Daily severe, disabling, crippling, or incapacitating pain;

  AND
- Less than clinically meaningful improvement with ALL of the following:
  - Activity modification for at least 6 weeks, or provider-directed exercise program for at least 6 weeks, or contraindication to activity modification or exercise program; AND
  - Prescription strength analgesics, steroids, and/or NSAIDs for at least 6 weeks; AND
  - At least 1 epidural steroid injection (ESI) or selective nerve root block (SNRB) performed at the same level(s) as the requested surgery;

AND

- Recent (within 6 months) MRI/CT identifies nerve root impingement caused by herniated disc(s) and/or osteophytes that is concordant with the patient's symptoms and physical examination findings; **AND**
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.

IV. Cervical Spinal Fusion at an Adjacent Level for Radiculopathy

Cervical spinal fusion at an adjacent level may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of radiculopathy with unremitting radicular pain to shoulder girdle and/or upper extremity resulting in disability; **AND**
- Prior cervical fusion procedure at the previous operative level was performed at least 6 months prior; **AND**
- Significant level of daily pain resulting in functional impairment as defined by ONE of the following:
  - Visual Analog Scale (VAS)/ Numeric Rating Scale (NRS) ≥ 7; OR
  - Oswestry Disability Index (ODI) ≥ 25; OR
  - Daily severe, disabling, crippling, or incapacitating pain;

  AND
- Less than clinically meaningful improvement with ALL of the following:
  - Activity modification for at least 6 weeks, or provider-directed exercise program for at least 6 weeks, or contraindication to activity modification or exercise program; AND
  - Prescription strength analgesics, steroids, and/or NSAIDs for at least 6 weeks; AND
  - At least 1 epidural steroid injection or selective nerve root block (SNRB) performed at the same level(s) as the requested surgery;

  AND
- Confirmatory post-operative MRI/CT within the last 6 months, and at a minimum 6 months after the initial procedure, identifies nerve root impingement at the symptomatic adjacent segment caused by herniated disc(s) or osteophytes that is concordant with the patient's symptoms and physical examination findings; **AND**
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.

V. Cervical Spinal Fusion for Myelopathy

Cervical spinal fusion may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of myelopathy; **AND**
- Confirmatory MRI/CT within the last 6 months identifies EITHER cervical spinal cord compression OR cervical spinal stenosis that is concordant with the patient's symptoms and physical examination findings.

VI. Cervical Spinal Fusion at an Adjacent Level for Myelopathy

Cervical spinal fusion at an adjacent level may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of myelopathy; **AND**
- Confirmatory post-operative MRI/CT within the last 6 months identifies EITHER cervical spinal cord compression OR cervical spinal stenosis that is concordant with the patient's symptoms and physical examination findings.

VII. Repeat Cervical Spinal Fusion at the Same Level

Repeat cervical spinal fusion at the same level may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- ONE OR MORE of the following indications:
  - Malposition or failure of implant as noted by:
    - Radiographic evidence of the malposition or failure of the implant on recent (within 6 months) post-operative X-rays of the cervical spine including flexion/extension lateral views;

    OR
  - Pseudoarthrosis AND ALL of the following:
    - Greater than 6 months since the last cervical fusion procedure at the same level; AND
    - Confirmatory post-operative MRI/CT within the last 6 months, and at a minimum 6 months after the initial procedure, that is concordant with the patient's symptoms and physical examination findings; AND
    - Initial relief of symptoms following previous cervical fusion procedure at the same level; AND
    - Significant level of daily pain resulting in functional impairment as defined by ONE of the following:
      - Visual Analog Scale (VAS)/ Numeric Rating Scale (NRS) ≥ 7; OR
      - Oswestry Disability Index (ODI) ≥ 25; OR
      - Daily severe, disabling, crippling, or incapacitating pain;

  AND
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.

VIII. Experimental/Investigative Uses

Cervical spinal fusion is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including when the above criteria are not met, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Written report describing findings from diagnostic imaging studies.
2. Clinical notes describing ALL of the following:
   - Diagnosis; AND
   - Duration, character, location, and radiation of pain; AND
   - Physical limitations; AND
   - If applicable, prior conservative treatment measures attempted, including:
     - Activity modification, exercise program, or contraindication; AND
     - Pharmacologic therapy; AND
     - Therapeutic injection(s);
3. For adjacent level or repeat procedures, outpatient records before, during, and after the initial procedure.
4. When required, documentation that the patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.

- **PET for Cardiac Applications, V-31**

NOTE:

- For Positron Emission Tomography (PET) for Miscellaneous Indications, see policy V-30.
- For Positron Emission Tomography (PET) for Oncologic Applications, see policy V-32.

I. Positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when ANY of the following criteria are met:

- ONE of the following:
  - Suspected diagnosis of cardiac sarcoidosis and/or extracardiac sarcoidosis; OR
  - Monitoring treatment of confirmed diagnosis of cardiac sarcoidosis and/or extracardiac sarcoidosis, repeating at 3- 6-month intervals;

  OR
- Myocardial perfusion assessment and diagnosis of coronary artery disease with ONE of the following:
  - Indeterminate SPECT; OR
  - The patient's body type or physique is expected to lead to an indeterminate SPECT (e.g., BMI ≥ 35 kg/m^2, chest wall deformity, breast implant); OR
  - Patient is unable to exercise (e.g., pharmacological stress situation);

  OR
- Myocardial viability assessment in patients with severe left ventricular dysfunction, as a technique to determine candidacy for revascularization;

  OR
- Suspected infection of prosthetic valve, left ventricle assistive device (LVAD), or cardiac implantable electronic device (e.g., pacemaker, implantable cardioverter-defibrillator, cardiac resynchronization therapy device) infection and BOTH of the following:
  - Clinical suspicion of infection; AND
  - Other imaging (e.g., echocardiography, computed tomography (CT), cardiac magnetic resonance imaging (MRI), and nuclear studies) is inconclusive or unable to be completed.

II. Positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the quantification of myocardial blood flow when the following criteria are met:

- Myocardial blood flow quantification will be conducted as an add-on procedure, with the primary myocardial PET study requested at the same time; AND
- Criteria in section I for the primary myocardial PET study are met.

III. PET or PET/CT is considered **EXPERIMENTAL/ INVESTIGATIVE** for all other cardiac applications including when the above criteria are not met, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Clinical notes describing the diagnosis (or suspected diagnosis) and clinical history.
2. Results of previous imaging and/or documentation as to why standard imaging modalities are not indicated.

- **PET for Oncologic Applications, V-32**

NOTE:

- For Positron Emission Tomography (PET) for Miscellaneous Applications, see policy V-30.
- For Positron Emission Tomography (PET) for Cardiac Applications, see policy V-31.

I. Initial Treatment Strategy

Positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as an initial treatment strategy (diagnosis and staging) for known or suspected malignancy when ALL of the following criteria are met:

- PET or PET/CT is for ONE of the following tumor types:
  - Solitary pulmonary nodule; OR
  - Multiple myeloma or plasmacytomas; OR
  - Non-Hodgkin or Hodgkin lymphoma; OR
  - Acute lymphoblastic/myeloid leukemia (ALL/AML) if extramedullary disease is suspected; OR
  - Solid malignant tumor (except those listed in Section II as experimental/investigative);

  AND
- PET or PET/CT is required to determine the location and/or extent of a suspected or proven malignancy in order to determine ONE OR MORE of the following:
  - Appropriateness for an invasive diagnostic or therapeutic procedure; OR
  - Optimal anatomic location for an invasive procedure; OR
  - Anatomic extent of malignancy when results will assist with selection of treatment;

  AND
- Other standard imaging modalities (e.g., CT, MRI, or ultrasound) are not indicated OR are unable to provide conclusive results.

II. Experimental/Investigative Tumor Types for Initial Treatment Strategy

PET or PET/CT is considered **EXPERIMENTAL/INVESTIGATIVE** as an initial treatment strategy (diagnosis and staging) for ALL of the following tumor types due to the lack of clinical evidence demonstrating an impact on improved health outcomes:

- Other non-solid primary tumors not listed in Section I; OR
- Early-stage melanoma (0, I, or II); OR
- Kidney; OR
- Non-muscle invasive bladder cancer; OR
- Penile cancers without lymph node positive disease.

III. Subsequent Treatment Strategy

Positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as a subsequent treatment strategy (restaging and monitoring) for known or suspected malignancy when ALL of the following criteria are met:

- PET or PET/CT is for ONE of the following tumor types:
  - Multiple myeloma or plasmacytomas; OR
  - Non-Hodgkin or Hodgkin lymphoma; OR
  - Acute lymphoblastic/myeloid leukemia (ALL/AML) if extramedullary disease is suspected; OR
  - Solid malignant tumor (except those listed in Section IV as experimental/investigative);

  AND
- PET or PET/CT is performed after completion of initial therapy for malignancy; **AND**
- PET or PET/CT is required to establish the need for any subsequent therapy, by determining ONE OR MORE of the following:
  - Presence or extent of residual disease; OR
  - Presence or extent of recurrent disease; OR
  - Presence or extent of metastasis; OR
  - Other assessment of tumor response;

AND

- Other standard imaging modalities (e.g., CT, MRI, or ultrasound) are not indicated OR are unable to provide conclusive results.

