Medical and Behavioral Health Policy Activity

Policies Effective: September 2, 2024 Notification Posted: July 1, 2024

Policies Developed
None

Policies Revised

- **Hematopoietic Stem Cell Transplantation for Primary Amyloidosis, II-119**
  - **I. Autologous Hematopoietic Stem Cell Transplantation**

    Autologous hematopoietic stem cell transplantation may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when ALL of the following criteria are met**:**
    - Diagnosis of primary systemic amyloidosis; **AND**
    - If symptomatic and/or medically refractory ventricular and atrial arrhythmias, pleural effusion, or heart failure is present, the conditions are well-controlled.

  - **II. Repeat Autologous Hematopoietic Stem Cell Transplantation**

    Repeat autologous hematopoietic stem cell transplantation may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as a treatment of primary systemic amyloidosis after prolonged remission (i.e., 2 years or greater).

  - **III. Allogeneic Hematopoietic Stem Cell Transplantation**

    Allogeneic hematopoietic stem cell transplantation for the treatment of primary systemic amyloidosis is considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- **Transcatheter Aortic Valve Implantation/Replacement (TAVI/TAVR) for Aortic Stenosis, IV-149**
  - **I. Native Valve Replacement**

    Transcatheter aortic valve replacement (TAVR) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for patients with native valve aortic stenosis when **ALL** of the following criteria are met:
    - Use of FDA-approved transcatheter heart valve system, performed via an approach consistent with the device's FDA-approved labeling; **AND**
    - Severe degenerative, native valve aortic stenosis as defined by one or more of the following criteria:
      - Aortic valve area (AVA) of less than or equal to 1 cm^2; OR
      - Aortic valve area (AVA) index of less than or equal to 0.6 cm/m; OR
      - Mean aortic valve gradient greater than or equal to 40 mm Hg; OR
      - Peak aortic-jet velocity greater than or equal to 4.0 m/s;

      AND
    - New York Heart Association (NYHA) heart failure Class II, III or IV symptoms; **AND**
    - NONE of the following comorbid conditions or contraindications that would preclude the expected benefit from aortic stenosis correction:
      - Intolerance or contraindication to anticoagulation/antiplatelet regimen; OR
      - Hypertrophic cardiomyopathy; OR
      - Unicuspid or bicuspid aortic valves; OR
      - Severe (greater than 3+) mitral regurgitation; OR

- Severe (greater than 3+) aortic regurgitation; OR
- Minimal survival benefits due to non-cardiac co-morbid conditions;

AND

- TAVR is performed by a cardiac surgeon/interventional cardiologist experienced in performing percutaneous approaches to structural heart disease.

II. Failed Surgical Bioprosthetic Valve (Valve-in-Valve)

Transcatheter aortic valve replacement (TAVR) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for patients with a failed or degenerated bioprosthetic valve when **ALL** of the following criteria are met:

- Use of FDA-approved transcatheter heart valve system approved for use in repair of a degenerated bioprosthetic valve; **AND**
- Failed (stenosed, insufficient, or combined) surgical bioprosthetic aortic valve; **AND**
- New York Heart Association (NYHA) heart failure Class II, III or IV symptoms; **AND**
- TAVR is performed by a cardiac surgeon/interventional cardiologist experienced in performing percutaneous approaches ~~to~~ for structural heart disease; **AND**
- ONE of the following:
  - Patient is not an operable candidate for open surgery, as judged by at least two cardiovascular specialists (cardiologist and cardiac surgeon) AND ONE of the following:
    - Predicted risk of operative mortality; OR
    - Risk of serious irreversible morbidity 50% or higher for open surgery; OR
    - Increased surgical risk for open surgery (e.g., repeated sternotomy, congenital anomaly);

    OR
  - Patient is an operable candidate but is at high risk for open surgery, as judged by at least two cardiovascular specialists (cardiologist and cardiac surgeon) as indicated by ONE of the following:
    - STS Risk Score (surgical mortality) > 8% at 30 days; OR
    - At 15% or greater surgical mortality risk for open surgery.

III. Experimental / Investigative Uses

Use of a cerebral embolic protection device (e.g., Sentinel) during transcatheter aortic valve replacement procedures is considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Transcatheter aortic valve replacement is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications due to 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:

- For native valve replacement:
  - Specific valve to be used and approach planned (e.g. transfemoral); AND
  - Aortic stenosis severity measurement; AND
  - New York Heart Association (NYHA) heart failure classification; AND
  - Attestation from cardiac surgeon describing personal experience in performing percutaneous approaches to structural heart disease management.
- For failed surgical bioprosthetic valve (Valve-in-Valve):

- Specific valve to be used and approach planned (e.g. transfemoral); AND
- Aortic stenosis severity measurement; AND
- New York Heart Association (NYHA) heart failure classification; AND
- If not an operable candidate, documentation from two cardiovascular specialists making this determination and EITHER:
  - Predicted risk of operative risk of mortality risk; OR
  - Percent risk of serious irreversible morbidity for open heart surgery; OR

- If operable candidate, documentation from two cardiovascular specialists making this determination and EITHER:
  - STS Risk Score (Mortality); OR
  - Percent risk of surgical mortality for open surgery;
- Attestation from cardiac surgeon describing personal experience in performing percutaneous approaches to structural heart disease management.