IV. Experimental/Investigative Tumor Types for Subsequent Treatment Strategy

PET or PET/CT is considered **EXPERIMENTAL/INVESTIGATIVE** as a subsequent treatment strategy (restaging and monitoring) for ALL of the following tumor types due to the lack of clinical evidence demonstrating an impact on improved health outcomes:

- Other non-solid primary tumors not listed in Section III; OR
- Early-stage melanoma (0, I, or II); OR
- Kidney; OR
- Non-muscle invasive bladder cancer; OR
- Pancreas; OR
- Penile cancers without lymph node positive disease; OR
- Small cell lung; OR
- Solitary pulmonary nodule; OR
- Squamous cell skin cancers.

V. Surveillance

Positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) is considered **EXPERIMENTAL/INVESTIGATIVE** as a surveillance tool for patients with cancer or with a history of cancer when there are no new or worsening symptoms, physical findings, lab tests, or other imaging tests suggesting recurrence or progression of malignancy due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Clinical notes describing the diagnosis (or suspected diagnosis) and clinical history.
2. Results of previous imaging and/or documentation as to why standard imaging modalities are not indicated.
3. For subsequent treatment strategy, confirmation of completion of initial therapy.

- **PET for Miscellaneous Applications, V-30**

NOTE:

- For Positron Emission Tomography (PET) for Cardiac Applications, see policy V-31.
- For Positron Emission Tomography (PET) for Oncologic Applications, see policy V-32.
- For Information on amyloid reducing medications, see pharmacy policy IC-0694 Leqembi™ (lecanemab-irmb)

I. FDG-Positron Emission Tomography (PET) and PET/CT for Epilepsy

Fluoro-2-deoxy-d-glucose (FDG) Positron emission tomography (FDG-PET) or PET/CT may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Used for the assessment of individuals with epileptic seizures who are candidates for surgery; **AND**
- MRI was unable to provide sufficient localization of refractory seizure activity; **AND**

- Results will help guide treatment; **AND**
- FDG-PET scan has not been obtained for the same indication.

II. FDG Positron Emission Tomography (FDG-PET), PET/CT for Dementia

FDG-PET and/or FDG-PET/CT may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Used to differentiate the diagnosis of frontotemporal dementia (FTD) and Alzheimer's disease (AD); **AND**
- A comprehensive clinical evaluation has been conducted, encompassing a medical history and physical, mental status examination (including formal documentation of cognitive, laboratory tests, and structural imaging such as magnetic resonance imaging (MRI) or computed tomography (CT)); **AND**
- Cognitive decline of at least 6 months; **AND**
- Results will help guide treatment.

III. Repeat Imaging

Repeat FDG-PET and/or FDG-PET/CT may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Noted changes in scope or severity of cognitive decline; **AND**
- ≥ 1 year since previous, inconclusive FDG-PET; **AND**
- Continued differential diagnosis of frontotemporal dementia (FTD) and Alzheimer's disease (AD).

IV. Amyloid PET (Amyloid-beta (Aβ))

Amyloid PET may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Patient is being considered for an amyloid reducing drug; **AND**
- Indicated during ONE of the following timeframes during therapy:
  - At initial consideration for therapy; OR
  - Post-treatment imaging at 18 months.

V. Experimental/Investigative Uses

- FDG-PET and/or FDG-PET/CT for individuals with a presumptive diagnosis of dementia-causing neurodegenerative disease (e.g., probable AD, clinically typical FTD, mild cognitive impairment (MCI), dementia of Lewy bodies, or Creutzfeld-Jacob disease) are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- The use of FDG-PET and/or FDG-PET/CT and/or Amyloid PETs are considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications including when the above criteria are not met, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Clinical notes describing the diagnosis (or suspected diagnosis) and clinical history.
2. Results of previous imaging and/or documentation as to why standard imaging modalities are not indicated.

- **Fractional Flow Reserve (FFR), IV-182**

I. Noninvasive fractional flow reserve (FFR) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** to guide decisions concerning the use of invasive coronary angiography when **ALL** of the following criteria are met:

- ONE of the following:
  - Intermediate-risk patients with acute or stable chest pain and no known history of coronary artery stenosis, with findings of 40-90% in proximal or middle coronary artery on coronary computed tomography angiography (CCTA); **OR**
  - Intermediate-risk patients with acute chest pain and known non-obstructive (<50%) CAD coronary artery stenosis with finding of 40-90% stenosis in proximal or middle coronary artery on CCTA; **OR**
  - Stable nonobstructive coronary artery disease (<50% stenosis) with persistent symptoms and findings of 40-90% stenosis on CCTA;

  AND
- FFR will be conducted following a positive CCTA; **AND**
- FFR will be used to guide decisions about the use of invasive coronary angiography.

II. Noninvasive fractional flow reserve (FFR) is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Clinical notes describing diagnosis and clinical history.
2. Written report describing findings from imaging studies, including coronary computed tomography angiography (CCTA).
3. The FDA-approved device to be utilized.

Policies Revised

- **Spinal Fusion: Lumbar, IV- 87**

Note: This policy applies to all approaches to lumbar fusion, including minimally invasive approaches. Axial (Percutaneous) Lumbar Interbody Fusion is addressed separately in policy IV-91.

I. **Lumbar Spinal Fusion for Scoliosis**

Lumbar spinal fusion (arthrodesis) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when ONE of the following are met:

- Diagnosis of adolescent idiopathic scoliosis ≥ 45-degree curvature; OR
- Progressive adolescent scoliosis or early onset scoliosis, despite bracing, in which substantial growth remains (e.g., open triradiate cartilage, Risser stage 1 or 2, premenarchal female, peak height velocity with a major curve > 30°); OR
- Congenital, neuromuscular, or infantile/juvenile scoliosis.

II. Lumbar Spinal Fusion for Emergent Conditions

Lumbar spinal fusion (arthrodesis) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- ONE OR MORE of the following emergent conditions:
  - Traumatic spinal fractures or dislocations with or without neural compression when instability is present; OR
  - Infection (e.g., discitis, epidural abscess, osteomyelitis) when instability is present; OR
  - Tumor involving the spine or spinal canal when instability is present; OR
  - Rapid progressive or profound neurological deficit;

  AND
- Confirmatory imaging studies within the last 6 months.

III. Lumbar Spinal Fusion with Decompression for Instability

Lumbar spinal fusion (arthrodesis) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Instability noted by ONE of the following:
  - Spondylolisthesis with spondylolysis including ONE OR MORE of the following:
    - Spondylolysis on plain X-rays or CT scan; OR
    - Symptomatic Meyerding Grade 1 or 2 spondylolisthesis (anterolisthesis); OR
    - Symptomatic Meyerding Grade 3 or higher spondylolisthesis (anterolisthesis) with 50% or more anterior slippage;

    OR
  - Degenerative spondylolisthesis without spondylolysis including ONE of the following:
    - Meyerding Grade II or higher spondylolisthesis; OR
    - Dynamic segmental instability on flexion-extension plain X-rays; OR
    - Comparison of a supine and upright image, with a difference in translational alignment between vertebrae greater than 2 mm between views;

    OR
  - Pars fracture; **OR**
  - Imaging documenting postoperative instability created by the disruption of the posterior elements due to facet joint excision that exceeds 50% bilaterally or 75% or more of a single facet;

  AND
- Confirmatory imaging studies within the last 6 months; **AND**
- Significant level of daily pain as defined by ONE of the following:
  - Visual Analog Scale (VAS)/ Numeric Rating Scale (NRS) ≥ 7; OR
  - Daily severe, disabling, crippling, or incapacitating pain;

  AND
- Clinically significant functional impairment as evidenced by an Oswestry Disability Index (ODI) ≥ 25; **AND**
- Less than clinically meaningful improvement with ALL of the following:
  - Activity modification for at least 6 weeks, or provider-directed exercise program for at least 6 weeks, or contraindication to activity modification or exercise program; AND
  - Prescription strength analgesics, steroids, and/or NSAIDs for at least 6 weeks; AND
  - At least 1 epidural steroid injection (ESI) or selective nerve root block(s) (SNRB) performed at the same level(s) as the requested surgery;

  AND

- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, nicotine products (not including nicotine replacement therapy (NRT)), and/or marijuana vaping/smoking use for a minimum of 6 weeks prior to surgery.

IV. Lumbar Spinal Fusion with Decompression for Anticipated Instability

Lumbar spinal fusion (arthrodesis) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Anticipated instability as noted by ONE of the following:
  - Disruption of the posterior elements due to facet joint excision that exceeds 50% bilaterally or 75% or more of a single facet during spinal decompression; OR
  - Removal of the pars interarticularis is performed that requires fusion to stabilize; OR
  - Primary extraforaminal or holo-foraminal disc herniation at L5-S1, in which a far lateral approach is not feasible; OR
  - Decompression for Meyerding Grade I or higher spondylolisthesis with foraminal stenosis;

  AND
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, nicotine products (not including nicotine replacement therapy (NRT)), and/or marijuana vaping/smoking use for a minimum of 6 weeks prior to surgery.

V. Lumbar Spinal Fusion with Decompression for Recurrent Disc Herniation

Lumbar spinal fusion (arthrodesis) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Recurrent disc herniation as noted by ONE of the following:
  - Segmental instability with 2 mm or more of anterior translation displacement of the vertebra on the adjacent vertebra below; OR
  - Meyerding Grade II or higher spondylolisthesis (i.e., instability)

  AND
- Confirmatory imaging studies within the last 6 months; **AND**
- Significant level of daily pain as defined by ONE of the following:
  - Visual Analog Scale (VAS)/ Numeric Rating Scale (NRS) ≥ 7; OR
  - Daily severe, disabling, crippling, or incapacitating pain;

  AND
- Clinically significant functional impairment as evidenced by an Oswestry Disability Index (ODI) ≥ 25; **AND**
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, nicotine products (not including nicotine replacement therapy (NRT)), and/or marijuana vaping/smoking use for a minimum of 6 weeks prior to surgery.

VI. Lumbar Spinal Fusion without Decompression for Degenerative Spondylolisthesis without Spondylolysis

Lumbar spinal fusion (arthrodesis) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Degenerative spondylolisthesis without spondylolysis as noted by ONE of the following:
  - Dynamic segmental instability on flexion-extension plain X-rays OR comparison of a supine and upright image, with a difference in translational alignment between vertebrae greater than 2 mm between views; OR

- Meyerding Grade II or higher spondylolisthesis;

AND

- Confirmatory imaging studies within the last 6 months; **AND**
- Significant level of daily pain as defined by ONE of the following:
  - Visual Analog Scale (VAS)/ Numeric Rating Scale (NRS) ≥ 7; OR
  - Daily severe, disabling, crippling, or incapacitating pain;

  AND
- Clinically significant functional impairment as evidenced by an Oswestry Disability Index (ODI) ≥ 25; **AND**
- Less than clinically meaningful improvement with ALL of the following:
  - Activity modification for at least 6 weeks, or provider-directed exercise program for at least 6 weeks, or contraindication to activity modification or exercise program; AND
  - Prescription strength analgesics, steroids, and/or NSAIDs for at least 6 weeks;

  AND
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, nicotine products (not including nicotine replacement therapy (NRT)), and/or marijuana vaping/smoking use for a minimum of 6 weeks prior to surgery.

VII. Lumbar Spinal Fusion without Decompression for Spondylolisthesis with Spondylolysis

Lumbar spinal fusion (arthrodesis) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Degenerative spondylolisthesis with spondylolysis as noted by ONE of the following:
  - Spondylolysis on plain X-rays; OR
  - Symptomatic Meyerding Grade 1 or 2 spondylolisthesis (anterolisthesis); OR
  - Symptomatic Meyerding Grade 3 or higher spondylolisthesis (anterolisthesis) identified on plain x-rays with 50% or more anterior slippage; OR
  - Plain X-rays supporting progression of anterolisthesis;

  AND
- Confirmatory imaging studies within the last 6 months; **AND**
- Significant level of daily pain as defined by ONE of the following:
  - Visual Analog Scale (VAS)/ Numeric Rating Scale (NRS) ≥ 7; OR
  - Daily severe, disabling, crippling, or incapacitating pain;

  AND
- Clinically significant functional impairment as evidenced by an Oswestry Disability Index (ODI) ≥ 25; **AND**
- Less than clinically meaningful improvement with ALL of the following:
  - Activity modification for at least 6 weeks, or provider-directed exercise program for at least 6 weeks, or contraindication to activity modification or exercise program; AND
  - Prescription strength analgesics, steroids, and/or NSAIDs for at least 3 months;

  AND
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, nicotine products (not including nicotine replacement therapy (NRT)), and/or marijuana vaping/smoking use for a minimum of 6 weeks prior to surgery.

VIII. Lumbar Spinal Fusion without Decompression for Isthmic Spondylolisthesis

Lumbar spinal fusion (arthrodesis) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Isthmic spondylolisthesis as noted by the following:
  - Confirmatory recent (within 6 months) imaging study identifies congenital or acquired pars defect; **AND**

- Significant level of daily pain as defined by ONE of the following:
  - Visual Analog Scale (VAS)/ Numeric Rating Scale (NRS) ≥ 7; OR
  - Daily severe, disabling, crippling, or incapacitating pain;

  AND
- Clinically significant functional impairment as evidenced by an Oswestry Disability Index (ODI) ≥ 25; **AND**
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, nicotine products (not including nicotine replacement therapy (NRT)), and/or marijuana vaping/smoking use for a minimum of 6 weeks prior to surgery.

IX. Lumbar Spinal Fusion for Adjacent Segment Disease

Lumbar spinal fusion (arthrodesis) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Adjacent segment disease as noted by the following:
  - Evidence of anterolisthesis on plain X-rays resulting in ONE of the following:
    - Dynamic segmental instability with 3 mm or more of anterior translation displacement of the vertebra on the adjacent vertebra below; OR
    - Meyerding Grade II or higher spondylolisthesis (i.e., instability);

    OR
  - Neural structure compression identified on plain X-rays

  AND
- Confirmatory imaging studies are within the last 6 months; **AND**
- The prior lumbar fusion (arthrodesis) procedure at an adjacent level was performed at least 6 months prior; **AND**
- Significant initial relief of symptoms following prior spinal fusion(s) **AND**
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, nicotine products (not including nicotine replacement therapy (NRT)), and/or marijuana vaping/smoking use for a minimum of 6 weeks prior to surgery.

X. Repeat Lumbar Spinal Fusion at the Same Level

Repeat lumbar spinal fusion (arthrodesis) at the same level may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- ONE OR MORE of the following indications:
  - Malposition or failure of implant as noted by:
    - Radiographic evidence of the malposition or failure of the implant on recent (within 6 months) post-operative X-rays;

    OR
  - Pseudoarthrosis or neural structure compression and ALL of the following:
    - Confirmatory post-operative imaging within the last 6 months, and at a minimum 6 months after the initial procedure, identifies pseudoarthrosis; AND
    - Greater than 6 months since the last fusion (arthrodesis) surgery at the same level; AND
    - Initial relief of symptoms following prior spinal fusion(s); AND
      - Significant level of daily pain as defined by ONE of the following:
        - Visual Analog Scale (VAS)/ Numeric Rating Scale (NRS) ≥ 7; OR
        - Daily severe, disabling, crippling, or incapacitating pain;

      AND
  - Clinically significant functional impairment as evidenced by an Oswestry Disability Index (ODI) ≥ 25;

  AND

- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, nicotine products (not including nicotine replacement therapy (NRT)), and/or marijuana vaping/smoking use for a minimum of 6 weeks prior to surgery.

XI. Experimental/Investigative Uses

Lumbar spinal fusion (arthrodesis) is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including discogenic lower back/degenerative disc disease, and when the above criteria are not met, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Written report describing findings from diagnostic imaging studies.
2. Clinical notes describing ALL of the following:
   - Diagnosis; AND
   - Duration, character, location, and radiation of pain; AND
   - Physical limitations; AND
   - If applicable, prior conservative treatment measures attempted, including:
     - Activity modification, exercise program, or contraindication; AND
     - Pharmacologic therapy; AND
     - Therapeutic injection(s);
3. For adjacent level or repeat procedures, outpatient records before, during, and after the initial procedure.
4. When required, documentation that the patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, nicotine products (not including nicotine replacement therapy (NRT)), and/or marijuana vaping/smoking use for a minimum of 6 weeks prior to surgery.

• Artificial Intervertebral Discs, IV-46

I. Artificial Cervical Intervertebral Discs

- Implantation of an artificial cervical intervertebral disc may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

  - Performed at one level or two contiguous levels from C3-C7; **AND**
  - The device is approved by the U.S. Food and Drug Administration (FDA) for use at the level(s) being treated and will be used in accordance with FDA requirements; **AND**
  - Patient is skeletally mature; **AND**
  - Diagnosis of degenerative cervical disc disease with intractable cervical radicular pain (radiculopathy), myelopathy, or myeloradiculopathy; **AND**
  - Continued episodes of severe, radiating, neurological pain and/or impairment (e.g., extremity weakness or stiffness, lack of arm and/or hand coordination, numbness and/or decreased sensation, back and/or lower extremity involvement); **AND**
  - Symptoms interfere with the ability to perform routine activities of daily living (e.g., writing and other small motor skills, household maintenance, bathing/grooming, food preparation); **AND**
  - X-ray, magnetic resonance imaging (MRI), computed tomography (CT), or myelography conducted within 6 months demonstrates degeneration; **AND**
  - Imaging identifies **ONE** of the following:
    - Nerve root impingement caused by herniated disc(s) or osteophytes that correlates with the patient's

symptoms or physical findings; **OR**
- Spinal cord compression, **OR**
- Stenosis with or without myelomalacia;

AND

- Less than clinically meaningful improvement with **ALL** of the following:
  - Provider directed exercise program or manual traction for at least 6 weeks, or contraindication to exercise program or manual traction; **AND**
  - Pharmacotherapy for at least 6 weeks (e.g., non-narcotic analgesics, anti-inflammatories, muscle relaxants, neuroleptics, and narcotics);

AND

- No contraindications to the procedure, including **NONE** of the following:
  - Active systemic or localized infection;
  - Allergy or sensitivity to implant materials;
  - Chronic non-specific neck or arm pain of an unknown etiology;
  - Combined use of a prosthesis and spinal fusion or other stabilizing procedure (hybrid construct);
  - Facet arthritis;
  - History of rheumatoid arthritis, ankylosing spondylitis or other auto-immune disease;
  - Metabolic bone disease (e.g., osteoporosis, osteopenia, osteomalacia);
  - Significant anatomical deformity or clinically compromised vertebral bodies at the level to be treated due to systemic disease, previous surgery, or trauma;
  - Spinal tumor or other active malignancy;
  - Translational instability;

AND

- Patient is a never-smoker **OR** has abstained from smoking, use of smokeless tobacco, and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery**;** **AND**
- For **subsequent** cervical disc arthroplasty at an adjacent level only, **ALL** of the following:
  - The device is FDA-approved for 2 levels; **AND**
  - The planned subsequent procedure is at a different cervical level than the initial cervical artificial disc replacement; **AND**
  - Clinical documentation that the initial cervical artificial intervertebral disc implantation is fully healed.