- **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 (cardiologist and cardiac surgeon/interventional cardiologist); 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 APPROPRIAT**E 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. Experimental / Investigative Uses

Transcatheter mitral valve replacement for a native or valve-in-valve procedure is considered **EXPERIMENTAL/INVESTIGATIVE** for all indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

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; AND
- If regurgitation is primary, 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
- Documentation risk for open surgery is from two cardiovascular specialists making this determination;
- 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)

- **Bioengineered Skin and Soft Tissue Substitutes, IV-137**

I. Breast reconstructive surgery following mastectomy using allogeneic acellular dermal matrix products, including but not limited to the following, is considered **MEDICALLY NECESSARY AND APPROPRIATE:**

- AlloDerm®
- AlloMend®
- Cortiva® (AlloMax™)
- DermACELL™
- DermaMatrix™
- FlexHD®
- Graftjacket®

II. Treatment of chronic, noninfected, full-thickness diabetic lower-extremity ulcers using the following tissue engineered skin substitutes may be considered **MEDICALLY NECESSARY AND APPROPRIATE:**

- AlloPatch®
- Apligraf®
- Dermagraft®
- Integra® Omnigraft Dermal Regeneration Matrix (also known as Omnigraft)
- mVASC®
- TheraSkin®

III. Treatment of chronic, noninfected, partial- or full-thickness lower-extremity skin ulcers due to venous insufficiency, which have not adequately responded following a 1-month period of conventional ulcer therapy, using the following tissue-engineered skin substitutes may be considered **MEDICALLY NECESSARY AND APPROPRIATE:**

- Apligraf®
- Oasis™ Wound Matrix

IV. Treatment of second (partial thickness) and third (full thickness) degree burns using the following tissue-engineered skin substitutes may be considered **MEDICALLY NECESSARY AND APPROPRIATE:**

- Epicel® for the treatment of deep dermal or full-thickness burns comprising a total body surface area ≥30%
- Integra Dermal Regeneration Template™

V. Treatment of dystrophic epidermolysis bullosa using OrCel™ for mitten-hand deformity when standard wound therapy has failed may be considered **MEDICALLY NECESSARY AND APPROPRIATE.**

VI. All other uses of the bioengineered skin and soft tissue substitutes listed above are considered **EXPERIMENTAL/ INVESTIGATIVE** for all other indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

VII. All other skin and soft tissue substitutes not listed above are considered **EXPERIMENTAL/ INVESTIGATIVE** for all indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes including, but not limited to:

- AC5® Advanced Wound System
- ACell® UBM Hydrated/Lyophilized Wound Dressing
- AlloSkin™
- AlloSkin™ RT
- Aongen™ Collagen Matrix
- Architect® ECM, PX, FX
- ArthroFlex™ (Flex Graft)
- Atlas Wound Matrix
- Avagen Wound Dressing
- AxoGuard® Nerve Protector
- BellaCell HD
- Biobrane®/ Biobrane®-L
- Biodesign Anal Fistula Plug
- Biodesign® Otologic Repair Graft
- CollaCare®
- CollaCare® Dental
- Collagen Wound Dressing (Oasis Research)
- CollaGUARD®
- CollaMend™
- CollaWound™
- Collexa®
- Collieva®
- Conexa™
- Coreleader Colla-Pad
- CorMatrix®
- Cymetra™ (Micronized AlloDerm™)
- Cytal™ (previously MatriStem®)
- Dermadapt™ Wound Dressing
- Derma-Gide®
- Derm-Maxx
- DermaPure™
- DermaSpan™
- DressSkin
- Durepair Regeneration Matrix®
- Endoform Dermal Template™
- ENDURAGen™
- Excellagen
- ExpressGraft™
- E-Z Derm™
- FlexiGraft®
- FlowerDerm™
- GammaGraft
- Geistlich Derma-Gide®
- Graftjacket® Xpress, injectable