- **Revision** of an artificial intervertebral cervical disc prosthesis may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when imaging confirms failure of the implanted device (e.g., loosening, dislodgement, fracture, discitis infection).
- Implantation of an artificial cervical intervertebral disc is considered **EXPERIMENTAL/ INVESTIGATIVE** for all other indications, including when the above criteria are not met, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

II. Artificial Lumbar Intervertebral Discs

- Implantation of an artificial lumbar intervertebral disc at a single level may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when performed at one-level from L-3 to S-1 and **ALL** of the following are met:
  - The device is FDA approved and will be used in accordance with FDA requirements; **AND**
  - Patient is skeletally mature; **AND**
  - Diagnosis of moderate to severe degenerative disc disease at only 1 level in the lumbar spine, from L3-S1; **AND**
  - Continued episodes of severe, radiating neurological pain and/or impairment (e.g., extremity weakness, foot drop, numbness and/or decreased sensation, bladder and/or bowel dysfunction); **AND**
  - Symptoms interfere with the ability to perform routine activities of daily living (e.g., standing, walking,

climbing steps, bathing/grooming, food preparation); **AND**
- Degeneration documented within 6 months by x-ray, magnetic resonance imaging (MRI), or computed tomography (CT); **AND**
- Imaging confirms advanced single-level disc degeneration which correlates with symptoms above; **AND**
- Less than clinically meaningful improvement with ALL of the following:
  - Provider directed exercise program or manual traction for at least 6 months, or contraindication to exercise program or manual traction; AND
  - Pharmacotherapy for at least 6 months (e.g., non-narcotic analgesics, anti-inflammatories, muscle relaxants, neuroleptics, and narcotics);

AND
- No contraindications to the procedure, including NONE of the following:
  - Active systemic or localized infection;
  - Allergy or sensitivity to implant materials;
  - Bony lumbar spinal stenosis;
  - Combined use of a prosthesis and spinal fusion or other stabilizing procedure (hybrid construct);
  - Implantation at more than one lumbar level;
  - Metabolic bone disease (e.g., osteoporosis, osteopenia, osteomalacia);
  - Pars defect;
  - Scoliosis;
  - Severe facet joint arthrosis;
  - Significant anatomical deformity or clinically compromised vertebral bodies at the level to be treated due to systemic disease, previous surgery, or trauma;
  - Spinal fracture;
  - Spinal tumor or other active malignancy;

AND
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery**.**

- **Revision** of an artificial intervertebral lumbar disc prosthesis may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when imaging confirms failure of the implanted device (e.g., loosening, dislodgement, fracture, discitis infection).
- Implantation of an artificial lumbar intervertebral disc is considered **EXPERIMENTAL/ INVESTIGATIVE** for all other indications, including when the above criteria are not met, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

III. Artificial Thoracic Intervertebral Discs

- Implantation of an artificial thoracic intervertebral disc is considered **EXPERIMENTAL/ INVESTIGATIVE** for all indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Written report describing findings from diagnostic imaging studies.
2. Clinical notes describing ALL of the following:
   - Diagnosis;
   - Duration, character, location, and radiation of pain;
   - Physical limitations;

- Prior non-surgical/ conservative treatment measures attempted, including:
  - Exercise program or manual traction, or contraindication;
  - Pharmacologic therapy;

3. For revision procedures, outpatient records before, during, and after the initial procedure.
4. If applicable, documentation that the patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.

- **Bone Morphogenetic Protein, IV-85**

I. Use of recombinant human bone morphogenetic protein-2 (rhBMP-2, InFUSE™) in skeletally mature individuals may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the following indications:

- Anterior lumbar interbody fusion procedures when the use of autograft is not feasible; **OR**
- Instrumented posterolateral intertransverse lumbar spinal fusion when use of an autograft is not feasible; **OR**
- Treatment of acute, open fracture of the tibial shaft when the use of autograft is not feasible.

II. Use of recombinant human bone morphogenetic protein-2 (rhBMP-2) is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including but not limited to craniomaxillofacial applications, due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

- **Percutaneous Facet Joint Denervation, IV-95**

I. **<u>Initial Procedure with Non-Pulsed Radiofrequency Facet Joint Denervation</u>**

Non-pulsed radiofrequency denervation of cervical, thoracic, and lumbar facet joints (C2-C3 through L5-S1 vertebrae) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as an initial procedure when **ALL** of the following criteria are met:

- No prior spinal fusion surgery in the vertebral level being treated; **AND**
- Non-radicular neck (cervical), back (thoracic), or low back (lumbosacral) pain, suggestive of facet joint origin as documented in the medical record, including ALL of the following:
  - History, consisting of mainly axial or non-radicular pain; AND
  - Physical examination, with positive provocative signs of facet disease; AND
  - Radiographic imaging, obtained within the previous 12 months, rules out other causes of spinal pain (e.g., nerve root compression, spinal stenosis or instability, fracture, etc.);

  AND
- Pain has failed to respond to 3 months of conservative management as documented in the medical record, including BOTH of the following:
  - Oral pain medications (e.g., non-steroidal anti-inflammatory medications, analgesics, muscle relaxants, or pharmacological therapy); AND
  - Course of physical therapy OR manipulative therapy;

  AND
- Two separate diagnostic blocks with local anesthetic (no steroids or other drugs) of the facet nerve (medial branch block) or injection under fluoroscopic guidance into the facet joint that have each achieved at least 80% reduction in pain for the duration of the specific local anesthetic used.

II. **<u>Repeat Procedure with Non-Pulsed Radiofrequency Facet Joint Denervation</u>**

Non-pulsed radiofrequency denervation of cervical, thoracic, and lumbar facet joints (C2-C3 through L5-S1 vertebrae) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as a repeat procedure when **ALL** of the following criteria are met:

- The repeat procedure will be performed on the same side and at the same anatomical level of the spine as the previous procedure; **AND**
- No prior spinal fusion surgery in the vertebral level being treated; **AND**
- A minimum of 6 months has elapsed since the previous procedure; **AND**
- Greater than 50% pain relief was obtained for at least 3 months following the previous procedure.

III. Experimental/ Investigative Uses

- Non-Pulsed radiofrequency denervation is considered **EXPERIMENTAL/ INVESTIGATIVE** for treatment of chronic spinal/back pain for all uses that do not meet the criteria listed above, including but not limited to treatment of sacroiliac joint pain, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.
- All other methods for percutaneous facet joint denervation (e.g., pulsed radiofrequency denervation, laser, cryodenervation, and chemical denervation) are considered **EXPERIMENTAL/ INVESTIGATIVE** for treatment of chronic spinal/back pain due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Patient diagnosis and clinical history.
2. Written report, from a radiologist, describing findings from imaging studies.
3. Procedure report describing the medial branch block(s) and follow-up report on the percent change in the level of pain, for the duration of the specific local anesthetic used.
4. Conservative treatment measures attempted and duration of treatment.
5. Positive results with two diagnostic blocks (i.e., at least 80% reduction in pain).
6. For repeat procedures, documentation of the following:
   - Date of prior non-pulsed radiofrequency denervation; AND
   - The length of time and percent change in the level of pain achieved from the previous procedure.

- **Single Photon Emission Computed Tomography (SPECT) of the Head, V-29**

I. Single photon emission computed tomography (SPECT) is considered **MEDICALLY NECESSARY AND APPROPRIATE** when used for the following conditions:

- Clinically uncertain Parkinson disease; **OR**
- Clinically uncertain dementia with Lewy bodies; **OR**
- Glioblastoma with suspected recurrent disease or results of imaging is indeterminate.

II. Single photon emission computed tomography (SPECT) of the head is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including other medical conditions of the head and mental health disorders, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- **Knee Arthroplasty, IV-122**

NOTE: When bilateral knee arthroplasty is planned, whether simultaneous or staged, the criteria below apply to each knee joint being considered.

I. Total Knee Arthroplasty (Total Knee Replacement) for Emergent Conditions

Total knee arthroplasty may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- **ONE** of the following emergent conditions:
  - Primary and secondary tumors of the distal femur or proximal tibia; OR
  - Displaced fractures of the distal femur or proximal tibia; OR
  - Failed previous knee fracture fixation; OR
  - Avascular necrosis (osteonecrosis) of the knee;

AND

- Confirmatory imaging studies within the last 6 months.

II. Total Knee Arthroplasty (Total Knee Replacement) for Non-Emergent Conditions

Total knee arthroplasty may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- **ONE** of the following:
  - Failed previous unicompartmental knee arthroplasty; OR
  - Failed previous knee osteotomy; OR
  - Hemophilic arthropathy of the knee; OR
  - Advanced knee joint disease due to osteoarthritis, rheumatoid arthritis, juvenile rheumatoid/idiopathic arthritis, or post-traumatic arthritis and ALL of the following criteria:
    - Clinically significant functional limitation resulting in impaired, age-appropriate activities of daily living and diminished quality of life; AND
    - Moderate to severe persistent knee pain; AND
    - Diagnostic imaging and/or arthroscopic evidence, obtained within the previous 12 months, of severe cartilage or bone damage or destruction (e.g., modified Outerbridge grade III or IV or Kellgren-Lawrence grade 3 or 4); AND
    - ONE of the following:
  - BMI <40 and BOTH of the following:
    - Activity modification or provider-directed exercise program for at least 3 months, or contraindication to activity modification or exercise program; AND
    - Pharmacotherapy for at least 3 months (e.g., non-narcotic analgesics, anti-inflammatories); OR
  - BMI ≥40 and BOTH of the following:
    - Activity modification or provider-directed exercise program for at least 6 months, or contraindication to activity modification or exercise program; AND
    - Pharmacotherapy for at least 6 months (e.g., non-narcotic analgesics, anti-inflammatories);

AND

- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery;

AND

- No contraindications to the procedure, including ALL of the following:
  - No active infection of the knee joint or active systemic bacteremia; AND
  - No active skin infection or open wound within the planned surgical site of the knee; AND
  - No known allergy to components of the knee implant (e.g., cobalt, chromium, aluminum).

III. Unicompartmental Knee Arthroplasty (Partial Knee Replacement)

Unicompartmental knee arthroplasty (e.g., partial knee replacement) may be considered **MEDICALLY**

NECESSARY AND APPROPRIATE when **ALL** of the following criteria are met:

- **ONE** of the following:
  - Advanced knee joint disease due to osteoarthritis; OR
  - Rheumatoid arthritis; OR
  - Juvenile rheumatoid/idiopathic arthritis; OR
  - Post-traumatic arthritis;

  AND
- Diagnostic imaging and/or arthroscopic evidence, obtained within the previous 12 months, of severe cartilage damage or destruction (e.g., modified Outerbridge grade III or IV or Kellgren-Lawrence grade 3 or 4) limited to a single compartment (e.g., medial, lateral, or patellofemoral); **AND**
- Clinically significant functional limitation resulting in impaired, age-appropriate activities of daily living and diminished quality of life; **AND**
- Moderate to severe persistent knee pain localized to the affected compartment (e.g., medial, lateral, or patellofemoral); **AND**
- **ONE** of the following:
  - BMI <40 and BOTH of the following:
    - Activity modification or provider-directed exercise program for at least 3 months, or contraindication to activity modification or exercise program; AND
    - Pharmacotherapy for at least 3 months (e.g., non-narcotic analgesics, anti-inflammatories); OR
  - BMI ≥40 and BOTH of the following:
    - Activity modification or provider-directed exercise program for at least 6 months, or contraindication to activity modification or exercise program; AND
    - Pharmacotherapy for at least 6 months (e.g., non-narcotic analgesics, anti-inflammatories);

  AND
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery; **AND**
- No contraindications to the procedure, including ALL of the following:
  - No active infection of the knee joint or active systemic bacteremia; AND
  - No active skin infection or open wound within the planned surgical site of the knee; AND
  - No known allergy to components of the knee implant (e.g., cobalt, chromium, aluminum).

IV. Revision Knee Arthroplasty

Revision of previous total or unicompartmental knee arthroplasty may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when ALL of the following criteria are met:

- **ONE** of the following:
  - Disabling pain or functional disability; OR
  - Progressive and substantial bone loss; OR
  - Instability, fracture, or mechanical failure of the prosthetic components or aseptic loosening; OR
  - Periprosthetic fractures; OR
  - Fractures or dislocation of the patella; OR
  - Tissue or systemic reaction to metal implant; OR
  - Infection of the prosthetic joint;

  AND
- Confirmatory imaging studies within the last 6 months; **AND**
- No contraindications to the procedure, including ALL of the following:
  - No active infection of the knee joint or active systemic bacteremia; AND

- No active skin infection or open wound within the planned surgical site of the knee; AND
- No known allergy to components of the knee implant (e.g., cobalt, chromium, aluminum).

V. Experimental/Investigative Uses

- Total knee arthroplasty, unicompartmental knee arthroplasty, and revision knee arthroplasty are considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including when the above criteria are not met, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.
- The following knee procedures are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes:
  - Bicompartmental knee arthroplasty;
  - Bi-unicompartmental knee arthroplasty;
  - Unicondylar interpositional spacer.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Written report describing findings from diagnostic imaging studies.
2. Clinical notes describing ALL of the following:
   - Diagnosis;
   - Duration, character, location, and radiation of pain;
   - Physical and/or functional limitations;
   - If applicable, prior conservative non-surgical treatment measures attempted, including:
     - BMI;
     - Activity modification, exercise program, or contraindication;
     - Pharmacologic therapy;
     - Therapeutic injections into the knee, as appropriate.
3. For revision procedures, outpatient records before, during, and after the initial procedure.
4. If applicable, documentation that the patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.

- **Hip Arthroplasty (Hip Replacement) and Hip Resurfacing, IV-107**
  NOTE: When bilateral hip arthroplasty is planned, whether simultaneous or staged, the criteria below apply to each hip joint being considered.

I. Total Hip Arthroplasty (Total Hip Replacement) for Emergent Conditions

Total hip arthroplasty may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- **ONE** of the following emergent conditions:
  - Primary and secondary tumors of the proximal femur; OR
  - Displaced femoral neck fracture; OR
  - Failed previous hip fracture fixation; OR
  - Avascular necrosis (osteonecrosis) of the hip;

  AND
- Confirmatory diagnostic imaging studies within the last 6 months.

II. Total Hip Arthroplasty (Total Hip Replacement) for Non-Emergent Conditions

Total hip arthroplasty may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- **ONE** of the following:
  - Failed previous femoral or acetabular osteotomy; OR
  - Developmental dysplasia of the hip (DDH) in skeletally mature patients; OR
  - Chronic dislocation of hip; OR
  - Advanced hip joint disease due to osteoarthritis, rheumatoid arthritis, or post-traumatic arthritis and ALL of the following criteria:
    - Clinically significant functional limitation resulting in impaired, age-appropriate activities of daily living and diminished quality of life; AND
    - Moderate to severe persistent hip pain resulting in limited ROM and antalgic gait; AND
    - Diagnostic imaging and/or arthroscopic evidence, obtained within the previous 12 months, of severe cartilage or bone damage or destruction (e.g., for advanced hip joint disease: modified Outerbridge grade III or IV or Kellgren-Lawrence grade 3 or 4); AND
    - ONE of the following:
      - BMI <40 and BOTH of the following:
        - Activity modification or provider-directed exercise program for at least 3 months, or contraindication to activity modification or exercise program; AND
        - Pharmacotherapy for at least 3 months (e.g., non-narcotic analgesics, anti-inflammatories);

        OR
      - BMI ≥40 and BOTH of the following:
        - Activity modification or provider-directed exercise program for at least 6 months, or contraindication to activity modification or exercise program; AND
        - Pharmacotherapy for at least 6 months (e.g., non-narcotic analgesics, anti-inflammatories);

AND

- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery; **AND**
- No contraindications to the procedure, including ALL of the following:
  - No active infection of the hip joint or active systemic bacteremia; AND
  - No active skin infection or open wound within the planned surgical site of the hip; AND
  - No known allergy to metal components of the hip implant (e.g., cobalt, chromium, aluminum).

III. Hemiarthroplasty (Partial Hip Replacement) for Emergent Conditions

Hemiarthroplasty may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- **ONE** of the following emergent conditions:
  - Displaced femoral neck fracture; OR
  - Fracture-dislocation of hip; OR
  - Pathologic femoral neck fracture;

AND

- Confirmatory imaging studies within the last 6 months.

IV. Hemiarthroplasty (Partial Hip Replacement) for Non-Emergent Conditions

Hemiarthroplasty may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- **ONE** of the following:
  - Failed hip fracture reduction; OR
  - Failed recent femoral neck fracture fixation (e.g., malunion, nonunion); OR
  - Advanced hip joint disease or avascular necrosis with collapse of the femoral head and ALL of the following criteria:
    - Clinically functional limitation resulting in impaired, age-appropriate activities of daily living and diminished quality of life; AND
    - Moderate persistent hip pain resulting in limited ROM and antalgic gait; moderate persistent hip pain resulting in limited ROM and antalgic gait; AND
    - Diagnostic imaging and/or arthroscopic evidence, obtained within the previous 12 months, of severe cartilage or bone damage or destruction (e.g., for advanced hip joint disease: modified Outerbridge grade III or IV or Kellgren-Lawrence grade 3 or 4); AND
    - ONE of the following:
      - BMI <40 and BOTH of the following:
        - Activity modification or provider-directed exercise program for at least 3 months, or contraindication to activity modification or exercise program; AND
        - Pharmacotherapy for at least 3 months (e.g., non-narcotic analgesics, anti-inflammatories); OR
      - BMI ≥40 and BOTH of the following:
        - Activity modification or provider-directed exercise program for at least 6 months, or contraindication to activity modification or exercise program; AND
        - Pharmacotherapy for at least 6 months (e.g., non-narcotic analgesics, anti-inflammatories);

  AND
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery; **AND**
- No contraindications to the procedure, including ALL of the following:
  - No active infection of the hip joint or active systemic bacteremia; AND
  - No active skin infection or open wound within the planned surgical site of the hip; AND
  - No known allergy to metal components of the hip implant (e.g., cobalt, chromium, aluminum).

V. Revision Hip Arthroplasty

Revision of previous total or partial hip arthroplasty may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- **ONE** of the following:
  - Recurrent or irreducible dislocation; OR
  - Periprosthetic fracture; OR
  - Infection of the prosthetic joint; OR
  - Implant component failure or FDA recall of the implant; OR
  - Instability of the prosthetic components or aseptic loosening; OR
  - Tissue or systemic reaction to metal implant; OR
  - Leg-length inequality;

  AND
- Confirmatory imaging studies within the last 6 months; **AND**
- No contraindications to the procedure, including ALL of the following:

- No active infection of the hip joint or active systemic bacteremia; AND
- No active skin infection or open wound within the planned surgical site of the hip; AND
- No known allergy to components of the hip implant (e.g., cobalt, chromium, aluminum).