- Helicoll™
- Hyalomatrix®
- Hyalomatrix® PA
- hMatrix®
- InnovaBurn®
- InnovaMatrix®
- InnovaMatrix FS®
- InnovaMatrix® XL
- Integra™ Flowable Wound Matrix
- Integra™ Bilayer Wound Matrix
- Keramatrix®/ Kerasorb
- Keroxx®
- MariGen™/ Kerecis™ Omega3™
- MatriDerm®
- MatriStem™
- Matrix HD™
- Mediskin®
- MemoDerm™
- Microderm® biologic wound matrix
- MicroMatrix®
- Miro3D® Wound Matrix
- MyOwnSkin™
- NeoMatriX® Wound Matrix
- NeoForm™
- NuCel
- Oasis® Burn Matrix
- Oasis® Ultra
- Pelvicol®/ PelviSoft®
- Permacol™
- PriMatrix™
- PriMatrix™ Dermal Repair Scaffold
- ProgenaMatrix™
- PuraPly™ Wound Matrix (previously FortaDerm™)
- PuraPly™ AM (Antimicrobial Wound Matrix)
- PuraPly™xt
- Puros® Dermis
- Recell®
- RegenePro™
- Repliform®
- Repriza™
- Resolve Matrix™
- Restrata® MiniMatrix
- Supra SDRM®
- SureDerm®
- SIS Fistula Plug
- SkinTE™
- StrataGraft®
- Strattice™ (xenograft)
- Suprathel®

- SurgiMend®
- Surgisis® (including Surgisis® AFP™ Anal Fistula Plug, Surgisis® Gold™ Hernia Repair Grafts, and Surgisis® RVP™ Recto-Vaginal Fistula Plug)
- Talymed®
- TenoGlide™
- TenSIX™ Acellular Dermal Matrix
- TissueMend
- TheraForm™ Standard/Sheet
- TransCyte™
- TruSkin™
- Veritas® Collagen Matrix
- XCM Biologic® Tissue Matrix
- XenMatrix™ AB

- **Gender Affirming Procedures, IV-123**

I. Criteria for All Procedures

Criteria are generally based on the *Standards of Care for the Health of Transgender and Gender Diverse People,* Version 8, from the World Professional Association for Transgender Health (WPATH).

Treatment of gender dysphoria may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when ALL of the following criteria are met in addition to criteria for specific procedures listed in sections II, III and V:

- A comprehensive diagnostic assessment has been completed by a health care professional with the following qualifications:
  - Active licensure by their statutory body and hold, at a minimum, a master's degree or equivalent training in a clinical field relevant to this role and granted by a nationally accredited statutory institution; and
  - Is experienced in the assessment and treatment of gender dysphoria, incongruence, and diversity; and
  - Has competence in the diagnosis of gender diverse identities and expressions, as well as in diagnosing possible comorbid disorders such as mood disorders, personality disorders, and substance related disorders; and
  - Has the ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria; and
  - Ability to assess capacity of the member to consent for treatment; and
  - Participates in engagement with other health care professionals from different disciplines within the field of transgender health for consultation and referral, as needed;

AND

- Based on the comprehensive evaluation, the individual meets the diagnostic criteria for gender dysphoria in adolescents and adults per the *Diagnostic and Statistical Manual of Mental Health Disorders* Fifth Edition, text revision (DSM 5-TR).
  - A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration as manifested by **at least two** of the following:
    - A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics.
    - A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender.
    - A strong desire for the primary and/or secondary sex characteristics of another gender.
    - A strong desire to be another gender
    - A strong desire to be treated as another gender

- A strong conviction that one has the typical feelings and reactions of another gender

AND

- The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning;

AND

- Demonstrates the emotional and cognitive maturity required to provide informed consent for the treatment; **AND**
- Other conditions (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been evaluated and addressed; **AND**
- The member has been under the care of a healthcare provider for gender dysphoria for at least 6 months; **AND**
- If surgical intervention is planned, the patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco and/or nicotine products, and/or nicotine replacement therapy, for a minimum of 6 weeks prior to surgery; **AND**
- Documentation Requirements:
  - One consultation letter must be provided from a qualified healthcare professional (qualifications noted above). The letter must address **ALL** of the following:
    - The member's gender identifying characteristics; and
    - Results of the member's psychosocial assessment, including all diagnoses; and
    - The duration of the health professional's relationship with the member including the type of evaluation and therapy or counseling to date; and
    - If applicable, an explanation that the criteria for surgery have been met, and a brief description of the clinical rationale for supporting the member's request for surgery; and
    - If applicable, a statement that the member has been informed that WPATH Standards of Care refer to breast/chest and genital surgical treatments as “irreversible,” and that reversal of breast/chest and genital surgical treatment are not eligible for coverage prior to providing informed consent for this surgery; and
    - If applicable, a statement that minor demonstrates emotional and cognitive maturity during the informed consent/assent to treatment process; and
    - A statement that informed consent has been obtained from the member. If the member is a minor informed consent from all legal guardians and assent from the minor has been obtained; and
    - A statement that the healthcare professional is available for coordination of care.
  - If surgical intervention is planned, documentation from the surgeon with recommendations for surgery-; **AND**
  - If surgical intervention is planned, documentation that the patient is a never-smoker OR has abstained from smoking, use of smokeless tobacco and/or nicotine products, and/or nicotine replacement therapy, for a minimum of 6 weeks prior to surgery.