VI. Total Hip Resurfacing

Total hip resurfacing with an FDA approved device may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as an alternative to total hip arthroplasty when **ALL** of the following criteria are met:

- Age ≤ 64 years; **AND**
- **ONE** of the following:
  - Avascular necrosis with <50% involvement of the femoral head and possible acetabular surface; OR
  - Advanced hip joint disease affecting both the femoral head and acetabulum due to osteoarthritis, rheumatoid arthritis, or post-traumatic arthritis; and ALL the following criteria:
    - Clinically functional limitation resulting in impaired, age-appropriate activities of daily living and diminished quality of life; AND
    - Moderate persistent hip pain resulting in limited ROM and antalgic gait; moderate persistent hip pain resulting in limited ROM and antalgic gait; AND
    - Diagnostic imaging and/or arthroscopic evidence, obtained within the previous 12 months, of severe cartilage or bone damage or destruction (e.g., for advanced hip joint disease: modified Outerbridge grade III or IV or Kellgren-Lawrence grade 3 or 4); AND
    - ONE of the following:
      - BMI <40 and BOTH of the following:
        - Activity modification or provider-directed exercise program for at least 3 months, or contraindication to activity modification or exercise program; AND
        - Pharmacotherapy for at least 3 months (e.g., non-narcotic analgesics, anti-inflammatories);
          OR
      - BMI ≥40 and BOTH of the following:
        - Activity modification or provider-directed exercise program for at least 6 months, or contraindication to activity modification or exercise program; AND
        - Pharmacotherapy for at least 6 months (e.g., non-narcotic analgesics, anti-inflammatories);

AND

- No contraindications to the procedure, including ALL of the following:
  - No avascular necrosis with > 50% involvement of the femoral head; AND
  - No active infection of the hip joint or active systemic bacteremia; AND
  - No active skin infection or open wound within the planned surgical site of the hip; AND
  - No known allergy to metal components of the hip resurfacing device (e.g., cobalt, chromium, aluminum).

VII. Partial Hip Resurfacing

Partial hip resurfacing with an FDA approved device may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Age ≤ 64 years; **AND**
- Has known or suspected metal sensitivity or concern about potential effects of metal ions; **AND**
- **ONE** of the following:
  - Avascular necrosis with <50% involvement of the femoral head; OR

- Advanced hip joint disease affecting the femoral head with joint space narrowing due to osteoarthritis, rheumatoid arthritis, or post-traumatic arthritis; and ALL the following criteria:
  - Clinically functional limitation resulting in impaired, age-appropriate activities of daily living and diminished quality of life; AND
  - Moderate persistent hip pain resulting in limited ROM and antalgic gait; moderate persistent hip pain resulting in limited ROM and antalgic gait; AND
  - Diagnostic imaging and/or arthroscopic evidence, obtained within the previous 12 months, of severe cartilage or bone damage or destruction (e.g., for advanced hip joint disease: modified Outerbridge grade III or IV or Kellgren-Lawrence grade 3 or 4); AND
  - ONE of the following:
    - BMI <40 and BOTH of the following:
      - Activity modification or provider-directed exercise program for at least 3 months, or contraindication to activity modification or exercise program; AND
      - Pharmacotherapy for at least 3 months (e.g., non-narcotic analgesics, anti-inflammatories); OR
    - BMI ≥40 and BOTH of the following:
      - Activity modification or provider-directed exercise program for at least 6 months, or contraindication to activity modification or exercise program; AND
      - Pharmacotherapy for at least 6 months (e.g., non-narcotic analgesics, anti-inflammatories);

AND

- No contraindications to the procedure, including ALL of the following:
  - No avascular necrosis with > 50% involvement of the femoral head; AND
  - No active infection of the hip joint or active systemic bacteremia; AND
  - No active skin infection or open wound within the planned surgical site of the hip.

VIII. Experimental/Investigative

Total and partial hip arthroplasty, revision hip arthroplasty, and total and partial hip resurfacing are considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including when the above criteria are not met, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Written report describing findings from diagnostic imaging studies.
2. Clinical notes describing ALL of the following:
   - Diagnosis;
   - Duration, character, location, and radiation of pain;
   - Physical and/or functional limitations;
   - If applicable, prior conservative non-surgical treatment measures attempted, including:
     - BMI;
     - Activity modification, exercise program, or contraindication;
     - Pharmacologic therapy;
     - Therapeutic injections into the hip, as appropriate.
3. For revision procedures, outpatient records before, during, and after the initial procedure.
4. If applicable, documentation that the patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco and/or nicotine products (not including nicotine replacement therapy (NRT)) for a

minimum of 6 weeks prior to surgery.

- **Meniscal Allografts and Other Meniscal Implants, IV-114**
  Note: See policy IV-115: Osteochondral Allografts and Autografts in the Treatment of Focal Articular Cartilage Lesions for criteria used for concurrent procedure.

I. **Meniscal Allograft Transplantation**

Meniscal allograft transplantation may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- ONE of the following:
  - Transplantation to correct alignment and/or stability of the meniscus; when focal articular cartilage lesion requires treatment (e.g., autologous chondrocyte implantation, osteochondral allografting/autografting); OR
  - Prior significant trauma resulting in an irreparable meniscal tear; OR
  - Patient has undergone a meniscectomy where at least 50% of the meniscus has been removed; **AND**
- Adult or skeletally mature adolescent with documented closure of growth plates, and not age-appropriate for total knee arthroplasty or other reconstructive knee surgery; **AND**
- BMI < 35 kg/m²; **AND**
- Disabling knee pain with activity that is refractive to conservative therapy for at least 3 months; **AND**
- Diagnostic imaging and/or arthroscopic evidence obtained within the previous 6 months shows minimal to absent diffuse degenerative changes in the surrounding articular cartilage (e.g., Outerbridge grade II or less, <50% joint space narrowing, Kellgren-Lawrence grade 2 or less); **AND**
- Normal knee biomechanics present, or alignment and stability achieved concurrently with meniscal transplantation; **AND**
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.

II. Experimental/ Investigative Uses

- Use of other meniscal implants or synthetic meniscal tissue (e.g., collagen and polyurethane) is considered **EXPERIMENTAL/INVESTIGATIVE** for all indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- Meniscal allograft transplantation is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including when the above criteria are not met, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Patient diagnosis and clinical history.
2. Progress report, history, and/or operative notes confirming injury and/or prior treatments/therapies.
3. Documentation of normal knee biomechanics, or normal alignment and stability of the knee with meniscal transplantation.
4. Documentation confirms the presence of normal surrounding articular cartilage.

5. Documentation of any planned concurrent procedures, with rationale for meniscus transplantation.
6. Documentation that the patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.

- **Osteochondral Allografts and Autografts in the Treatment of Focal Articular Cartilage Lesions, IV-115**

I. Osteochondral Autografts/Allografts

Osteochondral autograft/allograft transplantation may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- ONE of the following:
  - Full-thickness chondral defects of the femoral articular surface of the knee or patella caused by acute or repetitive trauma; OR
  - Large (area >1.5 cm^2) or cystic (volume >3.0 cm^3) osteochondral lesions of the talus;

AND

- For chondral defects of the femoral articular surface of the knee or patella, the patient is not a candidate for total knee replacement; **AND**
- For chondral defects of the femoral articular surface of the knee or patella, normal knee biomechanics, alignment, and stability currently present, or achieved concurrently with procedure; **AND**
- The patient is an adult or skeletally mature adolescent with documented closure of growth plates; **AND**
- BMI less than 35 kg/m^2; **AND**
- The patient is not a candidate for marrow stimulation techniques; **AND**
- There is disabling pain with activity that is refractive to conservative therapy for at least 3 months; **AND**
- Diagnostic imaging and/or arthroscopic evidence obtained within the previous 6 months shows minimal to absent diffuse degenerative changes in the surrounding articular cartilage bordering the defect. (e.g., Outerbridge grade II or less, Kellgren-Lawrence grade 2 or less); **AND**
- Absence of localized or systemic infection; **AND**
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, and/or nicotine products (not including nicotine replacement therapy (NRT)) a minimum of 6 weeks prior to surgery.

II. Experimental/Investigative Uses

- Treatment with autologous minced or particulated cartilage, allogeneic minced or particulated cartilage, decellularized osteochondral allograft plugs (e.g., Chondrofix), or reduced osteochondral allograft discs (e.g., ProChondrix, Cartiform) are considered **EXPERIMENTAL/INVESTIGATIVE** for all indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- Hybrid autologous chondrocyte implantations performed with osteochondral autograft transfer system (e.g., Hybrid ACI/OATS) technique for the treatment of osteochondral defects are considered **EXPERIMENTAL/INVESTIGATIVE** for all indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- Oseochondral allograft/autograft transplantation is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including when the above criteria are not met, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Patient diagnosis and clinical history.
2. Progress report, history, and/or operative notes confirming injury and prior treatments/therapies.
3. Documentation from diagnostic imaging and/or arthroscopy showing the presence of normal surrounding articular cartilage.
4. Documentation confirms normal alignment, or anticipated normal alignment will be achieved with a concurrent procedure
5. Documentation of any planned concurrent procedures with rationale for the concurrent procedure.
6. Documentation of BMI.
7. Documentation that the patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.

- **Spinal Cord Stimulation, IV-74**

I. <u>Temporarily Implanted Spinal Cord Stimulation or Dorsal Root Ganglion Stimulation</u>

An initial trial period of spinal cord stimulation or dorsal root ganglion stimulation with temporarily implanted electrodes may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Chronic neuropathic pain of the trunk or limbs (at least 6-month duration); **AND**
- Moderate to severe pain as defined by Visual Analog Scale (VAS)/ Numeric Rating Scale (NRS) ≥ 5; **AND**
- Pain has failed to respond to 6 months of conservative management as documented in the medical record, including ALL of the following:
  - Pharmacologic therapy; AND
  - Physical therapy; AND
  - Trigger point injections, nerve/epidural blocks, or epidural steroid injections;

  AND
- Psychological evaluation conducted by a mental/behavioral health professional (i.e., psychiatrist or PhD psychologist) states that any identified mental and/or behavioral health conditions/issues (e.g., substance use disorders, depression, or psychosis) are being or have been addressed; **AND**
- No medical contraindications to implantation (e.g., infection, coagulopathy, inability to operate the device); **AND**
- Patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.

II. <u>Permanently Implanted Spinal Cord Stimulation or Dorsal Root Ganglion Stimulation</u>

A permanently implanted spinal cord stimulator or dorsal root ganglion stimulator may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- ALL criteria in Section I have been met; **AND**
- At least 50% pain relief for at least 2 days with a temporarily implanted electrode; **AND**
- Improvement in function (e.g., increased ability to perform activities of daily living); **AND**
- Permanent electrodes are placed in the same spinal region(s) where the temporary trial produced relief.

III. <u>Replacement/Revision of Spinal Cord Stimulator or Dorsal Root Ganglion Stimulator</u>

Replacement or revision of an existing spinal cord stimulator or dorsal root ganglion stimulator may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when device is malfunctioning OR lead/electrode migration or fracture has occurred.

IV. Experimental/Investigative Uses

Spinal cord stimulation and dorsal root ganglion stimulation are considered **EXPERIMENTAL/ INVESTIGATIVE** for all other indications (e.g., critical limb ischemia as a technique to forestall amputation, refractory angina pectoris, heart failure, and cancer-related pain), including when the above criteria are not met, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Patient diagnosis and clinical history, including duration, location, and level (i.e., VAS/NRS) of pain.
2. Conservative management measures attempted and duration of treatment, including pharmacologic, physical, and injection therapies.
3. Records from psychological evaluation that reveal no inadequately controlled mental and/or behavioral health conditions/issues.
4. Documentation that the patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco, and/or nicotine products (not including nicotine replacement therapy (NRT)) for a minimum of 6 weeks prior to surgery.
5. For permanently implanted stimulator, functional improvement and percent change in the level of pain (including duration) from initial trial period.
6. For replacement/revision, documentation of device complication.

- **Transcatheter Mitral Valve Repair or Replacement, IV-152**

I. Transcatheter Mitral Valve Repair (TMVR) for Primary (Degenerative) Mitral Valve Regurgitation

Transcatheter mitral valve repair (TMVR) with an FDA-approved device may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as a treatment for **primary** mitral valve regurgitation when **ALL** of the following criteria are met:

- Performed via an approach consistent with the device's FDA-approved labeling; **AND**
- Severe mitral regurgitation (i.e., MR ≥ 3+) due to primary abnormality of the mitral apparatus (primary/degenerative MR); **AND**
- New York Heart Association (NYHA) heart failure Class III or IV symptoms; **AND**
- Prohibitive risk for open surgery including **BOTH** of the following:
  - Surgical risk judged by at least two cardiovascular specialists (one specialist being the cardiac surgeon); AND
  - Risk score indicating prohibitive surgical risk as defined by EITHER:
    - Society for Thoracic Surgeons (STS) predicted mortality risk of 12% or greater; or
    - EuroSCORE II of 20% or greater;

  AND
- NONE of the following intolerances or contraindications:
  - Procedural anticoagulation; or
  - Post procedural antiplatelet regimen;

  AND

- Existing comorbidities do not preclude the expected benefit from reduction of the mitral valve regurgitation; **AND**
- TMVR is performed by a cardiac surgeon/interventional cardiologist experienced in performing percutaneous approaches to structural heart disease.

II. Transcatheter Mitral Valve Repair (TMVR) for Secondary (Functional) Mitral Valve Regurgitation

Transcatheter mitral valve repair (TMVR) with an FDA-approved device may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as a treatment for secondary/functional mitral valve regurgitation when **ALL** of the following criteria are met:

- Moderate-to-severe mitral regurgitation (MR ≥ 3+) due to secondary/functional abnormality of the mitral apparatus; **AND**
- New York Heart Association (NYHA) heart failure Class II, III or IV symptoms despite maximally tolerated medical therapy including:
  - ALL of the following:
    - Angiotensin converting enzyme inhibitors (ACE inhibitor), angiotensin II receptor blocker (ARB), or angiotensin receptor-neprilysin inhibitor (ARNI); and
    - Beta blocker and mineralocorticoid receptor antagonist (e.g., spironolactone and eplerenone); and
    - Diuretic therapy if needed to treat volume overload;

    OR
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to guideline-based therapeutic agents;

  AND
- Left ventricular ejection fraction (LVEF) 20% - 50%; **AND**
- Left ventricular dilation (left ventricular end-systolic diameter [LVESD]) ≤ 70 mm; **AND**
- Pulmonary artery systolic pressure (PASP) ≤ 70 mm Hg; **AND**
- NONE of the following intolerances or contraindications:
  - Procedural anticoagulation; or
  - Post procedural antiplatelet regimen;

  AND
- Existing comorbidities do not preclude the expected benefit from reduction of the mitral valve regurgitation; **AND**
- TMVR is performed by a cardiac surgeon/interventional cardiologist experienced in performing percutaneous approaches to structural heart disease.

III. Transcatheter Mitral Valve Replacement/Valve-in-valve Replacement (TMViVR),

Transcatheter mitral valve replacement with an FDA-approved device may be considered **MEDICALLY NECESSARY AND APPROPRIAT**E as a treatment for mitral valve regurgitation when **ALL** of the following criteria are met:

- Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic mitral valve; **AND**
- Prohibitive risk for open surgery including **BOTH** of the following:
  - Surgical risk judged by at least two cardiovascular specialists (one specialist being the cardiac surgeon); AND
  - Risk score indicating prohibitive surgical risk as defined by EITHER:
    - Society for Thoracic Surgeons (STS) predicted mortality risk of 12% or greater; OR
    - EuroSCORE II of 20% or greater.

IV. Experimental / Investigative Uses

Transapical mitral valve repair is considered **EXPERIMENTAL/INVESTIGATIVE** for all indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Transcatheter mitral valve repair is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

Clinical notes describing the following:

- Specific valve repair system to be used and approach planned (e.g. transfemoral); AND
- Mitral regurgitation severity measurement; AND
- New York Heart Association (NYHA) heart failure classification; AND
- Documentation identifying primary or secondary cause of mitral valve regurgitation; AND
- Attestation from cardiac surgeon/interventional cardiologist describing personal experience in performing percutaneous approaches to structural heart disease management (e.g., performs ≥ 50 structural procedures per year including atrial septal defects (ASD), patent foramen ovale (PFO) and trans-septal punctures); AND
- Documentation risk for open surgery from two cardiovascular specialists making this determination (one being a cardiac surgeon); AND
- If regurgitation is primary or surgery is for replacement, risk score indicating prohibitive surgical risk:
  - Either of the following scoring systems:
    - Society for Thoracic Surgeons (STS) predicted risk of mortality score (STS-PROM); or
    - EuroSCORE II; AND
- If regurgitation is secondary, measurements of the following:
  - Left ventricular ejection fraction (LVEF)
  - Left ventricular dilation (left ventricular end-systolic diameter
  - Pulmonary artery systolic pressure (PASP)

- **Water Vapor Energy Ablation and Waterjet Tissue Ablation for Benign Prostatic Hyperplasia, IV-163**

I. Water vapor energy ablation (Rezum) for the treatment of benign prostatic hyperplasia (BPH) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Moderate to severe lower urinary tract symptoms [e.g., International Prostate Symptom Score (IPSS) score ≥13]; AND
- Failure or inability to tolerate medical therapy (a1-adrenergic antagonists maximally titrated, 5a-reductase inhibitors, or combination medication therapy maximally titrated) over an adequate trial period; AND
- Prostate volume 30-80 cm^3; AND
- Appropriate testing to exclude diagnosis of prostate cancer has been completed; AND
- No contraindications to the procedure, including urinary retention, urinary tract infection, or recent prostatitis within the past year.

II. Waterjet tissue ablation (AquaBeam) for the treatment of benign prostatic hyperplasia (BPH) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Moderate to severe lower urinary tract symptoms [e.g., International Prostate Symptoms Score (IPSS) ≥13]; AND

- Failure or inability to tolerate medical therapy (a1-adrenergic antagonists maximally titrated, 5a-reductase inhibitors, or combination medication therapy maximally titrated) over an adequate trial period; AND
- Prostate volume 30–150 cm^3; AND
- Appropriate testing to exclude diagnosis of prostate cancer has been completed; AND
- No contraindications to the procedure, including urinary retention, urinary tract infection, or recent prostatitis within the past year.

III. Water vapor energy ablation (Rezum) or waterjet tissue ablation (AquaBeam) is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- **Measurement of Serum Antibodies to Selected Biologic Agents, VI-55**

NOTE:

- This policy does not address therapeutic drug monitoring (peak/trough levels) when done alone.
- Coverage may be subject to legislative mandates, including but not limited to the following, which applies prior to the policy statements:
  - Minnesota Statute 62Q.473 Biomarker Testing.

I. <u>Measurement of Serum Antibodies</u>

Measurement of serum antidrug antibodies, either alone or as a combination test which includes the measurement of serum biologic agent levels, may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of inflammatory bowel disease (e.g., ulcerative colitis or Crohn's disease); **AND**
- Currently receiving treatment with a biologic agent (e.g., infliximab, adalimumab, ustekinumab, vedolizumab); **AND**
- Confirmed loss of response to the biologic agent despite an initial benefit.