Note: All formats of referral documentation including narrative and assessment templates are acceptable as long as criterion items are included.

II. Breast Surgery

- Breast surgery (mastectomy or augmentation) for treatment of gender dysphoria may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when ALL of the following criteria are met:
  - Criteria in Section I are met; **AND**
  - Age is ONE of the following:
    - The member is 18 years of age; OR
    - Members < 18 years of age will be considered on a case-by-case basis with evidence of ALL of the following:
      1. A multidisciplinary team approach is involved for eligible adolescents; and

2. Adolescent demonstrates emotional and cognitive maturity during the informed consent/assent to treatment process.

III. Genital Surgery

- Genital surgery for treatment of gender dysphoria may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when ALL of the following criteria are met:
  - One or more of the following procedures:
    - Electrolysis or laser hair removal to treat tissue donor sites for planned genital surgery;
    - Hysterectomy, salpingo-oophorectomy, orchiectomy, metoidioplasty or phalloplasty, urethroplasty, scrotoplasty, testicular prostheses, penectomy, vaginoplasty, labiaplasty, or clitoroplasty.

    AND
  - Criteria in Section I are met; **AND**
  - Age 18 years or older; **AND**
  - The member has completed 12 continuous months of living in the identity that is congruent with their gender identity.

IV. Reversal of Breast and Genital Surgery

Reversal of breast and genital surgical procedures are considered **NOT MEDICALLY NECESSARY.**

V. Additional Secondary Sex Characteristic Gender Affirming Medical and Surgical Procedures

- Non-surgical procedures for the treatment of gender dysphoria may be considered **MEDICALLY NECESSARY AND APPROPRIATE** to create and maintain gender specific characteristics as part of the overall desired GAMST treatment plan when ALL of the following criteria are met:
  - One or more of the following procedures:
    - Electrolysis or laser treatment for facial hair removal;
    - Voice therapy.

  AND
  - Criteria in Section I are met;
- The following surgical procedures may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when ALL of the following criteria are met:
  - One or more of the following procedures:
    - Voice modification surgery when voice/speech therapy has been ineffective;
    - Reduction thyroid chondroplasty or trachea shaving (reduction of Adam's apple);
    - Facial surgery;
    - Face lift or liposuction, only when performed in conjunction with facial surgery.

      AND
    - Criteria in Section I are met; **AND**
    - Age 18 years or older;

- The following procedures do not have criteria specific to gender dysphoria, and criteria for coverage are addressed in separate medical policies:
  - Panniculectomy/Abdominoplasty;
  - Liposuction

VI. Revision of Previous Surgery

- Revision of the initial gender affirming surgery may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for **ANY** of the following:

- Surgical complication (e.g., hematoma, infection, bleeding, fistula, stricture, wound dehiscence); OR
- A functional impairment interfering with activities of daily living (e.g., complete vaginal stenosis, urethral stricture or fistula, inability to have penetrative intercourse, difficulty with voiding while standing); OR
- Removal and/or replacement of breast, penile, or testicular prostheses when due to complications (e.g., Baker IV contracture).

- Revision of a previous gender affirming surgery because of dissatisfaction with appearance is considered **COSMETIC**.

VII. Cosmetic Procedures

The following procedures are considered **COSMETIC** unless otherwise addressed by member contract benefits:

- Gluteal augmentation;
- Pectoral implants;
- Calf implants.

Coverage

- Preventive health screening guidelines developed for the general population are appropriate for transgender and gender diverse persons for organ systems that are unlikely to be affected by hormone therapy.
- Gender-specific preventive services are also necessary for transgender and gender diverse persons appropriate to their anatomy. Examples include the following:
  - Routine Pap smears should be performed as recommended if cervical tissue is present
  - If mastectomy is not performed, mammograms should be performed as recommended.
  - Transgender and gender diverse persons treated with estrogen should follow the same screening guidelines for breast cancer as those for all women.
  - Screening for prostate cancer should be performed as recommended for those persons who have retained their prostate.
- Preservation of fertility is subject to the member's contract benefits. This includes but is not limited to procurement, cryopreservation/freezing, storage/banking, and thawing of reproductive tissues, such as oocytes, ovaries, embryos, spermatozoa, and testicular tissue.

Policies Inactivated
None

Policies Delegated to eviCore
None