II. <u>Experimental/Investigative Uses</u>

Measurement of serum antidrug antibodies in a patient receiving treatment with a biologic agent, either alone or as a combination test which includes the measurement of serum biologic agent levels, is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes (e.g., Anser® IFX, Anser® ADA, Anser® UST, and Anser® VDZ).

- **Microprocessor-Controlled Prostheses for the Lower Limb, VII-16**

NOTE: Coverage may be subject to legislative mandates, including but not limited to the following, which applies prior to the policy statements:

- Minnesota Statute §62Q.665 Coverage for Orthotic and Prosthetic Devices.
- Minnesota Statute §62Q.6651 Medical Necessity and Nondiscrimination Standards for Coverage of Prosthetics or Orthotics.

I. <u>Microprocessor-controlled Knee</u>

The use of a microprocessor-controlled knee may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for individuals with transfemoral or knee disarticulation amputation who meet **ALL** the following criteria:

- Demonstrated need for long distance ambulation greater than 400 cumulative yards at variable rates on a

daily basis **OR** demonstrated need for regular ambulation on uneven terrain or for regular use on stairs.; **AND**

- Individual has a functional ambulation level of K3 or K4
  - Level K3: Has ability or potential for ambulation at variable cadence typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
  - Level K4: Has ability or potential for prosthetic ambulation that exceeds basic ambulation skills such as those exhibiting high impact, stress, or energy levels typical of the prosthetic demands of an active adult or athlete; **AND**
- Meets requirements of the device specified by the manufacturer; **AND**
- Physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation; **AND**
- Cognitive ability to understand gait sequencing, use and care requirements for the technology; **AND**
- Functional evaluation indicates that with training, use of a microprocessor-controlled knee is likely to meet the maximum functional mobility and/or physical activity needs of the individual (e.g., ADLs, running, biking, swimming). This evaluation should consider the individual's needs for control, durability (maintenance), function (speed, work capability), and usability; **AND**
- Individual has demonstrated improved mobility or stability using a temporary microprocessor device, or when unable to complete such a trial, the prosthetics provider documents or attests that there is a reasonable likelihood of improved mobility or stability.

II. Microprocessor Knee Prosthesis with Polycentric 3-D Hip Joint

The microprocessor knee prosthesis with polycentric 3-D hip joint system may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for individuals who have sustained either a hip disarticulation amputation or hemipelvectomy when **BOTH** of the following are met:

- Meets all indications for a microprocessor-controlled knee prosthesis outlined in section I above; **AND**
- Currently utilizes a microprocessor-controlled knee or is being fitted for a microprocessor-controlled knee at the time of 3-D hip joint system fitting.

III. Microprocessor-controlled Ankle/Foot

The microprocessor-controlled ankle/foot system may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for individuals with transtibial or transfemoral amputation when **ONE** of the following criteria are met: with functional ambulation level of 3 or 4.

IV. Repair or Replacement

Repair of a microprocessor lower-limb prosthesis device and/or component may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following are met:*

- Individual meets medical necessity criteria for the current device; **AND**
- Repair required to make the prosthesis serviceable; **AND**
- Expenses for repairs do not exceed the estimated expense of purchasing another prosthesis; **AND**
- The component is not covered under warranty.

Replacement of a microprocessor lower-limb prosthesis device and/or component may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following are met:*

- Individual meets medical necessity criteria for the current device; **AND**
- At least one of the following is met:

- Change in the physiologic condition or functional level of the individual which necessitates replacement of the requested component(s); OR
- There is an irreparable change in the condition of the component(s) that is not a result of misuse or neglect; **AND**

- The condition of the component(s) requires repairs which would exceed the estimated expense of purchasing a new prosthesis; **AND**
- The component is not covered under warranty.

***** For more information on repair and replacement of DME, refer to Blue Cross Blue Shield of Minnesota reimbursement policy DME-001 DME and Supplies.

V. Not Medically Necessary

Use of a microprocessor-controlled knee prosthesis with or without a polycentric 3-D hip joint system is considered **NOT MEDICALLY NECESSARY** for any of the following:

- Individual does not meet medical necessity criteria in Section I or II of the policy;
- Duplication (e.g., back-up prosthetic device) or upgrade of a functional prosthesis;
- Repair or replacement of parts for a duplicate microprocessor lower limb prosthesis;
- Repair or replacement of a microprocessor lower limb prosthesis for any of the following:
  - Appearance or convenience;
  - Malicious damage or neglect;
  - Use in environments that limit functional life of the device (e.g., excessive moisture, dust or other conditions not recommended by manufacturer).

VI. Experimental/ Investigative

The following are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes:

- Use of a powered knee;
- Use of a powered ankle/foot;
- Use of an integrated/hybrid product with powered knee or powered ankle/foot;
- Use of a user-adjustable heel height feature.

Documentation Submission

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must be submitted by the treating physician, or a prosthetist experienced in fitting microprocessor lower-limb prostheses, including the following:

1. Clinical notes confirming:
   - The individual meets the requirements of the device specified by the manufacturer.
   - Evidence of functional evaluation demonstrating the individual's cognitive ability, strength, and balance to safely use the prosthesis;
   - Functional ambulation level;
   - Results of device trial including changes in mobility or stability; or evidence demonstrating the individual's ability to adequately control and use the prosthetic device;
2. If requesting repair or replacement, documentation of reason for repair and/or replacement.

- **Myoelectric Prosthetic and Orthotic Components for the Upper Limb, VII-60**
  NOTE: Coverage may be subject to legislative mandates, including but not limited to the following, which applies prior to the policy statements:
  - Minnesota Statute §62Q.665 Coverage for Orthotic and Prosthetic Devices.
  - Minnesota Statute §62Q.6651 Medical Necessity and Nondiscrimination Standards for Coverage of Prosthetics or Orthotics.

I. Myoelectric Upper Limb Prosthetic

Myoelectric upper limb prosthetic devices and/or components may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following conditions are met:

- The individual has an amputation or missing limb at the wrist or above (e.g., forearm, elbow, shoulder); **AND**
- Standard body-powered prosthetic devices cannot be used or are insufficient to meet the functional needs of the individual (e.g., gripping, releasing, holding, and coordinating movement of the prosthesis); **AND**
- The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device; **AND**
- Meets requirements of the device specified by the manufacturer; **AND**
- The individual has demonstrated sufficient neurological and cognitive function to operate the prosthesis effectively; **AND**
- The individual is free of comorbidities that could interfere with function of the prosthesis (e.g., neuromuscular disease); **AND**
- Functional evaluation indicates that with training, use of a myoelectric prosthesis is likely to meet the maximum functional mobility and/or physical activity needs of the individual (e.g., ADLs, running, biking, swimming). This evaluation should consider the individual's needs for control, durability (maintenance), function (speed, work capability), and usability.

II. Repair or Replacement

Repair of a myoelectric upper limb device and/or component may be considered **MEDICALLY NECESSARY** when **ALL** of the following are met:*

- Individual meets medical necessity criteria for the current device; **AND**
- Repair required to make the prosthesis serviceable; **AND**
- Expenses for repairs do not exceed the estimated expense of purchasing another prosthesis; **AND**
- The component is not covered under warranty.

Replacement of a myoelectric upper limb device and/or component may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following are met:*

- Individual meets medical necessity criteria for the current device; **AND**
- At least one of the following is met:
  - Change in the physiologic condition or functional level of the individual which necessitates replacement of the requested component(s); OR
  - There is an irreparable change in the condition of the component(s) that is not a result of misuse or neglect; **AN**
- The condition of the component(s) requires repairs which would exceed the estimated expense of purchasing a new prosthesis; **AND**
- The component is not covered under warranty.

***** For more information on repair and replacement of DME, refer to Blue Cross Blue Shield of Minnesota reimbursement policy DME-001 DME and Supplies.

III. Not Medically Necessary

Use of a myoelectric prosthesis of the upper limb is considered **NOT MEDICALLY NECESSARY** for any of the following:

- Individual does not meet medical necessity criteria in Section I of the policy;
- Duplication (e.g., back-up prosthetic device) or upgrade of a functional prosthesis;
- Repair or replacement of parts for a duplicate myoelectric upper limb prosthesis;
- Repair or replacement of a myoelectric upper limb prosthesis for any of the following:
  - Appearance or convenience;
  - Malicious damage or neglect;
  - Use in environments that limit functional life of the device (e.g., excessive moisture, dust or other conditions not recommended by manufacturer).

IV. Experimental/Investigative

The following are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes:

- A prosthesis with individually powered digits, including but not limited to a myoelectric partial hand prosthesis (e.g., ProDigits, iDigits);
- Upper-limb prosthetic components with both sensor and myoelectric control (e.g., Luke™ Arm);
- Myoelectric controlled upper-limb orthotic for home use (e.g., MyoPro®, MyoPro2® Motion).

Documentation Submission

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must be submitted by the treating physician, or a prosthetist experienced in fitting myoelectric upper-limb prostheses, including the following:

1. Clinical notes confirming:
   - The individual meets the requirements of the device specified by the manufacturer;
   - Sufficient neurological and cognitive function to operate the prosthesis;
   - Standard body-powered prosthetic devices cannot be used or are insufficient to meet the maximum functional mobility and/or physical activity needs of the individual;
   - Evidence of functional evaluation demonstrating the individual's ability to adequately control and use the prosthetic device;
2. If requesting repair or replacement, documentation of reason for repair and/or replacement.

Policies Delegated to eviCore

None

Policies Inactivated

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